



Tobacco Implementation Guide

Version 1.0 (Final)

Developed by the
CDISC Tobacco Implementation Guide Team

Notes to Readers

The Tobacco Implementation Guide Version 1.0 has been prepared with support from the US Food and Drug Administration Center for Tobacco Products using the CDISC standards development process. This document is a CDISC foundational standard that is a single, stand-alone, comprehensive implementation guide for tobacco product data submissions.

This document provides guidance for

- collection of data with case report forms using the Clinical Data Acquisition Standards Harmonization Model (Version 1.2),
- tabulation of data using the Study Data Tabulation Model (Version 2.1), and
- creation of analysis datasets using the Analysis Data Model (Version 2.1), with
- references to additional CDISC standards and resources to support implementation.

Revision History

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See [Appendix D](#) for Representations and Warranties, Limitations of Liability, and Disclaimer.

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1 Introduction

The Tobacco Implementation Guide Version 1.0 (TIG v1.0) has been prepared by the Tobacco Implementation Guide Team of the Clinical Data Interchange Standards Consortium (CDISC) with support from the US Food and Drug Administration Center for Tobacco Products (FDA CTP) using the CDISC standards development process. TIG v1.0 addresses concepts and endpoints for studies of tobacco products and translates them into CDISC standards to improve semantic understanding, support data sharing, and facilitate global regulatory applications.

This guide applies to products regulated by the FDA CTP including synthetic nicotine and all products deemed to be a tobacco product, such as:

- Cigarettes
- Electronic nicotine delivery systems (ENDS; vapes)
- Roll-your-own tobacco products
- Smokeless tobacco products
- Cigars
- Pipe tobacco products
- Waterpipe tobacco products
- Heated tobacco products (HTPs)

Requirements for data submission to FDA CTP are defined and managed by FDA CTP and are out of scope for this guide. Tobacco products listed above are for example purposes only. Users of this guide should refer to FDA CTP guidance for products regulated by the agency and for related submission requirements (available at <https://www.fda.gov/tobacco-products>).

1.1 Purpose

The purpose of the TIG is to guide the use of CDISC standards for the organization, structure, and format of tobacco product data submitted to a regulatory authority. The TIG provides guidance for the

- collection of study data with case report forms (CRFs) using the Clinical Data Acquisition Standards Harmonization (CDASH) model,
- tabulation of study data using the Study Data Tabulation Model (SDTM), and
- creation of analysis datasets using the Analysis Data Model (ADaM), with
- references to additional CDISC standards and resources to support implementation.

The TIG also provides examples for use cases inherent to tobacco product studies to demonstrate and support understanding of the intended use of standards.

1.2 Organization of this Document

This guide is organized into the following sections:

- Section 1, [Introduction](#), provides an overall introduction to the guide describing its purpose, organization, and relationship to other CDISC standards and resources.
- Section 2, [Standards for Tobacco Product Data](#), describes how to use CDISC standards and resources for the collection, representation, and exchange of tobacco product data.
- Section 3, [Examples](#), provides examples to demonstrate the intended use of CDISC standards for tobacco product data.
- [Appendices](#) provide additional background material and other supplemental material to support implementation.

1.3 Relationship to CDISC Standards and Resources

The TIG guides implementation of CDISC models to standardize collection, representation, and exchange of tobacco product data. CDISC models implemented in this guide include:

- CDASH Model Version 1.2, which provides a general framework for creating fields to collect information on CRFs
- SDTM Version 2.1, which provides a standard model for study data tabulations
- ADaM Version 2.1, which specifies the principles and standards to follow in the creation of analysis datasets and associated metadata

CDISC foundational standards are available at <https://www.cdisc.org/standards>.

The TIG also references additional standards and resources to support implementation:

- CDISC Controlled Terminology (available at <https://www.cdisc.org/standards/terminology/controlled-terminology>) provides consistent semantics for use across standards.
- The CDISC Non-standard Variables Registry (available at <https://www.cdisc.org/standards/terminology/non-standard-variables>) serves as a reference for using or creating NSVs, to drive consistency in implementing CDISC Standards.
- CDISC QRS supplements (available at <https://www.cdisc.org/foundational/qrs>) provide information on how to structure data in a standard format for public-domain and copyright-approved instruments.
- TIG Conformance Rules Version 1.0 (available at <https://www.cdisc.org/standards/foundational/tobacco-implementation-guide>) support the assessment of tabulation and analysis datasets' conformance to TIG standards.
- The CDISC eCRF Portal (available at <https://www.cdisc.org/kb/ecrf>) provides a platform from which to download standard CRFs, including metadata standardized per the Operational Data Model (ODM, available at <https://www.cdisc.org/standards/data-exchange/odm>). ODM is a vendor-neutral, platform-independent format for representing and exchanging CRF content in electronic data capture (EDC) tools.
- The CDISC Library (<https://www.cdisc.org/cdisc-library>) provides access to information regarding new relationships between standards as well as a number of versioned CDISC standards and controlled terminology packages.
- CDISC Define-XML Version 2.1 (available at <https://www.cdisc.org/standards/data-exchange/define-xml/>) provides a metadata standard used to describe any tabular dataset structure.
- Education curriculum (available at <https://www.cdisc.org/education>) to support understanding and use of TIG v1.0.

The TIG is a stand-alone implementation guide and is not intended to be inherently related to or dependent on other implementation guides published by CDISC. However, to support alignment across implementation approaches and for efficiency, the TIG was developed in part by leveraging content published in other CDISC implementation guides. Given this, implementers familiar with CDISC documents may recognize alignment and content shared between the TIG and the following guides:

- Version 3.1.1 of the Standard for Exchange of Nonclinical Data Implementation Guide: Nonclinical Studies (SENDIG; available at <https://www.cdisc.org/standards/foundational/send/>). SEND guides the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as applicants and contract research organizations (CROs), and for submission to regulatory authorities.
- Version 2.2 of the CDASH Implementation Guide (CDASHIG; available at <https://www.cdisc.org/standards/foundational/cdash/>). The CDASHIG defines basic standards for the collection of clinical trial data and describes how to implement the CDASH model for specific CRFs.
- Version 3.4 of the SDTM Implementation Guide: Human Clinical Trials (SDTMIG; available at <https://www.cdisc.org/standards/foundational/sdtmig/>). The SDTMIG is intended to guide the organization,

structure, and format of standard clinical trial tabulation datasets used for various purposes, including publication, warehousing, meta-analyses, and regulatory submission.

- Version 1.3 of the ADaM Implementation Guide (ADaMIG; available at <https://www.cdisc.org/standards/foundational/adam/>). The ADaMIG specifies ADaM standard dataset structures and variables, including naming conventions.

1.4 How to Read this Implementation Guide

1. It is recommended users of this guide review and understand applicable regulatory submission requirements prior to reading this guide. The TIG does not address or define regulatory submission requirements. Requirements for data submission are defined and managed by the regulatory authorities to whom data are submitted.
2. Refer to Appendix B, Glossary and Abbreviations, to gain familiarity with common terms and abbreviations used in this document.
3. Read the CDISC models upon which the TIG is based, described in Section 1.3, Relationship to CDISC Standards and Resources, to gain familiarity with the models and the basic rules for how they are implemented.
4. Read Section 2, Standards for Tobacco Product Data, to guide implementation of standards for collection, representation, and exchange of tobacco product data.
5. Refer to additional CDISC standards and resources described in Section 1.3, Relationship to CDISC Standards and Resources, when needed.
6. Read Section 3, Examples, to support understanding of implementation guidance.
7. Refer to Appendices as necessary.
8. Revisit any sections of particular interest.
9. Read this guide all the way through (without skipping any sections) at least once.

Tables in this guide may begin with column Num. Values in Num are consecutive numbers intended only to support ease of use (e.g., allowing implementers to reference rows in tables without describing row contents). Values in Num have no meaning beyond this use.

1.5 Known Issues

A *known issue* is a problem or concern with a CDISC standard of which CDISC is aware and is working actively to mitigate or resolve.

Num	Issue	Description and Resolution
1	Data collection variable definitions are in draft.	Draft definitions for data collection variables are provided in the DRAFT Collection Definition column as part of the metadata tables in Section 2.7.6, Metadata for Individual Health . Draft definitions are in development as part of a separate initiative and, once finalized, will be updated in a future version of the TIG.
2	The SDTM v2.1 refers to model implementers as "sponsors."	The TIG implements the SDTM; TIG v1.0 references SDTM v2.1. To date the SDTM has referred to those who implement the model as "sponsors," a term which is not inclusive of applicants. Refinements to language will be considered for a future version of the SDTM post-TIG publication. In the interim, the term "sponsor" is considered equivalent to "applicant" when using this guide with SDTM v2.1.
3	New datasets and domains for the TIG Product Description use case are not described in SDTM v2.1 metadata. These datasets are: Study Reference Datasets <ul style="list-style-type: none"> • Environmental Storage Conditions (ES) • Tobacco Product Identifiers and Descriptors (TO) 	These datasets and domains are used to represent data that characterize tobacco products. Tabulation standards for product data are new to both CDISC and stakeholders. At present, these datasets and domains will be restricted to TIG v1.0 and withheld from SDTM v2.1 to allow time for stakeholders use the standards in practice. Experience with these standards will inform subsequent refinements if needed. The standards and refinements, if any, will be incorporated into the next version of the TIG and the associated version of SDTM.

Num	Issue	Description and Resolution
	Special-Purpose Domains <ul style="list-style-type: none"> • Product Design Parameters (PD) • Tobacco Ingredients (IT) • Non-tobacco Ingredients (IN) • Ingredient Quantities by Component (IQ) 	
4	TIG ADaM variable labels reference products and product exposures and do not reference treatments. This is a change to a subset of variable labels in the ADaM.	The concept of exposure to products is applicable to tobacco product data, but exposure is not considered to be treatment or for the purpose of treatment. Where appropriate, variables from ADaM are implemented in the TIG with labels updated to reflect products and product exposure. Updates to labels in ADaM will be considered as part of the next version of the TIG and the associated version of ADaM.
5	The ADAM OTHER dataset structure for the TIG Product Description use case is non-subject based.	ADAM OTHER implemented for the TIG Product Description use case, unlike all other datasets in ADaM v2.1, is not based on USUBJID. Analysis standards for product data are new to both CDISC and stakeholders. At present, this implementation of ADAM OTHER will be restricted to TIG v1.0 and withheld from an associated version of ADaM to allow time for stakeholders to use the standard in practice. Experience with this standard will inform subsequent refinements if needed. The standards and refinements, if any, will be incorporated into the next version of the TIG and the associated version of ADaM.
6	The new REFERENCE dataset structure for the TIG Product Impact on Population Health use case is not described in ADaM v2.1.	The REFERENCE data structure is designed to represent initial input parameters used in population modeling. This structure is new to both CDISC and stakeholders. At present, this structure will be restricted to TIG v1.0 and withheld from an associated version of ADaM to allow time for stakeholders to use the standard in practice. Experience with this standard will inform subsequent refinements if needed. The standards and refinements, if any, will be incorporated into the next version of the TIG and the associated version of ADaM.
7	Some controlled terminology terms and codelists are referenced in the TIG but will not be published at the time of TIG publication.	Some controlled terminology terms and codelists will be published for use after TIG publication and are anticipated to be released end-September 2024. Codelists that will not be published at the time of TIG publication are: <p>Product Description Tabulation (SDTM):</p> <ul style="list-style-type: none"> • SPECPT (Tobacco Product Testing Specimen Type) • TPACN (Action Taken with Tobacco Product) • IGDCMPLX (Ingredient Complexity Response) • IQCAT (Category of Ingredient Quantities by Component) • PDPARMCD (Tobacco Product Design Parameters Code) • PDPARM (Tobacco Product Design Parameters Name) • PTTESTCD (Tobacco Product Testing Test Code) • PTTEST (Tobacco Product Testing Test Name) • PTCAT (Category of Tobacco Product Testing) • TOCAT (Category of Tobacco Products) <p>Nonclinical Tabulation (SEND):</p> <ul style="list-style-type: none"> • LVLDESCRS (Reference ID Level Description Response) • GTTEST (Genetic Toxicology In vitro Test Name) • GTTESTCD (Genetic Toxicology In vitro Test Code) <p>Product Impact on Population Health Analysis (ADaM):</p> <ul style="list-style-type: none"> • INPRM (Input Parameter) • STRATA (Analysis Stratum) • TBUTRS (Tobacco Use Transition Response) • TPUSRS (Tobacco Product Use Status Response) • TPCATRS (Tobacco Product Category Response)

2 Standards for Tobacco Product Data

This section describes how to implement CDISC standards for the collection, representation, and exchange of tobacco product data with focus on implementation for use cases inherent to tobacco product data. Use cases in this guide comprise concepts identified by 1 or more stakeholders as important in the context of tobacco product research.

The following use cases are specifically addressed in the TIG:

- *Product description*, which refers to concepts used to characterize tobacco products
- *Nonclinical*, which refers to concepts used to identify potential risks and effects on biological processes for tobacco products via in vitro and in vivo nonclinical studies
- *Product impact on individual health*, which refers to concepts used to assess the impact of tobacco products on individuals
- *Product impact on population health*, which refers to concepts used to assess the impact of tobacco products on populations of individuals

2.1 How To Determine Where Data Belong

The scientific subject matter of the data and related activities such as data collection, data tabulation, data analysis, and data exchange drive which standards to implement. Implementation of standards in this guide starts with determining which data standards should be used based on the nature of the data and activities to be supported. After an applicable set or sets of data standards have been identified, it is then possible to determine how the data are collected, represented, or exchanged using the standards.

Sets of data standards in this guide are aligned with both use cases and activities. Given this, determining which standards to use may begin by selecting standards for the use case and activity to be supported. All TIG guidance—both general and detailed—should be reviewed prior to implementing standards. The following table presents use cases, activities, and corresponding sections in this guide that provide detailed instructions for implementation. Detailed instructions referenced include:

- Section 2.7, [Standards for Collection](#), which guides development and use of CRFs by implementing the CDISC CDASH Model
- Section 2.8, [Standards for Tabulation](#), which guides organization of data collected, assigned, or derived for a study by implementing SDTM
- Section 2.9, [Standards for Analysis](#), which specifies the principles to follow in creating analysis datasets and associated metadata by implementing ADaM
- Section 2.10, [Standards for Data Exchange](#), which supports sharing of structured data between parties and across different information systems by implementing specified standards and resources

Use Case	Data Collection	Data Tabulation	Data Analysis	Data Exchange
Product description	Section 2.7, Standards for Collection	Section 2.8, Standards for Tabulation	Section 2.9, Standards for Analysis	Section 2.10, Standards for Data Exchange
Nonclinical				
Product impact on individual health			Section 2.9, Standards for Analysis	
Product impact on population health				

Once applicable standards are determined based on the use case and activity, the scientific subject matter of the data, its role, and analysis needs will determine where data belong (i.e., how the data are collected, represented, or exchanged using the standards). Standards for collection and tabulation in this guide collect and represent data using groupings of logically related data called *domains*. Domains are aligned between collection and tabulation standards to facilitate the transition of collected observations to their representation in tabulation datasets. Standards for

analysis are organized in relation to analysis requirements, with the structure of tabulation datasets facilitating the generation of analysis datasets.

To use standards for collection and tabulation, compare the nature or role of the data to the scope of a domain. Domain names provide short descriptions of intended scope and may be used to narrow down which domains to consider. A domain standard may be used when the nature of the data and the domain scope are aligned.

Observations will be collected using standardized collection fields when applicable and represented as rows in tabulation datasets. Each observation is described by a series of data points, which correspond to applicable data collection fields and variables in a tabulation dataset. A data collection field and/or tabulation variable may be used when the subject matter of a data point and the scope of a field and/or variable are aligned. The majority of data for a submission will be in scope for domains based on the General Observation Classes and a subset of Special Purpose domains described in the SDTM. Given this, referring to both the CDASH Model when applicable and the SDTM is highly recommended when using domains to support understanding of intended scope and to inform extensions and creation of custom domains when needed.

The design of analysis datasets is generally driven by the scientific and medical objectives of the study. A fundamental principle is that the structure and content of analysis datasets must support clear, unambiguous communication of the scientific and statistical aspects of the study. The purpose of ADaM is to provide a framework that both enables analysis of the data and allows reviewers and other recipients of the data to have a clear understanding of the data's lineage from collection to analysis to results. ADaM provides the core and defines the spirit and intent of its concepts and standards. The model outlines the fundamental principles to follow in constructing analysis datasets and related metadata. Four types of metadata—analysis dataset metadata, analysis variable metadata, analysis parameter value-level metadata, and analysis results metadata—are described in ADaM. To establish which components are required in a submission, review current relevant files provided by the agency to which the submission is being sent. Other relevant documentation might include the study protocol, the statistical analysis plan (SAP), mock shells that define desired outputs, and any dataset specifications that have been defined.

Standards for data exchange are applicable to all use cases and support sharing of standard CRFs developed using collection standards, tabulation datasets generated using tabulation standards, and analysis datasets designed using analysis standards.

2.2 How Standards Work Together

Standards in this guide are end-to-end implementations of CDISC models designed to ensure the traceability and transparency of data across activities in the data lifecycle. The TIG provides instructions and recommendations to implement these models for the collection, representation, and exchange of tobacco product data. Controlled terminology and formats support implementation of all models. Standards for data exchange are applicable to all use cases and allow for the exchange of metadata for CRFs, tabulation datasets, and analysis datasets.

The following table describes implementation of CDISC models with supporting standards and TIG sections.

Use Case	Standards for Data Collection	Standards for Data Tabulation	Standards for Data Analysis
Product description	Not applicable, as data are not collected via CRFs.	Data: <ul style="list-style-type: none"> CDISC SDTM CDISC TIG Standards for Tabulation Controlled terminology and formats: <ul style="list-style-type: none"> How to Use Controlled Terminology and Formats Data exchange: <ul style="list-style-type: none"> CDISC Define-XML Standards for Data Exchange 	Data: <ul style="list-style-type: none"> CDISC ADaM CDISC TIG Standards for Analysis Controlled terminology and formats: <ul style="list-style-type: none"> How to Use Controlled Terminology and Formats Data exchange: <ul style="list-style-type: none"> CDISC Define-XML Standards for Data Exchange
Nonclinical	Not applicable, as data are not collected via CRFs.	Data: <ul style="list-style-type: none"> CDISC SDTM CDISC TIG Standards for Tabulation 	Not applicable, as data may be analyzed directly from tabulation datasets.

		<p>Controlled terminology and formats:</p> <ul style="list-style-type: none"> • How to Use Controlled Terminology and Formats <p>Data exchange:</p> <ul style="list-style-type: none"> • CDISC Define-XML Standards for Data Exchange 	
Product impact on individual health	<p>Data:</p> <ul style="list-style-type: none"> • CDISC CDASH Model • CDISC TIG Standards for Collection <p>Controlled terminology and formats:</p> <ul style="list-style-type: none"> • How to Use Controlled Terminology and Formats <p>Data exchange:</p> <ul style="list-style-type: none"> • CDISC ODM Standards for Data Exchange 	<p>Data:</p> <ul style="list-style-type: none"> • CDISC SDTM • CDISC TIG Standards for Tabulation <p>Controlled terminology and formats:</p> <ul style="list-style-type: none"> • How to Use Controlled Terminology and Formats <p>Data exchange:</p> <ul style="list-style-type: none"> • CDISC Define-XML Standards for Data Exchange 	<p>Data:</p> <ul style="list-style-type: none"> • CDISC ADaM • CDISC TIG Standards for Analysis <p>Controlled terminology and formats:</p> <ul style="list-style-type: none"> • How to Use Controlled Terminology and Formats <p>Data exchange:</p> <ul style="list-style-type: none"> • CDISC Define-XML Standards for Data Exchange
Product impact on population health	<p>Not applicable, as data input parameters generated for population modeling are calculated via upstream analyses.</p>	<p>Not applicable, as data input parameters generated for population modeling are calculated via upstream analyses.</p>	<p>Data:</p> <ul style="list-style-type: none"> • CDISC ADaM • CDISC TIG Standards for Analysis <p>Controlled terminology and formats:</p> <ul style="list-style-type: none"> • How to Use Controlled Terminology and Formats <p>Data exchange:</p> <ul style="list-style-type: none"> • CDISC Define-XML Standards for Data Exchange

2.3 How to Use Controlled Terminology and Formats

Using controlled terminology and formatting from data collection through tabulation and analysis builds in traceability and transparency across study data. Controlled terminology and formats are required to be used as specified in this guide. General guidance for use of controlled terminology and formats is provided in this section; detailed instructions are provided as part of sections specific to collection, tabulation, and analysis standards. TIG metadata and specifications refer to controlled terminology and formats defined both within and external to this guide.

Controlled Terminology

CDISC Controlled Terminology and supporting documentation (available at <https://www.cdisc.org/standards/terminology/>) are managed as publications separate from this guide. Users of the TIG are encouraged to reference CDISC Controlled Terminology regularly to access controlled terms and for additional information.

CDISC Controlled Terminology codelists are either extensible or nonextensible. For extensible codelists, new terms (those not already listed as either a CDISC Submission Value, a CDISC Synonym, or a National Cancer Institute (NCI) Preferred Term) may be defined and used with the TIG. Terms in nonextensible codelists must be used as-is; new terms cannot be added or used. When extending a codelist, the case-sensitivity convention of the codelist will be followed. It is highly recommended that (1) new terms for CDISC Controlled Terminology extensible codelists and (2) changes to existing terms and requests for new codelists be submitted to the NCI Enterprise Vocabulary Services (EVS) for review and consideration. Submission of terminology requests to NCI-EVS helps ensure the consistency and transparency of data for all users of the TIG. Controlled terminology requests can be submitted to NCI-EVS by using the Term Suggestion form available at <http://ncitermform.nci.nih.gov/ncitermform/?version=cdisc>.

External sources for controlled terminology are referenced in this guide and will be used as indicated, in alignment with regulatory requirements.

The following table summarizes how controlled terminology supports implementation of standards.

Standards for Collection	Standards for Tabulation	Standards for Analysis
<ul style="list-style-type: none"> Ask specific questions on the CRF (e.g., Temperature) Collect data values using terminology (e.g., Y or N) Name variables in the operational database (e.g., TEMP_VSORRES for the collection of vital sign data when a unique variable name must be created for each vital sign result) 	<ul style="list-style-type: none"> Name domain datasets and variables in datasets when applicable Represent collected, assigned, and derived values in datasets 	<ul style="list-style-type: none"> Represent the level of imputation for numeric date/time variables Represent the subject status at different phases of the study Represent the derivation method for cases of data imputation Represent values for analysis concepts as applicable

Formats

Standards for tabulation and analysis require representation of dates and/or times, intervals of time, and durations of time in ISO 8601 format as defined by the International Organization for Standardization (<http://www.iso.org>). The appropriate date and/or time ISO format must be used when specified. Additional ISO formats are referenced in this guide and will be used as indicated in alignment with regulatory requirements.

2.4 About Questionnaires, Ratings, and Scales

Questionnaires, ratings, and scales (QRS) are used to assess the impact of tobacco products on the health of individuals and populations. QRS are standardized and often validated instruments. Given this, implementation of collection, tabulation, and analysis standards per this guide is specialized to maintain instrument standardization and, when applicable, the validity of validated instruments. CDISC provides descriptions for different types of QRS instruments and develops and publishes supplemental guidance for individual QRS instruments when the instrument is in the public domain or when permission has been granted by the copyright holder. CDISC QRS supplements are maintained as stand-alone guides available on the QRS page of the CDISC website at <https://www.cdisc.org/foundational/qrs>.

The TIG provides general guidance for the implementation of collection, tabulation, and analysis standards for QRS instruments. QRS supplements are used with the TIG to describe detailed guidance for implementation. QRS supplements support guidance in the TIG by providing a single source for standard annotated CRFs for collection, tabulation, and analysis dataset content conventions; controlled terminology; and examples for QRS instruments.

The following table lists assessments that are being pursued as potential supplements as part of the development work for this guide. QRS supplements are managed as publications separate from this guide, may or may not be finalized at the time of publication of this guide, and depend on copyright approval where applicable. CDISC cannot produce supplements for copyrighted measures without the express permission of the copyright holder. Users of this guide can refer to the QRS page of the CDISC website if a measure of interest is not included in the table. New measures are developed on an ongoing basis and all supplements are made available on the website as they are developed. See CDISC COP 001 at <https://www.cdisc.org/about/bylaws> for details on implementing or requesting development of CDISC standards.

Instrument Full Name and Abbreviation	Copyright Permission Status	Supplement Status
Fagerström Test for Cigarette Dependence (FTCD)	Granted	In development
Minnesota Tobacco Withdrawal Scale-Revised (MTWS-R)	Public domain	In development
Modified Cigarette Evaluation Questionnaire (mCEQ)	Granted	In development
National Youth Tobacco Survey (NYTS) 2022 Questionnaire	Public domain	In development
Penn State Cigarette Dependence Index (PSCDI)	Copyright exempt	In development
Questionnaire on Smoking Urges-Brief (QSU-Brief)	Granted	In development

2.5 Conformance to Standards

Conformant collection and representation of tobacco product data is ensured by full adherence to standards per this guide. Conformance to standards is assessed by confirming implementation of standards per this guide and by evaluating tabulation and analysis data in relation to conformance rules.

The following table illustrates minimum conformance to standards for **data collection using CRFs**.

Num	Conformance	Implementation
1	Following best practices for CRF design	The design of the CRF follows both recommendations for creating data collection instruments and recommendations for CRF design.
2	Following data collection variable naming conventions	Data collection variable naming conventions are applied in the operational database as specified.
3	Following standard wording for question text or prompts	The wording of CRF questions is standardized per specified question text or prompt for the data collection fields.
4	Following core designations.	All HR (Highly Recommended) and applicable R/C (Recommended/Conditional) data collection fields are present in the CRF and/or operational database.
5	Following guidance for CDISC Controlled Terminology	Controlled terminology is used as specified to collect the data using the CRF.
6	Presenting validated QRS questions and reply choices as validated in the CRF. In some cases, this may result in CRFs that do not conform to CDASH best practices. The use of such questionnaires in their native format does not affect conformance.	All QRS questions and reply choices are presented as validated in the CRF.
7	Aligning data collection variables values and target tabulation variables values when collection and tabulation variable names are the same. Minimal processing, such as changing case when mapping a data collection variable value into a tabulation variable, does not affect conformance.	Data output by the operational database into a tabulation dataset variable requires minimal processing when the data collection and tabulation variable names are the same.

The following table illustrates minimum conformance to standards for **tabulation datasets**.

Num	Conformance	Implementation
1	Representing all collected, assigned, and relevant derived data in applicable datasets	All data generated per scientific and regulatory requirements are included in tabulation datasets.
2	Using domain specifications in this guide wherever applicable	A dataset is created using a domain specification in this guide when the scientific nature or role of the data is within the scope of a domain. Domains are extended or custom domain specifications are only used when data are different in nature and are not in scope for domains in this guide.
3	Following conventions for dataset naming	The dataset name is standardized per naming conventions and per controlled terminology where applicable.
4	Following guidance for dataset record structure	Dataset content is aligned with the record structure specified per the domain specification.
5	Following core designations	All Required and Expected tabulation variables are included as columns in the dataset. Required tabulation variables are populated for all records in the dataset. Permissible variables used to collect data are included in the dataset, even when no data for those variables were collected.
6	Following conventions for variable naming	The names of variables in the dataset are standardized per domain specifications and other applicable guidance. Controlled terminology for domain prefixes is used as specified for variable naming.
7	Following guidance for variable types	The variables in the dataset are standardized for either numeric or character values as specified per the domain specification.
8	Populating variable values in alignment with this guide	All variables in the dataset are populated as expected per this guide including per general and domain-specific guidance, controlled terminology, and formatting.

The following table illustrates minimum conformance to standards for **analysis datasets**.

Num	Conformance	Implementation
1	ADaM fundamental principles are followed	<ul style="list-style-type: none"> Datasets and associated metadata clearly and unambiguously communicate the content and source of the

Num	Conformance	Implementation
		<p>datasets supporting the statistical analyses performed in a clinical study.</p> <ul style="list-style-type: none"> Datasets and associated metadata provide traceability to show the source or derivation of a value or a variable (i.e., the data's lineage or relationship between a value and its predecessor(s)). The metadata identify when and how analysis data have been derived or imputed. Datasets are readily usable with commonly available software tools. Datasets are associated with metadata to facilitate clear and unambiguous communication. Ideally the metadata are machine-readable. Datasets have a structure and content that allow statistical analyses to be performed with minimal programming. Such datasets are described as "analysis-ready." Datasets contain the data needed for the review and re-creation of specific statistical analyses. It is not necessary to collate data into analysis-ready datasets solely to support data listings or other nonanalytical displays.
2	ADaM datasets follow the normative data found in the TIG	Datasets follow the fundamental principles defined in ADaM and adhere as closely as possible to TIG variable naming and other conventions.
3	Traceability principles are followed	In ADaM, it is assumed that the original data sources for ADaM datasets are SDTM datasets, even when ADaM datasets are derived from other ADaM datasets. ADaM has features that enable traceability from analysis results to ADaM datasets and from ADaM datasets to SDTM datasets. These conventions must be followed for ADaM datasets with a CLASS value of BASIC DATA STRUCTURE, OCCURRENCE DATA STRUCTURE, and SUBJECT LEVEL ANALYSIS DATASET. Other analysis datasets should follow this convention where practical and feasible.

Tabulation and analysis dataset conformance can be formally evaluated in relation to defined sets of **conformance rules**. The CDISC TIG Conformance Rules Version 1.0 (available at <https://www.cdisc.org/standards/foundational/tobacco-implementation-guide>) includes rules for both tabulation and analysis datasets. Conformance rules for tabulation datasets assess the conformance of dataset structures and contents to the TIG tabulation standards. Conformance rules for analysis datasets assess the conformance of dataset construction to the TIG analysis standards.

2.6 Guidance for Datasets

Requirements for data submission are defined and managed by the regulatory authorities to whom data are submitted. This section describes general requirements for datasets that may be part of a submission. However, additional conventions may be defined by regulatory bodies or negotiated with regulatory reviewers. In such cases, additional requirements must be followed.

Tabulation Datasets

Observations about tobacco products and study subjects generated to support a submission are represented in a series of datasets aligned with logical groupings of data into domains. Domains described in this guide are generally aligned with implementation of a single dataset file in which to represent data in scope for a domain. All datasets are structured as flat files with rows representing observations and columns representing variables. In some cases, a dataset implemented for a domain may be split into physically separate dataset files to support submission when needed and as allowable by the regulatory authority.

The following guidance will be adhered to for tabulation datasets:

Num	Guidance For	Implementation
1	Dataset content	Data represented in datasets will include the following per regulatory requirements, scientific needs, and standards in this guide:

Num	Guidance For	Implementation
		<ul style="list-style-type: none"> • Data as originally collected or received (using controlled terminology where applicable) to support the submission • Data from external references relevant to the submission (e.g., study protocol) • Data assigned per conventions in the TIG • Data derived per regulatory and TIG conventions
2	Dataset naming	<ul style="list-style-type: none"> • Domain datasets based on the SDTM general observations classes will be named using the 2-character code for the domain or using the applicable 4-character code when a dataset is split (e.g., LB, LBHM). • Supplemental Qualifier datasets will be named using "SUPP" concatenated with the 2-character domain code for the parent domain (e.g., SUPPDM, SUPPFA) or the 4-character code for the parent dataset when a dataset is split (e.g., SUPPFACM). • All other datasets will be named using the code for the domain or dataset (e.g., DM, RELREC).
3	Variable order	<ul style="list-style-type: none"> • Dataset variables will be ordered per guidance in the SDTM. • Variable order in TIG domain specifications aligns with variable order in the SDTM.
4	Variable names	<ul style="list-style-type: none"> • Variables will be named per guidance in the SDTM. The SDTM guidance uses fragment names in the CDISC NSV Registry. • Variable names in TIG domain specifications align with naming conventions in the SDTM. • Variable names will be 8 characters or fewer and uppercase.
5	Variable labels	Descriptive labels per this guide, up to 40 characters, will be provided as data variable labels for all variables, including Supplemental Qualifier variables.
6	Variable length	<p>When variable length is referenced in the TIG, this refers to the length in bytes of ASCII character strings.</p> <ul style="list-style-type: none"> • The maximum length of character variables is 200 characters, and the full 200 characters should not be used unless necessary. • Applicants will consider the nature of the data and apply reasonable, appropriate lengths to variables. For example: <ul style="list-style-type: none"> ◦ --TESTCD and IDVAR values will never be longer than 8 characters, so the lengths of those variables can be set to 8. ◦ The length for variables that use controlled terminology can be set to the length of the longest term.
7	Variable value text case	<ul style="list-style-type: none"> • Values from controlled terminology or response values for QRS instruments specified by the instrument documentation will be in the case specified by those sources. • Otherwise, text data will be represented in upper case (e.g., NEGATIVE).
8	Missing variable values	Missing values for individual data items will be represented by nulls.
9	Splitting datasets	<p>A domain dataset may be split into physically separate datasets to support submission when needed and as allowable by the regulatory authority. The following conventions must be adhered to when splitting domains into separate datasets:</p> <ul style="list-style-type: none"> • A domain based on a General Observation Class may be split according to values in variable --CAT. When a domain is split on --CAT, --CAT must not be null. • The Findings About Events or Interventions (FA) domain may be split according to the domain in which the interventions or events in --OBJ are represented (or would be represented). <p>To ensure split datasets can be appended back into 1 domain dataset:</p> <ul style="list-style-type: none"> • The value of DOMAIN must be consistent across the separate datasets as it would have been if they had not been split (e.g., LB, FA). • All variables that require a domain prefix (e.g., --TESTCD, --LOC) must use the value of DOMAIN as the prefix value (e.g., LB, FA). • --SEQ must be unique within USUBJID for all records across all the split datasets. If there are 1000 records for a USUBJID across the separate datasets, all 1000 records need unique values for --SEQ. • When relationship datasets (e.g., SUPPx, FAXx, CO, RELREC) relate back to split parent domains, the value of IDVAR will be from a variable with unique values for each observation. • Permissible variables included in one split dataset need not be included in all split datasets. • For domains with 2-letter domain codes, split dataset names can be up to 4 characters in length. For example, if splitting by --CAT, dataset names would be the domain name plus up to 2 additional characters to indicate the value of --CAT (e.g., LBHM for LB if the value of

Num	Guidance For	Implementation
		<p>--CAT is HEMATOLOGY). If splitting Findings About by parent domain, then the dataset name would be the domain code, "FA", plus the two-character domain code for parent domain code (e.g., "FACM"). The 4-character dataset-name limitation allows the use of a Supplemental Qualifier dataset associated with the split dataset.</p> <ul style="list-style-type: none"> Supplemental Qualifier datasets for split domains will also be split. The nomenclature will include the additional 1 to 2 characters used to identify the split dataset (e.g., SUPPLBHM, SUPPFACM). The value of RDOMAIN in the SUPP-- datasets would be the 2-character domain code (e.g., LB, FA). In RELREC, if a dataset-level relationship is defined for a split Findings About domain, then RDOMAIN will contain the 4-character dataset name, rather than the domain name "FA" (e.g., the value of RDOMAIN will be FACM).

Analysis Datasets

Observations about tobacco products and study subjects generated to support analysis in a submission are represented in a series of datasets based on the CLASS values described in the TIG. Datasets described in this guide are generally created to support a certain type of analysis, but sometimes analysis datasets are created to support the creation of a subsequent dataset that will be used for analysis. All datasets are structured as flat files with rows representing observations and columns representing variables.

The following guidance will be adhered to for analysis datasets:

Num	Guidance For	Implementation
1	Dataset content	<p>Data represented in datasets will include the following per regulatory requirements, scientific needs, and standards in this guide:</p> <ul style="list-style-type: none"> Data as originally collected or received (using controlled terminology where applicable) to support the submission Data from external references relevant to the submission (e.g., reference data) Data assigned per conventions in the TIG Data derived per regulatory and TIG conventions
2	Dataset naming	<ul style="list-style-type: none"> Analysis dataset naming has no predefined values. The only predefined name for analysis datasets is ADSL (Subject-level Analysis Dataset), which is suggested for studies where a 1-record-per-subject dataset is created to capture subject-level demographics, product usage, and/or trial experience information. All other ADaM datasets (besides ADSL) should be named AD + applicant-defined name (ADXXXXXX). The exception to this general naming convention is the addition of the RF prefix for reference data that has been introduced in the TIG. There is no rule that noncompliant datasets must start with AX or that they cannot start with AD. ADaM datasets should be named logically, if possible, and consistent naming conventions should be used across studies within a submission.
3	Variable order	<ul style="list-style-type: none"> There is no variable ordering defined for the ADaM standards, although having variables ordered together within a variable group helps review and dataset understanding. Variable order in the ADaM dataset must match the order in the define.xml file.
4	Variable names	<ul style="list-style-type: none"> Variables will be named per ADaM guidance, which uses fragment names in the CDISC NSV Registry. Variable names in TIG ADaM specifications align with naming conventions in ADaM. Variable names will be 8 characters or fewer and uppercase.
5	Variable labels	<ul style="list-style-type: none"> Descriptive labels per this guide, up to 40 characters, will be provided as data variable labels for all variables. All variables must use labels defined in Section 2.9.5, Predefined Standard Variables for ADSL, Section 2.9.6, Predefined Standard Variables for BDS, and Section 2.9.7, Predefined Standard Variables for OCCDS (besides the 2 exceptions described therein).
6	Variable length	<p>When variable length is referenced in the TIG, this refers to the length in bytes of ASCII character strings.</p> <ul style="list-style-type: none"> The maximum length of character variables is 200 characters, and the full 200 characters should not be used unless necessary. Applicants will consider the nature of the data and apply reasonable, appropriate lengths to variables. For example:

Num	Guidance For	Implementation
		<ul style="list-style-type: none"> ○ PARAMCD values will never be longer than 8 characters, so the length of that variable can be set to 8. ○ The length for variables that use controlled terminology can be set to the length of the longest term.
7	Variable value text case	Variable value text case generally depends on the variable usage and how it is presented on outputs (but there is no requirement that this usage must be followed).
8	Missing variable values	Missing values for individual data items will be represented by nulls if necessary for analysis. Otherwise, it is up to the dataset creator whether to include missing values in an analysis dataset.
9	Splitting datasets	An analysis dataset may be split into physically separate datasets to support submission when needed. ADaM currently has no conventions as to the proper way to split analysis datasets, although like types of data should have similar dataset naming.

2.7 Standards for Collection

The CDASH Model establishes a standard way to collect data across studies. Guidance in this section implements the CDASH Model for the TIG Product Impact on Individual Health use case and provides:

- basic data collection guidance and best practices;
- guidance for developing, managing, and using CRFs, irrespective of the inclusion of collected data in subsequent tabulation datasets; and
- guidance for mapping data collected via CRFs to tabulation datasets be used to as applicable with guidance in Section 2.8, [Standards for Tabulation](#).

The TIG supports development of CRFs but does not formally address data collection via other sources. Guidance in this section suggests a format to be presented to those entering collected data using CRFs but does not dictate any data structure or system in which to store the collected data. Applicants may choose to develop libraries of CRFs for organizational use. In such cases, following both the CDASH Model and TIG recommendations, taking into consideration both scientific and regulatory requirements, is recommended. To gain the greatest benefit, CRFs should not be developed on a study-by-study basis within the implementer organization, but rather be brought into a study from a library of approved CRFs based on the CDASH Model and the TIG, whenever feasible.

2.7.1 How to Read Collection Metadata

Collection metadata in this guide are instructions for implementing the CDASH Model to develop CRFs and the underlying database or other data collection structure. Collection metadata for the TIG are provided in Section 2.7.6, [Metadata for Individual Health](#). Guidance in this section describes how to read collection metadata provided in Section 2.7.6. Implementers should refer to Section 2.7.6 when reading this guidance.

Collection metadata will be used with guidance in this section and are organized with 1 set of metadata per domain. All collection metadata begin with a description of the domain. A metadata table follows to describe data collection fields and their attributes. Assumptions for the domain are also provided to further guide implementation. Metadata tables are structured to present 1 or more rows for each data collection field with columns to describe attributes for each field. More than 1 row will be present in a metadata table when data collection for a field can be performed using different scenarios or options. Multiple data collection options may also be provided in single cell within a row for a field with each option separated by a semicolon.

Each column in a metadata table provides domain-specific guidance for data collection, including guidance for:

- CRF and system design, with attributes to assist the development of CRF(s) and the underlying database structure in conformance with the standard
- Tabulation dataset generation, with attributes to assist the electronic generation of tabulation datasets from compliant data (e.g., via programming)
- CRF completion instructions, to assist the creation of applicant documentation for instructing how to complete CRF fields

The columns present in each metadata table are described below with the column name, guidance, and purpose.

Num	Metadata Table Column Name	Guidance	Purpose of Column Content
1	Observation Class	Tabulation dataset generation	Specifies the SDTM class for the domain (see SDTM v2.1, Sections 2.1 and 3.1, for more information on Observation Classes)
2	Domain	Tabulation dataset generation	Specifies the 2-letter domain code
3	Data Collection Scenario	CRF and system design	<p>Specifies when there are different data collection contexts for collection fields in the same domain (e.g., central or local processing for collection of laboratory test results). Values provide context for values in the TIG Core column to determine when a field should be present on the CRF. Values in this column are:</p> <ul style="list-style-type: none"> A short description of the data collection context N/A for when only 1 context is provided for the domain <p>This column can be used to filter the metadata table for specific data collection scenarios when developing CRFs.</p>
4	Implementation Options	CRF and system design	<p>Specifies when a sampling of collection metadata is provided as a template for the metadata of the CRF in a denormalized structure. Values in this column are:</p> <ul style="list-style-type: none"> NA to indicate data are collected in a normalized structure using a general variable for the name of the test and 1 variable for the collected results, resulting in a vertical dataset structure in which there is 1 record for each test/result Horizontal-generic to indicate data are collected using a unique variable name for each test, resulting in a wide, horizontal dataset with multiple test results in each record
5	Order Number	CRF and system design	Provides a suggested order of fields to be displayed on a CRF
6	Collection Variable	Tabulation dataset generation	<p>Provides the data collection variable name</p> <p>When the value in the Observation Class column is Findings, controlled terms must be incorporated into the data collection variable name.</p>
7	Collection Variable Label	CRF and system design	Provides the data collection variable label
8	DRAFT Collection Definition	CRF and system design	<p>Provides the draft definition for the data collection variable to support understanding and intended usage. Values in this column are further described in Section 1.5, Known Issues.</p>
9	Question Text	CRF and system design	<p>Provides full sentence/question forms to prompt for data. Values in this column are:</p> <ul style="list-style-type: none"> Without text in brackets or parentheses, to be used as-is With text in brackets, indicating an option on the verb tense of the question or text that can be replaced with protocol-specified verbiage or controlled terminology With text in parentheses, indicating options for text (e.g., singular/plural) or optional text that may be omitted With text separated with a forward slash, indicating options for wording from which an implementer may choose. <p>The CDASH Model can be referenced to create conformant alternative question text.</p>
10	Prompt	CRF and system design	<p>Provides short phrases to prompt for data. Values in this column are phrases:</p> <ul style="list-style-type: none"> Without text in brackets or parentheses, to be used as-is With text in brackets, to be replaced with protocol-specified verbiage or controlled terminology With text in parentheses, indicating optional text With text with <i>NULL</i> indicating the prompt is not required on a CRF screen/page if not needed <p>The CDASH Model can be referenced to create conformant alternative prompt text.</p>

Num	Metadata Table Column Name	Guidance	Purpose of Column Content
11	Data Type	Tabulation dataset generation	<p>Specifies the data type of the variable. Values for in this column are:</p> <ul style="list-style-type: none"> • <i>Num</i> for numeric data • <i>Char</i> for character or alphanumeric data
12	Collection Core	CRF and system design	<p>Specifies expectations for inclusion of the collection field on the CRF. Values are used with values in the Data Collection Scenario column to determine when a field will be present on the CRF. Values in this column are:</p> <ul style="list-style-type: none"> • <i>HR</i>, for fields that are Highly Recommended and should always be included on the CRF • <i>R/C</i>, for fields that are Recommended/Conditional and should be included on the CRF per certain conditions • <i>O</i>, for fields that are Optional and should be included on the CRF when needed to support data collection <p>When the value in this column is <i>R/C</i>, conditions are described in the Implementation Notes column.</p>
13	Case Report Form Completion Instructions	CRF completion instructions	Provides recommended example instructions for the data collection field to support authoring of study-level instructions for how to enter collected information on the CRF
14	Tabulation Target	Tabulation dataset generation	<p>This column provides the suggested mapping to the tabulation dataset variable. Values in this column are:</p> <ul style="list-style-type: none"> • The name of the tabulation dataset variable to which the value of the data collection variable will be mapped • <i>N/A</i> for when no direct mapping to a tabulation dataset variable is available • Text with the prefix <i>SUPP</i> for when the value of the data collection variable will be mapped as a supplemental qualifier.
15	Mapping Instructions	Tabulation dataset generation	Provides information on the suggested mapping of the data collection variable to the tabulation variable. Additional guidance for mapping values may be described in the Implementation Notes column.
16	Controlled Terminology Codelist Name	CRF and system design Tabulation dataset generation	<p>Specifies the name or names of the CDISC Controlled Terminology codelist(s) associated with the data collection field and variable. Values in this column are:</p> <ul style="list-style-type: none"> • The codelist name in parentheses, when 1 codelist is associated • Codelist names in parentheses separated by commas, when more than 1 codelist is associated • <i>N/A</i> for when controlled terminology is not associated with the data collection field and variable
17	Subset Controlled Terminology/CDASH Codelist Name	CRF and system design Tabulation dataset generation	<p>Specifies CDISC CT terms or the name of the CDASH subset codelist associated with the data collection field and variable. Values in this column are:</p> <ul style="list-style-type: none"> • A controlled terminology term or a subset of terms from the codelist referenced in the Controlled Terminology Codelist Name column • The name of the CDASH subset codelist in parentheses • <i>N/A</i> for when specific controlled terms or CDASH subset terminology are not applicable
18	Implementation Notes	CRF and system design Tabulation dataset generation	<p>Provides further context for implementation of data collection fields and variables. Values in this column may include:</p> <ul style="list-style-type: none"> • Rationale for implementation guidance • Additional instructions for implementing fields and variables on the CRF and in the underlying database structure • Example values which could appear in the in the data collection field and variable • Additional guidance for mapping values from data collection to tabulation variables <p>Example values provided are intended to support understanding and are not intended to influence decisions regarding what data to collect. For guidance on the selection of data to collect, please refer to the appropriate regulatory authority.</p>

2.7.2 How to Extend Metadata

If data are in scope for a domain defined in this guide but not all data can be collected using the domain's collection fields, then collection fields may be added to the applicant's CRF from the CDASH Model, the SDTM, or created by the applicant using guidance in the TIG.

Prior to adding fields from the CDASH Model, the SDTM, or considering a new applicant-defined collection field, confirm that none of the fields in the domain will fit the need. Fields may be added from the CDASH Model, the SDTM, or created only when data are different in nature and are not in scope for collection fields in this guide.

Once confirmed, the overall process for extending metadata is as follows:

1. Using the root variables and other CDASH metadata in the CDASH Model, add any additional variables that are needed to meet the requirements of data collection.
 - a. Refer to both the CDASH Model and Appendix C, [CDASH Model Metadata Tables](#).
 - b. Follow CDASH root variable-naming conventions where they exist (e.g., --DAT for dates, --TIM for times, --YN for prompts, as described in the CDASH Model) and align with CDISC NSV Registry conventions as applicable.
2. Select variables from the SDTM when fields from the CDASH Model cannot be used. Selection of variables must align with SDTM usage restrictions.
3. Create a new applicant-defined collection field when fields in the CDASH Model and variables from the SDTM cannot be used.
 - a. When creating a new applicant-defined collection field, determine whether the data will be used for an operational use case (e.g., data cleaning) or are to be represented in a tabulation dataset. In general, new data collection fields (not already defined in the CDASH Model) will fall in 1 of following categories:
 - i. a field used for operational, data cleaning purposes only;
 - ii. a field used to collect data that have direct mapping to a target variable in the tabulation dataset; or
 - iii. a field used to collect data that have no direct mapping to a target variable in the tabulation dataset.
 - b. The following table provides implementation guidance aligned with both the category of the field and target variable.

Num	Field Category	Target Tabulation Variable	Implementation
1	Data cleaning	NA	The field --YN with Question Text "Were there any [interventions/events/findings]?" can be used for this purpose. Replace the 2 dashes (--) with the 2-character domain code and create the question text or prompt using generic question text or prompts from the CDASH Model as a base. Always create custom data-cleaning/operational variables using consistent naming conventions.
2	Direct mapping	Yes	If a value can be collected exactly as it will be reported in the tabulation dataset (i.e., same value, same data type, same meaning, same controlled terminology), the tabulation variable name will be used as the data collection variable name in the operational database to streamline the mapping process. Characters may be appended to the data collection variable name if needed to create a unique variable name in the collection database. Any collection variable whose meaning is the same as tabulation variable will align with tabulation variable and the meaning will not be modified for data collection.
3	No direct mapping	Yes	If a value cannot be collected in alignment with the tabulation dataset variable (e.g., collected data type is different from the data type in the corresponding tabulation variable) or if the tabulation variable is derived from the collected value, then the operational database should use a collection variable with a different name from tabulation variable into which it will be mapped.

Num	Field Category	Target Tabulation Variable	Implementation
		No	If a field does not align with a tabulation variable, a unique name should be assigned based on applicant business rules using CDASH naming fragments (e.g., --DAT, --TIM) as appropriate and CDISC variable naming fragments, found in the CDISC NSV Registry, where possible.

If data are not in scope for a domain in this guide, a custom domain can be used. An existing domain may help in selecting the fields and terminology needed for the custom domain. The custom domain must be based on one of the SDTM general observation classes. See Section 2.8.3, [How to Create New Specifications](#), for further information.

2.7.3 How to Develop Case Report Forms

The following steps are recommended to support development of CRFs using standards in this guide.

Order	Step	Implementation
1	Identify data collection requirements.	Determine requirements for data collection from the protocol and by reviewing internally maintained libraries of standardized CRFs when applicable.
2	Identify collection domains and fields.	Review collection standards in this guide to identify data collection domains and fields which align with collection requirements. As much as possible, domains in this guide will be used to collect data in a manner that will be effective for data collection. Develop the data collection tools using domains in this guide first. Create and use additional fields in alignment with guidance in Section 2.7.2, How to Extend Metadata . Create new domains in alignment with Section 2.8.3, How to Create New Specifications .
3	Identify the target tabulation domain.	During the development of conformant collection instruments, the tabulation domain to which the collected data will be mapped will be determined. A tabulation domain will be used when the nature of the data aligns with the scope of a domain and irrespective of the mode of data transmission, the methodology used to generate the data, the medium used to store the data, the person who recorded the data, or the subject described by the data.

2.7.4 General Collection Guidance

Guidance in this section will be used with detailed guidance in Section 2.7.6, [Metadata for Individual Health](#), to implement collection standards.

2.7.4.1 Collection Assumptions

Assumptions in this section are applicable to Interventions, Events, and Findings class domains and will be used with domain-specific assumptions as appropriate.

Hidden variables are variables in an operational database that are used to collect values assigned by the applicant that are not entered via a CRF. Such values are predetermined, fixed, and may or may not be displayed on the CRF as noneditable fields.

The following assumptions will be implemented for **Interventions** class domains.

Num	Collection Variable Use	Implementation
1	--YN	<ul style="list-style-type: none"> --YN ("Yes/No") questions are used to provide a definite answer. The absence of a response is ambiguous as it can mean "no," "none," or that the response is missing. Variables with the question text "Were there any interventions?" (e.g., "Were there any concomitant medications?") support the cleaning of data and confirmation that entry of collected data is complete. Values collected for these fields will not be represented in subsequent tabulation datasets.
2	--CAT, --SCAT	<ul style="list-style-type: none"> Categories and subcategories are determined per protocol design and values are generally not entered via CRF. Implementers may: <ul style="list-style-type: none"> Prepopulate and display category values to help individuals involved in data collection understand what data should be recorded on the CRF. Prepopulate hidden variables with the values assigned within their operational database. Populate values directly in the tabulation dataset during dataset creation.

Num	Collection Variable Use	Implementation
3	Variables for date and time	<ul style="list-style-type: none"> The time an intervention started will be collected if there is a scientific or regulatory reason to collect this level of detail and the time can be realistically determined. Collection variables for date (e.g., --DAT, --STDAT, --ENDAT) will be concatenated with collection variables for time (e.g., --TIM, --STTIM, --ENTIM) as applicable to populate tabulation variables for dates (e.g., --DTC, --STDTC, --ENDTC) using ISO 8601 format.
4	-- REASND	<ul style="list-style-type: none"> --REASND is used with tabulation variable --STAT. The value "NOT DONE" in --STAT indicates that the subject was not questioned about the intervention or that data were not collected; it does not mean that the subject had no interventions.
5	--SPID	<ul style="list-style-type: none"> --SPID may be populated by the implementer's data collection system. If collected, --SPID it can be used as an identifier in a data query to communicate clearly to individuals involved in data collection the record in question.
6	Coding	<ul style="list-style-type: none"> When free-text interventions/treatments are recorded, the location may be included in the --TRT variable to facilitate coding (e.g., lung biopsy). Location may be collected when the implementer needs to identify the specific anatomical location of the intervention. This location information does not need to be removed from the verbatim --TRT when creating tabulation datasets. The NSVs --ATC1 through --ATC5 and --ATC1CD through --ATC5CD are used only when the intervention is coded using the World Health Organization's Anatomical Therapeutic Chemical (ATC) classification system (https://www.who.int/medicines/regulation/): 1 = the anatomical main group, 2 = the therapeutic main group, 3 = the therapeutic/pharmacological subgroup, 4 = chemical/therapeutic/pharmacological subgroup, 5 = chemical substance. Implementers may add MedDRA coding elements as NSVs to the Interventions domain if that dictionary is used for coding.
7	Location (--LOC) and related variables (--LAT, --DIR, --PORTOT)	<ul style="list-style-type: none"> Applicants may collect location data using a subset list of controlled terminology on the CRF. Applicants may prepopulate hidden variables with values assigned within their operational database.

The following assumptions will be implemented for **Events** class domains.

Num	Field or Variable	Guidance
1	--YN	<ul style="list-style-type: none"> --YN ("Yes/No") questions are used to provide a definite answer. The absence of a response is ambiguous as it can mean "no," "none," or that the response is missing. Variables with the question text "Were there any <events>?" (e.g., "Were there any adverse events?") support the cleaning of data and confirmation that entry of collected data is complete. These questions can be used on any CRF. Values collected for these fields will not be represented in subsequent tabulation datasets.
2	--CAT, --SCAT	<ul style="list-style-type: none"> Categories and subcategories are determined per protocol design and values are generally not entered via CRF. Implementers may: <ul style="list-style-type: none"> Prepopulate and display category values to help individuals involved in data collection understand what data should be recorded on the CRF. Prepopulate hidden variables with the values assigned within their operational database. Populate values directly in the tabulation dataset during dataset creation.
3	Variables for date and time	<ul style="list-style-type: none"> The time of an event will be collected if there is a scientific or regulatory reason to collect this level of detail and the time can be realistically determined. Collection variables for date (e.g., --DAT, --STDAT, --ENDAT) will be concatenated with collection variables for time (e.g., --TIM, --STTIM, --ENTIM) as applicable to populate tabulation variables for dates (e.g., --DTC, --STDTC, --ENDTC) using ISO 8601 format.
4	--OCCUR	<ul style="list-style-type: none"> --OCCUR may be used when a specific event is solicited (preprinted) on the CRF and the CRF uses an applicant-defined codelist. --OCCUR = "N" indicates the pre-specified event did not occur. --OCCUR may be implemented while also allowing for a "NOT DONE" response.
5	--REASND	<ul style="list-style-type: none"> --REASND is used with tabulation variable --STAT. The value "NOT DONE" in --STAT indicates that the subject was not questioned about the event or that data were not collected; it does not mean that the subject had no events.
6	--SPID	<ul style="list-style-type: none"> --SPID may be populated by the applicant's data collection system.

Num	Field or Variable	Guidance
		<ul style="list-style-type: none"> If collected, --SPID it can be used as an identifier in a data query to communicate clearly to individuals involved in data collection the record in question.
7	Coding	<ul style="list-style-type: none"> The collection variables used for coding are not data collection fields that will appear on the CRF. Applicants will populate values through the coding process. When free-text event terms are entered, the location may be included in --TERM to facilitate coding and further clarify the event. This location information does not need to be removed from the verbatim term when creating tabulation datasets. The CDASH variables --LLT, --LLTCD, --PTCD, --HLT, --HLTC, --HLG, --HLGTCD, --SOC, and --SOCCD are only applicable to events coded in MedDRA.
8	Location (--LOC, --LAT, --DIR, --PORTOT)	<ul style="list-style-type: none"> Location is collected when the applicant needs to identify the specific anatomical location of the event. Implementers may collect location data using a subset list of controlled terminology on the CRF. Implementers may prepopulate hidden variables with values assigned within their operational database.

The following assumptions will be implemented for **Findings** class domains.

Num	Field or Variable	Guidance
1	--CAT, --SCAT	<ul style="list-style-type: none"> Categories and subcategories are determined per protocol design and values are generally not entered via CRF. Implementers may: <ul style="list-style-type: none"> Prepopulate and display category values to help individuals involved in data collection understand what data should be recorded on the CRF. Prepopulate hidden variables with the values assigned within their operational database. Populate values directly in the tabulation dataset during dataset creation.
2	--PERF, --STAT, --REASND	<ul style="list-style-type: none"> --PERF defines - variables to record whether an assessment has been performed/collected. --REASND is used to collect a reason why an assessment was not done. --PERF has the Question Text "[Were any/Was the] [-TEST/ topic] [measurement(s)/test(s) /examinations (s)/specimen(s) /sample(s)] [performed/collected]?" are intended to assist in the cleaning of data and in confirming that entry of collected data is complete. --PERF may be used at the page, panel, or question level. --PERF may be used during the creation of tabulation datasets to derive a value into the SDTM variable --STAT. The implementer can use a combination of --CAT, --SCAT, with the --TESTCD= "--ALL" and --TEST= "<Name of the CRF module>" to represent what tests were not performed. Implementers must decide how to model each test not performed (e.g., to denote that all tests were not performed using TESTCD = "--ALL"). --STAT has the Question Text "Was the [-TEST] not [completed/answered/done/assessed/evaluated]?; Indicate if (the [-TEST] was) not [answered/assessed/done/evaluated/collected]." This is intended to be used to collect a simple "NOT DONE" check box at the page, panel, or question level. --REASND is used with SDTM variable --STAT only. The value NOT DONE in --STAT indicates that a question was not asked or a test was not done, or a test was attempted but did not generate a result.
3	--SPID	<ul style="list-style-type: none"> --SPID may be populated by the applicant's data collection system. If collected, it can be beneficial to use an identifier in a data query to communicate clearly to the site the specific record in question. This field may be populated by the applicant's data collection system.
4	Variables for date and time	<ul style="list-style-type: none"> Time will be collected if there is a scientific or regulatory reason to collect this level of detail and the time can be realistically determined. <ul style="list-style-type: none"> Metadata tables generally include --DAT and --TIM will be added from the CDASH Model as appropriate. Collection variables for date and time (e.g., --DAT, --TIM) will be used to collect the date or date and time that the test was performed, or the specimen was collected. The start and end dates and times (e.g., for specimen collection) will be collected as appropriate. The date of collection of a test can be derived from the date of visit. In such cases, a separate date of observation field is not required to be present on the CRF. Date and time variables will not be used to collect dates that are the result of a tests. Test results will be collected using --ORRES.

Num	Field or Variable	Guidance
5	Horizontal (denormalized) and vertical data structures (normalized)	<ul style="list-style-type: none"> In metadata specifications, many of the Findings class domains are presented in a normalized structure (1 record for each test) similar to a tabulation dataset, even though many data management systems hold the data in a denormalized structure (1 variable for each test). When implementing collection standards in a denormalized structure, create variable names for the Findings --TEST and/or --TESTCD values. To do this: <ul style="list-style-type: none"> Define the denormalized variable names using available CDISC Controlled Terminology for --TESTCD; or When a system allows more than 8-character variable names, the value of variable --TESTCD can be concatenated with the tabulation variable name separated by an underscore (e.g., DIABP_VSORRES, DIABP_VSLOC). In the horizontal (denormalized) setting, collection variables such as --PERF, --LOC , and --STAT can be collected once for the whole horizontal record and applied to all of the observations on that record, or collected per test using collection variables, such as <>--TESTCD>_--PERF. When tabulation datasets are created, any variables collected for the entire horizontal record will be mapped to each vertical record per tabulation guidance. In the horizontal (denormalized) setting, an identifier can be used to identify all --TESTCD for the same collection record. This supports mapping of data collected in a horizontal setting to tabulation datasets and creation of RELRECs.
6	Tests and original results	<ul style="list-style-type: none"> The value in --TEST will be 40 characters or less. The corresponding codelist value for the short test name, 8 characters or less, will be populated in the tabulation variable --TESTCD. Variable --TESTCD should be used to create a variable name and --TEST be used as the prompt on the CRF. Both --TESTCD and --TEST are recommended for use in the operational database. Variable --ORRES is used to collect test results or findings in the original units as received or collected in character format. If results are modified for coding, the --MODIFY variable contains the modified text. Variables --ORNRL and --ORNRI and --NRIND are used when normal or reference ranges are collected for results. Standardization of the original results and/or normal/reference ranges will be performed during the creation of tabulation datasets.
7	Location variables (--LOC, --LAT, --DIR, --PORTOT)	<ul style="list-style-type: none"> Location variables are used to collect the location of the test. Applicants may collect location data using a subset list of controlled terminology on the CRF. Applicants may prepopulate hidden variables with values assigned within their operational database.
8	--ORRES, --RES, --DESC, and --RESOTH	<ul style="list-style-type: none"> Variables --ORRES, --RES, --DESC, and --RESOTH are used to collect results. It is recommended that: <ul style="list-style-type: none"> --ORRES is used when the result is collected using a single question. The result will map directly to the tabulation variable --ORRES. --RES and --DESC are used when a pair of questions are asked to collect the result; a question to collect the result with a follow-up question for a description of the result. For example, the question "Is the <condition> [absent/present]?" with a follow-up question "What is the finding that was observed?" where --RES is used to collect whether the finding is normal/abnormal or absent/present and --DESC is used to collect the description of the finding. --RES and --RESOTH are used when a question is asked that allows the selection of a prespecified finding, with a follow-up question to ask about the pre-specified response "OTHER". For example, the question "What is the result?" with a set of prespecified responses, including the choice "OTHER" with the follow-up question "Specify, Other".
9	Root variables	<ul style="list-style-type: none"> The Findings About Events and Intervention domains use the same root variables as the Findings domain, with the addition of the --OBJ variable.

2.7.4.2 How to Collect Timing

Timing variables defined in the CDASH Model and implemented per the TIG are used to collect when observations occur, and periods of time associated with observations. The following table describes how fields will be used to collect the timing of observations.

Num	Collection Variable Use	Implementation
1	By observation class	<ul style="list-style-type: none"> In Events and Interventions domains, timing variables will generally be used to collect the start date of the event or intervention. In Findings domains, timing variables will generally be used to collect the date associated with test results; except in cases where results are generated from the testing of specimens (e.g., laboratory testing). In such cases, timing variables will be used to collect the date of the specimen collection for the associated test.
2	Collection of visits	<ul style="list-style-type: none"> Protocols define visits to describe the timing of assessments and procedures. Variables VISIT and VISITNUM will generally be used to collect visits associated with observations. Variable VISDAT will generally be used to collect the date visits occurred.
3	Precision of dates	<ul style="list-style-type: none"> Dates will be collected in a way that allows individuals involved in data collection to record only the precision they know. <ul style="list-style-type: none"> Data collection and database processes will allow for the possibility of partial dates and times, because a partial date may be the most precise information that can be collected. The system will also store only the collected precision. Incomplete dates will remain incomplete in the system with no imputation and no "zero-filling" of missing components. If a full date is expected or collected, variable --DAT or all 3 date components (i.e., --DATYY, --DATMO, --DATDD) will be included on the CRF. If a partial date can be collected in a single field, variable --DAT will be used. If a partial date must be collected in separate fields for year, month, and day, refer to the CDASH Model for examples of standard naming fragments (--YY, --MO, --DD, --TIM). The capabilities of individual software systems (e.g., EDC) will determine which fragments will be used.
4	Imputation of dates	<ul style="list-style-type: none"> The collected value of variable VISDAT can be applied to all observations for a given visit as appropriate, or timing variables can be included for specific observations in the body of the CRF. Missing parts of the date will not be imputed by the system.
5	Variable DTHDAT	<ul style="list-style-type: none"> The CDASH Model defines DTHDAT as a timing variable, as it may be collected via any CRF deemed appropriate by the applicant. The date of death should only be collected once for a subject.

2.7.4.3 Collecting References and Relative Timing

Timeframes, fixed points in time, and other milestones may be defined in the context of a study as references to which the timing of other collected observations are related. In such cases, timeframes are referred to as "reference periods" and such fixed points in time and milestones are referred to as "reference timepoints." The following will be collected using TIG collection or CDASH Model timing fields when references for the timing of other observations are defined:

- Start and end dates, and times as applicable, for reference periods
- Dates, and times as applicable, for reference timepoints

The date, and time as applicable, of an observation to be related to a reference will be collected whenever possible. Only in cases where it is not possible to collect the date of a related observation (e.g., the date is not available), will a relative timing for the observation in relation to a reference be collected. Relative timing will be collected using collection variables:

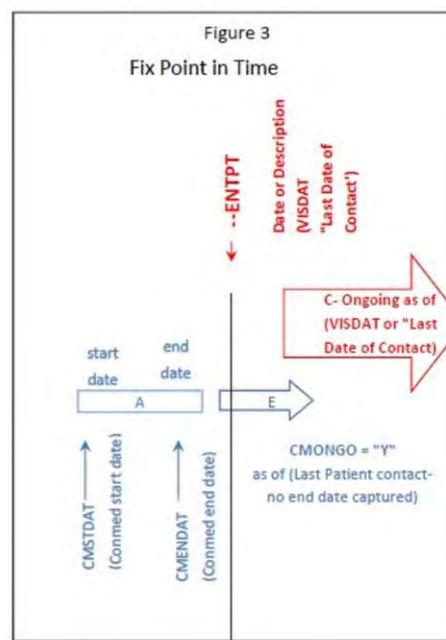
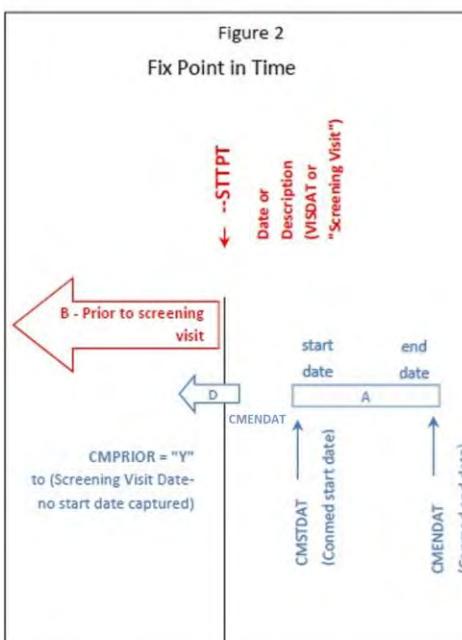
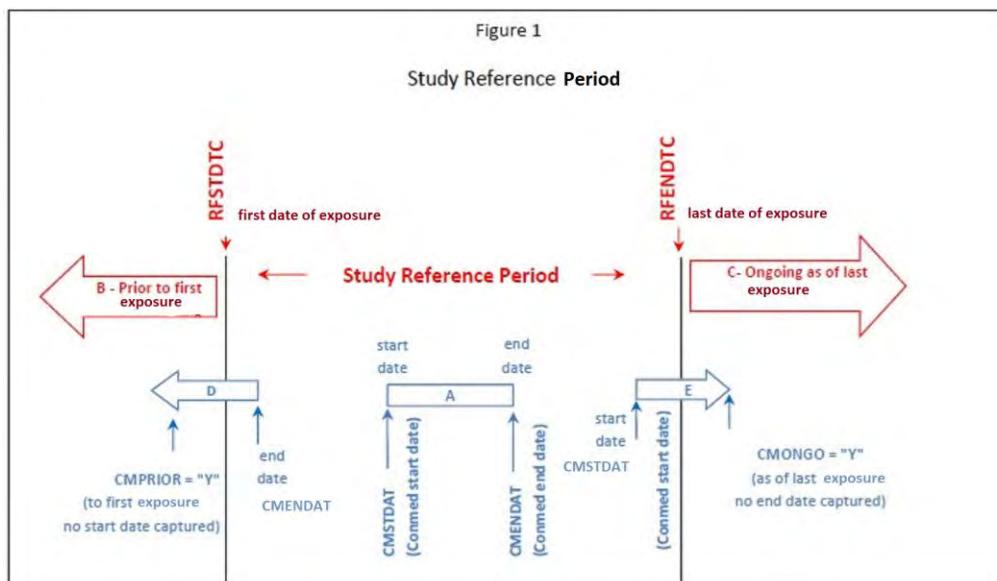
- PRIOR to indicate the timing of the observation was prior to the start date of a reference period or the date of a reference time point; or
- ONGO to indicate the timing of the observation was ongoing relative to the end date of a reference period or the date of a reference timepoint.

The following steps should be taken when designing CRFs to ensure observations of interest can be related to reference periods and reference timepoints:

- Define the reference period and/or reference timepoint(s) in the context of the study.
- Collect the start and end date/times of the reference period and/or the date/time of the reference timepoint(s) using appropriate TIG collection or CDASH Model fields.
- Collect the actual timing of observations when it is possible to collect the date(s) for a related observation.

4. Collect relative timing of observations when collection of actual dates is not possible using fields --PRIOR and --ONGO (e.g., "prior", "ongoing") for when an observation started or continued, in relation to the study reference period and/or reference timepoint(s).

The figures below show examples of collection of relative timing in relation to a reference period and reference timepoints; the table that follows describes the figures. Representation of collected reference dates and relative timing in subsequent tabulation datasets is noted below and further described in Section 2.8.7.6, [Representing References and Relative Timing](#).



Num	Figure(s)	Reference	Description
1	Figure 1	Reference period	<ul style="list-style-type: none"> The <i>reference period</i> is defined as the timeframe between the reference start date for the subject and the reference end date for the subject. This reference period is chosen by the applicant according to the needs of the study and may vary. In Figure 1 the study reference period corresponds to the time between subjects' first and last exposure to a tobacco product, which is a typical scenario for a study reference period. This reference period (represented by the time between B and C) is part of the overall context of the study.

Num	Figure(s)	Reference	Description
			<ul style="list-style-type: none"> • Observations about concomitant medications used by the subject with the timing of use are collected in relation to the study reference period: <ul style="list-style-type: none"> ◦ For A, the start and end dates for the concomitant medication are known and are collected. <ul style="list-style-type: none"> ▪ Collection fields CMSTDAT and CMENDAT are used to collect the start and end dates for the concomitant medication. ◦ For D, the start date for the concomitant medication is unknown and cannot be collected. <ul style="list-style-type: none"> ▪ Collection field CMPRIOR is used to collect that the known start of the concomitant medication relative to exposure is prior to the subject's first exposure. ▪ Collection field CMENDAT is used to collect the known end date. ◦ For E, the subject has not discontinued the concomitant medication and therefore the end date for the concomitant medication cannot be collected. <ul style="list-style-type: none"> ▪ Collection field CMSTDAT is used to collect the known start date. ▪ Collection field CMONGO is used to collect that the use of the concomitant medication is ongoing relative the subject's last exposure. • The following variables are used to represent collected data in subsequent tabulation datasets: <ul style="list-style-type: none"> ◦ RFSTDTC and RFENDTC represent the dates of the subject's first and last exposure to the tobacco product (per Figure 1), respectively, in the Demography (DM) dataset. ◦ CMSTRF and CMENRF represent values from collection variables CMPRIOR and CMONGO in the Concomitant Medications (CM) dataset.
2	Figures 2 and 3	Reference timepoint	<ul style="list-style-type: none"> • Two reference timepoints are defined for the subject: the screening visit and the date of last contact. The reference timepoints (represented by B and C) are part of the overall context of the study. • Observations about concomitant medications used by the subject with the timing of use are collected in relation to the reference timepoints: <ul style="list-style-type: none"> ◦ For A, the start and end dates for the concomitant medication are known and are collected. <ul style="list-style-type: none"> ▪ Collection fields CMSTDAT and CMENDAT are used to collect the start and end dates for the concomitant medication. ◦ For D, the start date for the concomitant medication is unknown and cannot be collected. <ul style="list-style-type: none"> ▪ Collection field CMPRIOR is used to collect that the known start of the concomitant medication relative to Screening is prior to the subject's screening visit. ▪ Collection field CMENDAT is used to collect the known end date. ◦ For E, the discontinuation date for the concomitant medication is unknown and cannot be collected. <ul style="list-style-type: none"> ▪ Collection field CMSTDAT is used to collect the known start date. ▪ Collection field CMONGO is used to collect that the use of the concomitant medication is ongoing relative the subject's date of last contact. • The following variables are used to represent collected data in subsequent tabulation datasets: <ul style="list-style-type: none"> ◦ CMSTTPT and CMENTPT represent the date or a short description of the subject's screening visit and last contact respectively in the CM dataset. ◦ CMSTRPT and CMENRPT represent values from collection variables CMPRIOR and CMONGO in the CM dataset.

2.7.5 Best Practices

This section provides content and operational recommendations to support data collection, suggested CRF development workflow, and methods for creating data-collection instruments. For additional guidance, see the Society for Clinical Data Management's Good Clinical Data Management Practices standard at <https://scdm.org/gcdmp/>.

2.7.5.1 Organizational Practices for Data Collection

The following best practice recommendations are general data collection principles for use by organizations to ensure data collected are fit for purpose, complete, and of high quality.

Num	Best Practice Recommendation	Rationale
1	Collect necessary data only. CRFs should focus on collecting only applicable data in alignment with regulatory needs.	Usually, only applicable data collected in alignment with regulatory needs should be collected on the CRF, due to the cost and time associated with collecting and fully processing

Num	Best Practice Recommendation	Rationale
	The protocol should clearly state which data will be collected in the study.	<p>The data. However, some fields on a CRF may be present to support EDC functionality and/or review and cleaning of data through automated edit checks.</p> <p>The protocol (and SAP, when it is prepared in conjunction with the protocol) should be reviewed to ensure that the parameters needed for analysis are collected and can be easily analyzed. The statistician and/or principal investigator is responsible for confirming that the CRF collects all of the data necessary to support the analysis.</p>
2	<p>CRF development should be a controlled, documented process that incorporates (as applicable):</p> <ul style="list-style-type: none"> • Design • Review • Approval • Versioning • Printing • Distributing CRFs • Accounting for unused CRFs <p>CRF development should be controlled by standard operating procedures (SOPs) covering these topics, as well as training.</p>	A controlled process for developing CRFs will help ensure that CRFs comply with applicable standards and processes.
3	<p>The CRF design process should include adequate review and approval steps, and each reviewer should be informed on the scope of the review they are expected to provide.</p> <p>The team that designs the data collection instruments for a study should be involved in the development of the protocol and should have appropriate expertise represented on the CRF design team, including the following:</p> <ul style="list-style-type: none"> • Scientific experts should provide sufficient information to ensure data standards staff, subject matter experts, and data management staff understand the background, context, and scientific relevance of study data being collected. • Data management, standards subject matter experts, and CRF designers should review the protocol to ensure that proposed data can be collected and should ensure that appropriate standards are used to develop the CRF. • Statisticians should review the CRF against their planned analyses to make sure all required data will be collected in an appropriate form for those analyses. • Operations experts should review the CRF to make sure the questions are unambiguous, requested data can be collected, and for compatibility with common workflow and procedures. • Programmers should review the CRF to ensure that the manner in which the data are collected on the CRF is consistent with relevant metadata standards. • Regulatory experts should review the CRF for compliance with all applicable regulations. • Data management experts should review the CRF to ensure that the data are collected in a form that can be entered accurately. <p>Ideally, the CRF should be developed in conjunction with the protocol (and the SAP, if available).</p> <p>All research-related data on the CRF should be addressed in the protocol to specify how and when it will be collected.</p>	Reviewers from different functions increase the probability that the CRF will be easier to complete and support the assessment of the product as defined in the protocol and SAP. The CRF design team should ensure that the data can be collected in a manner that is consistent with the implementer's processes and is easy to complete.
4	Translations of CRFs into other languages should be done under a controlled process by experts who understand both the study questions and the language and culture for which the CRF is being translated. The translation should	Cultural and language issues should be addressed appropriately during the process of translating CRFs to ensure the CRF questions have consistent meaning across languages.

Num	Best Practice Recommendation	Rationale
	<p>be a parallel process following the same set of steps with separate reviews and approvals by the appropriate experts. Translations may require author approval and a separate validation of the translated instrument.</p> <p>CRFs that are translated into other languages should follow the same development process as the original CRF to ensure the integrity of the data collected.</p> <p>Consideration of translation should be part of the CRF development process. Avoid the use of slang or other wording that would complicate or compromise translation into other languages.</p>	
5	<p>Data that are collected on CRFs should be databased. For some fields, such as "Were there any Adverse Events?" the response of "Yes/No" may need to be databased but will not be included in tabulation datasets.</p> <p>Some fields, such as Investigator's Signature, can be verified by the data entry staff, but an actual signature may not be databased unless there is an e-signature.</p>	<p>If certain data are not required in the CRF, but are needed to aid the investigator or monitor, those data should be recorded on a worksheet (e.g., entry criteria worksheet, dose titration worksheet).</p> <p>All such worksheets should be considered source documents or monitoring tools and should be maintained with the study files.</p>
6	<p>Establish and use standardized CRFs.</p>	<p>Using data collection standards across studies saves time and money across tobacco product development steps. Using standards:</p> <ul style="list-style-type: none"> • Reduces production time for CRF design and reduces review and approval time • Reduces retraining and queries and improves compliance and data quality at first collection • Facilitates efficient monitoring, reducing queries • Improves the speed and quality of data entry due to familiarity with standards and reduces the training burden in-house • Enables easy reuse and integration of data across studies and facilitates data mining and the production of integrated summaries • Reduces the need for new programming with each new study

2.7.5.2 Creating Data Collection Instruments

The following best practice recommendations are general principles for the development of data collection instruments to ensure data collected are complete and of high quality.

Num	Best Practice Recommendation	Rationale
1	<p>When a binary response is expected, "Yes/No" responses are preferred over "Check all that apply," because a missing response could lead to a misinterpretation of critical data.</p> <p>If an assessment has composite responses (e.g., presence or absence of 2 or more subject characteristics), "Yes/No" questions for each component response (e.g., characteristic) are preferred to "Check all that apply" questions.</p> <p>Exceptions to this recommendation include:</p> <ul style="list-style-type: none"> • Assessments where the majority of options would be answered "No". • When a validated instrument contains checkboxes. In this case, they should remain checkboxes in the CRF or eCRF. • When controlled terminology is required for the values being collected. <p>In cases where the applicant chooses to use "Check all that apply", additional quality checks should be considered (e.g., source data verification) to ensure the data collected in the CRF are correct and complete.</p>	<p>"Yes/No" questions provide a definite answer. The absence of a response is ambiguous as it can mean "No," "None," or that the response is missing.</p> <p>In situations where there is no other dependent or related field by which to gauge the completeness of the field in question, a "Yes/No" response ensures that the data are complete.</p>
2	The database should contain an indication that a planned exam/assessment was not performed. The mechanism for	This will provide a definitive indicator that a data field has missing data and has not been overlooked.

Num	Best Practice Recommendation	Rationale
1	<p>this may be different from system to system or from paper to EDC.</p> <p>A "Yes/No – assessment completed" question is preferred over a "Check if not done" box, unless the "Check if not done" field can be compared to a completed data field using a validation check to confirm that one or the other has data.</p> <ul style="list-style-type: none"> In situations where there is no other dependent or related field to gauge the completeness of the field in question, a "Yes/No" response format should be used to eliminate ambiguity. When another related field is present, the "Yes/No" response is optional. For example, when a value for temperature is missing, a simple "Not Done" box may be checked. It is not necessary to respond "Done" when a temperature value is present. 	<p>This will prevent unnecessary data queries to clarify whether an assessment has been performed.</p> <p>The use of the "Yes/No" format helps to eliminate ambiguity about whether an assessment has been completed.</p>
3	<p>Data-cleaning prompts should be used to confirm that blank CRFs are intentionally blank.</p> <p>Usually this will be a "Yes/No" question but it may be a "Check if blank" box, if a validation check can be used to confirm that either the "Check if blank" box is checked, or that there are data recorded in the CRF.</p>	<p>This will provide a definitive indicator that a CRF is blank on purpose and has not been overlooked.</p> <p>This will prevent unnecessary data queries.</p>
4	<p>The same data (i.e., the same information at the same time) should not be collected more than once.</p>	<p>Collecting the same data more than once:</p> <ul style="list-style-type: none"> Creates the opportunity for discrepancies between the entered values. For example, subject's birthdate or age is collected on the Demographics page; it is not necessary to collect age on the Lab CRF at every visit. Requires extra reconciliation. May affect frequency counts and analysis results.
5	<p>A "Check if ongoing" question is recommended to confirm ongoing against an end date.</p> <p>This is a special-use case of "Yes/No," where the data entry field may be presented as a single possible response of "Yes" in conjunction with an End Date variable. If the box is checked, the operational variable may contain "Yes". If the box is not checked and the End Date is populated, the value of the variable may be set to "No".</p> <p>For some EDC systems, it may be better to display the possible responses to the "Check if ongoing" question as radio buttons. Conditional logic can then be used to solicit the collection of the end date only if the answer to the "Ongoing" question is "N" (No).</p>	<p>For the use case of "Check if ongoing," for the data to be considered "clean," 1 of the 2 responses must be present and the other response must be blank. So, the presence of the end date provides confirmation that the event is not ongoing.</p>
6	<p>CRFs should use a consistent order of responses (e.g., "Yes/No") from question to question, for questions with response boxes or other standardized lists of values.</p> <p>Exceptions to this are validated instruments (e.g., a standardized assessment questionnaires) where the order of responses is dictated by the instrument.</p>	<p>A consistent order of response boxes promotes ease of use of the CRF to help reduce data entry errors and to avoid introducing bias or leading the investigator to a desired response.</p>
7	<p>CRF questions and completion instructions should be unambiguous and should not "lead" the answer to the question in a particular way.</p>	<p>Data should be collected in a way that does not introduce bias or errors into the study data. Questions should be clear and unambiguous. This includes making sure that the options for answering the question are complete, such as providing options for "Other" and "None" when applicable.</p>
8	<p>CRF questions should be as self-explanatory as possible, thereby reducing the need for separate instructions.</p> <p>If required, short instructions may be placed on the CRF page, especially if the prompt is not specific enough. More detailed instructions may be presented in a CRF completion guideline. All instructions should be concise.</p> <p>Instructions should be standardized as much as possible.</p>	<p>Putting short instructions and prompts on the CRF increases the probability that they will be read and followed, and can reduce the number of queries and the overall data cleaning costs.</p> <p>Having standard instructions supports all data collection using the same conventions for completing the fields.</p> <p>Providing short instructions and prompts on the CRF and moving long instructions to a separate instruction booklet, facing page, or checklist will decrease the number of CRF pages, with the following benefits:</p>

Num	Best Practice Recommendation	Rationale
		<ul style="list-style-type: none"> Decreased CDM costs (e.g., decreased data-entry costs) Allows CRF to be formatted so that the reader can easily identify the fields to be completed Format of the page is less cluttered, making it easier for individuals involved in data collection and monitoring to identify fields with missing responses
9	<p>Collection of dates should use an unambiguous format, such as DD-MON-YYYY, where each part of the date is a unique format: "DD" is the day as a 2-digit numeric value; "MON" is the month as a 3-character letter abbreviation in English, or similar character abbreviation or representation in the local language; and "YYYY" is the year as a 4-digit numeric value. For EDC, the user may be able to select a date from a calendar, and this would also meet the recommendation for an unambiguous date.</p> <p>If the recommended approach is not adaptable to the local language, a similarly unambiguous format should be used. The method for capturing date values should allow the collection of partial dates and should use a consistent method or convention for collecting the known date parts.</p>	<p>Using this data collection format (i.e., DD-MON-YYYY) will provide unambiguous dates. For example, the date "06/08/02" is ambiguous because it can be interpreted as June 8, 2002, or August 6, 2002.</p> <p>If subject-completed CRF pages are translated into a local language, the CDASH recommended date format for collection may make translation of the documents easier.</p>
10	<p>To eliminate ambiguity, times should be collected with the use of a 24-hour clock, using the hh:mm:ss format for recording times.</p> <p>Use only as many of the hh:mm:ss elements as are needed for a particular field. Individuals involved in data collection should be cautioned not to "zero-fill" time components if these are not known (for example 21:00:00 means "exactly 9 pm", but if how many seconds after 9 PM is unknown, seconds should not be recorded).</p> <p>Subject-completed times may be recorded using a 12-hour clock and an "am" or "pm" designation. The time should then be transformed to a 24-hour clock in the database.</p>	<p>SDTM-based datasets use ISO 8601 date/time formats. Collecting times using a 24-hour clock eliminates both ambiguity and the need to convert values from 12-hour to 24-hour clock time.</p>
11	<p>Manually calculated fields should not typically be recorded within the CRF when the raw data on which the calculation is based are recorded in the CRF.</p> <p>An exception is when a study conduct decision should be made based on those calculations. In such cases it may be useful for the calculated field to be recorded within the CRF.</p> <p>It may also be useful to provide the individuals involved in data collection a step-by-step worksheet to calculate this data.</p>	<p>Data items that can be calculated from other data captured within the CRF are more accurately reported if they are calculated programmatically using validated algorithms.</p> <p>The noted exception may be in cases where it is important to show how an investigator determined a protocol-defined endpoint from collected raw data.</p>
12	<p>Questions with free-text responses should be limited. Questions should be specific and clear rather than open-ended. Instead of free-text comment fields, a thorough review of the CRF by the protocol development team should be performed to maximize the use of predefined lists of responses.</p>	<p>The collection and processing of free text requires significant resources for data entry: It requires data management resources to review the text for safety information and for inconsistencies with other recorded data and is of limited use when analyzing and reporting data.</p> <p>Another risk is data entry into free-text fields that should be recorded elsewhere.</p>
13	<p>Subject-specific data should be collected and recorded and should not be prepopulated in the CRF/eCRF.</p>	<p>The CRF is a tool to collect subject-level data. However, prepopulation of some identifying (e.g., investigator name, protocol number) or timing information prevents errors and reduces data entry time.</p> <p>Fields on the CRF or in the database that are known to be the same for all subjects may be prepopulated (e.g., measurements for which there is only 1 possible unit, such as Pulse Rate = "beats/min"). The units can be displayed on the CRF and populated in the database.</p>
14	<p>The anatomical location of a measurement, position of subject, or method of measurement should be collected only if the protocol specifies the allowable options, or if the parameter is relevant to the consistency or meaning of the resulting data.</p>	<p>When parameters such as location, position, or method are specified in a protocol and are part of the analysis, the CRF may include the common options for these parameters to ensure what actually happened can be reported and protocol deviations can be identified. If the parameter is prepopulated on the CRF and other options are not available, then data</p>

Num	Best Practice Recommendation	Rationale
		<p>should not be recorded that was not collected per protocol specifications.</p> <p>Taking measurements in multiple anatomical locations may affect the value of the measurement and/or the ability to analyze the data in a meaningful way (e.g., when data obtained from different locations may bias or skew the analysis). In this case, collecting the location may be necessary to ensure consistent readings. For example, temperature obtained from the ear, mouth, or skin may yield different results.</p> <p>If there is no such rationale for collecting location, position, method, or any other value, it would be considered unnecessary data.</p>
15	Verbatim terms for nonsolicited adverse events, concomitant medications, or medical history-reported terms should be recorded. A preferred term should not be selected from a coding dictionary as a mechanism for recording data.	<p>When information about spontaneously reported adverse events or medical history reported, recording responses verbatim ensures that no information is omitted.</p> <p>Individuals involved in data collection are not expected to be coding experts and may not be familiar with the coding dictionaries used. Recording adverse events from a standardized list is the same as having them code these events.</p>
16	A tabulation variable name should only be used as a data collection/operational variable name if the collected value will directly populate the tabulation variable with no transformation (other than changing case). Otherwise, create a "collected" version of the variable and write a standard mapping to the tabulation variable.	This practice provides clearer traceability from data collection to submission and facilitates a more automated process of transforming collected data to the standardized data tabulations for submission.

2.7.5.3 CRF Design

The following best practice recommendations are general principles to ensure the design of the CRF supports ease of use to reduce data entry time and result in more reliable data. These recommendations may be implemented during CRF form design and/or database set-up in different ways, depending on the systems used.

Num	Best Practice Recommendation
1	Place fields that routinely appear on multiple forms at the top of the form. For example, if the collection date and time are both asked, they should appear first and second, respectively, on each form where they are used.
2	Fields should be placed on the form in the order that they are expected to be collected. It is acceptable to include fields from different domains on the same form if consistent with the data flow.
3	Group related fields for a single encounter together, although multiple time points or visits may appear together on one form. For example, if heart rate and temperature are taken every hour for 4 hours on study day 1, the form can collect the data for hour 1 (e.g., heart rate result and unit, temperature result and unit), followed by the data for hour 2, hour 3, and hour 4. In this scenario, there would be labels indicating each time point within study day 1.
4	Group related fields together. Test results and their associated units should always appear next to each other. For example, the results of "TEMP" should be followed by its allowable units of "F" and "C". In some cases, the result might have only 1 applicable unit. For example, the only applicable unit for "PULSE" is "beats/min". The unit should be displayed on the CRF and database.
5	Data fields that are dependent on other data fields should be placed in the CRF in such a way that this dependence is obvious. For example, if there is a question in a CRF where "Other, specify" is an option, the text box used to collect what is being specified should be placed in proximity to the "Other" question to indicate that it is a subpart of the "Other" question.
6	Lists of values that have a logical order should be provided on the CRF in that logical order. For example, the values of "Low", "Medium", and "High" are logically placed in this order. Do not list "Medium" first, "Low" second, and "High" third.

2.7.5.4 CRF Completion Instructions

The following best practice recommendations are general principles to ensure form-level instructions for CRF completion support ease of use to reduce data entry time and result in more reliable data.

Num	Focus of Recommendation	Best Practice Recommendation
1	Design considerations	<ul style="list-style-type: none"> Whenever possible, details related to the completion of a single field should be placed with the field itself on the CRF.

Num	Focus of Recommendation	Best Practice Recommendation
		<ul style="list-style-type: none"> If this is not possible due to the medium and/or system being used to create CRFs, then it is permissible to include the field-level instructions at the top of the form, in what is generally considered the form-level instruction area. In some cases (e.g., form-level instructions are very lengthy or include graphics or flowcharts), a separate CRF completion instruction guideline may be required.
2	Content considerations	<p>When creating form-level instructions for a CRF, the following should be considered:</p> <ul style="list-style-type: none"> The instructions should include clear references to the time period for which data are to be reported for the study, or to specific time windows that are allowed. The instructions should provide references to protocol sections for the specifics of and/or limitations on the data to be reported. The instructions should include any special instructions for additional reporting or actions required beyond what is collected on the CRF. The instructions should include considerations on how data collected on one CRF might have an impact on data that are reported on a different CRF. The instructions should refer to any other forms that are related to the CRF being completed.

2.7.6 Metadata for Individual Health

Collection metadata in this section are organized by domain.

2.7.6.1 CDASH Adverse Experiences (AE)

Description

An Events general observation class domain used for data describing untoward medical occurrences in subjects which may or may not have a causal relationship with the product. Events represented in the AE domain will be consistent with scientific and regulatory requirements. It is the applicant's responsibility to define an event and the appropriate collection period for events. This definition may vary based on product characterization and reporting of product safety. In consultation with regulatory authorities, applicants may extend or limit the scope of event collection. Fields may be added from the CDASH Model, the SDTM, or created using guidance in the TIG to ensure data needed to meet scientific and regulatory requirements are collected.

Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Events	AE	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. This field can be included into the database or populated during tabulation dataset creation.
Events	AE	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted for the CRFs that are shipped to each site. EDC: This should be prepopulated.
Events	AE	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system generated. This collection variable is typically collected for all domains. However, this collection variable is populated only in the tabulation DM dataset.
Events	AE	N/A	N/A	4	AEYN	Any Adverse Experience	An indication of whether any AEs were experienced during the study.	Were any adverse events experienced?	Any Adverse Experiences	Char	O	Indicate if the subject had any adverse experiences. If Yes, include the appropriate details where indicated on the CRF.	N/A	Does not map to an tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that all other fields on the CRF were deliberately left blank.
Events	AE	N/A	N/A	5	AECAT	Category for Adverse Experience	A grouping of topic-variable values based on user-defined characteristics.	What is the category of the adverse experience?	[Adverse Experience Category]; NULL	Char	O	Record the adverse experience category, if not preprinted on the CRF.	AECAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column heading.
Events	AE	N/A	N/A	6	AESCAT	Subcategory for Adverse Experience	A subdivision of the AECAT values based on	What is the subcategory of the adverse experience?	[Adverse Experience Subcategory]; NULL	Char	O	Record the adverse experience subcategory,	AESCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most

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							user-defined characteristics.					if not preprinted on the CRF.					commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer. AESCAT can only be used if there is an AEAT and it must be a subcategorization of AEAT.
Events	AE	N/A	N/A	7	AESPID	AE Applicant-Defined Identifier	A applicant-defined identifier. This is typically used for preprinted or auto-generated numbers on the CRF, or any other type of identifier that does not already have a defined identifier field.	[Applicant-defined question]	[Applicant defined]	Char	O	If collected on the CRF, applicant may insert instructions to ensure each record has a unique identifier.	AESPID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	Because SPID is an applicant-defined identifier, conformance to Question Text or Item Prompt is not applicable. Typically used as an identifier in a data query to communicate clearly to the site the specific record in question or to reconcile concomitant medications, procedures and/or medical history records with AEs. If CMAENO or PRAENO is used, this is the identifier to which CMAENO or PRAENO refers. May be used to record preprinted number (e.g., line number, record number) on the CRF. This field may be populated by the applicant's data collection system.
Events	AE	N/A	N/A	8	AETERM	Reported Term for the Adverse Experience	The reported or prespecified name of the adverse experience.	What is the adverse experience term?	Adverse Experience	Char	HR	Record only 1 diagnosis, sign, or symptom per line (e.g., nausea and vomiting should not be recorded in the same entry, but as 2 separate entries). Using accepted medical terminology, enter the diagnosis (if known); otherwise enter a sign or symptom.	AETERM	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Can be represented either as an open-entry field to capture verbatim terms reported by subjects or preprinted, in the situation where solicited AEs of interest are captured. In most cases, the verbatim term (i.e., investigator-reported term) will be coded to a standard medical dictionary (e.g., MedDRA, WHO-ART) after the data have been collected on the CRF.
Events	AE	N/A	N/A	9	AEOCCUR	Adverse Experience Occurrence	An indication of whether a prespecified adverse experience or a group of adverse experiences occurred when information about the occurrence of a specific experience is solicited.	Did the subject have [prespecified adverse experience/group of adverse experiences]?	[Specific Adverse Experience]	Char	O	Indicate if [specific adverse experience] has occurred/is occurring, by checking Yes or No.	FA.FAORRES	This does not map directly to an tabulation variable. The AE domain is intended to hold only adverse experiences that actually happen; all values collected in AEOCCUR for prespecified AEs should be represented in a Findings About Adverse Experiences data set (FAAE) where FAORRES=the value of AEOCCUR where FATESTCD="OCCUR". In addition, where AEOCCUR="Y", there should	(NY)	N/A	The collection variable AEOCCUR is used to indicate the occurrence of prespecified adverse experiences (e.g., "Did the subject have high blood pressure?"). AEOCCUR should not be used for spontaneously reported adverse experiences. The site should be able to indicate that the response was not asked or answered.

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														be a corresponding record in the AE domain.			
Events	AE	N/A	N/A	10	AEPRESP	Prespecified Adverse Experience	An indication that a specific experience or group of experiences are prespecified on a CRF.	N/A	N/A	Char	O	N/A	AEPRESP	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	A hidden field on a CRF defaulted to "Y", or added during tabulation dataset creation, when the AE is prespecified. Null for spontaneously reported experiences. If a study collects both prespecified and free-text adverse experiences, the value of AEPRESP should be "Y" for all prespecified experiences and null for experiences reported as free text. AEPRESP is a permissible field and may be omitted from the tabulation dataset if all experiences were collected as free text.
Events	AE	N/A	N/A	11	AESTDAT	Adverse Experience Start Date	The start date of the adverse experience, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What is the adverse experience start date?	Start Date	Char	HR	Record the start date of the adverse experience using this format (DD-MON-YYYY).	AESTDTC	This does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable AESTDTC in ISO 8601 format.	N/A	N/A	N/A
Events	AE	N/A	N/A	12	AESTTIM	Start Time of Adverse Experience	The start time of the adverse experience, represented in an unambiguous time format (e.g., hh:mm:ss).	What is the adverse experience start time?	Start Time	Char	R/C	Record the start time (as complete as possible) of the adverse experience.	AESTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable AESTDTC in ISO 8601 format.	N/A	N/A	Collecting the time an AE started is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail.
Events	AE	N/A	N/A	13	AELOC	AE Location of Experience	A description of the anatomical location relevant for the adverse experience.	What is the anatomical location of the adverse experience?	Anatomical Location	Char	O	Indicate the anatomical location of the adverse experience.	AELOC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LOC)	N/A	Collected or preprinted when the applicant needs to identify the specific anatomical location. applicants may collect the data using a subset list of controlled terminology on the CRF. LAT, DIR, PORTTOT are used to further describe the anatomical location.
Events	AE	N/A	N/A	14	AELAT	Adverse Experience Laterality	Qualifier for anatomical location, further detailing the side of the body relevant for the experience.	What is the side of the anatomical location of the adverse experience?	Side	Char	O	Record the side of the anatomical location of the adverse experience.	AELAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LAT)	N/A	May be preprinted or collected when the applicant needs to identify the specific side of the anatomical location. applicants may collect the data using a subset list of controlled terminology on the CRF.
Events	AE	N/A	N/A	15	AEDIR	Adverse Experience Directionality	Qualifier further detailing the position of the anatomical location, relative to the center of the body, organ, or specimen.	What is the directionality of the anatomical location of the adverse experience?	Directionality	Char	O	Record the directionality of the anatomical location of the adverse experience.	AEDIR	Maps directly to the tabulation variable listed in the Tabulation Target column.	(DIR)	N/A	May be preprinted or collected when the applicant needs to identify the directionality of the anatomical location. applicants may collect the data using a subset list of controlled terminology on the CRF.
Events	AE	N/A	N/A	16	AEPOROTOT	AE Location Portion or Totality	Qualifier for anatomical location, further detailing the distribution (i.e.,	What is the portion or totality of the anatomical location	Portion or Totality	Char	O	Indicate the portion or totality anatomical location of the adverse experience.	AEPOROTOT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(PORTTOT)	N/A	Collected when the applicant needs to identify the specific portability for the

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							arrangement of, apportioning of).	of the adverse experience?									anatomical locations. applicants may collect the data using a subset list of controlled terminology on the CRF.
Events	AE	N/A	N/A	17	AEONGO	Ongoing Adverse Experience	Indication that an adverse experience is ongoing when no end date is provided.	Is the adverse experience ongoing (as of [the study-specific time point or period])?	Ongoing (as of [the study-specific time point or period])	Char	O	Indicate if the adverse experience has not resolved at the time of data collection; leave the End Date blank.	AEENRTPT; AEENRF	This does not map directly to an tabulation variable. May be used to populate a value into a tabulation relative timing variable such as AEENRF or AEENRTPT. When populating AEENRF, if the value of AEONGO is "", the value of "DURING", "AFTER" or "DURING/AFTER" may be used. When populating AEENRTPT, if the value of AEONGO is "", the value of "ONGOING" may be used. When AEONGO refers to the Reference Period (defined in DM.RFSTDTC to DM.RFENDTC) the tabulation variable AEENRF should be populated. When AEONGO is compared to another time point, the tabulation variables AEENRTPT and AEENTPT should be used. Note: AEENRTPT must refer to a time-point anchor described in AEENTPT.	(NY)	N/A	Completed to indicate that the AE has not resolved at the time of data collection, when no end date is collected. In some cases the ongoing status may be determined from AE Outcome. The purpose of collecting this field is to help with data cleaning and monitoring; this field provides further confirmation that End Date was deliberately left blank. Often used as a tick/checkbox.
Events	AE	N/A	N/A	18	AEENDAT	Adverse Experience End Date	The date when the adverse experience resolved/ended, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the adverse experience end date?	End Date	Char	R/C	Record the date that the adverse experience resolved using this format (DD-MON-YYYY). If the AE is ongoing, leave the field blank.	AEENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable AEENDTC in ISO 8601 format.	N/A	N/A	The definition of resolved is applicant-specific. The preferred method is to collect a complete end date (if applicable). Partial dates (e.g., providing year only, month and year only) may be acceptable.
Events	AE	N/A	N/A	19	AEENTIM	End Time of Adverse Experience	The time when the adverse experience ended/resolved, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the adverse experience end time?	End Time	Char	R/C	Record the time (as complete as possible) that the adverse experience resolved.	AEENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable AEENDTC in ISO 8601 format.	N/A	N/A	Collecting the time an AE resolved is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail.
Events	AE	N/A	N/A	20	AESEV	AE Severity/Intensity	The severity or intensity of the experience.	What is the severity of the adverse experience?	Severity	Char	R/C	The reporting physician/heathcare professional will assess the severity of the experience using the applicant-defined categories. This assessment is subjective and the reporting physician/ healthcare professional should use medical judgment to compare the reported adverse experience to similar type experiences observed in clinical practice. Severity is not equivalent to seriousness.	AESEV	Maps directly to the tabulation variable listed in the Tabulation Target column.	(AESEV)	N/A	Either AESEV or AETOXGR must appear on the CRF. Some studies may mandate the collection of both.

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Events	AE	N/A	N/A	21	AETOXGR	AE Standard Toxicity Grade	The grade of the severity of the experience using a standard "toxicity" scale (e.g., NCI CTCAE).	What is the [NCI CTCAE/ Name of scale (toxicity) grade] of the adverse experience?	[NCI CTCAE/ Name of scale (toxicity) grade]	Char	R/C	The reporting physician/healthcare professional will assess the severity of the adverse experience using the specified grades scale.	AETOXGR	Maps directly to the tabulation variable listed in the Tabulation Target column. The applicant is expected to provide the toxicity scale name and version used to map the terms utilizing the Define-XML external codelist attributes.	N/A	N/A	Either AESEV or AETOXGR must appear on the CRF. Some studies may mandate the collection of both. Published toxicity-like scales can be used.
Events	AE	N/A	N/A	22	AESEN	AE Serious Experience	An indication of whether the adverse experience is determined to be "serious," based on what is defined in the protocol.	Was the adverse experience serious?	Serious	Char	R/C	Assess if the adverse experience should be classified as "serious," based on the criteria defined in the protocol.	AESEN	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	This field is related to the individual SAE-type fields, which may or may not be collected on the CRF. Either AESEN or all the SAE-type fields must be present on the CRF. Applicants should consult with regulatory agencies regarding the collection of this data.
Events	AE	N/A	N/A	23	AESDTH	Results in Death	An indication the serious adverse experience resulted in death.	Did the adverse experience result in death?	Death	Char	R/C	Record whether the serious adverse experience resulted in death.	AESDTH	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	If details regarding SAEs are collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each SAE type. applicants may only collect the AESEN field when collecting individual SAE types in a separate database. Applicants should consult with regulatory agencies regarding the collection of this data.
Events	AE	N/A	N/A	24	DTHDAT	Death Date	Date of death for any subject who died.	What [is/was] the subject's date of death?	Death Date	Char	O	Record the date of death.	DM.DTHDTC	This field does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable DTHDTC in ISO 8601 format.	N/A	N/A	In the CDASH model, Death Date is a timing variable; it is not included as a timing variable in the SDTM. It may be collected on any CRF deemed appropriate by the applicant, but should only be collected once. The tabulation variable DTHDTC is mapped to the DM domain during the tabulation dataset creation process. The tabulation variable DM.DTHFLG is not a collection variable, but it is typically populated during the tabulation dataset creation process. Death Date may be mapped to other tabulation domains, as deemed appropriate by the applicant (e.g., DS).
Events	AE	N/A	N/A	25	AESLIFE	Is Life Threatening	An indication the serious adverse experience was life threatening.	Was the adverse experience life threatening?	Life Threatening	Char	R/C	Record whether the serious adverse experience is life threatening.	AESLIFE	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	If details regarding SAEs are collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each SAE type. applicants may only collect the AESEN field when collecting individual SAE types in a separate

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																	pharmacovigilance database. applicants should consult with regulatory agencies regarding the collection of this data.
Events	AE	N/A	N/A	26	AESHOSP	Requires or Prolongs Hospitalization	An indication the serious adverse experience resulted in an initial or prolonged hospitalization.	Did the adverse experience result in initial or prolonged hospitalization for the subject?	Hospitalization (initial or prolonged)	Char	R/C	Record whether the serious adverse experience resulted in an initial or prolonged hospitalization.	AESHOSP	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	If details regarding SAEs are collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each SAE type. applicants may only collect the AESER field when collecting individual SAE types in a separate pharmacovigilance database. applicants should consult with regulatory agencies regarding the collection of this data.
Events	AE	N/A	N/A	27	AESDISAB	Persist or Signif Disability/Incapacity	An indication the serious adverse experience was associated with a persistent or significant disability or incapacity.	Did the adverse experience result in disability or permanent damage?	Disability or Permanent Damage	Char	R/C	Record whether the serious adverse experience resulted in a persistent or significant disability or incapacity.	AESDISAB	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	If details regarding SAEs are collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each SAE type. applicants may only collect the AESER field when collecting individual SAE types in a separate pharmacovigilance database. applicants should consult with regulatory agencies regarding the collection of this data.
Events	AE	N/A	N/A	28	AESCONG	Congenital Anomaly or Birth Defect	An indication the serious adverse experience was associated with a congenital anomaly or birth defect.	Was the adverse experience associated with a congenital anomaly or birth defect?	Congenital Anomaly or Birth Defect	Char	R/C	Record whether the serious adverse experience was associated with a congenital anomaly or birth defect.	AESCONG	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	If details regarding SAEs are collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each SAE type. Applicants may only collect the AESER field when collecting individual SAE types in a separate pharmacovigilance database. applicants should consult with regulatory agencies regarding the collection of this data.
Events	AE	N/A	N/A	29	AESINTV	Needs Intervention to Prevent Impairment	An indication an adverse experience required medical or surgical intervention to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, due to the use of a medical product.	Did the adverse experience require intervention to prevent permanent impairment or damage resulting from the use of a medical product?	Needs Intervention to Prevent Impairment	Char	O	Record whether the serious adverse experience required intervention to prevent permanent impairment or damage due to the use of a medical product.	SUPPAE.QVAL	This does not map directly to an tabulation variable. applicants should refer to requirements for reporting adverse experiences involving medical devices.	(NY)	N/A	If details regarding SAEs are collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each SAE type. Applicants may only collect the AESER field when collecting individual SAE types in a separate database. Applicants should consult with regulatory agencies regarding the collection of this data.

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Events	AE	N/A	N/A	30	AESMIE	Other Medically Important Serious Experience	An indication additional categories for seriousness apply.	Was the adverse experience a medically important event not covered by other serious criteria?	Other Serious (important medical experiences)	Char	R/C	Record whether the serious adverse experience is an "important medical event," which may be defined in the protocol or in the investigator brochure.	AESMIE	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	If details regarding SAEs are collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each SAE type. Applicants may only collect the AESER field when collecting individual SAE types in a separate database. Applicants should consult with regulatory agencies regarding the collection of this data.
Events	AE	N/A	N/A	31	AESCAN	Involves Cancer	An indication the serious experience was associated with the development of cancer.	Was the adverse experience associated with the development of cancer?	Cancer	Char	O	Record whether the serious adverse experience was associated with development of cancer.	AESCAN	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	If details regarding SAEs are collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each SAE type. Applicants may only collect the AESER field when collecting individual SAE types in a separate database. Applicants should consult with regulatory agencies regarding the collection of this data.
Events	AE	N/A	N/A	32	AESOD	Occurred with Overdose	An indication the serious experience occurred with an overdose.	Did the adverse experience occur with an overdose?	Overdose	Char	O	Record whether the serious adverse experience occurred with an overdose.	AESOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	If details regarding SAEs are collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each SAE type. Applicants may only collect the AESER field when collecting individual SAE types in a separate pharmacovigilance database. Applicants should consult with regulatory agencies regarding the collection of this data.
Events	AE	N/A	N/A	33	AEREL	AE Causality	An indication the study product had a causal effect on the adverse experience, as determined by the clinician/investigator.	Was this adverse experience related to study product?	Relationship to Study Product	Char	HR	Indicate if the cause of the adverse experience is related to the study product and cannot be reasonably explained by other factors (e.g., subject's clinical state, concomitant therapy, other interventions).	AEREL	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology is used to indicate the relationship between the AE and the study product. It is recommended that applicants check with the regulatory authority for population of this variable to ensure it meets expectations for submission. There is no industry-wide controlled terminology for relationship to product exposure. It is recommended that applicants establish terminology and apply it consistently.
Events	AE	N/A	N/A	34	AEACN	Action Taken with Study Product	A description of the action taken with study product	What action was taken with study product?	Action Taken with Study Product	Char	R/C	Record changes made to the study product	AEACN	Maps directly to the tabulation variable listed in the Tabulation Target column.	(TPACN)	N/A	CDISC Controlled Terminology is used to indicate the action taken

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							as a result of the experience.					resulting from the adverse experience.					with the product in response to the AE. How to handle multiple actions taken is up to the applicant. If this information is collected elsewhere (e.g., on the Exposure CRF), then it is not required to be collected on the AE CRF. This variable is not to be used for actions taken with devices.
Events	AE	N/A	N/A	35	AEACNDEV	Actions Taken with Device	A description of the action taken, with respect to a device used in a study (which may or may not be the device under study), as a result of the experience.	What action was taken with a device used in the study?	Action Taken with Device	Char	O	Record actions taken resulting from the adverse experience that are related to a study or non-study device.	SUPPAE.QVAL	This does not map directly an tabulation variable. Applicants may represent this data in a SUPPAE dataset where SUPPAE.QNAM = "AEACNDEV" and SUPPAE.QLABEL = "Actions Taken with Device".	N/A	N/A	Applicant-defined controlled terminology for actions that are related to the device.
Events	AE	N/A	N/A	36	AEACNOTH	Other Action Taken	A description of other action taken as a result of the experience that is unrelated to dose adjustments of the study product.	What other action was taken?	Other Action Taken	Char	O	Record all other action(s) taken resulting from the adverse experience that are unrelated to study products given because of this AE.	AEACNOTH	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This is usually collected as a free-text field. If possible/desired, the applicant can create controlled terminology.
Events	AE	N/A	N/A	37	AEOUT	Outcome of Adverse Experience	A description of the outcome of an experience.	What is the outcome of this adverse experience?	Outcome	Char	R/C	Record the appropriate outcome of the experience in relation to the subject's status.	AEOUT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(OUT)	N/A	CDISC Controlled Terminology is used to indicate the outcome of the experience as it relates to the subject's status. The use of this field is the recommended way to describe whether and how the AE resolved. Because the outcome of an AE may be death, if this field is not used, be sure to provide another form (e.g., Disposition) with clear instructions to record deaths there.
Events	AE	N/A	N/A	38	AEDIS	AE Caused Study Discontinuation	An indication of whether the experience caused the subject to discontinue from the study.	Did the adverse experience cause the subject to be discontinued from the study?	Caused Study Discontinuation	Char	O	Record if the adverse experience caused the subject to discontinue from the study.	SUPPAE.QVAL	This does not map directly an tabulation variable. May be used to create a RELREC tabulation dataset to link the AE to the DS dataset record. Applicants may also represent this data in a SUPPAE dataset where SUPPAE.QNAM = "AEDIS" and SUPPAE.QLABEL = "Caused Study Discontinuation", if appropriate.	(NY)	N/A	Because the Action Taken field only collects changes made in relation to the study product due to the AE, an additional field was created to identify the AE(s) that caused the subject to discontinue from the study. Some applicants opt to capture this information only on the Subject Disposition CRF. Others choose to collect this data on both the DS and AE CRFs so that specific AE term(s) and related data can be identified. If the CRF is designed to link the DS and AE tabulation records, then RELREC can be used to identify that relationship.

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Events	AE	N/A	N/A	39	AERLNSYN	AE Relationship to Non-Study Trtmnt or Prod	An indication whether, in the investigator's opinion, the experience may have been due to a product other than study product.	Was this adverse experience due to product other than study product?	Related to Non-Study Product	Char	O	Indicate if this adverse experience was due to product other than study product. If Yes, briefly describe this non-study product relationship.	N/A	Does not map to a tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that the AERELNST collection field on the CRF was deliberately left blank.
Events	AE	N/A	N/A	40	AERELNST	AE Relationship to Non-Study Trtmnt or Prod	Description of the investigator's opinion as to whether the adverse experience may have been due to a product other than study product.	What is the relationship to non-study product?	Relationship to Non-Study Product	Char	O	Record the investigator's opinion as to whether the experience may have been due to a product other than study product.	AERELNST	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	May be reported as free text (e.g., "MORE LIKELY RELATED TO ASPIRIN USE"). If possible/desired, applicants can create controlled terminology.
Events	AE	N/A	N/A	41	AESI	Adverse Experience of Special Interest	An adverse experience of special interest (serious or non-serious) is one of scientific and medical concern specific to the applicant's product or program, for which ongoing monitoring and rapid communication by the investigator to the applicant can be appropriate. Such an experience might warrant further investigation in order to characterize and understand it. Depending on the nature of the experience, rapid communication by the study applicant to other parties (e.g., regulators) might also be warranted.	Is this experience of special interest?	Adverse Experience of Special Interest	Char	O	Record the investigator's opinion as to whether the experience is an adverse experience of special interest by the applicant.	N/A	Does not map to a tabulation variable.	(NY)	N/A	This collection field may be used just to trigger other CRF pages, or populate a value in AEAT or AESCAT. This information could be represented in a SUPPAE dataset where SUPPAE.QNAM = "AESI" and SUPPAE.QLABEL = "Adverse experience of Special Interest."
Events	AE	N/A	N/A	42	AEPATT	Pattern of Adverse Experience	Used to indicate the pattern of the experience over time.	What is the adverse experience pattern?	Pattern	Char	O	For each adverse experience, check the pattern of the AE. If a single experience, choose Single.	AEPATT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Used to report the pattern of the AE (e.g., "INTERMITTENT", "CONTINUOUS", "SINGLE EVENT"). For crossover studies, it is not recommended to capture this field for intermittent AEs. Instead, the AE should have corresponding start and stop dates to capture when the AE started and stopped.
Events	AE	N/A	N/A	43	AECONTRT	Concomitant or Additional Product Given	An indication whether a concomitant or additional product given because of the occurrence of the experience.	Was a concomitant or additional product given due to this adverse experience?	Concomitant or Additional Product Given Due To This AE	Char	O	Indicate if any non-study treatments or products were received because of this adverse experience. If Yes, medications should be recorded on the ConMed CRF and procedures recorded on the Procedures CRF.	AECONTRT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	If medication data are reported, the CMAENO variable (on the CM CRF) may be used to collect the associated AE Identifier in order to populate RELREC. If procedures are reported, the PRAENO variable (on the PR CRF) may be used to collect the associated AE Identifier in order to populate RELREC.
Events	AE	N/A	N/A	44	AEMODIFY	AE Modified Reported Term	If the value for AETERM is modified to facilitate coding, then AEMODIFY	N/A	N/A	Char	R/C	N/A	AEMODIFY	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This is not a data collection field that would appear on the CRF. Applicants will populate

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							will contain the modified text.										this through the coding process.
Events	AE	N/A	N/A	45	AEDECOD	AE Dictionary-Derived Term	The dictionary or standardized text description of AETERM or the modified topic variable (AEMODIFY), if applicable.	N/A	N/A	Char	O	N/A	AEDECOD	Maps directly to the tabulation variable listed in the Tabulation Target column. Applicants should provide the dictionary name and version used to map terms utilizing Define-XML external codelist attributes.	N/A	N/A	This is typically not a data collection field that would appear on the CRF. applicants will populate this through the coding process. Equivalent to the Preferred Term (PT) in MedDRA.
Events	AE	N/A	N/A	46	AELLT	AE Lowest Level Term	The dictionary-derived text description of the lowest level term.	N/A	N/A	Char	R/C	N/A	AELLT	Maps directly to the tabulation variable listed in the Tabulation Target column. Applicants should provide the dictionary name and version used to map terms utilizing Define-XML external codelist attributes. Applicants should include an Origin in the define metadata document to indicate that the data was "ASSIGNED".	N/A	N/A	This field does not typically appear on the CRF. applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	AE	N/A	N/A	47	AELLTCD	AE Lowest Level Term Code	The dictionary-derived code for the lowest level term.	N/A	N/A	Num	R/C	N/A	AELLTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. Applicants should provide the dictionary name and version used to map terms utilizing Define-XML external codelist attributes. Applicants should include an Origin in the define metadata document to indicate that the data was "ASSIGNED".	N/A	N/A	This field does not typically appear on the CRF. applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	AE	N/A	N/A	48	AEPTCD	AE Preferred Term Code	The dictionary-derived code for the preferred term.	N/A	N/A	Num	R/C	N/A	AEPTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. Applicants should provide the dictionary name and version used to map terms utilizing Define-XML external codelist attributes. Applicants should include an Origin in the define metadata document to indicate that the data was "ASSIGNED".	N/A	N/A	This field does not typically appear on the CRF. applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	AE	N/A	N/A	49	AEHLT	AE High Level Term	The dictionary-derived text description of the high level term for the primary system organ class (SOC).	N/A	N/A	Char	R/C	N/A	AEHLT	Maps directly to the tabulation variable listed in the Tabulation Target column. Applicants should provide the dictionary name and version used to map terms utilizing Define-XML external codelist attributes. Applicants should include an Origin in the define metadata document to indicate that the data was "ASSIGNED".	N/A	N/A	This field does not typically appear on the CRF. applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	AE	N/A	N/A	50	AEHLTCD	AE High Level Term Code	The dictionary-derived code for the high level term for the primary SOC.	N/A	N/A	Num	R/C	N/A	AEHLTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. Applicants should provide the dictionary name and version used to map terms utilizing Define-XML external codelist attributes. Applicants should include an Origin in the define metadata document to indicate that the data was "ASSIGNED".	N/A	N/A	This field does not typically appear on the CRF. applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	AE	N/A	N/A	51	AEHLTG	AE High Level Group Term	The dictionary-derived text description of the high level group term for the primary SOC.	N/A	N/A	Char	R/C	N/A	AEHLTG	Maps directly to the tabulation variable listed in the Tabulation Target column. Applicants should provide the dictionary	N/A	N/A	This field does not typically appear on the CRF. applicants will populate this through the coding process.

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														name and version used to map terms utilizing Define-XML external codelist attributes. Applicants should include an Origin in the define metadata document to indicate that the data was "ASSIGNED".			coding process. This is applicable to items using MedDRA coding.
Events	AE	N/A	N/A	52	AEHLGTCD	AE High Level Group Term Code	The dictionary-derived code for the high level group term for the primary SOC.	N/A	N/A	Num	R/C	N/A	AEHLGTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. Applicants should provide the dictionary name and version used to map terms utilizing Define-XML external codelist attributes. Applicants should include an Origin in the define metadata document to indicate that the data was "ASSIGNED".	N/A	N/A	This field does not typically appear on the CRF. applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	AE	N/A	N/A	53	AESOC	AE Primary System Organ Class	The dictionary-derived text description of the primary SOC.	N/A	N/A	Char	R/C	N/A	AESOC	Maps directly to the tabulation variable listed in the Tabulation Target column. Applicants should provide the dictionary name and version used to map terms utilizing Define-XML external codelist attributes. Applicants should include an Origin in the define metadata document to indicate that the data was "ASSIGNED".	N/A	N/A	This field does not typically appear on the CRF. applicants will populate this through the coding process. This is applicable to items using MedDRA coding. Will be the same as the AEBODSYS if the primary SOC was used for analysis.
Events	AE	N/A	N/A	54	AESOCCD	AE Primary System Organ Class Code	The dictionary-derived code for the primary SOC.	N/A	N/A	Num	R/C	N/A	AESOCCD	Maps directly to the tabulation variable listed in the Tabulation Target column. Applicants should provide the dictionary name and version used to map terms utilizing Define-XML external codelist attributes. Applicants should include an Origin in the define metadata document to indicate that the data was "ASSIGNED".	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. This is applicable to items using MedDRA coding. Will be the same as AEBDSYCD if the primary SOC was used for analysis.
Events	AE	N/A	N/A	55	AEACNOYN	Any Other Actions Taken	An indication whether any other actions were taken in response to the adverse experience that were unrelated to study product changes or other treatments/products given because of this adverse experience.	Were any other actions taken in response to this adverse experience?	Any Other Action(s) Taken	Char	O	Indicate whether any other action(s) were taken in response to the adverse experience that are unrelated to study product changes or other treatments/products given because of this experience. If Yes, briefly describe these actions.	N/A	Does not map to a tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that the AEACNOTH field on the CRF was deliberately left blank.

Assumptions

1. The AEYN variable with the question text "Were any adverse events experienced?" is intended to assist in the cleaning of data and in confirming that there are no missing values. This collection variable will not be represented in the tabulation dataset.
2. Categories AECAT and AESCAT
 - a. AECAT and AESCAT should not be redundant with the dictionary coding provided by AEDECOD and AESOC (i.e., they should provide a different means of defining or classifying AE records).
 - b. AECAT and AESCAT are intended for categorizations that are defined in advance. For example, an applicant may have a separate CRF page for AEs of special interest and then another page for all other AEs. In cases where a category of AEs of special interest resembles a part of the dictionary hierarchy (e.g., "CARDIAC EVENTS"), the categorization represented by AECAT and AESCAT may differ from the categorization derived from the coding dictionary.
3. Presence or Absence of Adverse Experiences
 - a. AEs are most often collected as free-text, spontaneously reported adverse events. There may be cases where the occurrences of specific adverse experiences are solicited, per protocol requirements. In that case, the prespecified adverse experiences would be listed on the CRF with a "Yes/No" question (AEOCCUR) asking about the occurrence of each.
 - b. Collection variable AEOCCUR does not map directly to a tabulation variable. Because the tabulation AE domain is intended will only represent adverse experiences that actually happen, all values collected in AEOCCUR for pre-specified AEs should be represented in a tabulation Findings About Adverse Events domain (FAAE), where FAORRES = the value of AEOCCUR where FATESTCD = "OCCUR". In addition, where AEOCCUR = "Y", there should be a corresponding record in the AE domain.
4. Coding
 - a. AEDECOD is the preferred term derived by the applicant from the coding dictionary. It is a required tabulation variable and must have a value. It is expected that the reported term (AETERM) will be coded using a standard dictionary such as MedDRA.
 - b. AEMODIFY is a permissible tabulation variable and should be included if the applicant's coding procedure permits modification of a verbatim term. The modified term is listed in AEMODIFY. The variable should be populated per the applicants's coding procedure.
 - c. The collection elements AELLT, AELLTCD, AEPTCD, AEHLT, AEHLTCD, AEH LGT, AEH LGTCD, AEBDSYCD, AESOC, and AESOCCD are only applicable to events coded in MedDRA. These items are not expected for non-MedDRA coding.
5. Relative Timing Variables
 - a. The AEONGO field does not map directly to a tabulation variable, but it may be used to derive a value into a tabulation relative timing variable such as AEENRF or AEENRTPT. When populating AEENRF, if the AEONGO field is checked, a value of "DURING", "AFTER", or "DURING/AFTER" may be derived, as appropriate. When populating AEENRTPT, if the AEONGO field is checked, the value of "ONGOING" may be derived. AEENRTPT must refer to a time-point anchor as described in AEENTPT.
 - b. AEONGO is a special-use case of "Yes/No", where the question is usually presented as a single possible response of "Yes" when there is no applicable end date at the time of collection.
 - i. In this case, if the box is checked and the end date is blank, the desired tabulation relative timing variable can be derived according to assumption 5a.
 - ii. If the box is not checked (AEONGO is NULL) and an end date is present, no tabulation relative timing variable will be derived.

- iii. In some cases, unique to AE, the ongoing status may be determined from AE Outcome. AEONGO is only used to derive an appropriate tabulation relative timing variable and should not be represented on its own in the AE or SUPPAE dataset.
6. Collection Action Taken Variables
- a. Collection variables AEACN, AECONTRT, AEACNDEV, AEACNOYN, and AEACNOTH are used to collect the action taken as the result of an AE.
 - b. AEACN describes action taken with study product as a result of the experience. It is expected that a response will be provided for this question for all AEs. When a study includes exposure to multiple products, then corresponding variables should be created to capture the action taken for each product.
 - c. AEACNOTH describes Other Action(s) taken in response to an adverse experience that are unrelated to study product exposure changes or interventions given because of this adverse experience. This field is usually collected as a free-text field. If possible/desired, the applicant can create their own internal terminology. The collection variable AEACNOYN is used in conjunction with AEACNOTH to assist in the cleaning of data and in confirming that AEACNOTH is not missing. AEACNOYN is not included as part of the tabulation AE domain for submission and is annotated as "NOT SUBMITTED" on the CRF. The collection variable AEACNOYN should only be used on the AE CRF.
 - d. AECONTRT indicates if any interventions were received because of this adverse experience. If "Yes" is answered for this question, any drugs used are recorded on the Concomitant Medications CRF and any procedures performed are recorded on the Procedure CRF. The collection variables CMAENO (on the CM CRF) can be collected to identify the adverse experience associated with this intervention by recording the appropriate AESPID. The RELREC dataset can be used to identify this relationship.
 - e. AEACNDEV describes action taken with respect to a device in a study, which may or may not be the device under study. This field is usually collected as a free-text field. If possible/desired, the applicant can create applicant-defined controlled terminology.
7. Serious Adverse Experiences
- a. If details regarding serious adverse events are collected, then it is recommended that a separate "Yes/No" variable be defined for each SAE type (AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD, AESMIE).
 - b. Applicants should consult with the regulatory agencies regarding the collection of this data.
8. Collection Variables AESEV, AETOXGR
- a. In studies using a standard toxicity scale, AETOXGR should be used instead of AESEV. In most cases, either AESEV or AETOXGR is populated, but not both.
 - b. There may be cases in which an applicant may need to populate both variables.
9. Collection variable DTHDAT
- a. The CDASH Model allows the date of death to be collected on any CRF deemed appropriate by the applicant. The death date should only be collected on 1 form.

2.7.6.2 CDASH Demographics (DM)

Description

Demographics (DM) is a special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. The collection of some demographics data is useful to perform simple analyses based upon population stratification.

Privacy concerns surrounding DM and Subject Characteristics (SC) data were taken into account when these domains were created. For example, there are optional collection variables to collect the components of birthdate (e.g., BRTHDD, BRTHMO, BRTHYY); therefore, limited elements of birthday may be collected and later mapped to the tabulation variable BRTHDT. This approach provides flexibility in categorizing some variables to facilitate compliance with local privacy regulations.

Collection of Age vs. Date of Birth

It is recognized that applicants typically collect the age or date of birth of the subject but may collect both if required by the study. In multiregional studies, applicants may need to comply with local regulations. When only age is collected, the applicant is left with a window of uncertainty of, at most, 365 days. Although knowing the precise date of birth provides the ability to calculate accurately an age for any date, a precise (and complete) date of birth may be considered personally identifying information for some privacy oversight boards or government regulators.

Collect the date of birth to the extent that the local regulatory authorities will allow.

- The best method is to collect a complete date of birth and derive age.
- When there are privacy concerns with collecting the complete date of birth, the recommendation is to collect year of birth at a minimum.
- In cases when neither of the above can be implemented (e.g., cultural or regional considerations) then age and age unit should be collected, and date of collection should be collected or derived from the visit date.
- Use the AGETXT/CAGETXT variable in very rare cases, when only an age range or age description can be determined.

Date of birth should be implemented such that incomplete dates may be entered, as allowed by the EDC system.

Collection of Sex

Sex is the assemblage of properties or qualities by which male is distinguished from female. This is often collected as it is useful to perform simple analyses based upon population stratification.

Collection of Ethnicity and Race

Race and ethnicity will be collected per regulatory requirements.

Collect race if required for the protocol and not prohibited by local laws and regulations. The CDASH Model provides only 1 variable for Race. Applicants wishing to capture more than 1 race will need to create NSVs to store the collection of the multiple races and map appropriately to the tabulation DM domain. Race Other has been included as a free-text field to capture responses. The use of this variable is optional. RACE is Recommended/Conditional (R/C) because some applicants prefer to derive values that are compliant with the codelist RACE (e.g., as derived from values collected in CRACE). For the collection of such added detail or granularity, as the applicant may require, CDASH Model provides the variables CRACE and CETHNIC, respectively.

Collection of Special Optional Fields in Demographics

TIG collection standards allow for collection of the date of informed consent using the variable RFICDAT. (If an applicant chooses to collect informed consent using this variable, the data should not also be collected using DSSTDAT from the Disposition (DS) Domain.) The data from RFICDAT are mapped to the tabulation variable DSSTDTC and the companion variables (e.g., DSTERM, DSDECOD) must be populated accordingly.

The CDASH Model also defines a field for death date (DTHDAT) as a timing variable. It may be collected on any CRF deemed appropriate by the applicant. The tabulation variables DTHDTC and DTHFL are mapped to the DM domain during the dataset creation process. The collection field Death Date may be mapped to other tabulation domains (e.g., DS), as deemed appropriate by the applicant.

Data Collection Scenarios

This section describes 2 different data collection scenarios for the demographics domain. It is up to the applicant to determine which data collection scenario best meets the study needs:

- Scenario 1: Birth date collection using 3 date fields. This scenario includes date of birth collected as 3 fields (i.e., month, day, year).
- Scenario 2: Birth date collection using a single date field. This scenario includes date of birth collected as a full date, in a single date field. An example CRF is not shown for this scenario.

Specification

Metadata Specification

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Special-Purpose	DM	Birth date collection using three date fields	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Special-Purpose	DM	Birth date collection using three date fields	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Special-Purpose	DM	Birth date collection using three date fields	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.
Special-Purpose	DM	Birth date collection using three date fields	N/A	4	BRTHDD	Birth Day	Day of birth of the subject, in an unambiguous date format (e.g., DD).	What is the subject's day of birth?	Birth Day	Char	R/C	Record the subject's day of birth (e.g., 01 or 31).	BRTHDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable BRTHDTC in ISO 8601 format.	N/A	N/A	Day of Birth is the collected variable used for recording the day component of the Date of Birth. The applicant may choose to database the date of birth as a single variable (BRTHDAT), or as separate variables for each component of the date/time (BRTHYY, BRTHMO, BRTHDD, BRTHTM). The applicant may choose a method based on database considerations, or for regulatory reasons. It is expected that what is collected for BRTHDAT (e.g., complete date, components) is reported in the tabulation variable BRTHDTC in the ISO 8601 format. If data are collected in a manner resulting in a reduced precision level, then tabulation variable AGE, if not collected on the CRF, should be derived using a documented algorithm that describes how the age was derived and/or imputed for those birth dates collected with reduced precision.
Special-Purpose	DM	Birth date collection using three date fields	N/A	5	BRTHMO	Birth Month	Month of birth of the subject, in an unambiguous date format (e.g., MMM).	What is the subject's month of birth?	Birth Month	Char	R/C	Record the subject's month of birth [e.g., (in local language short month format) (JAN-DEC) or (ENE-DIE) or (JAN-DEZ)].	BRTHDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable BRTHDTC in ISO 8601 format.	N/A	N/A	Month of Birth is the collected variable used for recording the month component of the Date of Birth. The applicant may choose to database the date of birth as a single variable (BRTHDAT), or as separate variables for each

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																	component of the date/time (BRTHYY, BRTHMO, BRTHDD, BRTHTIM). The applicant may choose a method based on database considerations, or for regulatory reasons. It is expected that what is collected for BRTHDAT (e.g., complete date, components) is reported in the tabulation variable BRTHDTC in the ISO 8601 format. If data are collected in a manner resulting in a reduced precision level, then AGE, if not collected on the CRF, should be derived using a documented algorithm that describes how the age was derived and/or imputed for those birth dates collected with reduced precision.
Special-Purpose	DM	Birth date collection using three date fields	N/A	6	BRTHYY	Birth Year	The year of birth of the subject, in an unambiguous date format (e.g., YYYY).	What is the subject's year of birth?	Birth Year	Char	R/C	Record the subject's year of birth (e.g., YYYY, a four-digit year).	BRTHDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable BRTHDTC in ISO 8601 format.	N/A	N/A	Year of Birth is the collected variable used for recording the year component of the Date of Birth. The applicant may choose to database the date of birth as a single variable (BRTHDAT), or as separate variables for each component of the date/time (BRTHYY, BRTHMO, BRTHDD, BRTHTIM). The applicant may choose a method based on database considerations, or for regulatory reasons. It is expected that what is collected for BRTHDAT (e.g., complete date, components) is reported in the tabulation variable BRTHDTC in the ISO 8601 format. If data are collected in a manner resulting in a reduced precision level, then AGE, if not collected on the CRF, should be derived using a documented algorithm that describes how the age was derived and/or imputed for those birth dates collected with reduced precision.
Special-Purpose	DM	Birth date collection using three date fields	N/A	7	BRTHTIM	Birth Time	The time of birth of the subject, in an unambiguous time format (e.g., hh:mm).	What is the subject's time of birth?	Birth Time	Char	O	Record the time of birth (as completely as possible).	BRTHDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable BRTHDTC in ISO 8601 format.	N/A	N/A	The level of detail collected by Time of Birth may be necessary for analysis for some pediatric, natal, or neonatal studies. The applicant may choose to database the date of birth as a single variable (BRTHDAT), or as separate variables for each component of the date/time (BRTHYY, BRTHMO, BRTHDD, BRTHTIM). The applicant may choose a method based on database considerations, or for regulatory reasons. It is expected that what is collected for BRTHDAT (e.g., complete date, components) is reported in the tabulation variable BRTHDTC in the ISO 8601 format. If data are collected in a manner resulting in a reduced precision level, then AGE, if not

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																	collected on the CRF, should be derived using a documented algorithm that describes how the age was derived and/or imputed for those birth dates collected with reduced precision.
Special-Purpose	DM	Birth date collection using three date fields	N/A	8	AGE	Age	The age of the subject, expressed in AGEU.	What is the subject's age?	Age	Num	O	Record age of the subject.	AGE	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	If age is collected, it should be collected as a number and, to be correctly interpreted, the age value should be associated to a variable for the age unit. It may be necessary to know when the age was collected, as age may need to be recalculated for analysis, such as deriving age at a reference start time (tabulation variable RFSTDT). BRTHDTC may not be available in all cases (due to subject privacy concerns). If AGE is collected, then it is recommended that the date of collection also be recorded, either separately or by association to the date of the visit.
Special-Purpose	DM	Birth date collection using three date fields	N/A	9	AGEU	Age Units	Units of time routinely used to express the age of a person.	What is the age unit used?	Age Unit	Char	O	Record the appropriate age unit (e.g., YEARS, MONTHS, WEEKS).	AGEU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(AGEU)	N/A	If age is captured on the CRF, the age unit must be known to make the age value meaningful. The age unit might be collected on the CRF, in those cases where the protocol allows for any age group, or it may be preprinted on the CRF (typically with the unit of "years").
Special-Purpose	DM	Birth date collection using three date fields	N/A	10	DMDAT	Demographics Collection Date	The date of collection, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What is the date of collection?	Collection Date	Char	R/C	Record the date of collection using this format (DD-MON-YYYY).	DMDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable DMDTC in ISO 8601 format.	N/A	N/A	The date of collection may be determined from the date of visit; if so, a separate date field is not needed.
Special-Purpose	DM	Birth date collection using three date fields	N/A	11	SEX	Sex	Sex of the subject.	What is the sex of the subject?	Sex	Char	R/C	Record the appropriate sex (e.g., F (female), M (male)).	SEX	Maps directly to the tabulation variable listed in the Tabulation Target column.	(SEX)	N/A	Collect the subject's sex or gender. This is a phenotypic assessment and not a genotypic assessment.
Special-Purpose	DM	Birth date collection using three date fields	N/A	12	ETHNIC	Ethnicity	A social group characterized by a distinctive social and cultural tradition maintained from generation to generation, a common history and origin, and a sense of identification with the group; members of the group have distinctive features in their way of life, shared experiences and often a common genetic heritage; these features may be reflected in their experience of health and disease.	Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	Ethnicity	Char	O	Study participants should self-report ethnicity, with ethnicity being asked about before race.	ETHNIC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(ETHNIC)	N/A	When creating the DM form, regulatory guidance will be followed. Use ETHNIC when higher-level ethnicity categorizations are desired. Applicant may append a suffix to denote multiple collected ethnicities (e.g., ETHNIC1, ETHNIC2).
Special-Purpose	DM	Birth date collection using three date fields	N/A	13	CETHNIC	Collected Ethnicity	A social group characterized by a distinctive social and cultural tradition	What is the ethnicity of the subject?	Ethnicity	Char	O	Study participants should self-report ethnicity, with	SUPPDPM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPDPM dataset as the value of	(ETHNIC)	N/A	When creating the DM form, regulatory guidance will be followed. Use ETHNIC when more detailed ethnicity

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							maintained from generation to generation, a common history and origin, and a sense of identification with the group; members of the group have distinctive features in their way of life, shared experiences and often a common genetic heritage; these features may be reflected in their experience of health and disease.					ethnicity being asked about before race.		SUPPDM.QVAL where SUPPDM.QNAM = "CETHNIC" and SUPPDM.QLABEL= "Collected Ethnicity".			categorizations are desired. Applicants may append a suffix to denote multiple collected ethnicities (e.g., ETHNICC1, ETHNICC2).
Special-Purpose	DM	Birth date collection using three date fields	N/A	14	RACE	Race	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity (US Center for Disease Control).	Which of the following five racial designations best describes you? (More than one choice is acceptable.)	Race	Char	R/C	Study participants should self-report race, with race being asked about after ethnicity.	RACE	Maps directly to the tabulation variable listed in the Tabulation Target column.	(RACE)	N/A	When creating the DM form, regulatory guidance will be followed. Use RACE when higher-level race categorizations are desired. If multiple races are collected, an alternate applicant-defined variable structure would be required. Applicants may record multiple races for a subject by appending a suffix to denote multiple collected races (e.g., RACE1, RACE2) and populate RACE with the value MULTIPLE.
Special-Purpose	DM	Birth date collection using three date fields	N/A	15	CRACE	Collected Race	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity (US Centers for Disease Control).	Which of the following racial designations best describes you? (More than 1 choice is acceptable.)	Race	Char	R/C	Study participants should self-report race, with race being asked about after ethnicity. (The FDA guidance suggests that individuals be permitted to designate a multiracial identity. Check all that apply at the time of collection).	SUPPDM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPDM dataset as the value of SUPPDM.QVAL when SUPPDM.QNAM = "CRACE" and SUPPDM.QLABEL="Collected Race".	(RACEC)	N/A	When creating the DM form, regulatory guidance will be followed. Use CRACE when more detailed race categorizations are desired. If multiple races are collected, an alternate applicant-defined variable structure would be required. Applicants may record multiple self-reported races for a subject by appending a suffix to denote multiple collected races (e.g., CRACE1, CRACE2) and populate CRACE with the value MULTIPLE.
Special-Purpose	DM	Birth date collection using three date fields	N/A	16	RACEOTH	Race Other	A free-text field to be used when none of the preprinted values for RACE are applicable or if another, unprinted selection should be added to those preprinted values.	What was the other race?	Specify Other Race	Char	O	If none of the preprinted values for RACE are applicable or if another, unprinted selection should be added to those preprinted values, record the value in this free text field.	SUPPDM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPDM dataset as the value of SUPPDM.QVAL where SUPPDM.QNAM = "RACEOTH" and SUPPDM.QLABEL="RACE OTHER".	N/A	N/A	When creating the DM form, regulatory guidance will be followed. Applicants may choose to include another value ("Specify, Other") with a free-text field for extending the list of values. The RACEOTH variable contains the free text added by the site.
Special-Purpose	DM	Birth date collection using a single date field	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Special-Purpose	DM	Birth date collection using a single date field	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Special-Purpose	DM	Birth date collection using a single date field	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.
Special-Purpose	DM	Birth date collection using a single date field	N/A	4	BRTHDAT	Birth Date	A subject's date of birth (with or without the time of birth). The complete Date of Birth is made from the temporal components of Birth Year, Birth Month, Birth Day, and Birth Time..	What is the subject's date of birth?	Birth Date	Char	R/C	Record the date of birth to the level of precision known (e.g., day/month/year, year, monthly/year) in this format (DD-MON-YYYY).	BRTHDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable BRTHDTC in ISO 8601 format.	N/A	N/A	BRTHDAT is the collected field used for recording the full birth date. The applicant may choose to database the date of birth as a single variable (BRTHDAT), or as separate variables for each component of the date/time (BRTHYY, BRTHMO, BRTHDD, BRTHTIM). The applicant may choose a method based on database considerations, or for regulatory reasons. It is expected that what is collected for BRTHDAT (e.g., complete date, selected components) is reported in the tabulation variable BRTHDTC in ISO 8601 format. If data are collected in a manner resulting in a reduced precision level, then AGE, if not collected on the CRF, should be derived using a documented algorithm that describes how age was determined and/or imputed for those birth dates collected with reduced precision.
Special-Purpose	DM	Birth date collection using a single date field	N/A	5	BRTHTIM	Birth Time	The time of birth of the subject, in an unambiguous time format (e.g., hh:mm).	What is the subject's time of birth?	Birth Time	Char	O	Record the time of birth (as completely as possible).	BRTHDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable BRTHDTC in ISO 8601 format.	N/A	N/A	The level of detail collected by Time of Birth may be necessary for analysis for some pediatric, natal, or neonatal studies. Applicants may choose to database the date of birth as a single variable (BRTHDAT), or as separate variables for each component of the date/time (BRTHYY, BRTHMO, BRTHDD, BRTHTIM). The applicant may choose a method based on database considerations, or for regulatory reasons. It is expected that what is collected for BRTHDAT (e.g., complete date, components) is reported in the tabulation variable BRTHDTC in the ISO 8601 format. If data are collected in a manner resulting in a reduced precision level, then AGE, if not collected on the CRF, should be derived using a documented algorithm that describes how the age was derived and/or imputed for those birth dates collected with reduced precision.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Special-Purpose	DM	Birth date collection using a single date field	N/A	6	AGE	Age	The age of the subject, expressed in AGEU.	What is the subject's age?	Age	Num	O	Record age of the subject.	AGE	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	If age is collected, it should be collected as a number and, to be correctly interpreted, the age value should be associated to a variable for the age unit. It may be necessary to know when the age was collected, as age may need to be recalculated for analysis, such as deriving age at a reference start time (tabulation variable RFSTDTC). BRTHDTC may not be available in all cases (due to subject privacy concerns). If AGE is collected, then it is recommended that the date of collection also be recorded, either separately or by association to the date of the visit.
Special-Purpose	DM	Birth date collection using a single date field	N/A	7	AGEU	Age Units	Units of time that are routinely used to express the age of a person	What is the age unit used?	Age Unit	Char	O	Record the appropriate age unit (e.g., YEARS, MONTHS, WEEKS).	AGEU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(AGEU)	N/A	If age is captured on the CRF, the age unit must be known to make the age value meaningful. The age unit might be collected on the CRF; in those cases where the protocol allows for any age group, or it may be preprinted on the CRF (typically with the unit of "years").
Special-Purpose	DM	Birth date collection using a single date field	N/A	8	DMDAT	Demographics Collection Date	The date of collection, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What is the date of collection?	Collection Date	Char	R/C	Record the date of collection using this format (DD-MON-YYYY).	DMDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable DMDTC in ISO 8601 format.	N/A	N/A	The date of collection may be determined from the date of visit; if so, a separate date field is not needed.
Special-Purpose	DM	Birth date collection using a single date field	N/A	9	SEX	Sex	Sex of the subject.	What is the sex of the subject?	Sex	Char	R/C	Record the appropriate sex (e.g., F (female), M (male)).	SEX	Maps directly to the tabulation variable listed in the Tabulation Target column.	(SEX)	N/A	Collect the subject's sex or gender, as reported by the investigator. This is a phenotypic assessment and not a genotypic assessment.
Special-Purpose	DM	Birth date collection using a single date field	N/A	10	ETHNIC	Ethnicity	A social group characterized by a distinctive social and cultural tradition maintained from generation to generation, a common history and origin and a sense of identification with the group; members of the group have distinctive features in their way of life, shared experiences and often a common genetic heritage; these features may be reflected in their experience of health and disease..	Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	Ethnicity	Char	O	Study participants should self-report ethnicity, with ethnicity being asked about before race.	ETHNIC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(ETHNIC)	N/A	When creating the DM form, regulatory guidance will be followed. Use ETHNIC when higher-level ethnicity categorizations are desired. Applicants may append a suffix to denote multiple collected ethnicities (e.g. ETHNIC1, ETHNIC2).
Special-Purpose	DM	Birth date collection using a single date field	N/A	11	CETHNIC	Collected Ethnicity	A social group characterized by a distinctive social and cultural tradition maintained from generation to generation, a common history and origin and a sense of identification	What is the ethnicity of the subject?	Ethnicity	Char	O	Study participants should self-report ethnicity, with ethnicity being asked about before race.	SUPPDM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPDM dataset as the value of SUPPDM.QVAL where SUPPDM.QNAM = "CETHNIC" and SUPPDM.QLABEL= "Collected Ethnicity".	(ETHNICC)	N/A	When creating the DM form, regulatory guidance will be followed. Use ETHNICC when more detailed ethnicity categorizations are desired. Applicants may append a suffix to denote multiple collected ethnicities (e.g. ETHNICC1, ETHNICC2).

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
							with the group; members of the group have distinctive features in their way of life, shared experiences, and often a common genetic heritage; these features may be reflected in their experience of health and disease.										
Special-Purpose	DM	Birth date collection using a single date field	N/A	12	RACE	Race	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity (US Center for Disease Control).	Which of the following five racial designations best describes you? (More than one choice is acceptable.)	Race	Char	R/C	Study participants should self-report race, with race being asked about after ethnicity.	RACE	Maps directly to the tabulation variable listed in the Tabulation Target column.	(RACE)	N/A	When creating the DM form, regulatory guidance will be followed. Use RACE when higher level race categorizations are desired. If multiple races are collected, an alternate applicant-defined variable structure would be required. Applicants may record multiple self-reported races for a subject by appending a suffix to denote multiple collected races (e.g. RACE1, RACE2) and populate RACE with the value MULTIPLE.
Special-Purpose	DM	Birth date collection using a single date field	N/A	13	CRACE	Collected Race	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity (US Centers for Disease Control).	Which of the following racial designations best describes you? (More than one choice is acceptable.)	Race	Char	R/C	Study participants should self-report race, with race being asked about after ethnicity. (The FDA guidance suggests that individuals be permitted to designate a multiracial identity. Check all that apply at the time of collection).	SUPPDM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPDM dataset as the value of SUPPDM.QNAM = "CRACE" and SUPPDM.QLABEL="Collected Race".	(RACEC)	N/A	When creating the DM form, regulatory guidance will be followed. Use CRACE when more detailed race categorizations are desired. If multiple races are collected, an alternate applicant-defined variable structure would be required. Applicants may record multiple self-reported races for a subject by appending a suffix to denote multiple collected races (e.g. CRACE1, CRACE2) and populate CRACE with the value MULTIPLE.
Special-Purpose	DM	Birth date collection using a single date field	N/A	14	RACEOTH	Race Other	A free-text field to be used when none of the preprinted values for RACE are applicable or if another, unprinted selection should be added to those preprinted values.	What was the other race?	Specify Other Race	Char	O	If none of the preprinted values for RACE are applicable or if another, unprinted selection should be added to those preprinted values, record the value in this free-text field.	SUPPDM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPDM dataset as the value of SUPPDM.QNAM = "RACEOTH" and SUPPDM.QLABEL="RACE OTHER".	N/A	N/A	When creating the DM form, regulatory guidance will be followed. Applicants may choose to include another value ("Specify, Other") with a free-text field for extending the list of values. The RACEOTH variable contains the free text added by the site.

Assumptions

1. The collection DM domain is a special-purpose domain that collects specific data elements that are mapped to the tabulation DM domain. Additional data elements that are not within the scope of the demographics must be mapped to other domains.

2.7.6.3 CDASH Disposition (DS)

Description

Disposition is an Events domain used for information encompassing and representing data related to subject disposition. It provides an accounting for all subjects who entered the study. The DS domain includes both disposition events and protocol milestones (e.g., informed consent obtained, randomized). Applicants may choose which disposition events and milestones/other events to collect for a study in alignment with regulatory requirements.

In the DS domain, DSCAT is used to distinguish between disposition events, protocol milestones, and other events. The controlled terminology for DSCAT consists of "DISPOSITION EVENT", "PROTOCOL MILESTONE", and "OTHER EVENT". This section describes 2 different data collection scenarios for the disposition domain. The data collection scenario is similar for disposition events that are considered protocol milestones or other events, whereas the data collection scenario for subject disposition events is different.

Scenario 1: Protocol Milestone or Other Event

This scenario includes disposition events that are considered protocol-specified, point-in-time events and other events. Common protocol milestones include "INFORMED CONSENT OBTAINED" and "RANDOMIZED"; "OTHER EVENT" includes other important events occurring during a study, but which were not driven by protocol requirements nor captured in another Events or Interventions class dataset. The codelist used for DSDECOD is specific to the scenario. (PROTMLST) is used when DSCAT = "PROTOCOL MILESTONE" and (OTHEVENT) is used when DSCAT = "OTHER EVENT".

Scenario 2: Study Participation Disposition Event

This scenario includes disposition events that describe a subject's completion status or reason for discontinuation of the entire study or a phase or segment of the study, including screening and post-treatment follow-up. The codelist used for DSDECOD is specific to the scenario. (NCOMPLT) is used when DSCAT = "DISPOSITION EVENT".

Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Events	DS	PROTOCOL MILESTONE/OTHER EVENT	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Events	DS	PROTOCOL MILESTONE/OTHER EVENT	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Events	DS	PROTOCOL MILESTONE/OTHER EVENT	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.

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Events	DS	PROTOCOL MILESTONE/OTHER EVENT	N/A	4	DSCAT	Category for Disposition Event	A categorization of the disposition events, which is used to distinguish between disposition events, protocol milestones, and other events.	What was the category of the disposition?	[Disposition Category]	Char	HR	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	DSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(DSCAT)	N/A	This would most commonly be a heading on the CRF or screen, not a question to which the site would provide an answer. In this implementation scenario, DSCAT="PROTOCOL MILESTONE" or "OTHER EVENT".
Events	DS	PROTOCOL MILESTONE/OTHER EVENT	N/A	5	DSSCAT	Subcategory for Disposition Event	A sub-division of the DSCAT values based on user-defined characteristics.	What was the subcategory of the disposition?	[Disposition Subcategory]; NULL	Char	O	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	DSSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer. DSSCAT can only be used if there is an DSCAT and it must be a subcategorization of the Protocol Milestone or Other Event.
Events	DS	PROTOCOL MILESTONE/OTHER EVENT	N/A	6	EPOCH	Epoch	Trial Epoch (e.g., 'SCREENING', 'RUN-IN') for which subject disposition is being collected.	What is the trial period for this disposition event?	Trial Period	Char	R/C	Check the [epoch, or insert more appropriate wording] for which disposition event is being recorded.	EPOCH	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EPOCH)	N/A	If protocol milestones or other events are collected more than once in the study, EPOCH may be needed to differentiate them. Typically, the trial epoch will be preprinted on the CRF as part of the title of the page; however, some companies have a standard CRF module that includes a pick-list of epochs.
Events	DS	PROTOCOL MILESTONE/OTHER EVENT	N/A	7	DSDECOD	Standardized Disposition Term	The standardized terminology of the disposition term.	[Applicant-defined]	[Applicant-defined]	Char	R/C	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	DSDECOD	Maps directly to the tabulation variable listed in the Tabulation Target column. Both DSDECOD and DSTERM must be populated in the tabulation dataset.	(PROTMLST) (OTHEVENT)	N/A	Where DSCAT = "PROTOCOL MILESTONE", DSTERM contains the verbatim (as collected) and/or standardized text; DSDECOD uses the extensible controlled terminology codelist (PROTMLST). Where DSCAT="OTHER EVENT", DSDECOD uses the extensible controlled terminology codelist (OTHEVENT).
Events	DS	PROTOCOL MILESTONE/OTHER EVENT	N/A	8	DSTERM	Reported Term for the Disposition Event	The verbatim or prespecified name of the disposition term.	[Applicant-defined]	[Applicant-defined]	Char	R/C	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	DSTERM	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variables DSDECOD and DSTERM must be populated in the tabulation dataset.	N/A	N/A	When defining protocol milestones or other events, applicants may populate DSTERM and DSDECOD with the same value (e.g., INFORMED CONSENT OBTAINED). DSTERM may also be populated with a verbatim term, which is then standardized in DSDECOD.
Events	DS	PROTOCOL MILESTONE/OTHER EVENT	N/A	9	DSSTDAT	Disposition Event Start Date	The date of the specified protocol milestone (e.g., informed consent) represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the [protocol milestone/other event name] (start) date?	[Protocol Milestone/Other Event Name] (start) Date	Char	R/C	Record the date of the protocol milestone/other event as defined in the protocol and/or CRF completion instructions, using	DSSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable DSSTDTC in ISO 8601 format.	N/A	N/A	Applicants should define in the protocol and/or CRF completion instructions the criteria for completion of each protocol milestone/other event and its associated (start) date.

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												this format (DD-MON-YYYY).					
Events	DS	PROTOCOL MILESTONE/OTHER EVENT	N/A	10	DSSTTIM	Disposition Event Start Time	The time of the specified protocol milestone (e.g., informed consent) or other event, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the [protocol milestone/other event name] (start) time?	[Protocol Milestone/Other Event Name] (start) Time	Char	O	Record the time (as complete as possible) as defined in the protocol and/or CRF completion instructions.	DSSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable DSSTDTC in ISO 8601 format.	N/A	N/A	Applicants should define in the protocol and/or CRF completion instructions the criteria for completion of each protocol milestone/other event (start) time. Collecting the time of the event is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail.
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included into the database or populated during tabulation dataset creation.
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	4	DSCAT	Category for Disposition Event	A categorization of the disposition events which is used to distinguish between disposition events, protocol milestones, and other events.	What was the category of the disposition?	[Disposition Category]	Char	HR	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	DSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(DSCAT)	N/A	This would most commonly be a heading on the CRF or screen, not a question to which the site would provide an answer. This is used to distinguish a DISPOSITION EVENT, a PROTOCOL MILESTONE, or an OTHER EVENT. In this implementation scenario, DSCAT="DISPOSITION EVENT"
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	5	DSSCAT	Subcategory for Disposition Event	A sub-division of the DSCAT values based on user-defined characteristics.	What was the subcategory of the disposition?	[Disposition Subcategory]; NULL	Char	O	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	DSSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer. DSSCAT can only be used if there is an DSCAT, and it must be a

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																	subcategorization of the Disposition event.
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	6	EPOCH	Epoch	Trial epoch (e.g., 'SCREENING', 'RUN-IN') for which subject disposition is being collected.	What is the trial period for this disposition event?	Trial Period	Char	R/C	Check the [epoch, or insert more appropriate wording] for which disposition is being recorded.	EPOCH	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EPOCH)	N/A	If disposition events are collected more than once in the study, EPOCH may be needed to differentiate them. Typically, the trial epoch will be preprinted on the CRF as part of the title of the page; however, some companies have a standard CRF module that includes a pick-list of epochs.
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	7	DSDECOD	Standardized Disposition Term	The standardized terminology of the disposition term that describes whether a subject completed the study or a portion of a study (epoch), or the reason they did not complete.	What was the subject's status (at the EPOCH/study specific time frame)?	Status (at the EPOCH/study specific time frame)	Char	R/C	Document the subject's status at [insert text corresponding to the selected trial epoch/study specific time frame]. If the subject discontinued prematurely, record the primary reason for discontinuation.	DSDECOD	Maps directly to the tabulation variable listed in the Tabulation Target column. Both DSDECOD and DSTERM must be populated in the tabulation datasets. If DSTERM was collected as an "Other, Specify" free text, populate DSTERM with the free text and populate DSDECOD with the applicant-defined standardized text. If DSDECOD was collected with no free text, populate DSTERM and DSDECOD in the tabulation dataset with the DSDECOD value that was collected.	(TNCOMPLT)	N/A	DSDECOD can be used as the standardized coded list with DSTERM used to capture any "Specify, Other" information, or DSDECOD can be used on its own. For applicant- and/or study-specific reasons for discontinuation, it is recommended that these reasons be preprinted on the CRF, as subcategories of the appropriate standardized DSDECOD item. However, it is recommended to limit the use of applicant and study-specific reasons in order to promote consistent use of terminology and permit the combination of data across multiple applicants. Either DSTERM or DSDECOD must be on the CRF. Both may be used if DSTERM is used as a Specify, Other field.
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	8	DSTERM	Reported Term for the Disposition Event	The verbatim or prespecified name of the event. The reported or prespecified name for how a subject completed the study or a portion of a study (epoch), or the reason they did not complete.	What was the subject's status?; If [DSDECOD], specify	[Status]; [Specify]	Char	R/C	Document the subject's status at [insert text corresponding to the selected trial epoch]. If the subject discontinued prematurely, record the primary reason for discontinuation. (Or, if used with a DECOD list) If Other is selected from the Status list, provide the verbatim reason.	DSTERM	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variables DSDECOD and DSTERM must be populated in the tabulation dataset. If DSTERM was collected as an "Other, Specify" free text, populate the tabulation variable DSTERM with the free text and populate DSDECOD with the applicant-defined standardized text. If DSDECOD was collected with no free text, populate DSTERM and DSDECOD in the tabulation dataset with the DSDECOD value that was collected.	N/A	N/A	If used with a DECOD list, free-text description of the subject's "Other" status. DSTERM is the verbatim term for subject status when Other is selected from the DSDECOD code list. This field would only be used with the prompt and completion instructions provided as a Specify, Other field in conjunction with DSDECOD. DSTERM may be used by itself when no code list is provided for DSDECOD on the CRF. Either DSTERM or DSDECOD must be on the CRF. DSTERM is required in the tabulation dataset.
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	9	DSSTDAT	Disposition Event Start Date	The date of the specified disposition event (e.g., study completion or discontinuation), represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the disposition event date?	Disposition Event Date	Char	R/C	Record the date of disposition event as defined in the protocol and/or CRF completion instructions using this format (DD-MON-YYYY)	DSSTDTC	This does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable DSSTDTC in ISO 8601 format.	N/A	N/A	Applicants should define in the protocol and/or CRF completion instructions the criteria for completion of each epoch for which a Disposition CRF will be provided. Define also the date of completion or discontinuation. Only collect the date of the disposition event once.

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Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	10	DSSTIM	Disposition Event Start Time	The time of the specified disposition event (e.g., study completion or discontinuation), represented in an unambiguous time format (e.g., hh:mm:ss).	What was the disposition event time?	Disposition Event Time	Char	O	Record the time (as complete as possible) that the subject completed the study or portion of the study as defined in the protocol and/or CRF completion instructions. If the subject did not complete the study or portion of the study, record the time (as complete as possible) as defined in the protocol and/or CRF completion instructions.	DSSTDTC	This does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable DSSTDTC in ISO 8601 format.	N/A	N/A	Applicants should define in the protocol and/or CRF completion instructions the criteria for completion of each epoch for which a Disposition CRF will be provided. Define also the date of completion or discontinuation. Collecting the time of completion or discontinuation is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail. Typically, it is not recommended that a time be collected unless the subject is under the direct care of the site at the time of the event. Only collect the time of completion or discontinuation on the Disposition CRF module if the same information is not being collected on another CRF module.
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	11	DTHDAT	Death Date	Date of death for any subject who died.	What [is/was] the subject's date of death?	Death Date	Char	O	Record the date of death	DM.DTHDTC	This field does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable DTHDTC in ISO 8601 format.	N/A	N/A	The CDASH model defines Death Date as a timing variable; this is not included as a timing variable in the SDTM. It may be collected on any CRF deemed appropriate by the applicant, but should only be collected once. The tabulation variable DTHDTC is mapped to the DM domain during the tabulation dataset creation process. The tabulation variable DM.DTHFLG is not a collection variable, but is populated during the tabulation dataset creation process. Death Date may also be mapped to other tabulation domains (e.g., DS) as deemed appropriate by the applicant.
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	12	DSCONT	Subject Continue	The plan for subject continuation to the next phase of the study or another study at the time of completion of the CRF.	Will the subject continue?	Subject Continue	Char	O	Record if the subject will be continuing to [the next phase of this study/related study] (applicant to specify as appropriate).	SUPPDS.QVAL	This information could be represented in a SUPPDS dataset as the value of SUPPDS.QVAL when SUPPDS.QNAME= "DSCONT" and SUPPDS.QLABEL= "Subject Continue".	(NY)	N/A	Applicants should specify the next phase of the study or the related study on the CRF. Typically this is a prompt to aid in monitoring and data cleaning, and usually not represented in a SUPPDS dataset.
Events	DS	STUDY PARTICIPATION DISPOSITION EVENT	N/A	13	DSNEXT	Next EPOCH	Identifies the study epoch or new study in which the subject will participate.	What is the next [epoch/period/study/trial] the subject will [continue to/enter/enroll]?	Next [Epoch/Period/Study/Trial]	Char	O	Record the planned subsequent [study epoch/study] in which the subject intends to participate.	N/A	Applicant-defined tabulation mapping.	N/A	N/A	Applicants should specify the next phase of the study or the related study on the CRF. The data are to be used to aid in monitoring and data cleaning. No specific tabulation dataset mapping rules are provided because the mapping depends on the situation (e.g., next epoch, next trial). Per applicant

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	decision, plans to enter the next epoch within a study may be included in the tabulation datasets (e.g., SE). Actual subject entry into the next study is represented as part of Trial Design datasets of that study.

Assumptions

- Applicants may choose which disposition events and milestones to collect for a study. A *milestone* is a protocol-specified point in time that is not assigned to an epoch. A *disposition event* describes whether a subject completed the study or portion of a study (epoch), or the reason they did not complete. Applicants may collect 1 disposition event for the study as a whole, or they may collect dispositions for each epoch of a trial.
- Disposition data may be collected on a CRF dedicated to disposition data, or collected across several forms that also contain data that are not DS. In the latter case, the disposition should be mapped to the appropriate DS tabulation variable (e.g., DSCAT, DSSTDTC, DSTERM, DSDECOD). The same disposition data should not be collected both on domain-specific forms and on a DS form.
 - The collection DS domain does not specify where to collect protocol milestones within the CRF. Protocol milestones may be included in convenient places in the CRF. For example, informed consent date may be collected on the same CRF page as demographics data and mapped to the tabulation DS domain.
 - The CDASH Model allows for date of death to be collected on any CRF deemed appropriate by the applicant and mapped to the tabulation DS domain; the date of death also may be collected as part of a DS form. However, consideration should be given to designing the CRF to collect the date of death only once in a study. DTHDAT is included in scenario 2.
- Controlled Terminology (NCOMPLT) is focused on disposition events, and is used when DSCAT is "DISPOSITION EVENT". Because the complete list of CT may not be appropriate, applicants may choose to include only subsets of CT on the CRF. The choices that appear for a DS event are dependent upon the event itself, and the contents of the list can vary if data are collected for multiple epochs in a study.
- DSCONT and DSNEXT data are used to aid in monitoring and data cleaning. Because the questions relate to future plans, the validity of the responses cannot be ascertained until the subject enters the subsequent epoch or new study. DSCONT and DSNEXT are included in scenario 2.

2.7.6.4 CDASH ECG Test Results (EG)

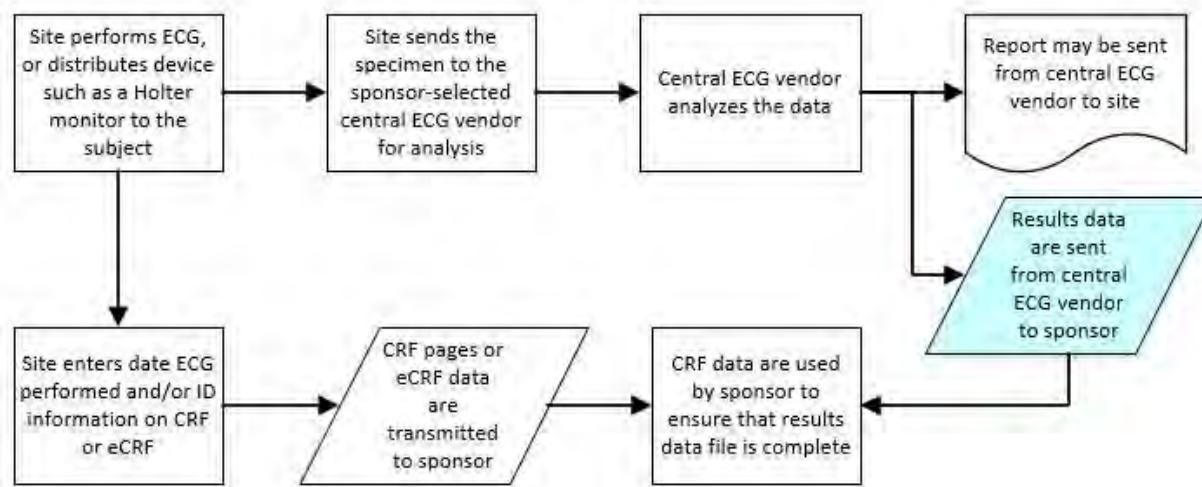
Description

ECG Test Results (EG) is a Findings domain used for electrocardiogram data, including position of the subject, method of evaluation, all cycle measurements and all findings from the ECG including an overall interpretation if collected.

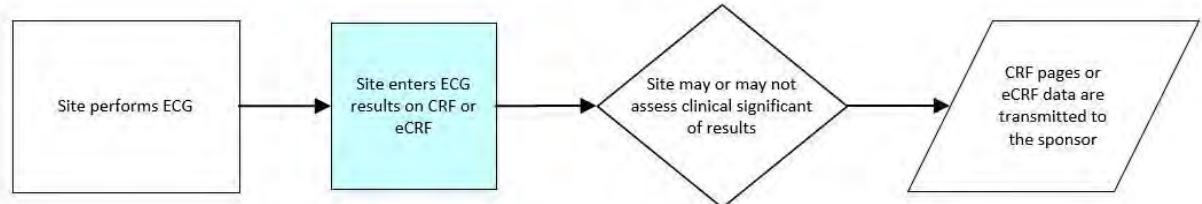
This section provides EG domain metadata for 3 different data collection scenarios.

Scenario 1: Central Reading

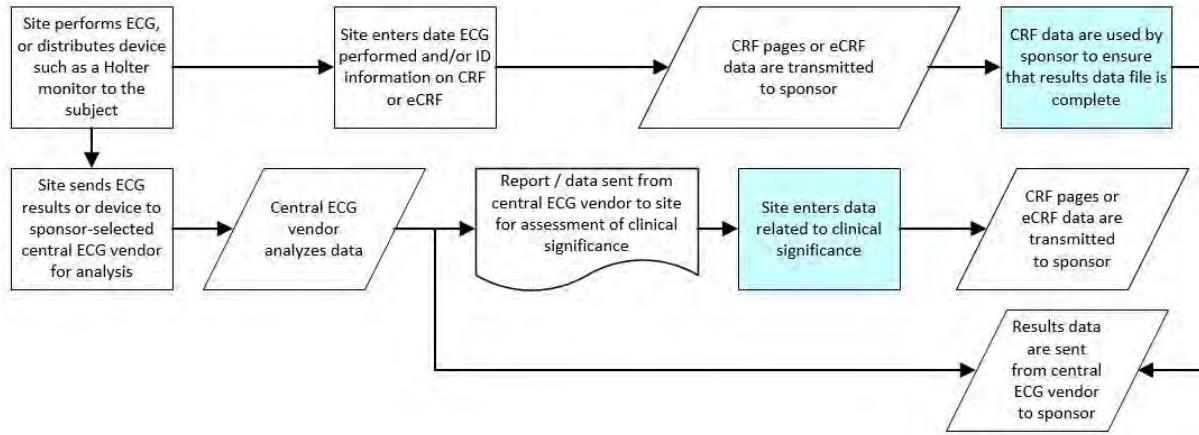
In this scenario, results are captured directly by an electronic device and transmitted separately or read by a central vendor, rather than recorded on the CRF. The accession number and date collected on the CRF can be used as an aid in reconciliation of the electronic data.

*Scenario 2: Local Reading*

In this scenario, subjects' ECGs are performed and analyzed, and then the results are recorded directly on the CRF.

*Scenario 3: Central Reading with Investigator Assessment of Clinical Significance Assessment and/or Overall Interpretation*

In this scenario, results are captured directly by an electronic device by a central vendor. The results are provided in an electronic file to the applicant. In addition, the results are provided to the investigator for assessment of clinical significance for any abnormal values, and that information is provided to the applicant on the CRF.



Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	EG	Central Reading	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	EG	Central Reading	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	EG	Central Reading	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This variable collection is typically collected in all collection domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	EG	Central Reading	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted or displayed within the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.

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Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
						performed on a subject.											
Findings	EG	Central Reading	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement test, observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable EGDTI in ISO 8601 format.	N/A	N/A	The date the ECG measurements were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the ECG measurements at that visit, or the collection date can be included on the ECG CRF using the date (EGDAT) field.
Findings	EG	Central Reading	N/A	6	EGCAT	Category for ECG	A grouping of topic-variable values based on user-defined characteristics.	What was the category of the ECG finding?	[ECG Category]; NULL	Char	O	Record the ECG finding category, if not preprinted on the CRF.	EGCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column header.
Findings	EG	Central Reading	N/A	7	EGSCAT	Subcategory for ECG	A sub-division of the EGCAT values based on user-defined characteristics.	What was the subcategory of the ECG finding?	[ECG Subcategory]; NULL	Char	O	Record the ECG finding subcategory, if not preprinted on the CRF.	EGSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included as the column header EGSCAT can only be used if there is an EGCAT, and it must be a subcategorization of EGCAT.
Findings	EG	Central Reading	N/A	8	EGPERF	ECG Performed	An indication of whether a planned ECG measurement, series of ECG measurements, tests, or observations was performed.	Was the ECG performed?	ECG Performed	Char	HR	Indicate whether or not an ECG or specific ECG test was done.	EGSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable EGSTAT. If the collection field EGPERF= "N", the value of EGSTAT will be "NOT DONE". If EGPERF = "Y", EGSTAT should be null. A combination of tabulation variables (e.g., EGCAT and EGSCAT, EGTPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable EGTESTCD would be populated as EGALL and an appropriate test name (EGTEST) provided.	(NY)	N/A	This may be implemented for an entire ECG, or a specific ECG test basis. General prompt question to be used as a data management tool to verify that missing results are confirmed missing.
Findings	EG	Central Reading	N/A	9	EGREPNUM	ECG Repetition Number	The incidence number of a test that is repeated within a given timeframe for the same test. The level of granularity can vary (e.g., within a timepoint, within a visit; multiple measurements of blood pressure, multiple analyses of a sample).	Which repetition of the ECG is this?	Repetition number	Char	O	Record which repetition of the ECG this is.	EGREPNUM	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	If there are multiple ECGs, this is used to record in which order this ECG occurred.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	EG	Central Reading	N/A	10	EGREFID	ECG Reference ID	An internal or external identifier of the ECG (e.g., waveform number).	What was the (ECG) [reference identifier/accession number]?	(ECG) [Reference Identifier/Accession Number]	Char	O	Record the identifier number assigned.	EGREFID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	This can be used to confirm that the appropriate data record is present in the electronic transfer if this reference ID happens to be available to the site at the time of collection. It can also be used to link the clinical significance assessment to the proper record in the electronic data. (e.g., UUID for external waveform file, session number automatically generated by electronic equipment).
Findings	EG	Central Reading	N/A	11	EGMETHOD	Method of ECG Test	Method of the test or examination.	What was the method used for the ECG?	Method	Char	O	Record the method used for the ECG.	EGMETHOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EGMETHOD)	N/A	Results may be affected by whether conditions for ECG as specified in the protocol were properly met. One possible condition is the method used to collect or calculate the ECG data. If the protocol requires this type of information, then this question may be included to confirm that the method used matches the protocol. The following are examples of when it is not necessary to collect these data on the CRF: <ul style="list-style-type: none"> • Method of ECG is provided as part of the electronic data. • Method of ECG is not pertinent to the protocol. • The protocol specifies only 1 possible method for collecting ECG measurements and the applicant does not feel there is significant risk of the sites performing the ECG using the incorrect method.
Findings	EG	Central Reading	N/A	12	EGLEAD	ECG Lead Location Used for Measurement	The lead used for the measurement (e.g., "LEAD I", "LEAD II", "LEAD III", "LEAD rV2", "LEAD V1")	Which lead location was used for this measurement?	Lead Location	Char	O	Record which lead was used for this measurement.	EGLEAD	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EGLEAD)	N/A	This is used when more specificity for the location is desired for the ECG data.
Findings	EG	Central Reading	N/A	13	EGPOS	ECG Position of Subject	The position of the subject during the ECG measurement.	What was the position of the subject during the ECG measurement?	Position	Char	O	Record the position of the subject during the ECG.	EGPOS	Maps directly to the tabulation variable listed in the Tabulation Target column.	(POSITION)	N/A	Results may be affected by whether conditions for ECG as specified in the protocol were properly met. One common condition is the subject's position. If the protocol requires this type of information, then this question may be included to confirm that the subject's position matches the protocol. The following are examples of when it is not necessary to collect these data on the CRF: <ul style="list-style-type: none"> • Position of the subject is provided as part of the electronic data.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	<ul style="list-style-type: none"> Position of the subject is not pertinent to the protocol. The protocol specifies only 1 possible position and the applicant does not feel there is significant risk of the sites performing the ECG with the subject in the wrong position.
Findings	EG	Central Reading	N/A	14	EGDAT	ECG Date	The date the ECG was performed, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date of the ECG?	ECG Date	Char	R/C	Record the date the ECG was done using this format (DD-MON-YYYY).	EGDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable EGDTC in ISO 8601 format.	N/A	N/A	A complete date is expected. The date of collection may be determined from the date of visit (VISDAT) and, if so, a separate assessment date field is not required.
Findings	EG	Central Reading	N/A	15	EGTPT	ECG Planned Time Point Name	A text description of planned time point when measurements should be taken as defined in the protocol.	What was the planned time point of the ECG measurement?	[Planned Time Point Name]	Char	R/C	Record the time point labels for, when the ECG test should be taken, if not preprinted on the CRF.	EGTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. Tabulation time-point anchors EGTPTRREF (text description) and EGRFTDTTC (date/time) may be needed, as well as tabulation variables EGPTNUM, EGELTM.	N/A	N/A	Planned time points are needed to differentiate multiple sequential assessments. It is recommended that time points should be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Planned Time Point" can be included as the column header.
Findings	EG	Central Reading	N/A	16	EGTIM	ECG Time	Time of ECG, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the time the ECG was collected?	ECG Time	Char	R/C	Record the time the ECG was done (as complete as possible).	EGDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable EGDTC in ISO 8601 format.	N/A	N/A	May be required when multiple assessments are done on 1 day or when the timing in relationship to study product is required for analysis.
Findings	EG	Local Reading	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	EG	Local Reading	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	EG	Local Reading	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all collection domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	EG	Local Reading	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed within the EDC for any visit-based data collection,

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Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
							unplanned study interventions, procedures, and assessments that may be performed on a subject.										most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.
Findings	EG	Local Reading	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement, test, observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable EGDT in ISO 8601 format.	N/A	N/A	The date the ECG measurements were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the ECG measurements at that visit, or the collection date can be included on the ECG CRF using the date (EGDAT) field.
Findings	EG	Local Reading	N/A	6	EGCAT	Category for ECG	A grouping of topic-variable values based on user-defined characteristics.	What was the category of the ECG finding?	[ECG Category]; NULL	Char	O	Record the ECG finding category, if not preprinted on the CRF.	EGCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column header.
Findings	EG	Local Reading	N/A	7	EGSCAT	Subcategory for ECG	A sub-division of the EGCAT values based on user-defined characteristics.	What was the subcategory of the ECG finding?	[ECG Subcategory]; NULL	Char	O	Record the ECG finding subcategory, if not preprinted on the CRF.	EGSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included as the column header. EGSCAT can only be used if there is an EGCAT, and it must be a subcategorization of EGCAT.
Findings	EG	Local Reading	N/A	8	EGPERF	ECG Performed	An indication of whether a planned measurement, series of measurements, test, or observation was performed.	Was the ECG performed?	ECG Performed	Char	HR	Indicate whether or not ECG or specific ECG test was done.	EGSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable EGSTAT. If the collection field EGPERF="N", the value of EGSTAT will be "NOT DONE". If EGPERF="Y", EGSTAT should be null. A combination of tabulation variables (e.g., EGCAT and EGSCAT, EGTPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable EGTESTCD would be populated as EGALL and an appropriate test name (EGTEST) provided. n.al information.	(NY)	N/A	This may be implemented for an entire ECG, or a specific ECG test basis. General prompt question to be used as a data management tool to verify that missing results are confirmed missing.
Findings	EG	Local Reading	N/A	9	EGREPNUM	ECG Repetition Number	The incidence number of a test that is repeated within a given timeframe for the same test. The level of granularity can vary (e.g., within	What repetition of the ECG is this?	Repetition Number	Char	O	Record which repetition of the ECG this is.	EGREPNUM	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	If there are multiple ECGs, this is used to record in which order this ECG occurred.

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							a timepoint, within a visit; multiple measurements of blood pressure, multiple analyses of a sample).										
Findings	EG	Local Reading	N/A	10	EGMETHOD	Method of ECG Test	Method of the test or examination.	What was the method used for the ECG?	Method	Char	O	Record the method used for the ECG.	EGMETHOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EGMETHOD)	N/A	Results may be affected by whether conditions for ECG as specified in the protocol were properly met. One possible condition is the method used to collect or calculate the ECG data. If the protocol requires this type of information, then this question may be included to confirm that the method used matches the protocol. The following are examples of when it is not necessary to collect these data on the CRF: <ul style="list-style-type: none"> • Method of ECG is provided as part of the electronic data. • Method of ECG is not pertinent to the protocol. • The protocol specifies only 1 possible method for collecting ECG measurements and the applicant does not feel there is significant risk of the sites performing the ECG using the incorrect method.
Findings	EG	Local Reading	N/A	11	EGLEAD	ECG Lead Location Used for Measurement	The lead used for the measurement (e.g., "LEAD I", "LEAD II", "LEAD III", "LEAD IV", "LEAD V1").	Which lead location was used for this measurement?	Lead Location	Char	O	Record which lead was used for this measurement.	EGLEAD	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EGLEAD)	N/A	This is used when more specificity for the location is desired for the ECG data.
Findings	EG	Local Reading	N/A	12	EGPOS	ECG Position of Subject	The position of the subject during the ECG measurement.	What was the position of the subject during the ECG measurement?	Position	Char	O	Record the position of the subject during the ECG.	EGPOS	Maps directly to the tabulation variable listed in the Tabulation Target column.	(POSITION)	N/A	Results may be affected by whether conditions for ECG as specified in the protocol were properly met. If the protocol requires this type of information, then this question may be included to confirm that the subject's position matches the protocol. The following are examples of when it is not necessary to collect these data on the CRF: <ul style="list-style-type: none"> • Position of the subject is provided as part of the electronic data. • Position of the subject is not pertinent to the protocol. • The protocol specifies only 1 possible position

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	and the applicant does not feel there is significant risk of the sites performing the ECG with the subject in the wrong position.
Findings	EG	Local Reading	N/A	13	EGDAT	Date of ECG	The date the ECG was performed, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date of the ECG?	ECG Date	Char	R/C	Record the date ECG was done using this format (DD-MON-YYYY).	EGDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable EGDTC in ISO 8601 format.	N/A	N/A	A complete date is expected. The date of collection may be determined from the date of visit (VISDAT) and if so, a separate assessment date field is not required.
Findings	EG	Local Reading	N/A	14	EGTPT	ECG Planned Time Point Name	A text description of planned time point when measurements should be taken as defined in the protocol.	What was the planned time point of the ECG measurement?	[Planned Time Point Name]	Char	R/C	Record the time point labels for when the ECG test should be taken, if not preprinted on the CRF.	EGTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. Tabulation time-point anchors EGTPTRREF (text description) and EGRFTDTC (date/time) may be needed, as well as tabulation variables EGTPNUM, EGELTM.	N/A	N/A	Planned time points are needed to differentiate multiple sequential assessments. It is recommended that time points should be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Planned Time Point" can be included as the column heading.
Findings	EG	Local Reading	N/A	15	EGTIM	Time of ECG	Time of ECG, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the time the ECG was collected?	ECG Time	Char	R/C	Record the time the ECG was done (as complete as possible).	EGDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable EGDTC in ISO 8601 format.	N/A	N/A	May be required when multiple assessments are done on 1 day or when the timing in relationship to study product is required for analysis.
Findings	EG	Local Reading	N/A	16	EGTEST	ECG Test or Examination Name	Descriptive name of the measurement or finding.	What was the ECG test name?	[ECG Test Name]	Char	HR	Record the name of the ECG measurement or finding, if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.	EGTEST; EGTESTCD	Maps directly to the tabulation variable listed in the column with the heading Tabulation Target. The tabulation variable EGTESTCD may be determined from the value collected in EGTEST. The tabulation variables EGTESTCD and EGTEST are required in the tabulation datasets. Use appropriate CDISC Controlled Terminology for the test and test code.	(EGTEST)	N/A	Required to identify which test the result is for. It is recommended that the test names be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Test" can be included as the column heading.
Findings	EG	Local Reading	N/A	17	EGORRES	ECG Result or Finding in Original Units	Result of the measurement or finding as originally received or collected.	What was the result of the ECG?	(Result)	Char	HR	Record test results, interpretations or findings.	EGORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Both quantitative results and interpretive findings or summaries may be recorded here.
Findings	EG	Local Reading	N/A	18	EGORRESU	ECG Original Units	The unit of the result as originally received or collected.	What was the unit of the ECG results?	Unit	Char	R/C	Record or select the original unit in which these data were collected, if not preprinted on CRF.	EGORRESU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	(EGORRESU)	May be included if quantitative results are recorded. Because units for quantitative ECG results are typically limited, units should be preprinted on the CRF with the associated test when possible, rather than having sites record the units. This item is not necessary for qualitative results.
Findings	EG	Local Reading	N/A	19	EGCLSIG	ECG Clinical Significance	An indication of whether the ECG results were clinically significant.	Was the ECG clinically significant?	Clinically Significant	Char	O	Record whether ECG results were clinically significant.	SUPPEG.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPEG dataset as the value of SUPPEG.QVAL where SUPPEG.QNAME = "EGCLSIG" and SUPPEG.QLABEL = "Clinically Significant".	(NY)	N/A	Could apply to specific measurements or to overall interpretation.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	EG	Central Reading with Investigator Assessment	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	EG	Central Reading with Investigator Assessment	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	EG	Central Reading with Investigator Assessment	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all collection domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	EG	Central Reading with Investigator Assessment	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically on the CRF or displayed within the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.
Findings	EG	Central Reading with Investigator Assessment	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started)	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement, test, observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDATA/VISTIM components and populating the tabulation variable EGDT in ISO 8601 format.	N/A	N/A	The date the ECG measurements were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the ECG measurements at that visit, or the collection date can be included on the ECG CRF using the date (EGDAT) field.
Findings	EG	Central Reading with Investigator Assessment	N/A	6	EGCAT	Category for ECG	A grouping of topic-variable values based on user-defined characteristics	What was the category of the ECG finding?	[ECG Category]; NULL	Char	O	Record the ECG finding category, if not on the CRF.	EGCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column heading.
Findings	EG	Central Reading with Investigator Assessment	N/A	7	EGSCAT	Subcategory for ECG	A sub-division of the EGCAT values based on user-defined characteristics	What was the subcategory of the ECG finding?	[ECG Subcategory]; NULL	Char	O	Record the ECG finding subcategory, if not on the CRF.	EGSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included as the column heading.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	heading. EGSCAT can only be used if there is an EGCAT, and it must be a subcategorization of EGCAT.
Findings	EG	Central Reading with Investigator Assessment	N/A	8	EGPERF	ECG Performed	An indication of whether a planned measurement, series of measurements, test, or observation was performed	Was the ECG performed?	ECG Performed	Char	HR	Indicate whether or not an ECG or specific ECG test was done.	EGSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable EGSTAT. If the collection field EGPERF="N", the value of EGSTAT will be "NOT DONE". If EGPERF="Y", EGSTAT should be null. A combination of tabulation variables (e.g., EGCAT and EGSCAT, EGPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable EGTESTCD would be populated as EGALL and an appropriate test name (EGTEST) provided.	(NY)	N/A	This may be implemented for an entire ECG, or a specific ECG test basis. General prompt question to be used as a data management tool to verify that missing results are confirmed missing.
Findings	EG	Central Reading with Investigator Assessment	N/A	9	EGREPNUM	ECG Repetition Number	The incidence number of a test that is repeated within a given timeframe for the same test. The level of granularity can vary (e.g., within a timewindow, within a visit; multiple measurements of blood pressure, multiple analyses of a sample).	Which repetition of the ECG is this?	Repetition Number	Char	O	Record which repetition of the ECG this is.	EGREPNUM	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	If there are multiple ECGs, this is used to record in which order this ECG occurred.
Findings	EG	Central Reading with Investigator Assessment	N/A	10	EGREFID	ECG Reference ID	An internal or external identifier of the ECG (e.g., waveform number)	What was the (ECG) [reference identifier/accession number]?	(ECG) [Reference Identifier/Accession Number]	Char	O	Record the identifier number assigned.	EGREFID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	This can be used to confirm that the appropriate data record is present in the electronic transfer if this reference ID happens to be available to the site at the time of collection. Examples: Universally Unique Identifier (UUID) for external waveform file, session number automatically generated by electronic equipment. This can also be used to link.
Findings	EG	Central Reading with Investigator Assessment	N/A	11	EGMETHOD	Method of ECG Test	Method of the test or examination	What was the method used for the ECG?	Method	Char	O	Record the method used for the ECG.	EGMETHOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EGMETHOD)	N/A	Results may be affected by whether conditions for ECG as specified in the protocol were properly met. If the protocol requires this type of information, then this question may be included to confirm that the method used matches the protocol. The following are examples of when it is not necessary to collect these data on the CRF: <ul style="list-style-type: none"> • Method of ECG is provided as part of the electronic data. • Method of ECG is not pertinent to the protocol. • The protocol specifies only 1 possible method for collecting ECG

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	measurements and the applicant does not feel there is significant risk of the sites performing the ECG using the incorrect method.
Findings	EG	Central Reading with Investigator Assessment	N/A	12	EGLEAD	ECG Lead Location Used for Measurement	The lead used for the measurement (e.g., "LEAD I", "LEAD II", "LEAD III", "LEAD IV", "LEAD V1")	Which lead location was used for this measurement?	Lead Location	Char	O	Record which lead was used for this measurement.	EGLEAD	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EGLEAD)	N/A	This is used when more specificity for the location is desired for the ECG data.
Findings	EG	Central Reading with Investigator Assessment	N/A	13	EGPOS	ECG Position of Subject	The position of the subject during the ECG measurement	What was the position of the subject during the ECG measurement?	Position	Char	O	Record the position of the subject during the ECG.	EGPOS	Maps directly to the tabulation variable listed in the Tabulation Target column.	(POSITION)	N/A	<p>Results may be affected by whether conditions for ECG as specified in the protocol were properly met. If the protocol requires this type of information, then this question may be included to confirm that the subject's position matches the protocol. The following are examples of when it is not necessary to collect these data on the CRF:</p> <ul style="list-style-type: none"> • Position of the subject is provided as part of the electronic data. • Position of the subject is not pertinent to the protocol. • The protocol specifies only 1 possible position and the applicant does not feel there is significant risk of the sites performing the ECG with the subject in the wrong position.
Findings	EG	Central Reading with Investigator Assessment	N/A	14	EGDAT	Date of ECG	The date the ECG was performed, represented in an unambiguous date format (e.g., DD-MON-YYYY)	What was the date of the ECG?	ECG Date	Char	R/C	Record the date ECG was done using this format (DD-MON-YYYY).	EGDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable EGDTC in ISO 8601 format.	N/A	N/A	A complete date is expected. The date of collection may be determined from the date of visit (VISDAT) and if so, a separate assessment date field is not required.
Findings	EG	Central Reading with Investigator Assessment	N/A	15	EGTPT	ECG Planned Time Point Name	A text description of planned time point when measurements should be taken as defined in the protocol	What was the planned time point of the ECG measurement?	[Planned Time Point Name]	Char	R/C	Record the time point labels for when the ECG test should be taken, if not on the CRF.	EGTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. Tabulation time point anchors EGTPREF (text description) and EGRFTDTC (date/time) may be needed, as well as tabulation variables EGTPNUM, EGELTM.	N/A	N/A	Planned time points are needed to differentiate multiple sequential assessments. It is recommended that time points should be on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Planned Time Point" can be included as the column heading.
Findings	EG	Central Reading with Investigator Assessment	N/A	16	EGTIM	Time of ECG	Time of ECG, represented in an unambiguous time format (e.g., hh:mm:ss)	What was the time the ECG was collected?	ECG Time	Char	R/C	Record the time the ECG was done (as complete as possible).	EGDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable EGDTC in ISO 8601 format.	N/A	N/A	May be required when multiple assessments are done on 1 day or when the timing in relationship to study product is required for analysis.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	EG	Central Reading with Investigator Assessment	N/A	17	EGEVAL	ECG Evaluator	The role of the person who provided the evaluation	Who provided the information? Who was the evaluator?	[Evaluator/Reporter]	Char	O	Select the role of the person who provided the evaluation (e.g., INVESTIGATOR, ADJUDICATION COMMITTEE, VENDOR).	EGEVAL	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EVAL)	N/A	Used only for results that are subjective (e.g., assigned by a person or a group). May be preprinted or collected. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Findings	EG	Central Reading with Investigator Assessment	N/A	18	INTP_EGORRES	ECG Interpretation	Overall interpretation of the result of the measurement or finding	What was the interpretation of the ECG?	Interpretation	Char	O	Record overall interpretations of the ECG.	EGORRES	This does not map directly to a tabulation variable. For the tabulation dataset, the recorded interpretation is populated into the tabulation variable EGORRES where EGTEST= "Interpretation", and EGTESTCD= "INTP".	N/A	N/A	The overall interpretation of an ECG is mapped into the appropriate tabulation test and result variables.
Findings	EG	Central Reading with Investigator Assessment	N/A	19	EGCLSIG	ECG Clinical Significance	An indication of whether the ECG results were clinically significant	Was the ECG clinically significant?	Clinically Significant	Char	HR	Record whether ECG results were clinically significant.	SUPPEG.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPEG dataset as the value of SUPPEG.QVAL where SUPPEG.QNAM = "EGCLSIG" and SUPPEG.QLABEL= "Clinically Significant".	(NY)	N/A	Could apply to specific measurements or to overall interpretation. In this scenario, clinical significance could be provided by the investigator.
Findings	EG	Central Reading with Investigator Assessment	N/A	20	EGMHNO	Related Medical History Event ID	Identifier for the medical history event that was reported as a clinically significant ECG finding	What was the identifier for the medical history event that was reported as a clinically significant ECG finding?	Medical History Event Identifier	Char	O	Record the identifier for the medical history event that was reported as a clinically significant ECG finding.	N/A	This does not map directly to a tabulation variable. For the tabulation datasets, may be used to create RELREC to link this record with a record in the MH domain.	N/A	N/A	Intent is to establish a link between the clinically significant ECG finding and the medical history event that was reported. EGMHNO can be used in RELREC to identify a relationship between records in EG dataset and records in the MH dataset.
Findings	EG	Central Reading with Investigator Assessment	N/A	21	EGAENO	Related Adverse Event ID	Identifier for the adverse event that was reported as a clinically significant ECG finding	What was the identifier for the adverse event(s) that was reported as a clinically significant ECG finding?	Adverse Event Identifier	Char	O	Record the identifier for the adverse event that was the reported as a clinically significant ECG finding.	N/A	This does not map directly to a tabulation variable. For the tabulation datasets, may be used to create RELREC to link this record with a record in the AE domain.	N/A	N/A	Intent is to establish a link between the clinically significant ECG finding and the AE that was reported. EGAENO can be used to identify a relationship between records in EG dataset and records in the AE dataset.

Assumptions

1. The ECG tests that should be collected are not specified by the TIG; this is a medical and scientific decision that should be based on the needs of the protocol and regulatory requirements.
2. Applicants should decide which scenario is appropriate for each protocol.
3. As required or defined by the study protocol, clinically significant results may need to be reported on the Adverse Event CRF.
4. As required or defined by the study protocol, changes that are worsening may need to be reported on the AE CRF.
5. As depicted in scenario 3, where the CRF includes site assessment of clinical significance and/or overall interpretation, results are returned to the sites, and the sites complete a CRF page of clinical significance for any abnormal/unexpected values and/or record an overall interpretation of the results. As in scenario 1, the actual testing results are transmitted electronically, but the CRF includes data necessary to identify and rate the clinical significance of the abnormal results.

2.7.6.5 CDASH Exposure (EX) and Exposure as Collected (EC)

Description

Exposure (EX) is an Interventions domain used for the details of a subject's exposure to a study product. Exposure as Collected (EC) is an interventions domain used for information about a subject's exposure to a study product, as collected. For collection, the EC domain is used to represent data as collected on the CRF, and is used in a study when the tabulation EX domain cannot be directly populated with the data collected on the CRF.

EC is used for collection when:

1. An alias for the actual product name is used rather than the actual product name.
2. Exposure data are collected in non-protocol-specified units.
3. Scheduled and/or missed exposures are collected.
4. Planned exposures are collected in addition to actual exposures.

An applicant may choose to always collect exposure data using the EC domain.

Specifications

Metadata Specification

Exposure (EX)

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Interventions	EX	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included into the database or populated during tabulation dataset creation.
Interventions	EX	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Interventions	EX	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Interventions	EX	N/A	N/A	4	EPOCH	Epoch	Name of the trial epoch with which this element of the arm is associated.	What is the trial epoch?	[Epoch](Period/Phase/Applicant-defined phrase)	Char	R/C	[protocol specific]	EPOCH	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EPOCH)	N/A	If the same information is collected more than once in different periods/parts of a study (e.g., Disposition), EPOCH may be needed to differentiate them. Typically, the trial epoch will be preprinted on the CRF as the title of the page.
Interventions	EX	N/A	N/A	5	EXYN	Any Study Product Taken	An indication of whether the subject used study product.	Were any [study product/dose] taken?	Any Study Products	Char	O	Indicate if the subject used any study products. If Yes, include the appropriate details where indicated.	N/A	Does not map to a tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that all other fields on the CRF were deliberately left blank. The EXYN variable is a cleaning or EDC convention meant to indicate that the exposure form should be completed or inserted into the case book.
Interventions	EX	N/A	N/A	6	EXCAT	Category of Product	A grouping of topic-variable values based on user-defined characteristics.	What is the category of the [study product/dose]?	[Study Product Category]; NULL	Char	O	Record the study product category, if not preprinted on the CRF.	EXCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column header.
Interventions	EX	N/A	N/A	7	EXSCAT	Subcategory of Product	A sub-division of the EXCAT values based on user-defined characteristics.	What is the subcategory of the [study product/dose]?	[Study Product Subcategory]; NULL	Char	O	Record the study product subcategory, if not preprinted on the CRF.	EXCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer. EXSCAT can only be used if there is an EXCAT

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	and it must be a subcategorization of EXCAT.
Interventions	EX	N/A	N/A	8	EXTRT	Name of Product	Name of the study product given for the observation.	What was the study product name?	[Study Product Name]	Char	R/C	Record the name of study product.	EXTRT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	EXTRT captures the name of the study product. This is typically collected for open label studies and populated for blinded studies during the tabulation dataset creation.
Interventions	EX	N/A	N/A	9	EXREFID	Exposure Reference ID	An internal or external identifier.	What is the [study product/dose] label identifier?	Product Label Identifier	Char	R/C	Record product label identifier.	EXREFID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This packaging identifier may be collected in different ways.
Interventions	EX	N/A	N/A	10	EXLOT	Lot Number	Lot number of the EXTRT product.	What was the lot number of the [study product/dose] used?	Lot Number	Char	R/C	Record the lot number that appears on the container holding the study product.	EXLOT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The lot number identifies the manufacturing batch of the study product. In open-label studies, the reference number on the study product container may represent an actual lot number and is represented using EXLOT. This variable may be populated during the process of creating the tabulation datasets. Do not collect other identification variables in this field.
Interventions	EX	N/A	N/A	12	EXDOSFRM	Exposure Dose Form	The dosage form in which the EXTRT is physically presented.	What was the dose form of the [study product/dose]?	Dose Form	Char	R/C	Record the dose form or enter the appropriate code from the code list.	EXDOSFRM	Maps directly to the tabulation variable listed in the Tabulation Target column.	(FRM)	(EXDOSFRM)	This must be collected if it cannot be determined from other sources or if there are multiple options.
Interventions	EX	N/A	N/A	13	EXSTDAT	Exposure Start Date	The start date of study product, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the ([intended/planned/actual]) ([study product/dose]) (start) date?	(Start) Date	Char	HR	Record the start date of the study product administration using this format (DD-MON-YYYY).	EXSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable EXSTDTC in ISO 8601 format.	N/A	N/A	Date when the constant interval of the study product use started, or single use occurred. When collecting the date for an individual dose, the word "start" may be omitted from the question text and prompt.
Interventions	EX	N/A	N/A	14	EXSTTIM	Exposure Start Time	The start time of the study product use, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the ([intended/planned/actual]) ([study product/dose]) (start) time?	(Start) Time	Char	R/C	Record the start time (as complete as possible) when administration of study product started.	EXSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable EXSTDTC in ISO 8601 format.	N/A	N/A	Recommend collecting the time a product was started only when a protocol or data collection scenario requires it.
Interventions	EX	N/A	N/A	15	EXENDAT	Exposure End Date	The end date of study product use represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the ([intended/planned/actual]) ([study product/dose]) (end) date?	(End) Date	Char	R/C	Record the end date or last date of administration of study product using this format (DD-MON-YYYY).	EXENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable EXENDTC in ISO 8601 format.	N/A	N/A	If start date and end date are not expected to be on the same date, the end date is required. If the study design indicates that the

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Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	start and end date are on the same day, the end date is not required because it can be assigned to be equal to the start date.
Interventions	EX	N/A	N/A	16	EXENTIM	Exposure End Time	The end time of study product use, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the ((intended/planned/actual) ([study product/dose]) (end) time?	(End) Time	Char	R/C	Record the time, (as complete as possible) when study product administration stopped.	EXENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable EXENDTC in ISO 8601 format.	N/A	N/A	Recommend collecting the time a product was ended when a protocol or data collection scenario requires it. For infusions, the end time of the infusion is typically needed.
Interventions	EX	N/A	N/A	17	EXDSTXT	Exposure Dose Description	Dose (per administration).	What was the dose [per administration] of [study product/dose]?	Dose	Char	R/C	Record the dose or amount of study product that was used by the subject in the period recorded; from the start date/time to the end date/time inclusive.	EXDOSTXT; EXDOSE	This does not map directly to a tabulation variable. Numeric values map to tabulation variable EXDOSE. Non-numeric values (e.g., 200-400) map to tabulation variable EXDOSTXT.	N/A	N/A	Dose or amount taken for single administration of study product or per constant dosing interval recorded. Dose must be collected if it cannot be determined via other methods (e.g., from diary data, product accountability data, protocol). The data collected in this dose text-format field should be mapped to either tabulation variable EXDOSE (if numeric) or EXDOSTXT (if text).
Interventions	EX	N/A	N/A	18	EXDOSU	Exposure Dose Unit	The unit for intended dose (per administration) for EXDOSE, EXDOSTOT, or EXDOSTXT.	What was the unit for the dose?	Unit	Char	R/C	Record the unit of dose or amount taken per period recorded (e.g., ng, mg, mg/kg).	EXDOSU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	N/A	Unit of dose or amount taken per constant dosing interval recorded. Dose unit must be collected if it cannot be determined via other methods (e.g., from protocol). The unit should be preprinted on the CRF or a field provided on the CRF to capture it. A CDASH Subset Controlled Terminology Codelist Name is available for general dose and volume units.
Interventions	EX	N/A	N/A	19	EXDOSFRQ	Exposure Dosing Frequency per Interval	The number of doses given/administered/taken during a specific interval.	What was the frequency of [study product/dose] dosing?	Frequency	Char	R/C	Record the frequency the study product was administered for a defined period of time.	EXDOSFRQ	Maps directly to the tabulation variable listed in the Tabulation Target column.	(FREQ)	N/A	This may be collected if it cannot be determined from other sources or if there are multiple options. When possible, the options for dose/amount frequency are preprinted on the

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	CRF. When collected, the recommendation is to collect dosing information in separate fields (e.g., ECDOSE, ECDOSEU, ECDOSEFRQ) for specific and consistent data collection and to enable programmatically using these data.
Interventions	EX	N/A	N/A	20	EXROUTE	Exposure Route of Administration	The route of administration of the study product.	What was the route of administration (of the [study product/dose])?	Route	Char	R/C	Record the route of administration (e.g., ORAL) or enter the appropriate code from the code list.	EXROUTE	Maps directly to the tabulation variable listed in the Tabulation Target column.	(ROUTE)	(EXROUTE)	This may be collected if it cannot be determined via other methods (e.g., from protocol) or if there are multiple options.
Interventions	EX	N/A	N/A	22	EXDOSADJ	Dose Adjusted	An indication of whether the dose was adjusted.	Was the dose adjusted?	(Dose) Adjusted	Char	O	Select either Yes or No to indicate whether there was a change in dosing.	N/A	When EXADJ is collected, does not map to a tabulation variable. When EXADJ is not collected, the applicant may represent this variable as a SUPPQ.	(NY)	N/A	Typically, the intent/purpose of collecting this field is to help with data cleaning and monitoring, as it provides a definitive response regarding any dose changes. It provides verification that the associate field on the CRF (EXADJ) was deliberately left blank. However, the applicant may collect whether the dose was adjusted, without collecting the reason for the change.
Interventions	EX	N/A	N/A	23	EXADJ	Reason for Dose Adjustment	Description of or explanation for why a dose of the study product was adjusted.	What was the reason the dose was adjusted (from planned)?	Reason Adjusted	Char	O	If there was a change in dosing, record the reason for change.	EXADJ	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Captures the reason the dose was changed or modified. The reason may be chosen from an applicant-defined list (e.g., adverse event) or entered as free text. May be used for variations from protocol-specified doses or changes from expected doses.
Interventions	EX	N/A	N/A	24	EXITRPYN	EX Exposure Interrupted	An indication of whether the exposure was interrupted.	Was the [(study) product/dose] interrupted?	[(Study) Product / Dose] Interrupted	Char	O	Record if there was an interruption in the study product use or dosing.	N/A	Does not map to a tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring when the actual duration of the exposure is collected using the collection field EXCINTD. In some situations, if the actual duration of the interruption is not

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	collected, or not derived, this information could be represented in a SUPPEX.QVAL dataset where SUPPEX.QNAM = "EXITRPN" and SUPPEX.QLABEL = "Exposure Interrupted".
Interventions	EX	N/A	N/A	25	EXCINTD	Exposure Interruption Duration	The collected duration of the product interruption.	If the dose was interrupted, how long was the interruption?	(Interruption) Duration	Char	O	Record the duration of product use interruption.	SUPPEX.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPEX dataset as the value of SUPPEX.QVAL where SUPPEX.QNAM="EXITRPD" and SUPPEX.QLABEL="Interruption Duration". Concatenate the collected product interruption duration and the duration unit components and create EXITRPD using ISO 8601 Period format.	N/A	N/A	In some situations, the duration of the interruption may be calculated from the administration start and end times recorded elsewhere in the CRF.
Interventions	EX	N/A	N/A	26	EXCINTDU	Exposure Interruption Duration Units	The unit for the collected duration of product interruption.	If the dose was interrupted, what were the units for the interruption duration?	(Interruption Duration) Unit	Char	O	Record the unit (e.g., MINUTES, HOURS, DAYS) for the duration of product use interruption.	SUPPEX.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPEX dataset as the value of SUPPEX.QVAL where SUPPEX.QNAM = "EXITRPD" and SUPPEX.QLABEL= "Interruption Duration". Concatenate the collected interruption duration and the duration unit components and create EXITRPD using ISO 8601 Period format.	(UNIT)	(EXINTPU)	The unit should be collected and converted into ISO 8601 period format.
Interventions	EX	N/A	N/A	27	EXLOC	Exposure Location of Dose Administration	A description of the anatomical location of administration.	What was the anatomical location of the ([study product/dose]) administration?	Anatomical Location	Char	O	Record the body location where the study product was administered (e.g., SHOULDER, HIP, ARM).	EXLOC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LOC)	N/A	Collected or preprinted when the applicant needs to identify the specific anatomical location where the study product was administered. LAT, DIR, PORTOT are used to further describe the anatomical location.
Interventions	EX	N/A	N/A	28	EXVAMT	Exposure Vehicle Amount	The amount of the prepared product (product + vehicle) administered or given.	What was the total amount (product + vehicle)(of [study product/dose]) administered?	Total Amount	Num	O	Record the total amount (product +vehicle) that was administered/given to the subject.	EXVAMT	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable ECTRIV may also be populated during the process of creating the tabulation datasets.	N/A	N/A	Administration amount that was given to the subject. Note: should not be the diluent amount alone. The ECTRIV field may be collected if it cannot be determined from other sources.
Interventions	EX	N/A	N/A	29	EXVAMTU	Exposure Vehicle Amount Units	The unit of measure for the prepared product (product + vehicle).	What was the unit for the amount (of [study product/dose]) administered?	Unit	Char	O	Record the unit of total amount (product +vehicle) administered/given to the subject (e.g., mL).	EXVAMTU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	(EXVOLTU)	Unit of the administration amount. A CDASH Subset Controlled Terminology Codelist Name is

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Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	available for dose and volume units.
Interventions	EX	N/A	N/A	32	EXTPT	Exposure Planned Time Point Name	A text description of the planned timepoint when measurements should be taken, as defined in the protocol.	What was the planned timepoint for [study product/dose]?	[Planned Time Point Name]	Char	R/C	Record the planned timepoint of study product administration if not preprinted on the CRF.	EXTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation time-point anchors EXPTPTREF (text description) and EXRFTDTC (date/time) may be needed, as well as tabulation variables EXPTNUM, EXELTM.	N/A	N/A	Planned timepoints are needed to differentiate multiple sequential assessments. It is recommended that timepoints should be preprinted on the CRF rather than collected in a field that requires the site to enter text. If the form is laid out as a grid, then words such as "Planned Time Point" can be included in the column heading.
Interventions	EX	N/A	N/A	34	EXLAT	Exposure Laterality	Qualifier for anatomical location, further detailing side of the body for the study product administration.	What was the side of the anatomical location of the ([study product/dose]) administration?	Side	Char	O	Record the side of the body location where the study product was administered (e.g., Left, Right).	EXLAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LAT)	N/A	Further details the laterality of the location where the study product was administered. This may be preprinted or collected. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Interventions	EX	N/A	N/A	35	EXDIR	Exposure Directionality	Qualifier further detailing the position of the anatomical location, relative to the center of the body, organ, or specimen.	What was the directionality of the anatomical location of the ([study product/dose]) administration?	Directionality	Char	O	Record the directionality of the body location where the study product was administered (e.g., Anterior, Lower, Proximal, Upper).	EXDIR	Maps directly to the tabulation variable listed in the Tabulation Target column.	(DIR)	N/A	May be preprinted or collected when the applicant needs to identify the directionality of the anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF.

Exposure as Collected (EC)

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Interventions	EC	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Interventions	EC	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Interventions	EC	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.
Interventions	EC	N/A	N/A	4	EPOCH	Epoch	Name of the trial epoch with which this element of the arm is associated.	What is the trial epoch?	[Epoch](Period/Phase/Applicant-defined phrase)	Char	R/C	[protocol specific]	EPOCH	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EPOCH)	N/A	If the same information is collected more than once in different periods/parts of a study (e.g., Disposition), EPOCH may be needed to differentiate them. Typically, the trial epoch will be preprinted on the CRF as the title of the page.
Interventions	EC	N/A	N/A	5	ECYN	Any Study Product Taken	An indication of whether the subject used the study product.SDTM-755	Were any[study product/dose] taken?	Any Study Products	Char	O	Indicate if the subject used any study products. If Yes, include the appropriate details where indicated.	N/A	Does not map to a tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that all other fields on the CRF were deliberately left blank. The ECYN is meant to indicate that the exposure as collected form should be completed or inserted into the case book. ECOCCUR would be used when the actual product name is preprinted on the CRF. While these might be equivalent in a single-product study, there are differences in how they would be used in most trials. Therefore, it does not map into the tabulation variable ECOCCUR; ECOCCUR indicates whether the subject actually used study product. If actual data is available (ECYN = "Y"), ECOCCUR may be populated based on whether subject was actually used study product.
Interventions	EC	N/A	N/A	6	ECCAT	Category of Product	A grouping of topic-variable values based on user-defined characteristics.	What is the category of the [study product/dose]?	[Study Product Category]; NULL	Char	O	Record the study product category, if not preprinted on the CRF.	ECCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would

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																	provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column heading.
Interventions	EC	N/A	N/A	7	ECSCAT	Subcategory of Product	A sub-division of the ECCAT values based on user-defined characteristics.	What is the subcategory of the [study product/dose]?	[Study Product Subcategory]; NULL	Char	O	Record the study product subcategory, if not preprinted on the CRF.	ECSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer. ECSCAT can only be used if there is an ECCAT and it must be a subcategorization of ECCAT.
Interventions	EC	N/A	N/A	8	ECTRT	Product	Name of the study product.	What was the [study product] name?	[Study Product Name]	Char	R/C	Record the name of study product.	ECTRT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	ECTRT is the name of the product.
Interventions	EC	N/A	N/A	9	ECPRESP	Exposure as Collected prespecified	An indication that a specific intervention or a group of interventions is prespecified on a CRF.	N/A	N/A	Char	O	N/A	ECPRESP	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	For prespecified interventions, a hidden field on a CRF defaulted to "Y", or added during the tabulation dataset creation. If a study collects both prespecified and free-text interventions, the value of ECPRESP should be "Y" for all prespecified interventions and null for interventions reported as free text.
Interventions	EC	N/A	N/A	10	ECOCCUR	Exposure as Collected Occurrence	An indication whether the study product was used when information about the occurrence of a specific intervention was solicited.	Was [study product/dose] used?; Has the subject taken [study product/dose]?	[Study Product]	Char	O	Indicate if the subject used study product. If Yes, include the appropriate details where indicated.	ECOCCUR	Maps directly to the tabulation variable listed in the Tabulation Target column. Not applicable when ECMOOD is "Scheduled".	(NY)	N/A	ECOCCUR is used to indicate whether the subject actually used study product. ECOCCUR should not be used to indicate that the question was not asked or answered.
Interventions	EC	N/A	N/A	11	ECREASOC	Exposure Reason for Occur Value	An explanation for why a scheduled study product administration did or did not occur.	What was the reason that the [study product/dose] was (not) used?	Reason (Not) Taken	Char	O	Indicate why the study product was or was not used.	SUPPEC.QVAL	This information could be represented in a SUPPEC dataset as the value of SUPPEC.QVAL where SUPPEC.QNAME="ECREASOC" and SUPPEC.QLABEL = "Reason for Occur Value".	N/A	N/A	The reason the study product was or was not taken may be chosen from an applicant-defined codelist or entered as free text. When -REASOC is used, --OCCUR must also be populated in the tabulation dataset with a value of "Y" or "N".
Interventions	EC	N/A	N/A	12	ECMOOD	Exposure as Collected Mood	Mode or condition of the record specifying whether the intervention (activity) is intended to	Does this record describe scheduled [study product/dose] or used [study product/dose]?	Scheduled/Performed	Char	O	Indicate if this record has happened or is intended to happen.	ECMOOD	Maps directly to the tabulation variable listed in the Tabulation Target column. When implemented, ECMOOD must be populated for all records.	(BRDGMOOD)	N/A	"SCHEDULED" is for collected subject-level intended dose records. "PERFORMED" is for collected subject-level actual dose records. "Planned" or "Scheduled" can be preprinted as the

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								happen or has happened.								CRF name or section header, as applicable. If collecting both the scheduled and performed dosing in the same horizontal record, the applicant may choose to append "_SCHEDULED" to the ECDOSE/ECDOSTXT variable name to delineate the scheduled dose from the performed dose. The performed dose would just be collected with ECDOSE/ECDOSTXT and ECDOSU.	
Interventions	EC	N/A	N/A	13	ECREFID	Exposure as Collected Reference ID	An internal or external identifier (e.g., kit number, bottle label, vial identifier).	What is the [study product/dose] label identifier?	[Study Product] Label Identifier	Char	O	Record product label identifier.	ECREFID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This packaging identifier (e.g., kit number, bottle label, vial identifier) may be collected in different ways (e.g., affixing label onto CRF, scanning a bar code). For some study dosing regimens that require greater granularity for product identifiers, applicants may need to use additional variables.
Interventions	EC	N/A	N/A	14	ECLOT	Lot Number	Lot number of the ECTRT product.	What was the lot number of the [study product/dose] used?	Lot Number	Char	R/C	Record the lot number that appears on the container holding the study product.	ECLOT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The lot number identifies the manufacturing batch of the study product. In open-label studies, the reference number on the study product container may represent an actual lot number and should be represented using ECLOT. This variable may be populated during the process of creating the tabulation datasets. Do not collect other identification variables in this field.
Interventions	EC	N/A	N/A	15	ECDOSEFRM	Exposure as Collected Dose Form	The dosage form in which the ECTRT is physically presented.	What was the dose form of the [studyproduct /dose]?	Dose Form	Char	R/C	Record the dose form (e.g., SOLUTION, TABLET, LOTION) or enter the appropriate code from the code list.	ECDOSEFRM	Maps directly to the tabulation variable listed in the Tabulation Target column.	(FRM)	(EXDOSFRM)	This must be collected if it cannot be determined from other sources or if there are multiple options for the same study product.
Interventions	EC	N/A	N/A	16	ECSTDAT	Exposure as Collected Start Date	The start date of study product, intended or actual, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the ([intended/planned/actual]) ([study product/dose]) (start) date?	(Start) Date	Char	HR	Record the start date of the study product administration using this format (DD-MON-YYYY).	ECSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable ECSTDTC in ISO 8601 format.	N/A	N/A	Date when constant dosing interval of the study product started or single administration occurred. When collecting the date for an individual dose, the word "start" may be omitted from the Question Text and Prompt. When ECMOD is collected and ECMOOD is "SCHEDULED", use "intended" in the question text and prompt. When ECMOOD is collected

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																	and ECMOOD is "PERFORMED", use "actual" in the question text and prompt.
Interventions	EC	N/A	N/A	17	ECSTTIM	Exposure as Collected Start Time	The start time of study product, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the ([intended/planned/actual]) ([study product/dose]) (start) time?	(Start) Time	Char	R/C	Record the start time (as complete as possible) when administration of study product started.	ECSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable ECSTDTC in ISO 8601 format.	N/A	N/A	Recommend collecting the time a product was started only when a protocol or data collection scenarios requires it. When collecting the time for an individual dose, the word "start" may be omitted from the question text and prompt.
Interventions	EC	N/A	N/A	18	ECENDAT	Exposure as Collected End Date	The end date of study product, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the ([intended/planned/actual]) ([study product/dose]) (end) date?	(End) Date	Char	R/C	Record the end date of the study product use using this format (DD-MON-YYYY).	ECENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable ECENDTC in ISO 8601 format.	N/A	N/A	Date when study product period stopped. If start date and end date are not expected to be the same date, the collection of the end date is required. If the study design indicates that the start and end are on the same day, the collection of the end date is not required because it can be assigned to be equal to the start date.
Interventions	EC	N/A	N/A	19	ECENTIM	Exposure as Collected End Time	The end time of study product use, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the ([intended/planned/actual]) ([study product/dose]) (end) time?	(End) Time	Char	R/C	Record the time, (as complete as possible) when study product use stopped (e.g., for infusions this is the time when the infusion ended).	ECENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable ECENDTC in ISO 8601 format.	N/A	N/A	Recommend collecting the time a med was ended when a protocol or data collection scenarios requires it. For infusions, the end time of the infusion is typically needed.
Interventions	EC	N/A	N/A	20	ECDSTXT	Exposure as Collected Dose Description	The dose of study product taken (per administration).	What was the dose (per administration) of [study product/dose]?	Dose	Char	R/C	Record the dose or amount of study product that was used to/taken by the subject in the period recorded; from the start date/time to the end date/time inclusive.	ECDOSTXT; ECDOSE	This does not map directly to a tabulation variable. The data collected in this dose text-format field should be mapped to either ECDOSE if numeric or ECDOSTXT if text.	N/A	N/A	Dose or amount taken for single use of study product or per constant use interval recorded. Dose must be collected if it cannot be determined via other methods (e.g., from diary data, product accountability data, protocol). Care should be taken when mapping ECDSTXT. The data collected in this dose text-format field should be separated or mapped to either ECDOSE if numeric or ECDOSTXT if text.
Interventions	EC	N/A	N/A	21	ECDOSU	Exposure as Collected Dose Units	The unit for intended dose (per administration) for ECDOSE, ECDOSTOT, or ECDOSTXT.	What were the units for the dose?	Units	Char	R/C	Record the unit of dose or amount taken per period recorded (e.g., ng, mg, mg/kg).	ECDOSU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	(EXDOSU)	Unit of dose or amount taken per constant dosing interval recorded. Dose unit must be collected if it cannot be determined via other methods (e.g., from protocol, randomization data). The unit should be preprinted on the CRF or a field provided on the CRF to capture it. A CDASH Subset Controlled Terminology Codelist Name is available for dose and volume units. In blinded

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																	trials, the collected unit may be tablet, capsule, etc., since the actual unit is also blinded.
Interventions	EC	N/A	N/A	22	ECDOSFRQ	EC Dosing Frequency per Interval	The number of doses taken during a specific interval.	What was the frequency of [study product/dose] dosing?	Frequency	Char	R/C	Record the frequency the study product was used for a defined period of time (e.g., BID, QID, TID).	ECDOSFRQ	Maps directly to the tabulation variable listed in the Tabulation Target column.	(FREQ)	(EXDOSFRQ)	This may be collected if it cannot be determined from other sources or if there are multiple options. When possible, the options for dose/amount frequency are preprinted on the CRF. When collected, the recommendation is to collect dosing information in separate fields (e.g., ECDOSE, ECDOSEU, ECDOSFRQ) for specific and consistent data collection and to enable programmatically using these data.
Interventions	EC	N/A	N/A	23	ECROUTE	EC Route of Administration	The route of administration of the study product	What was the route of use (of the [study product/dose])?	Route	Char	R/C	Record the route of administration (e.g., IV, ORAL, TRANSDERMAL) or enter the appropriate code from the code list.	ECROUTE	Maps directly to the tabulation variable listed in the Tabulation Target column.	(ROUTE)	(EXROUTE)	This may be collected if it cannot be determined via other methods (e.g., from protocol) or if there are multiple options.
Interventions	EC	N/A	N/A	24	ECDOSADJ	Dose Adjusted	An indication of whether the dose was adjusted.	Was the dose adjusted?	(Dose) Adjusted	Char	O	Select either Yes or No to indicate whether there was a change in dosing.	N/A	When ECADJ is collected, does not map to a tabulation variable. When ECADJ is not collected, applicant may represent this variable in SUPPEC.	(NY)	N/A	Typically, the intent/purpose of collecting this field is to help with data cleaning and monitoring, as it provides a definitive response regarding any dose changes. It provides verification that the associated field on the CRF (ECADJ) was deliberately left blank. However, the applicant may collect whether the dose was adjusted, without collecting the reason for the change. When using ECMOOD, this field should not be used.
Interventions	EC	N/A	N/A	25	ECADJ	Reason for Dose Adjustment	Description of or explanation for why a dose of the study product was adjusted.	What was the reason the dose was adjusted?	Reason Adjusted	Char	O	If there was a change in dosing, record the reason for change.	ECADJ	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Captures the reason the dose was changed or modified. The reason may be chosen from an applicant-defined list (e.g., adverse event, insufficient response) or entered as free text. May be used for variations from protocol-specified doses, or changes from expected doses. Used only when an adjustment is represented in EX dataset.
Interventions	EC	N/A	N/A	26	ECITRPYN	EC Exposure Interrupted	An indication of whether the exposure was interrupted.	Was the [(study) product/dose] interrupted?	[(Study) Product / Dose] Interrupted	Char	O	Record if there was an interruption in the study product use or dosing.	N/A	Does not map to a tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring when the actual duration of the

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																	exposure is collected using the collection field ECCINTD. In some situations, if the actual duration of the interruption is not collected or not derived, this information could be represented in a SUPPEC.QVAL dataset where SUPPEC.QNAM = "ECITRPYN" and SUPPEC.QLABEL = "Exposure Interrupted".
Interventions	EC	N/A	N/A	27	ECCINTD	EC Interruption Duration	The collected duration of the interruption in product use interruption.	What was the duration of the interruption in product use?	(Interruption) Duration	Char	O	Record the duration of the interruption in project use.	SUPPEC.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPEC dataset as the value of SUPPEC.QVAL where SUPPEC.QNAM = "ECITRPD" and SUPPEC.QLABEL = "Interruption Duration". Concatenate the collected interruption duration and the duration unit components and create ECITRPD using ISO 8601 Period format.	N/A	N/A	This field is used to collect the duration of the interruption. In some situations, the duration of the interruption may not be collected but calculated from the product start and end times recorded elsewhere in the CRF.
Interventions	EC	N/A	N/A	28	ECCINTDU	EC Interruption Duration Units	The unit for the collected duration of the interruption in product use.	What was the interruption duration unit?	(Interruption Duration) Unit	Char	O	Record the unit (e.g., MINUTES, HOURS, DAYS) for the duration of interruption in product use.	SUPPEC.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPEC dataset as the value of SUPPEC.QVAL where SUPPEC.QNAM = "ECITRPD" and SUPPEC.QLABEL = "Interruption Duration". Concatenate the interruption duration and the duration unit components and create ECITRPD using ISO 8601 Period format.	(UNIT)	(EXINTPU)	The unit should be collected as a qualifier to the number for duration.
Interventions	EC	N/A	N/A	29	ECLOC	EC Location of Dose Administration	A description of the anatomical location of administration.	What was the anatomical location of the ([study product/dose]) administration?	Anatomical Location	Char	O	Record the body location where the study product was administered (e.g., SHOULDER, HIP, ARM).	ECLOC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LOC)	N/A	Collected or preprinted when the applicant needs to identify the specific anatomical location where the study product was administered. LAT, DIR, PORTOI are used to further describe the anatomical location.
Interventions	EC	N/A	N/A	30	ECLAT	Exposure as Collected Laterality	Qualifier for anatomical location, further detailing side of the body for the study product administration.	What was the side of the anatomical location of the ([study product/dose]) administration?	Side	Char	O	Record the side of the body location where the study product was administered (e.g., Left, Right).	ECLAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LAT)	N/A	Further details the laterality of the location where the study product was administered. This may be preprinted or collected. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Interventions	EC	N/A	N/A	31	ECDIR	Exposure as Collected Directionality	Qualifier further detailing the position of the anatomical location relative to the center of the body, organ, or specimen.	What was the directionality of the anatomical location of the ([study product/dose]) administration?	Directionality	Char	O	Record the directionality of the body location where the study product was administered (e.g., Anterior, Lower, Proximal, Upper).	ECDIR	Maps directly to the tabulation variable listed in the Tabulation Target column.	(DIR)	N/A	May be preprinted or collected when the applicant needs to identify the directionality of the anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Interventions	EC	N/A	N/A	32	ECVAMT	EC Vehicle Amount	The amount of the prepared product	What was the total amount (Product + Vehicle) (of [study product/dose]) used?	Total Amount (Product + Vehicle)	Num	O	Record the total amount (product + vehicle) that was	ECVAMT	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable ECTRTV may also be	N/A	N/A	Administration amount that was used by the subject.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
							(product + vehicle) used.					administered/given to the subject.		populated during the process of creating the tabulation datasets.			Note: Should not be the diluent amount alone. The ECTRTV field may be collected if it cannot be determined from other sources.
Interventions	EC	N/A	N/A	33	ECVAMTU	EC Vehicle Amount Units	The unit of measurement for the prepared product (product + vehicle).	What was the unit for the amount of [study product/dose] used?	Unit	Char	O	Record the unit of total amount (product +vehicle) used by the subject (e.g., mL).	ECVAMTU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	N/A	Unit of the used amount
Interventions	EC	N/A	N/A	34	ECTPT	EC Planned Time Point Name	A text description of the planned timepoint when measurements should be taken, as defined in the protocol.	What was the planned timepoint for [product study /dose] use?	[Planned Time Point Name]	Char	R/C	Record the planned timepoint of study product use if not preprinted on the CRF.	ECTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation time-point anchors ECTPTREF (text description) and ECRFTDTC (date/time) may be needed, as well as tabulation variables ECTPTNUM, ECELTM.	N/A	N/A	Planned timepoints are needed to differentiate multiple sequential assessments. It is recommended that timepoints should be preprinted on the CRF rather than collected in a field that requires the site to enter text. If the form is laid out as a grid, then words such as "Planned Time Point" can be included as the column heading.

Assumptions

- If the tabulation EC dataset would be an exact duplicate of the tabulation EX dataset, then the applicant may choose to collect data using either the collection EC or EX domain.
- If an exposure is such that start and stop times are not required, and only 1 exposure date is collected, then the collected exposure date will map to both the start date (--STDTC) and end date (--ENDTC) in the tabulation exposure dataset(s).

2.7.6.6 CDASH Findings About Events and Interventions (FA)

Description

Findings About Events and Interventions (FA) is a domain is used to record findings related to events and interventions.

FA represents collected data about an event or intervention that cannot be represented within an Event or Intervention record or as a supplemental qualifier to such a record. For example, this may be the case when:

- The applicant collects information about prespecified symptoms of event of interest on a daily basis.
- The applicant collects the occurrence of prespecified adverse events at every visit.

Specific criteria on when to use this domain are provided in Section 2.8.4, [How to Use Findings About Events or Interventions](#).

Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings About Events or Interventions	FA	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in	N/A	N/A	Although this field is not typically captured on a CRF, it

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
														the Tabulation Target column.			should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings About Events or Interventions	FA	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings About Events or Interventions	FA	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.
Findings About Events or Interventions	FA	N/A	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned trial interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted or displayed within the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.
Findings About Events or Interventions	FA	N/A	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using	N/A	This field is not an tabulation variable. The date of a	N/A	N/A	The date the finding about measurements were collected

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes	
												this format (DD-MON-YYYY).					measurement, test, observation, or specimen collection can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the collection VISDAT/VISTIM components and populating the tabulation variable FADTC in ISO 8601 format.	can be determined from the visit date variable (VISDAT) and applying that date to all of the observations at that visit, or the collection date can be included on the FA CRF using the Findings About Date (FADAT) field.
Findings About Events or Interventions	FA	N/A	N/A	6	FAOBJ	Findings About Object of the Observation	A description of the object or focal point of the findings observation that is represented by FATEST.	[Applicantsdt-defined phrase]	[Applicant-defined phrase]	Char	HR	[Protocol-specific]	FAOBJ	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The FAOBJ will usually be preprinted or hidden, not solicited as an actual question. These FA domains are usually created by the applicant.	
Findings About Events or Interventions	FA	N/A	N/A	7	FAYN	Findings About Collected	An indication of whether data was collected for the finding topic.	Has the subject had any [Findings topic(s)] (after/before [study specific time frame])?; [Was/Were] (there) any [Findings topic(s)] (reported) (after/before [study specific time frame])?; Were all eligibility criteria met?	Any [Finding Topic]	Char	O	Indicate if there are findings. If Yes, include the appropriate details where indicated on the CRF.	N/A	Does not map to a tabulation variable.	(NY)	N/A	This is a field that can be used in any CRF to indicate whether there is data to record. Used primarily as a data cleaning field, it provides verification that all other fields on the CRF were deliberately left blank. FAPERF should be used to capture a response about whether planned measurements, tests, or observations were done.	
Findings About Events or Interventions	FA	N/A	N/A	8	FAPERF	Findings About Performed	An indication of whether a planned measurement, series of measurements, test, observation or specimen was performed or collected.	[Were any/Was the] [FATEST/topic] ([Measurement(s)/test(s)/examination(s)/specimen(s) sample(s)]) [performed/collected]?	([FATEST/ topic] ([Measurement(s)/Test(s)/Examination(s)/Specimen(s)/Sample(s)]) [Performed/Collected]?)	Char	O	Indicate if the [FATESTs] was/were collected. If Yes, include the appropriate details where indicated on the CRF.	FASTAT	This field does not map directly to an tabulation variable. May be used to populate a value into the tabulation variable FASTAT. If the collection variable FAPERF="N", the value of the tabulation variable FASTAT is "OT DONE". If FAPERF="Y", FASTAT is null. A combination of tabulation variables (e.g., FACAT and	(NY)	N/A	This field is used to capture a response to whether a planned measurement, test or observation was performed. A negative response can be collected as "N" and mapped to the tabulation FASTAT variable as "NOT DONE".	

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
														FASCAT, FATPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable FATESTCD would be populated with FAALL and an appropriate test name (FATEST) provided.			
Findings About Events or Interventions	FA	N/A	N/A	9	FADAT	Findings About Assessment Date	The date when the findings about assessment was performed, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date the findings about assessment was performed?	Date	Char	R/C	Record date of measurements using this format (DD-MON-YYYY).	FADTC	This field does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable FADTC in ISO 8601 format.	N/A	N/A	The date the FA measurements were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the observations at that visit, or the collection date can be included on the FA CRF using the Date of Collection (FADAT) field.
Findings About Events or Interventions	FA	N/A	N/A	10	FATIM	Findings About Assessment Time	The time of measurement, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the time of the findings about assessment?	Time	Char	R/C	Record time of measurement (as complete as possible).	FADTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable VSRTC in ISO 8601 format.	N/A	N/A	Collect time if it is relevant for the analysis.
Findings About Events or Interventions	FA	N/A	N/A	11	FATEST	Findings About Test Name	Descriptive name for the test being performed.	What [is/was] the name (of the [measurement/test/examination])?	[Measurement/Test/Examination/] (Name)	Char	HR	Record the name of the FATEST if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.	FATEST; FATESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable FATESTCD may be determined from the value collected in FATEST.	N/A	N/A	Required to identify which test the result is for. It is recommended that the test names be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Test" can be included in the column heading.
Findings About Events or Interventions	FA	N/A	N/A	12	FATSTDTL	Findings About Test Detail	A further description of FATESTCD and FATEST.	What [is/was] the [measurement/test/examination] detail name?	[Measurement/Test/Examination] Detail (Name)	Char	O	Record the detail of the [FATEST], if not preprinted on the CRF.	FATSTDTL	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	It is recommended that the test detail name be preprinted on the CRF. If the form is laid out as a grid, then words

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																	such as "Test," "Test Name" can be included in the column heading.
Findings About Events or Interventions	FA	N/A	N/A	13	FACAT	Category for Findings About	A grouping of topic-variable values based on user-defined characteristics.	What [is/was] the [type/category/name] (of the [measurement/test/examination/specimen/sample])?	[Category/Category Value]; NULL	Char	O	Record the FA category, if not preprinted on the CRF.	FACAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This is most commonly either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be a applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included in the column heading.
Findings About Events or Interventions	FA	N/A	N/A	14	FASCAT	Subcategory for Findings About	A sub-division of the FACAT values based on user-defined characteristics.	What [is/was] the [type/subcategory/name] (of the [measurement/test/examination/specimen/sample])?	[FA Subcategory/FA Subcategory Value]; NULL	Char	O	Record the FA subcategory, if not preprinted on the CRF.	FASCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This is most commonly either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be a applicant-defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included in the column heading. FASCAT can only be used if there is an FACAT, and it must be a subcategorization of FACAT.
Findings About Events or Interventions	FA	N/A	N/A	15	FAPOS	Findings About Position of Subject	The position of the subject during a measurement or examination.	In what position was the subject during the [measurement/ test/examination/specimen collection/sample collection]?; What was the position of the subject (during the [measurement/test/examination/specimen collection/sample collection])?	Position	Char	O	Record the position of the subject during the FA test.	FAPOS	Maps directly to the tabulation variable listed in the Tabulation Target column.	(POSITION)	N/A	N/A

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings About Events or Interventions	FA	N/A	N/A	16	FAORRES	FA Result or Finding in Original Units	Result of the measurement or finding as originally received or collected.	What [is/was] the [result/amount/(subject's) characteristic] (of the [measurement/test/examination/question/assessment])?	([Result/Amount] of) [value from FATEST]	Char	HR	Record the FATEST result.	FAORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Both quantitative results and interpretive findings or summaries may be recorded here.
Findings About Events or Interventions	FA	N/A	N/A	17	FAORRESU	FA Original Units	The unit of the result as originally received or collected.	What [is/was] the unit (of the [measurement/test/examination])?	Unit	Char	R/C	Select the unit of measure associated with the test, or record if not preprinted on the CRF.	FAORRESU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	N/A	Should be preprinted on the CRF with the associated test when possible, rather than collected in a free-text field. Should be included if applicable and not available elsewhere.
Findings About Events or Interventions	FA	N/A	N/A	18	FAORNRLO	FA Normal Range Lower Limit-Orig Unit	The lower end of normal range or reference range for continuous results stored in FAORRES.	What [is/was] the lower limit of the reference range (for the [measurement/test/examination])?	Normal Range Lower Limit	Char	O	Record the lower limit of the reference range of the FA test.	FAORNRLO	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	--ORNRL0 should be populated only for continuous findings. The tabulation variable -- STNRC should be populated only for noncontinuous results. These data may be obtained from the lab or the electronic equipment, or could be derived from a site- or lab-specific set of normal ranges stored in a look-up table.
Findings About Events or Interventions	FA	N/A	N/A	19	FAORNRHI	FA Normal Range Upper Limit-Orig Unit	The upper end of normal range or reference range for continuous results stored in FAORRES.	What [is/was] the upper limit of the reference range (for the [measurement/test/examination])?	Normal Range Upper Limit	Char	O	Record the upper limit of the reference range of the FA test.	FAORNRHI	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	--ORNRIH should be populated only for continuous findings. The tabulation variable -- STNRC should be populated only for noncontinuous results. These data may be obtained from the lab or the electronic equipment, or could be derived from a site- or lab-specific set of normal ranges stored in a look-up table.
Findings About	FA	N/A	N/A	20	FANRIND	Findings About Reference	An indication or description about how the value	How [did/do] the reported values compare within the [reference/normal/expected] range?	Comparison to [Reference/Expected/Normal] Range	Char	O	Record where the test results were categorized	FANRIND	Maps directly to the tabulation variable listed in	(NRIND)	N/A	Reference ranges may be defined by

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Events or Interventions						Range Indicator	compares to the normal range or reference range.					within the respective reference range (e.g. HIGH, LOW, ABNORMAL).		the Tabulation Target column.			FAORNRLO, FAORNRHI, FASTNRC or other objective criteria. Reference Range Indicator may be included if not derived or determined programmatically after data collection. Should not be used to indicate clinical significance.
Findings About Events or Interventions	FA	N/A	N/A	21	FASTAT	Findings About Completion Status	This variable is used to indicate that data are not available, by having the site recording the value as "Not Done".	Was the [-TEST] not [completed/answered/done/assessed/evaluated]?; Indicate if the([-TEST] was) not [answered/assessed/done/evaluated/ performed].	Not Done	Char	O	Indicate if the [FATEST] measurement was not done.	FASTAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(ND)	N/A	Used only when the response value is collected as NOT DONE or NULL or in addition to the collection FAPERF field. Typically a checkbox which indicates the test was NOT DONE. This field can be useful when multiple questions are asked to confirm that a blank result field is meant to be blank.
Findings About Events or Interventions	FA	N/A	N/A	22	FAREASND	Findings About Reason Not Performed	An explanation of why data are not available.	Was the [is/was] the reason that the [Findings topic/data/information/applicant-defined phrase] was not [collected/answered/done/assessed/ evaluated]?	Reason Not [Answered/Collected/Done/Evaluated/ Assessed/ Available]	Char	O	Provide the reason why an FA test was not collected.	FAREASND	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology may be used. The reason the data are not available may be chosen from applicant defined codelist (e.g., broken equipment, subject refused) or entered as free text. When --REASND is used, --STAT should also be populated in the tabulation dataset.
Findings About Events or Interventions	FA	N/A	N/A	23	FASPEC	Findings About Specimen Type	The type of specimen used for a measurement.	What [is/was] the specimen type?	Specimen Type	Char	O	Record the specimen material type.	FASPEC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(SPECTYPE)	N/A	The type of specimen used for a measure. Should be collected if not available elsewhere, or if required to differentiate multiple specimens.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings About Events or Interventions	FA	N/A	N/A	24	FASPCND	Findings About Specimen Condition	Description of the condition of the specimen.	What [is/was] the condition of the specimen?	Specimen Condition	Char	O	Record the condition of the specimen.	FASPCND	Maps directly to the tabulation variable listed in the Tabulation Target column.	(SPECCOND)	N/A	May be collected using free or standardized text. Results may be affected by whether conditions for specimen were properly met. When local processing is used, applicants may not routinely collect specimen condition.
Findings About Events or Interventions	FA	N/A	N/A	25	FALOC	Location of the Finding About	The anatomical location of the subject, relevant to the collection of the measurement.	What [is/was] the anatomical location (of the [measurement/test/examination]) or What [is/was] the anatomical location where the [measurement/specimen] was taken/collected)?	Anatomical Location	Char	O	Record or select location on body where the measurement was performed, if not preprinted on CRF.	FALOC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LOC)	N/A	Collected or preprinted when the applicant needs to identify the specific anatomical location (e.g., ARM for blood pressure). Applicants may collect the data using a subset list of controlled terminology on the CRF. LAT, DIR, and PORTOT are used to further describe the anatomical location.
Findings About Events or Interventions	FA	N/A	N/A	26	FALAT	L laterality of Location of Finding About	Qualifier for anatomical location, further detailing the side of the body.	What [is/was] the side (of the anatomical location of the [measurement/test/examination])?	Side	Char	O	Record the side of the anatomical location of the [FATEST] measurement.	FALAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LAT)	N/A	May be preprinted or collected when the applicant needs to identify the specific side of the anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Findings About Events or Interventions	FA	N/A	N/A	27	FADIR	Findings About Directionality	Qualifier further detailing the position of the anatomical location, relative to the center of the body, organ, or specimen.	What [is/was] the directionality (of the anatomical location of the [measurement/test/examination])?	Directionality	Char	O	Record the directionality.	FADIR	Maps directly to the tabulation variable listed in the Tabulation Target column.	(DIR)	N/A	May be preprinted or collected when the applicant needs to identify the directionality of the anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Findings About Events or Interventions	FA	N/A	N/A	28	FAPORTOT	FA Location Portion or Totality	Qualifier for anatomical location, further detailing the distribution	What [is/was] the portion or totality (of the anatomical location of the [measurement/test/examination])?	Portion or Totality	Char	O	Indicate the portion or totality anatomical location.	FAPORTOT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(PORTOT)	N/A	Collected when the applicant needs to identify the specific portability for

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes	
							(i.e., arrangement of, apportioning of).										the anatomical locations of the location of the FATEST. Applicants may collect the data using a subset list of controlled terminology on the CRF.	
Findings About Events or Interventions	FA	N/A	N/A	29	FAMETHOD	Findings About Method	Method of the test or examination.	What was the method (used for the [measurement/test/examination])?	Method	Char	O	Record the method used for the measurement, test, or examination.	FAMETHOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	(METHOD)	N/A	N/A	
Findings About Events or Interventions	FA	N/A	N/A	30	FALEAD	Findings About Lead	The lead or leads identified to capture the measurement for a test from an instrument.	What [is/was] the lead (used to measure [measurement/test/examination])?	Lead	Char	O	Record the lead used for measurement.	FALEAD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	N/A	
Findings About Events or Interventions	FA	N/A	N/A	31	FAFAST	Findings About Fasting Status	An indication that the subject has abstained from food/water for the specified amount of time.	[Is/Was] the subject fasting (prior to the [test being performed/sample being collected])?	Fasting	Char	O	Record whether the subject was fasting prior to the test being performed.	FAFAST	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	Results may be affected by whether the subject was fasting. This may not be relevant for all tests.	
Findings About Events or Interventions	FA	N/A	N/A	32	FAEVAL	Findings About Evaluator	The role of the person providing the evaluation.	Who provided the (applicant-defined phrase) information?; Who was the evaluator?	[Evaluator/Reporter]	Char	O	Select the role of the person who provided the evaluation (e.g., INVESTIGATOR, VENDOR).	FAEVAL	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EVAL)	N/A	Used only for results that are subjective (e.g., assigned by a person or a group). May be a preprinted, or collected. Applicants may collect the data using a subset list of controlled terminology on the CRF.	
Findings About Events or Interventions	FA	N/A	N/A	33	FAEVALID	Findings About Evaluator Identifier	An identifier used to distinguish multiple evaluators with the same role recorded in FAEVAL.	What [is/was] the identifier of the [evaluator name/reporter name] (providing the applicant-defined phrase-information)?	[Evaluator/Reporter] Identifier	Char	O	Record the unique identifier assigned to the person making the evaluation.	FAEVALID	Maps directly to the tabulation variable listed in the Tabulation Target column.	(MEDEVAL)	N/A	This variable is used in conjunction with FAEVAL to provide an additional level of detail.	
Findings About Events or Interventions	FA	N/A	N/A	34	FACLSIG	Findings About Clinical Significance	An indication whether the test results were clinically significant.	[Is/Was] the ([measurement/test/examination]) result clinically significant?	(Measurement/Test/Examination)/ Clinically Significant	Char	O	Record whether the [FATEST] result was clinically significant.	SUPPFA.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPFA dataset as the value of SUPPFA.QVAL when SUPPFA.QNAM = "CLSIG" and SUPPFA.QLABEL = "Clinical Significance".	(NY)	N/A	N/A	

Assumptions

1. The FA domain uses the same root variables as the Findings domain, with the addition of the --OBJ variable.

2.7.6.7 CDASH Inclusion/Exclusion Criteria Not Met (IE)**Description**

Inclusion/Exclusion Criteria Not Met (IE) is a Findings domain used for those criteria that cause the subject to be in violation of the inclusion/exclusion criteria. The IE domain is used to collect failures or exceptions to the inclusion/exclusion criteria during the screening process before a subject is enrolled in a study. It is not intended to collect protocol deviations or violations that occur after enrollment; protocol deviations are collected using the DV domain.

The recommendation is that individuals involved in data collection be given an entry criteria worksheet to be used for each subject, to record the results of eligibility review. This worksheet should be considered a source document, used in monitoring activities and maintained with the subject's files. The worksheet should identify each criterion using a unique identifier, which can be easily recorded on the CRF if a subject does not meet that criterion. If criteria lists are numbered the same for both inclusion and exclusion criteria (e.g., inclusion 001-100, exclusion 001-100), then this identifier could include a means of identifying the type of criterion (e.g., I001-I100, E001-E100). Alternatively, the criteria could be collected in 2 separate sections on the CRF labeled "Inclusion" and "Exclusion," and the output records could include the values of Inclusion or Exclusion on each record. These are only examples; an organization's numbering scheme may be different, but some method that captures both the Inclusion or Exclusion category and the unique criterion identifier should be used.

The recommended collection method has been simplified to require recording of a single "Y/N" value in the IEYN variable to indicate whether the subject met all of the criteria. If any criterion is not met, then this is recorded in the CRF. The result value for each unmet criterion may then be derived in the tabulation IE domain from the collection of the specific criterion that was not met. In other words, if the collected criterion is an inclusion criterion that was not met, the value of "N" can be derived into IEORRES and IESTRESC for that record in the tabulation IE domain. If it is an exclusion criterion, then "Y" can be derived into IEORRES and IESTRESC to indicate that the subject met the conditions for that exclusion record in IE.

The rationale for the recommended collection method is that what is being collected in the IE CRF is aligned with the data that would be in the tabulation IE domain.

This design allows criteria to change over the life of a study or project. If inclusion/exclusion criteria are amended, then each complete set of criteria will be included in the TI domain. TIVERS is used to distinguish between versions of eligibility criteria.

Use of uniquely numbered entry criteria are recommended within a study to effectively manage protocol changes and to facilitate the collection and submission of IE data. The Inclusion/Exclusion worksheet may need to be updated and renumbered/relettered whenever a protocol amendment changes 1 or more criteria. For example, if new versions of a criterion have not been given new numbers, separate values of IETESTCD might be created by appending letters (e.g., INCL003A, INCL003B). A field could be added to the CRF to capture the version number of the criteria being used; this can be mapped to the tabulation variable TI.TIVERS. This enables the retrieval of the full text of the criterion from the code used on the CRF.

Alternatively, an implementer may choose to include the full text of each criterion (IETEST) with a result field (IEORRES) in the CRF and request the site to record explicitly the "Y" or the "N" for each criterion, but only the recommended, simplified method is presented in the IE example CRF.

Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	IE	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	IE	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	IE	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant Identifier]	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all collection domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	IE	N/A	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed within the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.
Findings	IE	N/A	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using theis format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement, test, observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable IEDTC in ISO 8601 format.	N/A	N/A	The date the inclusion and exclusion assessments were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the observations at that visit or the collection date can be included on the Inclusion/Exclusion CRF using the date (IEDAT) field.
Findings	IE	N/A	N/A	6	IEYN	Any Incl/Excl Criteria Findings	Indication whether the subject met all the eligibility requirements for this study at the time the subject was enrolled.	Were all eligibility criteria met?	Met Criteria	Char	HR	Record Yes if all eligibility criteria were met at the time the subject was enrolled. Record No if subject did not meet all criteria at the time the subject was enrolled.	N/A	Does not map to an tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification if all other fields on the CRF were deliberately left blank.
Findings	IE	N/A	N/A	7	IEDAT	Inclusion/Exclusion Collection Date	The date of collection of the inclusion/exclusion criteria represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date the eligibility criteria assessment was performed?	Date	Char	O	Record complete date when the eligibility assessment was performed using this format (DD-MON-YYYY).	IEDTC	This does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable IEDTC in ISO 8601 format.	N/A	N/A	A complete date is expected. The date of collection may be determined from the date of visit (VISDAT) and, if so, a separate assessment date field is not required.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	IE	N/A	N/A	8	IECAT	Inclusion/Exclusion Category	A grouping category to denote whether the protocol entry criterion being assessed is inclusion criteria or exclusion criteria.	What was the category of the criterion?	Criterion Type	Char	R/C	Check the appropriate box to indicate whether the criterion exception was related to the subject's inclusion or exclusion.	IECAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(IECAT)	N/A	These categories have been defined in controlled terminology that must be used. Only records for criteria that are not met appear in the IE tabulation domain. IECAT must be populated. This criterion category may be collected on the CRF in a tick/checkbox format or it may be included as part of the criterion identification and mapped when the tabulation datasets are created.
Findings	IE	N/A	N/A	9	IESCAT	Inclusion/Exclusion Subcategory	A sub-division of the IECAT values based on user-defined characteristics.	What was the subcategory of the criterion?	[Criterion Subtype]; NULL	Char	O	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	IESCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included as the column heading. This can be used to distinguish criteria for a sub-study or to categorize the criterion as a major or minor exception.
Findings	IE	N/A	N/A	10	IETESTCD	Inclusion/Exclusion Criterion Short Name	The unique identifier associated with the criterion that was the exception.	What was the identifier of the inclusion criterion the subject did not meet or the exclusion criterion the subject met?	Exception Criterion Identifier	Char	HR	If the subject was not eligible, record the identifying code for each criterion that was an exception.	IETESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field is required to appear on the CRF, but may be null if there are no exceptions to the inclusion/exclusion criteria. The CRF should allow multiple exceptions to be recorded. Applicants may provide a list of inclusion/exclusion criteria and the unique identifying codes to the site. The list provided should be versioned/updated when the protocol changes and the criteria are changed. Applicants should use applicant-developed controlled terminology for IETESTCD.
Findings	IE	N/A	N/A	11	IETEST	Inclusion/Exclusion Criterion	Descriptive name of the inclusion or exclusion criterion that was the exception.	What was the description of the inclusion criterion the subject did not meet or the exclusion criterion the subject met?	Exception Criterion Description	Char	O	Record the description of the criterion, if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.	IETEST	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable IETESTCD may be determined from the value collected in IETEST. The tabulation variables IETESTCD and IETEST are required in the tabulation datasets.	N/A	N/A	Applicants could automatically populated the text in EDC systems when the criterion identifier is populated by the investigator. This can be verified by the PI to ensure the right exception identifier was selected.
Findings	IE	N/A	N/A	12	IEORRES	I/E Criterion Original Result	An indication of which inclusion criterion was not met or exclusion criterion was met.	What is the result?	(Result)	Char	HR	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	IEORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	(NY)	This is only a data collection field when a complete list of inclusion and exclusion criteria are included on the CRF with Yes/No response options. If the applicant collects only the criteria that are not fulfilled, then, when an inclusion criterion is not met, IEORRES is mapped to "N" and when an exclusion criterion is met, IEORRES is mapped to "Y".

Assumptions

1. The recommendation is for only those records for criteria that are not met to be collected on the IE CRF.
2. The complete list of inclusion/exclusion criteria and the version number of each of the criteria are provided in the SDTMIG TI dataset. The IETEST and IETESTCD values used to collect data on the IE CRF should match the values in the TI dataset.
3. Categories IECAT and IESCAT
 - a. The tabulation variable IECAT must be populated with INCLUSION or EXCLUSION. This criterion category may be collected on the CRF in a checkbox format using the collection field IECAT, or it may be included as part of the criterion identification and populated when the tabulation datasets are created.
 - b. IESCAT may be used by the applicant to further categorize the exception criteria within the larger categories of Inclusion or Exclusion (e.g., Major, Minor).
 - c. These categories may be collected on the CRF, or they may be used as titles on the CRF and hidden/defaulted in the operational system. If these categories are not collected on the CRF or created in the operational data management system, they are added when the tabulation datasets are created.
4. There should be a unique IETESTCD for each unique criterion text in IETEST, and these values must match the values in the TI domain.
5. It may be useful to collect the protocol version under which a subject was screened.
6. The collection date (IEDAT) is the date that the IE data were recorded for the study, and not the actual date the exception occurred. The visit date (VISDAT) may be used, instead, to populate the tabulation IEDTC variable.
7. The result (IEORRES)—"Y" or "N"—for each tabulation IETESTCD is derived or inferred from the collection of the specific criterion not met. IEORRES must be populated in the tabulation IE domain because it is a Required variable. Applicants will populate this in the operational data management system or in the creation of the tabulation datasets. When an inclusion criterion is not met, the tabulation variable IEORRES is populated with "N"; when an exclusion criterion is not met, IEORRES is populated with "Y".

2.7.6.8 CDASH Laboratory Test Results (LB)

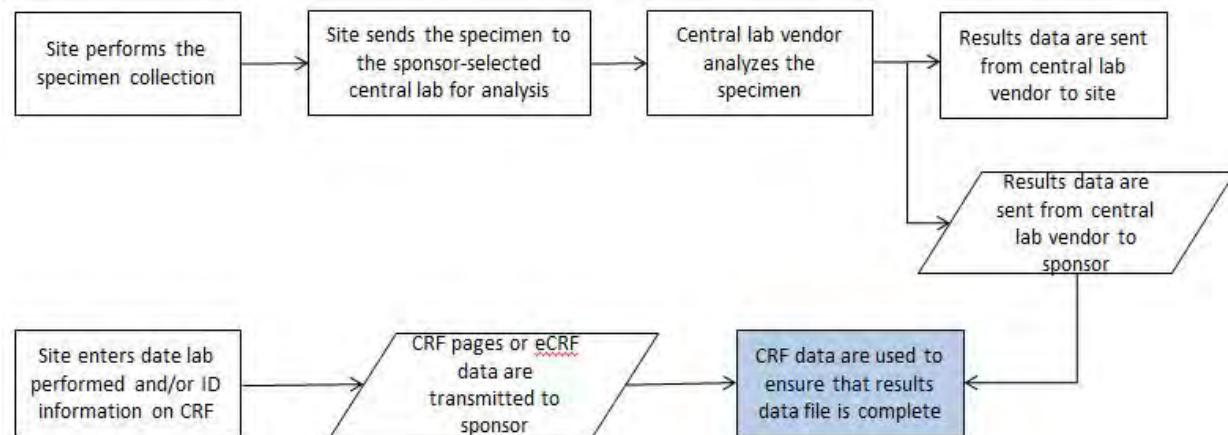
Description

Laboratory Test Results (LB) is a Findings domain used for laboratory test data, for tests and measurements performed on collected biological specimens. The LB domain includes but is not limited to hematology, clinical chemistry, and urinalysis data. The LB domain does not include pharmacokinetic data; pharmacokinetic concentrations are represented in the PC domain and pharmacokinetic parameters are represented in the PK domain.

This section describes 3 different data collection scenarios for laboratory test results. It is up to the applicant to determine which data collection scenario best meets the study needs.

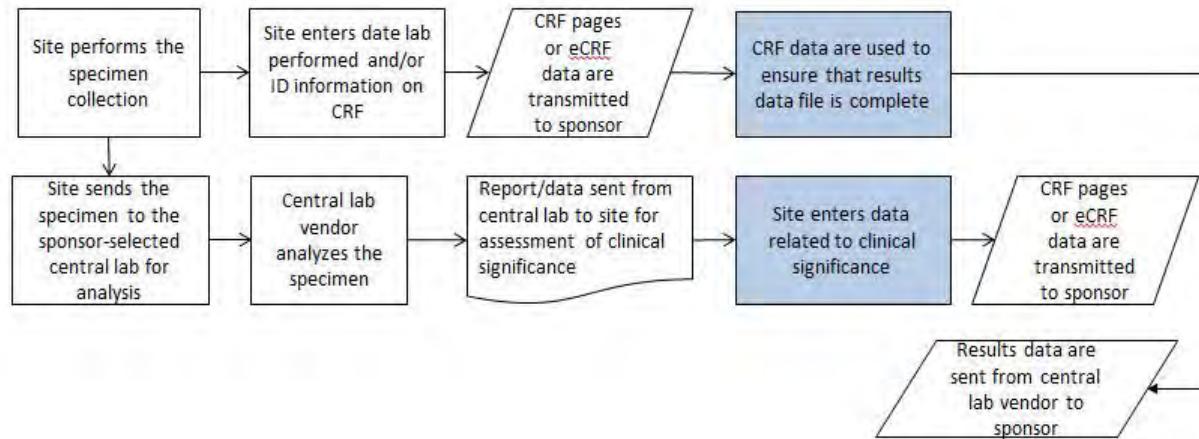
Scenario 1: Central Processing

In this scenario, subject specimens are taken at the site and sent out for processing. Results are provided in an electronic file; the applicant has chosen to collect reconciliation data (e.g., LBDAT, LBTIM, VISITNUM, LBREFID) on the CRF. This scenario may also apply if the central lab results are imported into an applicant's EDC system. The fields for test results are not defined here, as these data are not part of the CRF.



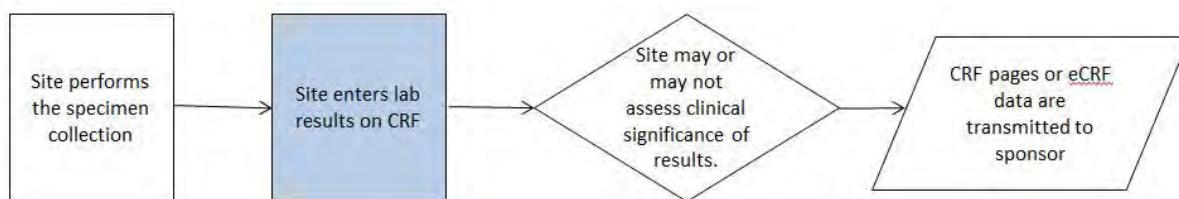
Scenario 2: Central Processing with Investigator Assessment of Clinical Significance Assessment for Abnormal Values

In this scenario, subject specimens are taken at the site and sent to a central lab for processing. The results are provided in an electronic file to the applicant. In addition, the results are provided to the investigator for assessment of clinical significance for any abnormal values, and that information is provided to the applicant on the CRF.



Scenario 3: Local Processing

In this scenario, subject specimens are taken and analyzed, and then the results are recorded directly on the CRF.



Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	LB	Central Processing	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	LB	Central Processing	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	LB	Central Processing	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	LB	Central Processing	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed in the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.
Findings	LB	Central Processing	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using DD-MON-YYYY format.	N/A	This field is not a tabulation variable. The date of a measurement, test, observation, or specimen collection can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable LBDTC in ISO 8601 format.	N/A	N/A	The date the laboratory specimens were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the laboratory tests at that visit, or the specimen collection date can be collected on the Laboratory CRF using the date (LBDAT) field.
Findings	LB	Central Processing	N/A	6	LPERF	Lab Performed	An indication of whether a planned lab measurement, series of lab measurements, tests, observations or was performed or specimens collected.	Was the sample collected?; Was the lab performed?	Lab Performed; Sample Collected	Char	HR	Indicate whether or not lab specimen was collected or measurement performed.	LBSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable LBSTAT. If the collection variable LPERF = "N", the value of LBSTAT will be "NOT DONE". If LPERF = "Y", LBSTAT should be null. A combination of tabulation variables (e.g., LBCAT and LBSCAT, LBTP) is used to indicate that multiple tests were not done. In this situation, the tabulation variable	(NY)	N/A	This may be implemented for an entire lab panel, or a specific lab test. General prompt question to be used as a data management tool to verify that missing results are confirmed missing.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/ CDASH Codelist Name	Implementation Notes
														LBTESTCD would be populated as LBALL and an appropriate test name (LBTEST) provided.			
Findings	LB	Central Processing	N/A	7	LBDAT	Specimen Collection Date	The date of specimen collection, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the (start) date of the lab specimen collection?	Specimen Collection (Start) Date	Char	R/C	Record the (start) date when specimen collection was done using this format (DD-MON-YYYY).	LBDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable LBDTC in ISO 8601 format.	N/A	N/A	A complete date is expected. The date of specimen collection may be determined from the date of visit (VISDAT) and, if so, a separate assessment date field is not required. The tabulation LBDTC variable contains either a date/time when a specimen is collected at a point in time or the start date/time, when a specimen is collected over time.
Findings	LB	Central Processing	N/A	8	LBTIM	Specimen Collection Time	The time of specimen collection, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the (start) time of the lab specimen collection?	Specimen Collection (Start) Time	Char	R/C	Record the (start) time of collection (as complete as possible).	LBDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable LBDTC in ISO 8601 format.	N/A	N/A	May be required when multiple assessments are done on 1 day or when the timing in relationship to study product is required for analysis or a specimen is collected over an extended time period.
Findings	LB	Central Processing	N/A	9	LBCAT	Category for Lab Test	A grouping of topic-variable values based on user-defined characteristics.	What was the name of the lab panel?	[Lab Panel Name]; NULL	Char	R/C	Record the lab test category, if not preprinted on the CRF.	LBCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included in the column heading. Laboratory tests have commonly recognized categories and subcategories that should be used whenever appropriate. LBCAT and or LBSCAT should be included if lab status (NOT DONE) is collected for each lab category/subcategory (e.g., HEMATOLOGY, CHEMISTRY, URINALYSIS).
Findings	LB	Central Processing	N/A	10	LBSCAT	Subcategory for Lab Test	A sub-division of the LBCAT values based on user-defined characteristics.	What was the name of the lab sub-panel?	[Lab Sub-Panel Name]; NULL	Char	R/C	Record the lab test subcategory, if not preprinted on the CRF.	LBSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology (e.g. electrolytes, liver function). This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer. Laboratory tests have commonly recognized categories and subcategories that should be used whenever appropriate. LBSCAT can only be used if there is an LBCAT, and it must be a subcategorization of LBCAT.
Findings	LB	Central Processing	N/A	11	LBTPT	Lab Planned Time Point Name	A text description of planned time point when measurements should be taken.	What was the planned time point of the lab?	[Planned Time Point Name]	Char	R/C	Record the planned time point labels for the lab test, if not	LBTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. Tabulation time-point anchors LBTPTREF (text description) and LBRFTDTC (date/time) may be	N/A	N/A	Planned time points are needed to differentiate multiple sequential assessments. It is recommended that time points should be preprinted on the

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Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/ CDASH Codelist Name	Implementation Notes
							as defined in the protocol.					preprinted on the CRF.		needed, as well as tabulation variables LBPTNUM, LBELTM.			CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Planned Time Point" can be included in the column heading.
Findings	LB	Central Processing	N/A	12	LBCOND	Lab Test Condition Met	Indication whether the testing conditions defined in the protocol were met (e.g., low-fat diet).	Were the protocol-defined testing conditions met?	Test Condition Met	Char	R/C	Record whether protocol defined testing conditions were met.	SUPPLB.QVAL	This does not map directly to a tabulation variable. This information could be submitted in a SUPPLB dataset as the value of SUPPLB.QVAL where SUPPLB.QNAM = "LBCOND" and SUPPLB.LABEL = "Test Condition Met".	(NY)	N/A	This information is collected when the laboratory test results may be affected by whether conditions for testing were properly met. The specific testing conditions required should be preprinted on the CRF. This may not be relevant for all tests.
Findings	LB	Central Processing	N/A	13	LBFAST	Lab Fasting Status	An indication that the subject has abstained from food/water for the specified amount of time.	Was the subject fasting?	Fasting	Char	R/C	Record whether the subject was fasting prior to the test being performed.	LBFAST	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	Results may be affected by whether the subject was fasting. This may not be relevant for all tests.
Findings	LB	Central Processing	N/A	14	LBREFID	Lab Specimen ID	An internal or external identifier (e.g., specimen identifier).	What was the (laboratory test) [reference identifier/accession number]?	(Laboratory) [Reference identifier/Accession Number]	Char	R/C	Record the specimen or accession number assigned.	LBREFID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	This can be used to confirm that the appropriate data record is present in the electronic transfer. May be included for linking back to specimens (e.g., Specimen ID).
Findings	LB	Central Processing with CS	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation before submission.
Findings	LB	Central Processing with CS	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	LB	Central Processing with CS	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	LB	Central Processing with CS	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed within the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.

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Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/ CDASH Codelist Name	Implementation Notes
Findings	LB	Central Processing with CS	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using DD-MON-YYYY format.	N/A	This field is not a tabulation variable. The date of a measurement, test, observation, or specimen collection can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable LBDTC in ISO 8601 format.	N/A	N/A	The date of the laboratory specimens were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the laboratory tests at that visit, or the collection date can be collected on the Laboratory CRF using the date (LBDAT) field.
Findings	LB	Central Processing with CS	N/A	6	LPERF	Lab Performed	An indication of whether a planned lab measurement, series of lab measurements, test, or observation was performed or specimens collected.	Was the sample collected?; Was the lab performed?	Lab Performed; Sample Collected	Char	HR	Indicate whether or not lab specimen was collected or measurement performed.	LBSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable LBSTAT. If the collection variable LPERF="N", the value of LBSTAT will be "NOT DONE". If LPERF="Y", LBSTAT should be null. A combination of tabulation variables (e.g., LBCAT and LBSCAT, LBPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable LBTESTCD would be populated as LBALL and an appropriate test name (LBTEST) provided.	(NY)	N/A	This may be implemented for an entire lab panel, or a specific lab test. This general prompt question is used as a data management tool to verify that missing results are confirmed missing.
Findings	LB	Central Processing with CS	N/A	7	LBDAT	Specimen Collection Date	The date of specimen collection, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the (start) date of the lab specimen collection	Specimen Collection (Start) Date	Char	R/C	Record the (start) date when the specimen collection was done using this format (DD-MON-YYYY).	LBDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable LBDTC in ISO 8601 format.	N/A	N/A	A complete date is expected. The date of specimen collection may be determined from the date of visit (VISDAT) and, if so, a separate assessment date field is not required. The tabulation LBDTC variable contains either a date/time when a specimen is collected at a point in time or the start date/time, when a specimen is collected over time.
Findings	LB	Central Processing with CS	N/A	8	LBTIM	Specimen Collection Time	The time of specimen collection, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the (start) time of the lab specimen collection?	Specimen Collection (Start) Time	Char	R/C	Record the (start) time of collection (as complete as possible).	LBDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable LBDTC in ISO 8601 format.	N/A	N/A	May be required when multiple assessments are done on 1 day or when the timing in relationship to study product is required for analysis or a specimen is collected over an extended time period.
Findings	LB	Central Processing with CS	N/A	9	LBCAT	Category for Lab Test	A grouping of topic-variable values based on user-defined characteristics.	What was the name of the lab panel?	[Lab Panel Name]: NULL	Char	R/C	Record the lab test category, if not preprinted on the CRF.	LBCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column heading. Laboratory tests have commonly recognized categories and subcategories that should be used whenever appropriate. LBCAT and or LBSCAT should be included if lab status (NOT DONE) is collected for each lab category (e.g., HEMATOLOGY, CHEMISTRY, URINALYSIS).

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Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/ CDASH Codelist Name	Implementation Notes
Findings	LB	Central Processing with CS	N/A	10	LBSCAT	Subcategory for Lab Test	A sub-division of the LBCAT values based on user-defined characteristics.	What was the name of the lab sub-panel?	[Lab Sub-Panel Name]; NULL	Char	R/C	Record the lab test subcategory, if not preprinted on the CRF.	LBSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology (e.g. electrolytes, liver function). This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer. Laboratory tests have commonly recognized categories and subcategories that should be used whenever appropriate. LBSCAT can only be used if there is an LBCAT, and it must be a subcategorization of LBCAT.
Findings	LB	Central Processing with CS	N/A	11	LBTPT	Lab Planned Time Point Name	A text description of planned time point when measurements should be taken, as defined in the protocol.	What was the planned time point of the lab?	[Planned Time Point Name]	Char	R/C	Record the planned time-point labels for the lab test, if not preprinted on the CRF.	LBTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. Tabulation time-point anchors LBTPTREF (text description) and LBRFTDTC (date/time) may be needed, as well as tabulation variables LBTPTNUM, LBELTM.	N/A	N/A	Planned time points are needed to differentiate multiple sequential assessments. It is recommended that time points should be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Planned Time Point" can be included in the column heading.
Findings	LB	Central Processing with CS	N/A	12	LBCOND	Lab Test Condition Met	Indication of whether the testing conditions defined in the protocol were met (e.g., low-fat diet).	Were the protocol-defined testing conditions met?	Test Condition Met	Char	O	Record whether protocol-defined testing conditions were met.	SUPPLB.QVAL	This does not map directly to a tabulation variable. This information could be submitted in a SUPPLB dataset as the value of SUPPLB.QVAL where SUPPLB.QNAM = "LBCOND" and SUPPLB.LABEL = "Test Condition Met".	(NY)	N/A	This information is collected when the laboratory test results may be affected by whether conditions for testing were properly met. The specific testing conditions required should be preprinted on the CRF (e.g., "Did subject meet diet requirements?"). This may not be relevant for all tests.
Findings	LB	Central Processing with CS	N/A	13	LBFAST	Lab Fasting Status	An indication that the subject has abstained from food/water for the specified amount of time.	Was the subject fasting?	Fasting	Char	R/C	Record whether the subject was fasting prior to the test being performed.	LBFAST	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	Results may be affected by whether the subject was fasting. This may not be relevant for all tests.
Findings	LB	Central Processing with CS	N/A	14	LBTEST	Lab Test or Examination Name	Descriptive name of the lab test or examination used to obtain the measurement or finding. Any test normally performed by a clinical laboratory is considered a lab test.	What was the lab test name?	[Laboratory Test Name]	Char	HR	Record the name of the lab measurement or finding, if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.	LBTEST; LBTESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable LBTESTCD may be determined from the value collected in LBTEST. The tabulation variables LBTESTCD and LBTEST are required in the tabulation datasets. Use appropriate CDISC Controlled Terminology for the test and test code.	(LBTEST)	N/A	Required to identify which test the result is for. It is recommended that the test names be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Test" can be included as the column heading.
Findings	LB	Central Processing with CS	N/A	15	LBORRES	Lab Result or Finding in Original Units	Result of the measurement or finding as originally received or collected.	What was the result of the lab test?	(Result)	Char	HR	Record the laboratory test result.	LBORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Optional if already provided from central lab.
Findings	LB	Central Processing with CS	N/A	16	LBORRESU	Lab Original Units	The unit of the result as originally received or collected.	What was the unit of the lab result?	Unit	Char	O	Record or select the original unit in which these data were collected.	LBORRESU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	N/A	Optional if already provided from central lab or an applicant stores units separately.

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Findings	LB	Central Processing with CS	N/A	17	LBCLSIG	Lab Clinical Significance	An indication whether lab test results were clinically significant.	Was this result clinically significant?	Clinically Significant	Char	HR	Record whether laboratory test results were clinically significant.	SUPPLB.QVAL	This does not map directly to a tabulation variable. This information could be submitted in a SUPPLB dataset as the value of SUPPLB.QVAL where SUPPLB.QNAM = "LBCLSIG" and SUPPLB.QLABEL = "Clinically Significant".	(NY)	N/A	Key data collected in this scenario.
Findings	LB	Central Processing with CS	N/A	18	LBREFID	Lab Specimen ID	An internal or external identifier (e.g., specimen identifier).	What was the (laboratory test) [reference identifier/Accession Number]	(Laboratory test) [Reference identifier/Accession Number]	Char	R/C	Record the specimen or accession number assigned.	LBREFID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	This can be used to confirm that the appropriate data record is present in the electronic transfer. May be included for linking back to specimens (e.g., Specimen ID).
Findings	LB	Central Processing with CS	N/A	19	LBMETHOD	Lab Method of Test or Examination	Method of the test or examination.	What was the method used for the lab test or examination?	Method of Test or Examination	Char	O	Record the method of test or examination.	LBMETHOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	(METHOD)	N/A	This information may be collected when more than 1 method is possible, and collecting the method used is necessary.
Findings	LB	Local Processing	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included into the database or populated during tabulation dataset creation.
Findings	LB	Local Processing	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	LB	Local Processing	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	LB	Local Processing	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed within the EDC for any visit-based data collection, most often Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.
Findings	LB	Local Processing	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement, test, observation, or specimen collection can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable LBDTC in ISO 8601 format.	N/A	N/A	The date of the laboratory specimens were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the laboratory tests at that visit, or the collection date can be collected on the Laboratory CRF using the date (LBDAT) field.

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Findings	LB	Local Processing	N/A	6	LPERF	Lab Performed	An indication of whether a planned lab measurement, series of lab measurements, test, or observation was performed or specimens collected.	Was the sample collected?; Was the lab performed?	Sample Collected; Lab Performed	Char	HR	Indicate whether or not lab specimen was collected or measurement performed.	LBSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable LBSTAT. If the collection variable LPERF = "N", the value of LBSTAT will be "NOT DONE". If LPERF = "", LBSTAT should be null. A combination of tabulation variables (e.g., LBCAT and LBSCAT, LBPTP) is used to indicate that multiple tests were not done. In this situation, the tabulation variable LBTESTCD would be populated as LBALL and an appropriate test name (LBTEST) provided.	(NY)	N/A	This may be implemented for an entire panel, or on a specific test basis. General prompt question to be used as a data management tool to verify that missing results are confirmed missing.
Findings	LB	Local Processing	N/A	7	LBDAT	Specimen Collection Date	The date of specimen collection, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the (start) date of the lab specimen collection?	Specimen Collection (Start) Date	Char	R/C	Record the (start) date of specimen collection using this format (DD-MON-YYYY).	LBDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable LBDTC in ISO 8601 format.	N/A	N/A	A complete date is expected. The date of collection may be determined from the date of visit (VISDAT) and, if so, a separate assessment date field is not required. The tabulation LBDTC variable contains either a date/time when a specimen is collected at a point in time or the start date/time, when a specimen is collected over time.
Findings	LB	Local Processing	N/A	8	LBTIM	Specimen Collection Time	The time of specimen collection, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the (start) time of the lab specimen collection?	Specimen Collection (Start) Time	Char	R/C	Record the (start) time of collection (as complete as possible)	LBDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable LBDTC in ISO 8601 format.	N/A	N/A	May be required when multiple assessments are done on 1 day or when the timing in relationship to study product is required for analysis or a specimen is collected over an extended time period.
Findings	LB	Local Processing	N/A	9	LBCAT	Category for Lab Test	A grouping of topic-variable values based on user-defined characteristics.	What was the name of the lab panel?	[Lab Panel Name]; NULL	Char	R/C	Record the lab test category, if not preprinted on the CRF.	LBCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column heading. Laboratory tests have commonly recognized categories and subcategories that should be used whenever appropriate. LBCAT and LBSCAT should be included if lab status (NOT DONE) is collected for each lab category (e.g., HEMATOLOGY, CHEMISTRY, URINALYSIS).
Findings	LB	Local Processing	N/A	10	LBSCAT	Subcategory for Lab Test	A sub-division of the LBCAT values based on user defined characteristics.	What was the name of the lab sub-panel?	[Lab Sub-Panel Name]; NULL	Char	R/C	Record the lab test subcategory, if not preprinted on the CRF.	LBSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be applicant-defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included

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																	as the column heading. Laboratory tests have commonly recognized categories and subcategories that should be used whenever appropriate. LBSCAT can only be used if there is an LBCAT, and it must be a subcategorization of LBCAT.
Findings	LB	Local Processing	N/A	11	LBPT	Lab Planned Time Point Name	A text description of planned time point when measurements should be taken as defined in the protocol.	What was the planned time point of the lab?	[Planned Time Point Name]	Char	R/C	Record the planned time-point labels for the lab test, if not preprinted on the CRF.	LBPT	Maps directly to the tabulation variable listed in the Tabulation Target column. Tabulation time-point anchors LBPTTREF (text description) and LBRFTDTC (date/time) may be needed, as well as tabulation variables LBPTNUM, LBLTM.	N/A	N/A	Planned time points are needed to differentiate multiple sequential assessments. It is recommended that time points be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Planned Time Point" can be included as the column heading.
Findings	LB	Local Processing	N/A	12	LBFAST	Lab Fasting Status	An indication that the subject has abstained from food/water for the specified amount of time.	Was the subject fasting?	Fasting	Char	R/C	Record whether the subject was fasting prior to the test being performed.	LBFAST	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	Results may be affected by whether the subject was fasting. This may not be relevant for all tests.
Findings	LB	Local Processing	N/A	13	LBCOND	Lab Test Condition Met	Indication of whether the testing conditions defined in the protocol were met	Were the protocol-defined testing conditions met?	Test Condition Met	Char	R/C	Record whether protocol-defined testing conditions were met.	SUPPLB.QVAL	This does not map directly to a tabulation variable. This information could be submitted in a SUPPLB dataset as the value of SUPPLB.QVAL where SUPPLB.QNAME = "LBCOND" and SUPPLB.LABEL = "Test Condition Met".	(NY)	N/A	This information is collected when the laboratory test results may be affected by whether conditions for testing were properly met. The specific testing conditions required should be preprinted on the CRF. This may not be relevant for all tests.
Findings	LB	Local Processing	N/A	14	LBSPCCND	Lab Specimen Condition	Description of the condition of the specimen.	What was the condition of the specimen?	Specimen Condition	Char	O	Record the condition of specimen.	LBSPCCND	Maps directly to the tabulation variable listed in the Tabulation Target column.	(SPECCOND)	N/A	May be collected using free or standardized text. Results may be affected by whether conditions for specimen were properly met. When local processing is used, applicants may not routinely collect specimen condition.
Findings	LB	Local Processing	N/A	15	LBTEST	Lab Test or Examination Name	Descriptive name of the lab test or examination used to obtain the measurement or finding. Any test normally performed by a clinical laboratory is considered a lab test.	What was the lab test name?	[Laboratory Test Name]	Char	HR	Record the name of the lab measurement or finding, if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.	LBTEST; LBTESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable LBTESTCD may be determined from the value collected in LBTEST. The tabulation variables LBTESTCD and LBTEST are required in the tabulation datasets. Use appropriate CDISC Controlled Terminology for the test and test code.	(LBTEST)	N/A	Required to identify which test the result is for. It is recommended that the test names be preprinted on the CRF rather than collected in a free-text field that requires the site to enter text. If the form is laid out as a grid, then words such as "Test" can be included as the column heading.
Findings	LB	Local Processing	N/A	16	LBORRES	Lab Result or Finding in Original Units	Result of the measurement or finding as originally received or collected.	What was the result of the lab test?	(Result)	Char	HR	Record the laboratory test result.	LBORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Both quantitative results and interpretive findings or summaries may be recorded here.
Findings	LB	Local Processing	N/A	17	LBMETHOD	Lab Method of Test or Examination	Method of the test or examination.	What was the method used for the lab test or examination?	Method of [Test/Examination]	Char	O	Record the method of test or examination.	LBMETHOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	(METHOD)	N/A	This information may be collected when more than 1 method is possible, and collecting the method used is necessary.

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Findings	LB	Local Processing	N/A	18	LBORRESU	Lab Original Units	The unit of the result as originally received or collected.	What was the unit of the lab result?	Unit	Char	R/C	Record or select the original unit in which these data were collected, if not preprinted on CRF.	LBORRESU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	N/A	Should be preprinted on the CRF with the associated test when possible, rather than collected in a free-text field. Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color).
Findings	LB	Local Processing	N/A	19	LBCRESU	Lab Collected Non-Standard Unit	The unit of the result as originally received if it were collected as a non-standard unit.	What was the unit of the lab result?	Unit	Char	O	Record or select the original unit in which these data were collected, if not preprinted on CRF.	SUPPLB.QVAL	This does not map directly to a tabulation variable. The collected, nonstandard unit(s) may be submitted in a supplemental qualifier dataset.	N/A	N/A	The collected, nonstandard unit(s) should be reported as an equivalent standard unit in LBORRESU.
Findings	LB	Local Processing	N/A	20	LBTOXGR	Lab Standard Toxicity Grade	The toxicity grade, using a standard toxicity scale (e.g., NCI CTCAE).	What is the toxicity grade?	Toxicity Grade	Char	O	Record the toxicity grade.	LBTOXGR	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This is commonly used in oncology studies, but applicants may not collect these toxicity grades on CRFs. Terminology codelists (TOXGRV3, TOXGRV4) are available for use.
Findings	LB	Local Processing	N/A	21	LBTOX	Lab Toxicity	A description of toxicity quantified by LBTOXGR (e.g., NCI CTCAE Short Name).	What is the description of the toxicity?	Toxicity	Char	O	Record the description of the toxicity.	LBTOX	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This would typically be the text description quantified by LBTOXGR (e.g., HYPERCALCEMIA, HYPOCALCEMIA)
Findings	LB	Local Processing	N/A	22	LBORNRL0	Lab Ref Range Lower Limit in Orig Unit	The lower end of normal range or reference range for continuous results stored in LBORRES.	What was the lower limit of the reference range for this lab test?	Normal Range Lower Limit	Char	R/C	Record the lower limit of the reference range of the lab test.	LBORNRL0	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	LBORNRL0 and LBORNRLH should be populated only for continuous results; LBSTNRC should be populated only for non-continuous results. These data may be obtained from the lab or the electronic equipment. These data could be determined from a site or lab specific set of normal ranges stored in a look-up table.
Findings	LB	Local Processing	N/A	23	LBORNRLH	Lab Ref Range Upper Limit in Orig Unit	The upper end of normal range or reference range for continuous results stored in LBORRES.	What was the high limit of the reference range for this lab test?	Normal Range Upper Limit	Char	R/C	Record the upper limit of the reference range of the lab test.	LBORNRLH	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	LBORNRL0 and LBORNRLH should be populated only for continuous results; LBSTNRC should be populated only for non-continuous results. These data may be obtained from the lab or the electronic equipment. These data could be determined from a site or lab specific set of normal ranges stored in a look-up table.
Findings	LB	Local Processing	N/A	24	LBNRIND	Lab Reference Range Indicator	An indication or description of how the value compares to the normal range or reference range.	How [did/do] the reported values compare within the [reference/normal/expected] range?	Comparison to [Reference/Expected/Normal] Range	Char	R/C	Record where the lab result fell with respect to the reference range (e.g., HIGH, LOW, ABNORMAL).	LBNRIND	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NRIND)	N/A	Reference ranges may be defined by LBORNRL0 and LBORNRLH or other objective criteria. Typically for local processing, "Reference Range Indicator" may be derived or determined programmatically and is not collected on the CRF. Should not be used to indicate clinical significance.
Findings	LB	Local Processing	N/A	25	LBCLSIG	Lab Clinical Significance	An indication whether lab test results were clinically significant.	Was this result clinically significant?	Clinically Significant	Char	O	Record whether lab results were clinically significant.	SUPPLB.QVAL	This does not map directly to a tabulation variable. This information could be submitted in a SUPPLB dataset as the value of SUPPLB.QVAL where SUPPLB.QNAME= "LBCLSIG" and SUPPLB.QLABEL= "Clinically Significant".	(NY)	N/A	May be included if required by the protocol.

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Findings	LB	Local Processing	N/A	26	LBNAM	Vendor Name	The name or identifier of the vendor (e.g., laboratory) that provided the test results.	What was the name of the laboratory used?	Laboratory Name	Char	R/C	Record the laboratory name.	LBNAM	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Recommended to collect on the CRF if lab name was not collected at the site/study level or if multiple labs are used by a site.

Assumptions

1. The lab parameters that should be collected are not specified by the TIG, as this is a medical and scientific decision that is based on the needs of the protocol and regulatory requirements.
2. Applicants should decide which scenario is appropriate for each protocol.
3. As required or defined by the study protocol, clinically significant results may need to be reported on the Medical History or Adverse Event CRF.
4. As required or defined by the study protocol, changes that are worsening may need to be reported on the AE CRF.
5. This is a specimen-based domain. LBDTC is the date the specimen was collected.
6. LOINC code should not be applied to local lab data by the applicant. LOINC codes are optional and are intended to come directly from the central laboratory.

2.7.6.9 CDASH Medical History (MH)

Description

Medical History (MH) is an Events domain used for data that includes the subject's prior medical history at the start of the study. The TIG collection metadata contain the most common general medical history data collection fields. In cases where more indication-specific medical history is required by the protocol, applicants should add fields as needed from the CDASH Model.

Specification

Metadata Specification

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Events	MH	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included into the database or populated during tabulation dataset creation.
Events	MH	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.

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Events	MH	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.
Events	MH	N/A	N/A	4	MHYN	Any Medical History Event	An indication of whether there was any medical history to report.	Were any medical conditions or events reported? Has the subject had any medical conditions or events?	Any Medical History	Char	O	Indicate if the subject experienced any medical conditions or events. If Yes, include the appropriate details where indicated on the CRF.	N/A	Does not map to a tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that all other fields on the CRF were deliberately left blank.
Events	MH	N/A	N/A	5	MHCAT	Category for Medical History	A grouping of topic-variable values based on user-defined characteristics.	What was the category of the medical history?	[Medical History Category]; NULL	Char	R/C	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	MHCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology (e.g., CARDIAC, GENERAL). This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column header. This would be used when specific medical history is captured, in addition to the general medical history.
Events	MH	N/A	N/A	6	MHSCAT	Subcategory for Medical History	A sub-division of the MHCAT values based on user-defined characteristics.	What was the subcategory of the medical history?	[Medical History Subcategory]; NULL	Char	O	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	MHSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer. Typically would be used when specific medical history (e.g., disease diagnosis) is captured, in addition to the general medical history. MHSCAT can only be used if there is an MHCAT, and it must be a subcategorization of MHCAT.
Events	MH	N/A	N/A	7	MHDAT	Medical History Collection Date	The date on which the medical history was collected, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date the medical history was collected?	Collection Date	Char	O	Record the date on which the medical history was collected using this format (DD-MON-YYYY).	MHDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable MHDTC in ISO 8601 format.	N/A	N/A	This should be a complete date. The date of collection may be determined from a collected visit date.
Events	MH	N/A	N/A	8	MHSPID	MH Applicant-Defined Identifier	A applicant-defined identifier. This is typically used for preprinted or auto-generated numbers	[Applicant-defined question]	[Applicant defined]	Char	O	If collected on the CRF, applicant may insert instructions to ensure each record	MHSPID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	Because SPID is a applicant-defined identifier, conformance to Question Text or Item Prompt is not applicable. Typically used as

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							on the CRF, or any other type of identifier that does not already have a defined identifier field.					has a unique identifier.					an identifier in a data query to communicate clearly to the site the specific record in question or to reconcile concomitant medications and/or procedure records with MH. May be used to record preprinted number (e.g. line number, record number) on the CRF. This field may be populated by the applicant's data collection system. If CMMHNO or PRMHNO is used, this is the identifier to which CMMHNO or PRMHNO refers.
Events	MH	N/A	N/A	9	MHEVDTYP	Medical History Event Date Type	Specifies the aspect of the medical condition or event by which MHSTDTC and/or MHENDTC is defined.	What was the medical history event date type?	Medical History Event Date Type	Char	O	The instructions depend upon the format of the CRF. Applicants may print these values on the CRF or use them as defaulted or hidden text.	MHEVDTYP	Maps directly to the tabulation variable listed in the Tabulation Target column.	(MHEDTTYP)	N/A	The type of start/ and or end date (e.g., DIAGNOSIS, SYMPTOMS, RELAPSE, INFECTION). It is not related to the trial's condition. This date type cannot be a PRIMARY DIAGNOSIS, SECONDARY DIAGNOSIS because these terms do not define the date type.
Events	MH	N/A	N/A	10	MHTERM	Reported Term for the Medical History	The reported or prespecified name of the medical condition or event.	What is the medical condition or event term?	Medical History Term	Char	HR	Record all relevant medical conditions or events, as defined in the protocol. Record only 1 medical condition or event per line. Ensure that the medical conditions or events listed on the Medical History page do not meet any of the exclusion criteria.	MHTERM	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicants should collect all relevant medical conditions or events, as defined in the protocol. It is a best practice for Applicants to collect all relevant history of surgeries or procedures using the associated diagnosis in the MH domain, while reporting relevant surgeries and procedures in the tabulation PR domain. Applicants should provide instructions on how surgeries and procedures will be handled based on the protocol requirements. Information on specified surgeries or procedures should be collected in the PR domain.
Events	MH	N/A	N/A	11	MHOCCUR	Medical History Occurrence	An indication of whether a prespecified medical condition/event or a group of medical conditions/events occurred when information about the occurrence of a specific event is solicited.	Did the subject have [prespecified medical condition/event/group of medical conditions]; Is the [prespecified medical occurring]?	[Medical condition/Event]	Char	O	Indicate if [specific medical condition/event] has occurred/is occurring by checking Yes or No.	MHOCCUR	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	MHOCCUR is used to report the occurrence of specified medical conditions or events. MHOCCUR is not used if the medical conditions or events are collected on the CRF in a manner that requires spontaneously free-text response. The site should be able to indicate that the question was not asked or answered.
Events	MH	N/A	N/A	12	MHPRESP	Medical History Event Prespecified	An indication that a specific event, or group of events, are prespecified on a CRF.	N/A	N/A	Char	O	N/A	MHPRESP	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	A hidden field on a CRF defaulted to "Y", or added during the tabulation dataset creation when the medical condition or event is prespecified. Null for spontaneously reported events. If a study collects both prespecified medical

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																	history and free-text events, the value of MHPRESP should be "Y" for all prespecified events and null for medical conditions or events reported as free text. MHPRESP is a permissible and may be omitted from the tabulation dataset if all events were collected as free text.
Events	MH	N/A	N/A	13	MHPRIOR	Prior Medical History Event	An indication of whether the event occurred prior to study start.	Did the medical condition or event start prior to [MHSTTPT]?; Did the medical condition or event start prior to study start?	Prior to [MHSTTPT]; Prior to Study	Char	O	Check if the medical condition or event started [before the study].	MHSTRTPT; MHSTRF	This does not map directly to a tabulation variable. May be used to populate a value into a tabulation relative timing variable such as MHSTRF or MHSTRTPT. When populating MHSTRF, or MHSTRTPT, if the value of the collection field MHPRIOR is "Y" a value from the CDISC CT (STENRF) may be used. When MHPRIOR refers to the Study Reference Period (defined in DM.RFSTDTC to DM.RFENDTC) the tabulation variable MHSTRF should be populated. When MHPRIOR is compared to another time point, the tabulation variables MHSTRTPT and MHSTTPT should be used. Note: MHSTRTPT must refer to the timepoint anchor described in MHSTTPT.	(NY)	N/A	Applicants may collect this information rather than start dates.
Events	MH	N/A	N/A	14	MHONGO	Ongoing Medical History Event	Indication the medical condition or event is ongoing (as of when no end date is provided.	Is the medical condition or event ongoing (as of the [study-specific timepoint or period])?	Ongoing (as of the [study-specific timepoint or period])	Char	O	Record the medical condition or event as ongoing ("") if it has not ended at the time of data collection. If the medical condition or event is ongoing, the end date should be left blank.	MHENRF; MHENRPT	This does not map directly to a tabulation variable. May be used to populate a value into a tabulation relative timing variable such as MHENRF or MHENRPT. When populating MHENRF, if the value of MHONGO is "Y", the value of "DURING", "AFTER" or "DURING/AFTER" may be used. When populating MHENRPT, if the value of MHONGO is "Y", the value of "ONGOING" may be used. When MHONGO refers to the Study Reference Period (defined in DM.RFSTDTC to DM.RFENDTC) the tabulation variable MHENRF should be populated. When MHONGO is compared to another time point, the tabulation variables MHENRPT and MHENTPT should be used. Note: MHENRPT must refer to a timepoint anchor described in MHENTPT.	(NY)	N/A	Completed to indicate that the condition has not resolved at the time of data collection. It is expected that every reported condition has either an end date or the Ongoing field is populated, but not both.
Events	MH	N/A	N/A	15	MHCTRL	MH Disease or Symptom Under Control	Indication of whether the medical condition or event is under control at the time of data collection.	Is the medical condition or event under control?	Medical Condition Under Control	Char	O	Select the most appropriate response.	SUPPMH.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPMH dataset as the value of SUPPMH.QVAL where SUPPMH.QNAME = "MHCTRL" and SUPPMH.LABEL = "Medical Condition Under Control".	(NY)	N/A	MHCTRL is not defined in the tabulation MH domain. If collected, it should be represented in the SUPPMH dataset. If MHCTRL is collected, the applicant must provide information on the relative timeframe. Generally, MHDAT is collected or determined using the visit date of the collection to indicate this is the subject's status at the time of data collection.

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Events	MH	N/A	N/A	16	MHSTDAT	Medical History Event Start Date	The start date of medical history event or condition, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What [is/was] the [medical event or condition/category of the event] start date?	Start Date	Char	O	Record the start date of the medical event or condition using this format (DD-MON-YYYY).	MHSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable MHSTDTC in ISO 8601 format.	N/A	N/A	The applicant may choose to capture a complete date or any variation thereof (e.g., month and year, year).
Events	MH	N/A	N/A	17	MHENDAT	Medical History Event End Date	The end date of medical history event or condition, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What[is/was] the[medical event or condition/category of the event] end date?	End Date	Char	O	Record the end date of the medical event or condition using this format (DD-MON-YYYY).	MHENDTA	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable MHENDTC in ISO 8601 format.	N/A	N/A	The applicant may choose to capture a complete date or any variation thereof (e.g., month and year, year).
Events	MH	N/A	N/A	18	MHLOC	Medical History Event Location	A description of the anatomical location relevant for the medical condition or event.	What was the anatomical location of the medical condition or event?	Anatomical Location	Char	O	Indicate the anatomical location of the medical event or condition.	MHLOC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LOC)	N/A	Collected or preprinted when the applicant needs to identify the specific anatomical location (e.g., ARM for skin rash). Could be a defaulted or hidden field on the CRF for prespecified [MHTERM/Event Topic]. Applicants may collect the data using a subset list of controlled terminology on the CRF. LAT, DIR, PORTOT are used to further describe the anatomical location.
Events	MH	N/A	N/A	19	MHLAT	Medical History Event Laterality	Qualifier for anatomical location, further detailing the side of the body relevant for the event.	What was the side of the anatomical location of the medical condition or event?	Side	Char	O	Record the side of the anatomical location of the medical event.	MHLAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LAT)	N/A	May be preprinted or collected when the applicant needs to identify the specific side of the anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Events	MH	N/A	N/A	20	MHDIR	Medical History Directionality	Qualifier further detailing the position of the anatomical location, relative to the center of the body, organ, or specimen.	What was the directionality of the anatomical location of the medical condition or event?	Directionality	Char	O	Record the directionality of the anatomical location of the medical event.	MHDIR	Maps directly to the tabulation variable listed in the Tabulation Target column.	(DIR)	N/A	May be preprinted or collected when the applicant needs to identify the directionality of the anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Events	MH	N/A	N/A	21	MHPORTOT	MH Event Location Portion or Totality	Qualifier for anatomical location, further detailing the distribution (i.e., arrangement of, apportioning of).	What was the portion or totality of the anatomical location of the medical condition or event?	Portion or Totality	Char	O	Indicate the portion or totality anatomical location of the medical event.	MHPORTOT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(PORTOT)	N/A	Collected when the applicant needs to identify the specific portionality for the anatomical locations. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Events	MH	N/A	N/A	22	MHMODIFY	MH Modified Reported Term	If the value for MHTERM is modified to facilitate coding, then MHMODIFY will contain the modified text.	N/A	N/A	Char	O	N/A	MHMODIFY	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This is not a data collection field that would appear on the CRF. Applicants will populate this through the coding process.
Events	MH	N/A	N/A	23	MHDECOD	MH Dictionary-Derived Term	The dictionary text description of MHTERM or the modified topic variable (MH MODIFY), if applicable.	N/A	N/A	Char	O	N/A	MHDECOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This is typically not a data collection field that will appear on the CRF. Applicants will populate this through the coding process. Equivalent to the Preferred Term (PT in MedDRA).
Events	MH	N/A	N/A	24	MHLLT	Medical History Event	The dictionary-derived text	N/A	N/A	Char	O	N/A	MHLLT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF.

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						Lowest Level Term	description of the lowest level term.										Applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	MH	N/A	N/A	25	MHLLTCD	MH Event Lowest Level Term Code	The dictionary-derived code for the lowest level term.	N/A	N/A	Num	O	N/A	MHLLTCD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	MH	N/A	N/A	26	MHPTCD	MH Event Preferred Term Code	The dictionary-derived code for the preferred term.	N/A	N/A	Num	O	N/A	MHPTCD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	MH	N/A	N/A	27	MHHLT	Medical History Event High Level Term	The dictionary-derived text description of the high level term for the primary system organ class (SOC).	N/A	N/A	Char	O	N/A	MHHLT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	MH	N/A	N/A	28	MHHLTCD	MH Event High Level Term Code	The dictionary-derived code for the high level term for the primary system organ class (SOC).	N/A	N/A	Num	O	N/A	MHHLTCD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	MH	N/A	N/A	29	MHHLGT	MH Event High Level Group Term	The dictionary-derived text description of the high level group term for the primary system organ class (SOC).	N/A	N/A	Char	O	N/A	MHHLGT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	MH	N/A	N/A	30	MHHLGTCD	MH Event High Level Group Term Code	The dictionary-derived code for the high level group term for the primary system organ class (SOC).	N/A	N/A	Num	O	N/A	MHHLGTCD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. This is applicable to items using MedDRA coding.
Events	MH	N/A	N/A	31	MHSOC	MH Event Primary System Organ Class	The dictionary-derived text description of the primary system organ class (SOC).	N/A	N/A	Char	O	N/A	MHSOC	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. This is applicable to items using MedDRA coding. Will be the same as MH BODSYS if the primary SOC was used for analysis.
Events	MH	N/A	N/A	32	MHSOCCD	MH Event Primary System Organ Class Code	The dictionary-derived code for the primary system organ class (SOC).	N/A	N/A	Num	O	N/A	MHSOCCD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. This is applicable to items using MedDRA coding. Will be the same as MHBDSYCD if the primary SOC was used for analysis.

Assumptions

1. Medical History Collection Period
 - a. Applicants should define the appropriate collection period for medical history in the protocol. The evaluation interval may be provided in the tabulation variable MHEVLINT or MHEVINTX. These intervals are populated by the applicant in the tabulation MH dataset. These intervals may be printed on the CRF as instruction text.
2. Medical History Coding
 - a. Applicants who code medical history should use appropriate dictionary variables for the coding.
 - b. Coding variables are not a data collection field that will appear on the CRF itself; applicants will populate this through the coding process. When MedDRA is used as the coding dictionary, the MedDRA coding variables are included in the tabulation dataset.
 - c. If coding using MedDRA, it is recommended that coding be done during the execution phase of a study rather than after it is completed, as this facilitates efficient resolution of any coding queries.
 - d. For uncoded medical history, an applicant-defined categorization of medical history events is recommended. One approach is to use the MHCAT variable.
3. Date of Collection (DAT)
 - a. This is the date that the data were recorded, and not the date that the condition started or the event occurred. The date of collection can be derived from the date of the visit.
4. Relative Timing Variables
 - a. The date of data collection in conjunction with a collected time point anchor date and the MHONGO Collection fields would determine how the tabulation relative timing variables would be populated.
 - b. The MHONGO field does not map directly to a tabulation variable, but it may be used to derive a value into a tabulation-based relative timing variable (e.g., MHENRF, MHENRTPT). When populating MHENRF, if the value of MHONGO is "Y", the values of "DURING", "AFTER", or "DURING/AFTER" may be derived. When populating MHENRTPT, if the value of MHONGO is "Y", the value of "ONGOING" may be derived. MHENRTPT must refer to a time-point anchor described in MHENTPT.
 - c. MHONGO is a special-use case of "Yes/No", where the question is usually presented as a single possible response of "Yes" when there is no applicable end date at time of collection. In this case, if the box is checked and the end date is blank, MHONGO is "Yes". If the box is not checked and an end date is present, MHONGO is "No".
 - d. MHPRIOR can be added to this domain from the CDASH Model and used when the applicant elects not to collect start dates (even partial dates) on the MH CRF. The applicant would derive a value into a tabulation relative Timing variable such as MHSTRF or MHSTRTPT. When populating MHSTRF, if the value of MHPRIOR is "Y", the value of "BEFORE" may be derived. When populating MHSTRTPT, if the value of MHPRIOR is "Y", the value of "BEFORE" may be derived. Note: MHSTRTPT must refer to a "time point anchor" as described in MHSTTPT.
5. Start and End Dates
 - a. Partial dates are commonly collected in MH where the subject may not remember the complete date of when a medical history condition started or ended. The applicant may choose to capture a complete date or any variation thereof (e.g., month and year or year).
6. Medical History Event Type
 - a. Medical History Event Type (MHEVDTYP) is used to specify the aspect of the medical condition or event by which its start date is defined. This variable (MHEVDTYP) is only to be used in the MH domain. This variable is used when the CRF records "multiple" dates such as the date when the condition was diagnosed, when symptoms were first reported prior to diagnosis, when the subject had a relapse, or when the infection associated with the diagnosis was reported. Example values for MHEVDTYP include DIAGNOSIS, SYMPTOMS, RELAPSE, and INFECTION.

2.7.6.10 CDASH Pharmacokinetics Concentrations (PC)

Description

Pharmacokinetics Concentrations (PC) is a Findings domain used for the concentrations of analyte or metabolites in biological fluids (e.g. blood, urine, saliva, breast milk) or tissues as a function of time. The measuring of nicotine blood concentrations after a subject is exposed to a tobacco product is often performed. Information about sampling for pharmacokinetic (PK) concentration is collected on CRFs with the goal to reconcile or link sampling information (e.g., collection timing, specimen volumes) with PK concentration results provided by the laboratory. Tabulation PC records are compiled when joining CRF sampling information and PK concentration results. This is similar to scenario 1 in Section 2.7.6.8, [CDASH Laboratory Test Results \(LB\)](#).

The goals of the PC domain are:

- To standardize specimen collection details in the CRF for PK samples collected at fixed time points or over timed intervals
- To provide examples as to the collection of data that is closely related to PK sampling (e.g., subject's most recent exposure to product, exposure record considered to be the reference for timed PK samples)
- To document the data flow from the CRF to the tabulation PC dataset

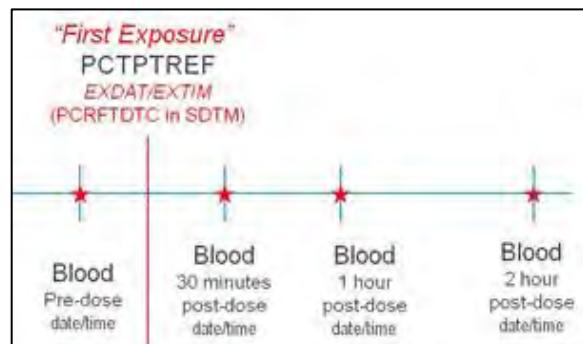
The CDASHIG PC domain defines fields for:

1. The date and time of PK sample collections for the scenarios listed below. Note that the sampling approach may depend on how the body metabolizes and clears the analyte.
 - a. Fixed defined time points (e.g., 4 HRS POSTDOSE)
 - b. Across a collection interval (e.g., 2-4 HRS POSTDOSE)
2. Specimen properties (e.g., pH, specimen volume)

Note that specimens collected to measure study product (usually nicotine) concentration at an instant in time are generally associated with specimen types such as plasma, serum, or whole blood. Specimens collected over a timed interval are generally associated with specimen types such as urine or feces.

In the case of fixed time points, the date (PCDAT) and time (PCTIM) of collection for each sample is recorded on the CRF. The protocol defines the time points at which samples are to be collected in relation to an intervention such as exposure to product. This "reference" is depicted in Figure 1 by the longer vertical line and would correspond to a date and time in the Exposure as Collected (EC) or Exposure (EX) domain.

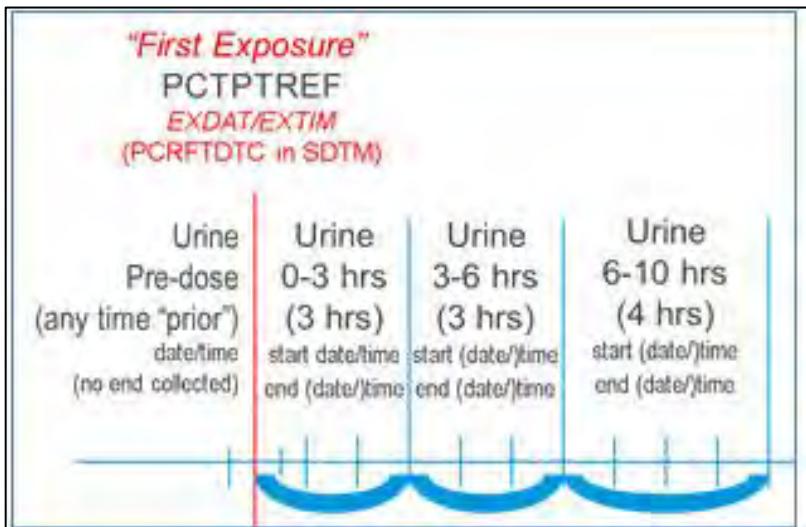
Figure 1. PK Sample Collection at Fixed Timepoints



PK Sample Collection Over a Time Interval

Similarly, for PK specimens collected to measure excretion over a time interval, PCDAT and PCTIM capture the start date and time of the interval collection. End date (PCENDAT) and end time (PCENTIM) capture the end of the timed interval collection. As with fixed-time point collections, these timed intervals are performed in relation to an intervention such as exposure to product. This "reference" is depicted in Figure 2 by the longer vertical line and would correspond to a date and time in the EC or EX domain.

Figure 2. PK Sample Collection over a Time Interval



Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all collection domains. However, this collection

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Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	variable is populated only in the tabulation DM domain.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed within the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement, test, observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable PCDTC in ISO 8601 format.	N/A	N/A	The date the PK samples were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the PK samples at that visit, or the collection date can be collected on the PK CRF using the date (PCDAT) field.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	6	PCPERF	PK Sampling Performed	An indication of whether PK samples were collected.	Were PK samples collected?	Collected	Char	O	Check "No" if none of the samples were collected.	PCSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable PCSTAT. If PCPERF="N", the value of PCSTAT will be "NOT DONE". If PCPERF="Y", PCSTAT should be null. PCTEST and PCTESTCD must reflect what tests were not done. A combination of tabulation variables (e.g., PCCAT and PCSAT, PCTPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable PCTESTCD would be populated as PCALL and an appropriate test name (PCTEST) provided.	(NY)	N/A	General prompt question to be used as a data management tool to verify that missing results are confirmed missing. This may be implemented at form level or sample level. These may be all samples of a particular type or all samples taken for some purpose and may need to be identified by the organization of the data on the form. Each sample collected could result in 1 or more tests performed, so there can be a one-to-one or one-to-many relationship between samples and tests/results.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	7	PCSTAT	PK Sampling Completion Status	This variable used to indicate that data are not available, by having the site record the value as "Not Done".	Record "Not Done" if the PK sample was not collected.	Not Done	Char	HR	Indicate if the specimen was not done.	PCSTAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(ND)	N/A	A Not Done checkbox, which indicates the test was "NOT DONE". Typically, there would be 1 checkbox for each measurement. This field can be useful on individual sample collections to confirm that a blank result field is meant to be blank.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	8	PCREASND	PK Sampling Reason Not Done	An explanation for why the data are not available.	What was the reason the PK sample was not collected?	Reason Not Collected	Char	O	Provide the reason why a PK sample was not collected.	PCREASND	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The reason the data are not available may be chosen from an applicant-defined list (e.g., broken equipment, subject refused) or entered as free text. When PCREASND is used, the tabulation variable PCSTAT should also be populated in the tabulation dataset.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	9	PCDAT	PK Sample Collection Date	The date of PK sample collection or the start date of PK sample collection over a period of time (protocol-defined time-point range), represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date of the PK sample collection?	Collection Date	Char	HR	Record the date when PK sample collection occurred using this format (DD-MON-YYYY). If left blank, "PCDATFL" for this specimen must be populated (or "PCPERF" must be flagged to indicate	PCDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable PCDTC in ISO 8601 format.	N/A	N/A	A complete date is expected. The date of collection may be determined from the date of visit (VISDAT); if so, a separate assessment date field is not required. The tabulation PCDTC variable contains either a date/time when a specimen is collected at a point in time or the start date/time, when a specimen is collected over time.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
												this sample was not collected).					
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	10	PCDATFL	PK Sampling Date Flag	Flag indicating that the PK date (or start date) is the same as the previous specimen collection date (or start date).	Was the specimen/sample collected on the same date as the [last/previous specimen/sample] [collected/collection ended]?	Same as Previous (Specimen/Sample Collection End) Date	Char	O	Select when the date of this specimen collection is the same as the date of the previous specimen collected. If left blank, "PCDAT" for this specimen must be populated. (or "PCPERF" must be flagged to indicate this sample was not collected)	N/A	Does not map to a tabulation variable.	N/A	N/A	When a series of specimens are collected on a single form, this field is tied to the collection date to allow for the flag to be used as a surrogate for the date field. Its selection means that the date of this specimen is the same as the date of the last specimen collected (in the series). This variable may be used when collecting PK data and re-entering dates is more cumbersome than selecting the checkbox.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	11	PCTIM	PK Sample Collection Time	The time of PK sample collection or start time for a specimen collected over a period of time (protocol-defined time-point range), represented in an unambiguous time format (e.g., hh:mm:ss).	What was the time of the PK sample collection?	Collection Time	Char	HR	Record time of collection (as complete as possible).	PCDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable PCDTC in ISO 8601 format.	N/A	N/A	A complete time is expected. The tabulation PCDTC variable contains either a date/time, when a specimen is collected at a point in time, or the start date/time, when a specimen is collected over time.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	12	PCTPT	PK Sampling Planned Time Point Name	A text description of planned timepoints when measurements should be taken, as defined in the protocol.	What was the planned timepoint of the PK sample collection?	[Planned Time Point Name]	Char	R/C	Record the planned time-point labels for the PK sample collection, if not preprinted on the CRF. Note: Planned timepoints are often described as relative to exposure to study product.	PCTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation time-point anchors PCTPTREF (text description) and PCRFDTDC (date/time) may be needed, as well as tabulation variables PCTPTNUM, PCELTM.	N/A	N/A	Planned timepoints are needed to differentiate multiple sequential assessments. It is recommended that timepoints should be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then terms such as "Planned Time Point" can be included in the column heading.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	13	PCCOND	PK Sampling Test Condition Met	Indication of whether the testing conditions defined in the protocol were met.	Were the protocol-defined testing conditions met?	Test Condition Met	Char	R/C	Record whether protocol-defined testing conditions were met.	SUPPPC.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPPC dataset as the value of SUPPPC.QVAL where SUPPPC.QNAM = "PCCOND" and SUPPPC.PCLABEL = "Test Condition Met".	(NY)	N/A	This information is collected when the test results may be affected by whether conditions for testing were properly met. The specific testing conditions required should be preprinted on the CRF. This may not be relevant for all tests.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	14	PCREFID	PK Sampling Reference ID	An internal or external identifier (e.g., specimen identifier).	What was the (PK) [reference identifier/accession number]?	(PK) [Reference Identifier/Accession Number]	Char	O	Record the specimen or accession number assigned.	PCREFID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	This can be used to reconcile CRF data. May be included for linking back to specimens (e.g., Specimen ID).
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	15	PCSPEC	PK Sampling Specimen Type	The type of specimen used for a PK sample.	What was the specimen (material) type?	[Specimen Type]	Char	HR	Record the specimen material type, if not preprinted on the CRF.	PCSPEC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(SPECTYPE)	N/A	The type of specimen used for a measure. Should be collected if not available elsewhere, or if required to differentiate multiple specimens.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	16	PCTEST	PK Sampling Test Name	Descriptive name of the analyte or specimen characteristics used to obtain the PK measurement or finding.	What was the test name?	[Test Name]	Char	O	Record the name of the measurement or finding, if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.	PCTEST; PCTESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable PCTESTCD may be determined from the value collected in PCTEST. The tabulation variables PCTESTCD and PCTEST are required in the tabulation datasets. Use appropriate CDISC Controlled Terminology for the test and test code.	N/A	N/A	Applicants typically collect tests related to the specimen characteristics on the CRF (e.g., Volume, Ph). Results for tests on an analyte (e.g., Concentration) would typically be populated when creating tabulation datasets. If the analyte test results are collected on the CRF, the test would be the analyte name. It is recommended that the test names be preprinted on the CRF rather than collected in a

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																	free-text field. If the form is laid out as a grid, then words such as "Test" can be included in the column heading.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	17	PCORRES	PK Sampling Result in Original Units	Result of the measurement or finding as originally received or collected.	What was the result of the test?	(Result)	Char	O	Record the test result, interpretation, or finding.	PCORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Should be preprinted on the CRF with the associated test when possible, rather than collected in a free-text field.
Findings	PC	PK Sample Collection at Fixed Time Points	N/A	18	PCORRESU	PK Sampling Original Units	The unit of the result as originally received or collected.	What was the unit of the result?	Unit	Char	O	Select the original unit in which these data were collected, or record if not preprinted on CRF.	PCORRESU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	N/A	Should be preprinted on the CRF with the associated test when possible, rather than collected in a free-text field.
Findings	PC	PK Sample Collection over a Time Interval	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	PC	PK Sample Collection over a Time Interval	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	PC	PK Sample Collection over a Time Interval	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study	What is the subject identifier?	Subject	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	PC	PK Sample Collection over a Time Interval	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed within the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.
Findings	PC	PK Sample Collection over a Time Interval	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started)	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement, test, or observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable PCDTIC in ISO 8601 format.	N/A	N/A	The date the PK samples were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the PK samples at that visit, or the collection date can be collected on the PK CRF using the date (PCDAT) field.
Findings	PC	PK Sample Collection over a Time Interval	N/A	6	PCPERF	PK Sampling Performed	An indication of whether PK samples were collected	Were PK samples collected?	Collected	Char	O	Indicate whether all of the PK samples in this group were collected.	PCSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable PCSTAT. If PCPERF="N", the value of PCSTAT will be "NOT DONE". If	(NY)	N/A	This general prompt question is used as a data management tool to verify that missing results are confirmed missing. This may be implemented at form level or sample level.

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Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
														PCPERF="Y", PCSTAT should be null. PCTEST and PCTESTCD must reflect what tests were not done. A combination of tabulation variables (e.g., PCCAT and PCSCAT, PCTPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable PCTESTCD would be populated as PCALL and an appropriate test name (PCTEST) provided.			These may be all samples of a particular type, or all samples taken for some purpose, and may need to be identified by the organization of the data on the form. Each sample collected could result in 1 or more tests performed, so there can be a one-to-one or one-to-many relationship between samples and tests/results.
Findings	PC	PK Sample Collection over a Time Interval	N/A	7	PCREASND	PK Sampling Reason Not Done	An explanation for why the data are not available	What was the reason the PK sample was not collected?	Reason Not Collected	Char	O	Provide the reason why a PK sample was not collected.	PCREASND	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The reason the data are not available may be chosen from an applicant-defined list (e.g., broken equipment, subject refused) or entered as free text. When PCREASND is used, the tabulation variable PCSTAT should also be populated in the tabulation dataset.
Findings	PC	PK Sample Collection over a Time Interval	N/A	8	PCDAT	PK Sample Collection Date	The date of PK sample collection or the start date of PK sample collection over a period of time (protocol-defined time-point range), represented in an unambiguous date format (e.g., DD-MON-YYYY)	What was the date of the PK sample collection?	Collection Date	Char	HR	Record the date when PK sample collection occurred using this format (DD-MON-YYYY). If left blank, "PCDATFL" for this specimen must be populated (or "PCPERF" must be flagged to indicate this sample was not collected).	PCDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable PCDTC in ISO 8601 format.	N/A	N/A	A complete date is expected. The tabulation PCDTC variable contains either a date/time when a specimen is collected at a point in time or the start date/time, when a specimen is collected over time.
Findings	PC	PK Sample Collection over a Time Interval	N/A	9	PCTIM	PK Sample Collection Time	The time of PK sample collection or start time for a specimen collected over a period of time (protocol-defined time-point range), represented in an unambiguous time format (e.g., hh:mm:ss)	What was the start time of the PK sample collection?	Collection Start Time	Char	HR	Record start time of collection (as complete as possible).	PCDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable PCDTC in ISO 8601 format.	N/A	N/A	A complete time is expected. In interval collection, start can be added as needed to the question text, prompt and CRF directions. The tabulation PCDTC variable contains either a date/time when a specimen is collected at a point in time or the start date/time, when a specimen is collected over time.
Findings	PC	PK Sample Collection over a Time Interval	N/A	10	PCENDAT	PK Sample Collection End Date	The end date of the specimen collection, represented in an unambiguous date format (e.g., DD-MON-YYYY)	What was the end date of the specimen collection?	(Collection) End Date	Char	HR	Record the date when PK sample collection stopped using this format (DD-MON-YYYY)	PCENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable PCENDTC in ISO 8601 format.	N/A	N/A	The end date of specimen collection may be determined from the date of visit and if so, a separate assessment date field is not required.
Findings	PC	PK Sample Collection over a Time Interval	N/A	11	PCENTIM	PK Sample Collection End Time	The end time of the specimen collection, represented in an unambiguous time format (e.g., hh:mm:ss)	What was the specimen collection end time?	(Collection) End Time	Char	HR	Record end time of collection (as complete as possible).	PCENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable PCENDTC in ISO 8601 format.	N/A	N/A	A complete end time is expected. The tabulation variable PCENDTC variable contains the end date/time, when a specimen is collected over time. If there is no end date/time, the tabulation variable PCENDTC should be Null.
Findings	PC	PK Sample Collection over a Time Interval	N/A	12	PCTPT	PK Sampling Planned Time Point Name	A text description of planned timepoints when measurements should be taken, as defined in the protocol	What was the planned timepoint of the PK sample collection?	[Planned Time Point Name]	Char	R/C	Record the planned time-point labels for the PK sample collection, if not preprinted on the CRF. Note: Planned timepoints are often described as relative	PCTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation time-point anchors PCTPTREF (text description) and PCRFDTDC (date/time) may be needed, as well as tabulation variables PCTPTNUM, PCELTM.	N/A	N/A	Planned timepoints are needed to differentiate multiple sequential assessments. It is recommended that timepoints should be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then terms such

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
												to exposure to study product.					as "Planned Time Point" can be included in the column heading.
Findings	PC	PK Sample Collection over a Time Interval	N/A	13	PCFAST	PK Sampling Fasting Status	An indication that the subject has abstained from food/water for the specified amount of time	Was the subject fasting?	Fasting	Char	R/C	Record whether the subject was fasting prior to the test being performed.	PCFAST	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	To be used when results may be affected by whether the subject was fasting.
Findings	PC	PK Sample Collection over a Time Interval	N/A	14	PCCOND	PK Sampling Test Condition Met	Indication of whether the testing conditions defined in the protocol were met (e.g., low fat diet)	Were the protocol-defined testing conditions met?	Test Condition Met	Char	R/C	Record whether protocol-defined testing conditions were met.	SUPPPC.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPPC dataset as the value of SUPPPC.QVAL where SUPPPC.QNAM = "PCCOND" and SUPP.PCLABEL = "Test Condition Met".	(NY)	N/A	This information is collected when the test results may be affected by whether conditions for testing were properly met. The specific testing conditions required should be preprinted on the CRF. This may not be relevant for all tests.
Findings	PC	PK Sample Collection over a Time Interval	N/A	15	PCREFID	PK Sampling Reference ID	An internal or external identifier (e.g., specimen identifier)	What was the (PK) [reference identifier/accession number]?	(PK) [Reference Identifier/Accession Number]	Char	O	Record the specimen or accession number assigned.	PCREFID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	This can be used to reconcile CRF data. May be included for linking back to specimens (e.g., Specimen ID).
Findings	PC	PK Sample Collection over a Time Interval	N/A	16	PCSPEC	PK Sampling Specimen Type	The type of specimen used for a PK sample	What was the specimen (material) type?	Specimen Type	Char	HR	Record the specimen material type, if not preprinted on the CRF.	PCSPEC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(SPECTYPE)	N/A	The type of specimen used for a measure. Should be collected if not available elsewhere, or if required to differentiate multiple specimens.
Findings	PC	PK Sample Collection over a Time Interval	N/A	17	PCTEST	PK Sampling Test Name	Descriptive name of the analyte or specimen characteristics used to obtain the PK measurement or finding	What was the test name?	[Test Name]	Char	O	Record the name of the measurement or finding, if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.	PCTEST; PCTESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable PCTESTCD may be determined from the value collected in PCTEST. The tabulation variables PCTESTCD and PCTEST are required in the tabulation datasets. Use appropriate CDISC Controlled Terminology for the test and test code.	N/A	N/A	Applicants typically collect tests related to the specimen characteristics on the CRF (e.g., Volume, pH). Results for tests on an analyte (e.g., Concentration) would typically be populated when the tabulation datasets are created. If analyte test results are collected on the CRF, the test would be the analyte name. It is recommended that test names be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Test" can be included in the column heading.
Findings	PC	PK Sample Collection over a Time Interval	N/A	18	PCORRES	PK Sampling Result in Original Units	Result of the measurement or finding as originally received or collected	What was the result of the test?	(Result)	Char	O	Record the PK sampling test result.	PCORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Both quantitative results and interpretive findings or summaries may be recorded here.
Findings	PC	PK Sample Collection over a Time Interval	N/A	19	PCORRESU	PK Sampling Original Units	The unit of the result as originally received or collected	What was the unit of the result?	Unit	Char	O	Record the PK sampling test result.	PCORRESU	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Both quantitative results and interpretive findings or summaries may be recorded here.

Assumptions

- It is up to the applicant to determine which data collection scenario best meets the study needs. Typically, only details regarding the collection of PK samples from subjects (e.g., timing of sample collection, associated specimen properties) are collected at the investigational site. Analyte test results are provided directly to the applicant from the bioanalytical laboratory and not on a CRF. The applicant would directly populate the analyte results when creating the SDTM-based datasets.
- If the applicant has occasion to collect the analyte test results on a CRF, the test would be the analyte name. It is recommended that the test names be pre-printed on the CRF rather than collected in a free-text field.
- Other data (e.g., demographics, vital signs, substance use, exposure) may be needed for PK analysis. See the TIG collection sections for these related domains.

2.7.6.11 CDASH Prior and Concomitant Medications (CM)

Description

Concomitant Medications (CM) is an Interventions domain used for concomitant and prior medications/products used by the subject, such as those given on an as needed basis or condition-appropriate medications. The same basic data collection variables should be collected for all medications, treatments, products and therapies (prior, general concomitant medications, and medications of interest). If additional fields are needed to collect other data about a medication of interest, those should be added as nonstandard fields.

Note:

- Applicants may use terms like "concomitant medications," "treatments," "products," or "therapies," as appropriate for the study. The following text may use one of these terms, but applicants can always use the term most appropriate for their study.
- The term *prior* refers to medications/treatments/products that were started before study participation, because limited information may be available on prior interventions taken by a subject; the core requirements were constrained to reflect this limitation.
- Applicants should define the appropriate collection period for prior and concomitant medications/treatments/products in the study protocol.

Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Interventions	CM	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. This field can be included into the database or populated during tabulation dataset creation.
Interventions	CM	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: For single-site studies, this is typically preprinted in the header of each CRF page. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on CRFs that are shipped to each site. EDC: This should be prepopulated.
Interventions	CM	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all collection domains. However, this collection variable is populated only in the tabulation DM domain.
Interventions	CM	N/A	N/A	4	CMCAT	Category for Medication	A grouping of topic-variable values based on user-defined characteristics.	What is the category for the (concomitant) [medication/treatment/therapy/product]?	(Concomitant) [Medication/Treatment/Therapy/Product Category]; NULL	Char	O	Record the (concomitant) [medication/treatment/therapy/ product] category, if not preprinted on the CRF.	CMCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is

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																	asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included in the column heading.
Interventions	CM	N/A	N/A	5	CMSCAT	Subcategory for Medication	A sub-division of the CMCAT values based on user-defined characteristics.	What is the subcategory for the (concomitant) [medication/treatment/therapy/product]?	(Concomitant) [Medication/Treatment/ Therapy/ Product subcategory]; NULL	Char	O	Record (concomitant) [medication/treatment/therapy/product] subcategory, if not preprinted on the CRF.	CMSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer.
Interventions	CM	N/A	N/A	6	CMLN	Any Concomitant Medications Taken	An indication of whether any (concomitant) medications/treatments/therapies/products were taken/given.	Were/Was any (concomitant) [medication/treatment/therapy/product] taken?	Any (Concomitant) [Medication(s)/Treatment(s)/Therapy(ies)/Product(s)]	Char	O	Indicate if the subject took any (concomitant) [medication(s)/treatment(s)/therapy(ies)/product(s)]. If Yes, include the appropriate details where indicated on the CRF.	N/A	Does not map to a tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that all other fields on the CRF were deliberately left blank.
Interventions	CM	N/A	N/A	7	CMSPID	CM Applicant-Defined Identifier	A applicant-defined identifier. This is typically used for preprinted or auto-generated numbers on the CRF, or any other type of identifier that does not already have a defined identifier field.	[Applicant-defined question]	[Applicant defined]	Char	O	If collected on the CRF, applicant may insert instructions to ensure each record has a unique identifier.	CMSPID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	Because SPID is an applicant-defined identifier, conformance to Question Text or Item Prompt is not applicable. Typically used as an identifier in a data query to communicate clearly to the site the specific record in question or to reconcile concomitant medication/treatment/product records with AEs and/or MH. May be used to record preprinted number (e.g. line number, record number) on the CRF. This field may be populated by the applicant's data collection system.
Interventions	CM	N/A	N/A	8	CMTRT	Reported Name of Drug, Med, or Therapy	Verbatim medication name of intervention	What was the (concomitant) [medication/treatment/therapy/product] name/term?	(Concomitant) [Medication/Treatment/Therapy/Product]	Char	HR	Record only 1 [medication/treatment/therapy/product] per line. Provide the full trade or proprietary name of the [medication/treatment/therapy/product]; otherwise the generic name may be recorded.	CMTRT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	In most cases, the verbatim intervention name will be coded to a standard dictionary (e.g., WHODrug) after data have been collected on the CRF. For the collection of verbatim intervention name, the recommendation is for sites to provide the full trade or proprietary name, which is more exact than the generic. The full trade name provides the base generic and the appropriate salt for that particular drug. In addition, for coding purposes, it helps with ATC selection (e.g., Tylenol with codeine #1 has a different ATC code than Tylenol with codeine #3). This field can be used for either prior or concomitant medication/treatments/product s.

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Interventions	CM	N/A	N/A	9	CMPRESP	CM prespecified	An indication that a specific intervention or a group of interventions is prespecified on a CRF.	N/A	N/A	Char	O	N/A	CMPRESP	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	For prespecified interventions, this is a hidden field on a CRF defaulted to "Y", or added during the tabulation dataset creation. If a study collects both prespecified and free-text interventions, the value of CMPRESP should be "Y" for all prespecified interventions and null for interventions reported as free text.
Interventions	CM	N/A	N/A	10	CMOCCUR	CM Occurrence	An indication whether the prespecified medication/treatment/therapy/ product (CMTRT) or the group of medications/treatments/therapies/products was administered when information about the occurrence of a specific intervention was solicited.	Did the subject take [prespecified (concomitant) medication/treatment/therapy/ product/dose]?; Has the subject taken [prespecified (concomitant) medication/treatment/ therapy/ product/dose/]?	[Specific (Concomitant) [Medication/Treatment/Therapy/Product]	Char	O	Indicate if [specific medication/treatment/product] was taken by checking Yes or No.	CMOCCUR	Maps directly to the tabulation variable listed in the Tabulation Target column. If the question was not asked or answered, populate the tabulation variable CMSTAT with "NOT DONE".	(NY)	N/A	CMOCCUR is used to report the occurrence of a prespecified medication/treatment/product. CMOCCUR is not used for spontaneously free-text reported concomitant medications/treatments/product s. The site should be able to indicate that the question was not asked or answered.
Interventions	CM	N/A	N/A	11	CMINGRD	Concomitant Meds Active Ingredients	Medication ingredients.	What were the active ingredients?	Active Ingredients	Char	O	Prior to a subject's clinical visit, remind all subjects to bring all medications bottles, packs etc. they are taking with them to their clinical visit. Record all active ingredient(s) off the intervention label and separate each ingredient with a comma for the name of drug, medication, treatment or product taken. For example, the medication Dolmen, if manufactured in Spain, the active ingredients should be collected as noted below: Active ingredient: Acetylsalicylic Acid, Ascorbic acid, codeine phosphate.	N/A	Does not map to a tabulation variable.	N/A	N/A	This may be collected in addition to the medication/treatment/product name. Collecting this provides more detailed information when coding to a medication dictionary like WHODrug Dictionary Enhanced Format C, which codes to the ingredient level for many trade-name medications. For example, depending on the country where it is manufactured, the active ingredients in the medication Dolmen may be different: In Spain, acetylsalicylic acid, ascorbic acid, codeine phosphate; in Italy and Czech Republic, tenoxicam; in Estonia and Latvia, dextketoprofen trometamol.
Interventions	CM	N/A	N/A	12	CMINDC	CM Indication	The condition, disease, symptom, or disorder that the concomitant (non-study) medication/treatment/therapy/ product was used to address or investigate (e.g., why the medication/treatment/therapy/ product	For what indication was the (concomitant) [medication/treatment/therapy/ product] taken?	Indication	Char	R/C	Record the reason the medication was taken based on clinical investigator's evaluation. If taken to treat a condition, and a diagnosis was made, the indication should be the diagnosis. If taken to treat a condition, and no diagnosis was made, the indication should be the signs and	CMINDC	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This is not the pharmacological/therapeutic classification of an agent (e.g., antibiotic, analgesic), but rather the reason for its administration to the subject. This additional information is collected on the CRF when applicants want to capture the reason(s) a subject took a medication/treatment/product. This information could be used as deemed appropriate for coding/analysis (e.g., in the

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							was taken or administered).					symptoms. If taken as prophylaxis, report as "Prophylaxis for " and include a description of the condition(s).					classification of medications); reconciling medications/treatments/products taken by a subject with provided medical history; and/or AEs/SAEs, as part of the data clean-up and monitoring process.
Interventions	CM	N/A	N/A	13	CMAENO	Related Adverse Event ID	Identifier for the adverse event that is the indication for this medication/treatment/therapy/ product.	What was the identifier for the adverse event(s) for which the (concomitant) [medication/treatment/therapy/ product] was taken?	Adverse Event Identifier	Char	O	Record the identifier of the Adverse Event for which this (concomitant) [medication/treatment/therapy/product] was taken.	N/A	This does not map directly to a tabulation variable. For tabulation datasets, may be used to create RELREC to link this record with a record in the AE domain.	N/A	N/A	The intent is to establish a link between the medication/treatment and the AE that was reported. CMAENO can be used to identify a relationship between records in CM dataset and records in the AE dataset.
Interventions	CM	N/A	N/A	14	CMMHNO	Related Medical History Event ID	Identifier for the medical history condition that is the indication for this medication /treatment/ therapy/ product.	What was the identifier for the medical history event(s) for which the (concomitant) [medication/treatment/ therapy/ product] was taken?	Medical History Event Identifier	Char	O	Record the identifier of the medical history event for which this (concomitant) [medication/treatment/therapy/product] was taken.	N/A	This does not map directly to a tabulation variable. For tabulation datasets, may be used to create RELREC to link this record with a record in the MH domain.	N/A	N/A	The intent is to establish a link between the medical history condition and the intervention taken for the condition. CMMHNO can be used to identify a relationship between records in the CM dataset and records in the MH dataset.
Interventions	CM	N/A	N/A	15	CMDOSE	CM Dose per Administration	The dose of medication/treatment/product (e.g., --TRT) given at one time, represented as a numeric value.	What was the individual dose (of the concomitant [medication/treatment /therapy /product] per administration)?	[Dose/Amount] (per administration)	Num	O	Record the dose of (concomitant) [medication/treatment/ product] taken per administration (e.g., 200).	CMDOSE	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Used when the dose/amount taken/administered/consumed has only numeric entries. If non-numeric entries are possible, use the collection field CMDSTXT.
Interventions	CM	N/A	N/A	16	CMDSTXT	Concomitant Meds Dose Description	The dose of medication/treatment/product taken per administration.	What was the individual dose of the (concomitant) [medication/treatment/therapy/ product]?	Dose	Char	O	Record the dose of (concomitant) [medication/treatment/ product] taken per administration (e.g., 200).	CMDOSTXT; CMDOSE	This does not map directly to a tabulation variable. Numeric values map to CMDOSE in the tabulation dataset. Non-numeric values (e.g., "200-400") map to CMDOSTXT in the tabulation dataset.	N/A	N/A	Defining this data collection field as a dose text field allows for flexibility in capturing dose entries as numbers, text, or ranges. The data collected in this text-format field should be separated or mapped to either tabulation CMDOSE if numeric or CMDOSTXT if text.
Interventions	CM	N/A	N/A	17	CMDOSTOT	CM Total Daily Dose	The total amount of CMTRT taken over a day, using the units in CMDOSU.	What was the total daily dose of the (concomitant) [medication/treatment/therapy/ product]?	Total Daily Dose	Num	O	Record the total dose of (concomitant) [medication/treatment/therapy/product] taken daily.	CMDOSTOT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	For use when only total daily dose is collected on the CRF. For general medications/treatments/products, it is not recommended to use Total Daily Dose. Instead, this can be calculated from other fields (e.g., Units, Dose, Frequency).
Interventions	CM	N/A	N/A	18	CMDOSU	CM Dose Units	The unit associated with the concomitant medication/treatment/therapy /product	What is the unit (for the dose of concomitant [medication/treatment/therapy/ product])?	(Dose) Unit	Char	R/C	Record the dose unit of the dose of concomitant [medication/treatment/	CMDOSU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	(CMDOSU)	When applicants collect data for amount of dose taken (i.e., Dose, Total Daily Dose), Unit must be collected as well (if applicable).

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							taken (e.g., mg in "2 mg 3 times per day").					therapy/product] taken (e.g., mg.).					
Interventions	CM	N/A	N/A	19	CMDOSFRM	CM Dose Form	The pharmaceutical dosage form in which the CMTRT is physically presented.	What was the dose form of the (concomitant) [medication/treatment/therapy/product]?	Dose Form	Char	O	Record the pharmaceutical dosage form (e.g., TABLET, CAPSULE, SYRUP) of delivery for the concomitant [medication/treatment/therapy/product] taken.	CMDOSFRM	Maps directly to the tabulation variable listed in the Tabulation Target column.	(FRM)	(CMDOSFRM)	Some drugs have multiple forms; this field may be needed to code the drug to an ATC level. However, in general, this level of detail should not be necessary except for medications/treatments/products of interest.
Interventions	CM	N/A	N/A	20	CMDOSFRQ	CM Dosing Frequency per Interval	The number of doses given/administered/taken during a specific interval.	What was the frequency of the (concomitant) [medication/treatment/therapy/product]?	Frequency	Char	O	Record how often the (concomitant) [medication/treatment/therapy/product] was taken (e.g., BID, PRN).	CMDOSFRQ	Maps directly to the tabulation variable listed in the Tabulation Target column.	(FREQ)	(CMDOSFRQ)	The frequency of the concomitant medication/treatment/product. When collected, the recommendation is to collect dosing information in separate fields (e.g., CMDOSE, CMDOSEU, CMDOSFRQ) for specific and consistent data collection and to enable programmatically using these data.
Interventions	CM	N/A	N/A	21	CMROUTE	CM Route of Administration	The route of administration of the concomitant medication/treatment/therapy/ product.	What was the route of administration of the (concomitant) [medication/treatment/therapy/product]?	Route	Char	R/C	Provide the route of administration for the (concomitant) [medication/treatment/therapy/product].	CMROUTE	Maps directly to the tabulation variable listed in the Tabulation Target column.	(ROUTE)	(CMROUTE)	This additional information may be important to collect on the CRF when the applicant wants to capture a medication's/treatment's /product's route of administration, for purposes such as coding; also, the medication/treatment/product may have more than 1 route. Some companies may use route in coding medications/treatments/products, to be able to choose a precise preferred name and ATC code.
Interventions	CM	N/A	N/A	22	CMSTDAT	Concomitant Meds Start Date	The start date is when the concomitant medication/treatment/therapy/ product was first taken, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the (concomitant) [medication/treatment/therapy/product/dose] start date?	Start Date	Char	R/C	Record the date the concomitant [medication/treatment/product] was first taken using this format (DD-MON-YYYY). If the subject has been taking the concomitant [medication/treatment/product] for a considerable amount of time prior to the start of the study, it is acceptable to have an incomplete date. Concomitant [medication/treatment/product] taken during the study are expected to have a complete start date. Prior concomitant [medication/treatment/product] that are exclusionary should have both a start and end date.	CMSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable CMSTDTC in ISO 8601 format.	N/A	N/A	The assumption is that applicants should either have a start date or will indicate that the medication, therapy, or product was started before, during, or after the study period. The preferred method is to collect a complete start date. Partial dates (e.g., providing year only) for medications/treatment/product started a considerable amount of time prior to the start of study are acceptable.

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Interventions	CM	N/A	N/A	23	CMSTTIM	Concomitant Meds Start Time	The time the concomitant medication/treatment/therapy/product was started, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the (concomitant) [medication/treatment/therapy/product/dose] start time?	Start Time	Char	R/C	Record the time (as complete as possible) that the concomitant [medication/treatment/product] was started.	CMSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable CMSTDTC in ISO 8601 format.	N/A	N/A	Recommend collecting the time a concomitant medication/treatment/product was started only when a protocol or data collection scenarios supports it. Typically, a start time is not collected unless the subject is under the direct care of the site at the time a concomitant medication/treatment/product administered or the subject records the start time in a diary.
Interventions	CM	N/A	N/A	24	CMPRIOR	Prior Concomitant Meds	Indication the concomitant medication/treatment/therapy/product was given or taken prior to [CMSTTPT] or prior to the date in DM.RFSTDTC.	Was the (concomitant) [medication/treatment/therapy/product] given/taken prior to [CMSTTPT]?; Was the (concomitant) [medication/treatment/therapy/product] given/taken prior to study start?	Prior to [CMSTTPT]; Prior to Study	Char	O	Check if the concomitant [medication/treatment/therapy/product] was started before the study.	CMSTRF; CMSTRTPPT	This does not map directly to a tabulation variable. May be used to populate a value into a tabulation relative timing variable such as CMSTRF or CMSTRTPPT. When populating CMSTRF or CMSTRTPPT, if the value of the collection field CMPRIOR is "Y" a value from the CDISC CT (STENRF) may be used. When CMPRIOR refers to the Study Reference Period (defined in DM.RFSTDTC to DM.RFENDTC), the tabulation variable CMSTRF should be populated. When CMPRIOR is compared to another timepoint, the tabulation variables CMSTRTPPT and CMSTTPT should be used. Note: CMSTRTPPT must refer to the time-point anchor	(NY)	N/A	Applicants may collect this information rather than start dates.

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														described in CMSTTPT.			
Interventions	CM	N/A	N/A	25	CMONGO	Ongoing Concomitant Meds	Indication the concomitant medication/treatment/therapy/product is ongoing when no end date is provided.	Was the (concomitant) [medication/treatment/therapy/product] ongoing (as of [the study-specific timepoint or period])?	Ongoing (as of [the study-specific timepoint or period])	Char	R/C	Record the concomitant [medication/treatment/therapy/product] as ongoing if the subject has not stopped taking the concomitant [medication/treatment/therapy/product] at [the timepoint defined by the study]. If the concomitant medication/treatment/therapy/product is ongoing, the end date should be left blank	CMENRF; CMENRPT	This does not map directly to a tabulation variable. May be used to populate a value into a tabulation relative timing variable (e.g., CMENRF, CMENRPT). When populating CMENRF, if the value of CMONGO is "Y", the values of "DURING", "AFTER", or "DURING/AFTER R" may be used. When populating CMENRPT, if the value of CMONGO is "Y", the value of "ONGOING" may be used. When CMONGO refers to the Study Reference Period (defined in DM.RFSTDTC to DM.RFENDTC) the tabulation variable CMENRF should be populated. When CMONGO is used in conjunction with another timepoint, the tabulation variables CMENRPT and CMENTPT should be used. Note: CMENRPT must refer to a time-point anchor described in CMENTPT.	(NY)	N/A	This box should be checked to indicate that the concomitant medication/treatment/product has not stopped at the time of data collection. It is expected that every recorded medication/treatment/product should have either an end date or be checked as ongoing, but not both. However, in cases where ongoing concomitant medications/treatments/products are not permitted, it may not be necessary to include an Ongoing field in the CRF.
Interventions	CM	N/A	N/A	26	CMENDAT	Concomitant Meds End Date	The date that the subject ended/stopped taking the	What was the (concomitant) [medication/treatment/therapy/product/dose] end date?	End Date	Char	R/C	Record the date the concomitant [medication/treatment/product] was stopped	CMENDTC	This does not map directly to a tabulation variable. For the	N/A	N/A	The assumption is that applicants should either have an end date or will indicate that the medication, therapy,

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							concomitant medication/treatment/therapy/product, represented in an unambiguous date format (e.g., DD-MON-YYYY).					using this format (DD-MON-YYYY). If the subject has not stopped taking the concomitant [medication/treatment/product] leave this field blank.		tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable CMENDTC in ISO 8601 format.			or product was ongoing at the time of collection or at the end of the study. However, in cases where the end date can be determined from dates collected elsewhere in the CRF it is not necessary to include an End Date field on the CRF. For example, if all concomitant medications/treatments/products are administered only once during a trial, the end date will be the same as the start date.
Interventions	CM	N/A	N/A	27	CMENITIM	Concomitant Meds End Time	The time when the subject ended/stopped taking the concomitant medication/treatment/therapy/product, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the [medication/treatment/therapy/product/dose] end time?	End Time	Char	R/C	Record the time (as complete as possible) that the concomitant medication/treatment/product was stopped.	CMENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable CMENDTC in ISO 8601 format.	N/A	N/A	Recommend collecting the time a concomitant medication/treatment, product was ended only when a protocol or data collection scenario requires it or the subject records the end time in a diary. Typically, an end time is not collected unless the subject is under the direct care of the site at the time a concomitant medication/treatment/product is stopped.
Interventions	CM	N/A	N/A	28	CMRSDISC	Reason for Intervention Discontinuation	The reason the Intervention was discontinued.	What was the reason the (concomitant) [medication/treatment/therapy/product/-TRT] was [discontinued/stopped/ended]?	Reason for discontinuation of concomitant medication/treatment/therapy/product.	Char	O	Record the reason the concomitant medication/treatment/product was stopped.	CMRSDISC	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although frequently used for prior meds, this can be used for any intervention at any timepoint. When the dosing is recorded over multiple successive records, this variable is applicable only for the (chronologically) last record for the intervention.
Interventions	CM	N/A	N/A	29	CMDECOD	Standardized Medication Name	The dictionary or applicant-defined standardized text description of the topic variable, CMTRT, or the modified topic variable (CMMODIFY), if applicable.	N/A	N/A	Char	O	N/A	CMDECOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. Equivalent to the generic drug name in published (e.g., WHODrug, SNOMED, ICD9) or applicant-defined dictionaries.
Interventions	CM	N/A	N/A	30	CMCLAS	CM Medication Class	The class for the intervention (often obtained from a coding dictionary).	N/A	N/A	Char	O	N/A	CMCLAS	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. This would generally be the class code used for analysis.
Interventions	CM	N/A	N/A	31	CMCLASC D	CM Medication Class Code	The assigned dictionary code for the class for the intervention.	N/A	N/A	Char	O	N/A	CMCLASCD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This field does not typically appear on the CRF. Applicants will populate this through the coding process. This would generally be the class code used for analysis.
Interventions	CM	N/A	N/A	32	CMATC1	ATC Level 1 Description	Dictionary text description of the first level of hierarchy within the Anatomical	N/A	N/A	Char	O	N/A	SUPPCM.QVAL	This does not map directly to a tabulation variable. This information	N/A	N/A	This field does not typically appear on the CRF. This is populated through the applicant's coding process.

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							Therapeutic Chemical (ATC) classification system; indicates the anatomical main group.							could be represented in a SUPPCM dataset as the value of SUPPCM.QVAL where SUPPCM.QNA M="CMATC1" and SUPPCM.QLAB EL="ATC Level 1 Description".			
Interventions	CM	N/A	N/A	33	CMATC1CD	ATC Level 1 Code	Dictionary code denoting the first level of hierarchy within the ATC classification system; indicates the anatomical main group.	N/A	N/A	Num	O	N/A	SUPPCM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPCM dataset as the value of SUPPCM.QVAL where SUPPCM.QNA M ="MATC1CD" and SUPPCM.QLAB EL="ATC Level 1 Code".	N/A	N/A	This field does not typically appear on the CRF. This is populated through the applicant's coding process.
Interventions	CM	N/A	N/A	34	CMATC2	ATC Level 2 Description	Dictionary text description for the second level of hierarchy within the ATC classification system; indicates the therapeutic main group.	N/A	N/A	Char	O	N/A	SUPPCM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPCM dataset as the value of SUPPCM.QVAL where SUPPCM.QNA M="CMATC2" and SUPPCM.QLAB EL="ATC Level 2 Description".	N/A	N/A	This field does not typically appear on the CRF. This is populated through the applicant's coding process.
Interventions	CM	N/A	N/A	35	CMATC2CD	ATC Level 2 Code	Dictionary code denoting the second level of hierarchy within the ATC classification system; indicates the therapeutic main group.	N/A	N/A	Num	O	N/A	SUPPCM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPCM dataset as the value of SUPPCM.QVAL where SUPPCM.QNA M="CMATC2CD" and SUPPCM.QLAB EL="ATC Level 2 Code".	N/A	N/A	This field does not typically appear on the CRF. This is populated through the applicant's coding process.

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Interventions	CM	N/A	N/A	36	CMATC3	ATC Level 3 Description	Dictionary text description of the third level of hierarchy within the ATC classification system; indicates the therapeutic/pharmacological subgroup.	N/A	N/A	Char	O	N/A	SUPPCM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPCM dataset as the value of SUPPCM.QVAL where SUPPCM.QNA M="CMATC3" and SUPPCM.QLAB EL="ATC Level 3 Description".	N/A	N/A	This field does not typically appear on the CRF. This is populated through the applicant's coding process.
Interventions	CM	N/A	N/A	37	CMATC3CD	ATC Level 3 Code	Dictionary code denoting the third level of hierarchy within the ATC classification system; indicates the therapeutic/pharmacological subgroup.	N/A	N/A	Num	O	N/A	SUPPCM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPCM dataset as the value of SUPPCM.QVAL where SUPPCM.QNA M="CMATC3CD" and SUPPCM.QLAB EL="ATC Level 3 Code".	N/A	N/A	This field does not typically appear on the CRF. This is populated through the applicant's coding process.
Interventions	CM	N/A	N/A	38	CMATC4	ATC Level 4 Description	Dictionary text description of the fourth level of hierarchy within the ATC classification system; indicates the chemical/therapeutic/pharmacological subgroup.	N/A	N/A	Char	O	N/A	SUPPCM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPCM dataset as the value of SUPPCM.QVAL where SUPPCM.QNA M="CMATC4" and SUPPCM.QLAB EL="ATC Level 4 Description".	N/A	N/A	This field does not typically appear on the CRF. This is populated through the applicant's coding process.
Interventions	CM	N/A	N/A	39	CMATC4CD	ATC Level 4 Code	Dictionary code denoting the fourth level of hierarchy within the ATC classification system; indicates the chemical/therapeutic/pharmacological subgroup.	N/A	N/A	Num	O	N/A	SUPPCM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPCM dataset as the value of SUPPCM.QVAL where SUPPCM.QNA	N/A	N/A	This field does not typically appear on the CRF. This is populated through the applicant's coding process.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
														M="CMATC4CD " and SUPPCM.QLAB EL="ATC Level 4 Code".			
Interventions	CM	N/A	N/A	40	CMATC5	ATC Level 5 Description	Dictionary text description of the fifth level of hierarchy within the ATC classification system; indicates the chemical substance.	N/A	N/A	Char	O	N/A	SUPPCM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPCM dataset as the value of SUPPCM.QVAL where SUPPCM.QNA M="CMATC5" and SUPPCM.QLAB EL="ATC Level 5 Description".	N/A	N/A	This field does not typically appear on the CRF. This is populated through the applicant's coding process.
Interventions	CM	N/A	N/A	41	CMATC5CD	ATC Level 5 Code	Dictionary code denoting the fifth level of hierarchy within the ATC classification system; indicates the chemical substance.	N/A	N/A	Num	O	N/A	SUPPCM.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPCM dataset as the value of SUPPCM.QVAL where SUPPCM.QNA M="CMATC5CD " and SUPPCM.QLAB EL="ATC Level 5 Code".	N/A	N/A	This field does not typically appear on the CRF. This is populated through the applicant's coding process.

Assumptions

1. General medications/treatments/products are defined as any medications/treatments/products reported by a subject when asked if they have taken any medications in an open-ended way that does not ask about any specific intervention. Additional information might be sourced by referring to a subject's medical record.
2. Medications of interest are defined as any medications or classes of interventions specifically mentioned in the protocol and were not the primary focus for determining the Collection Core designations for the domain.
3. As with all the data collection variables recommended in the TIG standard, it is assumed that applicants will add other data variables as needed to meet protocol-specific and other data collection requirements.
4. The CMOCUR field provides a structure for capturing the occurrence of specific interventions of interest.

2.7.6.12 CDASH Product Accountability (DA)

Description

Product Accountability (DA) is a Findings domain used to collect information about the dispensing and returning of investigational products used in a study.

Findings domains are typically represented in the vertical/normalized structure, which is usually the easiest and quickest way to collect, process, and clean data. However, users may have system constraints that prevent them from collecting data in the vertical/normalized manner. In such cases, the horizontal/denormalized version provides the structure necessary to collect the variables in another way.

Depending on the study design, the DA CRF/eCRF may not be required.

Care should be taken not to confuse product accountability with study product compliance or study product exposure. Comparing the amount dispensed to the subject and the amount returned by the subject does not necessarily mean the difference equates to the amount of consumed by the subject or the subject's compliance. For example, the subject could have misplaced some of the product and thus the return amount could provide a false estimate of compliance.

Because the actual product name may not be known to the site at the time of dispensing or returning, the word product in the context of the CDASHIG DA domain refers to the identifier that references the product (e.g., Product A, Product B,) rather than the actual (unblinded) product name.

The term *dispensed* refers to when the product is provided to the subject, not when the subject uses or consumes the study product. The term *returned* refers to when the subject returns the unused study product to the investigational site.

Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	DA	N/A	Horizontal-Generic	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	DA	N/A	Horizontal-Generic	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	DA	N/A	Horizontal-Generic	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This variable collection is typically collected in all collection domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	DA	N/A	Horizontal-Generic	4	VISIT	Visit Name	The name of a clinical encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column..	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed within the EDC for any visit-based data collection, most often Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.

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							performed on a subject.										
Findings	DA	N/A	Horizontal-Generic	5	VISDAT	Visit Date	Date the clinical encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement, test, observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable DADTC in ISO 8601 format.	N/A	N/A	The date the accountability assessments were collected can be determined from the Visit Date variable (VISDAT) and applying that date to all of the observations at that visit, or the collection date can be included on the DA CRF using the date (DADAT) field.
Findings	DA	N/A	Horizontal-Generic	6	DAGRIPID	Product Accountability Group ID	An applicant-defined identifier used to tie a block of related records in a single domain.	What is the test group identifier?	Test Group Identifier	Char	O	Record unique group identifier. Applicant may insert additional instructions to ensure each record has a unique group identifier.	DAGRIPID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	It can be beneficial to use an identifier in a data query to communicate clearly to the site the specific record in question. This group identifier ties together all the tests collected on this horizontal record. This field may be populated by the applicant's data collection system.
Findings	DA	N/A	Horizontal-Generic	7	[DATESTCD]_DAPERF	Product Accountability Performed	An indication of whether a planned product accountability assessment was performed.	Was [DATEST] collected?	[DATEST] Collected	Char	O	Indicate whether or not product accountability was performed.	DASTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable DASTAT. If DAPERF="N", the value of DASTAT will be "NOT DONE". If DAPERF="Y", DASTAT should be null. A combination of tabulation variables (e.g., DACAT and DASCAT, DATPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable DATESTCD would be populated as DAALL and an appropriate test name (DATEST) provided.	(NY)	N/A	This general prompt question is used as a data management tool to verify that missing results are confirmed missing. This may be implemented for all tests collected on the same horizontal record or for each specific test. When mapped to the tabulation dataset, the value of DAPERF would apply to all tests on the same record. Use the collection variable [DATESTCD]_DAPERF when implemented on a specific test basis. This is an example of the type of collection variable names that can be used in a denormalized data structure.
Findings	DA	N/A	Horizontal-Generic	8	[DATESTCD]_DACAT	DA Category of Assessment	A grouping of topic-variable values based on user-defined characteristics.	What was the type of product for which accountability was assessed?	Product Type	Char	O	Record the type of study product for which accountability is assessed.	DACAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. If the protocol allows dispensing different types of study product the CRF can capture the type of product using DACAT. This may be preprinted on the CRF. If DACAT is not collected (e.g., it is evident from the protocol design), it could be populated during the tabulation dataset creation process. The value of DACAT would apply to all measurements on that record when mapped to the tabulation dataset. If needed, the collection variable [DATESTCD]_DACAT may be used to collect a category for each DATEST.
Findings	DA	N/A	Horizontal-Generic	9	[DATESTCD]_DASCAT	DA Subcategory of Assessment	A sub-division of the DACAT values based on user-defined characteristics.	What was the name of the product for which accountability was assessed?	[DATEST] Product Name	Char	O	Record the name of the study product dispensed.	DASCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a category value preprinted on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be a applicant-

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included as the column header. If known at the time of data collection, the product name may be collected in DASCAT (with appropriate grouping values, but different from those for DACAT). The value of DASCAT would apply to all measurements on that record when mapped to the tabulation dataset. If needed, the collection variable [DATESTCD]_DASCAT may be used to collect a category for each DATEST.
Findings	DA	N/A	Horizontal-Generic	10	[DATESTCD]_DAREFID	Product Accountability Reference ID	An internal or external identifier such as product label identifier.	What is the [DATEST] product label identifier?	[DTEST] Product Label Identifier	Char	O	Record dispensed product label identifier.	DAREFID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in EX domain.	N/A	N/A	The packaging identifier may be collected in different ways (e.g., affixing label onto CRF, scanning a bar code). For some cases, greater granularity for product identifiers may be needed. In that situation, applicants may need to use additional variables. This is an example of the type of collection variable names that can be used in a denormalized data structure.
Findings	DA	N/A	Horizontal-Generic	11	[DATESTCD]_DADAT	Product Accountability Date of Assessment	The date the study product was dispensed or returned, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date [DATEST] product accountability was assessed?	[DATEST] Date	Char	R/C	Record the date product accountability was performed, using this format (DD-MON-YYYY).	DADTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable DADTC in ISO 8601 format.	N/A	N/A	The date study product dispensed/returned should be recorded for each dispensation for a study with multiple periods or multiple products dispensed. A single date may be collected when all observations are performed on the same date. The date of each observation can also be collected using the collection variable [DATESTCD]_DADAT. The date of the observation may be determined from a collected date of visit and in such cases a separate measurement date field is not required. This is an example of the type of collection variable names that can be used in a denormalized data structure.
Findings	DA	N/A	Horizontal-Generic	12	[DATESTCD]_DAORRES	DA Assessment Result in Original Units	Result of the product accountability assessment (e.g., actual amount).	What is the amount of the [DATEST] product accountability assessment?	[DATEST] Amount	Char	HR	Record the result of the product accountability assessment.	DAORRES; DATEST; DATESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. In addition to the tabulation variable DAORRES, create DATESTCD from the collection variable name and derive the value of DATEST from DATESTCD. The prompt may also contain DATEST. Use appropriate CDISC Controlled Terminology for the test and test code.	N/A	N/A	Each test may be collected using the collection variable [TESTCD] (e.g., RETAMT) or [TESTCD]_DAORRES, where TESTCD is the appropriate CT for the DA test code (e.g., RETAMT_DAORRES). For a study with multiple periods or multiple products dispensed, accountability amounts should be assessed for each dispensation and return. For the tabulation dataset, DAREFID should be used to link related records. This is an example of the types of collection variable names that can be used in a denormalized data structure.
Findings	DA	N/A	Horizontal-Generic	13	[DATESTCD]_DAORRESU	DA Original Units	The unit of the result as originally received or collected.	What was the unit of the [DATEST] result?	[DATEST] Unit	Char	HR	Record or select the original units in which these data were collected, if not preprinted on CRF.	DAORRESU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	(DAORRESU)	The unit should be preprinted on the CRF or a field provided on the CRF to capture it. This is an example of the types of collection variable names that can be used in a denormalized data structure.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	DA	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included into the database or populated during tabulation dataset creation.
Findings	DA	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	DA	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What is the subject identifier?	Subject	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system generated. This collection variable is typically collected in all collection domains. However, this collection variable is populated only in the tabulation domain.
Findings	DA	N/A	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed in the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.
Findings	DA	N/A	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement, test, observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable DADTC in ISO 8601 format.	N/A	N/A	The date the accountability assessments were collected can be determined from the Visit Date variable (VISDAT) and applying that date to all of the observations at that visit, or the collection date can be included on the DA CRF using the date (DADAT) field.
Findings	DA	N/A	N/A	6	DAPERF	Product Accountability Performed	An indication of whether a planned product accountability assessment was performed.	Was product accountability performed?	Product Accountability Performed	Char	O	Indicate whether or not product accountability was performed.	DASTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable DASTAT. If DAPERF="N", the value of DASTAT will be "NOT DONE". If DAPERF="Y", DASTAT should be null. A combination of tabulation variables (e.g., DACAT and DASCAT, DATPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable DATESTCD would be populated as DAALL and an appropriate test name (DATEST) provided.	(NY)	N/A	This may be implemented on a CRF page level on a visit-by-visit basis. This general prompt question is used as a data management tool to verify that missing results are confirmed missing.

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Findings	DA	N/A	N/A	7	DACAT	DA Category of Assessment	A grouping of topic-variable values based on user-defined characteristics.	What was the type of product for which accountability was assessed?	[Product Type]; NULL	Char	O	Record the type of product dispensed/returned.	DACAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer.
Findings	DA	N/A	N/A	8	DASCAT	DA Subcategory of Assessment	A sub-division of the DACAT values based on user-defined characteristics.	What was the name of the product for which product accountability was assessed?	[Product Name]; NULL	Char	O	Record the name of the study product dispensed/returned.	DASCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer. If known at the time of data collection, the product name may be collected in DASCAT (with appropriate grouping values, but different from those for DACAT). See tabulation DA domain examples for populating DACAT and DASCAT. DASCAT can only be used if there is an DACAT, and it must be a subcategorization of DACAT.
Findings	DA	N/A	N/A	9	DADAT	Product Accountability Date	The date the study product was dispensed or returned, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date the product accountability assessment was performed?	Date	Char	R/C	Record the exact date the study product was (dispensed or returned), using this format (DD-MON-YYYY).	DADTC	This does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable DADTC in ISO 8601 format.	N/A	N/A	The date investigational product dispensed/returned should be recorded for each dispensation for a study with multiple periods or multiple products dispensed.
Findings	DA	N/A	N/A	10	DAREFID	Product Accountability Reference ID	An internal or external identifier such as product label identifier.	What was the product label identifier?	Product Label Identifier	Char	O	Record product label identifier.	DAREFID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	For the tabulation dataset, DAREFID should be used to tie together a block of related records and to link dispensed product to returned product. The packaging identifier may be collected in different ways (e.g., affixing label onto CRF, scanning a bar code). For some cases, greater granularity for product identifiers may be needed. In this situation, applicants may need to use additional identifier variables.
Findings	DA	N/A	N/A	11	DATEST	Name of Accountability Assessment	Descriptive name of the measurement or finding (e.g., dispensed, returned).	What was the product accountability being assessed?	[Product Accountability Test Name]	Char	HR	Record the name of the product accountability assessment if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.	DATEST; DATESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable DATESTCD may be determined from the value collected in the collection field DATEST. The tabulation variables DATESTCD and DATEST are required in the tabulation datasets. Use appropriate CDISC Controlled Terminology for the test and test code.	(DATEST)	N/A	Required to identify which test the result is for. It is recommended that the test names preprinted on the CRF rather than collected in a field that requires the site to enter text. If the form is laid out as a grid, then words such as "Test" can be included as the column heading. For a study with multiple periods or multiple products dispensed, product accountability amounts should be assessed for each dispensation.
Findings	DA	N/A	N/A	12	DAORRES	DA Assessment Result in Original Units	Result of the product accountability assessment as originally dispensed or	What is the result of the product accountability assessment?	Amount	Char	HR	Record the actual amount of product dispensed or returned.	DAORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	For a study with multiple periods or multiple products dispensed, product accountability amounts should be assessed for each dispensation.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
							returned (e.g., actual amount).										
Findings	DA	N/A	N/A	13	DAORRESU	DA Original Units	The unit of the result as originally received or collected.	What was the unit?	Unit	Char	HR	Record or select the original units in which these data were collected, if not preprinted on CRF.	DAORRESU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	(DAORRESU)	Should be preprinted on the CRF with the associated test when possible, rather than collected in a free-text field.

Assumptions

1. The CRF collects the amount of study product transferred to or from the study subject. Hence, if no study product is transferred to a subject this CRF may not be needed.
2. Product accountability may be implemented for an entire study or on a visit-by-visit basis depending on the most logical approach for the protocol.

2.7.6.13 CDASH Protocol Deviations (DV)

Description

Protocol Deviations (DV) is an Events domain used for protocol violations and deviations during the course of the study. The collection DV domain is intended to collect protocol deviations or violations that occur after enrollment. It is not intended to collect information about inclusion/exclusion criteria; that data should be collected in the IE domain.

Considerations Regarding Use of a Protocol Deviations CRF

Applicants must employ a robust and systematic method for recording protocol deviations; this may include the use of a dedicated CRF for this purpose, or the intentional inclusion of data collection fields throughout the entire set of CRFs that will detect protocol deviations.

Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Events	DV	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Events	DV	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Events	DV	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all collection domains. However, this collection variable is populated only in the tabulation DM domain.
Events	DV	N/A	N/A	4	DVCAT	Category for Protocol Deviation	A grouping of topic-variable values based on user-defined characteristics.	What is the category of the protocol deviation?	[Protocol Deviation Category]: NULL	Char	O	Record the deviation category, if not preprinted on the CRF.	DVCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a

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																	question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column header.
Events	DV	N/A	N/A	5	DVSCAT	Subcategory for Protocol Deviation	A sub-division of the DVCAT values based on user-defined characteristics.	What is the subcategory of the protocol deviation?	[Protocol Deviation Subcategory]: NULL	Char	O	Record the deviation event subcategory, if not preprinted on the CRF.	DVSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer. DVSCAT can only be used if there is an DVCAT, and it must be a subcategorization of DVCAT.
Events	DV	N/A	N/A	6	DVYN	Any Protocol Deviation	An indication of whether there were any protocol deviations.	Were there any protocol deviations?	Any Deviations	Char	O	Enter Yes if a protocol deviation occurred and No if none occurred. Ensure that any adverse event which triggers a protocol deviation (e.g., concomitant medication use, newly discovered medical history) is noted in the respective CRF.	N/A	Does not map to a tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that all other fields on the CRF were deliberately left blank.
Events	DV	N/A	N/A	7	DVDECOD	Protocol Deviation Coded Term	The applicant-defined standardized text for the name of the protocol deviation.	What was the (standardized) protocol deviation (term/code)?	(Standardized) Protocol Deviation (Term)	Char	R/C	Record protocol deviations identified and/or select the appropriate code from the list of protocol deviation terms.	DVDECOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	DVTERM and DVDECOD may have the same value. If the CRF is collecting protocol deviations using a codelist of responses, then DVDECOD should be used to store the codelist response. Applicants must use either DVDECOD or DVTERM on the CRF and, in some cases, both may be used. For example, if the CRF collects "Specify, Other" or similar additional free-text descriptions of codelist items, then DVTERM should be used to store the detailed descriptive text.
Events	DV	N/A	N/A	8	DVTERM	Protocol Deviation Term	The reported or prespecified name of the protocol deviation.	What was the protocol deviation term?	(Specify) Protocol Deviation	Char	R/C	Record the appropriate code from the list of protocol deviation terms.	DVTERM	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	DVTERM and DVDECOD may have the same value. If the CRF is collecting protocol deviations using a free-text field, then DVTERM should be used to store the free-text response. Applicants may use either DVDECOD or DVTERM on the CRF, but a value in DVTERM is required in the tabulation datasets.
Events	DV	N/A	N/A	9	DVSTDAT	Deviation Start Date	The start date of deviation, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the protocol deviation start date?	Start Date	Char	O	Record the start date that the protocol deviation using this format (DD-MON-YYYY). This should be the start or occurrence of the protocol deviation, not the date it was discovered or reported.	DVSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable DVSTDTC in ISO 8601 format.	N/A	N/A	This may be derived if not collected on a CRF.
Events	DV	N/A	N/A	10	DVSTTIM	Deviation Start Time	The start time of the deviation, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the protocol deviation start time?	Start Time	Char	O	If appropriate, record the start time (as complete as possible) of the protocol deviation in an unambiguous time format (e.g., hh:mm:ss). This should be the start or occurrence of the protocol deviation, not the time it was discovered or reported.	DVSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable DVSTDTC in ISO 8601 format.	N/A	N/A	N/A
Events	DV	N/A	N/A	11	DVENDAT	Deviation End Date	The end date of the deviation, represented in an unambiguous date	What was the protocol deviation end date?	End Date	Char	O	Record the end date of the protocol deviation using this format (DD-MON-YYYY). This should	DVENDTC	This does not map directly to a tabulation variable. For the tabulation dataset,	N/A	N/A	N/A

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							format (e.g., DD-MON-YYYY).					be the date the protocol deviation stopped, not the date it was discovered or reported.		concatenate all collected END DATE and TIME components and populate the tabulation variable DVENDTC in ISO 8601 format.			
Events	DV	N/A	N/A	12	DVENTIM	Deviation End Time	The end time of the deviation, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the protocol deviation end time?	End Time	Char	O	If appropriate, record the end time (as complete as possible) of the protocol deviation in an unambiguous time format (e.g., hh:mm:ss). This should be the time the protocol deviation stopped, not the time it was discovered or reported.	DVENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable DVENDTC in ISO 8601 format.	N/A	N/A	N/A
Events	DV	N/A	N/A	13	DVSPID	DV Applicant-Defined Identifier	An applicant-defined identifier. This is typically used for preprinted or auto-generated numbers on the CRF, or any other type of identifier that does not already have a defined identifier field.	[Applicant-defined question]	[Applicant defined]	Char	O	If collected on the CRF, the applicant may insert instructions to ensure each record has a unique identifier.	DVSPID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	Because SPID is an applicant-defined identifier, conformance to Question Text or Item Prompt is not applicable. Typically used as an identifier in a data query to communicate clearly to the site the specific record in question or to reconcile data. May be used to record preprinted number (e.g., line number, record number) on the CRF. This field may be populated by the applicant's data collection system.

Assumptions

- Applicants who decide to use a DV CRF should not rely on this CRF as the only source of protocol deviation information for a study. Rather, they should also utilize monitoring, data review, and programming tools to assess whether there were protocol deviations in the study.

2.7.6.14 CDASH Questionnaires, Ratings, and Scales (QRS)

Description

Questionnaires (QS) is a Findings domain used for data from named stand-alone instruments designed to provide an assessment of a concept. Questionnaires have a defined standard structure, format, and content; consist of conceptually related items that are typically scored; and have documented methods for administration and analysis. Refer to Section 2.4, [About Questionnaires, Ratings, and Scales](#), when implementing collection standards. Because the nature of QRS precludes implementers from modifying the published data collection structure, TIG collection metadata does not include specifications for QRS. Instead, implementers should refer to instrument-specific QRS supplements on the QRS web page for example aCRFs, instrument-specific assumptions, and data examples.

Released QRS documentation is maintained on the CDISC QRS web page (<https://www.cdisc.org/standards/foundational/qrs>); see that page for definitions and descriptions of the different types of questionnaires, ratings, and scales.

Specification

Reference the QRS supplements posted on the QRS web page and the tabulation QS specification in the TIG.

Assumptions

- CDISC standards for QRS include controlled terminology for test codes (--TESTCD), test names (--TEST), standard timing values, standard results for database values, and an aCRF with tabulation domain variable names. These standards can be used to create an electronic data collection (EDC) structure following the same conventions that would be used for any Findings class domain. The QS domain utilizes a normalized data structure; that is, 1 variable (--TEST) is used to capture the test name and another variable (--ORRES) is used to capture the result. Even though these domain variables are presented as a

normalized structure in the collection metadata table, implementers using a denormalized structure (1 variable for each test) should create variable names that mirror the values in QRS Controlled Terminology (e.g., QTESTCD, RTESTCD, FTTESTCD).

2. Electronic representations of QRS instruments should reflect the title, subheadings, and exact numbering and wording of questions as they appear in original versions.
3. Electronic response fields should allow either the original response (--ORRES) or coded value (--STRESC) to be input—but usually not both, to avoid discrepancies.
4. Checkboxes that appear on validated QRS instruments should remain checkboxes in the CRF/eCRF.
5. Copyrighted instruments may include the copyright notice on the eCRF/CRF. For more copyright Information about QRS instruments, see the QRS web page.
6. Instrument-specific assumptions are included in the QRS supplements posted on the QRS web page.<http://www.cdisc.org/qrs>

2.7.6.15 CDASH Respiratory System Findings (RE)

Description/Overview

Respiratory System Findings (RE) is a Findings domain used for physiological and morphological findings related to the respiratory system, including the organs that are involved in breathing, such as the nose, throat, larynx, trachea, bronchi, and lungs.

Specification

Metadata Specification

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Findings	RE	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column .	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	RE	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	RE	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What is the subject identifier?	Subject	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be provided to the site using a prepopulated list in the system. This collection variable is typically collected in all domains. However, this collection variable is

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																	populated only in the tabulation DM domain.
Findings	RE	N/A	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned trial interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed in the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.
Findings	RE	N/A	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not an tabulation variable. The date of a measurement, test, observation can be determined from the date/time of visit (VISDAT/ISTIM) and then concatenating the VISDAT/ISTIM components and populating the tabulation variable VSDTC in ISO 8601 format.	N/A	N/A	The date the RE measurements were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the observations at that visit, or the collection date can be included on the RE CRF using the Respiratory Assessments (REDAT) field.
Findings	RE	N/A	N/A	6	REPERF	Respiratory Assessment Performed	An indication of whether a planned measurement, test, observation or specimen was performed/collected.	Was a respiratory assessment performed?	Respiratory Assessment Performed	Char	HR	Indicate whether or not a respiratory assessment was done.	RESTAT	This field does not map directly to an tabulation variable. May be used to populate a value into the tabulation variable RESTAT. If the collection variable REPERF="N", the value of the tabulation variable RESTAT is "NOT DONE". If REPERF= "Y", RESTAT is null. A combination of tabulation variables (e.g., RECAT and RESCAT, RETPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable RETESTCD would be populated with REAL and an appropriate test name (RETEST) provided.	(NY)	N/A	This field is used to capture a response to whether or not a planned measurement, test or observation was performed. A negative response can be collected as "N" and mapped to the -STAT variable in SDTM as " NOT DONE".
Findings	RE	N/A	N/A	7	REDAT	Respiratory Assessment Date	The date the respiratory measurement was performed, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date the respiratory measurement was taken?	Date	Char	R/C	Record date of measurements using this format (DD-MON-YYYY).	REDTA	This field does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable REDTC in ISO 8601 format.	N/A	N/A	The date the RE measurements were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the observations at that visit, or the collection date can be included on the RE CRF using the Date of Collection (REDAT) field.

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Findings	RE	N/A	N/A	8	RETIM	Respiratory Assessment Time	The time of measurement, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the time of the respiratory system measurement?	Time	Char	R/C	Record time of measurement (as complete as possible).	REDCD	This field does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable REDTC in ISO 8601 format.	N/A	N/A	A single collection time (e.g., RETIM) may be collected for all the measurements when they are performed at the same time. The time of each measurement can also be collected using a collection variable [RETESTCD]_RETIM.
Findings	RE	N/A	N/A	9	REPTPT	RE Assessment Planned Time Point Name	A text description of planned timepoints when measurements should be taken, as defined in the protocol.	What is the planned timepoint for this respiratory assessment measurement?	[Planned Time Point Name]	Char	R/C	Record the planned time-point labels for respiratory assessment, if not preprinted on the CRF.	REPTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation time-point anchors RETPTREF (text description) and RERFTDTC (date/time) may be needed, as well as tabulation variables RETPTNUM, REELTM.	N/A	N/A	Planned timepoints are needed to differentiate multiple sequential assessments. It is recommended that timepoints should be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then terms such as "Planned Time Point" can be included in the column heading.
Findings	RE	N/A	N/A	10	RETEST	Respiratory Test Name	Descriptive name of the test or examination used to obtain the measurement or finding.	What is the respiratory test name?	[Respiratory Test Name]	Char	HR	Record the name of the respiratory test, if not preprinted on the CRF.	RETEST; RETESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable RETESTCD may be determined from the value collected in RETEST using the Controlled Terminology List RETESTCD.	(RETEST)	N/A	The test name will usually be preprinted on the CRF, and not solicited as a question. If the form is laid out as a grid, then "Test" or "Test Name" can be included in the column heading. RETEST is most useful as the PROMPT on the field in which the RESULT for that test is collected.
Findings	RE	N/A	N/A	11	RECAT	Category for Respiratory Test	A grouping of topic-variable values based on user-defined characteristics.	What is the category of the respiratory test?	[Respiratory Test Category]; NULL	Char	R/C	Record the respiratory assessment category, if not preprinted on the CRF.	RECAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be a heading on the CRF or screen, not a question to which the site would provide an answer. RESCAT can only be used if there is a RECAT. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included in the column heading.
Findings	RE	N/A	N/A	12	RESCAT	Subcategory for Respiratory Test	A sub-division of the RECAT values based on user-defined characteristics.	What was the subcategory of the respiratory assessment?	[Respiratory Assessment Subcategory]; NULL	Char	O	Record the respiratory assessment subcategory, if not preprinted on the CRF.	RESCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would

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																	typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included in the column heading. RECAT can only be used if there is a RECAT, and it must be a subcategorization of RECAT.
Findings	RE	N/A	N/A	13	REORRES	RE Test Result in Original Units	Result of the measurement or finding as originally received or collected.	What was the result of the measurement?	[RETEST] Result	Char	HR	Record the respiratory test result.	REORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Both quantitative results and interpretive findings or summaries may be recorded here.
Findings	RE	N/A	N/A	14	REORRESU	Respiratory Test Original Unit	The unit of the result as originally received or collected.	What was the unit of the result?	Unit	Char	R/C	Record or select the original unit in which these data were collected, if not preprinted on CRF.	REORRESU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	N/A	Should be preprinted on the CRF with the associated test when possible, rather than collected in a free-text field. Should be included if applicable and not available elsewhere.
Findings	RE	N/A	N/A	15	RERES	Respiratory Test Result or Finding	The result of the measurement or finding as originally received or collected.	Was the result (normal/abnormal/absent/present/[applicant defined response])?	(Result)	Char	O	Indicate the overall assessment for [RETEST].	REORRES	This does not map directly to an tabulation variable. The mapping instructions depend on the implementation; for example: 1. RERES is used to collect Normal, Abnormal or similar type classifications (e.g., Absent/Present) with a description of the abnormal result using the collection field REDESC. For tabulation datasets, if the collection field RERES = "NORMAL", populate the tabulation variables REORRES and RESTRESC with the value of the collection field RERES. If the collection field RERES is "ABNORMAL", populate the tabulation variable REORRES with the collection field REDESC. If the reported findings in REDESC are coded using a dictionary, then the tabulation variable RESTRESC is populated with the dictionary preferred	N/A	N/A	The collection field RERES is used when the collected results are not mapped directly to the tabulation variable REORRES and must be transformed. For example, 1. RERES is used to collect standardized values on the CRF and the value of "OTHER" is included and "Specify Other" is collected. 2. REORES is collected using Normal, Abnormal and a description of the abnormality is collected.

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														term and REMODIFY is populated with the modified text used for coding. If the reported findings in REDESC are not coded, then the tabulation variable RESTRESC is populated with the collection REDESC field. The tabulation variable RENRIND may be populated with "NORMAL" or "ABNORMAL" if appropriate. 2. Where RERES is used to collect standardized values (e.g. a codelist) on the CRF and the value of "OTHER" is included, the collection field RERESOTH can be used to collect free-text values for "Specify Other". When using this field, the "OTHER" value recorded in the collect field RERES field is mapped to the tabulation variable RESTRESC and the value in the collection field RERESOTH is mapped to the tabulation variable REORRES.				
Findings	RE	N/A	N/A	16	REDESC	Description of Respiratory Test Finding	Text description of respiratory test findings.	What was the description of the (abnormality/observed finding/[Applicant-defined])?	(Abnormal) Findings	Char	O	Record all abnormal findings for the respiratory test in the space provided.	REORRES	This does not map directly to an tabulation variable. May be used to populate a value into the tabulation variable REORRES. If RERES="Normal", populate REORRES with the value of RERES. If RERES="Abnormal", populate REORRES with the value of REDESC.	N/A	N/A	RERES and REDESC are used when a question is asked to collect the finding result, with a follow-up question for a description of the finding.	
Findings	RE	N/A	N/A	17	RERESOTH	Respiratory Test Result Other	A free-text result which provides further information about the original received or collected result.	If other is selected, [explain/specify/provide more detail].	[Specify Other/Explain/Specify Details]	Char	O	Provide more detail for the "Other" result.	REORRES	When using this collection field, the "OTHER" value collected in the collection field RERES is mapped to the tabulation variable RESTRESC and the value in the collection field RERESOTH is	N/A	N/A	In cases where RERES is used to collect standardized values on the CRF and the value of "OTHER" is included, the collection field RERESOTH can be used to collect free-text values for "Specify Other".	

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
														mapped to the tabulation variable REORRES.			
Findings	RE	N/A	N/A	18	REORNRLO	RE Ref Range Lower Limit-Original Unit	The lower end of normal range or reference range for continuous results stored in REORRES.	What was the lower limit of the reference range?	Normal Range Lower Limit	Char	O	Record the lower limit of the reference range of the respiratory test.	REORNRLO	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	REORNRLO should be populated only for continuous findings. The tabulation variable RESTNRC should be populated only for noncontinuous results. These data may be obtained from the lab or the electronic equipment. These data could be derived from a site or lab specific set of normal ranges stored in a look-up table.
Findings	RE	N/A	N/A	19	REORNRHI	RE Ref Range Upper Limit-Original Unit	The upper end of normal range or reference range for continuous results stored in REORRES.	What was the upper limit of the reference range?	Normal Range Upper Limit	Char	O	Record the upper limit of the reference range of the respiratory test.	REORNRHI	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	REORNRHI should be populated only for continuous findings. The tabulation variable RESTNRC should be populated only for noncontinuous results. These data may be obtained from the lab or the electronic equipment. These data could be derived from a site or lab specific set of normal ranges stored in a look-up table.
Findings	RE	N/A	N/A	20	RENRIND	RE Reference Range Indicator	An indication or description about how the value compares to the normal range or reference range.	How do the reported values compare within the [reference/normal/expected] range?	Comparison to [Reference/Expected/Normal] Range	Char	O	Record where the test result fell with respect to the reference range.	RENRIND	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NRIND)	N/A	Reference ranges may be defined by REORNRLO, REORNRHI, RESTNRC or other objective criteria. Reference Range Indicator (e.g., Y, N; HIGH, LOW; NORMAL, ABNORMAL) may be included if not derived or determined programmatically after data collection. Should not be used to indicate clinical significance.
Findings	RE	N/A	N/A	21	RESTAT	Completion Status	This variable is used to indicate that data are not available, by having the site recording the value as "Not Done".	Indicate if the [RETEST] was not [answered/assessed/done/evaluated/ performed].	Not Done	Char	O	Indicate if the respiratory assessment or measurement was not done.	RESTAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(ND)	N/A	Used only when the response value is collected as NOT DONE or NULL in lieu of or in addition to the collection REPERF field. Typically a checkbox which indicates the test was NOT DONE. This field can be useful when multiple questions are asked to confirm that a blank result field is meant to be blank.
Findings	RE	N/A	N/A	22	REREASND	Reason Not Done	An explanation for why the data are not available.	Was the reason that the respiratory (assessment/[RETEST]) was not [collected / answered / done / assessed / evaluated]?	Reason Not [Answered/Collected/Done/Evaluated/ Assessed/Available]	Char	O	Provide the reason the measurement or test was not done.	REREASND	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology may be used. The reason the data are not available may be

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																	chosen from an applicant-defined codelist (e.g., broken equipment, subject refused) or entered as free text. When REREASND is used, RESTAT should also be populated in the SDTM-based dataset.
Findings	RE	N/A	N/A	23	REPOS	Position of Subject During Observation	The position of the subject during a measurement or examination.	What was the position of the subject during the assessment?	Position	Char	O	Record the position of subject at time of test.	REPOS	Maps directly to the tabulation variable listed in the Tabulation Target column.	(POSITION)	N/A	Results may be affected by whether conditions for respiratory test, as specified in the protocol, were properly met. One common condition is the subject's position. If the protocol requires this type of information, then a collection variable [RETESTCD]_REPOS may be created for each RETESTCD and added to the CRF, if needed.
Findings	RE	N/A	N/A	24	RELOC	Location	Location used for the measurement.	What was the anatomical location where the measurement was taken?	Anatomical Location	Char	O	Record or select location on body where the measurement was performed.	RELOC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LOC)	N/A	Collected or preprinted when the applicant needs to identify the specific anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF. LAT, DIR, and PORTOT are used to further describe the anatomical location.
Findings	RE	N/A	N/A	25	RELAT	Laterality	Qualifier for anatomical location, further detailing the side of the body.	What was the side of the anatomical location of the [measurement/test/examination])?	Side	Char	O	Record the side of the anatomical location of the respiratory test or measurement.	RELAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LAT)	N/A	May be preprinted or collected when the applicant needs to identify the specific side of the anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Findings	RE	N/A	N/A	26	REDIR	Directionality	Qualifier further detailing the position of the anatomical location, relative to the center of the body, organ, or specimen.	What was the directionality of the anatomical location of the respiratory test?	Directionality	Char	O	Record the directionality of the anatomical location of the respiratory test.	REDIR	Maps directly to the tabulation variable listed in the Tabulation Target column.	(DIR)	N/A	May be preprinted or collected when the applicant needs to identify the directionality of the anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Findings	RE	N/A	N/A	27	REMETHOD	Method of Respiratory Test	The method of the test or examination.	What was the method (used for the [measurement/test/examination])?	Method	Char	O	Record the method used for the respiratory test.	REMETHOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	(METHOD)	N/A	This information may be collected when more than 1 method is possible, and collecting the method used is necessary.
Findings	RE	N/A	N/A	28	REEVAL	Respiratory Test Evaluator	The role of the person who provided the evaluation.	Who was the evaluator?	Evaluator	Char	O	Select the role of the person who provided the evaluation.	REEVAL	Maps directly to the tabulation variable listed in the Tabulation Target column.	(EVAL)	N/A	Used only for results that are subjective (e.g., assigned by a person or a group). May be a preprinted or collected.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	Applicants may collect the data using a subset list of controlled terminology on the CRF.
Findings	RE	N/A	N/A	29	REEVALID	Respiratory Test Evaluator Identifier	An identifier used to distinguish multiple evaluators with the same role recorded in REEVAL.	What is the identifier of the evaluator?	Evaluator Identifier	Char	O	Record the unique identifier assigned to the person making the evaluation.	REEVALID	Maps directly to the tabulation variable listed in the Tabulation Target column.	(MEDEVAL)	N/A	Collect if multiple evaluators are used in the study (may be omitted if multiple evaluators are not used); values should follow controlled terminology.
Findings	RE	N/A	N/A	30	REACPTFL	Accepted Record Flag	An indication that the evaluation is considered, by an independent assessor, to be the accepted or final evaluation.	Was this record considered to be the accepted evaluation?	Accepted Evaluation	Char	O	Indicate whether or not the evaluation is considered, by an independent assessor, to be the accepted or final evaluation.	REACPTFL	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	Use where more than one assessor provides an evaluation of a result or response. Typically a checkbox with the value of "Y" or "NULL", which indicates the evaluation was accepted.
Findings	RE	N/A	N/A	31	REREPNUM	Respiratory Test Repetition Number	The instance number of a test that is repeated within a given timeframe for the same test. The level of granularity can vary (e.g., within a timepoint, within a visit).	What was the repetition number within the timepoint for this measurement?	Repetition Number	Char	O	Record the repetition number of the measurement within the timepoint.	SUPPRE.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPRE dataset as the value of SUPPRE.QVAL where SUPPRE.QNAM = "REREPNUM" and SUPPRE.QLABEL = "Repetition Number within Time Point".	N/A	N/A	The repetition number of the test/measurement within the timepoint may be preprinted on the CRF.
Findings	RE	N/A	N/A	32	RECLSIG	Clinical Significance	An indication of whether the test results were clinically significant.	Was this result clinically significant?	Clinically Significant	Char	O	Record whether respiratory test results were clinically significant.	SUPPRE.QVAL	This does not map directly to a tabulation variable. This information could be represented in a SUPPRE dataset as the value of SUPPRE.QVAL when SUPPRE.QNAM = "CLSIG" and SUPPRE.QLABEL = "Clinical Significance".	(NY)	N/A	Could apply to specific measurements or to overall interpretation, as required by the protocol.

Assumptions

1. This domain is used to represent the results/findings of a respiratory diagnostic procedure (e.g., spirometry).
2. Many respiratory assessments require the use of a device. When data about the device used for an assessment or additional information about its use in the assessment are collected, SPDEVID should be included in the record.
3. Any identifier variables, timing variables, or Findings general observation class qualifiers may be added to the RE domain, but the following qualifiers would generally not be used in the RE domain: --MODIFY, --BODSYS, and --FAST.

2.7.6.16 CDASH Subject Characteristics (SC)

Description/Overview

Subject Characteristics (SC) is a Findings domain that describes protocol-specified characteristics of the study subjects and serves as an extension of the data contained in the Demographics (DM) domain. It is important to note that:

1. Data in this domain are collected only once per subject.
2. SC data are collected once at the beginning of the study and are not expected to change during the study.
3. SC contains data such as information about education level, marital status, and national origin.
4. There is extensible Controlled Terminology for SCTEST. These data might be useful, for example, for risk-benefit or quality-of-life analyses, or for subsetting a subject population.
5. The tabulation SC domain utilizes a normalized data structure; that is, 1 variable (SCTEST) is used to capture the test name and another variable (SCORRES) is used to capture the result. Subject characteristics are presented as a normalized structure in the collection metadata table, but implementers using a denormalized structure (1 variable for each test) should create variable names that mirror the SCTESTCDs in controlled terminology.

Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	SC	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	SC	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	SC	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be provided to the site using a prepopulated list in the system. This collection variable is typically collected in all domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	SC	N/A	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed within the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.

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Findings	SC	N/A	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement, test, observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the collection VISDAT/VISTIM components and populating the tabulation variable SCDC in ISO 8601 format.	N/A	N/A	The date the subject characteristics were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the subject characteristics at that visit, or the collection date can be included on the SC CRF using the date (SCDAT) field.
Findings	SC	N/A	N/A	6	SCCAT	Category for Subject Characteristic	A grouping of topic-variable values based on user-defined characteristics.	What was the category of the subject characteristics?	[Subject Characteristics Category]; NULL	Char	O	Record the subject characteristics category, if not preprinted on the CRF.	SCCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included in the column heading.
Findings	SC	N/A	N/A	7	SCSCAT	Subcategory for Subject Characteristic	A sub-division of the SCCAT values based on user-defined characteristics.	What was the subcategory of the subject characteristics?	[Subject Characteristics Subcategory]; NULL	Char	O	Record the subject characteristics subcategory, if not preprinted on the CRF.	SCSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be a applicant-defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included in the column heading. SCSCAT can only be used if there is an SCCAT, and it must be a subcategorization of SCCAT.
Findings	SC	N/A	N/A	8	SCPERF	SC Assessment Performed	An indication of whether any subject characteristics were collected.	Were subject characteristics collected?	Subject Characteristics Collected	Char	O	Indicate if subject characteristics information was collected. If Yes, record the appropriate details.	SCSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable SCSTAT. If SCPERF="N", the value of SCSTAT will be "NOT DONE". If SCPERF="Y", SCSTAT should be null. A combination of tabulation variables (e.g., SCCAT and SCSCAT, SCTPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable SCTESTCD would be populated as SCALL and an appropriate test name (SCTEST) provided.	(NY)	N/A	General prompt question to be used as a data management tool to verify that missing results are confirmed missing.
Findings	SC	N/A	N/A	9	SCSPID	SC Applicant-Defined Identifier	An applicant-defined identifier. This is typically used for preprinted or auto-generated numbers on the CRF, or any other type of identifier that does not already have a defined collection identifier field.	[Applicant-defined question]	[Applicant defined]	Char	O	If collected on the CRF, the applicant may insert instructions to ensure each record has a unique identifier.	SCSPID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Because SPID is a applicant-defined identifier, conformance to Question Text or Item Prompt is not applicable. Typically used as an identifier in a data query to communicate clearly to the site the specific record in question or to reconcile data. May be used to record preprinted number (e.g., line number, record number) on the CRF. This field may be populated by the applicant's data collection system.

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Findings	SC	N/A	N/A	10	SCDAT	Subject Characteristic Collection Date	The date of collection represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date the subject characteristics were collected?	Date	Char	R/C	Record the date the subject characteristics were collected using the format (DD-MON-YYYY).	SCDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected collection DATE and TIME components and populate the tabulation variable SCDTC in ISO 8601 format.	N/A	N/A	The date of collection can be determined from a collected date of the visit (VISDAT); in such cases, a date field is not required.
Findings	SC	N/A	N/A	11	SCTEST	Subject Characteristic	Descriptive name of the subject characteristic of interest.	What is the subject characteristics name?	[Subject Characteristic Test Name]	Char	HR	Record the name of the subject characteristics if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.	SCTEST; SCTESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable SCTESTCD may be determined from the value collected in SCTEST. Use appropriate CDISC Controlled Terminology for the test and test code.	(SCTEST)	N/A	Required to identify which test the result is for. It is recommended that the test names be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Test" can be included in the column header.
Findings	SC	N/A	N/A	12	SCORRES	SC Result or Finding in Original Units	Result of the subject characteristic as originally received or collected.	What is the subject characteristic?	(Result)	Char	HR	Record the subject characteristic.	SCORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	N/A
Findings	SC	N/A	Horizontal-Generic	1	STUDYID	Study Identifier	A unique identifier for a study	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	SC	N/A	Horizontal-Generic	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	SC	N/A	Horizontal-Generic	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant Identifier]	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all collection domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	SC	N/A	Horizontal-Generic	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This collection variable is typically collected in all collection domains. However, this collection variable is represented only in the tabulation DM domain.
Findings	SC	N/A	Horizontal-Generic	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement, test, observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the collection VISDAT/VISTIM components	N/A	N/A	The date the subject characteristics were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the subject characteristics at that visit, or the collection date can be included on

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														and populating the tabulation variable SCDCAT in ISO 8601 format.			the SC CRF using the date (SCDAT) field.
Findings	SC	N/A	Horizontal-Generic	6	[SCTESTCD]_SCCAT	Category for Subject Characteristic	A grouping of topic-variable values based on user-defined characteristics.	What was the category of the subject characteristics??	[Subject Characteristics Category]; NULL	Char	O	Record the subject characteristics category, if not preprinted on the CRF.	SCCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included in the column heading. This is an example of the types of collection variable names that can be used in a denormalized data structure.
Findings	SC	N/A	Horizontal-Generic	7	[SCTESTCD]_SCSCAT	Subcategory for Subject Characteristic	A sub-division of the SCAT values based on user-defined characteristics.	What was the subcategory of the subject characteristics?	[Subject Characteristics Subcategory]; NULL	Char	O	Record the subject characteristics subcategory, if not preprinted on the CRF.	SCSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included in the column header. SCSCAT can only be used if there is an SCAT, and it must be a subcategorization of SCAT. This is an example of the types of collection variable names that can be used in a denormalized data structure.
Findings	SC	N/A	Horizontal-Generic	8	[SCTESTCD]_SCPERF	SC Assessment Performed	An indication of whether any subject characteristics were collected.	Were subject characteristics collected for [SCTESTCD]?	[SCTEST] Collected	Char	O	Indicate if subject characteristics information was collected. If Yes, include the appropriate details where indicated on the CRF.	SCSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable SCSTAT. If [SCTESTCD]_SCPERF = "N", the value of SCSTAT will be "NOT DONE". If [SCTESTCD]_SCPERF = "Y", SCSTAT should be null. A combination of tabulation variables (e.g., SCAT and SCSCAT, SCTPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable SCTESTCD would be assigned SCALL and an appropriate test name (SCTEST) provided.	(NY)	N/A	General prompt question to be used as a data management tool to verify that missing results are confirmed missing. This may be implemented for all tests collected on the same horizontal record or for each specific test. When the tabulation datasets are created, the value of SCPERF would apply to all tests on the same record. Use the collection variable [SCTESTCD]_SCPERF when implemented on a specific test basis. This is an example of the types of collection variable names that can be used in a denormalized data structure.
Findings	SC	N/A	Horizontal-Generic	9	SCGRPID	Subject Characteristics Group ID	An applicant-defined identifier used to tie together a block of related records in a single domain.	What is the test group identifier?	Test Group ID	Char	O	Record unique group identifier. Applicants may insert additional instructions to ensure each record has a unique group identifier.	SCGRPID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	It can be beneficial to use an identifier in a data query to communicate clearly to the site the specific record in question. This group identifier ties together all the tests collected on this horizontal record. This field may be populated by the applicant's data collection system.
Findings	SC	N/A	Horizontal-Generic	10	[SCTESTCD]_SCORRES	SC Result or Finding in Original Units	Result of the subject characteristics as originally received or collected.	What is the subject's [SCTEST]?	[SCTEST] Result	Char	HR	Record the subject characteristic.	SCORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	N/A

Assumptions

- The subject characteristics that should be collected are not specified by the TIG; this is a scientific decision that should be based on the needs of the protocol.
- The tabulation variable SCDTC can be determined from a collected date of the visit (VISDAT); in such cases, a date of collection field is not required on the CRF.

2.7.6.17 CDASH Substance Use (SU)

Description/Overview

Substance Use (SU) is an Interventions domain used for information on the use of recreational products such as caffeine, alcohol, tobacco/nicotine, and other recreational drugs that may be of interest to the study. The amount of information collected for the SU domain depends upon regulatory requirements and the applicant's protocol.

Using collection variable SUNCF with responses of "Never", "Current", and "Former" for each substance-use type, rather than a simple "Yes/No" response is recommended. Based on the wide variability of definitions of *use*, the specific definitions and timeframes for the SUNCF responses would be applicant/protocol-defined. By using the SUNCF response categories for usage, a number of questions about use and frequency can be collapsed, in turn decreasing the number of data points required in the SU domain. More detailed information about duration, amount, and start and end dates are optionally captured.

Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Interventions	SU	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included into the database or populated during tabulation dataset creation.
Interventions	SU	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Interventions	SU	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system generated. This collection variable is typically collected in all collection domains. However, this collection variable populated only in the tabulation DM domain.
Interventions	SU	N/A	N/A	4	SUTRT	Reported Name of Substance	The type of substance (e.g., TOBACCO, ALCOHOL, CAFFEINE or CIGARETTES, CIGARS, COFFEE).	What [is/was] the [name/type] of (the) substance used?	[Type of Substance]	Char	HR	N/A	SUTRT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicants may require different types of substance-use data (e.g., illicit drug use, cigarettes); the value for category may be preprinted on the CRF as a label for the prompt for Substance Use. If a more detailed type of substance appears on the CRF (e.g., CIGARETTES, CIGARS rather than TOBACCO), SUCAT should be TOBACCO and SUTRT should be CIGARETTES.
Interventions	SU	N/A	N/A	5	SUCAT	Category for Substance Use	A grouping of topic-variable values based on user-defined characteristics.	What is/was the category of the substance (used)?	[Substance (Used) Category]; NULL	Char	R/C	Record the Substance Used category, if not preprinted on the CRF.	SUCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology (e.g., TOBACCO, ALCOHOL, CAFFEINE). Applicants may require different types of substance-use data (e.g., illicit drug use, cigarettes); the value for category may be preprinted on the CRF. If a more detailed type of substance appears on the CRF (e.g.,

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																	CIGARETTES, CIGARS, rather than TOBACCO), SUCAT is TOBACCO and SUTRT is CIGARETTES. If the applicant does not specify a type of tobacco on the CRF, SUTRT is TOBACCO. If SUCAT is not collected (e.g., it is evident from the protocol design), it could be populated during the tabulation dataset creation process.
Interventions	SU	N/A	N/A	6	SUSCAT	Subcategory for Substance Use	A sub-division of the SUCAT values based on user-defined characteristics.	What was the subcategory of the substance (used)?	[Substance (Used) Subcategory]; NULL	Char	O	Record the Substance Use subcategory, if not preprinted on the CRF.	SUSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. The value for subcategory may be preprinted on the CRF or hidden. SUSCAT can only be used if there is a SUCAT and it must be a subcategorization of SUCAT.
Interventions	SU	N/A	N/A	7	SUPRESP	SU Prespecified	An indication that a specific intervention or a group of interventions is prespecified on a CRF.	N/A	N/A	Char	O	N/A	SUPRESP	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	For prespecified interventions, a hidden field on a CRF defaulted to "Y", or added during the tabulation dataset creation. If a study collects both prespecified and free-text interventions, the value of SUPRESP should be "Y" for all prespecified interventions and null for interventions reported as free text.
Interventions	SU	N/A	N/A	8	SUYN	Any Substance Used	An indication of whether any data was collected for the intervention topic.	Were any [applicant-phrase/substance name/recreational drugs] used?	Any [Substance Name (Used)]	Char	O	Indicate if the subject had used any (applicant-defined phrase/recreational drugs/alcohol/substance name).	N/A	Does not map to a tabulation variable.	(NY)	N/A	General prompt question to aid in monitoring and data cleaning. This provides verification that all other fields on the CRF were deliberately left blank. This is a field that can be used on any Interventions CRF to indicate whether there is data to record.
Interventions	SU	N/A	N/A	9	SUNCF	Never Current Former Usage	Indication the prespecified substance was used.	Has the subject ever [used/consumed] [SUTRT/SUCAT]?	([Substance]) Usage	Char	R/C	Check the appropriate box to indicate if the subject has ever used/consumed tobacco/alcohol/caffeine, currently consumes tobacco/alcohol/caffeine, or formerly used/consumed tobacco/alcohol/caffeine.	SUOCCUR; SUSTRPT; SUSTRF; SUENRPT; SUENRF; SUPPSU.QVAL	This does not map directly to a tabulation variable. May be used to populate SUOCCUR and relative timing variables.	(NCF)	(SUNCF)	The 3 options (NEVER, CURRENT, FORMER) are applicant-defined in relation to the protocol. If the applicant has specific definitions, these definitions are detailed in the instructions to the site. As this type of response does not correspond exactly to a tabulation variable, collection variable SUNCF is recommended. Applicants must decide how to populate the appropriate relative timing variables when creating the tabulation datasets. For example, if SUNCF = "Never", the value of SUOCCUR will be "N" and all relative timing variables will be null. If the applicant chooses to populate the relative start references (SUSTRPT, SUSTRF) the value will be "BEFORE" when SUNCF= "CURRENT" and "FORMER". If the applicant also chooses to use relative end references (SUENRF, SUENRPT), the SUENRPT value will be "ONGOING" when SUNCF="CURREN" while the value of SUENRF will be "DURING/AFTER". Note: When using SUSTRPT and/or SUENRPT, these must refer to a time-point anchor (e.g., SCREENING, in SUPTP/SUENTP).
Interventions	SU	N/A	N/A	10	SUSPID	Substance Use Applicant-Defined Identifier	A applicant-defined identifier. This is typically used for preprinted or auto-generated numbers on the CRF, or any other type of identifier that does not already have a	[Applicant-defined question]	[Applicant defined]	Char	O	If collected on the CRF, applicants may insert instructions to ensure each record has a unique identifier.	SUSPID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	Because SPID is an applicant-defined identifier, conformance to Question Text or Item Prompt is not applicable. Typically used as an identifier in a data query to communicate clearly to the site the specific record in question or to reconcile data. May be used to record preprinted number (e.g., line number, record number) on the CRF. This field

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						defined identifier field.											may be populated by the applicant's data collection system.
Interventions	SU	N/A	N/A	11	SUREASND	Reason Substance Use Not Collected	An explanation for why data are not available.	What was the reason the data was not collected?	Reason Not Collected	Char	O	Provide the reason why the substance used data were not collected.	SUREASND	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The reason data are not available may be chosen from an applicant-defined list (e.g., subject refused) or entered as free text. When PRREASND is used, the tabulation variable PRSTAT should also be populated in the tabulation dataset.
Interventions	SU	N/A	N/A	12	SUDSTXT	Substance Dose Description	The amount of substance used (e.g., 1-2 packs, 8 oz).	What is/was the amount of [SUTRT] used/consumed?	Amount	Char	O	Check the appropriate box to indicate the amount of tobacco/alcohol/caffeine the subject consumes on a regular basis.	SUDOSE; SUDOSU; SUDOSTXT	This does not map directly to a tabulation variable. Numeric values map to SUDOSE in the tabulation dataset. Non-numeric values (e.g., 200-400) map to SUDOSTXT in the tabulation dataset.	N/A	N/A	Where possible, the options for dose/amount are preprinted on the CRF. In the example given in the definition, "packs" and "ounces" are included as a point of reference. They would be represented as SUDOSU. Care should be taken to map each record to the appropriate tabulation variable SUDOSTXT (text results that cannot be represented in a numeric field) and SUDOSE (numeric results).
Interventions	SU	N/A	N/A	13	SUDOSFRQ	Substance Use Frequency per Interval	The number/amount of the substance consumed per a specific interval.	What [is/was] the frequency of [SUTRT] [use/consumption]?	Frequency	Char	O	Record how often the subject regularly [uses / consumes] (the) [substance].	SUDOSFRQ	Maps directly to the tabulation variable listed in the Tabulation Target column.	(FREQ)	N/A	When possible, the options for dose/amount frequency are preprinted on the CRF. (e.g., PER DAY, PER WEEK, OCCASIONAL).
Interventions	SU	N/A	N/A	14	SUSTDAT	Substance Use Start Date	The date substance use started, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the start date of [SUTRT/SUCAT] use/consumption?	Start Date	Char	O	Record the start date of the substance use using this format (DD-MON-YYYY).	SUSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable SUSTDTC in ISO 8601 format.	N/A	N/A	The applicant may choose to capture a complete date or any variation thereof (e.g., month and year, year).
Interventions	SU	N/A	N/A	15	SUENDAT	Substance Use End Date	The date substance use ended, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the end date of [SUTRT/SUCAT] use/consumption?	End Date	Char	O	Record the end date of the substance use using this format (DD-MON-YYYY).	SUENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable SUENDTC in ISO 8601 format.	N/A	N/A	The applicant may choose to capture a complete date or any variation thereof (e.g., month and year, year).
Interventions	SU	N/A	N/A	16	SUCDUR	Substance Use Collected Duration	Collected duration of the substance use.	What was the duration of [SUTRT/SUCAT] use/consumption?	Duration	Char	O	Provide the duration of the substance use (e.g., Record how long the subject has smoked).	SUDUR	This does not map directly to a tabulation variable. For the tabulation dataset, concatenating the collected duration and collected duration unit and populate the tabulation variable SUDUR in ISO 8601 format. Example: P1DT2H (for 1 day, 2 hours).	N/A	N/A	This is only collected on the CRF if this level of detail is needed and if SUSTDAT and SUENDAT are not collected on the CRF.
Interventions	SU	N/A	N/A	17	SUCDURU	Substance Use Collected Duration Unit	Unit of the collected duration of the substance use. Used only if duration	What was the unit of duration of [SUTRT/SUCAT] use/consumption?	(Duration) Unit	Char	O	Select the appropriate duration unit of the substance use.	SUDUR	This does not map directly to a tabulation variable. For the tabulation	(UNIT)	N/A	Applicant-defined options should be preprinted on the CRF to avoid making this a free-text field. This will allow the

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							was collected on the CRF.							dataset, concatenating the collected duration and collected duration unit and populate the tabulation variable SUDUR in ISO 8601 format. Example: P1DT2H (for 1 day, 2 hours).			response to be translated into ISO 8601 format.
Interventions	SU	N/A	N/A	18	SUMODIFY	Modified Substance Name	If the value for SUTERM is modified for coding purposes, then the modified text is placed here.	N/A	N/A	Char	O	N/A	SUMODIFY	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This is not a data collection field that would appear on the CRF. If the applicant chooses to code the substance use, the applicant will populate this through the coding process.
Interventions	SU	N/A	N/A	19	SUDECOD	Standardized Substance Name	The dictionary or applicant-defined standardized text description of SUTRT, or the modified topic variable (SUMODIFY), if applicable.	N/A	N/A	Char	O	N/A	SUDECOD	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This is typically not a data collection field that will appear on the CRF. If the applicant chooses to code the substance use, the applicant will populate this through the coding process. Equivalent to the generic drug name in published (e.g., WHODrug, SNOMED, ICD9) or applicant-defined dictionaries. If SUPRESP is used, and the information about a specific standardized substance name is being solicited, the data from SUTRT may map directly to the tabulation SUDECOD variable.

Assumptions

1. Categories SUCAT and SUSCAT
 - a. Applicants may require different types of substance-use data (e.g., illicit drug use, cigarettes, recreational drugs) to be collected; the value for category may be preprinted on the CRF.
 - b. SUCAT and SUSCAT should not be redundant with SUTRT. For example, if a more detailed type of substance usage is collected on the CRF (e.g., "CIGARETTES", "CIGARS"), SUCAT should be "TOBACCO" and SUTRT could be "CIGARETTES", "CIGARS". If the applicant does not solicit responses about specific types of substances used on the CRF (e.g., "CIGAR", "CIGARETTE"), the value of SUTRT is the more general description of the substance (e.g., "TOBACCO") and SUCAT is generally null. This practice avoids assigning the same value to both SUTRT and SUCAT. However, for consistency across studies, the applicant may elect to repeat the values of SUTRT in SUCAT.
2. The tabulation variable SUPRESP should be prepopulated to the value of "Y" when information about the use of a specific substance is solicited on the CRF.
3. Relative Timing Variables
 - a. Relative timing variables are used to represent collected data in the tabulations in those cases where a start date or an end date has not been collected, but some indication of when/if the intervention or event started or ended has been collected. In the collection SU domain, if the collection variable SUNCF is used (with the possible responses of "Never", "Current", and "Former"), the collected values may be used to derive a value into a tabulation relative timing variable to represent when the subject started or stopped using the substance relative to either a time point or to a period of time in the study.
For example, if the value collected in SUNCF is "Current", the value of "ONGOING" may be represented in the tabulation variable SUENRPTP to indicate that the subject was still using cigarettes as of the time point described in SUENTPT. It is recommended that the applicant collect either a date or a description of a time point that will be used in conjunction with relative timing variables.
 - b. If the actual, complete start date or end date of the substance use has been collected, there is no need to use relative timing variables.
4. Start and End Dates

- a. Start and end dates can be collected if this level of detail is required by the protocol. Partial dates may be collected when the subject does not remember the complete date of when substance use started or ended. The applicant may choose to capture a complete date or any variation thereof (e.g., month and year, year).
 - b. Applicants may elect to capture only a start date, or only an end date, and use the associated tabulation relative timing variables to represent information about the date not collected.
 - c. If the applicant is only interested in collecting whether or not the subject is consuming a particular substance, start and end dates are optional and may be omitted, and SUNCF may be collected as described above.
5. Coding
- a. Coding may be performed if deemed necessary by the applicant. The tabulation variable SUDECOD is a permissible variable in the tabulation SU domain.
 - b. Coding variables are not usually displayed on CRFs. If an applicant chooses to display coding on the form, it should not be used as a field for entry by site personnel.

2.7.6.18 CDASH Tobacco Product Events and Malfunctions (EM)

Description/Overview

The EM domain is an Events domain used to collect information on malfunctions and events that may occur in the use or testing of a tobacco product device. These events may include malfunctions, calibrations, or parts replacement. It is an optional domain, to be used only if the applicant has events/issues with the tobacco product device that should be reported.

Events represented in the EM domain will be consistent with scientific and regulatory requirements. It is the applicant's responsibility to define an event and the appropriate collection period for events. This definition may vary based on product characterization and reporting of product safety. In consultation with regulatory authorities, applicants may extend or limit the scope of event collection.

Records are specific to an individual tobacco product device. The entries may be related to 1 or many subjects, depending upon the type of tobacco product device and scope of its use. Applicants will ensure that appropriate regulatory guidelines for reporting tobacco product device events are followed. If a coding dictionary is used, NSVs may need to be added to represent the various coding level variables defined in the dictionary. Event terms may be captured either as free text or via a prespecified list of terms.

If a malfunction or other product event results in a subject adverse experience, then that information should be recorded in the AE domain.

Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Events	EM	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. This field can be included into the database or populated during tabulation dataset creation.
Events	EM	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted for the CRFs that are shipped to each site. EDC: This should be prepopulated.
Events	EM	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	R/C	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system generated. This collection variable is typically

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																	collected for all domains. However, this collection variable is populated only in the tabulation DM dataset. R/C rather than HR because events may happen to or with a device that do not involve subjects, and may even be before the device was in contact with a subject.
Events	EM	N/A	N/A	4	SPTOBID	Applicant-Defined Tobacco Product ID	Applicant-Defined Tobacco Product ID	[Applicant-defined question]	[Applicant-Defined Tobacco Product ID]	Char	HR	Record the identifier for the study device.	SPTOBID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Identifier used to uniquely identify a tobacco product across all studies for all applications/submissions involving the product.
Events	EM	N/A	N/A	5	EMYN	Any Tobacco Device Event	An indication of whether any tobacco device events were experienced during the study.	Were any tobacco device events experienced?	Any Tobacco Device Events	Char	O	Indicate if the subject experienced any tobacco device events. If Yes, include the appropriate details where indicated on the CRF.	N/A	Does not map to an tabulation variable.	(NY)	N/A	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that all other fields on the CRF were deliberately left blank.
Events	EM	N/A	N/A	6	EMCAT	Category for Device Event	A grouping of topic-variable values based on user-defined characteristics.	What is the category of the device Event?	[Device Event Category]; NULL	Char	O	Record the device event category, if not preprinted on the CRF.	EMCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, and not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included as the column heading.
Events	EM	N/A	N/A	7	EMSCAT	Subcategory for Device Event	A sub-division of the EMCAT values based on user-defined characteristics.	What is the subcategory of the device event?	[Device Event Subcategory]; NULL	Char	O	Record the device event subcategory, if not preprinted on the CRF.	EMSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be preprinted on the CRF or screen and prepopulated in the data management system. This is not typically a question to which the site would provide an answer. EMSCAT can only be used if there is an EMCAT and it must be a subcategorization of EMCAT.
Events	EM	N/A	N/A	8	EMSPID	EM Applicant Defined Identifier	An applicant-defined identifier. This is typically used for preprinted or auto-generated numbers on the CRF, or any other type of identifier that does not already have a defined identifier field.	[Applicant-defined question]	[Applicant defined]	Char	O	If collected on the CRF, applicant may insert instructions to ensure each record has a unique identifier.	EMSPID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	Because SPID is an applicant-defined identifier, conformance to Question Text or Item Prompt is not applicable. Typically used as an identifier in a data query to communicate clearly to the site the specific record in question or to reconcile concomitant medications, procedures and/or medical history records with AEs or device events. If CMAENO or PRAENO is used, this is the identifier to which CMAENO or PRAENO refers. May be used to record preprinted number (e.g., line number, record number) on the CRF. This field may be populated by the applicant's data collection system.
Events	EM	N/A	N/A	9	EMTERM	Reported Term for the Device Event	The reported or prespecified name of the device event.	What is the device event term?	Device Event	Char	HR	Record only 1 device event. Use accepted terminology.	EMTERM	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Can be represented either as an open-entry field to capture verbatim terms reported by subjects or preprinted, in the situation where solicited device events of interest are captured. In most cases, the verbatim term (i.e.

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																	investigator-reported term) will be coded to a standard dictionary.
Events	EM	N/A	N/A	10	EMOCCUR	Device Event Occurrence	An indication of whether a prespecified device event or a group of device events occurred when information about the occurrence of a specific event is solicited.	Did the subject have [prespecified device event/group of device events]?	[Specific Device Event]	Char	O	Indicate if [specific Device Event] has occurred/is occurring, by checking Yes or No.	EMOCCUR	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	The collection variable EMOCCUR is used to indicate the occurrence of prespecified device events (e.g. "Did the device batteries malfunction?". EMOCCUR should not be used for spontaneously reported device events. The site should be able to indicate that the response was not asked or answered.
Events	EM	N/A	N/A	11	EMPRESP	prespecified Device Event	An indication that a specific event or group of events are prespecified on a CRF.	N/A	N/A	Char	O	N/A	EMPRESP	Maps directly to the tabulation variable listed in the Tabulation Target column.	(NY)	N/A	A hidden field on a CRF defaulted to "Y", or added during tabulation dataset creation, when the EM is prespecified. Null for spontaneously reported events. If a study collects both prespecified and free-text device events, the value of EMPRESP should be "Y" for all prespecified events and null for events reported as free-text. EMPRESP is a permissible field, and may be omitted from the tabulation dataset if all events were collected as free text.
Events	EM	N/A	N/A	12	EMSTDAT	Device Event Start Date	The start date of the device event, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What is the device event start date?	Start Date	Char	HR	Record the start date of the device event using this format (DD-MON-YYYY).	EMSTDTC	This does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable EMSTDTC in ISO 8601 format.	N/A	N/A	N/A
Events	EM	N/A	N/A	13	EMSTTIM	Start Time of Device Event	The start time of the device event, represented in an unambiguous time format (e.g., hh:mm:ss).	What is the device event start time?	Start Time	Char	R/C	Record the start time (as complete as possible) of the device event.	EMSTDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected START DATE and TIME components and populate the tabulation variable EMSTDTC in ISO 8601 format.	N/A	N/A	Collecting the time an event resolved is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail.
Events	EM	N/A	N/A	14	EMONGO	Ongoing Device Event	Indication that an device event is ongoing when no end date is provided.	Is the device event ongoing (as of [the study-specific time point or period])?	Ongoing (as of [the study-specific time point or period])	Char	O	Indicate if the device event has not resolved at the time of data collection; leave the End Date blank.	EMENRPT; EMENRF	This does not map directly to an tabulation variable. May be used to populate a value into a tabulation relative timing variable such as EMENRF or EMENRPT. When populating EMENRF, if the value of EMONGO is "Y", the value of "DURING", "AFTER" or "DURING/AFTER" may be used. When populating EMENRPT, if the value of EMONGO is "Y", the value of "ONGOING" may be used. When EMONGO refers to the Reference Period (defined in DM.RFSTDTC to DM.RFENDTC) the tabulation variable EMENRF should be populated. When EMONGO is compared to another time point, the tabulation variables EMENRPT and EMENTPT	(NY)	N/A	Completed to indicate that the event has not resolved at the time of data collection, when no end date is collected. In some cases the ongoing status may be determined from Outcome. The purpose of collecting this field is to help with data cleaning and monitoring; this field provides further confirmation that End Date was deliberately left blank. Often used as a tick/checkbox.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
														should be used. Note: EMENRPT must refer to a timestamp anchor described in EMENTPT.			
Events	EM	N/A	N/A	15	EMENDAT	Device Event End Date	The date when the device event resolved/ended, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the device event end date?	End Date	Char	R/C	Record the date that the device event resolved using this format (DD-MON-YYYY). If the EM is ongoing, leave the field blank.	EMENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable EMENDTC in ISO 8601 format.	N/A	N/A	The definition of resolved is applicant-specific. The preferred method is to collect a complete end date (if applicable). Partial dates (e.g., providing year only, month and year only) may be acceptable.
Events	EM	N/A	N/A	16	EMENTIM	End Time of Device Event	The time when the Device Event ended/resolved, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the Device Event end time?	End Time	Char	R/C	Record the time (as complete as possible) that the Device Event resolved.	EMENDTC	This does not map directly to a tabulation variable. For the tabulation dataset, concatenate all collected END DATE and TIME components and populate the tabulation variable EMENDTC in ISO 8601 format.	N/A	N/A	Collecting the time an event resolved is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail.
Events	EM	N/A	N/A	17	EMSEV	EM Severity/Intensity	The severity or intensity of the event.	What is the severity of the device event?	Severity	Char	R/C	The reporting physician/healthcare professional will assess the severity of the event using the applicant-defined categories. This assessment is subjective and the reporting physician/ healthcare professional should use judgment to compare the reported device event to similar type events observed. Severity is not equivalent to seriousness.	EMSEV	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	N/A
Events	EM	N/A	N/A	18	EMACNDEV	Actions Taken with Device	A description of the action taken, with respect to a device used in a study (which may or may not be the device under study), as a result of the event.	What action was taken with a device used in the study?	Action Taken with Device	Char	O	Record actions taken resulting from the device event that are related to a study or non-study device.	EMACNDEV	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology for actions that are related to the device (e.g., device replacement, battery replacement).
Events	EM	N/A	N/A	19	EMSI	Device Event of Special Interest	An device event of special interest (serious or non-serious) is one of scientific and medical concern specific to the applicant's product or program, for which ongoing monitoring and rapid communication by the investigator to the applicant can be appropriate. Such an event might warrant further investigation in order to characterize and understand it. Depending on the nature of the event, rapid communication by the study applicant to other parties (e.g., regulators) might also be warranted.	Is this event of special interest?	Device Event of Special Interest	Char	O	Record the investigator's opinion as to whether the event is an device event of special interest by the applicant.	N/A	Does not map to a tabulation variable.	(NY)	N/A	This collection field may be used just to trigger other CRF pages, or populate a value in EMCAT or EMSCAT. This information could be represented in a SUPPEM dataset where SUPPEM.QNAME = "EMSI" and SUPPEM.QLABEL = "Device Event of Special Interest."

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Events	EM	N/A	N/A	20	EMPATT	Pattern of Device Event	Used to indicate the pattern of the event over time.	What is the device event pattern?	Pattern	Char	O	For each device event, check the pattern of the device event. If a single event, choose Single.	EMPATT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Used to report the pattern of the EM (e.g., "INTERMITTENT", "CONTINUOUS", "SINGLE EVENT"). For crossover studies, it is <i>not</i> recommended to capture this field for intermittent events. Instead, the corresponding start and stop dates should be captured.
Events	EM	N/A	N/A	21	EMMODIFY	EM Modified Reported Term	If the value for EMTERM is modified to facilitate coding, then EMMODIFY will contain the modified text.	N/A	N/A	Char	R/C	N/A	EMMODIFY	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	This is not a data collection field that would appear on the CRF. applicants will populate this through the coding process.
Events	EM	N/A	N/A	22	EMDECOD	EM Dictionary-Derived Term	The dictionary or standardized text description of EMTERM or the modified topic variable (EMMODIFY), if applicable.	N/A	N/A	Char	O	N/A	EMDECOD	Maps directly to the tabulation variable listed in the Tabulation Target column. The applicant is expected to provide the dictionary name and version used to map the terms utilizing the Define-XML external codelist attributes.	N/A	N/A	This is typically not a data collection field that would appear on the CRF. applicants will populate this through the coding process.

Assumptions

1. The EMYN variable with the question text "Were any tobacco product device events ?" is intended to assist in the cleaning of data and in confirming that there are no missing values. This collection variable will not be represented in the tabulation dataset.
2. Coding
 - a. EMDECOD is the preferred term derived by the applicant from the coding dictionary. It is a required tabulation variable and must have a value. It is expected that the reported term (EMTERM) will be coded using a dictionary. Applicants are expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.
 - b. EMMODIFY is a permissible tabulation variable and should be included if the applicant's coding procedure permits modification of a verbatim term. The modified term is listed in EMMODIFY. The variable should be populated per the applicants's coding procedure.
3. Relative Timing Variables
 - a. The EMONGO field does not map directly to a tabulation variable, but it may be used to derive a value into a tabulation relative timing variable such as EMENRF or EMENRTPT. When populating EMENRF, if the EMONGO field is checked, a value of "DURING", "AFTER", or "DURING/AFTER" may be derived, as appropriate. When populating EMENRTPT, if the EMONGO field is checked, the value of "ONGOING" may be derived. EMENRTPT must refer to a time-point anchor as described in EMENTPT.
 - b. EMONGO is a special-use case of "Yes/No", where the question is usually presented as a single possible response of "Yes" when there is no applicable end date at the time of collection.
 - i. In this case, if the box is checked and the end date is blank, the desired tabulation relative timing variable can be derived according to assumption 3a.
 - ii. If the box is not checked (EMONGO is NULL) and an end date is present, no tabulation relative timing variable will be derived.
4. Action Taken Variables
 - a. Collection variable EMACNDEV is used to collect the action taken with the tobacco product device. The tobacco product device may or may not be the device under study. This field is usually a free-text field. If possible/desired, the applicant can create applicant-defined controlled terminology.

5. If a malfunction or other product event results in an adverse event, then that information should be recorded in the AE domain. The relationship between the AE and EM can be recorded on the CRF using EMSPID and/or EMAENO. EMAENO would be a data capture (CDASH) variable that is not submitted in SDTM-based datasets but is used to create a RELREC that links the event records.

2.7.6.19 CDASH Vital Signs (VS)

Description/Overview

Vital Signs (VS) is a Findings domain used for vital signs measurements including but not limited to blood pressure, temperature, respiration, body surface area, body mass index (BMI), height, and weight.

Specification

Metadata Specification

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
Findings	VS	N/A	Horizontal-Generic	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	VS	N/A	Horizontal-Generic	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	VS	N/A	Horizontal-Generic	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What [is/was] the (study) [subject/participant] identifier?	[Subject/Participant] (Identifier)	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be system-generated. This collection variable is typically collected in all collection domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	VS	N/A	Horizontal-Generic	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be performed on a subject.	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed within the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.
Findings	VS	N/A	Horizontal-Generic	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not a tabulation variable. The date of a measurement, test, observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable VSDTC in ISO 8601 format.	N/A	N/A	The date the VS measurements were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the observations at that visit, or the collection date can be included on the VS CRF using the date field (VSDAT).
Findings	VS	N/A	Horizontal-Generic	6	[VTESTCD]_VSPERF	Vital Signs Performed	An indication of whether a planned vital	Were [vital signs] [VTEST] performed?	Vital Signs Performed ;	Char	O	Indicate if the vital signs were collected. If Yes,	VSSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the	(NY)	N/A	This general prompt question is used as a data management tool to verify that missing results are

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
								signs measurement, series of vital signs measurements, tests, or observations was performed.	[VTEST] Performed			include the appropriate details where indicated on the CRF.		tabulation variable VSSTAT. If VSPERF="N", the value of VSSTAT will be "NOT DONE". If VSPERF="Y", VSSTAT should be null. A combination of tabulation variables (e.g., VSCAT and VSSCAT, VSTPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable VTESTCD would be populated as VSALL and an appropriate test name (VTEST) provided.			confirmed missing. This may be implemented for all tests collected on the same horizontal record or for each specific test. When mapped to the tabulation dataset, the value of VSPERF would apply to all tests on the same record. Use the collection variable [VTESTCD]_VSUPERF when implemented on a specific test basis.
Findings	VS	N/A	Horizontal-Generic	7	[VTESTCD]_VSDAT	Vital Signs Date	The date of the vital signs measurement, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date of the measurement(s)?	[VTEST] Date	Char	R/C	Record date of measurements using this format (DD-MON-YYYY).	VSDTC	This does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable VSDTC in ISO 8601 format.	N/A	N/A	A single date may be collected for all the vital sign measurements when they are performed on the same date. The date of each measurement can also be collected for each measurement using a collection variable [VTESTCD]_VSDAT. The date of the measurements may be determined from a collected date of visit; in such cases, a separate measurement date field is not required.
Findings	VS	N/A	Horizontal-Generic	8	[VTESTCD]_VSTIM	Vital Signs Time	The time of measurement, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the time of the measurement(s)?	[VTEST] Time	Char	R/C	Record time of measurement (as complete as possible).	VSDTC	This does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable VSDTC in ISO 8601 format.	N/A	N/A	A single collection time (e.g., VSTIM) may be collected for all the measurements when they are performed at the same time. The time of each measurement can also be collected using a collection variable [VTESTCD]_VSTIM.
Findings	VS	N/A	Horizontal-Generic	9	VSCAT	Category for Vital Signs	A grouping of topic-variable values based on user-defined characteristics.	What was the category of the vital signs?	[Vital Signs Category]; NULL	Char	O	Record the vital signs category, if not preprinted on the CRF.	VSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be from an applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included in the column heading.
Findings	VS	N/A	Horizontal-Generic	10	VSSCAT	Subcategory for Vital Signs	A sub-division of the VSCAT values based on user-defined characteristics.	What was the subcategory of the vital signs?	[Vital Signs Subcategory]; NULL	Char	O	Record the vital signs subcategory, if not preprinted on the CRF.	VSSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This would most commonly be either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be an applicant-defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included in the column header. VSSCAT can only be used if there is a VSCAT, and it must be a subcategorization of VSCAT.
Findings	VS	N/A	Horizontal-Generic	11	VSGRPID	Vital Signs Group ID	An applicant-defined identifier used to tie a block of related records in a single domain.	What is the vital signs group identifier?	Test Group ID	Char	O	Record unique group identifier. The applicant may insert additional instructions to	VSGRPID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	It can be beneficial to use an identifier in a data query to communicate clearly to the site the specific record in question. This group identifier ties together all the tests collected on the

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												ensure each record has a unique group identifier.					same horizontal record. This field may be populated by the applicant's data collection system.
Findings	VS	N/A	Horizontal-Generic	12	[VTESTCD]_VSTPT	Vital Signs Planned Time Point Name	A text description of planned timepoints when measurements should be taken, as defined in the protocol.	What is the planned timepoint for this vital signs measurement?	[Planned Time Point Name]	Char	R/C	Record the planned time-point labels for vital signs, if not preprinted on the CRF.	VSTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation time-point anchors VSTPTREF (text description) and VSRTDTC (date/time) may be needed, as well as tabulation variables VSTPTNUM, VSELTM.	N/A	N/A	Planned timepoints are needed to differentiate multiple sequential assessments. It is recommended that timepoints should be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Planned Time Point" can be included in the column heading. The planned timepoint of each measurement can also be collected using the collection variable [VTESTCD]_VSTPT.
Findings	VS	N/A	Horizontal-Generic	13	[VTESTCD]_VSSTAT	Vital Signs Completion Status	This variable is used to indicate that data are not available, by having the site recording the value as "Not Done".	Indicate if the [VTEST] measurement was not done.	Not Done	Char	O	Indicate if the vital signs measurement was not done.	VSSTAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(ND)	N/A	A single "Not Done" can be collected once for all tests on the same horizontal record using VSSTAT. The value of VSSTAT applies to all measurements on that record when mapped to the tabulation dataset. If needed, for each test "NOT DONE" may be collected using the collection variable [VTESTCD]_VSSTAT.
Findings	VS	N/A	Horizontal-Generic	14	[VTESTCD]_VSORRES	VS Result or Finding in Original Units	Result of the vital signs measurement as originally received or collected.	What was the result of the [VTEST] measurement?	[VTEST] (Result)	Char	HR	Record the vital sign results.	VSORRES; VTEST; VTESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. In addition to the tabulation variable VSORRES, create VTESTCD from the collection variable name and determine the value of VTEST from VTESTCD. The prompt may also contain the VTEST. Use appropriate CDISC Controlled Terminology for the test and test code.	N/A	N/A	Each test may be collected using the collection variable [TESTCD] e.g., SYSBP or [TESTCD]_VSORRES where TESTCD is the appropriate CT for the VS test code e.g., SYSBP_VSORRES. This is an examples of the types of collection variable names that can be used in a denormalized data structure.
Findings	VS	N/A	Horizontal-Generic	15	[VTESTCD]_VSORRESU	VS Original Units	The unit of the result as originally received or collected.	What was the unit of the [VTEST] measurement?	[VTEST] Unit	Char	R/C	Record or select the original unit in which these data were collected, if not preprinted on CRF.	VSORRESU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	N/A	A single Unit field can be collected once for all measurements collected on the same horizontal record using VSUNIT. The value of VSUNIT applies to all measurements on that record when mapped to the tabulation dataset. If needed for each measurement, unit may be collected using the collection variable [VTESTCD]_VSORRESU. Should be preprinted on the CRF (or enterable from a picklist) with the associated test when possible, rather than collected as free-text.
Findings	VS	N/A	Horizontal-Generic	16	[VTESTCD]_VSCLSIG	Vital Signs Clinical Significance	An indication of whether the vital signs results were clinically significant.	Was the [VTEST] result clinically significant?	[VTEST] Clinically Significant	Char	O	Record whether the vital sign result was clinically significant.	SUPPVS.QVAL	This does not map directly to an tabulation variable. This information could be represented in a SUPPVS dataset as the value of SUPPVS.QVAL where SUPPVS.QNAM = "VSCLSIG" and SUPPVS.QLABEL="Clinically Significant".	(NY)	N/A	In horizontal data collection, a collection variable [VTESTCD]_VSCLSIG may be created for each VTESTCD and added to the CRF if needed.
Findings	VS	N/A	Horizontal-Generic	17	[VTESTCD]_VSPOS	Vital Signs Position of Subject	The position of the subject during a	What was the position of the subject during the	[VTEST] Position	Char	R/C	Record the position of subject at time	VSPOS	Maps directly to the tabulation variable listed in the Tabulation Target column.	(POSITION)	(VSPOS)	Results may be affected by whether conditions for vital signs as specified in the protocol were properly met. One common

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							measurement or examination.	[VTEST] measurement?				of test (e.g. SITTING).					condition is the subject's position. If the protocol requires this type of information, then a collection variable [VTESTCD]_VSPOS may be created for each VTESTCD and added to the CRF, if needed.
Findings	VS	N/A	Horizontal-Generic	18	[VTESTCD]_VSLOC	Location of Vital Signs Measurement	A description of the anatomical location of the subject, relevant to the collection of vital signs measurements.	What was the anatomical location where the [VTEST] measurement was taken?	[VTEST] Anatomical Location	Char	O	Record or select location on body where measurement was performed, if not preprinted on CRF.	VSLOC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LOC)	N/A	Collected or preprinted on the CRF when the applicant needs to identify the specific anatomical location (e.g., ARM for blood pressure). Applicants may collect the data using a subset list of controlled terminology on the CRF. In horizontal data collection, a collection variable [VTESTCD]_VSLOC may be created for each VTESTCD and added to the CRF, if needed. LAT, DIR, and PORTOT are used to further describe the anatomical location.
Findings	VS	N/A	Horizontal-Generic	19	[VTESTCD]_VSLAT	Vital Signs Laterality	Qualifier for anatomical location, further detailing the side of the body.	What was the side of the anatomical location of the [VTEST] measurement?	Side	Char	O	Record the side of the anatomical location of the vital signs measurement.	VSLAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LAT)	N/A	May be preprinted or collected when the applicant needs to identify the specific side of the anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Findings	VS	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Although this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or in the EDC system. This field can be included in the database or populated during tabulation dataset creation.
Findings	VS	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically preprinted in the header of each CRF page for single-site studies. For studies with multiple sites, this field may be left blank so that the number can be recorded by the site, or it may be preprinted on the CRFs that are shipped to each site. EDC: This should be prepopulated.
Findings	VS	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What is the subject identifier?	Subject	Char	HR	Record the identifier for the subject.	DM.SUBJID	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be provided to the site using a prepopulated list in the system. This collection variable is typically collected in all collection domains. However, this collection variable is populated only in the tabulation DM domain.
Findings	VS	N/A	N/A	4	VISIT	Visit Name	The name of an encounter that encompasses planned and unplanned study interventions, procedures, and assessments that may be	What is the visit name?	[Visit]	Char	R/C	N/A	VISIT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	The name of the clinical encounter is typically preprinted on the CRF or displayed within the EDC for any visit-based data collection, most often in Findings domains. This Visit text description is then available in any EDC data extract for that Findings domain.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
							performed on a subject.										
Findings	VS	N/A	N/A	5	VISDAT	Visit Date	Date the encounter occurred (or started).	What [is/was] the date of the visit?	(Visit) Date	Char	R/C	Record the [date/start date] of the visit using this format (DD-MON-YYYY).	N/A	This field is not an tabulation variable. The date of a measurement, test, observation can be determined from the date/time of visit (VISDAT/VISTIM) and then concatenating the VISDAT/VISTIM components and populating the tabulation variable VSRTC in ISO 8601 format.	N/A	N/A	The date the VS measurements were collected can be determined from the visit date variable (VISDAT) and applying that date to all of the observations at that visit, or the collection date can be included on the VS CRF using the Vital Signs Date (VSDAT) field.
Findings	VS	N/A	N/A	6	VSPERF	Vital Signs Performed	An indication of whether a planned vital signs measurement, series of vital signs measurements, tests, or observations was performed.	Were vital signs performed?	Vital Signs Performed	Char	O	Indicate if vital signs were collected. If Yes, include the appropriate details where indicated on the CRF.	VSSTAT	This does not map directly to a tabulation variable. May be used to derive a value into the tabulation variable VSSTAT. If VSPERF="N", the value of VSSTAT will be "NOT DONE". If VSPERF="Y", VSSTAT should be null. A combination of tabulation variables (e.g., VSCAT and VSSCAT, VSTPT) is used to indicate that multiple tests were not done. In this situation, the tabulation variable VTESTCD would be populated as VSALL and an appropriate test name VTEST provided.	(NY)	N/A	This general prompt question is used as a data management tool to verify that missing results are confirmed missing.
Findings	VS	N/A	N/A	7	VISDAT	Vital Signs Date	The date of the vital signs measurement, represented in an unambiguous date format (e.g., DD-MON-YYYY).	What was the date of the vital signs measurement?	Date	Char	R/C	Record date of measurements using this format (DD-MON-YYYY).	VSDTC	This does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable VSDTC in ISO 8601 format.	N/A	N/A	The date of measurement can be determined from a collected date of visit (VISDAT); in such cases, a separate measurement date field is not required.
Findings	VS	N/A	N/A	8	VISTIM	Vital Signs Time	The time of measurement, represented in an unambiguous time format (e.g., hh:mm:ss).	What was the time of the vital signs measurement?	Time	Char	R/C	Record time of measurement (as complete as possible).	VSDTC	This does not map directly to an tabulation variable. For the tabulation dataset, concatenate all collected DATE and TIME components and populate the tabulation variable VSDTC in ISO 8601 format.	N/A	N/A	Collect time if it is relevant for the analysis.
Findings	VS	N/A	N/A	9	VSSPID	Vital Signs Applicant-Defined Identifier	An applicant-defined identifier. This is typically used for preprinted or auto-generated numbers on the CRF, or any other type of identifier that does not already have a defined identifier field.	[Applicant-defined question]	[Applicant defined]	Char	O	If collected on the CRF, the applicant may insert instructions to ensure each record has a unique identifier.	VSSPID	Maps directly to the tabulation variable listed in the Tabulation Target column. May be used to create RELREC to link this record with a record in another domain.	N/A	N/A	Because SPID is an applicant-defined identifier, conformance to Question Text or Item Prompt is not applicable. Typically used as an identifier in a data query to communicate clearly to the site the specific record in question or to reconcile data. May be used to record preprinted number (e.g. line number, record number) on the CRF. This field may be populated by the applicant's data collection system.
Findings	VS	N/A	N/A	10	VSTPT	Vital Signs Planned Time Point Name	A text description of planned timepoints when measurements should be taken, as defined in the protocol.	What is the planned timepoint for this vital signs measurement?	[Planned Time Point Name]	Char	R/C	Record the planned time-point labels for vital signs, if not preprinted on the CRF.	VSTPT	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation time-point anchors VSTPTREF (text description) and VSRFTDTC (date/time) may be needed, as well as tabulation variables VSTPTNUM, VSELM.	N/A	N/A	Planned timepoints are needed to differentiate multiple sequential assessments. It is recommended that timepoints should be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Planned Time Point" can be included in the column heading.
Findings	VS	N/A	N/A	11	VSCAT	Category for Vital Signs	A grouping of topic-variable values based on user-defined characteristics.	What was the category of the vital signs?	[Vital Signs Category]; NULL	Char	O	Record the vital signs category, if not preprinted on the CRF.	VSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This is most commonly either a heading or a preprinted category value on the CRF, not a question to which the

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
																	site would provide an answer. If a question is asked, the response would typically be from a applicant-defined codelist. If the form is laid out as a grid, then words such as "Category" can be included in the column heading.
Findings	VS	N/A	N/A	12	VSSCAT	Subcategory for Vital Signs	A sub-division of the VSCAT values based on user-defined characteristics.	What was the subcategory of the vital signs?	[Vital Signs Subcategory]; NULL	Char	O	Record the vital signs subcategory, if not preprinted on the CRF.	VSSCAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	Applicant-defined controlled terminology. This is most commonly either a heading or a preprinted category value on the CRF, not a question to which the site would provide an answer. If a question is asked, the response would typically be a applicant-defined codelist. If the form is laid out as a grid, then words such as "Subcategory" can be included in the column heading. VSSCAT can only be used if there is a VSCAT, and it must be a subcategorization of VSCAT.
Findings	VS	N/A	N/A	13	VSREPNUM	Vital Signs Repetition Number	The instance number of a test that is repeated within a given timeframe for the same test. The level of granularity can vary (e.g., within a timepoint, within a visit).	What was the repetition number within the timepoint for this measurement?	Repetition Number	Char	O	Record the repetition number of the measurement within the timepoint.	SUPPVS.QVAL	This does not map directly to an tabulation variable. This information could be represented in a SUPPVS dataset as the value of SUPPVS.QVAL where SUPPVS.QNAME= "VSREPNUM" and SUPPVS.QLABEL= "Repetition Number within timepoint".	N/A	N/A	The repetition number of the test/measurement within the timepoint may be preprinted on the CRF (e.g., multiple measurements of blood pressure, multiple analyses of a sample).
Findings	VS	N/A	N/A	14	VTEST	Vital Signs Test Name	Descriptive name of the test or examination used to obtain the measurement or finding.	What is the vital sign test name?	[Vital Signs Test Name]	Char	HR	Record the name of the vital sign test if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.	VTEST; VTESTCD	Maps directly to the tabulation variable listed in the Tabulation Target column. The tabulation variable VTESTCD may be determined from the value collected in VTEST. Both VTESTCD and VTEST are required in the tabulation datasets. Use appropriate CDISC Controlled Terminology for the test and test code.	(VTEST)	N/A	Required to identify which test the result is for. It is recommended that test names be preprinted on the CRF rather than collected in a free-text field. If the form is laid out as a grid, then words such as "Test" can be included in the column heading.
Findings	VS	N/A	N/A	15	VSSTAT	Vital Signs Completion Status	This variable is used to indicate that data are not available, by having the site recording the value as "Not Done".	Indicate if the vital signs measurement was not done	Not Done	Char	O	Indicate if the vital sign measurement was not done.	VSSTAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(ND)	N/A	A Not Done checkbox, which indicates the test was NOT DONE. Typically, there would be 1 checkbox for each measurement. This field can be useful on individual VS tests to confirm that a blank result field is meant to be blank.
Findings	VS	N/A	N/A	16	VSORRES	VS Result or Finding in Original Units	Result of the vital signs measurement as originally received or collected.	What was the result of the measurement?	(Result)	Char	HR	Record the vital sign result.	VSORRES	Maps directly to the tabulation variable listed in the Tabulation Target column.	N/A	N/A	N/A
Findings	VS	N/A	N/A	17	VSORRESU	VS Original Units	The unit of the result as originally received or collected.	What was the unit of the measurement?	Unit	Char	R/C	Record or select the original unit in which these data were collected, if not	VSORRESU	Maps directly to the tabulation variable listed in the Tabulation Target column.	(UNIT)	N/A	This should be preprinted on the CRF (or enterable from a picklist) with the associated test when possible, rather than collected as free-text.

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	Collection Variable	Collection Variable Label	DRAFT Collection Definition	Question Text	Prompt	Data Type	Collection Core	Case Report Form Completion Instructions	Tabulation Target	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology/CDASH Codelist Name	Implementation Notes
												preprinted on CRF.					
Findings	VS	N/A	N/A	18	VSCLSIG	Vital Signs Clinical Significance	An indication whether the vital sign result was clinically significant.	Was the result clinically significant?	Clinically Significant	Char	O	Record whether the vital sign result was clinically significant.	SUPPVS.QVAL	This does not map directly to an tabulation variable. This information could be represented in a SUPPVS dataset as the value of SUPPVS.QVAL where SUPPVS.QNAM = "VSCLSIG" and SUPPVS.QLABEL="Clinically Significant".	(NY)	N/A	N/A
Findings	VS	N/A	N/A	19	VSLOC	Location of Vital Signs Measurement	A description of the anatomical location of the subject, relevant to the collection of vital signs measurements.	What was the anatomical location where the measurement was taken?	Anatomical Location	Char	O	Record or select location on body where measurement was performed, if not preprinted on CRF.	VSLOC	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LOC)	N/A	Collected or preprinted when the applicant needs to identify the specific anatomical location (e.g., ARM for blood pressure). Applicants may collect the data using a subset list of controlled terminology on the CRF. LAT, DIR, and PORTOT are used to further describe the anatomical location.
Findings	VS	N/A	N/A	20	VSPOS	Vital Signs Position of Subject	The position of the subject during a measurement or examination.	What was the position of the subject during the measurement?	Position	Char	R/C	Record the position of subject at time of test (e.g., SITTING).	VSPOS	Maps directly to the tabulation variable listed in the Tabulation Target column.	(POSITION)	(VSPOS)	Results may be affected by whether conditions for vital signs, as specified in the protocol, were properly met. One common condition is the subject's position.
Findings	VS	N/A	N/A	21	VSDIR	Vital Signs Directionality	Qualifier further detailing the position of the anatomical location, relative to the center of the body, organ, or specimen.	What was the directionality of the anatomical location of the measurement?	Directionality	Char	O	Record the directionality.	VSDIR	Maps directly to the tabulation variable listed in the Tabulation Target column.	(DIR)	N/A	May be preprinted or collected when the applicant needs to identify the directionality of the anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF.
Findings	VS	N/A	N/A	22	VSLAT	Vital Signs Laterality	Qualifier for anatomical location, further detailing the side of the body.	What was the side of the anatomical location of the vital signs measurement?	Side	Char	O	Record the side of the anatomical location of the vital signs measurement.	VSLAT	Maps directly to the tabulation variable listed in the Tabulation Target column.	(LAT)	N/A	May be preprinted or collected when the applicant needs to identify the specific side of the anatomical location. Applicants may collect the data using a subset list of controlled terminology on the CRF.

Assumptions

1. Vital signs may be collected using either a normalized or a denormalized horizontal data structure, depending on the functionality of the data management or data capture system being used.
2. In a denormalized structure, vital signs are collected using a unique variable name for each test, resulting in a wide, horizontal dataset with multiple test results in each record. The tabulation VS structure is normalized, using 1 variable (VSTEST) for the name of the test and 1 variable (VSORRES) for the collected results, resulting in a vertical data structure in which there is 1 record for each test/result. Collection recommendations are intended to facilitate moving denormalized data to the tabulation normalized data structure, because standard transformation programming can be written when the variable naming syntax is consistent and uses CDISC root variables and Controlled Terminology.
3. The set of variables needed for a particular study may include only test result and result unit, or may include other variables such as location, laterality, position, or method.

2.8 Standards for Tabulation

The SDTM establishes a standard way to tabulate data across studies. Guidance in this section implements the SDTM for TIG Product Description, Nonclinical, and Product Impact on Individual Health use cases. SEND is a specialized approach to implement the SDTM for nonclinical research. Guidance for nonclinical use cases in this section reflects implementation of the SDTM per SEND. Implementation of the SDTM is simply referred to as "SDTM" for all other use cases in this section.

2.8.1 How to Read Domain Specifications

Domain specifications in this guide are instructions for implementing the SDTM to build datasets for representation of collected, assigned, or derived data. Domain specifications for the TIG are provided in:

- Section 2.8.8, [Specifications for Product Description](#)
- Section 2.8.9, [Specifications for Nonclinical](#)
- Section 2.8.10 [Specifications for Individual Health](#)

Guidance in this section describes how to read domain specifications provided in the sections listed above. Implementers should refer to these sections when reading this guidance.

Domain specifications will be used with guidance in this section and are organized with 1 specification per domain or dataset. All domain specifications begin with a description, expected name, and expectations for the record structure for the resulting dataset. A domain specification table follows to describe dataset variables and their attributes. Assumptions for the domain are also provided to further guide implementation. Domain specification tables are structured to present 1 row for each variable with columns to describe expected attributes of the variable in resulting datasets. The order of variables in a domain specification table reflects the expected order of variables in the resulting dataset.

The columns present in each domain specification are described below with the column name and purpose:

Num	Domain Specification Column Name	Purpose of Column Content
1	Variable Name	Specifies the name of the variable in the resulting dataset
2	Variable Label	Specifies a descriptive label for the variable
3	Type	Specifies the data type of the variable. Values for in this column are: <ul style="list-style-type: none"> • <i>Num</i> for numeric data • <i>Char</i> for character or alphanumeric data
4	Controlled Terms, Codelist, or Format	Specifies applicable controlled terminology or formats with which to populate the variable. Values in this column are: <ul style="list-style-type: none"> • The value for variable DOMAIN from CDISC Controlled Terminology (e.g., VS) • Names of 1 or more CDISC Controlled Terminology codelist, with each codelist name in parentheses • Short references to an external terminology (e.g., MedDRA) • The name of an external ISO 8601 format
5	Role	Specifies the role of the variable in the resulting dataset including information conveyed by the variable in the context of a data record and how the variable can be used. Values in this column are: <ul style="list-style-type: none"> • <i>Identifier</i> for variables which identify the study, subject, domain, pool identifier, and sequence number of the record • <i>Topic</i> for variables which specify the focus of the data record • <i>Grouping Qualifier</i> for variables which are used to group together a collection of observations within the same domain • <i>Result Qualifier</i> for variables which describe the specific results associated with the topic variable in a Findings dataset • <i>Synonym Qualifier</i> for variables which specify an alternative name for a particular variable in an observation • <i>Record Qualifier</i> for variables which define additional attributes of the observation record as a whole, rather than describing a particular variable within a record • <i>Variable Qualifier</i> for variables which are used to further modify or describe a specific variable within an observation and are only meaningful in the context of the variable they qualify

Num	Domain Specification Column Name	Purpose of Column Content
		<ul style="list-style-type: none"> <i>Rule</i> for variables which express an algorithm or executable method to define start, end, and branching or looping conditions in the Trial Design Model datasets <i>Timing</i> for variables which describe the timing of the observation
6	CDISC Notes	<p>Provides additional context for the intended use of the variable and may include:</p> <ul style="list-style-type: none"> A description of the purpose of the variable and/or what the variable means Guidelines for variable use including rules for when or how the variable should be populated, or how the contents should be formatted Example values which could appear in the variable. Such values are intended to support understanding and are not intended to influence decisions regarding data to collect and subsequently represent in the variable. For guidance on the selection of data to collect, please refer to the appropriate regulatory authority.
7	Core	<p>Specifies expectations for inclusion of the variable in the resulting dataset. Values in this column are:</p> <ul style="list-style-type: none"> <i>Req</i> for variables which are Required and must be included in the resulting dataset and cannot be null for any record. Such variables are basic to the identification of a data record or are necessary to make the record meaningful. <i>Exp</i> for variables which are Expected to be included in the resulting dataset, even if all values are null. Such variables are considered necessary to make the data record useful in the context of the domain. <i>Perm</i> for variables for which it is Permissible to include or exclude from the resulting dataset. Permissible variables must be included in the resulting dataset when data appropriate for the variable have been collected or derived, even if all values are null.

2.8.2 How to Extend Domains

If a logically related grouping of data is in scope for a domain defined in this guide but not all data can be represented using the domain variables, then data may be represented by adding variables from the SDTM to the domain or by using a Supplemental Qualifier dataset related to the domain. Prior to adding variables from the SDTM or considering a Supplemental Qualifier dataset, confirm that none of the existing domain variables will fit the need. Variables may be added to a domain and Supplemental Qualifier datasets may only be used when data are different in nature and are not in scope for existing domain variables.

Once confirmed, determine whether adding a variable from the SDTM will fit the need. If adding a variable from the SDTM meets the need, then a Supplemental Qualifier dataset will not be implemented. Supplemental Qualifier datasets will only be implemented for domains when data are not in scope for a variable defined in the SDTM.

The overall process for extending a domain is as follows:

- Select variables for the domain from the SDTM. Selection of variables must align with SDTM usage restrictions. The general approach for adding variables to a domain from the SDTM is to:
 - Include applicable Identifier variables.
 - Include applicable Qualifier variables in alignment with the SDTM General Observation Classes.
 - Include applicable Timing variables.
 - Apply the domain code to the variables as appropriate by replacing all variable prefixes (shown in the SDTM as “--”) with the domain code.
 - Set the order of variables consistent with the order defined in the SDTM.
 - Adjust the labels of the variables only as appropriate to convey their meaning in the context of the data in domain. Use title case for all labels.
 - Ensure that appropriate standard variables are being properly applied by comparing their use in the domain to their use in related TIG domains.
- Place any NSVs in a Supplemental Qualifier dataset when variables cannot be selected from the SDTM.

2.8.3 How to Create New Specifications

If data cannot be represented in a domain dataset defined in this guide, then a custom domain may be used. A custom domain may only be created when data are different in nature and are not in scope for domains described in

this guide. Custom domains will be used to represent logically related observations based on the scientific subject matter of the data and will not be created based on:

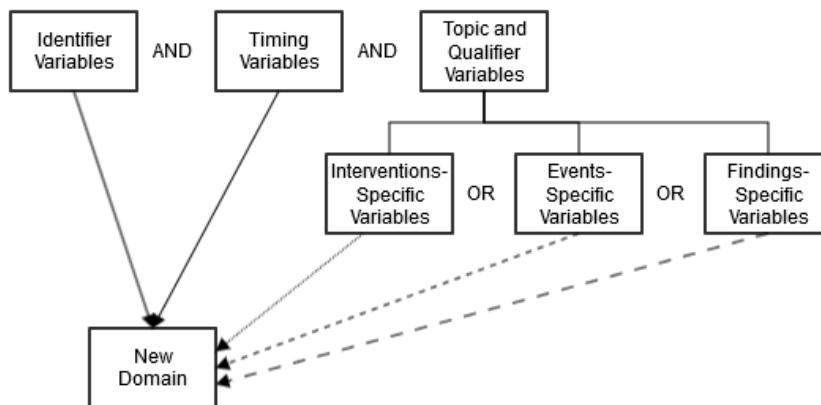
- The timing of collected observations (e.g., all vital signs measurements will be represented in the Vital Signs (VS) domain irrespective of when measurements occurred)
- How collected data are used (e.g., all vital signs measurements will be represented in VS and a custom "safety" domain will not be created for measurements used to assess safety)
- Data collection methodology (e.g., all vital signs measurements will be represented in VS irrespective of whether measurements were recorded using separate CRFs, a medical device like a fitness tracker, or an electronic diary)

Prior to creating a custom domain, confirm that none of the existing published domains will fit the need. Once confirmed, drafting a specification using conventions in Section 2.8.1, [How to Read Domain Specifications](#), is recommended to ensure expectations for the custom domain are clear. Custom domains and corresponding specifications must be created based on the 3 general observation classes (i.e., Interventions, Events, Findings) described in the SDTM. In most cases, the choice of observation class appropriate to a specific collection of data can be determined according to descriptions of these classes in the SDTM. The majority of data—which typically consists of measurements or responses to questions, usually at specific visits or time points—will fit the Findings general observation class.

The overall process for creating a custom domain is:

1. Establish a common topic or topics for the data. The common topic or topics will reflect a collection of logically related observations based on the scientific subject matter of the data.
 - a. If more than 1 topic is identified, then more than 1 domain may be needed.
 - i. In such cases, consider whether topics are hierarchical in nature, where data for 1 topic must be observed before data for a second topic can be observed. If a hierarchical relationship between topics exists, then paired domains will be created (e.g., Pharmacokinetics Concentrations (PC) and Pharmacokinetics Parameters (PP) is an established domain pair). Relationships between records in paired domains may then be represented in the Related Records (RELREC) dataset as appropriate.
2. Categorize data within the domain using Grouping Qualifier variables (e.g., --CAT, --SCAT) and identify other Qualifiers applicable to the data (e.g., --METHOD, --SPEC) as appropriate.
3. Look for a domain within this guide to serve as a prototype. If no domain seems appropriate, choose the general observation class in the SDTM (Interventions, Events, or Findings) that best fits the data given the topic of the observations.
4. Select variables for the domain from the SDTM. Selection of variables must align with SDTM usage restrictions. As illustrated in the following figure, the general approach for selecting variables for a custom domain is to:
 - a. Include applicable Identifier variables. Identifier variables STUDYID, USUBJID, DOMAIN, and --SEQ are required in all domains based on the general observation classes. Additional Identifiers may be added as needed.
 - b. Include the Topic variable from the SDTM general observation class (e.g., --TESTCD for Findings).
 - c. Include the relevant Qualifier variables from the identified SDTM general observation class.
 - d. Include the applicable SDTM Timing variables. In general, the domain must have at least 1 timing variable.
5. Determine the 2-character domain code.
 - a. To eliminate the risk of using a name that CDISC later determines to have a different meaning, domain codes beginning with the letters X, Y, and Z have been reserved for the creation of custom domains. Any letter or number may be used in the second position. The use of codes beginning with X, Y, or Z is optional, and not required for custom domains.
6. Apply the domain code to the appropriate variables in the domain by replacing all variable prefixes (shown in the SDTM as "--") with the domain code.

7. Set the order of variables consistent with the order defined in the SDTM for the general observation class.
8. Adjust the labels of the variables only as appropriate to convey their meaning in the context of the data in the newly created domain. Use title case for all labels.
9. Ensure that appropriate standard variables are being properly applied by comparing their use in the custom domain to their use in related TIG domains.
10. Place any non-SDTM variables in a Supplemental Qualifier dataset.



2.8.4 How to Use Findings About Events or Interventions

The Findings About Events or Interventions structure ("the FA structure") represents collected data about an event or intervention that cannot be represented within an Event or Intervention record or as a supplemental qualifier to such a record. For example, this may be the case when:

- There are several items which may be grouped together. If so, the FA structure allows the use of FAGRPID, FACAT, or FASCAT to group the items.
- The observation is best represented in a Findings general observation class structure. If so, the FA structure allows the use of FAORRES, FAORRESU, and FAMETHOD for results, units, and methods respectively.
- There are multiple evaluators. If so, the FA structure allows the use of FAEVALID.

The variable --OBJ is unique to the FA structure and is used with FATESTCD to represent what the topic of the observation is. FATESTCD describes the measurement/evaluation and FAOBJ describes the event or intervention that the measurement/evaluation is about. When collected data will be represented in a qualifier variable and are represented in the FA domain, the name of the variable will be used as the value of FATESTCD (e.g., FATESTCD = "OCCUR" and FATEST = "Occurrence Indicator"). The use of the same names (e.g., OCCUR) for both qualifier variables in the observation classes and FATESTCD is deliberate, but should not lead implementers to conclude that the collection of such data (e.g., occurrence) must be stored in the FA domain. If the data describe the underlying event or intervention as a whole and share its timing, then the data should be stored as a qualifier of the events or interventions record. A record in FA may or may not have a parent record in an Events or Interventions domain. If an FA record does have a parent record, the value in FAOBJ should match the value in --TERM or --TRT, unless the parent domain is dictionary coded or subject to controlled terminology. In such cases, the value represented in FAOBJ will match the value represented in --DECOD.

When to Use the FA Structure

The FA structure will be used when the following criteria are met:

Num	Criteria	Description
1	The timing of collected observations is different from the timing of the associated event or intervention as a whole.	<ul style="list-style-type: none"> • If the data item represents some action during or after the event or intervention, it may be considered to have its own timing, and meets criterion 1. • This criterion is less likely to apply to Interventions records than to Events records.

Num	Criteria	Description
		<ul style="list-style-type: none"> A finding that is about part of an event, rather than the event as a whole, meets this criterion for the use of FA. An assessment of an event that is not about the whole of an event may be a <i>snapshot</i>, an assessment at a point in time, or a <i>slice</i>, an assessment over a period of time (i.e., evaluation interval) during the event. Assessments of parts of events (snapshots or slices) are represented in FA and may or may not have parent records. <ul style="list-style-type: none"> If the FA dataset is split by parent domain, the applicant will decide which Events domain would have held a parent record for a parent-less FA record.
2	Representation of a complex quality of an observation requires 2 or more related variables not in the events or interventions classes.	<ul style="list-style-type: none"> The need to represent data which require more than 1 variable in a findings about structure, rather than by adding 2 or more supplemental qualifiers to an Events or Interventions domain, is driven by the fact that each supplemental qualifier is in a separate record that links only to the parent record. For example, a finding about an event that has a result with an associated unit.
3	Collected observations represent the occurrence of prespecified adverse events.	<ul style="list-style-type: none"> Every record in the AE domain must represent an event that actually occurred. Therefore, AE probing questions that are answered in the negative (e.g., did not occur, unknown, not done) cannot be stored in the AE domain. All answers to probing questions about the occurrence of prespecified adverse events (e.g., "Y", "N", or "NOT DONE") will be stored in the FA domain. For each "Y" response to a probing question there will be a record in the AE domain. The FA record and the AE record will be linked via RELREC.

Creating Datasets

Applicants may choose to represent data in a single FA dataset, split FA datasets, or in separate datasets with unique custom 2-character domain codes.

Num	Representation	Implementation
1	Single FA domain	<ul style="list-style-type: none"> A single FA dataset Observations will be grouped as applicable by values in FACAT and/or FASCAT.
2	Split FA domain	<ul style="list-style-type: none"> Split FA datasets per guidance in Section 2.6, Guidance for Datasets.
3	Separate domains	<ul style="list-style-type: none"> Separate datasets where: <ul style="list-style-type: none"> The DOMAIN value is applicant-defined and does not begin with FA. All guidance for the FA Structure is adhered to. <ul style="list-style-type: none"> The --OBJ variable cannot be added to a standard Findings domain. A domain is either a Findings domain or a Findings About domain, not one or the other depending on the situation. When the --OBJ variable is included in a domain, this identifies it as an FA domain. Refer to guidance in Section 2.8.3, How to Create New Specifications.

2.8.5 How to Represent Relationships

This section describes how the SDTM will be implemented to represent relationships between records within a domain, between records in different domains, and between datasets.

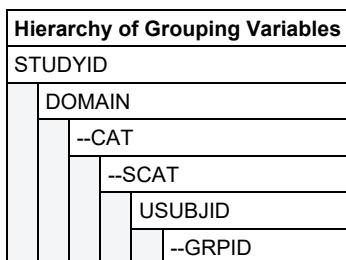
When applicable, variables IDVAR and IDVARVAL will represent variable and value pairs used as record-level keys to merge/join records between datasets. In such cases, variables represented in IDVAR may have values that are unique for:

- Each observation within a domain
- Groups of observations within a domain

The uniqueness of values by observation or groups of observations can be used to represent relationships efficiently. In cases where values are unique to observations, the variable represented in IDVAR will have values from collected data (e.g., --SPID, --RECID), when possible. When this is not possible, variables with derived values may also be used (e.g., --SEQ, LNKID, --LNKGRP).

2.8.5.1 Relating Grouping Records with Variable Values

Grouping variables are a subset of Identifier and Grouping Qualifier variables used to group records in datasets by study, domain, across subjects, by subject, and for a subject. When used per this guidance, grouping variables and their values adhere to the following hierarchy:



The following are expectations for how values in these variables will group records given their hierarchy.

Variables	Record Grouping	Purpose of Grouping
STUDYID	By study	All records with the same STUDYID value are a group of records that describe that study.
DOMAIN	By domain	All records with the same DOMAIN value are a group of records that describe that domain.
--CAT, --SCAT	Across subjects	--CAT and --SCAT values subset groups of records within a domain and apply to all subjects within the domain.
USUBJID	By subject	All records with the same USUBJID value are a group of records that describe that subject.
--GRPID	For subjects	All records in the same domain with the same --GRPID value are a group of records within USUBJID.

The optional grouping identifier variable --GRPID may be used in all domains based on the general observation classes. --GRPID identifies relationships between records within a USUBJID within a single domain and has no inherent meaning across subjects or across domains. Relationships between observations are defined by assigning the same unique character value to the --GRPID variable for sets of related observations. The values used for --GRPID can be any values the applicant chooses. --GRPID values are not intended to have any meaning across subjects and are usually assigned during or after data collection.

Using --GRPID in the general-observation class domains can reduce the number of records in the RELREC, SUPP--, and CO datasets, when those datasets represent relationships/associations for records or values to a "group" of general observation class records.

2.8.5.2 Relating Subject Records and Datasets

The Related Records (RELREC) special-purpose dataset is used to describe relationships between records for a subject in different datasets and relationships between datasets. RELREC will not be used to represent relationships already represented in Supplemental Qualifier (SUPP--) datasets for nonstandard variables and attributions or the Comments (CO) dataset for unstructured free-text.

Relationships represented in RELREC are *collected* relationships. The RELREC dataset should be used to represent either:

- explicit relationships, (e.g., concomitant medications taken as a result of an adverse event) or
- information of a nature that necessitates using multiple datasets and that may need to be examined together for analysis or proper interpretation.

Subject records or datasets expressing a relationship are specified using the key variables STUDYID, RDOMAIN (the domain code of the record or dataset in the relationship) with IDVAR (the variable that identifies the related record(s)). Each record in the RELREC special-purpose dataset contains keys that identify a record (or group of records) and an identifier for the relationship which is stored in the RELID variable. The value of RELID is chosen by the applicant and it is recommended that applicants use a standard system or naming convention for RELID (e.g., all letters, all numbers, capitalized).

Relationships Between Records for a Subject

Relationships between records for a subject in different datasets are specified using the key variables STUDYID, RDOMAIN, and USUBJID, along with IDVAR and IDVARVAL (the value of the identifying variable).

IDVARVAL will contain the value of the variable described in IDVAR. Single records can be related by using a unique-record-identifier variable such as --SEQ in IDVAR. Groups of records can be related by using grouping variables such as --LNKID or --LNKGRP in IDVAR. Using --LNKID or --LNKGRP can be a more efficient method of representing relationships in RELREC when relating a single or group of records in one dataset to a group of records in another dataset. Variable RELTYPE will not be used when relating records for a subject and is only

used when representing relationships between datasets. The value of RELID will be identical for all related records within USUBJID.

Relationships Between Datasets

Relationships between datasets are represented using a single record for each related dataset that identifies the key(s) of the dataset that can be used to relate the respective records. Relationships between datasets are specified using the key variables STUDYID, RDOMAIN, and IDVAR only. The values of variables USUBJID and IDVARVAL will be null as relationships between specific subject records will not be identified. The variable RELTYPE will identify the type of relationship between the datasets (e.g., a one-to-one or parent-child relationship). The allowable values for RELTYPE are ONE and MANY per CDISC Controlled Terminology. This information defines how a merge/join would be written, and what would be the result of the merge/join. The possible combinations are:

Num	Combination	Description
1	ONE, ONE	Indicates there is not a hierarchical relationship between the datasets and the records in the datasets. Only 1 record from each dataset will potentially have the same value of the IDVAR within USUBJID.
2	ONE, MANY	Indicates there is a hierarchical (parent-child) relationship between the datasets. One record within USUBJID in the dataset identified by RELTYPE = "ONE" will potentially have the same value of the IDVAR with many (1 or more) records in the dataset identified by RELTYPE = "MANY".
3	MANY, MANY	This combination is unusual and challenging to manage in a merge/join, and may represent a relationship that was never intended to convey a usable merge/join.

2.8.5.3 Relating NSVs and Attributions to a Domain

The Supplemental Qualifiers (SUPP--) special-purpose dataset model is used to represent both NSVs and attributions with their relationship to records in a parent dataset. SUPP-- datasets will only be used with datasets based on the general-observation classes described in the SDTM (Events, Findings, Interventions) and Demographics (DM).

There will be only 1 SUPP-- dataset for a parent dataset. Relationships between records in the SUPP-- dataset and observations in the parent dataset are specified using the key variables STUDYID, RDOMAIN (the domain code of the observation in the relationship), USUBJID or POOLID (for nonclinical studies only), along with IDVAR (the name of the variable from the parent dataset that identifies the related observation(s)) and IDVARVAL (the value of the identifying variable). IDVAR and IDVARVAL will be populated in all SUPP-- datasets with the exception of SUPPDM. IDVAR and IDVARVAL will not be populated in SUPPDM. When populated, IDVARVAL will contain the value of the variable described in IDVAR. Single records can be related by using a unique-record-identifier variable, such as --SPID or --SEQ, in IDVAR. Groups of records can be related by using grouping variables such as --GRPID in IDVAR. Using --GRPID can be a more efficient method of representing relationships when relating an NSV or attribution to a group of observations in the parent dataset. Variable QORIG represents where values represented in IDVARVAL originated (e.g., a value was collected via CRF). QORIG be populated with origin types for SDTM datasets described in the CDISC Define-XML standard.

Nonstandard Variables

SUPP-- represents the metadata and data for each NSV/value combination and relates this to the observation or observations qualified by the NSV in the parent dataset. The name, label, and value of the NSV are represented in SUPP-- dataset variables QNAM, QLABEL, and QVAL, respectively. The origin of the NSV value will be represented in variable QORIG. When the value of an NSV is assigned, variable QEVAL will represent the role of the individual or individuals who assigned the value.

Attributions

An *attribution* is typically an interpretation or subjective classification of 1 or more observations by a specific evaluator. A SUPP-- dataset can contain both objective data (where values are collected or derived algorithmically) and subjective data (attributions where values are assigned by a person or committee). A variable name, label, and value for the attribution are represented in SUPP-- dataset variables QNAM, QLABEL, and QVAL, respectively. The origin for the attribution will be represented in variable QORIG. For objective data, the value in QEVAL will be null. For subjective data, the value in QEVAL should reflect the role of the person assigning the value.

For Interventions and Events general-observation class domains, all subjective data are assumed to be attributed to the investigator. For observations that have primary and secondary evaluations of specific qualifier variables, applicants should put data from the primary evaluation into the parent dataset and data from the secondary

evaluation into the Supplemental Qualifier datasets (SUPP--). Within each SUPP-- record, the value for QNAM should be formed by appending a "1" to the corresponding standard domain variable name. In cases where the standard domain variable name is already 8 characters in length, applicants should replace the last character with a "1" (incremented for each additional attribution).

2.8.5.4 Relating Comments to a Domain

The Comments (CO) special-purpose domain is used to capture unstructured free-text comments. It allows for the submission of comments related to a particular domain or those collected on separate general-comment log-style pages not associated with a domain. Comments may be related to a subject, a domain for a subject, or to specific parent records in any domain. The CO special-purpose domain is structured similarly to the Supplemental Qualifiers (SUPP--) dataset, in that it uses the same set of keys (STUDYID, RDOMAIN, USUBJID, IDVAR, and IDVARVAL) to identify related records. All comments except those collected on log-style pages not associated with a domain are considered child records of subject data captured in domains. STUDYID, USUBJID (or POOLID), and DOMAIN (with the value CO) must always be populated. RDOMAIN, IDVAR, and IDVARVAL should be populated as follows:

- Comments related only to a subject in general would have RDOMAIN, IDVAR, IDVARVAL null, as the only key needed to identify the relationship/association to that subject is USUBJID (or POOLID in the case of comments on a pool of subjects).
- Comments related only to a specific domain (and not to any specific record(s)) for a subject would populate RDOMAIN with the domain code for the domain with which they are associated. IDVAR and IDVARVAL would be null.
- Comments related to specific domain record(s) for a subject would populate the RDOMAIN, IDVAR, and IDVARVAL variables with values that identify the specific parent record(s).

Additional information may be placed in COREF (e.g., CRF page number or name) to further describe the comment's relationship to the parent record. This can only be done if the relationship cannot be represented using the variables RDOMAIN, IDVAR, and IDVARVAL. Timing variables may also be added to the CO special-purpose domain per guidance in Section 2.8.9.4, [SEND Comments \(CO\)](#).

As with Supplemental Qualifiers (SUPP--) and Related Records (RELREC), --GRPID and other grouping variables can be used as the value in IDVAR to identify comments with relationships to multiple domain records. The limitation of this is that a single comment may only be related to a group of records in 1 domain (RDOMAIN can have only 1 value). If a single comment relates to records in multiple domains, the comment may need to be repeated in the CO special-purpose domain to facilitate the understanding of the relationships.

2.8.5.5 Relating Findings to Pooled Subjects

In nonclinical studies it is common that a single finding may be captured for multiple subjects. Variable POOLID will be used with the Clinical Observation (CL), Food and Water Consumption (FW), Laboratory Test Results (LB), Pharmacokinetics Concentrations (PC), and Pharmacokinetics Parameters (PP) domains to support subject pooling in conjunction with the POOLDEF special-purpose domain.

The following table lists some common examples where pooling may occur.

Num	Domain	Example
1	Clinical Observations (CL)	Clinical signs for group-housed subjects may contain cage-level findings for which a particular subject cannot or has not been identified. For example, the technician may notice liquid stool in the cage but did not see which subject produced the stool.
2	Food and Water Consumption (FW)	Food consumption for group-housed subjects may be recorded at the cage level. This method for pooling allows grams/cage/day or grams/cage/week to be reported.
3	Laboratory Test Results (LB)	In small-animal studies there may be scheduled clinical chemistry tests where a single subject may not be able to provide the volume of blood needed for testing. Therefore, blood from multiple subjects may be drawn to get the appropriate volume.
4	Pharmacokinetics Concentrations (PC)	In animal studies there may be scheduled blood draws at various time points, to be analyzed for the compound of interest. These concentrations are then used in pharmacokinetic or toxicokinetic calculations. A single subject may not be able to provide the volume of blood needed for testing and therefore blood from multiple subjects may be drawn to get the appropriate volume.

5	Pharmacokinetics Parameters (PP)	In most small animal studies it is not feasible to create a complete pharmacokinetic profile over time on an individual subject. Multiple subjects are sampled at any given time point and all contribute to a single pharmacokinetic profile. The POOLID reflects the pool of subjects that contributed to a pharmacokinetic profile. Note, however, that this does not indicate whether a subject contributed once or several times. In some instances, blood samples may have been pooled prior to analysis to achieve a certain volume, and POOLID will be reflected in the PC domain. When multiple pools in the PC domain contribute to a single pharmacokinetic profile, a new POOLID composed of all the subjects is used in PP.
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POOLID and USUBJID are mutually exclusive. When POOLID is used, USUBJID will be null; if a USUBJID is recorded, the POOLID will be null. POOLID values are unique for a given set of subjects and a pool will consist of at least one subject. Although the same value of POOLID may not be re-used to refer to different sets of subjects, different POOLIDs may be used to refer to the same set of subjects. Because POOLID is unique for a set of subjects, **a new POOLID must be generated if the subjects within the pool change**. An example of this is when a member of a pool dies, and the number of subjects in the pool is either reduced or a new subject is assigned to that pool. The values of POOLID are applicant defined. Some examples of POOLIDs include:

- A concatenation of subject IDs: "ABC-1001, ABC-1002, ABC-1003, Cage1-1001, Cage2-1002"
- Cage identifier and study day: "Cage1-Day 1-Day-27, Cage1-Day-28-54"
- Sequential: "POOL1," "POOL2"

2.8.5.6 Relating Findings to Information Sources

In nonclinical in vitro studies the source of information may be from a variety of levels within an experiment. To identify the relationship of the findings data to the source of the information in the experiment a relationship dataset, Related References Dataset (RELREF) is used. The RELREF dataset will identify how information is related to the design of the study and to other sources of information within the study. For example, a genetic toxicology study may have information that is expressed for an entire assay, other information based on replicate sets of petri plates from the same trial set (having the same test conditions), and additional information for the individual petri plates.

The relref.xpt dataset shows each source of information (REFID), how it is related to the study design (STUDYID, SETCD), and how it relates to other sources of information on the assay (PARENT, LEVEL, LVLDESC).

2.8.6 Guidance for Trial Design Datasets

The purpose of the SDTM Trial Design Model is to represent a brief, clear description of the overall plan and design of studies of tobacco products. Trial Design datasets contain study-level, rather than subject-level, information. The Trial Design datasets based on the Trial Design Model describe the planned design of the study and provide the representation of the study product in its most granular components, as well as the representation of all sequences of these components as described in the protocol.

Guidance in this section is applicable to TIG Nonclinical and Product Impact on Individual Health use cases only. In this section, the term "trial" is equivalent to "study." The TIG guides implementation of the Trial Design datasets described in the following table for use cases as indicated.

Num	Dataset	Description	Use Case(s)
1	Trial Arms (TA)	Represents each planned arm in the study including the sequences of elements in each epoch for each arm. The TA and TE datasets are interrelated and provide the building blocks for subject-level information.	<ul style="list-style-type: none"> • Nonclinical • Product Impact on Individual Health
2	Trial Elements (TE)	Represents the elements used in the study including unique codes for each element, element descriptions, and the rules for starting and ending an element. The TA and TE datasets are interrelated and provide the building blocks for subject-level information.	<ul style="list-style-type: none"> • Nonclinical • Product Impact on Individual Health
3	Trial Visits (TV)	Represents the planned order and number of visits in the study within each arm	<ul style="list-style-type: none"> • Product Impact on Individual Health
4	Trial Inclusion/Exclusion (TI)	Represents the inclusion and exclusion criteria for the study	<ul style="list-style-type: none"> • Product Impact on Individual Health
5	Trial Summary (TS)	Represents key summary characteristics for the study	<ul style="list-style-type: none"> • Nonclinical • Product Impact on Individual Health

Num	Dataset	Description	Use Case(s)
6	Trial Sets (TX)	Represents planned sets of subjects (e.g., in vivo studies) or sources of information (e.g., in vitro studies) that result from combinations of experimental factors defined for the study	<ul style="list-style-type: none"> Nonclinical

2.8.6.1 Summary of Trial Design Concepts

The following table describes concepts represented using Trial Design datasets. When concepts or aspects of concepts are related to either Nonclinical or Product Impact on Individual Health use cases but not both, this is denoted in the Description column.

Num	Concept	Description
1	Trial design	The design of a study is a plan for outlining the activities subjects will experience and what data will be collected about them, in the course of the study, to address the study's objectives.
2	Trial group	Nonclinical only: A <i>study group</i> describes the applicant-defined protocol structure commonly used in nonclinical studies, where study subjects or sources of information (REFIDs) are allocated to study groups within the study protocol. These groups may be defined for a variety of experimental purposes. Groups are frequently defined to separate subjects exposed to different products, but there may be other considerations involved in the design of any particular study. For purposes of the TIG, a <i>study group</i> is a collection of subjects which have been designated with the same applicant-defined protocol group code. A study group consists of 1 or more study sets and is represented in the datasets with the TX parameter SPGRPCD (Applicant-Defined Group Code).
3	Trial set	Nonclinical only: A <i>study set</i> is a collection of subjects or sources of information (REFIDs) that have a common set of parameters defined in the protocol, where those parameters include experimental parameters (e.g., diet restriction), product exposure parameters, and/or applicant-defined attributes (e.g., control-group designation). Each subject or source of information (REFID) must be assigned to 1 and only 1 study set. Each study set in an in vivo study should be assigned to a single study arm. In vivo studies: There should be no planned parameters of interest that could further subdivide a study set. Each study set should be assigned to a single group. Each study set in an in vivo study should be assigned to a single study arm. In vitro studies: study sets can be further subdivided into additional study sets.
4	Epoch	As part of the design of a study, the planned periods or phases of subjects' participation are divided into epochs. Each epoch is a period of time that serves a purpose in the study as a whole. Typically, the purpose of an epoch will be to expose subjects to a product, to prepare for such a period (e.g., screening period, wash-out period), or to gather data on subjects after exposure to a product has ended. It is possible for epochs to span multiple elements for some or all study arms.
5	Arm	An <i>arm</i> is a planned path through the study. This path covers the entire time of the study. The group of subjects assigned to a planned path is also often referred to as an "arm." Each subject is assigned to 1 and only 1 planned arm. Nonclinical in vitro studies only: Nonclinical in vitro studies do not typically have defined arms.
6	Study cell	Product Impact on Individual Health only: Each planned path through the study (i.e., each arm) is divided into pieces, 1 for each epoch. Each of these pieces is called a <i>study cell</i> . Thus, there is a study cell for each combination of arm and epoch. Each study cell represents an implementation of the purpose of its associated epoch. For an epoch whose purpose is to expose subjects to product, each study cell associated with the epoch has an associated strategy.
7	Element	An <i>element</i> is a basic building block in the study design. All elements are related to planned interventions, which may involve exposure to a product or no exposure to a product, during a period of time. Elements for which the planned intervention does not involve exposure to a product could include but are not limited to screening and wash-out.
8	Study cells and elements	Product Impact on Individual Health only: Many studies involve a single, planned exposure within a study cell. For some studies, however, the strategy associated with a study cell involves a complex series of exposures to product. In such cases it may be important to track the component steps in a strategy operationally; analyses also might require that data be grouped by the exposure step during which it was collected. The steps within a strategy may involve different exposures to product or exposure to more than one product. When the strategy for a study cell is simple, the study cell will contain a single element, and for many purposes there is little value in distinguishing between the study cell and the element. However, when the strategy for a study cell consists of a complex series of exposures, a study cell can contain multiple elements. There may be a fixed sequence of elements, or a repeating cycle of elements, or some other complex pattern. In these cases, the distinction between a study cell and an element is very useful.
9	Branch	In a study or trial with multiple arms, the protocol plans for each subject to be assigned to 1 arm. The time at which this assignment takes place is often the point at which arms with common elements diverge and is referred to as a <i>branch point</i> . For many studies or trials, the assignment to an arm happens once so there is a single branch point. Subjects are assigned to an arm all at the same time. For other studies or trials, there may be 2 or more branches that collectively assign a subject to an arm. The process that makes this assignment may be a randomization, but this is not always the case.

Num	Concept	Description
10	Products	<p>The word "product" may be used in connection with epochs or elements, but has somewhat different meanings in each context:</p> <ul style="list-style-type: none"> Because epochs cut across arms, an epoch involving exposure to a product is a higher-level concept that does not specify anything that differs between arms. Product Impact on Individual Health only: A <i>study cell exposure</i> is specific to a particular arm. For example, a parallel study might have study cell exposures to 2 products, without any additional detail being specified. A study cell is at a relatively high level, the level at which exposures might be planned in an early conceptual draft of the study, or in the title or objectives of the study. An element may be fairly detailed and may be a short description of exposure to product.
11	Visit	<p>Product Impact on Individual Health only: The notion of a visit—an encounter with a subject—derives from studies where subjects interact with the investigator during visits to the investigator's clinical site. However, the term is used in other studies, where a study visit may not correspond to a physical visit. For example, in a study with inpatients, time may be subdivided into visits, even though subjects are in hospital throughout the study. For example, data for a screening visit may be collected over the course of more than 1 physical visit. One of the main purposes of visits is the performance of assessments, but not all assessments need take place at clinic visits; some assessments may be performed by means of telephone contacts, electronic devices, or call-in systems. The protocol should specify what contacts are considered visits and how they are defined.</p>

2.8.6.2 Steps for Representing Trial Design

The following are recommended steps to support implementation of Trial Design datasets. Implementers are encouraged to start with representation of more-familiar concepts, such as arms, and move to less-familiar concepts, such as elements and epochs. In practice, the actual process to implement Trial Design datasets may depart from these steps with some steps overlapping and some steps not relevant to a specific study design. When steps or aspects of steps are specific to Product Impact on Individual Health use cases only, this is denoted in the step.

1. Start with a clear understanding of your study design based on the protocol, especially the distinct paths of activities subjects will experience that spans the entire study. These paths are the arms for the study. Each path can have decision points where the paths diverge based on some criteria.
 - a. **Product Impact on Individual Health only:** Start from the flow chart or schema diagram usually included in the protocol. This diagram will show how many arms the study has, and the branch points or decision points where the arms diverge.
2. Write down the decision rule for each branching point in the diagram. Does the assignment of a subject to an arm depend on a randomization? On whether the subject responded to a study assessment? On some other criterion?
3. If the study has multiple branching points, check whether all the branches that have been identified really lead to different arms. The arms will relate to the major comparisons the study is designed to address. For some studies, there may be a group of somewhat different paths through the study that are all considered to belong to a single arm.
4. For each arm, identify the major time periods of evaluations of the tobacco product that subjects assigned to that arm will go through. These are the elements, or building blocks, of which the arm is composed.
5. Define the starting point of each element. Define the rule for how long the element should last. Determine whether the element is of fixed duration.
6. Re-examine the sequences of elements that make up the various arms and consider alternative element definitions. Would it be better to "split" some elements into smaller pieces or "lump" some elements into larger pieces? Such decisions will depend on the aims of the study and plans for analysis.
7. Compare the various arms and, where appropriate, define epochs.
 - a. **Product Impact on Individual Health only:** In most studies especially blinded studies, the pattern of elements will be similar for all arms, and it will make sense to define epochs. Assign names to these epochs. During the conduct of a blinded study, it will not be known which arm a subject has been assigned to, or which product exposure elements they are experiencing, but the epochs they are passing through will be known.

8. **Product Impact on Individual Health only:** Identify the visits planned for the study. Define the planned start timings for each visit, expressed relative to the ordered sequences of elements that make up the arms. Define the rules for when each visit should end.
9. **Product Impact on Individual Health only:** Identify the inclusion and exclusion criteria to be able to populate the Trial Inclusion/Exclusion Criteria (TI) dataset. If inclusion and exclusion criteria were amended so that subjects entered under different versions, populate TIVERS to represent the different versions.
10. Populate the TS dataset with summary information.

2.8.7 How to Populate Records and Variables

Guidance in this section will be used with detailed guidance in the following sections to implement tabulation standards.

- Section 2.8.8, [Specifications for Product Description](#)
- Section 2.8.9, [Specifications for Nonclinical](#)
- Section 2.8.10, [Specifications for Individual Health](#)

2.8.7.1 General Guidance

Guidance in this section describes conventions for the population of tabulation records and variables. Conventions in this section are both general and provided by general observation class. When conventions are applicable to TIG Nonclinical and Product Impact on Individual Health use cases, this is denoted in the Implementation column.

The following are **general conventions** for variable population:

Num	Variable Population	Implementation						
1	Text strings greater than 200 characters	<p>When text strings greater than 200 characters are collected, the following conventions for general observation class variables and SUPP-- datasets will be adhered to:</p> <ul style="list-style-type: none"> • The first 200 characters of text should be stored in the parent domain variable and each additional 200 characters of text should be stored in a record in the SUPP-- dataset. <ul style="list-style-type: none"> ◦ When splitting a text string into several SUPP-- records, the text should be split between words to improve readability. ◦ The value of the first QNAM representing text over 200 characters will be the original domain variable name without any numeric suffix. ◦ The values for subsequent QNAMs will be sequential variable names, formed by appending a 1-digit integer, beginning with 1, to the original domain variable name. In cases where the standard domain variable name is already 8 characters in length, applicants will replace the last character with a digit when creating values for QNAM. <ul style="list-style-type: none"> ▪ e.g., For Other Action Taken in Adverse Events (AEACNOTH), values for QNAM for the SUPPAE records would have the values AEACNOT1, AEACNOT2, AEACNOT3, and so on. ◦ The value for QLABEL should be the original domain variable label for all QNAM values. 						
2	"Yes/No" values	<ul style="list-style-type: none"> • For variables where the response is "Yes" or "No", both "Y" and "N" will be populated for responses. This eliminates confusion regarding whether a blank response indicates "N" or is a missing value. • Some variables are collected or derived in a manner that allows only 1 response (e.g., a single checkbox for "Yes"). In situations such as these, where it is unambiguous to populate only the response of interest, only 1 value will be populated ("Y" or "N") and the alternate value will be blank. 						
3	--FOCID	<ul style="list-style-type: none"> • Variable --FOCID is populated when a specific part of a subject or specimen is identified as a study-specific point of interest (e.g., injection site, biopsy site, treated site, region of the body). • When used, the variable serves as a cross-domain identifier for the study-specific focus of interest; any records relating to the same focus would have the same FOCID value. 						
4	--SEQ, --RECID	<p>Variables --SEQ and --RECID are populated to explicitly identify domain records in different ways. Differences in variable population are described below.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>--SEQ</th> <th>--RECID</th> </tr> </thead> <tbody> <tr> <td>Values uniquely identify <i>records for subjects</i> within a domain.</td> <td>Values uniquely identify <i>records</i> within a domain.</td> </tr> <tr> <td>The relationship between records and values is not one-to-one. <ul style="list-style-type: none"> • Values may change between versions of datasets. </td> <td>There is a one-to-one relationship between records and values. <ul style="list-style-type: none"> • Values for records do not change between versions of datasets even when content is modified. </td> </tr> </tbody> </table>	--SEQ	--RECID	Values uniquely identify <i>records for subjects</i> within a domain.	Values uniquely identify <i>records</i> within a domain.	The relationship between records and values is not one-to-one. <ul style="list-style-type: none"> • Values may change between versions of datasets. 	There is a one-to-one relationship between records and values. <ul style="list-style-type: none"> • Values for records do not change between versions of datasets even when content is modified.
--SEQ	--RECID							
Values uniquely identify <i>records for subjects</i> within a domain.	Values uniquely identify <i>records</i> within a domain.							
The relationship between records and values is not one-to-one. <ul style="list-style-type: none"> • Values may change between versions of datasets. 	There is a one-to-one relationship between records and values. <ul style="list-style-type: none"> • Values for records do not change between versions of datasets even when content is modified. 							

Num	Variable Population	Implementation	
		<ul style="list-style-type: none"> When a record is deleted, the value for the record may be reused to identify another record. 	<ul style="list-style-type: none"> When a record is deleted, the value for the record will not be reused to identify another record.
		Variable is numeric with numeric values.	Variable is character with numeric, character, or alphanumeric values.
		Conventions for establishing and maintaining values are applicant-defined. Values may or may not be sequential depending on data processes and sources.	
5	--GRPID	The value of --GRPID is generally assigned during or after data collection at the discretion of the applicant.	
6	--REFID	Values for --REFID are applicant-defined and can be any alphanumeric strings the applicant chooses, consistent with their internal practices.	
7	--CAT, --SCAT	<ul style="list-style-type: none"> Values for --CAT and/or --SCAT are known (identified) about the data before it is collected. Variable --SCAT will be populated only when there is a value in variable --CAT. Values for --CAT and --SCAT will not be the domain name or dictionary classification represented in --DECOD and --BODSYS. 	
8	--STAT	<ul style="list-style-type: none"> In general observation class domains, --STAT will be populated with "NOT DONE" when data are not collected for the topic of the observation. 	

The following are conventions for variable population in **Interventions and Events** class domains.

Num	Variable Population	Implementation																																		
1	Prespecified interventions and events (--PRESP, --OCCUR, --STAT, --REASND)	Product Impact on Individual Health only: Interventions (e.g., concomitant medications) and events (e.g., medical history) can be collected as responses to a prespecified list of treatments or terms. In such cases:																																		
		<ul style="list-style-type: none"> --PRESP represents when topic variable values, specific interventions (--TRT), or events (-TERM) were prespecified at the time of data collection. Values will be "Y" (for "Yes") or a null value. --OCCUR represents whether prespecified interventions or events occurred or did not occur. Values will be populated for prespecified interventions and events only. Possible values are "Y" and "N" (for "Yes" and "No"). When an intervention or event is not prespecified, the value of --OCCUR will be null. --STAT and --REASND can be used to provide information about prespecified interventions and events for which there is no response (e.g., investigator forgot to ask). In such cases the value of --STAT will be "NOT DONE" and the value of --REASND will be the reason when collected. 																																		
		The following table shows the population of --PRESP, --OCCUR, --STAT, and --REASND for different data collection scenarios.																																		
		<table border="1"> <thead> <tr> <th>Collection Scenario</th> <th>--PRESP Value</th> <th>--OCCUR Value</th> <th>--STAT Value</th> <th>--REASND Value</th> </tr> </thead> <tbody> <tr> <td>An intervention or event was prespecified at the time of collection and occurred.</td> <td>Y</td> <td>Y</td> <td></td> <td></td> </tr> <tr> <td>An intervention or event was prespecified at the time of collection and did not occur.</td> <td>Y</td> <td>N</td> <td></td> <td></td> </tr> <tr> <td>An intervention or event was prespecified at the time of collection with no response and no reason collected.</td> <td>Y</td> <td></td> <td>NOT DONE</td> <td></td> </tr> <tr> <td>An intervention or event was prespecified at the time of collection with no response and reason collected.</td> <td>Y</td> <td></td> <td>NOT DONE</td> <td>Forgot to ask.</td> </tr> <tr> <td>A spontaneously reported intervention or event was collected.</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>					Collection Scenario	--PRESP Value	--OCCUR Value	--STAT Value	--REASND Value	An intervention or event was prespecified at the time of collection and occurred.	Y	Y			An intervention or event was prespecified at the time of collection and did not occur.	Y	N			An intervention or event was prespecified at the time of collection with no response and no reason collected.	Y		NOT DONE		An intervention or event was prespecified at the time of collection with no response and reason collected.	Y		NOT DONE	Forgot to ask.	A spontaneously reported intervention or event was collected.				
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A spontaneously reported intervention or event was collected.																																				
2	Reason for an action or activity	<ul style="list-style-type: none"> For Interventions class domains, --INDC will represent the medical condition for which the intervention was given and --ADJ will represent the reason for an adjustment to exposure, when collected. For Events class domains, reasons for performing an activity will be represented using nonstandard variable(s) in the SUPP-- dataset with QNAME = --REAS. 																																		

The following are conventions for variable population in **Findings** class domains.

Num	Record and Variable Population	Implementation
1	Result precision	<ul style="list-style-type: none"> For numeric non-derived data, --ORRES will represent results to precision collected. Precision will not be artificially changed due to computer storage considerations. For numeric derived data, --ORRES and --STRESC will represent the correct number of significant figures based upon the calculation used to derive the value. Trailing zeroes will be retained when significant.
2	Standardized units	Applicants may standardize units within a study for a given test per scientific and regulatory requirements. Standardization of units is recommended when data for the same test are collected via

Num	Record and Variable Population	Implementation																					
		different sources using different units. In such cases, --ORRESU will represent the collected unit and --STRESU will represent the standardized unit.																					
3	Original and standardized results (--ORRES, --ORRESU, --STRESC, --STRESU, --STRESN)	<p>If supplemental free text is collected for a result via CRF, then refer to Section 2.8.7.4, Free Text from Case Report Forms (CRFs). For responses collected via QRS instruments, refer to Section 2.8.7.2, Questionnaires, Ratings, and Scales.</p> <p>For all other results:</p> <pre> graph LR A["--ORRES (All original values)"] --> B["--STRESC (Derive or copy all results)"] B --> C["--STRESN (Numeric results only)"] </pre> <ul style="list-style-type: none"> --ORRES will be populated with the result of the measurement or finding as originally collected or received, using controlled terminology when applicable. <ul style="list-style-type: none"> When applicable, the unit associated with the value of --ORRES will be populated in --ORRESU, using controlled terminology. Values will be populated in --STRESC when --ORRES is populated. The value of --STRESC will be: <ul style="list-style-type: none"> Derived by the conversion of numeric values in --ORRES to numeric values with standard units. Standard units will be represented in --STRESU using controlled terminology. <ul style="list-style-type: none"> Numeric --ORRES values with characters attached (e.g., a greater than (>) or less than (<) sign) will be converted to standard units and the value of --STRESC will maintain the attached character (e.g., >10,000, <1). The assigned of the value of --ORRES. <ul style="list-style-type: none"> For nonclinical studies, in the Macroscopic and Microscopic Findings (MA/MI) domains, --ORRES may contain a finding with multiple concatenated modifiers. In this case, --STRESC would represent only the finding without the modifiers. Numeric values represented in --STRESC will be assigned to --STRESN. If --STRESC is a character value, then, --STRESN will be null. <ul style="list-style-type: none"> Numeric values with attached characters (e.g., >10,000, <1) are considered to be character results and will not be populated in --STRESN. 																					
4	Reason Test Performed (-REASPF)	--REASPF will represent the reason a test was performed, if collected.																					
5	Tests not done	<p>When an entire examination (e.g., Laboratory Test Results (LB)), a group of tests (e.g., hematology or urinalysis), or an individual test (e.g., glucose) is not done for a USUBJID, POOLID, or SPTOBID and this information is explicitly captured with or without the reason for not collecting the information, record(s) can be created in the dataset to represent these data.</p> <p>In such cases, applicants may include:</p> <ul style="list-style-type: none"> individual records for each test not done for each subject or pool; or one record for each subject or pool for a group of tests that were not done. In such cases: <ul style="list-style-type: none"> The paired values of --TESTCD and --TEST will represent a general description of testing in scope for the domain and will be used for all groupings of not done tests within the domain. <ul style="list-style-type: none"> --TESTCD will be the domain code concatenated with the word "ALL". --TEST will be the domain description per controlled terminology. --CAT will represent the group of tests not done. --ORRES will be null. --STAT will be "NOT DONE". --REASND will be the reason the group of tests was not done, if collected. <p>For example, if a group of hematology or urinalysis tests represented in the LB domain are not done for a subject, then:</p> <table border="1"> <thead> <tr> <th>USUBJID</th> <th>LBTESTCD</th> <th>LBTEST</th> <th>LBCAT</th> <th>LBORRES</th> <th>LBSTAT</th> <th>LBREASND</th> </tr> </thead> <tbody> <tr> <td>ABC-001</td> <td>LBALL</td> <td>Laboratory Test Results</td> <td>HEMATOLOGY</td> <td></td> <td>NOT DONE</td> <td></td> </tr> <tr> <td>ABC-001</td> <td>LBALL</td> <td>Laboratory Test Results</td> <td>URINALYSIS</td> <td></td> <td>NOT DONE</td> <td>No urine specimen present</td> </tr> </tbody> </table>	USUBJID	LBTESTCD	LBTEST	LBCAT	LBORRES	LBSTAT	LBREASND	ABC-001	LBALL	Laboratory Test Results	HEMATOLOGY		NOT DONE		ABC-001	LBALL	Laboratory Test Results	URINALYSIS		NOT DONE	No urine specimen present
USUBJID	LBTESTCD	LBTEST	LBCAT	LBORRES	LBSTAT	LBREASND																	
ABC-001	LBALL	Laboratory Test Results	HEMATOLOGY		NOT DONE																		
ABC-001	LBALL	Laboratory Test Results	URINALYSIS		NOT DONE	No urine specimen present																	
6	Biological significance	<p>Nonclinical only:</p> <ul style="list-style-type: none"> For assessments of biological significance when the overall interpretation is a record in the domain, use the supplemental qualifier (SUPP--) record (with QNAM = --BIOSIG) linked to the record that contains the overall interpretation or a particular result. <ul style="list-style-type: none"> An example would be a QNAM value of LBBIOSIG in SUPPLB with a value of "Y", indicating that a lab result for albumin of 30 mg/mL was biologically significant. 																					

Num	Record and Variable Population	Implementation																									
		<ul style="list-style-type: none"> Biological significance is not the same as the concepts of normal and abnormal, which are generally represented in --ORRES. 																									
7	Clinical significance	<p>Product Impact on Individual Health only:</p> <ul style="list-style-type: none"> For assessments of clinical significance when the overall interpretation is a record in the domain, use the --CLSIG (Clinically Significant) variable on the record that contains the overall interpretation or a particular result. <ul style="list-style-type: none"> For example, EGCLSIG = "Y" indicates that an ECG result of "ATRIAL FIBRILLATION" was clinically significant. Clinical significance is not the same as the concepts of normal and abnormal and lab values out of normal range, which are generally submitted in --ORRES and normal range/indicator variables respectively. 																									
8	Records for derived results	<p>Nonclinical:</p> <ul style="list-style-type: none"> When there is a need to derive results based on collected values in --ORRES (e.g., means or ratios based on collected values), a new record for the derived result will be created in the dataset. In such cases, --DRVFL will be populated with "Y" in the derived record. --GRPID may be used to explicitly define the relationship between a derived record and the records from which it was derived. This practice would be especially important in the case of multiple derived records in a domain for the same subject (e.g., 2 baseline averages). <ul style="list-style-type: none"> For example, a mean systolic blood pressure derived from collected systolic blood pressure would be represented in the following way: <table border="1"> <thead> <tr> <th>CVGRPID</th> <th>CVTEST</th> <th>CVORRES</th> <th>CVDRFL</th> <th>CVDTG</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Systolic Blood Pressure</td> <td>154</td> <td></td> <td>2023-04-02T09:52</td> </tr> <tr> <td>1</td> <td>Systolic Blood Pressure</td> <td>149</td> <td></td> <td>2023-04-02T09:54</td> </tr> <tr> <td>1</td> <td>Systolic Blood Pressure</td> <td>153</td> <td></td> <td>2023-04-02T09:55</td> </tr> <tr> <td>1</td> <td>Systolic Blood Pressure</td> <td>152</td> <td>Y</td> <td>2023-04-02</td> </tr> </tbody> </table> <p>Product Impact on Individual Health:</p> <ul style="list-style-type: none"> Derived records will only be created for QRS domains as applicable. Refer to Section 2.8.7.2, Questionnaires, Ratings, and Scales (QRS). Otherwise, records for derived results will not be created. When needed such results will be derived as part of analysis. 	CVGRPID	CVTEST	CVORRES	CVDRFL	CVDTG	1	Systolic Blood Pressure	154		2023-04-02T09:52	1	Systolic Blood Pressure	149		2023-04-02T09:54	1	Systolic Blood Pressure	153		2023-04-02T09:55	1	Systolic Blood Pressure	152	Y	2023-04-02
CVGRPID	CVTEST	CVORRES	CVDRFL	CVDTG																							
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1	Systolic Blood Pressure	153		2023-04-02T09:55																							
1	Systolic Blood Pressure	152	Y	2023-04-02																							
9	Dates collected as results	<ul style="list-style-type: none"> When appropriate, dates that are collected results will be represented as results in variable --ORRES. Dates will be represented in --ORRES in ISO 8601 format. Prior to representing a date as a result, confirm the date is actually a finding for an observation and not the timing of an observation. 																									

2.8.7.2 Questionnaires, Ratings, and Scales (QRS)

For the TIG Product Impact on Individual Health use case, assumptions in this section will be used with:

- CDISC QRS Supplements for specific instruments referred to in Section 2.4, [About Questionnaires, Ratings, and Scales](#)
- Domain specifications for domain Questionnaires (QS)

Num	Record or Variable Population	Implementation
1	Instrument name	<p>Names of instruments, represented in --CAT, may be either abbreviations or longer names. Applicants will reference CDISC Controlled Terminology:</p> <ul style="list-style-type: none"> The list of QRS instruments that have published CDISC Controlled Terminology with NCI/EVS are available at: https://www.cdisc.org/standards/terminology/controlled-terminology. Refer to the following CDISC Controlled Terminology codelists for QRS instrument --CAT terminology: <ul style="list-style-type: none"> Category of Clinical Classification Category of Functional Test Category of Questionnaire QRS --TESTCD/-TEST terminology codelists are listed separately by instrument name.
2	Subcategories for groups of items/questions	<p>Names of subcategories for groups of items/questions are described under the --SCAT variable. --SCAT values are not included in the CDISC Controlled Terminology system but rather controlled as described in the QRS supplements in which they are used.</p>

Num	Record or Variable Population	Implementation
3	Numeric standardized responses	<p>When text responses have assigned standardized numeric responses, both the text and numeric responses will be represented in the tabulation dataset using variables --ORRES and --STRESC/--STRESN respectively. Assigned numeric responses are those documented in instrument specific documentation, such as QRS CRF instructions, a user manual, and/or a website specific to the QRS instrument.</p> <p>This is irrespective of data collection (e.g., when a QRS CRF does not include numeric standardized responses for collected text).</p>
4	Derived records for results	<p>Applicants will consult published QRS supplements for guidance on submitting derived information in a QRS domain. Derived variable results in QRS are usually considered captured data. If applicants operationally derive variable results in a new record, then this will be represented in --DRVFL.</p> <p>The following rules apply for "total"-type scores in QRS datasets.</p> <ul style="list-style-type: none"> • QRS subtotal, total, etc. scores listed on the CRF are considered captured data and are included in the instrument's controlled terminology. • QRS subtotal, total, etc. scores not listed on the CRF but documented in an associated instrument manual or reference paper are considered captured data and are included in the instrument's controlled terminology. • QRS subtotal, total, etc. scores not listed on the CRF, but known to be included in eData by applicants are considered captured data and are included in the instrument's controlled terminology. The QRS instrument's controlled terminology is considered extensible for this case and the subtotal or total score should be requested to be added. <ul style="list-style-type: none"> ◦ Any imputations/calculations done to numeric "standardized responses" to produce the total score via transforming numeric "standardized responses" are done as part of analysis. • The QRS instrument subtotal or total score, which is the sum of the numeric responses for an instrument, is populated in --ORRES, --STRESC, and --STRESN. It is considered a captured subtotal or total score without any knowledge of the applicant data management processes related to the score. <ul style="list-style-type: none"> ◦ If operationally derived by the applicant, it is the applicant's responsibility to set the --DRVFL flag based on their eCRF process to derive subtotal and total scores. An investigator-derived score written on a CRF will be considered a captured score and not flagged. When subtotal and total scores are derived by the applicant, the derived flag (--DRVFL) is set to "Y". However, when the subtotal and total scores are received from a central provider or vendor, the value would go into --ORRES and --DRVFL would be null.
5	Multiple repeats of a question	The variable --REPNUM is populated when there are multiple repeats of the same question. When records are related to the first trial of the question, the variable --REPNUM should be set to "1". When records are related to the second trial of the same question, --REPNUM should be set to "2", and so forth.
6	Evaluator	If needed, evaluators may be represented in SUPP-- datasets and variables --EVAL and --EVALID will not be used.
7	Allowable variables	Any identifiers, timing variables, or findings general observation class qualifiers may be added to a QRS domain, but the following qualifiers would generally not be used: --POS, --BODSYS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STRNC, --NRIND, --XFN, --LOINC, --SPEC, --SPCCND, --LOC, --FAST, --TOX, --TOXGR, --SEV.

2.8.7.3 Adhering to Dataset Record Structure

All datasets will adhere to the record structure defined for the domain, regardless of whether multiple values are collected for a variable. Guidance in this section describes conventions for maintaining the record structure defined for a domain or dataset when multiple values are collected. When concepts are related to either Nonclinical or Product Impact on Individual Health use cases but not both, this is denoted in the Implementation column.

Num	Record and Variable Population	Implementation
1	Multiple values for an Intervention or Event topic variable	<p>Product Impact on Individual Health only:</p> <p>If multiple values are reported for an Intervention or Event general-observation class topic variable (e.g., --TRT in Intervention, --TERM in Events), then the applicant will split the values into multiple records or otherwise resolve the multiplicity per the data management standard operating procedures (e.g., query the data for clarification).</p> <ul style="list-style-type: none"> • The Disposition (DS) dataset is an exception to the general rule of splitting multiple topic values into separate records. For DS, 1 record for each disposition or protocol milestone. For cases of multiple reasons for discontinuation, refer to the domain specifications for DS.
2	Multiple values for a Findings result variable	If multiple result values (represented in --ORRES) are collected for a test, then multiple records will be represented for the test (represented in --TESTCD).
3	Multiple values for a variable with role:	<p>Product Impact on Individual Health only:</p> <p>For multiple values (e.g., due to a "Check all that apply" instruction on a CRF):</p>

Num	Record and Variable Population	Implementation
	<ul style="list-style-type: none"> • Grouping qualifier • Synonym qualifier • Record qualifier • Variable qualifier 	<ul style="list-style-type: none"> • The variable will be populated with "MULTIPLE". • The SUPP-- dataset will represent individual responses. <ul style="list-style-type: none"> ◦ The values for QNAM will be sequential variable names, formed by appending a 1-digit integer, beginning with 1, to the original domain variable name. In cases where the standard domain variable name is already 8 characters in length, applicants will replace the last character with a digit when creating values for QNAM. ◦ The value for QLABEL should be the original domain variable label for all QNAM values.
4	Multiple values for a parameter	If multiple values (--VAL) are reported for a parameter in a Trial Design dataset (e.g., TS), multiple records should be submitted for the --PARMCD, unless the CDISC notes for the parameter indicate otherwise (e.g., TXPARMCD=LIGHT)
5	Single concept represented by multiple values	Nonclinical only: <ul style="list-style-type: none"> • A single value may represent a combination of multiple contributing items, delimited by slashes ("/"). In such cases, the combination is the collected value, the value analyzed, and so on—not the individual contributing items composing the value. • When controlled terminology applies to the variable, the combination of concepts may already exist as a controlled terminology term. If this is not the case, then a new term will be constructed by combining existing controlled terms, when possible. • For example, DEGENERATION/REGENERATION is a microscopic finding that is a single concept represented by multiple values (which is different from having 2 separately collected findings of degeneration and regeneration, with 2 separate records respectively).
6	Multiple concepts represented by multiple values	Nonclinical only: <ul style="list-style-type: none"> • A variable value may represent multiple individual values. In such cases, each contributing value is a separately collected or analyzed item. • When controlled terminology applies to the variable, controlled terms for each value will be represented delimited by semicolons. • For example, multiple distinct values may be collected for directionality (--DIR), may be collected for a result. Values may be represented using controlled terminology as "VENTRAL;SURFACE".

2.8.7.4 Free Text from Case Report Forms (CRFs)

For the TIG Product Impact on Individual Health use case, applicants may collect free text data on a CRF to supplement a standard field. A common example is collection using a list of choices with a field to collect "Other, specify". In such cases, collected free text will be populated in the domain based on the scope or role of the variable used to represent data from the standard collection field.

Num	Variable Population	Implementation												
1	Data from a standard field is represented in a variable with role: <ul style="list-style-type: none"> • Grouping qualifier • Synonym qualifier • Record qualifier • Variable qualifier 	When free text is collected to supplement a standard non-result qualifier field, the free text value will be represented in the SUPP-- dataset.												
2	Data from a standard field is a result represented in --ORRES	<p>When free text is collected to supplement a result, representation of the value will depend on the applicant's coding practice and analysis requirements.</p> <ul style="list-style-type: none"> • To maintain controlled terminology prespecified on the CRF, free text will be represented in --ORRES and controlled terminology will be represented in --STRESC. For example, if eye color is collected as a subject characteristic and "blueish gray" is collected for "Other, specify", then free text may be represented in SCORRES and controlled terminology may be represented in SCSTRESC. <table border="1"> <thead> <tr> <th>CRF</th> <th colspan="3">Representation</th> </tr> <tr> <th>Eye Color:</th> <th>SCTEST</th> <th>SCORRES</th> <th>SCSTRESC</th> </tr> </thead> <tbody> <tr> <td>Brown, Black, Blue, Green, Other, Specify:</td> <td>Eye Color</td> <td>BLUEISH GRAY</td> <td>OTHER</td> </tr> </tbody> </table> • To expand terminology based on values collected from "Other, specify", free text will be represented in --ORRES and the value of --STRESC will reflect the applicant's coding decision. 	CRF	Representation			Eye Color:	SCTEST	SCORRES	SCSTRESC	Brown, Black, Blue, Green, Other, Specify:	Eye Color	BLUEISH GRAY	OTHER
CRF	Representation													
Eye Color:	SCTEST	SCORRES	SCSTRESC											
Brown, Black, Blue, Green, Other, Specify:	Eye Color	BLUEISH GRAY	OTHER											

Num	Variable Population	Implementation					
		CRF		Representation			
		Eye Color: Brown, Black, Blue, Green, Other, Specify:		SCTEST	SCORRES	SCSTRESP	
		Eye Color		BLUEISH GRAY	GRAY		
<ul style="list-style-type: none"> If the applicant does not require that controlled terminology is maintained, then the verbatim value will also be represented in --STRESP.. 		CRF		Representation			
3	Data from a standard field is represented in a topic variable	Eye Color: Brown, Black, Blue, Green, Other, Specify:		SCTEST	SCORRES	SCSTRESP	
		Eye Color		BLUEISH GRAY	BLUEISH GRAY		
4	Data from a standard field is represented in variable --OBJ	<p>When findings are collected about an intervention or event, and the name of the event or intervention is collected in an "Other, specify" CRF field, the value in --OBJ variable depends on whether the Findings record has a parent record and whether the "Other, specify" value was coded.</p> <pre> graph TD A[Findings about data for an event or intervention where the name of the event or intervention was entered as free text] --> B{Topic variable coded?} B -- Yes --> C[Populate --OBJ with --DECOD] B -- No --> D[Populate --OBJ with topic variable value] C --> E{Parent record exists?} E -- Yes --> F[Populate --OBJ with coded value] E -- No --> G{Name of event or intervention coded?} G -- Yes --> F G -- No --> H[Populate --OBJ with verbatim value] </pre>					

2.8.7.5 Representing Planned and Actual Timing

The timing of collection of observations is generally planned, but observations may also be collected outside a planned schedule. Additionally, the actual timing of observations is collected. Guidance in this section describes the expected population of variables to represent the planned, unplanned, and actual timing of observations. When guidance is applicable only to TIG Nonclinical or Product Impact on Individual Health use cases, this is denoted in the Implementation column.

Planned Timing

Num	Variable Population	Implementation
1	Visits (VISIT, VISITNUM, VISITDY)	<p>Product Impact on Individual Health only:</p> <p>There will be a one-to-one relationship between values of VISIT and VISITNUM.</p> <ul style="list-style-type: none"> Values of VISIT, VISITNUM, and VISITDY will be represented as defined in the Trial Visits (TV) dataset. Values of VISITNUM are: <ul style="list-style-type: none"> Expected when observations in a domain have been collected more than once per subject (e.g., vital signs in domain VS when collected for subjects over multiple visits) Used for sorting and will, wherever possible, match the planned chronological order of visits For visits that last more than 1 calendar day, VISITDY will be the planned day of the start of the visit. <p>For unplanned visits, applicant practices for populating visit variables can vary:</p> <ul style="list-style-type: none"> VISITNUM will generally be populated, as it may be expected in a domain and will be populated when time points are represented.

Num	Variable Population	Implementation
		<ul style="list-style-type: none"> ○ The easiest method of populating VISITNUM for unplanned visits is to assign the same value (e.g., 99) to all unplanned visits, although this method provides no differentiation between the unplanned visits and does not provide chronological sorting. ○ Methods that provide a one-to-one relationship between visits and values of VISITNUM, that are consistent across domains, and that assign VISITNUM values that sort chronologically require more work and must be applied after all of a subject's unplanned visits are known. • VISIT can be left null or may be populated with a generic value (e.g., "Unscheduled") for all unplanned visits, or individual values may be assigned to different unplanned visits. • VISITDY will not be populated for unplanned visits; VISITDY is, by definition, the planned study day of visit.
2	Nominal Study Day (--NOMDY, NOMLBL)	<p>Nonclinical only:</p> <ul style="list-style-type: none"> • Variable --NOMDY will be used to group records collected over multiple days under a single nominal study day for reporting purposes. • Variable --NOMLBL is a label for a given value of --NOMDY as presented in the study report (e.g., "Week 4", "Day 28", "Terminal Sac"). • The value of --NOMLBL does not have to be unique for a given value of --NOMDY. • Variables --NOMDY and --NOMLBL will be used together (i.e., --NOMLBL will not be used without --NOMDY).
3	--USCHFL	<p>Nonclinical only:</p> <ul style="list-style-type: none"> • Nonclinical studies are conducted in the context of a planned study schedule. • The unscheduled flag (--USCHFL) variable is populated when the timing of a performed test or observation was not driven by the study schedule. • In such cases, the value of --USCHFL will be "Y". Otherwise, the value of --USCHFL will be null.
4	Epochs	<p>Values in EPOCH reflect study design and will be populated for observations that start during a subject's study participation. Values of EPOCH are generally derived and will not be imputed. Values of EPOCH will be derived using collected dates. However, when this is not possible, EPOCH may be assigned per data collection sources (e.g., CRF instructions and structure). If it is not possible to determine the epoch of an observation, then the value of EPOCH will be null.</p> <p>When EPOCH is included in:</p> <ul style="list-style-type: none"> • a Findings class domain, its value be based on the --DTC variable, since this is the date/time of the test or, for tests performed on specimens, the date/time of specimen collection. <ul style="list-style-type: none"> ○ An unlikely exception may be a finding based on an interval specimen collection that started in one epoch but ended in another. In such cases, --ENDTC may be a more appropriate for EPOCH. • an Interventions or Events class domain, EPOCH will be based on the --STDTC variable, since this is the start of the intervention or event.
5	Variables for timepoints	Timepoints will be represented using both --TPT and --TPTNUM. There will be a one-to-one relationship between values of --TPT and --TPTNUM.

Actual Timing

In general-observation class domains, the dates and times (when applicable) observations were collected are represented in variable --DTC. In Interventions and Events domains, variable --STDTC is used to represent the start dates and times (when applicable) of interventions and events. In Findings class domains, the collection date is often aligned with when the source of the finding was collected (e.g., a specimen for laboratory testing) and may not be aligned with when the finding for the observation was generated (e.g., the date the specimen was assayed, and results were generated). Given this, for consistency, variable --DTC is always used in Findings domains to represent the start date/time of an observation and variable --STDTC is not used. Variable --ENDTC is used in all general-observation class domains to represent the end date and time (when applicable) of the observation.

The length of time an observation continues (i.e., the duration of the observation) is represented using variables:

- --DTC or --STDTC for the start of the observation and --ENDTC for the end of the observation when date/times are collected
- --DUR when only the duration of the observation is collected and, start and end dates have not been collected

2.8.7.6 Representing References and Relative Timing

Timeframes, fixed points in time, and other milestones may be defined in the context of a study as references to which the timing of other collected observations is related. In such cases, timeframes are referred to as *reference periods* and such fixed points in time and milestones are referred to as *reference points*.

Timing Relative to Reference Periods and Other Dates

The start and end dates (and times when applicable) of an applicant-defined reference period for a study are represented using variables RFSTDTC and RFENDTC, respectively, in the Demographics (DM) domain. Applicants may also define dates/times, in addition to a study reference period, from which to reference the relative timing of observations. In both cases, such dates are used as references from which to populate the variables described below.

Num	Variable Population	Implementation
1	Days relative to a reference start date	<p>Variables --DY, --STDY, and --ENDY represent the timing of observations in days relative to the reference start date in RFSTDTC where the value of:</p> <ul style="list-style-type: none"> --DY is the relative day of the date populated in --DTC for the observation, --STDTC is the relative day of the date populated in --STDTC for the observation, and --ENDY is the relative day of the date populated in --ENDTC for the observation. <p>All relative day values will be integers and there will be no study day 0. The reference start date is considered day 1 and the study day value is increased by 1 for each date following the reference start date and decreased by 1 for each date prior to the reference start date, e.g.:</p> $\text{--DY} = (\text{date portion of --DTC}) - (\text{date portion of RFSTDTC}) + 1 \text{ if --DTC is on or after RFSTDTC}$ $\text{--DY} = (\text{date portion of --DTC}) - (\text{date portion of RFSTDTC}) \text{ if --DTC precedes RFSTDTC}$
2	Days relative to other applicant-defined reference dates	<p>Days may be represented relative to other applicant-defined reference dates beyond a reference period for a study. In such cases:</p> <ul style="list-style-type: none"> Relative days will be represented in a nonstandard variable (NSV) in a --SUPP dataset associated with the domain. All relative day values will be integers and there will be no day 0. The reference date is considered day 1 and the relative day value is increased by 1 for each date following the reference date and decreased by 1 for each date prior to the reference date.
3	Timing of observation start relative to the reference period	<ul style="list-style-type: none"> Variable --STRF represents the timing of observations relative to an applicant-defined reference period represented in RFSTDTC and RFENDTC, when relative timing such as "BEFORE", "PRIOR", "ONGOING", or "CONTINUING" is collected instead of an actual date and is collected in relation to the applicant-defined study reference period. Variable --STRF is used to identify the start of an observation relative to the applicant-defined study reference period. Allowable values for --STRF are "BEFORE", "DURING", "DURING/AFTER", "AFTER", and "UNKNOWN". Although "COINCIDENT" and "ONGOING" are in the STENRF codelist, they describe timing relative to a point in time rather than an interval of time, so are not appropriate for use with --STRF variables. It would be unusual for an event or intervention to be recorded as starting "AFTER" the study reference period, but could be possible, depending on how the study reference period is defined in a particular study.
4	Timing of observation end relative to the reference period	<ul style="list-style-type: none"> Variable --ENRF represents the timing of observations relative to an applicant-defined reference period represented in RFSTDTC and RFENDTC, when relative timing such as "BEFORE", "PRIOR", "ONGOING", or "CONTINUING" is collected instead of an actual date and is collected in relation to the applicant-defined study reference period. Variable --ENRF is used to identify the end of an observation relative to the applicant-defined study reference period. Allowable values for --ENRF are "BEFORE", "DURING", "DURING/AFTER", "AFTER" and "UNKNOWN". If --ENRF is used, then --ENRF = "AFTER" means that the event did not end before or during the study reference period. Although "COINCIDENT" and "ONGOING" are in the STENRF codelist, they describe timing relative to a point in time rather than an interval of time, so are not appropriate for use with --ENRF variables.

Timing Relative to Reference Points

Applicants may define fixed reference points within a study from which to reference the relative timing of observations. In such cases, timepoints are used as references from which to populate the variables described below.

Num	Variable Population	Implementation
1	Observation start timing relative to a fixed reference point	<ul style="list-style-type: none"> Variable --STTPT represents an applicant-defined fixed reference point that characterizes the start of an observation. Allowable values for --STTPT are a description of or the date and/or time of the fixed reference time point. Variable --STRPT represents the start of an observation relative to a reference time point represented in --STTPT. Allowable values are that an observation can: <ul style="list-style-type: none"> start "BEFORE" the reference point, start "AFTER" the reference point, start "COINCIDENT" with the reference point, or be "UNKNOWN" when it started.

Num	Variable Population	Implementation												
2	Observation end timing relative to a fixed reference point	<ul style="list-style-type: none"> Variable --ENTPT represents an applicant-defined fixed reference point that characterizes the end of an observation. Allowable values for --ENTPT are a description of or the date and/or time of the fixed reference time point. Variable --ENRPTPT represents the start of an observation relative to a reference time point represented in --ENTPT. Allowable values are that an observation can: <ul style="list-style-type: none"> end "BEFORE" the reference point, end "COINCIDENT" with the reference point, end "AFTER" the reference point, be known that it did not end but was "ONGOING", or be "UNKNOWN" when it ended or if it was ongoing. 												
3	Planned intervals relative to a fixed reference point	<p>When instances of an activity are scheduled at planned time intervals relative to a fixed reference point (e.g., an exposure), the following timing variables will be used:</p> <table border="1"> <thead> <tr> <th>Variable</th><th>Description of Use</th></tr> </thead> <tbody> <tr> <td>--TPTREF</td><td>Represents a description of the fixed reference point from which the planned observation will be made</td></tr> <tr> <td>--RFTDTC</td><td>Represents the actual date/time of the value of --TPTREF</td></tr> <tr> <td>--ELTM</td><td>Represents the planned elapsed time from the fixed timepoint reference to the planned observation. The value of this variable is usually also reflected in the value of variable --TPT.</td></tr> <tr> <td>--TPT</td><td>Represents the label for the timepoint relative to the value of --TPTREF</td></tr> <tr> <td>--TPTNUM</td><td>Represents the order of timepoints represented in --TPT relative to the value of --TPTREF</td></tr> </tbody> </table> <p>The diagram shows a horizontal timeline labeled 'Time' with arrows indicating direction. A vertical line connects three boxes: 'Planned Elapsed Time -ELTM (ISO 8601)' on the left, 'Reference Time Point --TPTREF (Description) --RFTDTC (Date/Time)' at the bottom, and 'Collection Time Point --TPT (Description) --TPTNUM (Number) --DTC (Date/Time)' on the right. Arrows point from the 'Planned Elapsed Time' box to the 'Collection Time Point' box, and from the 'Reference Time Point' box to the 'Collection Time Point' box.</p>	Variable	Description of Use	--TPTREF	Represents a description of the fixed reference point from which the planned observation will be made	--RFTDTC	Represents the actual date/time of the value of --TPTREF	--ELTM	Represents the planned elapsed time from the fixed timepoint reference to the planned observation. The value of this variable is usually also reflected in the value of variable --TPT.	--TPT	Represents the label for the timepoint relative to the value of --TPTREF	--TPTNUM	Represents the order of timepoints represented in --TPT relative to the value of --TPTREF
Variable	Description of Use													
--TPTREF	Represents a description of the fixed reference point from which the planned observation will be made													
--RFTDTC	Represents the actual date/time of the value of --TPTREF													
--ELTM	Represents the planned elapsed time from the fixed timepoint reference to the planned observation. The value of this variable is usually also reflected in the value of variable --TPT.													
--TPT	Represents the label for the timepoint relative to the value of --TPTREF													
--TPTNUM	Represents the order of timepoints represented in --TPT relative to the value of --TPTREF													

2.8.8 Specifications for Product Description

Tabulation domain specifications in this section are organized by domain.

2.8.8.1 SDTM Tobacco Product Identifiers and Descriptors (TO)

Description

A study reference dataset that provides a consistent identifier (SPTOBID) for the representation of a tobacco product. The dataset contains a list of the identifying and descriptive characteristics of the tobacco product.

to.xpt, Tobacco Product Identifiers and Descriptors — Study Reference. One record per parameter code per applicant-defined tobacco product, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study. Serves as a key to indicate that all datasets containing the same value of this variable are related by the purpose for which they were collected.	Req
DOMAIN	Domain Abbreviation	Char	TO	Identifier	Two-character abbreviation for the domain.	Req
SPTOBID	Applicant-Defined Tobacco Product ID	Char		Identifier	Identifier used to uniquely identify a tobacco product across all studies for all applications/submissions involving the product. It must be unique for each unique	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					tobacco product as defined by the specific values of the product's TOPARMCD-TOVAL pairs.	
TOSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a parameter within a tobacco product (SPTOBID) within the dataset.	Req
TOPARMCD	Tobacco Product ID Element Short Name	Char	(TOPARMCD)	Topic	Short name of the identifier or descriptor being described. Examples: "MANUF", "TRADENAM", "CIRCUMF".	Req
TOPARM	Tobacco Product ID Element Name	Char	(TOPARM)	Synonym Qualifier	Name of the identifying parameter or descriptor being described. Examples: "Manufacturer", "Trade Name", "Circumference".	Req
TOCAT	Category of Tobacco Product ID Element	Char	(TOCAT)	Grouping Qualifier	Used to define a category of records based on whether the product is new or a predicate product Examples: "NEW PRODUCT", "PREDICATE PRODUCT", "ORIGINAL PRODUCT", and "COMPARISON PRODUCT".	Req
TOSCAT	Subcategory of Tobacco Prod ID Element	Char		Grouping Qualifier	Used to define a sub-category of related records (e.g., PRODUCT IDENTIFIER, PRODUCT DESCRIPTOR).	Perm
TOVAL	Tobacco Product ID Element Value	Char		Result Qualifier	Value for the parameter in TOPARMCD/TOPARM for the product identified by SPTOBID.	Req
TOVALU	Tobacco Product ID Element Value Unit	Char	(UNIT)	Result Qualifier	Unit for the value in TOVAL. Will be blank for unitless identifying descriptors (e.g., "Trade Name"). Must be used where applicable (e.g., "Circumference").	Perm

Assumptions

1. TO is a study reference dataset that provides a consistent identifier, the Applicant-defined Tobacco Product Identifier (SPTOBID), for a tobacco product in a study. It contains the identifying and descriptive characteristics of a tobacco product and merges those characteristics on this single identifier. This dataset is required for studies of tobacco products.
 - a. SPTOBID is applicant-defined, but it must be unique with regard to the identifying and descriptive characteristics contained in the TO dataset.
 - b. SPTOBID is used in the Product Design (PD), Tobacco Ingredients (IT), Non-Tobacco Ingredients (IN), and Ingredient Quantities by Component (IQ) domains, as well as any domain in the general observation classes where there are records pertaining to the tobacco product it identifies/describes (e.g., PT). Every value of SPTOBID in any dataset must correspond to a product described in the TO dataset.
 - c. SPTOBID should be used through all phases of the development lifecycle for the product it identifies/describes.
2. TOPARMCD is the topic variable for this dataset. A minimally meaningful TO dataset must include at least the parameter for tobacco product category (TOPARMCD = TPRDCAT)
3. TOCAT is a required variable used to differentiate records relating to a new product from those relating to a predicate product, subject to the published controlled terminology for this variable.
4. TOSCAT (Subcategory) can be used to group records by identifying characteristic (e.g., manufacturer, trade name) and descriptive characteristics (e.g., length, circumference).
5. A minimally conformant TO dataset must include the parameters for tobacco product category, manufacturer, and trade name.

2.8.8.2 SDTM Product Design Parameters (PD)

Description

A special-purpose domain that lists the target, minimum, and maximum allowable values for design parameters of a product as allowed per manufacturer specifications. Therefore these data are not experimentally determined.

pd.xpt, Product Design Parameters — Special-Purpose. One record per parameter code per unit of measure per applicant-defined tobacco product, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study. Serves as a key to indicate that all datasets containing the same value of this variable are related by the purpose for which they were collected.	Req
DOMAIN	Domain Abbreviation	Char	PD	Identifier	Two-character abbreviation for the domain.	Req
SPTOBID	Applicant-Defined Tobacco Product ID	Char		Identifier	Identifier used to uniquely identify a tobacco product across all studies for all applications/submissions involving the product. In product description studies (i.e., where there are no human subjects) it is the top-level identifier.	Req
IGDCMPID	Ingredient or Component Identifier	Char		Identifier	Identifier given to an ingredient, substance or component of a tobacco product (e.g., "Burley Tobacco", "Reconstituted Tobacco"). It originates in the IT or IN domain. See PD assumption 2.	Perm
PDSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a design parameter within a tobacco product (SPTOBID) within the dataset.	Req
PDPARMCD	Design Parameter Element Short Name	Char	(PDPARMCD)	Topic	Short name of the parameter being described. Examples: "TOCUTSIZ", "BATCAPC".	Req
PDPARM	Design Parameter Element Name	Char	(PDPARM)	Synonym Qualifier	Name of the parameter being described. Examples: "Tobacco Cut Size", "Battery Capacity".	Req
PDVALTRG	Design Parameter Element Target Value	Char		Result Qualifier	Target value, according to the manufacturer's design specifications, for the parameter in PDPARMCD/PDPARM for the product identified by SPTOBID.	Req
PDVALMIN	Design Parameter Element Minimum Value	Char		Result Qualifier	Minimum allowable value, according to the manufacturer's design specifications, for the parameter in PDPARMCD/PDPARM for the product identified by SPTOBID.	Exp
PDVALMAX	Design Parameter Element Maximum Value	Char		Result Qualifier	Maximum allowable value, according to the manufacturer's design specifications, for the parameter in PDPARMCD/PDPARM for the product identified by SPTOBID.	Exp
PDVALU	Design Parameter Element Value Unit	Char	(UNIT)	Result Qualifier	The single unit for the values in PDVALTRG, PDVALMIN and PDVALMAX. Will be blank for unitless parameters (e.g., "Number of Heating Elements"). Must be used where applicable (e.g., "Circumference").	Perm

Assumptions

1. PD is a special-purpose domain for listing the design parameters of a product as specified by the manufacturer. These parameters are listed with their target, minimum, and maximum values allowed by the design. They are not test data (i.e., these are not experimentally determined values). Testing for manufactured product conformance to these listed specifications is represented in the Tobacco Product Testing (PT) domain.
2. IGDCMPID is a permissible variable in PD whose value originates in the Tobacco Ingredients (IT) or Non-Tobacco Ingredients (IN) domain. When a design parameter value varies by ingredient or component, IDGCMPIID is used to indicate the ingredient or component to which the parameter value applies.
3. PDUNIT represents the single, unified unit for all 3 values shown in PDVALTRG, PDVALMIN, and PDVALMAX (i.e., target, minimum, and maximum values, respectively).
4. Design parameter data must be provided for all new tobacco products in the application.

2.8.8.3 SDTM Tobacco Product Testing (PT)

Description

A findings domain for representing results of testing performed on tobacco products or samples from tobacco products. PT is not a subject-level domain and is not used for results from testing products in human or animal subjects.

pt.xpt, Tobacco Product Testing — Findings. One record per test, per replicate, per timepoint, per tobacco product, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study. Serves as a key to indicate that all datasets containing the same value of this variable are related by the purpose for which they were collected.	Req
DOMAIN	Domain Abbreviation	Char	PT	Identifier	Two-character abbreviation for the domain.	Req
SPTOBID	Applicant-Defined Tobacco Product ID	Char		Identifier	Identifier used to uniquely identify a tobacco product across all studies for all applications/submissions involving the product. In product description studies (i.e., where there are no human subjects) it is the top-level identifier.	Req
IGDCMPID	Ingredient or Component Identifier	Char		Identifier	Identifier given to an ingredient, substance or component of a tobacco product (e.g., "Burley Tobacco", "Reconstituted Tobacco"). It originates in the IT or IN domain. See assumption 7a.	Perm
STOCONID	Applicant-defined Storage Conditions ID	Char		Identifier	Applicant-defined identifier for a set of storage conditions that are represented in the ES domain, where this identifier originates. See assumption 7b. (See also ES domain Specification and Assumptions for more information on the ES domain).	Perm
PTSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
PTGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
PTREFID	Reference ID	Char		Identifier	Internal or external identifier. In PT it is used to represent a smoking regimen, and serves as a link to the Device-In Use Properties (DU) domain, where a matching value of DUREFID indicates parameters of the smoking regimen performed by the smoking machine.	Perm
PTSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. Can be used to identify an instance of an observation. Examples: a value preprinted on a form; an identifier from the applicant's operational database.	Perm
PTTESTCD	Test or Examination Short Name.	Char	(PTTESTCD)	Topic	Short name of the measurement or test described in PTTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PTTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PTTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "NH4", "BENZ".	Req
PTTEST	Test or Examination Name	Char	(PTTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in PTTEST cannot be longer than 40 characters. Examples: "Ammonia", "Benzene".	Req
PTTSTDTL	Test Detail	Char		Record Qualifier	Further description of the test performed in producing the PT result (e.g., "DRY WEIGHT BASIS" in HPHC testing or stability testing).	Perm
PTCAT	Category of Test	Char	(PTCAT)	Grouping Qualifier	Used to define a category of related records by purpose. Examples: "HPHC TESTING", "STABILITY TESTING", "DESIGN PARAMETER TESTING". Note: given the vast amount of data types that will use this domain, PTCAT is a required variable in the PT domain to differentiate and group the records by purpose.	Req
PTSCAT	Subcategory of Test	Char		Grouping Qualifier	A further categorization of a test category. Examples: "HPHC" (for constituents designated as HPHCs under PTCAT=HPHC TESTING), "OTHER" (for constituents like	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					tar, which are categorized under PTCAT=HPHC TESTING but that are not formally designated HPHCs).	
PTORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
PTORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for PTORRES. Example: "mg/mL".	Exp
PTLLOD	Lower Limit of Detection	Char		Variable Qualifier	The lowest threshold (as originally received or collected) for reliably detecting the presence or absence of substance measured by a specific test. The value for the field will be as described in documentation from the instrument or lab vendor.	Perm
PTSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from PTORRES in a standard format or standard units. PTSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in PTSTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in PTORRES and these results effectively have the same meaning, they could be represented in standard format in PTSTRESC as "NEGATIVE". For other examples, see general assumptions.	Exp
PTSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from PTSTRESC. PTSTRESN should store all numeric test results or findings.	Exp
PTSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for PTSTRESC or PTSTRESN.	Exp
PTSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate exam not done. Should be null if a result exists in PTORRES.	Perm
PTREASND	Reason Test Not Done	Char		Record Qualifier	Describes why a measurement or test was not performed, e.g., "BROKEN EQUIPMENT", or "SAMPLE LOST". Used in conjunction with PTSTAT when value is "NOT DONE".	Perm
PTXFN	External File Path	Char		Record Qualifier	The filename and/or path to external data not stored in the same format and possibly not the same location as the other data for a study. For example, when submitting lab methodology as a separate document, the name of the document or path to the file in the folder structure in the submission should be referred to in this variable.	Perm
PTNAM	Vendor Name	Char		Record Qualifier	The name or identifier of the laboratory that performed the test.	Perm
PTSPEC	Specimen Material Type	Char	(SPECPT)	Record Qualifier	Defines the type of sample/matrix used for a measurement. Examples: "TOBACCO", "E-LIQUID", "SMOKE", "AEROSOL".	Exp
PTSPCCND	Specimen Condition	Char	(SPECCOND)	Record Qualifier	The physical state or quality of a sample for an assessment. Examples: "AS-IS", "DRY WEIGHT BASIS".	Perm
PTMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method used to arrive at the result of the test or examination. Not for representing smoking regimens or sample storage conditions. If lab methodology is too complex for this single variable, and supplemental lab documentation is instead submitted, a file name or path to such documentation should be included in the PTXFN variable instead.	Perm
PTBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. Should be "Y" or null. Note that PTBLFL is retained for backward compatibility. The authoritative baseline for statistical analysis is in an ADaM dataset.	Perm
PTDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be "Y" or null. Records that represent the average of other records, or do not come from the CRF, or are not as originally received or collected are examples of records that might be derived for the submission datasets. If PTDRVFL = "Y", then PTORRES may be null, with PTSTRESC and (if numeric) PTSTRESN having the derived value.	Perm
PTLLOQ	Lower Limit of Quantitation	Num		Variable Qualifier	The lowest threshold for reliably quantifying the amount of substance measured by a specific test, in standardized units.	Perm
PTULOQ	Upper Limit of Quantitation	Num		Variable Qualifier	The highest threshold for reliably detecting the result of a specific test in standardized units.	Perm
PTREPNUM	Repetition Number	Num		Record Qualifier	The instance number of a test that is repeated within a given time frame for the same test performed. The level of granularity can vary (e.g., within a time point). Example:	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					multiple measurements of tobacco product testing for a specific test.	
PTDTC	Date/Time of Sample Testing	Char	ISO 8601 datetime or interval	Timing	Date/time of sample testing represented in ISO 8601 character format.	Exp
PTENDTC	End Date/Time of Sample Collection	Char	ISO 8601 datetime or interval	Timing	End date/time of sample collection represented in ISO 8601 character format. Used when 1 sample is collected over a period of time, and the length of time is deemed significant to the test or the interpretation if its result.	Perm
PTTPT	Planned Time Point Name	Char		Timing	1. Text description of time when sample should be tested. 2. This may be represented as an elapsed time relative to a fixed reference point, such as date of manufacture. See PTTPTNUM and PTTPTREF. Examples: "Week 12".	Perm
PTTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of PTTPT to aid in sorting.	Perm
PTELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601) relative to a planned fixed reference (PTTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date/time variable. Represented as ISO 8601 duration. Example: "PT60D" to represent the period of 60 days after the reference point indicated by PTTPTREF.	Perm
PTTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by PTELTM, PTTPTNUM, and PTTPT. Example: "DATE OF MANUFACTURE".	Perm
PTRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/time of the reference time point, PTTPTREF.	Perm

Assumptions

1. PT is used to represent the results of all testing of tobacco products. Examples of the types of testing that would be represented here include:
 - a. Testing products for conformance to design parameter specifications
 - b. Testing for harmful and potentially harmful constituents (PHHCs) in samples of the product
 - c. Product stability study testing results
2. PTCAT (Category of Test) is a required variable since the same analyte (same value of PTEST) may appear in more than one context. PTCAT differentiates the records in these cases (e.g., PHHC TESTING, STABILITY TESTING)
 - a. PTSCAT can be used to further differentiate constituents.
 - b. Constituents like tar, which are not formally designated PHHCs but which are tested along with designated PHHCs, should be categorized as "PHHC TESTING" with PTSCAT="OTHER".
3. The original result of a test and its associated units are represented in PTORRES and PTORRESU, respectively. If the result is standardized to a different set of units, the standardized value and its units are represented in PTSRESC and PTSTRESU. Additionally, PTSRESN should be populated if the standard result is numeric.
 - a. PTORRES, PTSTRESC and PTSTRESN are all Expected variables. PTSTRESN can be left null if the result is not numeric
 - b. If the original results are not standardized to different units, the value in PTORRES should be carried over to PTSTRESC and PTSRESN (the latter is only used if numeric). The value in PTORRESU should be carried over into PTSTRESC.
4. The variable PTSPEC (Specimen Type) is used to represent the specimen matrix (e.g, E-LIQUID, TOBACCO, SMOKE, VAPOR).
5. PTSPCCND (Specimen Condition) is used for conditions such as "AS-IS" or "DRIED".

6. When lab methodology is too complex for the single PTMETHOD variable, PTXFN should be used to reference a file name or path to a file in the application that describes the methodology used. Either PTMETHOD or PTXFN should be included in the data.
7. The following Permissible identifiers can be used as follows:
 - a. IGDCMPID is used when necessary to identify that a particular test was performed on a specific component of the tobacco product, and when this component would not be obvious without identifying it explicitly. For example, IGDCMPID is necessary when the same test is performed on 2 different components, such as 2 different types of tobacco in a leaf product.
 - b. STOCONID is used in stability studies testing to identify the set of conditions under which the product being tested was stored.

2.8.8.4 SDTM Tobacco Ingredients (IT)

Description

A special-purpose domain that provides an identifier for each unique tobacco ingredient (IGDCMPID) in a tobacco product, and lists those tobacco ingredients and their attributes that contribute to their uniqueness.

it.xpt, Tobacco Ingredients — Special-Purpose. One record per unique tobacco ingredient per applicant-defined tobacco product, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study. Serves as a key to indicate that all datasets containing the same value of this variable are related by the purpose for which they were collected.	Req
DOMAIN	Domain Abbreviation	Char	IT	Identifier	Two-character abbreviation for the domain.	Req
SPTOBID	Applicant-Defined Tobacco Product ID	Char		Identifier	Identifier used to uniquely identify a tobacco product across all studies for all applications/submissions involving the product. In product description studies (i.e., where there are no human subjects) it is the top-level identifier.	Req
IGDCMPID	Ingredient or Component Identifier	Char		Identifier	Identifier given to an ingredient, substance or component of a tobacco product. In IT, it must be a tobacco ingredient of the product represented in SPTOBID (e.g., "Burley Tobacco", "Reconstituted Tobacco").	Req
TPMF	Tobacco Product Master File ID	Char		Identifier	The tobacco product master file number, if applicable.	Perm
ITSPECIF	Specification or Variety of Tobacco Ingr	Char		Variable Qualifier	A qualifier of IGDCMPID. Used to represent the specification (variety) of tobacco ingredient (e.g., "USDA Nicotiana Collection PI 552747", "KT215LC").	Exp
ITIGDPLX	Ingredient Complexity	Char	(IGDCMPLX)	Grouping Qualifier	Used to denote whether a tobacco ingredient is a single or complex ingredient (i.e., "SINGLE INGREDIENT" or "COMPLEX INGREDIENT").	Exp
ITCIGIND	Applicant-Customized Ingredient Indic	Char	(NY)	Record Qualifier	Used to indicate whether a complex tobacco ingredient was made to the applicant's specification. Expected to be populated where ITIGDPLX = COMPLEX INGREDIENT. Values restricted to "Y" or "N".	Perm
ITCURMTH	Cure Method	Char		Record Qualifier	Method by which the tobacco ingredient is cured (e.g., "Air", "Sun", "Flue").	Exp

Assumptions

1. IT is a special-purpose domain for listing the tobacco ingredients (only) for a tobacco product. Non-tobacco ingredients (e.g., wrapping paper, filter) would not be represented in this domain (see Section 2.8.8.5, [Non-Tobacco Ingredients](#), for specification, assumptions, and other information on non-tobacco ingredients).
2. IT is 1 of 2 domains (along with IN) that serve as the origin of the consistent identifier variable IGDCMPID (Ingredient or Component Identifier).
 - a. IGDCMPID must represent a unique tobacco ingredient with regard to the attributes listed in assumptions 3a-3c. If 2 or more sources of the same variety of tobacco ingredient differ on any of

- these attributes, they must each be assigned a different value for IDGCMPIID (e.g., Burley Tobacco 1, Burley Tobacco 2)
- b. IGDCMPID is also used in the Ingredient Quantities by Component (IQ) domain (see [Section 2.8.8.6](#)), where the ingredients identified by those values are quantified by component. When quantifying ingredients in IQ, every ingredient (every value of IGDCMPID in IT) must be accounted for in IQ.
 3. IT additionally contains variables for representing the following attributes of each tobacco ingredient:
 - a. Tobacco product master file, if applicable
 - b. Specification or variety of the tobacco
 - c. Complexity of the ingredient, to differentiate between single tobacco ingredients and complex ingredients (tobacco blends), and a separate indicator as to whether a complex tobacco ingredient was made to specifications
 - d. Tobacco cure method
 4. At least 1 record representing the overall tobacco component/tobacco filler for the product must be included in the dataset. The individual tobacco ingredients of which the overall tobacco filler/component of the tobacco product is comprised must also be represented, if available. This will be necessary when quantifying the ingredients in the IQ domain.

2.8.8.5 SDTM Non-Tobacco Ingredients (IN)

Description

A special-purpose domain that provides an identifier for each unique non-tobacco ingredient (IGDCMPID) in a tobacco product, and lists those ingredients and their attributes that contribute to their uniqueness.

in.xpt, Non-Tobacco Ingredients — Special-Purpose. One record per unique non-tobacco ingredient per applicant-defined tobacco product, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study. Serves as a key to indicate that all datasets containing the same value of this variable are related by the purpose for which they were collected.	Req
DOMAIN	Domain Abbreviation	Char	IN	Identifier	Two-character abbreviation for the domain.	Req
SPTOBID	Applicant-Defined Tobacco Product ID	Char		Identifier	Identifier used to uniquely identify a tobacco product across all studies for all applications/submissions involving the product. In product description studies (i.e., where there are no human subjects) it is the top-level identifier.	Req
IGDCMPID	Ingredient or Component Identifier	Char		Identifier	Identifier given to an ingredient, substance or component of a product. In IN, it must be a non-tobacco ingredient of the product represented in SPTOBID (e.g., "Cocoa Extract", "Cellulose Pulp").	Req
INMANUF	Manufacturer Name	Char		Identifier	The name of the manufacturer of a complex ingredient/component represented in IGDCMPID. Does not need to be populated for single ingredients.	Perm
INMANUIN	Manufacturer Unique Identifying Item Num	Char		Identifier	The unique identifying item number assigned by the manufacturer to the ingredient or component shown in IGDCMPID (e.g, catalog number).	Perm
TPMF	Tobacco Product Master File Number	Char		Identifier	The tobacco product master file number for the ingredient/component represented in IGDCMPID, if applicable. Used for proprietary purchased ingredients when the manufacturer does not want to disclose the formula to the public and has instead provided these details in a file directly to regulators.	Perm
IUPACNAM	Preferred IUPAC Name	Char	IUPAC Nomenclature	Identifier	The preferred International Union of Pure and Applied Chemistry (IUPAC) name of the ingredient represented in IGDCMPID, if applicable.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
CASNO	CAS Registry Number	Char	CAS	Identifier	The Chemical Abstract Service (CAS) registry number for the ingredient represented in IGDCMPID.	Perm
UNII	Unique Ingredient Identifier	Char	UNII	Identifier	The FDA Unique Ingredient Identifier (UNII) number for the ingredient represented in IGDCMPID.	Perm
INIGDPLX	Ingredient Complexity	Char	(IGDCMPLX)	Grouping Qualifier	Used to denote whether an ingredient is a single or complex ingredient (e.g., "SINGLE INGREDIENT", "COMPLEX INGREDIENT").	Exp
INCIGIND	Applicant-Customized Ingredient Indic	Char	(NY)	Record Qualifier	Used to indicate whether a complex ingredient was made to the applicant's specification. Expected to be populated where INIGDPLX = "COMPLEX INGREDIENT". Values restricted to "Y" or "N".	Perm
INGRADE	Ingredient Grade	Char		Record Qualifier	The grade of the ingredient represented in IGDCMPID (e.g., "USP", "FOOD").	Exp
INPURITY	Ingredient Purity	Char		Record Qualifier	The purity of the ingredient represented in IGDCMPID, provided for any ingredient for which this information is available (e.g., "99%", ">99%").	Exp

Assumptions

1. IN is a special-purpose domain for listing the non-tobacco ingredients (only) for a tobacco product. Tobacco ingredients (e.g., individual tobacco varieties) would not be represented in this domain (see Section 2.8.8.4, [SDTM Tobacco Ingredients](#), for IT domain specification and assumptions).
2. IN is 1 of 2 domains (along with IT) that serve as the origin of the consistent identifier variable IGDCMPID (Ingredient or Component Identifier).
 - a. IGDCMPID must represent a non-tobacco ingredient that is unique with regard to the attributes listed in assumption 3 below. If 2 or more sources of the same non-tobacco ingredient differ on any of these attributes, they must each be assigned a different value for IGDCMPID (e.g., 1,3-Butanediol A, 1,3-Butanediol B).
 - b. IGDCMPID is also used in the Ingredient Quantities by Component (IQ) domain, where the ingredients identified by those values are quantified by component. When quantifying ingredients in IQ, every ingredient (every value of IGDCMPID in IN) must be accounted for in IQ (see [Section 2.8.8.6](#) for IQ domain specification and assumptions).
3. Additionally, IN contains variables for representing the following attributes:
 - a. Manufacturer's name and registration number (INMANUF)
 - b. Manufacturer's unique identifying item number for the ingredient or component (INMANUIN)
 - c. Tobacco product master file number (TPMF)
 - d. IUPAC name (IUPACNAM), CAS registry number (CASNO), and FDA Unique Ingredient Identifier (UNII), with the following requirements for inclusion in the IN dataset:
 - i. IUPACNAM is an expected variable, and should be populated with the preferred IUPAC name for all ingredients for which an IUPAC name is available. IUPAC nomenclature is available at <https://iupac.org/>.
 - ii. At least 1 of the 2 permissible variables CASNO or UNII should also be provided if available. CAS numbers are available at <https://www.cas.org/>. UNII identifiers are available <https://precision.fda.gov/unisearch>.
 - e. The complexity of the ingredient (INIGDPLX), to differentiate between single ingredients and complex ingredients, and a separate indicator (INCIGIND) as to whether a complex ingredient was made to the applicant's specifications
 - f. Ingredient grade (INGRADE) and purity (INPURITY). According to the PMTA rule, at least 1 of these 2 attributes must be included. If the data are proprietary and only available via the TPMF, then TPMF should be populated.

2.8.8.6 SDTM Ingredient Quantities by Component (IQ)

Description

A special purpose domain for representing the quantity of an ingredient/component of a product by the parent ingredient/component in which it occurs.

iq.xpt, Ingredient Quantities by Component — Special-Purpose. One record per ingredient/component (IGDCMPID) per parent ingredient/component, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study. Serves as a key to indicate that all datasets containing the same value of this variable are related by the purpose for which they were collected.	Req
DOMAIN	Domain Abbreviation	Char	IQ	Identifier	Two-character abbreviation for the domain.	Req
SPTOBID	Applicant-Defined Tobacco Product ID	Char		Identifier	Identifier used to uniquely identify a tobacco product across all studies for all applications/submissions involving the product. In product description studies (i.e., where there are no human subjects) it is the top-level identifier.	Req
IGDCMPID	Ingredient or Component Identifier	Char		Identifier	Identifier given to an ingredient, substance or component of a tobacco product represented in SPTOBID. In IQ, it must match a value of IGDCMPID in either the IT dataset (if the ingredient is a tobacco ingredient) or IN (if the ingredient is a non-tobacco ingredient). (e.g., "Burley Tobacco", "Propylene Glycol", "Cocoa Extract", "Cellulose Pulp").	Req
IQCAT	Category of Ingredient or Component	Char	(IQCAT)	Grouping Qualifier	Used to group ingredients/components by tobacco and non-tobacco ingredients. Required to enable conformance checks to ensure IGDCMPID is present in either the IT or IN domain.	Req
IQIGDPLX	Ingredient Complexity	Char	(IGDCMPLX)	Grouping Qualifier	Used to denote whether a ingredient is a single or complex ingredient (e.g., "SINGLE INGREDIENT", "COMPLEX INGREDIENT").	Exp
IQPARENT	Parent of Ingredient or Component	Char		Record Qualifier	Identifies the parent of which the ingredient or component represented in IGDCMPID is a part. (i.e., IGDCMPID is a child of the ingredient shown in IQPARENT). IQPARENT must equal a value of IGDCMPID from another record in the same dataset. IQPARENT will therefore always be a complex ingredient. If the ingredient is at the top level (i.e., it has no parent other than the tobacco product itself), IQPARENT will be null and IQLEVEL will be set to 1 (see IQLEVEL).	Perm
IQLEVEL	Ingredient Level in Hierarchy	Num		Record Qualifier	An integer that identifies the level of the ingredient or component within the hierarchy. The value of IQLEVEL will be $n+1$, where n is the IQLEVEL of the parent ingredient. IQLEVEL will be set to 1 if the ingredient is at the top level (i.e., if the ingredient has no parent ingredient/component other than the tobacco product itself). Must be populated when IQPARENT is populated.	Req
IQFUNCT	Ingredient Function	Char		Record Qualifier	The function of the ingredient in the tobacco product or the parent component (e.g., "Adhesive", "Flavorant").	Exp
IQVALTRG	Ingredient Target Value	Num		Result Qualifier	Target value (quantity) of the ingredient shown in IGDCMPID according to the manufacturer's ingredient design specifications. If the ingredient appears in multiple components of the tobacco product, IQVALTRG represents the target quantity within the parent component, not the overall quantity in the tobacco product.	Req
IQVALMIN	Ingredient Minimum Value	Num		Result Qualifier	Minimum value (quantity) of the ingredient shown in IGDCMPID according to the manufacturer's ingredient design specifications. If the ingredient appears in multiple components of the tobacco product, IQVALMIN represents the minimum quantity within the parent component.	Exp
IQVALMAX	Ingredient Maximum Value	Num		Result Qualifier	Maximum value (quantity) of the ingredient shown in IGDCMPID according to the manufacturer's ingredient design specifications. If the ingredient appears in multiple components of the tobacco product, IQVALMAX represents the maximum quantity within the parent component.	Exp
IQVALU	Ingredient Value Unit	Char	(UNIT)	Result Qualifier	The single unit for the values in IQVALTRG, IQVALMIN, and IQVALMAX.	Exp

Assumptions

1. IQ is a special-purpose domain for listing the target, minimum, and maximum quantities of both tobacco ingredients and non-tobacco ingredients of a tobacco product. These values represent design specifications, not test data. IQ additionally shows the function of each ingredient by component in which the ingredient appears.
2. IDGCMPIID represents the unique ingredient name established in either the Tobacco Ingredients (IT) domain or the Non-Tobacco Ingredients (IN) domain. Therefore, every value of IDGCMPIID in the IQ domain must have an exact match in either IT or IN (See [Sections 2.8.8.4](#) and [2.8.8.5](#) for IT and IN domain specifications and assumptions).
3. IQCAT represents whether the ingredient is a tobacco ingredient or a non-tobacco ingredient. Populating this variable facilitates checks for conformance to assumption 2.
4. Ingredients that appear in more than 1 component of the tobacco product (or which are part of a complex ingredient) are quantified separately for each component/complex ingredient in which they appear. The hierarchical relationship of these ingredients is made explicit by the use of the IQPARENT and IQLEVEL variables as follows:
 - a. IQPARENT represents the complex ingredient or component of the tobacco product in which ingredient or subcomponent (IDGCMPIID for the record) appears.
 - i. IQPARENT must equal the IDGCMPIID of another record in IQ (i.e., the parent ingredient/component must be listed in IQ).
 - ii. If the ingredient is not a part of another ingredient or component (i.e., it is a top-level component with no parent other than the tobacco product itself) IQPARENT is null.
 - b. IQLEVEL is an integer that represents the level in the hierarchy of an ingredient's relationship to other ingredients.
 - i. IQLEVEL cannot be null. Every ingredient, including top-level ingredients as defined in assumption 4.a.ii, must have a value for IQLEVEL.
 - ii. Top-level ingredients have IQLEVEL = 1
 - iii. Subcomponents of complex ingredients have IQLEVEL = n+1, where n equals the IQLEVEL of the parent ingredient or component.
5. IQFUNCT is used to represent the function of the ingredient in the component in which it appears (e.g., FLAVORANT, ADHESIVE).

2.8.8.7 SDTM Environmental Storage Conditions (ES)

Description

A study reference dataset that provides a consistent identifier (STOCONID) for the representation of a set of environmental conditions under which a test article is stored, and contains a list of those conditions.

es.xpt, Environmental Storage Conditions — Study Reference. One record per parameter code per defined set of storage conditions, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study. Serves as a key to indicate that all datasets containing the same value of this variable are related by the purpose for which they were collected.	Req
DOMAIN	Domain Abbreviation	Char	ES	Identifier	Two-character abbreviation for the domain.	Req
STOCONID	Applicant-defined Storage Conditions ID	Char		Identifier	Applicant-defined identifier for representing a set of storage conditions. Can also be used in the PT domain where storage conditions of the product being tested are applicable (e.g., stability studies). STOCONID should be populated with an	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					intuitive name based on a description of the storage conditions. If a published standard set of conditions is used, the value should represent that (e.g., "E-Liquid Standard Long Term Conditions"). If the study applicant creates their own set of storage conditions, or modifies a standard set, the value should reflect that (e.g., "Modified E-Liquid Standard Long Term Conditions"). It must be unique for each unique set of storage conditions as defined by the specific values of ESPARMCD-ESVAL pairs.	
ESSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a parameter within the set of storage conditions represent by STOCONID within the dataset.	Req
ESPARMCD	Storage Conditions Element Short Name	Char	(ESPARMCD)	Topic	Short name of the identifier or descriptor being described. Examples: "TEMP", "HUMID".	Req
ESPARM	Tobacco Product ID Element Name	Char	(ESPARM)	Synonym Qualifier	Name of the identifying parameter or descriptor being described. Examples: "Temperature", "Humidity".	Req
ESVAL	Tobacco Product ID Element Value	Char		Result Qualifier	Value for the parameter in ESPARMCD/ESPARM for a condition within a set of conditions identified by STOCONID.	Req
ESVALU	Tobacco Product ID Element Value Unit	Char	(UNIT)	Result Qualifier	Unit for the value in ESVAL. Must be used when value for the parameter has units.	Perm

Assumptions

1. ES is a study reference dataset that provides a consistent identifier—the Applicant-defined Storage Conditions ID (STOCONID)—for the set of conditions under which a product was stored during testing. The dataset contains these storage condition parameters (e.g., temperature, humidity) and merges those characteristics on this single identifier.
 - a. STOCONID is applicant-defined, but it must be unique with regard to the specific set of storage conditions contained in the ES dataset.
 - b. STOCONID can also be used in the Tobacco Product Testing (PT) domain, where the storage conditions it identifies are applicable to observations contained in that domain (e.g., when representing the results of stability studies in the PT domain that were conducted under a set of storage conditions represented in ES).
2. ESPARMCD/ESPARM are the parameters of the storage conditions (e.g., temperature, humidity, percent oxygen, climate zone).
3. Timing and duration of storage would be determined in the context of the testing of stored samples from the timing variables used in the domain where the testing results are represented (i.e., the PT domain).

2.8.9 Specifications for Nonclinical

Tabulation domain specifications in this section are organized by domain.

2.8.9.1 SEND Body Weights (BW)

Description

This domain captures body weights collected for subjects during the study and at the end of the study (terminal body weights).

bw.xpt, Body Weights — Findings. One record per test per observation time per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	BW	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
BWSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
BWTESTCD	Test Short Name	Char	(BWTESTCD)	Topic	Short name of the measurement, test, or examination described in BWTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in BWTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). BWTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
BWTEST	Test Name	Char	(BWTEST)	Synonym Qualifier	Long name for BWTESTCD. The value in BWTEST cannot be longer than 40 characters.	Req
BWORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
BWORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.	Exp
BWSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from BWORRES in a standard format or standard units. BWSTRESC should store all results or findings in character format; if results are numeric, they should also be submitted in numeric format in BWSTRESN.	Exp
BWSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of BWSTRESC. BWSTRESN should store all numeric test results or findings.	Exp
BWSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for BWSTRESC and BWSTRESN.	Exp
BWSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in BWORRES.	Perm
BWREASND	Reason Not Done	Char		Record Qualifier	Describes why BWSTAT is NOT DONE, such as BROKEN EQUIPMENT or TECHNICIAN OVERSIGHT.	Perm
BWBLFL	Baseline Flag	Char	(NY)	Record Qualifier	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is applicant defined.	Exp
BWFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status. The value should be Y or null.	Perm
BWEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Y if the result should be excluded from all calculations, otherwise null.	Perm
BWRELEASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when BWEXCLFL is Y.	Perm
BWUSCHFL	Unscheduled Flag	Char	(NY)	Record Qualifier	Indicates whether the timing of a performed test or observation was unscheduled. If a test or observation was performed based upon a schedule defined in the protocol, this flag should be null. Expected values are Y or null.	Perm
VISITDY	Planned Study Day of Collection	Num		Timing	Planned study day of collection. Should be an integer.	Perm
BWDTC	Date/Time Animal Weighed	Char	ISO 8601 datetime or interval	Timing	Date/Time of body weight collection in ISO 8601 format.	Exp
BWDY	Study Day Animal Weighed	Num		Timing	Study day of body weight collection, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
BWNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for observations that may occur on different days into a single reported study day. Should be an integer.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
BWNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of BWNOMDY as presented in the study report. Examples: "Week 4," "Day 28," "Terminal Sac".	Perm

Assumptions

1. Definition: The Body Weight (BW) domain captures body weights collected for subjects during the study and at the end of the study (terminal body weights).

2.8.9.2 SEND Cardiovascular (CV)**Description**

A findings domain that contains physiological and morphological findings related to the cardiovascular system, including the heart, blood vessels and lymphatic vessels.

cv.xpt, Cardiovascular System Findings — Findings. One record per test per observation time or evaluation interval per subject, Tabulation.

Specification**Domain Specification Table**

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	CV	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all application or submissions involving the product.	Req
CVSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
CVGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject and can be used to support relationships within the domain and between domains using RELREC. This is not the dosing group number.	Perm
CVSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference identifier.	Perm
CVTESTCD	Test Short Name	Char	(SCVTSTCD)	Topic	Short name of the measurement, test, or examination described in CVTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in CVTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). CVTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: DIABP, HR, MAP, SYSBP.	Req
CVTEST	Test Name	Char	(SCVTST)	Synonym Qualifier	Long name for CVTESTCD. The value in CVTEST cannot be longer than 40 characters. Examples: Diastolic Blood Pressure, Heart Rate, Mean Arterial Pressure, Systolic Blood Pressure.	Req
CVPOS	Position of Subject During Test	Char	(POSITION)	Record Qualifier	Position of the subject during the measurement or examination. If the subject is restrained, populate with the position (e.g., SITTING, STANDING); otherwise, populate with UNCONSTRAINED.	Exp
CVORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
CVORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology (http://www.cdisc.org/terminology) list.	Exp
CVSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from CVORRES in a standard format or standard units. CVSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in CVSTRESN.	Exp
CVSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; contains the numeric form of CVSTRESC. CVSTRESN should store all numeric test results or findings.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
CVSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for CVSTRESC and CVSTRESN.	Exp
CVSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in CVORRES.	Perm
CVREASND	Reason Not Done	Char		Record Qualifier	Describes why CVSTAT is NOT DONE, such as BROKEN EQUIPMENT.	Perm
CVMETHOD	Method of Test	Char		Record Qualifier	Method of the test or examination. Examples: Intravascular, External Cuff.	Exp
CVCSTATE	Consciousness State	Char	(CSTATE)	Record Qualifier	Consciousness state of the subject at the time of measurement. Examples: CONSCIOUS, SEMI-CONSCIOUS, UNCONSCIOUS.	Exp
CVBLFL	Baseline Flag	Char	(NY)	Record Qualifier	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is applicant defined.	Exp
CVDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null.	Perm
CVEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Y if the result should be excluded from all calculations, otherwise null.	Perm
CVREASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when CVEXCLFL is Y.	Perm
CVUSCHFL	Unscheduled Flag	Char	(NY)	Record Qualifier	Indicates whether the timing of the performed test or observation was unscheduled. If a test or observation was performed based upon a schedule defined in the protocol, this flag should be null. Expected values are Y or null.	Perm
CVDTC	Date/Time of Cardiovascular Test	Char	ISO 8601 datetime or interval	Timing	Date/time of cardiovascular data collection, in ISO 8601 format. For measurements related to a continuous evaluation interval, CVDTC should be used to indicate the start date/time of that interval.	Exp
CVENDTC	End Date/Time of Cardiovascular Test	Char	ISO 8601 datetime or interval	Timing	Date/time of end of a cardiovascular evaluation interval, in ISO 8601 format. Should be populated when CVDTC represents the start date/time of a continuous evaluation interval.	Perm
CVDY	Study Day of Cardiovascular Test	Num		Timing	Study day of cardiovascular data collection, in integer days. For measurements related to a continuous evaluation interval, CVDY can be used to indicate start day of that interval. The algorithm for calculating the day must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
CVENDY	Study Day of End of Cardiovascular Test	Num		Timing	Study day of the end of a cardiovascular evaluation interval, in integer days. Can be populated when CVDY represents the start day of a continuous evaluation interval. The algorithm for calculating the day must be relative to the applicant-defined RFSTDTC variable in the DM domain.	Perm
CVNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for observations that may occur on different days into a single reported study day. Should be an integer.	Exp
CVNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of CVNOMDY as presented in the study report Examples: Pretreatment, Week 4, Day 28.	Perm
CVTPT	Planned Time Point Name	Char		Timing	Text description of time when data should be collected. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See CVTPTNUM and CVTPTREF. Examples: Predose, 1 Hour Postdose.	Exp
CVTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of CVTPT to aid in sorting.	Exp
CVELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601 format) relative to a fixed time point reference (CVTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by CVTPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by CVTPTREF.	Exp
CVTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by CVELTM, if used for CVTPTNUM, and CVTPT. It is recommended that CVTPTREF be as descriptive as possible so the reference time point can be inferred without looking at others variables. Example: DAY 1 FIRST DOSE.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
CVRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/Time of the reference time point, CVTPTREF.	Perm
CVEVLINT	Evaluation Interval	Char	ISO 8601 duration or interval	Timing	Length of evaluation interval in ISO 8601 duration format. Used in place of CVSTINT and CVENINT when CVTPTREF is not available.	Perm
CVSTINT	Planned Start of Assessment Interval	Char	ISO 8601 duration	Timing	Planned start of an assessment interval relative to Time Point Reference (CVTPTREF) in ISO 8601 duration format. Example: When the evaluation interval is from 1 to 2 hours after dosing, the value would be PT1H.	Exp
CVENINT	Planned End of Assessment Interval	Char	ISO 8601 duration	Timing	Planned end of an assessment interval relative to Time Point Reference (CVTPTREF) in ISO 8601 duration format. Example: When the evaluation interval is from 1 to 2 hours after dosing, the value would be PT2H.	Exp

Assumptions

1. The CV domain contains dynamic measurements, collected or derived, related to the cardiovascular system, except those that follow the definition of the measurements in the ECG Test Results (EG) domain.
2. The timing variables CVDTC, CVENDTC, CVDY, and CVENDY are used to represent the actual start and end of the evaluation period during which data that contributed to the reported result were collected. This may be a portion of a longer period over which the instrument was continuously collecting data.
3. CVSTINT and CVENINT should be used to describe a known assessment interval whenever there is a reference time point (CVTPTREF).
4. CVMETHOD and CVCSTATE are considered important for comparison purposes and should be populated whenever available or collected.

2.8.9.3 SEND Clinical Observations (CL)

Description

This domain captures clinical sign information including ophthalmology, physical examination, and dermal examination collected in life while executing the study.

cl.xpt, Clinical Observations — Findings. One record per finding per observation time per subject or pool, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	CL	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Either USUBJID or POOLID must be populated.	Exp
POOLID	Pool Identifier	Char		Identifier	Identifier used for pooling subjects to assign a single finding to multiple subjects. If POOLID is entered, POOLDEF records must exist for each subject and the USUBJID must be null. Either USUBJID or POOLID must be populated.	Perm
FOCID	Focus of Study-Specific Interest	Char		Identifier	Identification of a focus of study-specific interest on or within a subject or specimen as defined in the protocol, for which a measurement, test, or examination was performed (e.g., for a drug application site, "Injection site 1," "Biopsy site 1," "Treated site 1") The value in this variable should have inherent semantic value.	Perm
CLSEQ	Sequence Number	Num		Identifier	The sequence number must be unique for each record within a USUBJID or POOLID, whichever applies for the record.	Req
CLGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject or pool. This is not the product exposure group number.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
CLSPID	Mass Identifier	Char		Identifier	Mass identifier such as MASS 1 or MASS A. Used when the mass was discovered during the in-life phase and assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.	Perm
CLTESTCD	Test Short Name	Char		Topic	Short name of the measurement, test, or examination described in CLTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in CLTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). CLTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
CLTEST	Test Name	Char		Synonym Qualifier	Long name for CLTESTCD. The value in CLTEST cannot be longer than 40 characters.	Req
CLCAT	Category for Clinical Observations	Char	(CLCAT)	Grouping Qualifier	Used to define a category of the clinical observation.	Req
CLSCAT	Subcategory for Clinical Observations	Char		Grouping Qualifier	Used to further categorize a group of clinical observations within a category. For example "Whole Body Appearance" and "Sensory Organ Appearance" may be subcategories within Clinical Signs.	Perm
CLBODSYS	Body System or Organ Class	Char	(BODSYS)	Record Qualifier	Body system or organ class associated with the measurement performed.	Perm
CLORRES	Result or Findings as Collected	Char		Result Qualifier	Text description of the finding as originally received or collected. If the examination was not performed on a particular body system, or at the subject level, then the value should be null, and NOT DONE should appear in CLSTAT.	Exp
CLSTRESC	Standardized Result in Character Format	Char		Result Qualifier	The base finding from CLORRES without modifiers. If the examination was completed and there were no abnormal findings, the value must be NORMAL.	Exp
CLRESCAT	Result Category	Char		Variable Qualifier	Used to categorize the result of a finding post collection. Examples: Color or Facial.	Perm
CLSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate examination not done or result is missing. Should be null if a result exists in CLORRES.	Perm
CLREASND	Reason Not Done	Char		Record Qualifier	Describes why CLSTAT is NOT DONE, such as SUBJECT MORIBUND.	Perm
CLLOC	Location of a Finding	Char		Record Qualifier	Can be used to specify where a clinical sign occurred. Example: LEFT EAR for skin rash.	Exp
CLEVAL	Evaluator	Char		Record Qualifier	Role of the person who provided the evaluation. Example: TOX TECHNICIAN, OPHTHALMOLOGIST, VETERINARIAN.	Perm
CLSEV	Severity	Char		Record Qualifier	Describes the severity or intensity of a particular finding.	Perm
CLEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Y if the result should be excluded from all calculations, otherwise null.	Perm
CLRELEASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when CLEXCLFL is Y.	Perm
CLUSCHFL	Unscheduled Flag	Char	(NY)	Record Qualifier	Indicates whether the timing of a performed test or observation was unscheduled. If a test or observation was performed based upon a schedule defined in the protocol, this flag should be null. Expected values are Y or null.	Perm
VISITDY	Planned Study Day of Collection	Num		Timing	Planned study day of collection. Should be an integer.	Perm
CLDTC	Date/Time of Observation	Char	ISO 8601 datetime or interval	Timing	Date/Time of the clinical observation in ISO 8601 format. For measurements related to a continuous evaluation interval, CLDTC should be used to indicate the start date/time of that interval.	Exp
CLENDTC	End Date/Time of Observation	Char	ISO 8601 datetime or interval	Timing	Date/Time of end of observation interval, in ISO 8601 format. Should be populated when CLDTC represents the start date/time of a continuous evaluation interval.	Perm
CLDY	Study Day of Observation	Num		Timing	Study day of observation, in integer days. For measurements related to a continuous evaluation interval, CLDY can be used to indicate start day of that interval. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
CLENDY	Study Day of End of Observation	Num		Timing	Study day of the end of observation, in integer days. Can be populated when CLDY represents the start day of a continuous evaluation interval. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
CLNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for observations that may occur on different days into a single reported study day. Should be an integer.	Exp
CLNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of CLNOMDY as presented in the study report. Examples: "Week 4," "Day 28," "Terminal Sac".	Perm
CLTPT	Planned Time Point Name	Char		Timing	Text description of time when an observation should be taken, as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time postdose.	Perm
CLTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of CLTPT to aid in sorting.	Perm
CLELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned Elapsed time (in ISO 8601 format) relative to a planned reference (CLTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: "- PT15M" to represent the period of 15 minutes prior to the reference point indicated by CLTPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by CLTPTREF.	Perm
CLTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by CLELTM, if used for CLTPTNUM, and CLTPT. It is recommended that CLTPTREF be as descriptive as possible, so the reference time point can be inferred without looking at other variables. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
CLRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/time of the reference time point, CLTPTREF.	Perm

Assumptions

1. Definition: The Clinical Observations (CL) domain captures clinical sign information in addition to ophthalmology, physical examination, and dermal examination collected during the in-life phase of the study.
2. Categorization: CLSCAT, CLTESTCD, and CLTEST can be used by the applicant to categorize data that were collected during in-life observation. CLCAT is fixed to the values specified in CDISC Controlled Terminology CLCAT list.
3. Results definition:
 - a. CLORRES contains the complete description of the clinical observation.
 - b. CLSTRESC should contain only the finding without modifiers. At this time it is not necessary to submit the additional modifiers elsewhere in this domain.
 - c. CLRESCAT is used for post-collection categorization of results and should not be a duplication of CLTEST or CLSCAT, which are considered categories at the time of collection.
4. The CLSPID variable is intended to reflect the identifier for any observed masses. This variable should be used to link in-life findings with pathology findings. The mass identifier in --SPID should be consistent across domains (CL, Palpable Masses, Macroscopic Findings, and Microscopic Findings).
5. Timing variables:
 - a. Information about the time of collection for any observation is needed to identify the record. CLDTC is expected, and the data will, in most cases, contain CLDTC, CLDY, or both. However, some studies (e.g., legacy studies) may not collect CLDTC or CLDY; in those cases, CLNOMDY must be populated.
 - b. CLTPT, CLTPTNUM, and CLELTM can be used when observations are made based on an elapsed time from a reference time point (e.g., 1 hour post-dose).

2.8.9.4 SEND Comments (CO)

Description

A special-purpose domain that contains comments that may be collected alongside other data.

co.xpt, Comments — Special-Purpose. One record per comment, Tabulation.**Specification****Domain Specification Table**

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	CO	Identifier	Two-character abbreviation for the domain.	Req
RDOMAIN	Related Domain Abbreviation	Char		Record Qualifier	Domain abbreviation of the parent record(s). Null for comments collected as a general comment or additional information.	Exp
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Either USUBJID or POOLID must be populated unless the record contains a study comment unrelated to a USUBJID or POOLID.	Exp
POOLID	Pool Identifier	Char		Identifier	Identifier used for pooled subjects to assign a single result to multiple subjects. Either USUBJID or POOLID must be populated unless the record contains a study comment unrelated to a USUBJID or POOLID.	Perm
COSEQ	Sequence Number	Num		Identifier	The sequence number must be unique for each record within a USUBJID or POOLID, whichever applies for the record.	Req
IDVAR	Identifying Variable	Char		Record Qualifier	Variable in the parent dataset that identifies the record(s) to which the comment applies, which is contained in IDVAR. Examples: BWSEQ or CLGRPID. Used only when individual comments are related to domain records.	Exp
IDVARVAL	Identifying Variable Value	Char		Record Qualifier	Value of identifying variable of the parent record(s). Used only when individual comments are related to domain records. Cannot be populated if IDVAR is null.	Exp
COREF	Comment Reference	Char		Record Qualifier	Applicant-defined reference associated with the comment. May be the logbook page number, name (e.g., Logbook), or a combination of information that identifies the reference (e.g., Logbook, page 650, Day 28, morning).	Perm
COVAL	Comment	Char		Topic	The text of the comment. Text over 200 characters can be added to additional columns COVAL1-COVALn.	Req
COEVAL	Evaluator	Char		Record Qualifier	Used to describe the originator of the comment. Examples: TECHNICIAN, STUDY DIRECTOR, VET.	Perm
CODTC	Date/Time of Comment	Char	ISO 8601 datetime or interval	Timing	Date/time of the comment, in ISO 8601 format. May be null if this is a child record of another domain or if the comment date was not collected. In all other cases, this represents the date/time of the comment in ISO 8601 format.	Exp
CODY	Study Day of Comment	Num		Timing	Study day of the comment, in integer days. May be null if this is a child record of another domain or if the comment date was not collected. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

Assumptions

1. The Comments special-purpose domain provides a solution for submitting free-text comments related to data in 1 or more SEND domains. Comments are generally not responses to specific questions; instead, they usually consist of voluntary, free-text, or unsolicited observations.
2. When RDOMAIN and USUBJID are not populated, it is assumed that a comment pertains to a study as a whole.
3. The CO dataset accommodates 3 sources of comments:
 - a. Related to a specific parent record or group of parent records, in which case the value of the variable RDOMAIN is set to the DOMAIN code of the parent record(s), and the variables IDVAR and IDVARVAL are populated with the key variable name and value of the parent record(s).
 - b. Unrelated to a specific domain or parent record(s), in which case the values of the variables RDOMAIN, IDVAR, and IDVARVAL are null. CODTC should be populated if captured.

- c. Related to a domain but not to specific parent record(s), in which case the value of the variable RDOMAIN is set to the DOMAIN code of the parent domain and the variables USUBJID, IDVAR, and IDVARVAL are null. CODTC should be populated if captured.
- 4. When the comment text is longer than 200 characters, the first 200 characters of the comment will be in COVAL, the next 200 in COVAL1, and additional text represented as needed to COVALn. **Note:** When using COVAL1-COVALn, the variable label should match the corresponding variable name (e.g., Comment1, Comment2).
- 5. See Section 2.8.5.4, [Relating Comments to a Domain](#), for additional information about how to relate comments to parent records.
- 6. The following identifier and timing variables are permissible and may be added as appropriate when comments are not related to other domain records: COGRPID, COREF, COREFID, COSPID, TAETORD, CODY, COTPT, COTPTNUM, COELTM, COTPTREF, and CORFTDTC.

2.8.9.5 SEND Death Diagnosis and Details (DD)

Description

A findings domain that contains the diagnosis of the cause of death for a subject.

dd.xpt, Death Diagnosis and Details — Findings. One record per diagnosis per subject (for unscheduled deaths only), Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DD	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
DDSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DDTESTCD	Death Diagnosis Short Name	Char	(DDTESTCD)	Topic	Short name of the measurement, test, or examination described in DDTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DDTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). DDTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
DDTEST	Death Diagnosis Name	Char	(DDTEST)	Synonym Qualifier	Long name for DDTESTCD. The value in DDTEST cannot be longer than 40 characters.	Req
DDORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the diagnosis of the subject's cause of death, as originally received or collected.	Req
DDSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the diagnosis information, copied or derived from DDORRES in a standard format. Examples: UNKNOWN, Gavage ERROR.	Exp
DDRESCAT	Result Category	Char		Variable Qualifier	Used to categorize the result of a finding. Examples: EXPOSURE RELATED, NON-EXPOSURE RELATED, UNDETERMINED, ACCIDENTAL, etc.	Perm
DDEVAL	Evaluator	Char		Record Qualifier	Role of the person who provided the evaluation. Examples: TOX PATHOLOGIST, PEER REVIEW, VETERINARIAN.	Perm
DDDTCT	Date/Time	Char	ISO 8601 datetime or interval	Timing	The date/time of subject disposition, in ISO 8601 format.	Perm
DDDY	Study Day	Num		Timing	Study day of subject disposition, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

Assumptions

1. The Death Diagnosis and Details (DD) domain captures the diagnosis of the cause of death for a subject.
2. No records will be present for subjects where a cause of death was not collected. The DD domain should be utilized only for subjects with an unscheduled death. This may include moribund subjects, subjects found dead, accidental deaths, and so on.
3. The DD domain will not include findings of "planned sacrifice" or other scheduled reasons for termination.
4. The information in this domain may duplicate "death relationship" information in other domains. The cause of death will be explicitly presented here if available, even when a --DTHREL implies cause of death in another domain.

2.8.9.6 SEND Demographics (DM)

Description

A special-purpose domain that includes a set of essential standard variables that describe each subject in a nonclinical study. One record will exist for each subject.

dm.xpt, Demographics — Special-Purpose. One record per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SUBJID	Subject Identifier for the Study	Char		Topic	Subject (i.e., animal) identifier used within the study.	Req
RFSTDTC	Subject Reference Start Date/Time	Char	ISO 8601 datetime or interval	Record Qualifier	Reference start date/time for the subject in ISO 8601 format. Usually equivalent to date/time when subject was first exposed to study product. Study day calculation (the --DY variable) in all domains will be based on this date. The collected date used to populate RFSTDTC must be defined in the data definition file.	Req
RFENDTC	Subject Reference End Date/Time	Char	ISO 8601 datetime or interval	Record Qualifier	Reference end date/time for the subject in ISO 8601 format. Usually equivalent to the date/time when the subject was determined to have left the study. The collected date used to populate RFSTDTC must be defined in the data definition file.	Exp
RFXSTDTC	Date/Time of First Study Exposure	Char	ISO 8601 datetime or interval	Record Qualifier	First date/time of exposure to any protocol-specified product exposure, equal to the earliest value of EXSTDTC. Note: Absolute first.	Perm
RFXENDTC	Date/Time of Last Study Exposure	Char	ISO 8601 datetime or interval	Record Qualifier	Last date/time of exposure to any protocol-specified product, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing). Note: Absolute last.	Perm
SITEID	Study Site Identifier	Char		Record Qualifier	Unique identifier for a study site within a submission. Use only if subjects are housed at different sites.	Perm
BIRTHDTC	Date/Time of Birth	Char	ISO 8601 datetime or interval	Record Qualifier	Date/time of birth of the subject, in ISO 8601 format.	Perm
AGE	Age	Num		Record Qualifier	May be derived (RFSTDTC - BIRTHDTC), but BIRTHDTC may not be available in all cases. Age may also be collected.	Perm
AGETXT	Age Range	Char	number-number	Record Qualifier	Used when the age is a range and the exact birthdate is not known. This variable is a character field for the purposes of defining age ranges (e.g., if the information available for the age of the subject is 6-8 and AGEU is WEEKS). Populate only when BIRTHDTC or AGE is not specified. The format for AGETXT is number-number (e.g., 6-8).	Perm
AGEU	Age Unit	Char	(AGEU)	Variable Qualifier	Units associated with AGE and AGETXT.	Exp
SEX	Sex	Char	(SEX)	Record Qualifier	The sex of the subject.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
SPECIES	Species	Char	(SPECIES)	Record Qualifier	If this variable is excluded in the DM domain, the information must be present at a higher level (either Trial Sets or Trial Summary).	Perm
STRAIN	Strain/Substrain	Char	(STRAIN)	Record Qualifier	Used to identify the vendor-supplied strain, substrain, or breed designation for the test system under study. It may combine the background strain, substrain, and associated genetic modifications as supplied by the vendor (e.g., C57BL/6, A/J, B6.129-Pparg<tm2Rev>/J, FISCHER 344, SPRAGUE-DAWLEY IGS, WISTAR Kyoto, BEAGLE, Cynomolgus, and CHIMPANZEE). The SEND Controlled Terminology codelist consists of commonly used wild type strains. It is extensible to accommodate strains not listed and genetically modified substrains. If this variable is excluded in the DM domain, the information must be present at a higher level (either Trial Sets or Trial Summary). Country of origin for non-human primates should not go into STRAIN. In general, details related to coat color (e.g., white and red designations for New Zealand Rabbits) should not go into STRAIN.	Perm
SBSTRAIN	Strain/Substrain Details	Char		Record Qualifier	Free-text field that allows the to enter further details qualifying the SPECIES and/or STRAIN, depending on the level to which these variables were defined. Examples include the description of a specific genetic alteration, country of origin for non-human primates, details related to coat color (e.g., white and red designations for New Zealand Rabbits), and important animal husbandry information (e.g., SPF, BR, VAF).	Perm
ARMCD	Planned Arm Code	Char		Record Qualifier	Short name for ARM (may be up to 20 characters) used for sorting and programming. Should be populated when Arms have been defined in the TA domain.	Exp
ARM	Description of Planned Arm	Char		Synonym Qualifier	Descriptive name given to a specific trial arm to which the subject was assigned.	Perm
SETCD	Set Code	Char		Record Qualifier	Short name of a specific trial set to which the subject was assigned, as defined by the applicant. Maximum of 8 characters. This represents the trial set for which parameters are being submitted.	Req

Assumptions

1. Subject identification: It is presumed that every subject (i.e., animal) in a study will have a subject identifier (SUBJID). In some cases, a subject may be included in more than 1 study within a submission, and, more commonly, subjects from different studies may have the same subject identifier. To identify a subject uniquely across a submission, a unique identifier (USUBJID) should be assigned and included in all subject-related datasets in the submission.
2. Arm identification: When submitting study design information, the values of ARMCD and ARM should be identical to the values defined for that subject in the Subject Elements (SE) dataset. The assignment of values should be consistent, if possible, within a submission.
3. When additional information is reported about the subjects, this information should be placed in the Subject Characteristics (SC) domain, adding the specific variable as a value in SCTEST. Study design information that does not vary on an individual subject level should be placed in the Trial Sets (TX) table.
4. BIRTHDTC, AGE, and AGETXT: These variables represent 3 levels of precision for the age of the subject, and they should be used according to the information available.
 - a. AGE and AGETXT should never both be populated for the same subject. AGEU refers to whichever variable is used.
 - b. If information is available about the time of birth for the subject, it should be presented in the variable BIRTHDTC in ISO 8601 format, even if this is only partial information (not a complete date of birth).
 - c. Data in BIRTHDTC should never be derived from another variable. Either this information is collected or this variable should be blank.
 - d. If a specific age for the subject is known, but no information regarding date/time of birth is available, then AGE and AGEU should be populated, using the most descriptive/precise unit for the data (e.g., 1 year, 2 months would be AGE = "14" and AGEU = "MONTHS").

- e. AGE and AGEU may be derived using an algorithm involving BRTHDTC and RFSTDTC. In this case, comments in the define file should indicate how AGE was populated.
- f. If only an approximate age is known (e.g., 6-8 weeks), then use AGETXT in conjunction with AGEU (e.g., AGETXT = "6-8" and AGEU = "WEEKS"). The format for AGETXT is number-number (e.g., "6-8").
- 5. RFSTDTC, RFENDTC, and BRTHDTC represent date/time values, but they are considered to have a record qualifier role in DM. They are not considered to be timing variables as described in SDTM v1.5, Section 2.2.6, because they are not intended for use in the general observation classes. The subject may have records in other domains with a date/time prior to RFSTDTC and after the RFENDTC.
- 6. SPECIES and STRAIN: These variables are permissible and should be used only if different species or strains are used during 1 study. If all the subjects in 1 study are of the same species, strain, and substrain, then this information is collected in the Trial Summary (TS) table. TX can have multiple species and/or strains if they are different by set.
- 7. The SETCD variable is to be used to uniquely identify all distinct "groups" or "trial sets." A *trial set* is a collection of subjects that have a common set of parameters defined in the protocol, where those parameters include experimental parameters, product exposure strategies, inherent characteristics (e.g., strain) parameters, and/or applicant-defined attributes (e.g., control group designation). In general, if a distinction between arms does not cause the subjects to be summarized or grouped independently, then the arms should not be reflected as a separate trial set. A subject may belong to 1 and only 1 trial set.
- 8. ARM: An *arm* is a planned path through a study. This path covers the entire time of the study. The group of subjects assigned to an arm is also often colloquially called an "arm." The group of subjects assigned to an arm is also often called an "exposure group," although it is not necessarily a product exposure group. The same arm can be used to separate subjects into different satellites. For example, use SETCD for assigning main study subjects and TK study subjects.

2.8.9.7 SEND Device Identifiers (DI)

Description

A study reference dataset that provides a mechanism for using multiple identifiers to create a single identifier for each device.

di.xpt, Device Identifiers — Study Reference. One record per device identifier per device, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DI	Identifier	Two-character abbreviation for the domain.	Req
SPDEVID	Applicant Device Identifier	Char		Identifier	Applicant-defined identifier for the device. The value of SPDEVID may be linked to a nonclinical trial set by a matching value of the parameter APDEVID in the TX dataset. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, combination of identifiers).	Req
DISEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a parameter within a device (SPDEVID) within dataset. If there is only one value for DIPARMCD for each value of SPDEVID, then DISEQ will be 1 for all records. DISEQ must be a valid number.	Exp
DIPARMCD	Device Identifier Element Short Name	Char		Topic	Short name of the identifier characteristic of the device (e.g., "SERIAL", "MODEL"). A record with DIPARMCD = "DEVTYPE" should be included (see below).	Req
DIPARM	Device Identifier	Char		Synonym Qualifier	Name of the identifier characteristic of the device. Examples: Serial Number, Model. A record with DIPARM = "DEVTYPE" should be included (see below).	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
	Element Name					
DIVAL	Device Identifier Element Value	Char		Result Qualifier	Value for the parameter. Value for the parameter. When DIPARMCD=DEVTYPE it should use controlled terminology defined by FDA in their Preferred Term codelist. FDA has stated a preference for the Global Medical Device Nomenclature (GMDN), but as of the date of this publication, the GMDN is not freely available to the public. In its Unique Device Identification rule (https://www.fda.gov/MedicalDevices/), FDA indicated that GMDN will not be required unless it is available to the public at no cost. There is a lookup tool on the FDA website to map GMDN codes to FDA PT codes.	Req

Assumptions

1. Definition: Device Identifiers (DI) is a Study Reference domain that provides a mechanism for using multiple identifiers to create a single identifier for each device.
2. The primary purpose of this domain is to provide a consistent variable (SPDEVID) for linking data across Device domains, independent of the level of granularity by which a device might be identified by a applicant in a study. One of the challenges of identifying devices consistently is that different types of devices use different characteristics and different numbers of characteristics as identifiers. For example, it may be sufficient to use a serial number only to identify an MRI machine, but identifying a box of screws may require a batch number and a box number. In study-specific datasets this could be accomplished by using different numbers of identifier variables, but this is not feasible for a general standard. SPDEVID is a mechanism for aggregating any number of identifiers into one, allowing for a consistent structure for identifying all devices. SPDEVID is a surrogate identifier that represents all the characteristics of a device in the Study DI domain, but is a simple, short identifier that can appear in each dataset. Having different identifier variables in different submissions does not help interoperability, and this approach allows for a single identifier while preserving access to the identifying information needed for the submission. It also facilitates merging datasets.
3. DI was modeled as a Study Reference domain because it has none of the characteristics (except identifiers) of a Findings domain, and is clearly not an event or intervention. DI contains the total set of characteristics necessary for device identification.
4. In order to determine the right level of granularity for the parameters defined in DI, it is critical that the applicant think carefully about how the devices will need to be tracked (e.g., in Device-In-Use, Device Events) and design SPDEVID to reflect that level of specificity. For example, if surgical screws only need to be tracked by box and not by individual screw, then the value in SPDEVID might be a box number. If each screw needs to be tracked, then the parameters would need to include the identifier on each screw.
5. The DI domain must exist if SPDEVID is used in any domain in a study. It is required when any device-specific information is submitted. This includes information about the device under study as well as parameters captured for devices not under study (e.g., MRI slice thickness, field strength). If none of this applies (e.g., ECG machine used to generate a tracing, but no information about the machine is needed), then DI is not required.
6. If the DI domain exists, at a minimum it must contain a record with DIPARMCD=DEVTYPE, and this parameter must be populated.
7. SPDEVID should not change during a specific device's lifetime.
8. DISEQ must be unique within each value of DIPARMCD within a SPDEVID. If there is only 1 value of DIPARMCD per device, then DISEQ will always be 1.
9. The DI domain was designed to be able to handle situations where SPDEVID is needed to identify individual devices. In some situations, such as studies in which a device is not the product under study and is used only to conduct assessments, SPDEVID may need only to identify a kind of device. For example, an oncology trial might need to identify the kind of device used to image a tumor, in which case SPDEVID might be used to distinguish MRI, CT, and X-Ray devices. In such cases, the minimum requirement for a

SPDEVID for a kind of device is DEVTYPE (DIPARMCD=DEVTYPE). Applicants should define the appropriate level of granularity for unique identification; in some cases it may be a serial number, whereas in others it may be a box, lot, or batch number, or some combination of these or other identifiers.

10. The DI domain is often referred to as the Study DI domain to help distinguish it from the FDA's Unique Device Identifier (UDI).
11. This domain should not be used for device characteristics other than identifiers.
12. This structure allows for the association between one SPDEVID and as many identifiers as a applicant feels necessary to support all the submitted data. This easily transforms into a one-record-per-SPDEVID structure for potential merging with other device-related datasets that would contain the SPDEVID variable, as shown in these samples for a set of Study DI records for a single device.

DI data arranged vertically (normalized) showing correspondence between identifiers and SPDEVID (SDTM structure):

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
DEVM-0004-0003	DI	ABC001	1	DEVTYPE	Device Type	STENT
DEVM-0004-0003	DI	ABC001	2	MANUF	Manufacturer	Acme Stents
DEVM-0004-0003	DI	ABC001	3	MODEL	Model	45-JFI
DEVM-0004-0003	DI	ABC001	4	BATCH	Batch identifier	2011-1307
DEVM-0004-0003	DI	ABC001	5	LOT	Lot Identifier	45678
DEVM-0004-0003	DI	ABC001	6	SERIAL	Serial Number	456789132-AXQ
DEVM-0004-0003	DI	ABC001	7	Y	Manufacturer Y-code	32110
DEVM-0004-0003	DI	ABC001	8	Z	Manufacturer Z-code	6A-55

DI data arranged horizontally (non-normalized) showing identifiers and SPDEVID on a single record (non-SDTM structure):

SPDEVID	DEVTYPE	MANUF	MODEL	BATCH	LOT	SERIAL	IDENTIFIER Y	IDENTIFIER Z
ABC001	STENT	Acme Stents	45-JFI	2011-1307	45678	456789132-AXQ	32110	6A-55

13. The data in this domain may be derived (manually or electronically).
14. No date variables have been included in this domain because the characteristics defined in Study DI should not change over the course of the trial and because temporal associations will generally be captured in other domains.
15. No additional variables can be added to this dataset.
16. DIPARMCD values are limited to 8 characters and cannot begin with a number or underscore, as they can be used as variable names when the dataset is transposed to a non-normalized structure.
17. If FDAUDI is used, it is intended to hold the FDA's UDI assigned after device approval. For post-approval studies, SPDEVID could be the FDAUDI value only. If the device is pre-approval, this variable would be null.
18. If the FDAUDI can be populated, the DEVTYPE should still be included. Applicants may include additional parameters as needed.
19. An incomplete list of DIPARMCD and DIPARM values is shown in the following table.

DIPARMCD	DIPARM
FDAUDI	FDA Unique Device Identifier
DEVTYPE	Device Type
MANUF	Manufacturer
MODEL	Model
BATCH	Batch identifier
LOT	Lot Identifier
SERIAL	Serial Number

20. Generally, the SPDEVID should include the set of parameters necessary for identifying the device uniquely, and would also have all of the higher level parameters. For example, if serial number were sufficient to identify the device, generally model, manufacturer, and device type would be included (if available or relevant). The FDAUDI is effectively a surrogate key for the rest of the identifiers, so the combination of FDAUDI and DEVTYPE could be sufficient to identify each device for a post-marketing study. Alternatively, if information embedded in the FDAUDI is needed for data aggregation, analysis, or

appropriate interpretation of the data, other identifier variables can also be extracted from FDAUDI and included.

2.8.9.8 SEND Device-in-Use (DU)

Description

A findings domain that contains the measurements and settings that are intentionally set on a device when it is in use. These are characteristics that exist for the device, and have a specific setting for a use instance.

du.xpt, Device-in-Use — Findings. One record per property or setting per time point per visit or test date per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DU	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Expected in this domain as devices may have settings or uses that either may not involve subjects (e.g., diagnostic tools) or devices that are removed from the study prior to contact with a subject (e.g., device has malfunction).	Exp
SPDEVID	Applicant Device Identifier	Char		Identifier	Applicant-defined identifier for the device. The value of SPDEVID may be linked to a nonclinical trial set by a matching value of the parameter APDEVID in the TX dataset. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, combination of identifiers).	Exp
DUSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of device records within subject records within a domain. May be any valid number. It should be unique within every subject/device combination.	Req
DUGRPID	Group ID	Char		Identifier	Identifier for a group or block of related records. Used to tie together a block of related records in a single domain for a subject or a group of subject related records (e.g., group records specifying all the settings for a specific imaging scan, such as field strength, repetition time and echo time).	Perm
DUREFID	Reference ID	Char		Identifier	Internal or external identifier. This could be a scan code or equivalent. The value of DUREFID may be linked to a nonclinical trial set by a matching value of the parameter SMKRGM. SMKRGM is an identifier used to represent a smoking regimen in the TX dataset and serves as a link to the Device-In-Use (DU) domain, where a matching value of DUREFID indicates parameters of the smoking regimen performed by the smoking machine.	Perm
DUSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number.	Perm
DUTESTCD	Device-In-Use Test Short Name	Char	(DUTESTCD)	Topic	Short name of the measurement, test, or examination described in DUTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DUTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). DUTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "COILSTR", "CNTMEDIA".	Req
DUTEST	Device-In-Use Test Name	Char	(DUTEST)	Synonym Qualifier	Vernacular name of the test or examination used to obtain the measurement or finding. The value in DUTEST cannot be longer than 40 characters. Examples: "Coil Strength", "Contrast Media".	Req
DUCAT	Category for Device-In-Use	Char		Grouping Qualifier	Defines a category of related records.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					It can be used to define the type of device for which settings are recorded if the DI domain is not used (e.g., if the device is not under study); may also be used to record the type of setting (e.g., "HARDWARE" vs. "SOFTWARE").	
DUSCAT	Subcategory for Device-In-Use	Char		Grouping Qualifier	A further categorization of a measurement or examination. For example, if DUCAT = "SOFTWARE", DUSCAT might be "NOMINAL" or "POST-ADJUSTMENT".	Perm
DUORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement as originally received or collected. DUORRES should contain the setting or other device condition in effect at the time the device was used.	Exp
DUORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for DUORRES. Examples: Tesla, mm.	Exp
DUSTRESC	Result or Finding in Standard Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from DUORRES in a standard format or standard units. DUSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in DUSTRESN. For example, if a test has results "NONE," "NEG," and "NEGATIVE" in DUORRES, and these results effectively have the same meaning, they could be represented in standard format in DUSTRESC as "NEGATIVE".	Exp
DUSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format. Copied in numeric format from DUSTRESC. DUSTRESN should store all numeric test results or findings.	Exp
DUSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for DUSTRESC and DUSTRESN. The unit for standardized results may or may not be the same as for the original results.	Exp
VISITNUM	Visit Number	Num		Timing	A clinical encounter number. A numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	Protocol-defined description of clinical encounter. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics (DM). This value is usually derived.	Perm
DUDTC	Date/Time Device Used with Test/Setting	Char	ISO 8601 datetime or interval	Timing	Date/time that the device was used with this setting. This is not the date/time that the setting was set on the device, but rather that date/time that a measurement or test was done using that setting.	Exp
DUDY	Study Day of Observation	Num		Timing	Study day of DU measurement, measured as integer days. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in DM.	Perm

Assumptions

1. Definition: The Device In-Use (DU) domain represents properties of an ancillary device that are intentionally set when the device is used in the context of a study.
2. Tobacco products—including ENDS devices—are not considered ancillary devices and would not be represented here. An *ancillary device* is a device used within a study but which is not the target of the study (e.g., a smoking machine that performs a smoking regimen). If settings for an ancillary device in a study need to be recorded and the device needs to be identified in the data, Device Identifiers (DI) must be used for that identification.
3. The DU domain captures characteristics and properties of a device that can vary from subject to subject or usage to usage over the course of a study. For example:
 - a. While the full range of field strengths for a given MRI machine might be 0.5 to 3 tesla, DU would record the specific settings used for a given subject (e.g., the field strength for the MRI scan for subject 123 was 0.5T for visit 1).
 - b. The software for a pacemaker may start at version 1, and be updated to version 2 during the study. This change can be captured in the DU domain.
4. There are 2 primary identifiers in this domain: USUBJID and SPDEVID. Both are Expected. Either 1 or the other or both must be used. For example, a device under study will always have a SPDEVID, but may or

may not have a USUBJID. An ancillary device (one not under study) for which in-use data are required may have a USUBJID but may or may not have SPDEVID. In all cases where SPDEVID is used, it must be defined in the DI domain.

5. This domain is not intended to capture manufacturer-set (i.e., nominal) settings, but rather the customized settings for a given usage.
6. Because any number of device settings (e.g., coil strength, placement of leads) can be reported in this domain, each setting is represented by a separate row and is defined in the topic variable DUTESTCD. The original result goes into DUORRES.
7. DUREFID is the identifier for a unique scan or other test result to link a group of settings (e.g., field strength or slice thickness in an MRI scan) to the results obtained from the reading or interpretation of the test (e.g., the MRI image).
8. The DUSPID variable can be used to link this domain to other domains if necessary, such as Clinical Observations (CL), and/or Exposure.
9. The following Qualifiers would not generally be used in DU: --MODIFY, --BODSYS, --POS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STNRC, --NRIND, --RESCAT, --REASND, --XFN, --NAM, --LOINC, --SPEC, --SPCCND, --LOC, --METHOD, --FAST, --DRVFL, --EVAL, --TOX, --TOXGR, --SEV, --DTHREL, --LLOQ.

2.8.9.9 SEND Disposition (DS)

Description

An events domain that contains information encompassing and representing data related to subject disposition.

ds.xpt, Disposition — Events. One record per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
DSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DSTERM	Reported Term for the Disposition Event	Char		Topic	DSTERM is the original term recorded for subject disposition. DSTERM is not under controlled terminology, but should be mapped to DSDECOD.	Req
DSDECOD	Standardized Disposition Term	Char	(DSDECOD)	Synonym Qualifier	Contains the result in a standard format.	Req
DSUSCHFL	Unscheduled Flag	Char	(NY)	Record Qualifier	Indicates whether the subject's disposition was unscheduled. If the subject's disposition was based upon a schedule defined in the protocol, this flag should be null. Expected values are Y or null.	Exp
VISITDY	Planned Study Day of Disposition	Num		Timing	Planned study day of collection. Should be an integer. VISITDY should be populated only when DSTERM represents a scheduled activity.	Perm
DSSTDTC	Date/Time of Disposition	Char	ISO 8601 datetime or interval	Timing	Date/Time of the disposition event, in ISO 8601 format.	Req
DSSTDY	Study Day of Disposition	Num		Timing	Study day of the disposition event, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
DSNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for observations that may occur on different days into a single reported study day. Should be an integer.	Exp
DSNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of DSNOMDY as presented in the study report. Examples: Week 4, Day 28, Terminal Sac.	Perm

Assumptions

1. Definition: The Disposition (DS) dataset provides a record of the final disposition of subjects, which can be recorded at any stage throughout a study. At study completion, a record must exist for each subject in the study.
2. DS Description and coding: DSTERM is not under controlled terminology, but should be mapped to controlled terminology for DSDECOD.
3. DSSTDTC is used for the date/time of the disposition event. Disposition events do not have end dates, because these events do not span an interval but occur at a single date/time (e.g., date of terminal sacrifice). An interval of uncertainty cannot be used for DSSTDTC.

2.8.9.10 SEND ECG Test Results (EG)

Description

A findings domain that contains ECG data, including position of the subject, method of evaluation, all cycle measurements and all findings from the ECG including an overall interpretation if collected or derived.

eg.xpt, ECG Test Results — Findings. One record per test per observation time per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	EG	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
EGSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
EGGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject. This is not the dosing group number.	Perm
EGREFID	ECG Reference Identifier	Char		Identifier	Internal or external ECG identifier. Example: UUID.	Perm
EGSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference identifier.	Perm
EGTESTCD	ECG Test Short Name	Char	(EGTESTCD)	Topic	Short name of the measurement, test, or examination described in EGTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in EGTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). EGTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: EGHRMN, QTMAX.	Req
EGTEST	ECG Test Name	Char	(EGTEST)	Synonym Qualifier	Long name for EGTESTCD. The value in EGTEST cannot be longer than 40 characters. Examples: ECG Mean Heart Rate, Summary (Max) QT Duration.	Req
EGCAT	Category for ECG	Char	(EGCATSND)	Grouping Qualifier	Used to define a category of the ECG test performed. Examples: MEASUREMENT, DIAGNOSIS, INTERPRETATION.	Perm
EGPOS	ECG Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. If the subject is restrained, populate with the position (example SITTING or STANDING); otherwise, populate with UNCONSTRAINED.	Exp
EGORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the ECG measurement or finding as originally received or collected.	Exp
EGORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology (http://www.cdisc.org/terminology) list.	Exp
EGSTRESC	Standardized Result in Character Format	Char	(EGSTRESC)	Result Qualifier	Contains the result value for all findings, copied or derived from EGORRES, in a standard format or standard units. EGSTRESC should store all results or findings in character format, using controlled terminology, where possible. If	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					results are numeric, they should also be stored in numeric format in EGSTRESN.	
EGSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of EGSTRESC. EGSTRESN should store all numeric test results or findings.	Exp
EGSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for EGSTRESC and EGSTRESN.	Exp
EGSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in EGORRES.	Perm
EGREASND	Reason Not Done	Char		Record Qualifier	Describes why EGSTAT is NOT DONE, such as BROKEN EQUIPMENT.	Perm
EGXFN	ECG External File Name	Char		Record Qualifier	File name and path for the external ECG Waveform file. Would be used if applicant is requested to submit waveform.	Perm
EGNAM	Laboratory Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor that provided the test results.	Perm
EGMETHOD	Method of ECG Test	Char	(EGMETHOD)	Record Qualifier	Method of the test or examination. Examples: 12 LEAD STANDARD, 6 LEAD STANDARD.	Exp
EGLEAD	Lead Used for Measurement	Char	(EGLEAD)	Record Qualifier	Lead identified to capture the measurement.	Exp
EGCSTATE	Consciousness State	Char	(CSTATE)	Record Qualifier	Consciousness state of the subject at the time of measurement. Examples: CONSCIOUS, SEMI-CONSCIOUS, UNCONSCIOUS.	Exp
EGBLFL	Baseline Flag	Char	(NY)	Record Qualifier	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is applicant defined.	Exp
EGDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records that represent the average of other records, or that are not as originally received or collected, are examples of records that might be derived for the submission datasets.	Perm
EGEVAL	Evaluator	Char		Record Qualifier	Role of the person who provided the evaluation. Should be null for records that contain collected or derived data. Examples: RESPONSIBLE SCIENTIST, PRINCIPAL INVESTIGATOR, PEER REVIEWER.	Perm
EGEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Y if the result should be excluded from all calculations, otherwise null.	Perm
EGREASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when EGEXCLFL is Y.	Perm
EGUSCHFL	Unscheduled Flag	Char	(NY)	Record Qualifier	Indicates whether the timing of the performed test or observation was unscheduled. If a test or observation was performed based upon a schedule defined in the protocol, this flag should be null. Expected values are Y or null.	Perm
VISITDY	Planned Study Day of Collection	Num		Timing	Planned study day of collection. Should be an integer.	Perm
EGDTC	Date/Time of ECG Collection	Char	ISO 8601 datetime or interval	Timing	Date/time of ECG data collection, in ISO 8601 format. For indicating measurement over a continuous period, DTC should be used to indicate start date/time of collection.	Exp
EGENDTC	End Date/Time of ECG Collection	Char	ISO 8601 datetime or interval	Timing	Date/time of end of the ECG data collection, in ISO 8601 format. Should be populated for measurement over a continuous period only.	Perm
EGDY	Study Day of ECG Collection	Num		Timing	Study day of the ECG measurement collection, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
EGENDY	Study Day of End of ECG Collection	Num		Timing	Study day of the end of the ECG measurement collection, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the DM domain.	Perm
EGNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for observations that may occur on different days into a single reported study day. Should be an integer.	Exp
EGNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of EGNOMDY as presented in the study report. Examples: Pre-Exposure, Week 4, Day 28.	Perm
EGTPT	Planned Time Point Name	Char		Timing	Text description of time when ECG data should be collected. Note: This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See EGTPNUM and EGTPTRREF. Examples: Predose, 1 Hour Postdose.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
EGPTNUM	Planned Time Point Number	Num		Timing	Numerical version of EGPT to aid in sorting.	Perm
EGELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601 format) relative to a fixed time point reference (EGPTREF). This variable is useful where there are repetitive measures. Not a clock-time or a date-time variable. Represented as an ISO 8601 duration. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by EGPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by EGPTREF.	Perm
EGPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by EGELTM, if used for EGPTNUM, and EGPT. It is recommended that EGPTREF be as descriptive as possible so the reference time point can be inferred without looking at others variables. Example: DAY 1 FIRST DOSE.	Perm
EGRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/time of the reference time point, EGPTREF.	Perm
EGEVINT	Evaluation Interval	Char	ISO 8601 duration or interval	Timing	Length of evaluation interval in ISO 8601 duration format. Used in place of EGSTINT and EGENINT when EGPTREF is not available.	Perm
EGSTINT	Planned Start of Assessment Interval	Char	ISO 8601 duration	Timing	Planned start of an assessment interval relative to Time Point Reference (EGPTREF) in ISO 8601 duration format.	Perm
EGENINT	Planned End of Assessment Interval	Char	ISO 8601 duration	Timing	Planned end of an assessment interval relative to EGPTREF in ISO 8601 duration format.	Perm

Assumptions

1. The EG domain captures ECG-specific parameters, as well as interpretations and diagnoses derived from those measurements.
2. The timing variables EGDTC, EGENDTC, EGDY and EGENDY are used to represent the actual start and end of the evaluation period during which data that contributed to the reported result were collected. This may be a portion of a longer period over which the instrument was continuously collecting data.
3. EGPOS, EGLEAD, EGMETHOD, and EGCSTATE are considered important for comparison purposes and should be populated whenever available or collected.

2.8.9.11 SEND Exposure (EX)

Description

An interventions domain that contains the details of a subject's exposure to protocol-specified study products. A study product may be any intervention that is prospectively defined as a test material within a study, and is typically but not always supplied to the subject.

ex.xpt, Exposure — Interventions. One record per protocol-specified study product per constant-dosing interval per subject or pool, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	EX	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Either USUBJID or POOLID must be populated.	Exp
POOLID	Pool Identifier	Char		Identifier	Identifier used for pooling subjects to assign a single finding to multiple subjects. If POOLID is entered, POOLDEF records must exist for each subject and the USUBJID must be null. Either USUBJID or POOLID must be populated.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
FOCID	Focus of Study-Specific Interest	Char		Identifier	Identification of a focus of study-specific interest on or within a subject or specimen as defined in the protocol for which a measurement, test, or examination was performed (e.g., for a drug application site, "Injection site 1," "Biopsy site 1," "Treated site 1"). The value in this variable should have inherent semantic value.	Perm
EXSEQ	Sequence Number	Num		Identifier	The sequence number must be unique for each record within a USUBJID or POOLID, whichever applies for the record.	Req
EXTRT	Name of Actual Product	Char		Topic	Name of the product, as defined by the protocol.	Req
EXDOSE	Dose per Administration	Num		Record Qualifier	Amount of product administered.	Exp
EXDOSTXT	Dose Description	Char		Record Qualifier	If the amount of product administered cannot be represented as a number and populated in EXDOSE, this field is used to describe the amount of product administered. Example: 200-400.	Perm
EXDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for EXDOSE or EXDOSTXT. Examples: ng, mg, or mg/kg.	Exp
EXDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for product (form administered). Examples: TABLET, LOTION.	Exp
EXDOSFRQ	Dosing Frequency Per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of EXDOSE within a specific time period. Examples: QD (once daily), BID (2x daily).	Req
EXROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for EXTRT. Examples: ORAL, GAVAGE, DERMAL, INTRAVENOUS.	Req
EXLOT	Lot Number	Char		Record Qualifier	Lot number(s) or batch number(s) of the EXTRT test article. If mixed lots of the test article are administered during the same constant dosing interval, this should be represented as "Lot A; Lot B." Mixed lots are produced by the mixing of lots A and B of the test article into 1 solution, suspension, or dietary food concentration. If no test article was administered, EXLOT should be null.	Exp
EXLOC	Location of Dose Administration	Char		Record Qualifier	Specifies anatomical location (site) of administration. Example: LEFT HINDLIMB for a topical application or an injection site number. Each administration will require its own record.	Perm
EXMETHOD	Method of Administration	Char		Record Qualifier	Method of the dose administration. Example: INFUSION.	Perm
EXRTTV	Product Vehicle	Char		Record Qualifier	Describes vehicle used for exposure. Example: SALINE.	Exp
EXVAMT	Amount Administered	Num		Record Qualifier	The amount (volume or weight) of the product plus vehicle administered in a single dose. This is not to be confused with EXDOSE. EXDOSE refers to the amount of test material administered to the subject.	Perm
EXVAMTU	Amount Administered Units	Char	(UNIT)	Variable Qualifier	Units for EXVAMT (per dose administration).	Perm
EXADJ	Reason for Dose Adjustment	Char		Record Qualifier	Describes reason or explanation of why a dose is adjusted. Used only when an adjustment is represented in EX. May be used for variations from protocol-specified doses or changes from expected doses (e.g., when dose is adjusted due to toxicity).	Perm
EXSTDTC	Start Date/Time of Exposure	Char	ISO 8601 datetime or interval	Timing	Date/time when administration of the product indicated by EXTRT and EXDOSE began, in ISO 8601 format.	Exp
EXENDTC	End Date/Time of Exposure	Char	ISO 8601 datetime or interval	Timing	Date/time when administration of the product indicated by EXTRT and EXDOSE ended, in ISO 8601 format.	Perm
EXSTDY	Study Day of Start of Exposure	Num		Timing	Study day when administration of the product began, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
EXENDY	Study Day of End of Exposure	Num		Timing	Study day when administration of the product ended, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the DM domain.	Perm
EXDUR	Duration of Exposure	Char	ISO 8601 duration	Timing	Duration and unit of time for a continuous exposure. This may be used to denote the length of an infusion (e.g., PT10M to indicate 10 minutes).	Perm
EXTPT	Planned Time Point Name	Char		Timing	Text description of time when a dose should be given. Note: This may be represented as an elapsed time relative to a fixed	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					reference point, such as time of last dose. See EXPTNUM and EXPTREF.	
EXPTNUM	Planned Time Point Number	Num		Timing	Numerical version of EXPT to aid in sorting.	Perm
EXELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601 format) relative to the planned fixed reference (EXPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: "- PT15M" to represent the period of 15 minutes prior to the reference point indicated by EXPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by EXPTREF.	Perm
EXPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by EXELTM, if used for EXPTNUM, and EXPT. It is recommended that EXPTREF be as descriptive as possible so the reference time point can be inferred without looking at other variables. Examples: Previous dose, previous feed.	Perm
EXRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/Time of the reference time point, EXPTREF.	Perm

Assumptions

1. Definition:
 - a. The Exposure (EX) domain model records the details of a subject's administered dose of protocol-specified study product. "Study product" may be any intervention that is prospectively defined as a test material within a study, and is typically, but not always, administered to the subject. Examples include but are not limited to placebo, active comparators, and investigational products. Only protocol-specified products should be included in this domain.
 - b. This domain should contain 1 record per constant dosing interval per subject per administration site (as identified in FOCID). A *constant dosing interval* is applicant-defined and represents a specific period of time during which a subject was exposed with a specific lot at a constant dose level. For example, for a study with once-a-week administration of a standard dose for 6 weeks, the administered dose may be represented with a single record per subject, spanning the entire dosing phase. Alternatively, a separate entry can be made for each dose administration and for any deviations in dosing that occur. For this example, there could be up to 6 records (1 for each weekly administration).
 - c. Either USUBJID or POOLID must be populated.
2. Exposure Product Description:
 - a. EXTRT captures the name of the protocol-specified study product and is the topic variable. It is a Required variable and must have a value. EXTRT must include only the product name and must not include dosage, formulation, or other qualifying information. For example, "4mg Nicotine Lozenge" is not a valid value for EXTRT. This example should be expressed as EXTRT = "Nicotine", EXDOSE = "4", EXDOSU = "mg", and EXDOSFRM = "LOZENGE".
 - b. A single control for multiple compounds should contain values separated with a pipe/vertical bar (|).
3. If a subject is exposed sequentially with different lots, then a new record must be created for each lot number given.
4. EXDOSE: The applicant's data definition file should indicate whether the values in EXDOSE represent intended or actual dose levels.
5. Timing variables: The timing of dosing of study product is captured by the start/end date and start/end time of each constant-dosing interval. The applicant defines the dosing interval.
6. Other additional qualifiers from the SDTM Interventions class may be added to this domain.

2.8.9.12 SEND Food and Water Consumption (FW)

Description

This domain captures food/water consumption of animals in the study. The data in this domain is derived data.

fw.xpt, Food and Water Consumption — Findings. One record per test per interval per subject or pool, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	FW	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Either USUBJID or POOLID must be populated.	Exp
POOLID	Pool Identifier	Char		Identifier	Identifier used for pooling subjects to assign a single finding to multiple subjects. If POOLID is entered, POOLDEF records must exist for each subject and the USUBJID must be null. Either USUBJID or POOLID must be populated.	Perm
FWSEQ	Sequence Number	Num		Identifier	The sequence number must be unique for each record within a USUBJID or POOLID, whichever applies for the record.	Req
FWGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject or pool. This is not the dosing group number.	Perm
FWTESTCD	Food/Water Consumption Short Name	Char	(FWTESTCD)	Topic	Short name of the measurement, test, or examination described in FWTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in FWTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). FWTESTCD cannot contain characters other than letters, numbers, or underscores. Extensible controlled values are FC, FCRELBW, WC, and WCRELBW.	Req
FWTEST	Food/Water Consumption Name	Char	(FWTEST)	Synonym Qualifier	Long name for FWTESTCD. The value in FWTEST cannot be longer than 40 characters. Extensible controlled values are Food Consumption, Food Consumption Relative to Body Wt, Water Consumption, Water Consumption Relative to Body Wt.	Req
FWORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
FWORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology (http://www.cdisc.org/terminology) list.	Exp
FWSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from FWORRES, in a standard format or standard units. FWSTRESC should store all results or findings in character format; if results are numeric, they should also be submitted in numeric format in FWSTRESN.	Exp
FWSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of FWSTRESC. FWSTRESN should store all numeric test results or findings.	Exp
FWSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for FWSTRESC and FWSTRESN.	Exp
FWSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in FWORRES.	Perm
FWREASND	Reason Not Done	Char		Record Qualifier	Describes why FWSTAT is NOT DONE, such as FOOD WET.	Perm
FWEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Y if the result should be excluded from all calculations, otherwise null.	Perm
FWRELEASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when FWEXCLFL is Y.	Perm
FWDTC	Start Date/Time of Observation	Char	ISO 8601 datetime or interval	Timing	Date/time of the start of the observation in ISO 8601 format.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
FWENDTC	End Date/Time of Observation	Char	ISO 8601 datetime or interval	Timing	Date/time of the end of the observation in ISO 8601 format.	Exp
FWDY	Study Day of Start of Observation	Num		Timing	Study day of the start of the observation, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
FWENDY	Study Day of End of Observation	Num		Timing	Study day of the end of the observation, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the DM domain.	Perm

Assumptions

1. The Food and Water Consumption (FW) domain captures food/water consumption of subjects in the study. The data in this domain are derived data.
2. POOLID is used when a single finding may be collected for multiple subjects using POOLID (e.g., group-housed subjects).
3. The reported results may be in units defined per subject or per cage, and the corresponding FWSTRESU must reflect whether the reported result is per subject or per cage.
4. The FWSTRESC and FWSTRESN must have the appropriate units when they represent a calculation: */animal/* — (e.g., g/animal/day, g/animal/week; kg/animal/day, kg/animal/week).
5. FWDTC and FWENDTC variables, if applicable, are used.

2.8.9.13 SEND Genetic Toxicology In Vitro Test Results (GT)

Description

A findings domain that contains in vitro genetic toxicology test results.

gt.xpt, Genetic Toxicology In Vitro Test Results — Findings. One record per information source per test per summary result type per run, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	GT	Identifier	Two-character abbreviation for the domain.	Req
GTSEQ	Sequence Number	Num		Identifier	The sequence number must be unique for each record within a domain. Sequence number given to ensure uniqueness of records within a domain. May be any valid number.	Req
GTREFID	Reference ID	Char		Identifier	A sequence of characters used to uniquely identify a source of information (e.g., lab specimen, petri dish, flask, well, group of petri dishes, group of flasks, an entire assay).	Req
GTTESTCD	Lab Test or Examination Short Name	Char	(GTTESTCD)	Topic	Short name of the measurement, test, or examination described in GTTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in GTTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). GTTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: RVERT, CYTOTOX.	Req
GTTEST	Lab Test or Examination Name	Char	(GTTEST)	Synonym Qualifier	Long name for GTTESTCD. The value in GTTEST cannot be longer than 40 characters. Examples: Revertants, Cytotoxicity.	Req
GTORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
GTORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
GTCELLEV	Number of Cells Evaluated	Num		Result Qualifier	The number of cells evaluated.	Perm
GTCOLSRT	Collected Summary Result Type	Char	(COLSTYP)	Variable Qualifier	Used to indicate the type of collected summary result. For example, MAXIMUM, MINIMUM, and MEAN.	Perm
GTSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from GTORRES in a standard format or standard units. GTSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in GTSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in GTORRES and these results effectively have the same meaning, they could be represented in standard format in GTSTRESC as NEGATIVE. For other examples, see general assumptions.	Exp
GTSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of GTSTRESC. GTSTRESN should store all numeric test results or findings.	Exp
GTSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for GTSTRESC, GTSTRESN, GTSTRLO, and GTSTRHI.	Exp
GTSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in GTORRES.	Perm
GTREASND	Reason Not Done	Char		Record Qualifier	Describes why GTSTAT is NOT DONE, such as BROKEN EQUIPMENT or SPECIMEN LOST.	Perm
GTSPCCND	Specimen Condition	Char	(SPECCOND)	Record Qualifier	Free or standardized text describing the condition of the specimen. Example: PRECIPITATION PRESENT, CONTAMINATED, etc. If multiple conditions are present on a sample, concatenate the values with a semicolon and no spaces as a separator.	Perm
GTSPCUFL	Specimen Usability for the Test	Char	(NY)	Record Qualifier	Describes the usability of the specimen for the test. Should be N if the specimen is not usable; otherwise it should be null.	Perm
GTMETHOD	Method of Test or Examination	Char		Record Qualifier	Method of the test or examination. Examples: MANUALLY COUNTED, INSTRUMENT COUNTED.	Perm
GTRUNID	Run ID	Char		Record Qualifier	A sequence of characters used to uniquely identify a particular run of a test on a particular batch of samples.	Perm
GTEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Y if the result should be excluded from all calculations, otherwise null.	Perm
GTREASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when GTEXCLFL is Y.	Perm
GTDTC	Date/Time of Collection	Char	ISO 8601 datetime or interval	Timing	The date or date and time of the assessment or the specimen or data collection, represented in a standardized character format. For an Ames test, this is the date the bacterial culture is plated.	Perm

Assumptions

1. The GT domain captures in vitro data collected by the lab executing the study or received from a provider. This domain is designed for exchanging data for the following in vitro tests: neutral red cytotoxicity assay, bacterial reverse mutation assay (also known as Ames), mammalian cell gene mutation assay, and micronucleus assay. Other in vitro tests have not yet been modeled in this version of this domain.
2. Results:
 - a. GTSTRESC (or corresponding numeric GTSTRESN) is used to represent standardized format of original results.
 - b. GTSTAT and GTREASND are Permissible and used to indicate when a test was not completed. In these cases GTSTAT should contain “NOT DONE”; GTORRES, GTSTRESC, and GTSTRESN should be null; and GTREASND should contain the reason for not completing the test.
3. Other Assumptions:
 - a. The discussion in SENDIG Section 4.5.1.3, Tests Not Done, does not apply to this domain.
 - b. GTEXCLFL and GTREASEX are Permissible and used to indicate when a result is to be excluded from further analysis. In these cases GTREASEX should contain the reason for exclusion.

2.8.9.14 SEND Laboratory Test Results (LB)

Description

A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.

Ib.xpt, Laboratory Test Results — Findings. One record per test per specimen per observation time per subject or pool, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	LB	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all application or submissions involving the product. Either USUBJID or POOLID must be populated.	Exp
POOLID	Pool Identifier	Char		Identifier	Identifier used for pooling subjects to assign a single finding to multiple subjects. If POOLID is entered, POOLDEF records must exist for each subject and the USUBJID must be null. Either USUBJID or POOLID must be populated.	Perm
LBSEQ	Sequence Number	Num		Identifier	The sequence number must be unique for each record within a USUBJID or POOLID, whichever applies for the record.	Req
LBGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject or pool. This is not the dosing group number.	Perm
LBREFID	Specimen Identifier	Char		Identifier	Internal or external specimen identifier. Example: 1009570101.	Perm
LBSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference identifier. Example: Line number on the Lab page.	Perm
LBTESTCD	Lab Test or Examination Short Name	Char	(LBTESTCD)	Topic	Short name of the measurement, test, or examination described in LBTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in LBTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). LBTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: ALT, LDH.	Req
LBTEST	Lab Test or Examination Name	Char	(LBTEST)	Synonym Qualifier	Long name for LBTESTCD. The value in LBTEST cannot be longer than 40 characters. Examples: Alanine Aminotransferase, Lactate Dehydrogenase.	Req
LBCAT	Category for Lab Test	Char		Grouping Qualifier	Used to define a category of the lab test performed. Examples: URINALYSIS, CLINICAL CHEMISTRY, HEMATOLOGY, etc.	Exp
LBSCAT	Subcategory for Lab Test	Char		Grouping Qualifier	A further categorization of a test category. Examples: DIFFERENTIAL, LIVER FUNCTION, ELECTROLYTES.	Perm
LBORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
LBORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology (http://www.cdisc.org/terminology) list.	Exp
LBORNRL0	Reference Range Lower Limit-Orig Unit	Char		Variable Qualifier	Lower end of reference range used at the time of collection for continuous measurements in original units. Should be populated only for continuous results.	Perm
LBORNRHI	Reference Range Upper Limit-Orig Unit	Char		Variable Qualifier	Upper end of reference range used at the time of collection for continuous measurements in original units. Should be populated only for continuous results.	Perm
LBSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from LBORRES, in a standard format or standard units. LBSTRESC should store all results or findings in character format; if results are numeric, they should also be submitted in numeric format in LBSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in LBORRES and these results effectively have the same meaning, they could be represented in standard format in LBSTRESC as NEGATIVE. For other examples, see general assumptions.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
LBSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of LBSTREC. LBSTRESN should store all numeric test results or findings.	Exp
LBSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for LBSTREC and LBSTRESN.	Exp
LBSTNRLO	Reference Range Lower Limit-Std Unit	Num		Variable Qualifier	Lower end of reference range for continuous measurements in standardized units. Should be populated only for continuous results.	Perm
LBSTNRHI	Reference Range Upper Limit-Std Unit	Num		Variable Qualifier	Upper end of reference range for continuous measurements in standardized units. Should be populated only for continuous results.	Perm
LBSTNRC	Reference Range for Char Rslt-Std Unit	Char		Variable Qualifier	For normal range values that are character in ordinal scale or if categorical ranges were supplied (e.g., -1 to +1; NEGATIVE TO TRACE).	Perm
LBNRIND	Reference Range Indicator	Char		Variable Qualifier	Indicates where value falls with respect to reference range defined by LBORNRL and LBORNRI, LBSTRNRLO and LBSTRNRHI, or by LBSTNRC. Examples: NORMAL, ABNORMAL, HIGH, LOW. Applicants should specify in the study metadata (Comments column in the data definition file) whether LBNRIND refers to the original or standard reference ranges and results. Should not be used to indicate biological significance.	Perm
LBSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in LBRES.	Perm
LBREASND	Reason Not Done	Char		Record Qualifier	Describes why LBSTAT is NOT DONE, such as BROKEN EQUIPMENT or SPECIMEN LOST.	Perm
LBNAM	Laboratory Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor that provided the test results.	Perm
LBSPEC	Specimen Material Type	Char	(SPEC)	Record Qualifier	Defines the type of specimen analyzed to obtain the measurement or finding. Examples: WHOLE BLOOD, SERUM, PLASMA, URINE, LIVER, HEART.	Exp
LBANTREG	Anatomical Region of Specimen	Char		Variable Qualifier	Defines the specific anatomical or biological region of a tissue, organ specimen, or the region from which the specimen was obtained, such as a section or part of what is defined in the LBSPEC variable. If the anatomical region is not included in the specimen description LBSPEC, it may be included in this variable. This field can be a combination of terms where needed. This field can be null if not applicable. Examples: CORTEX, MEDULLA, MUCOSA, SEROSA, ISLET, ZONA FASICULATA, ZONA RETICULARIS, CRANIAL, MEDIAN, ACCESSORY, SPINAL, LUMBAR, FRONTAL.	Perm
LBSPCCND	Specimen Condition	Char		Record Qualifier	Free or standardized text describing the condition of the specimen. Examples: HEMOLYZED, ICTERIC, LIPEMIC.	Perm
LBSPCUFL	Specimen Usability for the Test	Char	(NY)	Record Qualifier	Describes the usability of the specimen for the test. Should be "N" if the specimen is not usable; otherwise it should be null.	Perm
LBLOC	Specimen Collection Location	Char		Record Qualifier	Location relevant to the collection of specimen for the measurement.	Perm
LBLAT	Specimen Laterality within Subject	Char	(LAT)	Variable Qualifier	Qualifier for laterality of the specimen within the subject for paired specimens. Examples: LEFT, RIGHT, BILATERAL.	Perm
LBDIR	Specimen Directionality within Subject	Char	(DIR)	Variable Qualifier	Qualifier for directionality of the specimen within the subject. Examples: DORSAL, PROXIMAL.	Perm
LBPORTOT	Portion or Totality	Char	(PORTOT)	Variable Qualifier	Qualifier for anatomical location or specimen further detailing the portion or totality, which means arrangement of, or apportioning of. Examples: ENTIRE, SINGLE, SEGMENT, MANY.	Perm
LBMETHOD	Method of Test or Examination	Char		Record Qualifier	Method of the test or examination. Examples: EIA (Enzyme Immunoassay), ELECTROPHORESIS, DIPSTICK.	Exp
LBBLFL	Baseline Flag	Char	(NY)	Record Qualifier	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is applicant defined.	Exp
LBFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status. The value should be "Y" or null.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
LBDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be "Y" or null. Records that represent the average of other records, or are not as originally received or collected are examples of records that might be derived for the submission datasets.	Perm
LBTOX	Toxicity	Char		Variable Qualifier	Description of toxicity quantified by LBTOXGR. The applicant is expected to provide the name and version of the scale used to map the terms, utilizing the data definition file external codelist attributes.	Perm
LBTOXGR	Standard Toxicity Grade	Char		Record Qualifier	Records toxicity grade value using a standard toxicity scale (such as the NCI CTCAE). If value is from a numeric scale, represent only the number (e.g., "2" and not "Grade 2"). The applicant is expected to provide the name of the scale and version used to map the terms, utilizing the data definition file external codelist attributes.	Perm
LBEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	"Y" if the result should be excluded from all calculations, otherwise null.	Perm
LBREASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when LBEXCLFL is "Y".	Perm
LBUSCHFL	Unscheduled Flag	Char	(NY)	Record Qualifier	Indicates whether the timing of the specimen collection was unscheduled. If a specimen collection was performed based upon a schedule defined in the protocol, this flag should be null. Expected values are "Y" or null.	Exp
VISITDY	Planned Study Day of Collection	Num		Timing	Planned study day of specimen collection. Should be an integer.	Perm
LBDTC	Date/Time of Specimen Collection	Char	ISO 8601 datetime or interval	Timing	Date/time of specimen collection, in ISO 8601 format.	Exp
LBENDTC	End Date/Time of Specimen Collection	Char	ISO 8601 datetime or interval	Timing	Date/time of the end of specimen collection in ISO 8601 format. Should be populated only for continuous sample collection.	Perm
LBDY	Study Day of Specimen Collection	Num		Timing	Study day of specimen collection, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
LBENDY	Study Day of End of Specimen Collection	Num		Timing	Study day of the end of specimen collection, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the DM domain.	Perm
LBNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for specimen collections that may occur on different days into a single reported study day. Should be an integer.	Exp
LBNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of LBNOMDY as presented in the study report. Examples: Week 4, Day 28, Terminal Sac.	Perm
LBTPT	Planned Time Point Name	Char		Timing	Text description of time when specimen should be taken. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See LBTPTNUM and LBTPTREF. Examples: Start, 5 min post.	Perm
LBTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of LBTPT to aid in sorting.	Perm
LBELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Elapsed time (in ISO 8601 format) relative to a planned fixed reference (LBTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: "- P15M" to represent the period of 15 minutes prior to the reference point indicated by LBTPTREF, or "P8H" to represent the period of 8 hours after the reference point indicated by LBTPTREF.	Perm
LBTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by LBELTM, if used for LBTPTNUM, and LBTPT. It is recommended that LBTPTREF be as descriptive as possible so the reference time point can be inferred without looking at other variables. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
LBRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/time of the reference time point, LBTPTREF.	Perm

Assumptions

1. The Laboratory Test Results (LB) domain captures laboratory data collected by the lab executing the study or data received from a central provider.
2. Results:
 - a. LBSTRESC (or corresponding numeric LBSTRESN) is used to represent standardized format of original results. For instance, original results such as "NEG" or "NEGATIVE" may be represented in standard format as "NEGATIVE" in LBSTRESC.
 - b. LBORNRL and LBORNRI represent the reference range in original units, and LBSTNRLO and LBSTNRHI represent the reference range in standard units. These variables are Permissible, since many tests may not have well-established ranges or the ranges would not apply.
 - c. For lab tests that do not have continuous numeric results (e.g., urine protein as measured by dipstick, descriptive tests such as urine color), LBSTNRC could be populated either with normal character range values in an ordinal scale (e.g., "NEGATIVE to TRACE") or a delimited set of values that are considered to be normal (e.g., "YELLOW", "AMBER").
 - d. LBSTAT and LBREASND are Permissible and are used to indicate when a test was not completed. In these cases, LBSTAT should contain "NOT DONE"; LBORNRL, LBSTRESC, and LBSTRESN should be null. LBREASND should contain the reason for not completing the test.
3. Specimen collection location - organ/tissue definition:
 - a. The location of specimen collection for a subject is described by the following fields: LBSPEC, LBANTREG, and LBLOC.
 - b. LBSPEC is Expected and defines the specimen type or the base organ or tissue analyzed.
 - c. LBANTREG is Permissible and further specifies a part or section of the organ/tissue specified in LBSPEC. Examples include the cortex of the kidney or a study-specific sectioning of the organ (e.g., top section of left liver lobe).
 - d. LBLOC is permissible to specify location of specimen collection. If a sample of blood is taken, LBLOC may be used to indicate the location of sampling (e.g., jugular vein, portal vein). Another example could be if the specimen type (LBSPEC) is "BONE MARROW"; LBLOC could be "Femoral" or "Sternal".
4. Timing variables:
 - a. Information about the time of collection for any observation is needed to identify the record. LBDTC is expected, and the data will, in most cases, contain LBDTC, LBDY, or both. However, some studies (e.g., legacy studies) may not collect LBDTC or LBDY; in such cases, LBNOMDY must be populated.
 - b. For lab tests where the specimen is collected over time (e.g., 24-hour urine collection), the start date/time of the collection goes into LBDTC and the end date/time of collection goes into LBENDTC.
5. Pooling:
 - a. For lab results that correspond to samples pooled from different subjects, POOLID will be populated with a unique number identifying the pool.
 - b. One record will exist for each pool in LB. Populating POOLID will mark the result as being collected at a pool level and not on a subject level.
6. Other assumptions:
 - a. A value derived by a lab according to their procedures is considered as having an origin value of collected, rather than derived.
 - b. A single reference range can be included for either standard results (LBSTNRLO and LBSTNRHI) or original results (LBORNRL and LBORNRI), but not both. LBNRIND is used as a reference range indicator for the range being used.

2.8.9.15 SEND Macroscopic Findings (MA)

Description

The gross pathology findings recorded at necropsy.

ma.xpt, Macroscopic Findings — Findings. One record per finding per specimen per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	MA	Identifier	Two-character code for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
FOCID	Focus of Study-Specific Interest	Char		Identifier	Identification of a focus of study-specific interest on or within a subject or specimen as defined in the protocol, for which a measurement, test, or examination was performed (e.g., for a drug application site, "Injection site 1," "Biopsy site 1," "Treated site 1"). The value in this variable should have inherent semantic value.	Perm
MASEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MAGRIPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject. This is not the dosing group number.	Perm
MAREFID	Specimen Reference Identifier	Char		Identifier	Internal or external specimen identifier. Example: 1009570101.	Perm
MASPID	Mass Identifier	Char		Identifier	Mass identifier (e.g., MASS 1, MASS A). Used when the mass was discovered during the in-life phase or during pathology and was assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.	Perm
MATESTCD	Macroscopic Examination Short Name	Char	(MATESTCD)	Topic	Short name of the measurement, test, or examination described in MATEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in MATESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). MATESTCD cannot contain characters other than letters, numbers, or underscores.	Req
MATEST	Macroscopic Examination Name	Char	(MATEST)	Synonym Qualifier	Long name for MATESTCD. The value in MATEST cannot be longer than 40 characters. Extensible controlled values are Gross Pathological Examination, Clinical Signs Follow-up.	Req
MABODSYS	Body System or Organ Class	Char	(BODSYS)	Record Qualifier	Body system or organ class associated with the specimen examined.	Perm
MAORRES	Result or Findings as Collected	Char		Result Qualifier	Text description of the findings as originally received or collected, including the base gross pathological observation and any modifiers (e.g., severity, origin, classification, size, color).	Exp
MASTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains only the base gross pathological observation (e.g., ENLARGED) from MAORRES, without any modifiers. If the examination was completed and there were no findings, the value must be "UNREMARKABLE".	Exp
MASTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate examination not done or result is missing. Should be null if a result exists in MAORRES.	Perm
MAREASND	Reason Not Done	Char		Record Qualifier	Describes why MASTAT is NOT DONE. Example: Tissue not examined, Tissue Autolyzed.	Perm
MANAM	Laboratory Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor that provided the test results.	Perm
MASPEC	Specimen Material Type	Char	(SPEC)	Record Qualifier	Defines the type of tissue, organ, or fluid examined. Examples: GLAND, ADRENAL; KIDNEY; VESSEL, LYMPHATIC. See also Assumption 4.b.	Exp
MAANTREG	Anatomical Region of Specimen	Char		Variable Qualifier	Defines the specific anatomical or biological region of a tissue, organ specimen, or the region from which the specimen was obtained, such as a section or part of what is defined in the MASPEC variable. If the anatomical region is not included in the specimen description MASPEC, it may be included in this variable. This field can be a combination of	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					terms where needed. This field can be null if not applicable. Examples: CORTEX, MEDULLA, MUCOSA, SEROSA, ISLET, ZONA FASICULATA, ZONA RETICULARIS, CRANIAL, MEDIAN, ACCESSORY, SPINAL, LUMBAR, FRONTAL.	
MASPCCND	Specimen Condition	Char		Record Qualifier	Free or standardized text describing the condition of the specimen. Example: AUTOLYZED.	Perm
MASPCUFL	Specimen Usability for the Test	Char	(NY)	Record Qualifier	Describes the usability of the specimen for the test. Should be "N" if the specimen is not usable; otherwise it should be null.	Perm
MALAT	Specimen Laterality within Subject	Char	(LAT)	Variable Qualifier	Qualifier for laterality of the specimen within the subject for paired specimens. Examples: LEFT, RIGHT, BILATERAL.	Perm
MADIR	Specimen Directionality within Subject	Char	(DIR)	Variable Qualifier	Qualifier for directionality of the specimen within the subject. Examples: DORSAL, PROXIMAL.	Perm
MAPORTOT	Portion or Totality	Char	(PORTOT)	Variable Qualifier	Qualifier for anatomical location or specimen further detailing the portion or totality, which means arrangement of, or apportioning of. Examples: ENTIRE, SINGLE, SEGMENT, MANY.	Perm
MAEVAL	Evaluator	Char		Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (i.e., assigned by a person or a group). Examples: PRINCIPAL PATHOLOGIST, PEER REVIEW, Applicant PATHOLOGIST.	Perm
MASEV	Severity	Char	(SEV)	Record Qualifier	Describes the severity or intensity of a particular finding. Examples: MILD, MODERATE, SEVERE.	Perm
MADTHREL	Relationship to Death	Char	(NY)	Record Qualifier	Describes the relationship of a particular finding to the death of a subject ("Y" = caused death, "N" = did not cause death, "U" = unknown). May be left null if not available.	Perm
MADTC	Date/Time	Char	ISO 8601 datetime or interval	Timing	For a specimen collected or observed post mortem, this is the date/time of subject disposition in ISO 8601 format.	Perm
MADY	Study Day	Num		Timing	For a specimen collected or observed post mortem, this is the study day of subject disposition, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

Assumptions

1. Definition:
 - a. The Macroscopic Findings (MA) dataset provides a record for each macroscopic finding observed.
 - b. Every subject examined at necropsy should have at least 1 record in the MA domain (e.g., the record could be NORMAL (in MAORRES) for MASPEC value of "ALL TISSUES", implying all protocol-required tissues).
2. MATESTCD and MATEST are either GROSPATH and gross pathological examination or CLSFUP and clinical signs follow-up.
 - a. In most cases, MATESTCD and MATEST will be GROSPATH and gross pathological examination.
 - b. As part of the necropsy review, a follow-up examination may be performed on clinical signs to verify existence at necropsy (present/not present) and to correlate them to gross pathological examinations. To record these in the MA domain, the result should be represented as the text result of the examination (e.g., "SKIN LESION NOT FOUND AT NECROPSY").
3. The date/time of the subject disposition (in DS) is the most relevant date for interpretation of macroscopic observations and is used to populate MADTC.
4. Organ/tissue definition:
 - a. The subject organ/tissue of examination is described by up to 5 fields: MASPEC, MAANTREG, MALAT, MADIR, and MAPORTOT.
 - b. MASPEC defines the base organ or tissue examined and is required when MATEST is "Gross Pathological Examination." It should not be used when MATEST is "Clinical Signs Follow-up". The

- value is singular in cases of multilateral organs when the MALAT or MADIR fields can be used to describe laterality and/or position.
- c. MAANTREG should be used where applicable, and further specifies a part or section of the organ/tissue specified in MASPEC. Examples include the cortex of the kidney or a study-specific sectioning of the organ (e.g., top section of left liver lobe).
 - d. Specify laterality and/or position for those organs that can exist in multiple locations: Use "SINGLE" for MAPORTOT for cases where 1 of the multilateral organs is examined, but which one was used is unknown. Use "BILATERAL" for MALAT for cases where the finding was recorded on the paired organs of a bilateral pair.
 - e. For bilateral organs, records may be included for the left, right, and/or both left and right organs.
5. Result definition:
- a. When the results of all tissues are normal, the special value of "ALL TISSUES" may be used in MASPEC, with a single record whose value in MAORRES is NORMAL and in MASTRESC is UNREMARKABLE, without individually listing each tissue.
 - b. MASTRESC: This variable is important for standardizing the value in MAORRES.
 - i. Modifiers of the base gross pathological observation (in MASTRESC) should be included within supplemental qualifiers (see SUPPMA Example 1):
 - ii. QNAM = "--RESMOD"
 - iii. QLABEL = "Result Modifiers"
 - iv. QVAL = concatenated modifiers of the base gross pathological process, separated by semicolons
 - v. If a severity was received or collected, MASEV must be populated.
6. MASPID variable is intended to reflect the mass identification. This variable should be used to link in-life findings with pathology findings. The mass identifier in --SPID should be consistent across domains (Clinical Observations, Palpable Masses, MA, Microscopic Findings, and Tumor Findings).
7. Macroscopic findings commonly correlate to clinical findings and microscopic findings. Establishing this relationship may be accomplished by using the RELREC table.

2.8.9.16 SEND Microscopic Findings (MI)

Description

A findings domain that contains histopathology findings and microscopic evaluations.

mi.xpt, Microscopic Findings — Findings. One record per finding per specimen per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	MI	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
FOCID	Focus of Study-Specific Interest	Char		Identifier	Identification of a focus of study-specific interest on or within a subject or specimen as defined in the protocol for which a measurement, test, or examination was performed (e.g., for a drug application site, "Injection site 1," "Biopsy site 1," "Treated site 1"). The value in this variable should have inherent semantic value.	Perm
MISEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MIGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject. This is not the dosing group number.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
MIREFID	Specimen Reference Identifier	Char		Identifier	Internal or external specimen identifier. Example: Specimen barcode number.	Perm
MISPID	Mass Identifier	Char		Identifier	Mass identifier (e.g., MASS 1, MASS A). Used when the mass was discovered during the in-life phase or during pathology and was assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.	Perm
MITESTCD	Microscopic Examination Short Name	Char	(MITESTCD)	Topic	Short name of the measurement, test, or examination described in MITEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in MITESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). MITESTCD cannot contain characters other than letters, numbers, or underscores. Extensible controlled value is MIEXAM covering an assessment by microscope (e.g., light, electron, confocal).	Req
MITEST	Microscopic Examination Name	Char	(MITEST)	Synonym Qualifier	Long name for MITESTCD. The value in MITEST cannot be longer than 40 characters. Extensible controlled value is Microscopic Examination.	Req
MIBODSYS	Body System or Organ Class	Char	(BODSYS)	Record Qualifier	Body system or organ class associated with the specimen examined.	Perm
MIORRES	Result or Findings as Collected	Char		Result Qualifier	Microscopic finding as originally recorded, including all modifiers.	Exp
MISTRESC	Standardized Result in Character Format	Char	(NONNEO) (NEOPLASM)	Result Qualifier	For non-neoplastic findings, contains only the base pathological process (e.g., NECROSIS) without any modifiers such as severity, distribution, chronicity, or characteristics. If the examination was completed and there were no findings, the value must be "UNREMARKABLE". The base pathological process from MIORRES should be mapped to a synonymous term from the controlled list, NONNEO, where possible. Neoplastic findings must be populated using the NEOPLASM controlled list.	Exp
MIRESCAT	Result Category	Char	(MIRESCAT)	Variable Qualifier	Used to categorize the result of a finding. Example: MALIGNANT for tumor findings or NON-NEOPLASTIC for pathology findings.	Perm
MICHRON	Chronicity of Finding	Char	(CHRNCY)	Variable Qualifier	Describes the apparent relative duration of a particular finding. Examples: ACUTE, CHRONIC.	Exp
MIDISTR	Distribution Pattern of Finding	Char	(DSTRBN)	Variable Qualifier	Distribution pattern of a particular finding(s) within the examined area. Examples: DIFFUSE, FOCAL, MULTIFOCAL.	Exp
MISTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a test was not done or a test was attempted but did not generate a result. Should be null or have a value of "NOT DONE".	Perm
MIREASND	Reason Not Done	Char		Record Qualifier	Describes why MISTAT is NOT DONE, such as SAMPLE AUTOLYZED or SPECIMEN LOST.	Perm
MINAM	Laboratory Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor that provided the test results.	Perm
MISPEC	Specimen Material Type	Char	(SPEC)	Record Qualifier	Defines the type of tissue, organ, or fluid specimen examined. Examples: LIVER, HEART, BONE MARROW.	Req
MIANTREG	Anatomical Region of Specimen	Char		Variable Qualifier	The protocol-defined subregion of the specimen examined. Example: Cortex or Medulla (if the MISPEC is, for example, GLAND, ADRENAL).	Perm
MISPCCND	Specimen Condition	Char		Record Qualifier	Free or standardized text describing the condition of the specimen. Example: AUTOLYZED.	Exp
MISPCUFL	Specimen Usability for the Test	Char	(NY)	Record Qualifier	Describes the usability of the specimen for the test. Should be "N" if the specimen is not usable; otherwise it should be null.	Exp
MILAT	Specimen Laterality within Subject	Char	(LAT)	Variable Qualifier	Qualifier for laterality of the specimen within the subject for paired specimens. Examples: LEFT, RIGHT, BILATERAL.	Perm
MIDIR	Specimen Directionality within Subject	Char	(DIR)	Variable Qualifier	Qualifier for directionality of the specimen within the subject. Examples: DORSAL, PROXIMAL.	Perm
MIMETHOD	Method of Test or Examination	Char		Record Qualifier	Method of the test or examination. This could be different types of staining used for the slides whenever appropriate. Example: H&E.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
MIEVAL	Evaluator	Char		Record Qualifier	Role of the person who provided the evaluation. Examples: TOX PATHOLOGIST, PEER REVIEW.	Perm
MISEV	Severity	Char	(SEV)	Record Qualifier	Describes the severity of a particular finding.	Exp
MIDTHREL	Relationship to Death	Char	(NY)	Record Qualifier	Describes the relationship of a particular finding to the death of a subject ("Y" = caused death, "N" = did not cause death, "U" = unknown). May be left null if not available.	Perm
MIDTC	Date/Time	Char	ISO 8601 datetime or interval	Timing	For a specimen collected or observed post mortem, this is the date/time of subject disposition, in ISO 8601 format.	Perm
MIDY	Study Day	Num		Timing	For a specimen collected or observed post mortem, this is the study day of subject disposition, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

Assumptions

1. Definition:
 - a. The Microscopic Findings (MI) domain captures the microscopic evaluations/histopathology of the study.
 - b. This domain should contain at least 1 record for every protocol-scheduled tissue for all subjects in the study (e.g., if an organ was examined and no pathological changes were present, it should have a record indicating "UNREMARKABLE"). Unscheduled tissues that were examined should also have a record. Subjects that were not scheduled for examination should not have records unless they were examined. This assumption supports the creation of incidence tables and statistical analysis on histopathological data.
 - c. The MI dataset provides a record for each microscopic finding observed throughout the study.
2. The date/time of the subject disposition in DS is the most relevant date for interpretation of microscopic observations and is used to populate MIDTC.
3. Specimen definition:
 - a. The protocol-scheduled organ/tissue for examination is described by up to 5 fields: MISPEC, MIANTREG, MILAT, MIDIR, and FOCID.
 - b. MISPEC defines the base organ or tissue examined.
 - c. MIANTREG should be used where applicable and further specifies a part or section of the organ/tissue specified in MISPEC, when that subregion is the targeted area for examination. Examples include the cortex of the kidney, when separated from the kidney medulla, or a study-specific sectioning of the organ (e.g., top section of left liver lobe), but not a case where the liver is examined as a whole, but a specific finding is found for one of the lobes.
 - d. For a paired organ, the organ used for the specimen should be specified as left, right, or bilateral, using the MILAT variable.
4. Result definition:
 - a. In MIORRES, a finding should comprise only 1 base pathological process and its modifiers (e.g., severity, chronicity, distribution, characteristics). However, it is recognized that data may not have been captured in this way; see Section 3.2.2.12, Microscopic Findings (MI), [Example 2](#), for a way to handle this situation.
 - b. When MIORRES is populated, there must be an entry in MISTRESC. Other relevant components of the MIORRES finding must be parsed into 1 or more of these variables: MISEV, MIDISTR, MICHRON, and the supplemental qualifier MIRESMOD, which are used in combination to standardize the value in MIORRES.
 - c. MISTRESC: This variable is important for standardizing the value in MIORRES and where possible must use the controlled lists NONNEO and NEOPLASM. If a microscopic finding in a tissue includes

- 2 related processes, then it can be described by a combination term that has both terms entered, separated by a "/" with no spaces. For example, features of degeneration and regeneration may be observed in a tissue as a continuum of the pathology. The processes can be identified separately or as part of a combined process of degeneration/regeneration. When the process of degeneration/regeneration is used to describe both components, this base process should be recorded in MISTRESC in a single row. The most common combination terms have been included on the NONNEO codelist. Other combination terms that represent 2 related processes can be constructed using preferred terms on the NONNEO codelist, separated by a "/" with no spaces. Terms should not be combined for processes that are unrelated (e.g., NECROSIS and CYST). Unrelated processes should be presented in 2 separate rows.
- d. The variables MISTRESC, MIDISTR, and MICHRON use CDISC Controlled Terminology derived from INHAND (International Harmonization of Nomenclature and Diagnostic Criteria for Lesions in Rats and Mice), a collaboration among international societies of toxicological pathologists.
 - e. The supplemental qualifier MIRESMOD is used to further qualify the finding recorded in MISTRESC. MIRESMOD must be populated if 1 or more modifiers were part of the result in MIORRES and not otherwise reported in the modifier variables part of the MI domain structure (e.g., MISEV, MIDISTR, and MICHRON). In addition to describing observed characteristics of a lesion (e.g., cell type), this variable may be used to identify a specific region affected by the finding within the specimen. For example, when the liver is examined as a whole, but a finding is noted for a specific lobe, this location goes into MIRESMOD. Note that MIANTREG qualifies the excised specimen, whereas MIRESMOD qualifies the particular base pathological process identified within that excised specimen. In general, values for MIRESMOD should be separated by a semicolon unless they only make sense together. An example of an anatomic term is "bile duct"; this cannot be split into "bile" and "duct." An example of a term that should be separated is "centrilobular hepatocytic," which contains 2 terms that stand independently ("centrilobular" and "hepatocytic"). See the SUPPMI examples for further guidance on the use of MIRESMOD.
 - f. The use of MIRESMOD does not preclude applicants from creating other supplemental qualifiers containing specifically defined modifiers. It is currently expected that MIRESMOD will contain the complete list of modifiers not contained in standard variables (e.g., MISEV, MIDISTR, MICHRON) regardless of their being part of applicant-defined supplemental qualifiers.
 - g. Tumor findings should have a record in this domain, even if they also have records in the TF domain. It is, however, not required to populate MIRESCAT for tumor findings in the MI domain.
 - i. When MIORRES contains a tumor finding the corresponding term from NEOPLASM (CDISC Controlled Terminology list) should be used to populate MISTRESC.
 - ii. For TF domain: When MISTRESC contains a tumor finding, the corresponding term from the NEOPLASM CT list should be used to populate TFSTRESC. Additional variables populated in the MI domain (e.g., MICHRON, MIDISTR, MIRESMOD) are not populated in the TF domain.
 - h. Expectations of when MISTAT is "NOT DONE":
 - i. If an organ (scheduled for histopathology or introduced later because of adverse findings) for some reason was not examined, the record will have a blank value in MIORRES and MISTAT will be "NOT DONE".
 - ii. Use of MISTAT and MIREASND: Whenever MISTAT is "NOT DONE", MIREASND should provide the reason for not completing the evaluation as described in the study plan.
 - i. For microscopic evaluations that have numeric results (e.g., specific cell count tests), MISTRESN and MISTRESU should be included, as well as other applicable variables for the Findings observation class to reflect the data accurately.
 - 5. The MISPID variable is intended to reflect the mass identification. This variable should be used to link in-life findings (e.g., mass identification) with pathology findings. The mass identifier in --SPID should be consistent across domains (Clinical Observations, Palpable Masses, Macroscopic Findings, MI, and TF).
 - 6. The value in FOCID should have semantic value; that is, although "1" is not considered adequate, "Injection site 1" is acceptable.

2.8.9.17 SEND Organ Measurements (OM)

Description

Findings from organ measurement evaluations.

om.xpt, Organ Measurements — Findings. One record per test per specimen per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	OM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
OMSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
OMTESTCD	Test Short Name	Char	(OMTESTCD)	Topic	Short name of the measurement, test, or examination described in OMTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in OMTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). OMTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
OMTEST	Test Name	Char	(OMTEST)	Synonym Qualifier	Long name for OMTESTCD. The value in OMTEST cannot be longer than 40 characters.	Req
OMORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
OMORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.	Exp
OMSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from OMORRES in a standard format or in standard units. OMSTRESC should store all results or findings in character format; if results are numeric, they should also be submitted in numeric format in OMSTRESN.	Exp
OMSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of OMSTRESC. OMSTRESN should store all numeric test results or findings.	Exp
OMSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for OMSTRESC and OMSTRESN.	Exp
OMSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in OMORRES.	Perm
OMREASND	Reason Not Done	Char		Record Qualifier	Describes why OMSTAT is NOT DONE, such as BROKEN EQUIPMENT or TECHNICIAN OVERSIGHT.	Perm
OMSPEC	Specimen Material Type	Char	(SPEC)	Record Qualifier	Defines the type of tissue, organ, or fluid specimen used as the object for the finding. Examples: GLAND, ADRENAL, KIDNEY, VESSEL, LYMPHATIC.	Req
OMANTREG	Anatomical Region of Specimen	Char		Variable Qualifier	Defines the specific anatomical or biological region of a tissue, organ specimen, or the region from which the specimen was obtained, such as a section or part of what is defined in the OMSPEC variable. If the anatomical region is not included in the specimen description OMSPEC, it may be included in this variable. This field can be a combination of terms where needed. This field can be blank if not applicable. Examples: CORTEX, MEDULLA, MUCOSA, SEROSA, ISLET, ZONA FASICULATA, ZONA RETICULARIS, CRANIAL, MEDIAN, ACCESSORY, SPINAL, LUMBAR, FRONTAL.	Perm
OMSPCCND	Specimen Condition	Char		Record Qualifier	Free or standardized text describing the condition of the specimen. Example: FIXED.	Perm
OMSPCUFL	Specimen Usability for the Test	Char	(NY)	Record Qualifier	Describes the usability of the specimen for the test. Should be "N" if the specimen is not usable; otherwise it should be null.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
OMLAT	Specimen Laterality within Subject	Char	(LAT)	Variable Qualifier	Qualifier for laterality of the specimen within the subject for paired specimens. Examples: LEFT, RIGHT, BILATERAL.	Perm
OMDIR	Specimen Directionality within Subject	Char	(DIR)	Variable Qualifier	Qualifier for directionality of the specimen within the subject. Examples: DORSAL, PROXIMAL.	Perm
OMPORTOT	Portion or Totality	Char	(PORTOT)	Variable Qualifier	Qualifier for anatomical location or specimen further detailing the portion or totality, which means arrangement of, or apportioning of. Examples: ENTIRE, SINGLE, SEGMENT, MANY.	Perm
OMEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	"Y" if the result should be excluded from all calculations, otherwise null.	Perm
OMREASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when OMEXCLFL is "Y".	Perm
OMDTC	Date/Time Organ Measured	Char	ISO 8601 datetime or interval	Timing	Date/Time of specimen/tissue weighing, in ISO 8601 format.	Exp
OMDY	Study Day of Measurement	Num		Timing	Study day of specimen/tissue weighing, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
OMNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day: Used for grouping records for observations that may occur on different days into a single reported study day. Should be an integer.	Exp
OMNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of OMNOMDY as presented in the study report (examples: "Week 4," "Day 28," "Terminal Sac").	Perm

Assumptions

1. The Organ Measurements (OM) domain contains details of organ measurements and relative organ weights.
2. Terminal body weight will be recorded in the BW domain.
3. Organ measurement ratios within a single test or measurement should either be pure ratios with the unit shown as "RATIO" or percentages with the unit shown as "%."
4. Currently in this model, the applicant is not expected to attempt to relate the organ weight ratios to their underlying source results used in the calculation through the RELREC or GRPID mechanisms.

2.8.9.18 SEND Palpable Masses (PM)

Description

This domain captures information of any palpable masses examined during the experimental phase.

pm.xpt, Palpable Masses — Findings. One record per test per palpable mass per observation time per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	PM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
PMSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
PMGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject. This is not the dosing group number.	Perm
PMSPID	Mass Identifier	Char		Identifier	Mass identifier (e.g., MASS 1, MASS A). Used when the mass was discovered during the in-life phase or during	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					pathology and was assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.	
PMTESTCD	Test Short Name	Char	(PHSPRPCD)	Topic	Short name of the measurement, test, or examination described in PMTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PMTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PMTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
PMTEST	Test Name	Char	(PHSPRP)	Synonym Qualifier	Long name for PMTESTCD. The value in PMTEST cannot be longer than 40 characters.	Req
PMORRES	Result or Findings as Collected	Char		Variable Qualifier	Text description of findings as originally received or collected. If the examination was not performed, then the value should be null, and NOT DONE should appear in PMSTAT.	Exp
PMORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	Units for PMORRES, if available (e.g., for length, width, or depth findings). The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.	Exp
PMSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied, or derived from PMORRES in a standard format or standard units. PMSTRESC should store all results or findings (without location of finding) in character format; if results are numeric, they should also be submitted in numeric format in PMSTRESN.	Exp
PMSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of PMSTRESC. PMSTRESN should store all numeric test results or findings.	Exp
PMSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for PMSTRESC and PMSTRESN.	Exp
PMSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in PMORRES.	Perm
PMREASND	Reason Not Done	Char		Record Qualifier	Describes why PMSTAT is NOT DONE, such as MEASUREMENT IMPOSSIBLE DUE TO EXCESSIVE ULCERATION OF MASS.	Perm
PMLOC	Location of a Finding	Char		Record Qualifier	Specifies the location of the palpable mass finding. Example: LEFT SHOULDER.	Exp
PMEVAL	Evaluator	Char		Record Qualifier	Role of the person who provided the evaluation. Example: TECHNICIAN.	Perm
PMUSCHFL	Unscheduled Flag	Char	(NY)	Record Qualifier	Indicates whether the timing of a performed test or observation was unscheduled. If a test or observation was performed based upon a schedule defined in the protocol, this flag should be null. Expected values are "Y" or null.	Perm
VISITDY	Planned Study Day of Collection	Num		Timing	Planned study day of collection. Should be an integer.	Perm
PMDTCT	Date/Time of Observation	Char	ISO 8601 datetime or interval	Timing	Date/Time of the observation in ISO 8601 format.	Exp
PMDY	Study Day of Observation	Num		Timing	Study day of the observation, measured as integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
PMNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for observations that may occur on different days into a single reported study day. Should be an integer.	Exp
PMNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of PMNOMDY as presented in the study report. Examples: "Week 4," "Day 28," "Terminal Sac".	Perm

Assumptions

1. The Palpable Masses (PM) domain captures information regarding any palpable masses examined during the experimental phase in the study.
2. Results definition:

- a. PMORRES should reflect the original result as collected. The data should be reported the way it was collected. Example: A lab may choose to collect all their information on a mass in one long text string, in which case the PMTEST should be "Description" and PMORRES would contain the text string. Another lab may collect the data separately, in which case PMTEST would contain the specific measurement done on the mass. In either case, PMTEST always reflects the granularity of how the data were collected.
 - b. PMSTRESC should contain the finding without the location specified in PMLOC.
3. The PMSPID variable is intended to reflect mass identification. This variable should be used to link in-life findings with pathology findings. The mass identifier in --SPID should be consistent across domains (Clinical Observations, PM, Macroscopic Findings, Microscopic Findings, and Tumor Findings).
 4. PMDTC is expected and the dataset should contain either PMDTC or PMDY to identify the timing of the collection of the observation.

2.8.9.19 SEND Pharmacokinetics Concentrations (PC)

Description

A findings domain that contains concentrations of drugs or metabolites in fluids or tissues as a function of time.

pc.xpt, Pharmacokinetics Concentrations — Findings. One record per test per specimen per observation time per subject or pool, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	PC	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Either USUBJID or POOLID must be populated.	Exp
POOLID	Pool Identifier	Char		Identifier	Identifier used for pooling subjects to assign a single finding to multiple subjects. If POOLID is entered, POOLDEF records must exist for each subject and the USUBJID must be null. Either USUBJID or POOLID must be populated.	Perm
PCSEQ	Sequence Number	Num		Identifier	The sequence number must be unique for each record within a USUBJID or POOLID, whichever applies for the record.	Req
PCGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject or pool. This is not the dosing group number.	Perm
PCREFID	Sample Identifier	Char		Identifier	Internal or external specimen identifier. Example: 1009570101.	Perm
PCSPID	applicant-Defined Identifier	Char		Identifier	Applicant-defined reference identifier.	Perm
PCTESTCD	Test Short Name	Char		Topic	Short name of the analyte (or measurement) described in PCTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PCTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PCTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
PCTEST	Test Name	Char		Synonym Qualifier	Long name for PCTESTCD, such as the name of the analyte (or measurement). The value in PCTEST cannot be longer than 40 characters.	Req
PCCAT	Test Category	Char		Grouping Qualifier	Used to define a category of the pharmacokinetic test performed. Examples: ANALYTE, METABOLITE, SPECIMEN PROPERTY.	Perm
PCSCAT	Test Subcategory	Char		Grouping Qualifier	A further categorization of a test category.	Perm
PCORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
PCORRESU	Unit of the Original Result	Char	(PKUNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology (http://www.cdisc.org/terminology) list.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
PCSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from PCORRES in a standard format or standard units. PCSTRESC should store all results or findings in character format; if results are numeric, they should also be submitted in numeric format in PCSTRESN. Results beyond limits of quantitation should be represented with the term "BLQ" for results below the limit and "ALQ" for results above the limit.	Exp
PCSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of PCSTRESC. PCSTRESN should store all numeric test results or findings. For results beyond limits of quantitation, this variable should be left null (e.g., if PCSTRESC is "BLQ", PCSTRESN would be null).	Exp
PCSTRESU	Unit of the Standardized Result	Char	(PKUNIT)	Variable Qualifier	Standardized unit used for PCSTRESC and PCSTRESN.	Exp
PCSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in PCORRES.	Perm
PCREASND	Reason Not Done	Char		Record Qualifier	Describes why PCSTAT is NOT DONE, such as SPECIMEN LOST.	Perm
PCNAME	Laboratory Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor providing the test results.	Perm
PCSPEC	Specimen Material Type	Char	(SPEC)	Record Qualifier	Defines the type of specimen used for a measurement. Examples: SERUM, PLASMA, URINE.	Req
PCSPCCND	Specimen Condition	Char		Record Qualifier	Free or standardized text describing the condition of the specimen. Examples: HEMOLYZED, ICTERIC, LIPEMIC.	Perm
PCSPCUFL	Specimen Usability for the Test	Char	(NY)	Record Qualifier	Describes the usability of the specimen for the test. Should be "N" if the specimen is not usable; otherwise it should be null.	Perm
PCMETHOD	Method of Test or Examination	Char		Record Qualifier	Method of the test or examination. Examples: HPLC/MS, ELISA. This should contain sufficient information and granularity to allow differentiation of various methods that might have been used within a study.	Perm
PCBLFL	Baseline Flag	Char	(NY)	Record Qualifier	A baseline indicator may be used to calculate differences or changes from baseline. Value should be "Y" or null. The baseline flag is applicant-defined.	Perm
PCFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status. The value should be "Y" or null.	Perm
PCDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be "Y" or null. Records that represent the average of other records are examples of records that would be derived for the submission datasets.	Perm
PCLLOQ	Lower Limit of Quantitation	Num		Variable Qualifier	Indicates the lower limit of quantitation for an assay. Units should be those used in PCSTRESU.	Exp
PCEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	"Y" if the result should be excluded from all calculations, otherwise null.	Perm
PCREASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when PCEXCLFL is "Y".	Perm
PCUSCHFL	Unscheduled Flag	Char	(NY)	Record Qualifier	Indicates whether the timing of the specimen collection was unscheduled. If a specimen collection was performed based upon a schedule defined in the protocol, this flag should be null. Expected values are "Y" or null.	Perm
VISITDY	Planned Study Day of Collection	Num		Timing	Planned day of collection. Should be an integer.	Perm
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601 datetime or interval	Timing	Date/Time of specimen collection, in ISO 8601 format. If there is no end time, this will be the collection time.	Perm
PCENDTC	End Date/Time of Specimen Collection	Char	ISO 8601 datetime or interval	Timing	End date/time of specimen collection, in ISO 8601 format. If there is no end time, the collection time should be represented in PCDTC, and PCENDTC should be null.	Perm
PCDY	Study Day of Specimen Collection	Num		Timing	Study day of specimen collection, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in Demographics (DM) domain.	Perm
PCENDY	Study Day of End of Specimen Collection	Num		Timing	Study day of the end of specimen collection, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in DM domain.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
PCNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for specimen collections that may occur on different days into a single reported study day. Should be an integer.	Exp
PCNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of PCNOMDY as presented in the study report. Examples: "Week 4", "Day 28".	Perm
PCTPT	Planned Time Point Name	Char		Timing	Text description of time when specimen should be taken. Note: This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See PCTPTNUM and PCTPTREF. Examples: Start, 5 min post.	Perm
PCTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of PCTPT to aid in sorting.	Perm
PCELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601 format) relative to a planned fixed reference (PCTPTREF) such as "Day 1, Dose 1". This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: "PTOH" to represent any predose values; "PT8H" to represent the period of 8 hours after the reference point indicated by PCTPTREF.	Exp
PCTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by PCELTM, if used for PCTPTNUM, and PCTPT. It is recommended that PCTPTREF be as descriptive as possible so the reference time point can be inferred without looking at other variables. Example: "Day 1, Dose 1".	Exp
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601 datetime or interval	Timing	Date/Time of the reference time point, PCTPTREF.	Exp
PCEVLINT	Evaluation Interval	Char	ISO 8601 duration or interval	Timing	Planned evaluation interval associated with a PCTEST record in ISO 8601 format. Example: "-P2H" to represent a planned interval of collection of 2 hours prior to the time point described in PCTPT.	Perm

Assumptions

1. The Pharmacokinetics Concentrations (PC) domain represents concentration measurements for administered compounds and their metabolites in a sample. The sample may be from an individual or a pool. In addition to concentration measurements, specimen properties (e.g., volume, pH) are handled as separate tests in this dataset.
2. The intent of the PC domain is to accurately and clearly represent the raw bioanalytical data (e.g., unaltered and non-transformed drug concentration data). Transformations for toxicokinetics (e.g., BQL values treated as zero) can be described in SUPPPC and PCCALCN.
3. This domain should support creation of time-series graphs and automatic calculation of pharmacokinetic parameters from sets of related plasma concentrations.
4. The timing variables needed for toxicokinetic analysis are:
 - a. PCNOMDY
 - b. PCTPTREF
 - c. PCELTM
5. The combination of NOMDY and --TPTREF, when properly constructed, allows grouping within each time series of the PC records with their respective Pharmacokinetics Parameters (PP) records. In order to achieve this, ensure that the combination of PPNOMDY and PPTPTREF is equivalent to the combination of PCNOMDY and PCTPTREF.
 - a. Similar to other domains, NOMDY in the PC domain should be used as a grouping variable. For example, if animal subjects are dosed on day 90 and have a scheduled 48-hour time point collection, PCDY is "92"; NOMDY is "90", as the reported TK profile is of day 90.
 - b. Because --TPTREF must identify a unique dose, it is recommended that --TPTREF include both the NOMDY and the time point description in order (e.g., "Day 1, Dose 1" and "Day 1, Dose 2" for twice-daily dosing); ambiguous references such as "Most recent dose" should be avoided.

6. PCELTM must be populated with the nominal time from the reference (dose) in order to accurately construct a graph. Because PCELTM should be the timing used to calculate the profile, PCELTM should not be null for plasma concentrations used to calculate a profile.
 - a. When a pre-dose sample is collected as part of the profile analysis, then PCELTM must be populated as "PT0H" because negative elapsed time would lead to an incorrect area under the curve.
 - b. In studies with both pre-dose and immediate post-dose sampling, there should not be 2 "PT0H" records for the same profile. The pre-dose sampling should be represented by "PT0H" and the immediate post-dose sampling should be represented by a number slightly higher than zero but lower than the next time point post-dose. PCTPT would then be used to describe these as pre-dose and immediate post-dose, respectively.
7. If the PCORRES result is outside the limit of quantification,
 - a. PCSTRESN should be null and not populated with the value of zero.
 - b. When appropriate, populate PCCALCN in the SUPPPC domain with the value used.
 - c. When a measurement is identified as being below a limit of quantification threshold in PCSTRESC, both PCLLOQ and PCSTRESU must be populated; PCLLOQ states the level and PCSTRESU provides the units for PCLLOQ.
8. Concentration records can be added for unscheduled tests. In this case, the planned fields and those that depend upon the planned fields are left null: PCTPT, PCTPTNUM, PCELTM, PCTPTREF, PCRFTDTC, and PCEVLINT.

2.8.9.20 SEND Pharmacokinetics Parameters (PP)

Description

A findings domain that contains pharmacokinetic parameters derived from pharmacokinetic concentration-time (PC) data.

pp.xpt, Pharmacokinetics Parameters — Findings. One record per PK parameter per time-concentration profile per modeling method per subject or pool, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	PP	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Either USUBJID or POOLID must be populated.	Exp
POOLID	Pool Identifier	Char		Identifier	Identifier used for pooling subjects to assign a single finding to multiple subjects. If POOLID is entered, POOLDEF records must exist for each subject and the USUBJID must be null. Either USUBJID or POOLID must be populated.	Perm
PPSEQ	Sequence Number	Num		Identifier	The sequence number must be unique for each record within a USUBJID or POOLID, whichever applies for the record.	Req
PPGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject or pool. This is not the dosing group number.	Perm
PPTESTCD	Parameter Short Name	Char	(PKPARMCD)	Topic	Short name of the measurement, test, or examination described in PPTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PPTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PPTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: AUCINT, TMAX, CMAX.	Req
PPTEST	Parameter Name	Char	(PKPARM)	Synonym Qualifier	Long name for PPTESTCD. The value in PPTEST cannot be longer than 40 characters. Examples: AUC from T1 to T2, Time of CMAX, Max Conc.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
PPCAT	Parameter Category	Char		Grouping Qualifier	Used to define a category of parameters associated with a specific analyte. This must be the analyte in PCTEST whose profile the parameter is associated with.	Exp
PPSCAT	Parameter Subcategory	Char		Grouping Qualifier	Categorization of the model type used to calculate the pharmacokinetic parameters. Examples include COMPARTMENTAL, NON-COMPARTMENTAL.	Perm
PPORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as calculated.	Exp
PPORRESU	Unit of the Original Result	Char	(PKUNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the CDISC Controlled Terminology list.	Exp
PPSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from PPORRES in a standard format or standard units. PPSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in PPSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in PPORRES and these results effectively have the same meaning, they could be represented in standard format in PPSTRESC as NEGATIVE. For other examples, see general assumptions.	Exp
PPSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of PPSTRESC. PPSTRESN should store all numeric test results or findings.	Exp
PPSTRESU	Unit of the Standardized Result	Char	(PKUNIT)	Variable Qualifier	Standardized unit used for PPSTRESC and PPSTRESN.	Exp
PPSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a parameter was not calculated. Should be null if a result exists in PPORRES.	Perm
PPREASND	Reason Not Done	Char		Record Qualifier	Describes why a parameter was not performed, such as INSUFFICIENT DATA. Used in conjunction with PPSTAT when value is NOT DONE.	Perm
PPSPEC	Specimen Material Type	Char	(SPEC)	Record Qualifier	Defines the type of specimen used for a measurement. Examples: SERUM, PLASMA, URINE. If multiple specimen types are used for a calculation (e.g., serum and urine for creatinine clearance), refer to TIG guidance on how to populate.	Exp
VISITDY	Planned Study Day of Collection	Num		Timing	Planned study day of collection. Should be an integer.	Perm
PPNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for specimen collections that may occur on different days into a single reported study day. Should be an integer.	Exp
PPNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of PPNOMDY as presented in the study report. Examples: "Week 4", "Day 28".	Perm
PPTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point used as a basis for PPRFTDTC.	Exp
PPRFTDTC	Date/Time of Reference Point	Char	ISO 8601 datetime or interval	Timing	Date/Time of the reference time point, PPTPTREF. The values in PPRFTDTC should be the same as that in PCRFTDTC for related records.	Exp
PPSTINT	Start of Assessment Interval	Char	ISO 8601 duration	Timing	Start of the assessment interval relative to Time Point Reference (PPTPTREF) in ISO 8601 duration format. Example: When the area under the curve is calculated from 12 to 24 hours (PPTESTCD=AUCT1T2), the value would be PT12H.	Perm
PPENINT	End of Assessment Interval	Char	ISO 8601 duration	Timing	End of the assessment interval relative to Time Point Reference (PPTPTREF) in ISO 8601 duration format. Example: When the area under the curve is calculated from 12 to 24 hours (PPTESTCD=AUCT1T2), the value would be PT24H.	Perm

Assumptions

1. The PP domain represents the pharmacokinetic parameter values for each of the time-concentration profiles.

2. If a parameter needs to be qualified by an additional parameter, records for both parameters should be included (e.g., AUCLST and TLST).
3. The combination of --NOMDY and --TPTREF, when properly constructed, allows grouping within each time series of the PC records with their respective PP records.
4. In studies with *serial sampling* (i.e., all time points collected from a single animal in order to construct the time-concentration profile), then PCRFTDTC should match PPRFTDTC. Small animal toxicology studies often involve *sparse sampling* of time points; that is, due to blood volume collection in small animals, sometimes only 2-3 blood collections per day may be possible. In such cases the time-concentration profile may be constructed from 2-3 time points per animal across several animals. In cases of sparse sampling and composite time-concentration curves, it is acceptable to leave PPRFTDTC null. In the event that all subjects in a pool have the same reference time point date, it would also be acceptable to populate PPRFTDTC with the date (no time) that corresponds to the description in TPTREF.

2.8.9.21 SEND Pool Definition (POOLDEF)

Description

A dataset that identifies individual subjects included in a pool of subjects for which a single observation record (pool level) is captured.

pooldef.xpt, Pool Definition — Relationship. One record per subject per pool, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
POOLID	Pool Identifier	Char		Identifier	Identifier used for pooling subjects to assign a single finding to multiple subjects.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify across all studies for all applications or submissions involving the product.	Req

Assumptions

There are no additional POOLDEF-specific assumptions; all are included in Section 2.8.5.5, [Relating Findings to Pooled Subjects](#).

2.8.9.22 SEND Related Records (RELREC)

Description

A dataset used to describe relationships between records for a subject within or across domains, and relationships of records across datasets.

relrec.xpt, Related Records — Relationship. One record per related record, related group of records (e.g.,--GRPID), or related dataset, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
RDOMAIN	Related Domain Abbreviation	Char		Identifier	Two-character abbreviation for the domain of the parent record(s).	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Unique subject identifier of the parent record(s). Either USUBJID or POOLID must be populated, except for certain domain-to-domain relationships.	Exp
POOLID	Pool Identifier	Char		Identifier	Pool identifier of the parent record(s). If POOLID is entered, POOLDEF records must exist for each subject and the USUBJID must be null. Either USUBJID or POOLID must be populated.	Perm
IDVAR	Identifying Variable	Char		Identifier	Name of the identifying variable in the general observation class domain that identifies the related record(s). Examples: BWSEQ, BWGRPID.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
IDVARVAL	Identifying Variable Value	Char		Identifier	Value of identifying variable described in IDVAR. For example, if BWSEQ is the variable being used to describe this record, then the value of BWSEQ would be entered here.	Exp
RELTYPE	Relationship Type	Char	(RELTYPE)	Record Qualifier	Identifies the hierarchical level of the records in the relationship. Values are only necessary when identifying a relationship between domains (as described in Section 2.8.5.2). Values should be either ONE or MANY.	Perm
RELIID	Relationship Identifier	Char		Record Qualifier	Unique value within a study that identifies the relationship. RELID can be any value the applicant chooses and is only meaningful within the df dataset to identify the related/associated domain records.	Req

Assumptions

1. Timing variables cannot be added to RELREC datasets.
2. Additional RELREC assumptions are included in Section 2.8.5.2, [Relating Subject Records and Datasets](#).

2.8.9.23 SEND Related Reference Identifiers (RELREF)

Description

A relationship dataset used to describe how information is related to the design of the study and to other sources of information within the study.

relref.xpt, Related References — Relationship. One record per Reference ID, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	A sequence of characters used by the applicant to uniquely identify the study.	Req
SETCD	Trial Set Code	Char		Identifier	The short sequence of characters used to represent the trial set.	Req
REFID	Reference ID	Char		Identifier	A sequence of characters used to uniquely identify a source of information.	Req
PARENT	Parent Reference ID	Char		Identifier	The identifier for the immediate progenitor of a source of information. Identifies the REFID of the parent.	Exp
LEVEL	Reference ID Generation Level	Num		Variable Qualifier	The generation number of the information source in relation to the first generation of the source of information. Identifies the level number of the reference ID.	Exp
LVLDESC	Reference ID Level Description	Char	(LVLDSCRS)	Variable Qualifier	A description of the generation number of the information source in relation to the first generation of the source of information. Examples: ASSAY, TRIAL SET, EXPERIMENTAL UNIT, OBSERVATIONAL UNIT.	Perm

Assumptions

1. The Related References domain (RELREF) is a relationship dataset used to describe how information is related to the design of the study and to other sources of information within the study.
2. To identify a source of information from a genetic toxicology assay within a study, a unique identifier (REFID) must be assigned and populated in all datasets containing the REFID column. In other words, each GTREFID that exists in the GT dataset must exist in the RELREF dataset.
3. Each REFID that exists in the RELREF dataset must exist in the GT dataset.
4. For each value in PARENT there must exist one record with REFID value = PARENT value. The value of REFID must be unique in the RELREF dataset.
5. The value for LEVEL must be 1 for a record without a PARENT record. This record may or may not have a child record.
6. If a record has a PARENT, LEVEL must be populated with a LEVEL that is sequentially one greater than the PARENT record (e.g., value for LEVEL = value for PARENT LEVEL + 1).

2.8.9.24 SEND Respiratory Test Results (RE)

Description

A findings domain that contains physiological and morphological findings related to the respiratory system, including the organs that are involved in breathing such as the nose, throat, larynx, trachea, bronchi and lungs.

re.xpt, Respiratory System Findings — Findings. One record per test per observation time or evaluation interval per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	RE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all application or submissions involving the product.	Req
RESEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
REGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject and can be used to support relationships within the domain and between domains using RELREC. This is not the dosing group number.	Perm
RESPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference identifier.	Perm
RETESTCD	Test Short Name	Char	(SRETSTCD)	Topic	Short name of the measurement, test, or examination described in RETEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in RETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). RETESTCD cannot contain characters other than letters, numbers, or underscores. Examples: RESPRATE, TIDALVOL, MV.	Req
RETEST	Test Name	Char	(SRETST)	Synonym Qualifier	Long name for RETESTCD. The value in RETEST cannot be longer than 40 characters. Examples: Respiratory Rate, Tidal Volume, Minute Volume.	Req
REPOS	Position of Subject During Test	Char	(POSITION)	Record Qualifier	Position of the subject during the measurement or examination, If the subject is restrained, populate with the position (example SITTING or STANDING); otherwise, populate with UNCONSTRAINED.	Exp
REORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
REORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.	Exp
RESTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from REORRES in a standard format or standard units. RESTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in RESTRESN.	Exp
RESTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; contains the numeric form of RESTRESC. RESTRESN should store all numeric test results or findings.	Exp
RESTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for RESTRESC and RESTRESN.	Exp
RESTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in REORRES.	Perm
REREASND	Reason Not Done	Char		Record Qualifier	Describes why RESTAT is NOT DONE, such as BROKEN EQUIPMENT.	Perm
REMETHOD	Method of Test	Char		Record Qualifier	Method of the test or examination. Examples: Whole body plethysmograph, Head-out plethysmograph, Invasive.	Exp
RECSTATE	Consciousness State	Char	(CSTATE)	Record Qualifier	Consciousness state of the subject at the time of measurement. Examples: CONSCIOUS, SEMI-CONSCIOUS, UNCONSCIOUS.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
REBLFL	Baseline Flag	Char	(NY)	Record Qualifier	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is applicant defined.	Exp
REDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be "Y" or null.	Perm
REEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	"Y" if the result should be excluded from all calculations, otherwise null.	Perm
REREASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when REEXCLFL is Y.	Perm
REUSCHFL	Unscheduled Flag	Char	(NY)	Record Qualifier	Indicates whether the timing of the performed test or observation was unscheduled. If a test or observation was performed based upon a schedule defined in the protocol, this flag should be null. Expected values are "Y" or null.	Perm
REDTA	Date/Time of Respiratory Measurement	Char	ISO 8601 datetime or interval	Timing	Date/time of respiratory data collection, in ISO 8601 format. For measurements related to a continuous evaluation interval, REDTC should be used to indicate the start date/time of that interval.	Exp
REENDTA	End Date/Time of Respiratory Measurement	Char	ISO 8601 datetime or interval	Timing	Date/time of end of the respiratory evaluation interval, in ISO 8601 format. Should be populated when REDTC represents the start date/time of a continuous evaluation interval.	Perm
REDY	Study Day of Respiratory Measurement	Num		Timing	Study day of respiratory data collection, in integer days. For measurements related to a continuous evaluation interval, REDY can be used to indicate start day of that interval. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
REENDY	End Study Day of Respiratory Measurement	Num		Timing	Study day of the respiratory data collection, in integer days. Can be populated when REDY represents the start day of a continuous evaluation interval. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the DM domain.	Perm
RENOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for observations that may occur on different days into a single reported study day. Should be an integer.	Exp
RENOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of RENOMDY as presented in the study report. Examples: Pretreatment, Week 4, Day 28.	Perm
RETPT	Planned Time Point Name	Char		Timing	Text description of time when respiratory data should be collected. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See RETPTNUM and RETPTREF. Examples: Predose, 1 Hour Postdose.	Exp
RETPTNUM	Planned Time Point Number	Num		Timing	Numerical version of RETPT to aid in sorting.	Exp
REELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601 format) relative to a fixed time point reference (RETPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by RETPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by RETPTREF.	Exp
RETPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by REELTM, if used for RETPTNUM, and RETPT. It is recommended that RETPTREF be as descriptive as possible so the reference time point can be inferred without looking at other variables. Example: DAY 1 FIRST DOSE.	Exp
RERFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/Time of the reference time point, RETPTREF.	Perm
REEVLINT	Evaluation Interval	Char	ISO 8601 duration or interval	Timing	Length of evaluation interval in ISO 8601 duration format. Used in place of RESTINT and REENINT when RETPTREF is not available.	Perm
RESTINT	Planned Start of Assessment Interval	Char	ISO 8601 duration	Timing	Planned start of an assessment interval relative to Time Point Reference (RETPTREF) in ISO 8601 duration format. Example: When the evaluation interval is from 1 to 2 hours after dosing, the value would be PT1H.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
REENINT	Planned End of Assessment Interval	Char	ISO 8601 duration	Timing	Planned end of an assessment interval relative to Time Point Reference (REPTPTREF) in ISO 8601 duration format. Example: When the evaluation interval is from 1 to 2 hours after dosing, the value would be PT2H.	Exp

Assumptions

1. The RE domain contains dynamic measurements, collected or derived, related to the respiratory system.
2. The actual timing variables REDTC, REENDTC, REDY and REENDY are used to represent the start and end of the evaluation period during which data that contributed to the reported result were collected. This may be a portion of a longer period over which the instrument was continuously collecting data.
3. RESTINT and REENINT should be used to describe a known assessment interval whenever there is a reference time point (REPTPTREF).
4. REMETHOD and RECSTATE are considered important for comparison purposes and should be populated whenever available or collected.

2.8.9.25 SEND Subject Characteristics (SC)

Description

A findings domain that contains subject-related data not collected in other domains.

sc.xpt, Subject Characteristics — Findings. One record per characteristic per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SC	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across a study for all applications or submissions involving the product.	Req
SCSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
SCGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject. This is not the dosing group number.	Perm
SCTESTCD	Subject Characteristic Short Name	Char	(SBCCDSND)	Topic	Short name of the measurement, test, or examination described in SCTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in SCTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). SCTESTCD cannot contain characters other than letters, numbers, or underscores. Some extensible controlled values are: SPLRNAM, SPLRLOC, HAIRCOLR.	Req
SCTEST	Subject Characteristic	Char	(SBCSND)	Synonym Qualifier	Long name for SCTESTCD. The value in SCTEST cannot be longer than 40 characters. Examples: Test Subject Supplier, Test Subject Supplier Site, and Hair Coat Color.	Req
SCORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the subject characteristic as originally received or collected.	Exp
SCORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.	Perm
SCSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from SCORRES in a standard format or standard units. SCSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in SCSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in SCORRES, these results effectively have the same meaning. In this case, they could be represented in standard format in SCSTRESC with a single term NEGATIVE.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
SCSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of SCSTRESC. SCSTRESN should store all numeric test results or findings.	Perm
SCSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for SCSTRESC and SCSTRESN.	Perm
SCDTC	Date/Time of Collection	Char	ISO 8601 datetime or interval	Timing	Date/time of collection of the subject characteristic information, in ISO 8601 format.	Perm
SCDY	Study Day of Collection	Num		Timing	Study day of collection, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

Assumptions

1. Subject Characteristics consists of data that is collected once per subject (per test). SC contains data that is either not normally expected to change during the study or whose change is not of interest after the initial collection.
2. Applicants should ensure that data considered for submission in SC (e.g., hair coat, physical markings) do not actually belong in another domain. It is up to the applicant to determine whether such data have any information relevant to this domain.
3. The structure for SC is based on the Findings general observation class. It is an extension of the Demographics (DM) dataset. Any data that can be submitted in the DM variables should not be submitted in SC.

2.8.9.26 SEND Subject Elements (SE)

Description

A special-purpose domain that contains the actual order of elements followed by the subject, together with the start date/time and end date/time for each element.

se.xpt, Subject Elements — Special-Purpose. One record per element experienced per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SESEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a USUBJID within a domain. May be any valid number.	Req
ETCD	Element Code	Char		Topic	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions.	Req
ELEMENT	Description of Element	Char		Synonym Qualifier	The name of the element.	Perm
SESTDTC	Start Date/Time of Element	Char	ISO 8601 datetime or interval	Timing	Start date/time for an element for each subject, in ISO 8601 format.	Req
SEENDTC	End Date/Time of Element	Char	ISO 8601 datetime or interval	Timing	End date/time for an element for each subject, in ISO 8601 format.	Exp
SEUPDES	Description of Unplanned Element	Char		Synonym Qualifier	Description of what happened to the subject during an unplanned element. Used only if ETCD has the value of UNPLAN.	Perm

Assumptions

1. The Subject Elements domain allows the submission of data on the individual experience: the actual timing and sequence of elements a subject experienced. There are, by definition, no time gaps between elements;

therefore, the value of SEENDTC for one element will always be immediately before or the same as the value of SESTDTC for the next element. Each element continues until the time at which the next element begins, and a subject must be in only 1 element at a time.

2. For any particular subject, the dates in the SE table are the dates when the transition events identified in the TE table occurred.
3. If the start date/time of an element was not collected directly, the method used to infer the element start date/time should be explained in the Comments column of the data definition file.
4. If the applicant decides that the subject's experience for a particular period of time cannot be represented with one of the planned elements, then that period of time should be represented as an unplanned element.
5. For unplanned elements, ETCD should be populated with "UNPLAN", ELEMENT should be left blank, and SEUPDES should be populated with a description of the unplanned element.
6. With the exception of unplanned elements, the values of ETCD used in this domain should match values for the same element in the TE dataset.
7. The values of SESTDTC provide the chronological order of the actual subject elements. SESEQ should be assigned to be consistent with the chronological order. Note that the requirement that SESEQ be consistent with chronological order is more stringent than in most other domains, where --SEQ values need only be unique within subject.

2.8.9.27 SEND Supplemental Qualifiers (SUPP--)

Description

A relationship dataset used to describe nonstandard variables and their association to parent records in general-observation class datasets.

supp--xpt, Supplemental Qualifiers for [domain name] — Relationship. One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique study identifier of the parent record(s).	Req
RDOMAIN	Related Domain Abbreviation	Char		Identifier	Two-character abbreviation for the domain of the parent record(s).	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Unique subject identifier of the parent record(s). Either USUBJID or POOLID must be populated.	Exp
POOLID	Pool Identifier	Char		Identifier	Pool identifier of the parent record(s). If POOLID is entered, POOLDEF records must exist for each subject and the USUBJID must be null. Either USUBJID or POOLID must be populated.	Perm
IDVAR	Identifying Variable	Char		Identifier	Identifying variable in the dataset that identifies the related record(s). Examples: BWSEQ, CLGRPID.	Exp
IDVARVAL	Identifying Variable Value	Char		Identifier	Value of identifying variable of the parent record(s).	Exp
QNAM	Qualifier Variable Name	Char		Topic	The short name of the Qualifier variable, which is used as a column name in a domain view with data from the parent domain. The value in QNAM cannot be longer than 8 characters nor can it start with a number (e.g., "1TEST" is not valid). QNAM cannot contain characters other than letters, numbers, or underscores. This will often be the column name in the applicant's operational dataset. The value in QNAM may not be the same as any variable name defined in another domain or the SDTM. The QNAM should uniquely correspond to a QLABEL within a single domain.	Req
QLABEL	Qualifier Variable Label	Char		Synonym Qualifier	This is the long name or label associated with QNAM. The value in QLABEL should be in title case and cannot be longer than 40 characters. This will often be the column label in the sponsor's operational dataset.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
QVAL	Data Value	Char		Result Qualifier	Result of, response to, or value associated with QNAM. A value for this column is required; no records can be in SUPP-- with a null value for QVAL.	Req
QORIG	Origin	Char		Record Qualifier	QORIG is used to indicate the origin of the data. Possible values are COLLECTED, DERIVED, OTHER, and NOT AVAILABLE.	Perm
QEVAL	Evaluator	Char		Record Qualifier	Used only for results that are subjective (i.e., assigned by a person or a group). Should be null for records that contain objectively collected or derived data. Examples: PATHOLOGIST, VETERINARIAN.	Perm

Assumptions

- Timing variables cannot be added to SUPPQUAL datasets.
- Additional SUPPQUAL assumptions are included in Section 2.8.5.3, [Relating NSVs and Attributions to a Domain](#).

2.8.9.28 SEND Trial Arms (TA)

Description

A trial design domain that contains each planned arm in the trial.

ta.xpt, Trial Arms — Trial Design. One record per planned Element per Arm, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TA	Identifier	Two-character abbreviation for the domain.	Req
ARMCD	Planned Arm Code	Char		Topic	Short name of a specific arm (may be up to 20 characters) used for sorting and programming. Should be populated in Demographics when arms have been defined in this domain.	Req
ARM	Description of Planned Arm	Char		Synonym Qualifier	Descriptive name given to a specific trial arm (e.g., Low Dose, Mid Dose, 10 mg/kg/day dose).	Req
TAETORD	Order of Element within Arm	Num		Timing	Number that provides the order of the planned element within the arm. This value should be an integer.	Req
ETCD	Element Code	Char		Record Qualifier	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions.	Req
ELEMENT	Description of Element	Char		Synonym Qualifier	The name of the element.	Perm
TABRANCH	Branch	Char		Rule	Conditions subjects meet, occurring at the end of an element, which cause an arm to branch off from other arms (e.g., randomization to product X).	Perm
TATRANS	Transition Rule	Char		Rule	If the study/trial design allows for a subject to transition to an element other than the next sequential element, as defined by TAETORD, then the conditions for transitioning to those other elements, as well as the alternative element sequences, are specified in this rule (e.g., TATRANS = "Subject with Hypoactivity Transitions to Rest Period to Product Exposure 2").	Perm
EPOCH	Trial Epoch	Char		Timing	Name of the study epoch with which this element of the arm is associated (e.g., screening). Equivalent to "phase" or "period."	Exp

Assumptions

- The Trial Arms (TA) dataset provides a record of the complete planned sequence of elements for each arm.
- ARM and ARMCD values in Demographics (DM) and TA must coincide (ARM and ARMCD are defined as the planned trial arms in TA, and the planned arms are then applied to subjects in DM).
- TAETORD is an integer and is used to order the elements within an arm. In general the value of TAETORD is "1" for the first element in each arm, "2" for the second element in each arm, and so on.

Occasionally, the sequential order of the elements may not be known in advance, in which case the TA domain is populated after the study has been conducted (e.g., for an unknown number of cycles of product exposure and recovery in a group). Although the values of TAETORD need not always be consecutive, the values must always be populated according to the correct order of the elements within an arm, with the first element equivalent to the lowest value of TAETORD and the last element equivalent to the highest value of TAETORD.

4. The values of ETCD used in the TA dataset must match values for the same element in the Trial Elements (TE) dataset.
5. The elements in each arm must be consecutive in time; it is not correct to leave any gaps in time between elements. If a multiday pause in product exposure is part of the study design, that should either be reflected within one of the existing element definitions, or a new element representing the lack of product exposure should be included.
6. Elements in different arms with the same value of TAETORD may or may not happen at the same time, depending on the design of the study.
7. The same element may occur more than once within an arm.
8. TABRANCH describes the outcome of a branch decision point in the trial design for subjects in the arm. A branch decision point takes place between epochs and is associated with the element end, at which point the branching decision is made. For instance, if subjects are assigned to an arm where they receive Product A through a randomization at the end of element X, the value of TABRANCH for element X would be "Randomized to A".
9. Branch decision points may be based on decision processes other than randomizations, such as clinical evaluations of disease response.
10. There is usually some gap in time between the performance of a randomization and the start of randomized product exposure. However, in many studies this gap in time is small and it is not intended that subjects will leave the study between randomization and product exposure. In these circumstances, the study does not need to be modeled with this time period between randomization and start of product exposure as a separate element.
11. TATRANS describes the decision points that may lead to a shortened path within an arm (e.g. if some elements within the arm are skipped). If an element does not end with a decision that could lead to a shortened path within the arm, then TATRANS will be null. If there is a decision being represented within the value of TATRANS, the TATRANS rule should be populated as an "if-then" statement (e.g., "If condition X is true, then go to element with TAETORD = Z").
12. EPOCH is the conceptual basis for comparisons between arms. EPOCH is not strictly necessary for describing the sequence of elements in an arm path. The values of EPOCH should provide a description of a time period that is independent of the value of ARM.
13. EPOCH should be assigned in such a way that elements from different arms with the same value of EPOCH are comparable in some sense (e.g., EPOCH="Exposure", where specific doses may be different across arms but the subjects are all being dosed in some manner).
14. In vitro studies do not typically include trial arms.

2.8.9.29 SEND Trial Elements (TE)

Description

A trial design domain that contains the element code that is unique for each element, the element description, and the rules for starting and ending an element.

te.xpt, Trial Elements — Trial Design. One record per planned Element, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TE	Identifier	Two-character abbreviation for the domain.	Req
ETCD	Element Code	Char		Topic	ETCD (the short form of ELEMENT) is limited to 8 characters and does not have special character restrictions.	Req
ELEMENT	Description of Element	Char		Synonym Qualifier	The name of the element.	Req
TESTRL	Rule for Start of Element	Char		Rule	Expresses rule for beginning element.	Req
TEENRL	Rule for End of Element	Char		Rule	Expresses rule for ending element. Either TEENRL or TEDUR must be present for each element; both may be present.	Perm
TEDUR	Planned Duration of Element	Char	ISO 8601 duration	Timing	Planned duration of element in ISO 8601 format. Use when an element represents a fixed duration. TEENRL or TEDUR must be present for each element; both may be present.	Perm

Assumptions

1. Trial elements are the building blocks of arms. Arms consisting of elements are the paths that subjects will follow throughout a trial. All elements are related to study product exposure. Therefore, an element is defined by the product exposure (or lack of product) to be administered to subjects during the element, as well as either the planned duration or start/end rules of the element.
2. Elements with different start and end rules are different elements and must be represented as unique values in ELEMENT and ETCD (i.e., elements involving the same product exposure but different durations are different elements). The same applies to nonexposure elements (e.g., a wash-out with a fixed duration of 14 days is different from a wash-out that ends after 7 days if drug cannot be detected in a blood sample or after 14 days if drug can be detected in a blood sample).
3. ELEMENT and ETCD values in TE, Subject Elements (SE), and Trial Arms (TA) must coincide (ELEMENT and ETCD are defined as the planned trial elements in TE, and the planned elements are then applied to subjects in SE and to arms in TA).
4. Additional factors beyond product exposure, start rule, and either end rule or duration do not distinguish separate elements. For example, a restricted vs. ad libitum diet for the same product exposure does not necessarily imply different trial elements for the subjects experiencing these conditions, even though the subjects may be analyzed differently or be assigned to different groups or trial sets.
5. Elements often appear in more than one arm or epoch and can be reused within the same arm or epoch and across arms and epochs. Therefore, it is not recommended that the values of ETCD and ELEMENT refer to arms or epochs.
6. There are no gaps between elements. The instant one element ends, the next element begins. A subject spends no time "between" elements.
7. The ELEMENT variable contains the description of the element and often indicates the product being administered during an element. If no product is administered, as is often the case with a screening element, the other activities that define this period of time (as related to a trial element) become the value of ELEMENT (e.g., "Screening," "Recovery," "Washout," where screening, recovery, and wash-out all take place within the context of the trial element).
8. For product exposure elements, the ELEMENT variable may include the following information (if appropriate for the element): product exposure amount; product exposure frequency; and total daily dose, if different from product exposure amount.

9. TESTRL is the rule that defines the start of element. TESTRL identifies the event that marks the transition into an element. For elements that involve product exposure, TESTRL is usually populated with a value that indicates product exposure administration.
10. The start of the study for a particular arm is defined by the value of TESTRL for the first element within that arm.
11. TESTRL for a product exposure element may be thought of as active while the start rule for a nonexposure element, particularly a recovery or wash-out element, may be passive. The start of a product exposure element will not occur until a dose is given, no matter how long that dose is delayed. Note that the date/time of the event that starts an element, which is described in TESTRL, will be used to populate the SESTDTC date/times in the SE dataset. Therefore, TESTRL should refer to an event of that the date/time will be captured during the course of the study.
12. TESTRL and TEENRL should be expressed without referring to arm or epoch.
13. TEENRL describes the circumstances under which an element ends, causing subjects to enter into another element. Element end rules may depend on a variety of conditions. The TA dataset, not the TE dataset, describes where the subject moves next; therefore, TEENRL values must be expressed independently of arms.
14. For elements that do not involve product exposure, TESTRL can be more difficult to define. For wash-out and recovery elements, which often follow exposure elements, the start of the element may be defined relative to the end of a preceding exposure. For example, a wash-out period might be defined as starting after the last dose of drug for the preceding exposure element. This type of definition will place constraints on how the element can be sequenced within the TA dataset.
15. Defining a clear starting point for the start of a nonexposure element that always follows another nonexposure element can be particularly difficult. The transition may be defined by a decision-making activity such as randomization. For example, every arm of a study that involves treating disease episodes might start with a screening element followed by an element that consists of waiting until a disease episode occurs after an initial randomization of subjects. The activity that marks the beginning of the wait element might then be the randomization.

2.8.9.30 SEND Tumor Findings (TF)

Description

A findings domain that captures the post-mortem tumor findings of the study. Records in this domain are a subset of the records in the Microscopic Findings (MI) domain.

tf.xpt, Tumor Findings — Findings. One record per tumor per specimen per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TF	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product within the submission.	Req
TFSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
TFGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject. This is not the dosing group number.	Perm
TFREFID	Specimen Identifier	Char		Identifier	Internal or external specimen identifier. Example: Specimen barcode number.	Perm
TFSPID	Mass Identifier	Char		Identifier	Mass identifier (e.g., MASS 1, MASS A). Used when the mass was discovered during the in-life phase or during pathology and was assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
TFTESTCD	Tumor Examination Short Name	Char	(TFTESTCD)	Topic	Short name of the measurement, test, or examination described in TFTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in TFTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). TFTESTCD cannot contain characters other than letters, numbers, or underscores. Example: TUMEX.	Req
TFTEST	Tumor Examination Name	Char	(TFTEST)	Synonym Qualifier	Long name for TFTESTCD. The value in TFTEST cannot be longer than 40 characters. Example: Tumor Examination.	Req
TFORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the histopathological examination as originally received or collected.	Exp
TFSTRESC	Standardized Result in Character Format	Char	(NEOPLASM)	Result Qualifier	Contains the tumor name mapped from TFORRES into a standard format from the controlled terms list.	Exp
TFRESCAT	Tumor Malignancy Status	Char	(NEOSTAT)	Variable Qualifier	Used to record the malignancy of the tumor as determined by the pathologist. It may be copied or derived from a description in TFORRES. Examples: BENIGN, MALIGNANT, METASTATIC, and UNDETERMINED.	Req
TFNAM	Laboratory Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor that provided the test results.	Perm
TFSPEC	Specimen Material Type	Char	(SPEC)	Record Qualifier	Defines the type of tissue, organ, or fluid specimen examined. Examples: LIVER, HEART.	Req
TFANTREG	Anatomical Region of Specimen	Char		Variable Qualifier	Defines the specific anatomical or biological region of a tissue, organ specimen, or the region from which the specimen was obtained, such as a section or part of what is defined in the TFSPEC variable. If the anatomical region is not included in the specimen description TFSPEC, it may be included in this variable. This field can be a combination of terms where needed. This field can be null if not applicable. Examples: CORTEX, MEDULLA, MUCOSA, SEROSA, ISLET, ZONA FASICULATA, ZONA RETICULARIS, CRANIAL, MEDIAN, ACCESSORY, SPINAL, LUMBAR, FRONTAL.	Perm
TFSPCCND	Specimen Condition	Char		Record Qualifier	Free or standardized text describing the condition of the specimen. Example: AUTOLYZED.	Perm
TFLAT	Specimen Laterality within Subject	Char	(LAT)	Variable Qualifier	Qualifier for laterality of the specimen within the subject for paired specimens. Examples: LEFT, RIGHT, BILATERAL.	Perm
TFDIR	Specimen Directionality within Subject	Char	(DIR)	Variable Qualifier	Qualifier for directionality of the specimen within the subject. Examples: DORSAL, PROXIMAL.	Perm
TFMETHOD	Method of Test or Examination	Char		Record Qualifier	Method of the test or examination. This could be different types of staining used for the slides. Example: H&E.	Perm
TFEVAL	Evaluator	Char		Record Qualifier	Role of the person who provided the evaluation. Example: TOX PATHOLOGIST, PEER REVIEW.	Perm
TFDTHREL	Relationship to Death	Char	(NY)	Record Qualifier	Describes the relationship of a particular finding to the death of a subject. Example: Y if the tumor was the cause of death, N if the tumor was not the cause of death, or U for Unknown. Null cannot be used because the variable is required.	Req
TFDTC	Date/Time	Char	ISO 8601 datetime or interval	Timing	For a specimen collected or observed post mortem, this is the date/time of subject disposition, in ISO 8601 format.	Perm
TFDY	Study Day	Num		Timing	For a specimen collected or observed post mortem, this is the study day of subject disposition, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
TFDETECT	Time in Days to Detection of Tumor	Num		Timing	The number of days from the start of dosing to the earliest detection of the tumor in the experimental phase. This variable must be populated for every tumor discovered during the experimental phase.	Req

Assumptions

1. The TF domain captures the post-mortem tumor findings of the study. Records in this domain are a subset of records in the Microscopic Findings (MI) domain.
2. One subject may have multiple records for any organ, if multiple tumors were found.
3. The TFDETECT variable is the number of days relative to the first day of product exposure when the tumor was first detected. Depending on how the tumor was detected, this could be derived from CLDTC, PMDTC, or DSSTDTC.
 - a. If the tumor was detected as a clinical sign, then TFDETECT is based on the Clinical Observations (CL) domain start date/time of observation variable (CLDTC). This is calculated as (CLDTC – EXSTDTC) + 1.
 - b. If the tumor was detected as a palpable mass, then TFDETECT is based on the Palpable Masses (PM) domain start date/time of observation variable (PMDTC). This is calculated as (PMDTC – EXSTDTC) + 1.
 - c. If the tumor was initially detected during necropsy (the MA domain), then TFDETECT is based on the Disposition (DS) domain start date/time of observation variable (DSSTDTC). This is calculated as (DSSTDTC – EXSTDTC) + 1.
 - d. If the tumor was initially detected during histopathology examination (the MI domain), then TFDETECT is based off the DS domain variable DSSTDTC. This is calculated as (DSSTDTC – EXSTDTC) + 1.
4. The TFSPID variable is intended to reflect the mass identification. This variable should be used to link in-life findings with pathology findings. The mass identifier in --SPID should be consistent across domains (CL, PM, MA, MI, and TF).

2.8.9.31 SEND Trial Sets (TX)

Description

A trial design domain that contains one record for each trial set characteristic including experimental factors, treatment factors, inherent characteristics, or distinct applicant designations. This domain is not subject oriented.

tx.xpt, Trial Sets — Trial Design. One record per Trial Set parameter per Trial Set, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TX	Identifier	Two-character abbreviation for the domain.	Req
SETCD	Set Code	Char		Identifier	Short name of the trial set. The same element may occur more than once within an arm. Maximum 8 characters. This represents the trial set for which parameters are being submitted.	Req
SET	Set Description	Char		Synonym Qualifier	Long description of a specific trial set, as defined by the applicant.	Req
TXSEQ	Sequence Number	Num		Identifier	Unique number for this record within this dataset (This sequence should be unique within the entire dataset because there is no USUBJID.).	Req
TXPARMCD	Trial Set Parameter Short Name	Char	(STSPRMCD)	Topic	Short character value for the trial set parameter described in TXPARM. Maximum 8 characters.	Req
TXPARM	Trial Set Parameter	Char	(STSPRM)	Synonym Qualifier	Term for the trial set parameter. Maximum 40 characters.	Req
TXVAL	Trial Set Parameter Value	Char		Result Qualifier	Value of the trial set parameter (e.g., Fed ad libitum or Restricted Feeding when TXPARM is FEEDREG). Some parameters may be subject to controlled terminology.	Req

Assumptions

1. The Trial Sets (TX) domain provides the list of distinct sets of subjects or sources of information (REFIDs) having different experimental factors, product exposure factors, inherent characteristics, or distinct applicant designations as specified in the trial design.
2. Each trial set must be identified by a SETCD that is unique within the trial. The SETCD is assigned by the applicant.
3. Each trial set should have a SPGRPCD in TXPARMCD with corresponding parameter value under TXVAL. In many cases, more than 1 trial set may be assigned the same group number in the protocol. The inclusion of this parameter facilitates the ability to reference information in the protocol provided and as part of the submission.
4. The SPGRPCD parameter value may be used for sorting when viewing the data. applicants should consider utilizing values that will sort alphabetically in an order intended by the applicant.
5. The TXPARMCD and TXPARM list may be extended by the applicant as needed to provide the information on experimental factors that differentiate trial sets.
6. In general, each set should have a distinct combination of TXPARMCD, TXPARM, and TXVAL whenever possible. If 2 trial sets (identified by distinct SETCD values) have the same set of TXPARMCD, TXPARM, and TXVAL entries, the SET variable must contain information that distinguishes the sets from each other.
7. Some --PARMCD values are available to both the Trial Summary (TS) and TX domains in order to allow for further description of how those values apply to individual trial sets. However, if the attributes (TXPARMCD) are identical across trial set, including them in TS is sufficient.
8. In vivo studies:
 - a. There should be no planned parameters of interest that could further subdivide a trial set. Each trial set should be assigned to a single group. Each trial set in an in vivo study should be assigned to a single trial arm.
 - b. Trial sets should be designed so that each individual subject shall participate in 1 and only 1 trial set.
 - c. The ARMCD parameter should be used to associate each trial set with a trial arm as defined in the Trial Arms (TA) table. Each trial set should only have 1 ARMCD parameter, but more than 1 trial set may have the same value of the ARMCD parameter.
 - d. The applicant may choose to define subjects of different sexes as distinct trial sets if this is appropriate based upon the trial design. Alternatively, if all other parameters are the same, sets can be defined to contain both sexes under the assumption that it is common practice to analyze male and female subjects separately.
 - e. The TCNTRL parameter must be included if the Trial Set is considered to be a control for the study (or part of a control). This parameter is used to define the type of control (e.g., VEHICLE CONTROL, POSITIVE CONTROL, etc.)
9. In vitro studies:
 - a. Each source of information is directly associated with only one trial set. The RELREF dataset establishes relationships between sources of information via the REFID which indirectly establishes relationships between trial sets.
 - b. Trial arms do not typically apply to in vitro studies.
 - c. A study can include more than one genetic toxicology assay (indicated by values for GNTXAID) but a trial set must be associated with only one assay.
 - d. To describe the intervention for in vitro studies use parameter codes such as ITVNAME, ITVTYPE, ITVCONC, ITVCONCU.

2.8.9.32 SEND Trial Summary (TS)

Description

A trial design domain that contains one record for each trial summary characteristic. This domain is not subject oriented.

ts.xpt, Trial Summary — Trial Design. One record per trial summary parameter value, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study within the submission.	Req
DOMAIN	Domain Abbreviation	Char	TS	Identifier	Two-character abbreviation for the domain most relevant to the observation.	Req
TSSEQ	Sequence Number	Num		Identifier	Sequence number used to ensure uniqueness within a TSPARMCD. Allows inclusion of multiple records for the same TSPARMCD, and can be used to join related records.	Req
TSGRPID	Group Identifier	Char		Identifier	Used to tie together a group of related records. This is not the applicant-defined protocol group number.	Exp
TSPARMCD	Trial Summary Parameter Short Name	Char	(STSPRMCD)	Topic	Short character value for the trial design characteristic described in TSPARM. Value must be 8 characters or less.	Req
TSPARM	Trial Summary Parameter	Char	(STSPRM)	Synonym Qualifier	Term for the trial parameter. Value must be 40 characters or less.	Req
TSVAL	Parameter Value	Char		Result Qualifier	Value of the TS parameter (e.g., "FDA" when TSPARM is GLP Type). The values for some parameters may be subject to controlled terminology. TSVAL can only be null if TSVALNF is populated.	Exp
TSVALNF	Parameter Null Flavor	Char	ISO 21090 NullFlavor	Record Qualifier	Null flavor for the value of TSPARM, to be populated only if TSVAL is null.	Perm

Assumptions

1. The intent of the Trial Summary (TS) domain is to provide a summary of the study information in dataset format. This is not subject-level data.
2. TSVAL may have controlled terminology, depending on the value of TSPARMCD.
3. TS allows for 1 TSVAL value to span multiple variables (TSVAL-TSVALn), in order to accommodate values longer than 200 characters. This is similar to the conventions used in the Comments (CO) domain to accommodate COVAL values longer than 200 characters. TS and CO are special-purpose domains that allow additional TSVAL/COVAL variables to be added to the dataset, in order to accommodate values longer than 200 characters.
4. For some types of studies, there will be multiple records in the TS dataset for a single parameter, such as GLP type when a study is conducted in such a way that it complies with several GLP guidances. In this case, when TSPARMCD = GLPTYP there may be 2 (or more) records for TSVAL, one with the value "OECD" and the other with the value "FDA."
5. Use TSGRPID for linking together multiple parameters (e.g., assign a TSGRPID to show a relationship between multiple species to multiple strains, or assign a TSGRPID to show a relationship between several laboratory sites and locations and individual investigators). Note that any parameters with the same GRPID are related.
6. The TSSEQ variable is required to identify each record as unique, in cases where the same TSPARMCD is used within the dataset. The TSSEQ variable must be populated for all records within the TS dataset.
7. Some --PARMCD values are available to both the TS and Trial Sets (TX) domains in order to show the relevant information at the appropriate level. If TSPARMCD values do not differ across trial sets, then these should be described in the TS and need not be in the TX domain.
8. A study can include more than one genetic toxicology assay (indicated by values for GNTXAID).

2.8.9.33 SEND Vital Signs (VS)

Description

A findings domain that contains measurements including but not limited to blood pressure, temperature, respiration, body surface area, body mass index, height and weight.

vs.xpt, Vital Signs — Findings. One record per measurement per observation time per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	VS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
VSGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject. This is not the dosing group number.	Perm
VSSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference identifier.	Perm
VTESTCD	Vital Signs Test Short Name	Char	(SVSTSTCD)	Topic	Short name of the measurement described in VTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). VTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
VTEST	Vital Signs Test Name	Char	(SVSTST)	Synonym Qualifier	Long name for VTESTCD. The value in VTEST cannot be longer than 40 characters.	Req
VSCAT	Category for Vital Signs	Char		Grouping Qualifier	Used to define a category of the vital signs measurement performed.	Perm
VSSCAT	Subcategory for Vital Signs	Char		Grouping Qualifier	A further categorization of the vital signs measurement performed.	Perm
VSPOS	Vital Signs Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during the measurement. If the subject is restrained, populate with the position (e.g., SITTING, STANDING).	Perm
VSORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the vital signs measurement as originally received or collected.	Exp
VSORRESU	Unit of the Original Result	Char	(UNIT)	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.	Exp
VSSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from VSORRES in a standard format or standard units. VSSTRESC should store all results in character format; if results are numeric, they should also be submitted in numeric format in VSSTRESPN.	Exp
VSSTRESPN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of VSSTRESC. VSSTRESPN should store all numeric test results or findings.	Exp
VSSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for VSSTRESC and VSSTRESPN.	Exp
VSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists in VSORRES.	Perm
VSREASND	Reason Not Done	Char		Record Qualifier	Describes why VSSTAT is NOT DONE, such as BROKEN EQUIPMENT.	Perm
VSLOC	Location of Vital Signs Measurement	Char		Record Qualifier	Location relevant to the collection of the vital signs measurement. Example: RECTAL for Temperature.	Perm
VSCSTATE	Consciousness State	Char	(CSTATE)	Record Qualifier	Consciousness state of the subject at the time of measurement. Examples: CONSCIOUS, SEMI-CONSCIOUS, UNCONSCIOUS.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
VSLFL	Baseline Flag	Char	(NY)	Record Qualifier	A baseline indicator may be used to calculate differences or changes from baseline. Value should be "Y" or null. The baseline flag is applicant defined.	Exp
VSDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be "Y" or null.	Perm
VSEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	"Y" if the result should be excluded from all calculations, otherwise null.	Perm
VSREASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when VSEXCLFL is Y.	Perm
VSUSCHFL	Unscheduled Flag	Char	(NY)	Record Qualifier	Indicates whether the timing of the performed test or observation was unscheduled. If a test or observation was performed based upon a schedule defined in the protocol, this flag should be null. Expected values are "Y" or null.	Perm
VISITDY	Planned Study Day of Collection	Num		Timing	Planned day of the vital signs measurement. Should be an integer.	Perm
VSDTC	Date/Time of Measurement	Char	ISO 8601 datetime or interval	Timing	Date/time of the vital sign measurement, in ISO 8601 format. For indicating measurement over a period, DTC should be populated with the start date/time of collection.	Exp
VSENDTC	End Date/Time of Measurement	Char	ISO 8601 datetime or interval	Timing	Date/time of the end of the vital sign measurement, in ISO 8601 format. Should be populated for continuous period only.	Perm
VSDY	Study Day of Vital Signs Measurement	Num		Timing	Study day of vital signs measurements, in integer days. For indicating measurement over a continuous period, VSDY can be used to indicate start day of that interval. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
VSENDY	Study Day of End of Measurement	Num		Timing	Study day of the end of the vital signs measurement, in integer days. Can be populated when VSDY represents the start day of a continuous evaluation interval. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the DM domain.	Perm
VSNOMDY	Nominal Study Day for Tabulations	Num		Timing	Nominal study day used for grouping records for observations that may occur on different days into a single reported study day. Should be an integer.	Exp
VSNOMLBL	Label for Nominal Study Day	Char		Timing	A label for a given value of VSNOMDY as presented in the study report. Examples: Pre-exposure, Week 4, Day 28.	Perm
VSTPT	Planned Time Point Name	Char		Timing	Text description of time when the vital signs measurement should be taken. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See VSTPTNUM and VSTPTREF. Examples: Predose, 1 Hour Postdose.	Perm
VSTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of VSTPT to aid in sorting.	Perm
VSELTMR	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601 format) relative to a planned fixed reference (VSTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as a duration in ISO 8601 format. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by VSTPTREF, "PT8H" to represent the period of 8 hours after the reference point indicated by VSTPTREF.	Perm
VSTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by VSELTMR, if used for VSTPTNUM, and VSTPT. It is recommended that VSTPTREF be as descriptive as possible so the reference time point can be inferred without looking at other variables. Examples: DAY 1 DOSE, DAY 1 MEAL.	Perm
VSRTDTC	Date/Time of Time Point Reference	Char	ISO 8601 datetime or interval	Timing	Date/time of the reference time point, VSTPTREF.	Perm

Assumptions

1. The VS domain is intended to hold vital signs measurements (e.g., body temperature) that are not otherwise covered in domains for respiratory and cardiovascular test data.

2.8.10 Specifications for Individual Health

Tabulation domain specifications in this section are organized by domain.

2.8.10.1 SDTM Adverse Events (AE)

Description

An events domain used for data describing unintended signs, symptoms, or diseases temporally associated with the defined study period.

ae.xpt, Adverse Events — Events. One record per adverse event per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	AE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SPDEVID	Applicant Device Identifier	Char		Identifier	A sequence of characters used by the applicant to uniquely identify a specific device. Used to represent a device associated in some way with the adverse experience. SPDEVID values are defined in the Device Identifiers (DI) domain.	Perm
AESEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
AEGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
AEREFID	Reference ID	Char		Identifier	Internal or external identifier such as a serial number on an SAE reporting form.	Perm
AESPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined identifier. It may be preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Line number on an Adverse Experiences CRF page.	Perm
AETERM	Reported Term for the Adverse Experience	Char		Topic	Verbatim name of the experience.	Req
AEMODIFY	Modified Reported Term	Char		Synonym Qualifier	If AETERM is modified to facilitate coding, then AEMODIFY will contain the modified text.	Perm
AELLT	Lowest Level Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the lowest level term.	Exp
AELLTCD	Lowest Level Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the lowest level term.	Exp
AEDECOD	Dictionary-Derived Term	Char	MedDRA	Synonym Qualifier	Dictionary-derived text description of AETERM or AEMODIFY. Equivalent to the Preferred Term (PT in MedDRA). The applicant is expected to provide the dictionary name and version used to map the terms utilizing the external codelist element in the Define-XML document.	Req
AEPTCD	Preferred Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the preferred term.	Exp
AEHLT	High Level Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the high level term for the primary system organ class (SOC).	Exp
AEHLTCD	High Level Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the high level term for the primary SOC.	Exp
AEHLCAT	High Level Group Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the high level group term for the primary SOC.	Exp
AEHLCATCD	High Level Group Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the high level group term for the primary SOC.	Exp
AECAT	Category for Adverse Experience	Char		Grouping Qualifier	Used to define a category of related records. Examples: "BLEEDING", "NEUROPSYCHIATRIC".	Perm
AESCAT	Subcategory for Adverse Experience	Char		Grouping Qualifier	A further categorization of adverse experience. Example: "NEUROLOGIC".	Perm
AEPRESP	Pre-Specified Adverse Experience	Char	(NY)	Variable Qualifier	A value of "Y" indicates that this adverse experience was prespecified on the CRF. Values are null for	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					spontaneously reported experiences (i.e., those collected as free-text verbatim terms).	
AEBODSYS	Body System or Organ Class	Char		Record Qualifier	Dictionary derived. Body system or organ class used by the applicant from the coding dictionary (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the 's analyses and summary tables, which may not necessarily be the primary SOC.	Exp
AEBDSYCD	Body System or Organ Class Code	Num	MedDRA	Variable Qualifier	Dictionary derived. Code for the body system or organ class used by the applicant When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the applicant's analyses and summary tables, which may not necessarily be the primary SOC.	Exp
AESOC	Primary System Organ Class	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the primary SOC. Will be the same as AEBODSYS if the primary SOC was used for analysis.	Exp
AESOCCD	Primary System Organ Class Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the primary SOC. Will be the same as AEBDSYCD if the primary SOC was used for analysis.	Exp
AELOC	Location of Experience	Char	(LOC)	Record Qualifier	Describes anatomical location relevant for the experience (e.g., "ARM" for skin rash).	Perm
AESEV	Severity/Intensity	Char	(AESEV)	Record Qualifier	The severity or intensity of the experience. Examples: "MILD", "MODERATE", "SEVERE".	Perm
AESER	Serious Experience	Char	(NY)	Record Qualifier	Is this a serious experience? Valid values are "Y" and "N".	Exp
AEACN	Action Taken with Study Product	Char	(TPACN)	Record Qualifier	Describes actions taken with study product, as the result of the experience.	Exp
AEACNOTH	Other Action Taken	Char		Record Qualifier	Describes actions taken unrelated to study product, as the result of the experience.	Perm
AEACNDEV	Action Taken with Device	Char	(DEACNDEV)	Record Qualifier	An action taken with a device as the result of the experience. The device may or may not be a device under study.	Perm
AEREL	Causality	Char		Record Qualifier	Records the investigator's opinion as to the causality of the experience to the product. ICH does not establish any required or recommended terms for non-device relatedness. ICH E2A and E2B examples include (up-cased here for alignment to SDTM conventions) terms such as "NOT RELATED", "UNLIKELY RELATED", "POSSIBLY RELATED", "RELATED", but these example terms do not establish any conventions or expectations. Controlled terminology may be defined in the future. Check with regulatory authority for population of this variable.	Exp
AERLDEV	Relationship of Experience to Device	Char		Record Qualifier	A judgment as to the likelihood that the device caused the adverse experience. The relationship is to a device identified in the data (i.e., has an SPDEVID). The device may be ancillary or under study. Terminology: <ul style="list-style-type: none">In the EU, follow the European Commission Guidelines on Medical Devices, Clinical Investigations: SAE Reporting (MEDDEV 2.7/3; e.g., Not Related, Unlikely, Possible, Probable, Causal Relationship), with device-specific definitions.No required controlled terminology in US.	Perm
AERELNST	Relationship to Non-Study Trtmnt or Prod	Char		Record Qualifier	Records the investigator's opinion as to whether the experience may have been due to a treatment or product other than study product. May be reported as free text. Example: "MORE LIKELY RELATED TO METHYLPHENIDATE USE".	Perm
AEPATT	Pattern of Adverse Experience	Char		Record Qualifier	Used to indicate the pattern of the experience over time. Examples: "INTERMITTENT", "CONTINUOUS", "SINGLE EVENT".	Perm
AEOUT	Outcome of Adverse Experience	Char	(OUT)	Record Qualifier	Description of the outcome of an experience.	Perm
AESCAN	Involves Cancer	Char	(NY)	Record Qualifier	Was the serious experience associated with the development of cancer? Valid values are "Y" and "N". This is a legacy seriousness criterion. It is not included in ICH E2A or E2B.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
AESCONG	Congenital Anomaly or Birth Defect	Char	(NY)	Record Qualifier	Was the serious experience associated with congenital anomaly or birth defect? Valid values are "Y" and "N".	Perm
AESDISAB	Persist or Signif Disability/Incapacity	Char	(NY)	Record Qualifier	Did the serious experience result in persistent or significant disability/incapacity? Valid values are "Y" and "N".	Perm
AESDTH	Results in Death	Char	(NY)	Record Qualifier	Did the serious experience result in death? Valid values are "Y" and "N".	Perm
AESHOSP	Requires or Prolongs Hospitalization	Char	(NY)	Record Qualifier	Did the serious experience require or prolong hospitalization? Valid values are "Y" and "N".	Perm
AESLIFE	Is Life Threatening	Char	(NY)	Record Qualifier	Was the serious experience life-threatening? Valid values are "Y" and "N".	Perm
AESOD	Occurred with Overdose	Char	(NY)	Record Qualifier	Did the serious experience occur with an overdose? Valid values are "Y" and "N". This is a legacy seriousness criterion. It is not included in ICH E2A or E2B.	Perm
AESMIE	Other Medically Important Serious Event	Char	(NY)	Record Qualifier	Do additional categories for seriousness apply? Valid values are "Y" and "N".	Perm
AESINTV	Needs Intervention to Prevent Impairment	Char	(NY)	Record Qualifier	Records whether medical or surgical intervention was necessary to preclude permanent impairment of a body function, or to prevent permanent damage to a body structure, with either situation suspected to be due to the use of a medical product. This variable is used in conjunction with the other "seriousness" variables (e.g., fatal, life-threatening). It is part of the US federal government definition of a serious adverse event; see 21 CFR Part 803.3(w)(3).	Perm
AEUNANT	Unanticipated Adverse Device Effect	Char	(NY)	Record Qualifier	Any serious adverse effect on health or safety or any life-threatening problem or death caused by or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. (21 CFR Part 812.3(s)). This variable applies only to serious AEs and should hold collected data; if the value is derived, it should be held in ADaM.	Perm
AERLPRT	Rel of AE to Non-Dev-Rel Study Activity	Char		Record Qualifier	The investigator's opinion as to the causality of the experience as related to other protocol-required activities, actions, or assessments (e.g., medication changes, tests/assessments, other procedures). The relationship is to a protocol-specified, non-device-related activity where the device is identified in the data (i.e., has an SPDEVID). The device may be ancillary or under study. Terminology: <ul style="list-style-type: none">In the EU, follow the European Commission Guidelines on Medical Devices, Clinical Investigations: SAE Reporting (MEDDEV 2.7/3; e.g., Not Related, Unlikely, Possible, Probable, Causal Relationship), with device-specific definitions.No required controlled terminology in US.	Perm
AERLPRC	Rel of AE to Device-Related Procedure	Char		Record Qualifier	The investigator's opinion as to the likelihood that the device-related study procedure (e.g., implant/insertion, revision/adjustment, explant/removal) caused the AE. The relationship is to a device-related procedure where the device is identified in the data (i.e., has an SPDEVID). The device may be ancillary or under study. Terminology: <ul style="list-style-type: none">In the EU, follow the European Commission Guidelines on Medical Devices, Clinical Investigations: SAE Reporting (MEDDEV 2.7/3; e.g., Not Related, Unlikely, Possible, Probable, Causal Relationship), with device-specific definitions.No required controlled terminology in US.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
AECONTRT	Concomitant or Additional Trtmt Given	Char	(NY)	Record Qualifier	Was another treatment given because of the occurrence of the experience? Valid values are "Y" and "N".	Perm
AETOXGR	Standard Toxicity Grade	Char		Record Qualifier	Toxicity grade according to a standard toxicity scale (e.g., CTCAE). Applicants should specify the name of the scale and version used in the metadata (see assumption 7d). If value is from a numeric scale, represent only the number (e.g., "2", not "Grade 2").	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the adverse experience. Example: "SCREENING".	Perm
AESTDTC	Start Date/Time of Adverse Experience	Char	ISO 8601 datetime or interval	Timing	Start date/time of the adverse experience represented in ISO 8601 character format.	Exp
AEENDTC	End Date/Time of Adverse Experience	Char	ISO 8601 datetime or interval	Timing	End date/time of the adverse experience represented in ISO 8601 character format.	Exp
AESTDY	Study Day of Start of Adverse Experience	Num		Timing	Study day of start of adverse experience relative to the applicant-defined RFSTDTC.	Perm
AEENDY	Study Day of End of Adverse Experience	Num		Timing	Study day of end of experience relative to the applicant-defined RFSTDTC.	Perm
AEDUR	Duration of Adverse Experience	Char	ISO 8601 duration	Timing	Collected duration and unit of an adverse experience. Used only if collected on the CRF and not derived from start and end date/times. Example: "P1DT2H" (for 1 day, 2 hours).	Perm
AEENRF	End Relative to Reference Period	Char	(STENRE)	Timing	Describes the end of the experience relative to the applicant-defined reference period. The applicant-defined reference period is a continuous period of time defined by a discrete starting point (RFSTDTC) and a discrete ending point (RFENDTC) of the trial.	Perm
AEENRTPT	End Relative to Reference Time Point	Char	(STENRE)	Timing	Identifies the end of the experience as being before or after the reference time point defined by variable AEENTPT.	Perm
AEENTPT	End Reference Time Point	Char		Timing	Description of date/time in ISO 8601-character format of the reference point referred to by AEENRTPT. Examples: "2003-12-25", "VISIT 2".	Perm

Assumptions

1. In consultation with regulatory authorities, applicants may extend or limit the scope of adverse event collection. The events included in the AE dataset should be consistent with the protocol requirements. Adverse events may be captured either as free text or via a prespecified list of terms.
2. AE description and coding
 - a. AETERM captures the verbatim term collected for the event. It is the topic variable for the AE dataset. AETERM is a required variable and must have a value.
 - b. AEMODIFY is a permissible variable and should be included if the applicant's procedure permits modification of a verbatim term for coding. The modified term is listed in AEMODIFY. The variable should be populated as per the applicant's procedures.
 - c. AEDECOD is the preferred term derived by the applicant from the coding dictionary. It is a required variable and must have a value. It is expected that the reported term (AETERM) will be coded using a standard dictionary such as MedDRA.
 - d. AEBODSYS is the system organ class (SOC) from the coding dictionary associated with the adverse event by the applicant. This value may differ from the primary SOC designated in the coding dictionary's standard hierarchy.
3. Additional categorization and grouping
 - a. AECAT and AESCAT should not be redundant with the domain code or dictionary classification provided by AEDECOD and AEBODSYS (i.e., they should provide a different means of defining or classifying AE records). AECAT and AESCAT are intended for categorizations that are defined in advance. For example, an applicant may have a CRF page for AEs of special interest and another page

- for all other AEs. AECAT and AESCAT should not be used for after-the-fact categorizations such as "clinically significant." In cases where a category of AEs of special interest resembles a part of the dictionary hierarchy (e.g., "CARDIAC EVENTS"), the categorization represented by AECAT and AESCAT may differ from the categorization derived from the coding dictionary.
- b. AEGRPID may be used to link (or associate) different records together to form a block of related records at the subject level within the AE domain.
4. Prespecified terms; presence or absence of events
- a. Adverse events are generally collected in 2 different ways, either by recording free text or using a prespecified list of terms. In the latter case, the solicitation of information on specific adverse events may affect the frequency at which they are reported; therefore, the fact that a specific adverse event was solicited may be of interest to reviewers. An AEPRESP value of "Y" is used to indicate that the event in AETERM was prespecified on the CRF.
 - b. If it is important to know which adverse events from a prespecified list were not reported as well as those that did occur, these data should be submitted in a Findings class dataset such as Findings About Events and Interventions. A record should be included in that Findings dataset for each prespecified adverse-event term. Records for adverse events that actually occurred should also exist in the AE dataset with AEPRESP set to "Y."
 - c. If a study collects both prespecified adverse events and free-text events, the value of AEPRESP should be "Y" for all prespecified events and null for events reported as free text. AEPRESP is a permissible field and may be omitted from the dataset if all adverse events were collected as free text.
 - d. When adverse events are collected with the recording of free text, a record may be entered into the applicant's data management system to indicate "no adverse events" for a specific subject. For these subjects, do not include a record in the AE submission dataset to indicate that there were no events. Records should be included in the submission AE dataset only for adverse events that have actually occurred.
5. Timing variables
- a. Relative timing assessment "Ongoing" is common in the collection of AE information. AEENRF may be used when this relative timing assessment is made coincident with the end of the study reference period for the subject represented in the Demographics (DM) dataset (RFENDTC). AEENRTPT with AEENTPT may be used when "Ongoing" is relative to another date (e.g., the final safety follow-up visit date).
 - b. Additional timing variables (e.g., AEDTC) may be used when appropriate.
6. Actions taken
- a. Actions other than concomitant interventions are recorded in:
 - AEACN, only for actions taken with study product
 - AEACNDEV, for actions with a device
 - AEACNOTH, for actions that do not involve product or a device
7. Other qualifier variables
- a. If categories of serious events are collected secondarily to a leading question the values of the variables that capture reasons an event is considered serious (e.g., AESCAN, AESCONG) may be null. On the other hand, if the CRF is structured so that a response is collected for each seriousness category, all category variables (e.g., AESDTH, AESHOSP) would be populated and AESER would be derived.
 - b. The serious categories "Involves cancer" (AESCAN) and "Occurred with overdose" (AESOD) are not part of the ICH definition of a serious adverse event, but these categories are available for use in studies conducted under guidelines that existed prior to the FDA's adoption of the ICH definition.
 - c. When a description of "Other Medically Important Serious Adverse Events" category is collected on a CRF, applicants should place the description in the SUPPAE dataset using the standard supplemental qualifier name code AESOSP.

- d. In studies using toxicity grade according to a standard toxicity scale such as the Common Terminology Criteria for Adverse Events v3.0 (CTCAE), published by the National Cancer Institute (NCI; available at <https://ctep.cancer.gov/protocoldevelopment/>), AETOXGR should be used instead of AESEV. In most cases, either AESEV or AETOXGR is populated but not both. There may be cases when an applicant may need to populate both variables.
 - e. The structure of the AE domain is 1 record per adverse event per subject. It is the applicant's responsibility to define an event. This definition may vary based on the applicant's requirements for characterizing and reporting product safety and is usually described in the protocol. For example, the applicant may submit 1 record that covers an adverse event from start to finish. Alternatively, if there is a need to evaluate AEs at a more granular level, an applicant may submit a new record when severity, causality, or seriousness changes or worsens. By submitting these individual records, the applicant indicates that each is considered to represent a different event. The tabulation dataset structure may differ from the structure at the time of collection. For example, an applicant might collect data at each visit in order to meet operational needs, but submit records that summarize the event and contain the highest level of severity, causality, seriousness, and so on. Examples of dataset structure include:
 - i. One record per adverse event per subject for each unique event. Multiple adverse event records reported by the investigator are submitted as summary records "collapsed" to the highest level of severity, causality, seriousness, and the final outcome.
 - ii. One record per adverse event per subject. Changes over time in severity, causality, or seriousness are submitted as separate events. Alternatively, these changes may be submitted in a separate dataset based on the Findings About Events and Interventions model.
 - iii. Other approaches may also be reasonable as long as they meet the applicant's safety evaluation requirements and each submitted record represents a unique event.
8. Use of EPOCH and TAETORD: When EPOCH is included in the AE domain, it should be the epoch of the start of the adverse event. Similarly, if TAETORD is included in the AE domain, it should be the value for the start of the adverse event.
 9. Any additional identifier variables may be added to the AE domain.
 10. The following qualifiers would not be used in AE: --OCCUR, --STAT, and--REASND. They are the only qualifiers from the SDTM Events class not in the AE domain. They are not permitted because the AE domain contains only records for adverse events that actually occurred. See assumption 4b for information on how to deal with negative responses or missing responses to probing questions for prespecified adverse events.
 11. Variable order in the domain should follow variable order in the SDTM.
 12. The addition of AELLT, AELLTCD, AEPTCD, AEHLT, AEHLTC, AEHLGT, AEHLGTC, AEBDSYCD, AESOC, and AESOCCD is applicable to submissions coded in MedDRA only. Data items are not expected for non-MedDRA coding.

2.8.10.2 SDTM Comments (CO)

Description

A special-purpose domain that contains comments that may be collected alongside other data.

co.xpt, Comments — Special-Purpose. One record per comment per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	CO	Identifier	Two-character abbreviation for the domain.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
RDOMAIN	Related Domain Abbreviation	Char	(DOMAIN)	Record Qualifier	Two-character abbreviation for the domain of the parent record(s). Null for comments collected on a general comments or additional information CRF page.	Perm
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
COSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
IDVAR	Identifying Variable	Char		Record Qualifier	Identifying variable in the parent dataset that identifies the record(s) to which the comment applies. Examples: AESEQ or CMGRPID. Used only when individual comments are related to domain records. Null for comments collected on separate CRFs.	Perm
IDVARVAL	Identifying Variable Value	Char		Record Qualifier	Value of identifying variable of the parent record(s). Used only when individual comments are related to domain records. Null for comments collected on separate CRFs.	Perm
COREF	Comment Reference	Char		Record Qualifier	Applicant-defined reference associated with the comment. May be the CRF page number (e.g., 650), or a module name (e.g., DEMOG), or a combination of information that identifies the reference (e.g. 650-VITALS-VISIT 2).	Perm
COVAL	Comment	Char		Topic	The text of the comment. Text over 200 characters can be added to additional columns COVAL1-COVALn.	Req
COEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Example: "INVESTIGATOR".	Perm
COEVALID	Evaluator Identifier	Char	(MEDEVAL)	Record Qualifier	Used to distinguish multiple evaluators with the same role recorded in -EVAL. Examples: "RADIOLOGIST", "RADIOLOGIST 1", "RADIOLOGIST 2".	Perm
CODTC	Date/Time of Comment	Char	ISO 8601 datetime or interval	Timing	Date/time of comment on dedicated comment form. Should be null if this is a child record of another domain or if comment date was not collected.	Perm
CODY	Study Day of Comment	Num		Timing	Study day of the comment, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

Assumptions

1. The Comments special-purpose domain provides a solution for submitting free-text comments related to data in 1 or more SDTM domains (as described in Section 2.8.5.4, [Relating Comments to a Domain](#)) or collected on a separate CRF page dedicated to comments. Comments are generally not responses to specific questions; instead, comments usually consist of voluntary free-text or unsolicited observations.
2. Although the structure for the Comments domain in the SDTM is "One record per comment", USUBJID is required in the comments domain for human clinical studies, so the structure of the Comments domain in the TIG is "One record per comment per subject."
3. The CO dataset accommodates 3 sources of comments:
 - a. Those unrelated to a specific domain or parent record(s), in which case the values of the variables RDOMAIN, IDVAR, and IDVARVAL are null. CODTC should be populated if captured.
 - b. Those related to a domain but not to specific parent record(s), in which case the value of the variable RDOMAIN is set to the DOMAIN code of the parent domain and the variables IDVAR and IDVARVAL are null. CODTC should be populated if captured.
 - c. Those related to a specific parent record or group of parent records, in which case the value of the variable RDOMAIN is set to the DOMAIN code of the parent record(s) and the variables IDVAR and IDVARVAL are populated with the key variable name and value of the parent record(s). Assumptions for populating IDVAR and IDVARVAL are further described in Section 2.8.5.4, [Relating Comments to a Domain](#).
 - d. CODTC should be null because the timing of the parent record(s) is inherited by the comment record.
4. When the comment text is longer than 200 characters, the first 200 characters of the comment will be in COVAL, the next 200 in COVAL1, and additional text stored as needed to COVALn. See Example 1, rows 3-4. Additional information about how to relate comments to parent SDTM records is provided in Section 2.8.5.4, [Relating Comments to a Domain](#).

5. The variable COREF may be null unless it is used to identify the source of the comment.
6. Identifier variables and Timing variables may be added to the CO domain, but the following qualifiers would generally not be used in CO: --GRPID, --REFID, --SPID, TAETORD, --TPT, --TPTNUM, --ELTM, --TPTREF, --RFTDTC.

2.8.10.3 SDTM Concomitant/Prior Medications (CM)

Description

An interventions domain that contains concomitant and prior medications used by the subject, such as those given on an as needed basis or condition-appropriate medications.

cm.xpt, Concomitant/Prior Medications — Interventions. One record per recorded intervention occurrence or constant-dosing interval per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	CM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
CMSEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness of subject records within a domain. May be any valid number.	Req
CMGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
CMSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. Example: a number preprinted on the CRF as an explicit line identifier or record identifier defined in the applicant's operational database. Example: line number on a concomitant medication page.	Perm
CMTRT	Reported Name of Drug, Med, or Therapy	Char		Topic	Verbatim medication name that is either preprinted or collected on a CRF.	Req
CMMODIFY	Modified Reported Name	Char		Synonym Qualifier	If CMTRT is modified to facilitate coding, then CMMODIFY will contain the modified text.	Perm
CMDECOD	Standardized Medication Name	Char		Synonym Qualifier	Standardized or dictionary-derived text description of CMTRT or CMMODIFY. Equivalent to the generic drug name in WHO Drug. If an intervention term does not have a decode value in the dictionary, then CMDECOD will be left blank.	Perm
CMCAT	Category for Medication	Char		Grouping Qualifier	Used to define a category of interventions (e.g., medications/treatments/products). Examples: "PRIOR", "CONCOMITANT", "ANTI-CANCER MEDICATION", "GENERAL CONMED".	Perm
CMSCAT	Subcategory for Medication	Char		Grouping Qualifier	A further categorization of interventions (e.g., medications/treatments/products). Examples: "CHEMOTHERAPY", "HORMONAL THERAPY", "ALTERNATIVE THERAPY".	Perm
CMPRESP	CM Pre-specified	Char	(NY)	Variable Qualifier	Used to indicate whether ("Y"/null) information about the use of a specific medication was solicited on the CRF.	Perm
CMOCCUR	CM Occurrence	Char	(NY)	Record Qualifier	When the use of a specific medication is solicited. CMOCCUR is used to indicate whether ("Y"/"N") use of the medication occurred. Values are null for medications not specifically solicited.	Perm
CMSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a question about the occurrence of a prespecified intervention was not answered. Should be null or have a value of "NOT DONE".	Perm
CMREASND	Reason Medication Not Collected	Char		Record Qualifier	Reason not done. Used in conjunction with CMSTAT when value is "NOT DONE".	Perm
CMINDC	Indication	Char		Record Qualifier	Denotes why a medication was taken or administered. Examples: "NAUSEA", "HYPERTENSION".	Perm
CMCLAS	Medication Class	Char		Variable Qualifier	Drug class. May be obtained from coding. When coding to a single class, populate with class value. If using a dictionary and coding to multiple classes, then populate multiple values per TIG guidance or omit CMCLAS.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
CMCLASCD	Medication Class Code	Char		Variable Qualifier	Class code corresponding to CMCLAS. Drug class. May be obtained from coding. When coding to a single class, populate with class code. If using a dictionary and coding to multiple classes, then populate multiple values per TIG guidance or omit CMCLASCD.	Perm
CMDOSE	Dose per Administration	Num		Record Qualifier	Amount of CMTRT given. Not populated when CMDOSTXT is populated.	Perm
CMDOSTXT	Dose Description	Char		Record Qualifier	Dosing amounts or a range of dosing information collected in text form. Units may be stored in CMDOSU. Examples: "200-400", "15-20". Not populated when CMDOSE is populated.	Perm
CMDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for CMDOSE, CMDOSTOT, or CMDOSTXT. Examples: "ng", "mg", "mg/kg".	Perm
CMDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for CMTRT. Examples: "TABLET", "LOTION".	Perm
CMDOSFRQ	Dosing Frequency per Interval	Char	(FREQ)	Record Qualifier	Usually expressed as the number of repeated administrations of CMDOSE within a specific time period. Examples: "BID" (twice daily), "Q12H" (every 12 hours).	Perm
CMDOSTOT	Total Daily Dose	Num		Record Qualifier	Total daily dose of CMTRT using the units in CMDOSU. Used when dosing is collected as total daily dose. Total dose over a period other than day could be recorded in a separate supplemental qualifier variable.	Perm
CMDOSRGM	Intended Dose Regimen	Char		Record Qualifier	Text description of the (intended) schedule or regimen for the Intervention. Example: "TWO WEEKS ON, TWO WEEKS OFF".	Perm
CMROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for the intervention. Examples: "ORAL", "INTRAVENOUS".	Perm
CMADJ	Reason for Dose Adjustment	Char		Record Qualifier	Describes reason or explanation of why a dose is adjusted. Examples: "ADVERSE EVENT", "INSUFFICIENT RESPONSE", "NON-MEDICAL REASON".	Perm
CMRSDISC	Reason the Intervention Was Discontinued	Char		Record Qualifier	When dosing of a treatment is recorded over multiple successive records, this variable is applicable only for the (chronologically) last record for the treatment.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm for the element in which the medication administration started. Null for medications that started before study participation.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the medication administration. Null for medications that started before study participation.	Perm
CMSTDTC	Start Date/Time of Medication	Char	ISO 8601 datetime or interval	Timing	Start date/time of the medication administration represented in ISO 8601 character format.	Perm
CMENDTC	End Date/Time of Medication	Char	ISO 8601 datetime or interval	Timing	End date/time of the medication administration represented in ISO 8601 character format.	Perm
CMSTDY	Study Day of Start of Medication	Num		Timing	Study day of start of medication relative to the applicant-defined RFSTDTC.	Perm
CMENDY	Study Day of End of Medication	Num		Timing	Study day of end of medication relative to the applicant-defined RFENDTC.	Perm
CMDUR	Duration	Char	ISO 8601 duration	Timing	Collected duration for a treatment episode. Used only if collected on the CRF and not derived from start and end date/times.	Perm
CMSTRF	Start Relative to Reference Period	Char	(STENRF)	Timing	Describes the start of the medication relative to applicant-defined reference period. The applicant-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR" was collected, this information may be translated into CMSTRF.	Perm
CMENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the medication relative to the applicant-defined reference period. The applicant-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", "ONGOING", or "CONTINUING" was collected, this information may be translated into CMENRF.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
CMSTRPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the start of the medication as being before or after the applicant-defined reference time point defined by variable CMSTTP.	Perm
CMSTTP	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the applicant-defined reference point referred to by CMSTRPT. Examples: "2003-12-15", "VISIT 1".	Perm
CMENTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the medication as being before or after the applicant-defined reference time point defined by variable CMENTPT.	Perm
CMENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the applicant-defined reference point referred to by CMENTPT. Examples: "2003-12-25", "VISIT 2".	Perm

Assumptions

1. The structure of the CM domain is 1 record per medication intervention episode, constant-dosing interval, or prespecified medication assessment per subject. It is the applicant's responsibility to define an intervention episode. This definition may vary based on the applicant's requirements for review and analysis. The submission dataset structure may differ from the structure used for collection. One common approach is to submit a new record when there is a change in the dosing regimen. Another approach is to collapse all records for a medication to a summary level with either a dose range or the highest dose level. Other approaches may also be reasonable as long as they meet the applicant's evaluation requirements.
2. CM description and coding
 - a. CMTRT is the topic variable and captures the name of the concomitant medication/therapy or the prespecified term used to collect information about the occurrence of any of a group of medications and/or therapies. It is a required variable and must have a value. CMTRT only includes the medication/therapy name and does not include dosage, formulation, or other qualifying information. For example, "ASPIRIN 100MG TABLET" is not a valid value for CMTRT. This example should be expressed as CMTRT= "ASPIRIN", CMDOSE= "100", CMDOSU= "MG", and CMDOSFRM= "TABLET". When referring to a prespecified group of medications/therapies, CMTRT contains the description of the group used to solicit the occurrence response.
 - b. CMMODIFY should be included if the applicant's procedure permits modification of a verbatim term for coding.
 - c. CMDECOD is the standardized medication/therapy term derived by the applicant from the coding dictionary. It is expected that the reported term (CMTRT) or the modified term (CMMODIFY) will be coded using a standard dictionary. The applicant is expected to provide the dictionary name and version used to map the terms utilizing the external codelist element in the Define-XML document.
 - d. When CMDECOD values from WHODrug are longer than 200 characters, split the values at semicolons rather than spaces when implementing guidance in Section 2.8.7.1, [General Guidance](#).
3. Prespecified terms; presence or absence of concomitant medications
 - a. Information on concomitant medications is generally collected in 2 different ways, either by recording free text or using a prespecified list of terms. Because the solicitation of information on specific concomitant medications may affect the frequency at which they are reported, the fact that a specific medication was solicited may be of interest to reviewers. CMPRESP and CMOCCUR are used together to indicate whether the intervention in CMTRT was prespecified and whether it occurred, respectively.
 - b. CMOCCUR is used to indicate whether a prespecified medication was used. A value of "Y" indicates that the medication was used and "N" indicates that it was not.
 - c. If a medication was not prespecified, the value of CMOCCUR should be null. CMPRESP and CMOCCUR are permissible fields and may be omitted from the dataset if all medications were collected as free text. Values of CMOCCUR may also be null for prespecified medications if no Y/N

response was collected; in such cases, CMSTAT = "NOT DONE", and CMREASND could be used to describe the reason the answer was missing.

4. Variables for timing relative to a time point
 - a. CMSTRPT, CMSTTPT, CMENRTPT, and CMENTPT may be populated as necessary to indicate when a medication was used relative to specified time points. For example, assume a subject uses birth control medication. The subject has used the same medication for many years and continues to do so. The date the subject began using the medication (or at least a partial date) would be stored in CMSTDTC. CMENDTC is null because the end date is unknown/has not yet happened. This fact can be recorded by setting CMENTPT = "2007-04-30" (the date the assessment was made) and CMENRTPT = "ONGOING".
5. Although any identifier variables, timing variables, or interventions general observation-class qualifiers may be added to the CM domain, the following qualifiers would generally not be used: --MOOD, --LOT.

2.8.10.4 SDTM Demographics (DM)

Description

A special-purpose domain that includes a set of essential standard variables that describe each subject in study. One record will exist for each subject.

dm.xpt, Demographics — Special-Purpose. One record per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique value, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	Req
SUBJID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req
RFSTDTC	Subject Reference Start Date/Time	Char	ISO 8601 datetime or interval	Record Qualifier	Reference start date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study product.	Exp
RFENDTC	Subject Reference End Date/Time	Char	ISO 8601 datetime or interval	Record Qualifier	Reference end date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the study/trial, and often equivalent to date/time of last exposure to study product. Required for all randomized subjects; null for screen failures or unassigned subjects.	Exp
RFXSTDTC	Date/Time of First Study Exposure	Char	ISO 8601 datetime or interval	Record Qualifier	First date/time of exposure to any protocol-specified product, equal to the earliest value of EXSTDTC.	Exp
RFXENDTC	Date/Time of Last Study Exposure	Char	ISO 8601 datetime or interval	Record Qualifier	Last date/time of exposure to any protocol-specified product, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing).	Exp
RFICDTC	Date/Time of Informed Consent	Char	ISO 8601 datetime or interval	Record Qualifier	Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent.	Exp
RFPENDTC	Date/Time of End of Participation	Char	ISO 8601 datetime or interval	Record Qualifier	Date/time when subject ended participation or follow-up in a study/trial, as defined in the protocol, in ISO 8601 character format. Should correspond to the last known date of contact. Examples include completion date, withdrawal date, last follow-up, date recorded for lost to follow up, and death date.	Exp
DTHDTC	Date/Time of Death	Char	ISO 8601 datetime or interval	Record Qualifier	Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-study database.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
DTHFL	Subject Death Flag	Char	(NY)	Record Qualifier	Indicates the subject died. Should be "Y" or null. Should be populated even when the death date is unknown.	Exp
SITEID	Study Site Identifier	Char		Record Qualifier	Unique identifier for a site within a study.	Req
INVID	Investigator Identifier	Char		Record Qualifier	An identifier to describe the Investigator for the study. May be used in addition to SITEID. Not needed if SITEID is equivalent to INVID.	Perm
INVNAM	Investigator Name	Char		Synonym Qualifier	Name of the investigator for a site.	Perm
BRTHDTC	Date/Time of Birth	Char	ISO 8601 datetime or interval	Record Qualifier	Date/time of birth of the subject.	Perm
AGE	Age	Num		Record Qualifier	Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns).	Exp
AGEU	Age Units	Char	(AGEU)	Variable Qualifier	Units associated with AGE.	Exp
SEX	Sex	Char	(SEX)	Record Qualifier	Sex of the subject.	Req
RACE	Race	Char	(RACE)	Record Qualifier	Race of the subject. Race will be collected and represented per regulatory requirements.	Exp
ETHNIC	Ethnicity	Char	(ETHNIC)	Record Qualifier	The ethnicity of the subject. Ethnicity will be collected and represented per regulatory requirements.	Perm
ARMCD	Planned Arm Code	Char		Record Qualifier	ARMCD is limited to 20 characters. It is not subject to the character restrictions that apply to TESTCD. The maximum length of ARMCD is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover studies/trials. For example, if ARMCD values for a 7-period crossover were constructed using 2-character abbreviations for each product and separating hyphens, the length of ARMCD values would be 20. If the subject was not assigned to an arm, ARMCD is null and ARMNRS is populated. With the exception of studies which use multistage arm assignments, must be a value of ARMCD in the Trial Arms (TA) dataset.	Exp
ARM	Description of Planned Arm	Char		Synonym Qualifier	Name of the arm to which the subject was assigned. If the subject was not assigned to an arm, ARM is null and ARMNRS is populated. With the exception of studies which use multistage arm assignments, must be a value of ARM in the TA dataset.	Exp
ACTARMCD	Actual Arm Code	Char		Record Qualifier	Code of actual arm. ACTARMCD is limited to 20 characters. It is not subject to the character restrictions that apply to TESTCD. The maximum length of ACTARMCD is longer than for other short variables to accommodate the kind of values that are likely to be needed for crossover studies/trials. With the exception of studies which use multistage arm assignments, must be a value of ARMCD in the TA dataset. If the subject was not assigned to an arm or followed a course not described by any planned arm, ACTARMCD is null and ARMNRS is populated.	Exp
ACTARM	Description of Actual Arm	Char		Synonym Qualifier	Description of actual arm. With the exception of studies which use multistage arm assignments, must be a value of ARM in the TA dataset. If the subject was not assigned to an arm or followed a course not described by any planned arm, ACTARM is null and ARMNRS is populated.	Exp
ARMNRS	Reason Arm and/or Actual Arm is Null	Char	(ARMNULRS)	Record Qualifier	A coded reason that arm variables (ARM and ARMCD) and/or actual arm variables (ACTARM and ACTARMCD) are null. Example: "SCREEN FAILURE". It is assumed that if the arm and actual arm variables are null, the same reason applies to both arm and actual arm.	Exp
ACTARMUD	Description of Unplanned Actual Arm	Char		Record Qualifier	A description of actual product for a subject who did not receive the product described in one of the planned arms.	Exp
COUNTRY	Country	Char		Record Qualifier	Country of the investigational site in which the subject participated in the study/trial. Generally represented using ISO 3166-1 Alpha-3. Regulatory agencies may require other terminologies; in such cases, follow regulatory requirements.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
DMDTC	Date/Time of Collection	Char	ISO 8601 datetime or interval	Timing	Date/time of demographic data collection.	Perm
DMDY	Study Day of Collection	Num		Timing	Study day of collection measured as integer days.	Perm

Assumptions

1. Investigator and site identification: Companies use different methods to distinguish sites and investigators. CDISC assumes that SITEID will always be present, with INVID and INVNAME used as necessary.
2. Every subject in a study must have a subject identifier (SUBJID). In some cases a subject may participate in more than 1 study. To identify a subject uniquely across all studies for all applications or submissions involving the product, a unique identifier (USUBJID) must be included in all datasets. Subjects occasionally change sites during the course of a clinical study. Applicants must decide how to populate variables such as USUBJID, SUBJID, and SITEID based on their operational and analysis needs, but only 1 Demographics (DM) record should be submitted for each subject. The Supplemental Qualifiers dataset may be used if appropriate to provide additional information.
3. Concerns for subject privacy suggest caution regarding the collection of variables like BIRTHDTC. This variable is included in the DM model in the event that an applicant intends to submit it; however, applicants should follow regulatory guidelines and guidance as appropriate.
4. With the exception of studies that use multistage processes to assign subjects to arms described below, ARM and ACTARM must be populated with ARM values from the Trial Arms (TA) dataset and ARMCD and ACTARMCD must be populated with ARMCD values from the TA dataset or be null. The ARM and ARMCD values in the TA dataset have a one-to-one relationship, and that one-to-one relationship must be preserved in the values used to populate ARM and ARMCD in DM, and to populate the values of ACTARM and ACTARMCD in DM.
 - a. Rules for the arm-related variables:
 - i. If ARMCD is null, then ARM must be null and ARMNRS must be populated with the reason ARMCD is null.
 - ii. If ACTARMCD is null, then ACTARM must be null and ARMNRS must be populated with the reason ACTARMCD is null. Both ARMCD and ACTARMCD will be null for subjects who were not assigned to an arm. The same reason will provide the reason that both are null.
 - iii. ARMNRS may not be populated if both ARMCD and ACTARMCD are populated. ARMCD and ACTARMCD will be populated if the subject was assigned to an arm and received exposure consistent with 1 of the arms in the TA dataset. If ARMCD and ACTARMCD are not the same, that is sufficient to explain the situation; ARMNRS should not be populated.
 - b. Multistage assignment to an arm: Some studies use a multistage process for assigning a subject to an arm. In such a case, best practice is to create ARMCD values composed of codes representing the results of the multiple stages of the assignment process. If a subject is partially assigned, then truncated codes representing the stages completed can be used in ARMCD, and similar truncated codes can be used in ACTARMCD. The descriptions used to populate ARM and ACTARM should be similarly truncated, and the one-to-one relationship between these truncated codes should be maintained for all affected subjects in the study. Note that this use of values not in the TA dataset is allowable only for studies with multistage assignment to arms and to subjects in those studies who do not complete all stages of the assignment.
5. Study population flags should not be included in SDTM data. ADaM ADSL specifies standard variable names for the most common populations and requires the inclusion of these flags when necessary for analysis.
6. Race and ethnicity will be represented per regulatory requirements. Submission of multiple race responses should be represented in the DM domain and Supplemental Qualifiers (SUPPDM) dataset. If multiple races are collected, then the value of RACE should be “MULTIPLE” and the additional information will be

included in the Supplemental Qualifiers dataset. Controlled terminology for RACE should be used in both DM and SUPPDM so that consistent values are available for summaries regardless of whether the data are found in a column or row. If multiple races were collected and 1 was designated as primary, RACE in DM should be the primary race and additional races should be reported in SUPPDM. For subjects who refuse to provide or do not know their race information, the value of RACE could be “UNKNOWN”.

7. RFSTDTC, RFENDTC, RFXSTDTC, RFXENDTC, RFCSTDTC, RFCENDTC, RFICDTC, RFPENDTC, DTHDTTC, and BRTHDTTC represent date/time values, but they are considered to have a record qualifier role in DM. They are not considered to be timing variables because they are not intended for use in the general observation classes.
8. Additional permissible identifier, qualifier, and timing variables:
 - a. Only the following timing variables are permissible and may be added as appropriate: VISITNUM, VISIT, VISITDY. The record qualifier DMXFN (External File Name) is the only additional qualifier variable that may be added, which is adopted from the Findings general observation class, may also be used to refer to an external file, such as a patient narrative.
 - b. The order of these additional variables within the domain should follow variable order in the SDTM.
9. RFSTDTC is used to calculate study day variables. RFSTDTC is usually defined as the date/time when a subject was first exposed to study product.
10. The DM domain contains several pairs of reference period variables: RFSTDTC and RFENDTC, RFXSTDTC and RFXENDTC, RFCSTDTC and RFCENDTC, and RFICDTC and RFPENDTC. There are 4 sets of reference variables to accommodate distinct reference-period definitions and there are instances when the values of the variables may be exactly the same, particularly with RFSTDTC-RFENDTC and RFXSTDTC-RFXENDTC.
 - a. RFSTDTC and RFENDTC: This pair of variables is applicant-defined, but usually represents the date/time of first and last study exposure. However, there are certain study designs where the start of the reference period is defined differently, such as studies that have a washout period. In these cases, RFSTDTC may be the enrollment date, which is prior to first exposure. Because study day values are calculated using RFSTDTC, in this case study days would not be based on the date of first exposure.
 - b. RFXSTDTC and RFXENDTC: This pair of variables defines a consistent reference period for all studies and is not open to customization. RFXSTDTC and RFXENDTC always represent the date/time of first and last study exposure. This reference period often duplicates the reference period defined in RFSTDTC and RFENDTC, but not always. Therefore, this pair of variables is important as they guarantee that a reviewer will always be able to reference the first and last study exposure reference period. RFXSTDTC should be the same as SESTDTC for the first element described in the SE dataset. RFXENDTC may often be the same as the SEENDTC for the last element described in the SE dataset.
 - c. RFICDTC and RFPENDTC: The definitions of this pair of variables are consistent in every study in which they are used: They represent the entire period of a subject’s involvement in a study, from providing informed consent through the last participation event or activity. There may be times when this period coincides with other reference periods but that is unusual. RFICDTC should correspond to the date of the informed consent protocol milestone in Disposition (DS), if that protocol milestone is documented in DS. In the event that there are multiple informed consents, this will be the date of the first. RFPENDTC will be the last date of participation for a subject for data included in a submission. This should be the last date of any record for the subject in the database at the time it is locked for submission. As such, it may not be the last date of participation in the study if the submission includes interim data.

2.8.10.5 SDTM Device Identifiers (DI)

Description

A study reference dataset that provides a mechanism for using multiple identifiers to create a single identifier for each device.

di.xpt, Device Identifiers — Study Reference. One record per device identifier per device, Tabulation.**Specification****Domain Specification Table**

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DI	Identifier	Two-character abbreviation for the domain.	Req
SPDEVID	Applicant Device Identifier	Char		Identifier	Applicant-defined identifier for the device. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, combination of identifiers).	Req
DISEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a parameter within a device (SPDEVID) within dataset. If there is only one value for DIPARMCD for each value of SPDEVID, then DISEQ will be 1 for all records. DISEQ must be a valid number.	Exp
DIPARMCD	Device Identifier Element Short Name	Char		Topic	Short name of the identifier characteristic of the device (e.g., "SERIAL", "MODEL"). A record with DIPARMCD = "DEVTYPE" should be included (see below).	Req
DIPARM	Device Identifier Element Name	Char		Synonym Qualifier	Name of the identifier characteristic of the device. Examples: Serial number, model. A record with DIPARM = "DEVTYPE" should be included.	Req
DIVAL	Device Identifier Element Value	Char		Result Qualifier	Value for the parameter. When DIPARMCD=DEVTYPE it should use controlled terminology defined by the FDA Preferred Term codelist. FDA has stated a preference for the Global Medical Device Nomenclature (GMDN), but as of the date of this publication the GMDN is not freely available to the public. In its Unique Device Identification rule (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/), FDA indicated that GMDN will not be required unless it is available to the public at no cost. There is a lookup tool on the FDA website to map GMDN codes to FDA PT codes.	Req

Assumptions

1. Device Identifiers (DI) is a Study Reference dataset that provides a mechanism for using multiple identifiers to create a single identifier for each device.
2. The primary purpose of this domain is to provide a consistent variable (SPDEVID) for linking data across Device domains, independent of the level of granularity by which a device might be identified by an applicant in a study. One of the challenges of identifying devices consistently is that different types of devices use different characteristics and different numbers of characteristics as identifiers. For example, it may be sufficient to use a serial number only to identify an MRI machine, but identifying a box of screws may require a batch number and a box number. In study-specific datasets this could be accomplished by using different numbers of identifier variables, but this is not feasible for a general standard. SPDEVID is a mechanism for aggregating any number of identifiers into one, allowing for a consistent structure for identifying all devices. SPDEVID is a surrogate identifier that represents all the characteristics of a device in the Study DI domain, but is a simple, short identifier that can appear in each dataset. Having different identifier variables in different submissions does not help interoperability, and this approach allows for a single identifier while preserving access to the identifying information needed for the submission. It also facilitates merging datasets.
3. DI was modeled as a Study Reference domain because it has none of the characteristics (except identifiers) of a Findings domain, and is clearly not an event or intervention. This is separated from the Device Properties (DO) domain because DI contains the total set of characteristics necessary for device identification, whereas DO contains information important for submission but that are not part of the device identifier.
4. In order to determine the right level of granularity for the parameters defined in DI, it is critical that the applicant think carefully about how the devices will need to be tracked (e.g., in Device-In-Use, Device Events) and design SPDEVID to reflect that level of specificity. For example, if surgical screws only need

to be tracked by box and not by individual screw, then the value in SPDEVID might be a box number. If each screw needs to be tracked, then the parameters would need to include the identifier on each screw.

5. The DI domain must exist if SPDEVID is used in any domain in a study. It is required when any device-specific information is submitted. This includes information about the device under study as well as parameters captured for devices not under study (e.g., MRI slice thickness, field strength). If none of this applies (e.g., ECG machine used to generate a tracing, but no information about the machine is needed), then DI is not required.
6. If the DI domain exists, at a minimum it must contain a record with DIPARMCD=DEVTYPE, and this parameter must be populated.
7. SPDEVID should not change during a specific device's lifetime.
8. DISEQ must be unique within each value of DIPARMCD within a SPDEVID. If there is only 1 value of DIPARMCD per device, then DISEQ will always be 1.
9. The DI domain was designed to be able to handle situations where SPDEVID is needed to identify individual devices. In some situations, such as studies in which a device is not the product under study and is used only to conduct assessments, SPDEVID may need only to identify a kind of device. For example, an oncology trial might need to identify the kind of device used to image a tumor, in which case SPDEVID might be used to distinguish MRI, CT, and x-ray devices. In such cases, the minimum requirement for a SPDEVID for a kind of device is DEVTYPE (DIPARMCD=DEVTYPE). Applicants should define the appropriate level of granularity for unique identification; in some cases it may be a serial number, whereas in others it may be a box, lot, or batch number, or some combination of these or other identifiers.
10. The DI domain is often referred to as the Study DI domain to help distinguish it from the FDA's Unique Device Identifier (UDI).
11. This domain should not be used for device characteristics other than identifiers. Any additional non-identifier attributes that the applicant needs to submit should be placed in DO instead.
12. This structure allows for the association between one SPDEVID and as many identifiers as an applicant feels necessary to support all the submitted data. This easily transforms into a 1-record-per-SPDEVID structure for potential merging with other device-related datasets that would contain the SPDEVID variable, as shown in these samples for a set of Study DI records for a single device.

DI data arranged vertically (normalized) showing correspondence between identifiers and SPDEVID (SDTM structure):

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
DEVM-0004-0003	DI	ABC001	1	DEVTYPE	Device Type	STENT
DEVM-0004-0003	DI	ABC001	2	MANUF	Manufacturer	Acme Stents
DEVM-0004-0003	DI	ABC001	3	MODEL	Model	45-JFI
DEVM-0004-0003	DI	ABC001	4	BATCH	Batch identifier	2011-1307
DEVM-0004-0003	DI	ABC001	5	LOT	Lot Identifier	45678
DEVM-0004-0003	DI	ABC001	6	SERIAL	Serial Number	456789132-AXQ
DEVM-0004-0003	DI	ABC001	7	Y	Manufacturer Y-code	32110
DEVM-0004-0003	DI	ABC001	8	Z	Manufacturer Z-code	6A-55

DI data arranged horizontally (non-normalized) showing identifiers and SPDEVID on a single record (non-SDTM structure):

SPDEVID	DEVTYPE	MANUF	MODEL	BATCH	LOT	SERIAL	IDENTIFIER Y	IDENTIFIER Z
ABC001	STENT	Acme Stents	45-JFI	2011-1307	45678	456789132-AXQ	32110	6A-55

13. The data in this domain may be derived (manually or electronically).
14. No date variables have been included in this domain because the characteristics defined in Study DI should not change over the course of the trial and because temporal associations will generally be captured in other domains.
15. No additional variables can be added to this dataset.
16. DIPARMCD values are limited to 8 characters and cannot begin with a number or underscore, as they can be used as variable names when the dataset is transposed to a non-normalized structure.

17. If FDAUDI is used, it is intended to hold the FDA's UDI assigned after device approval. For post-approval studies, SPDEVID could be the FDAUDI value only. If the device is pre-approval, this variable would be null.
18. If the FDAUDI can be populated, the DEVTYPE should still be included. Applicants may include additional parameters as needed.
19. An incomplete list of DIPARMCD and DIPARM values is shown in the following table.

DIPARMCD	DIPARM
FDAUDI	FDA Unique Device Identifier
DEVTYPE	Device Type
MANUF	Manufacturer
MODEL	Model
BATCH	Batch identifier
LOT	Lot Identifier
SERIAL	Serial Number

20. Generally, the SPDEVID should include the set of parameters necessary for identifying the device uniquely, and would also have all of the higher level parameters. For example, if serial number were sufficient to identify the device, generally model and manufacturer and device type would be included (if available or relevant). In the smallest shapes, lot, batch, and serial number are usually considered to be on the same level. The FDAUDI is effectively a surrogate key for the rest of the identifiers, so the combination of FDAUDI and DEVTYPE could be sufficient to identify each device for a post-marketing study. Alternatively, if information embedded in the FDAUDI is needed for data aggregation, analysis, or appropriate interpretation of the data, other identifier variables can also be extracted from FDAUDI and included.

2.8.10.6 SDTM Device-in-Use (DU)

Description

A findings domain that contains the measurements and settings that are intentionally set on a device when it is in use. These are characteristics that exist for the device, and have a specific setting for a use instance.

du.xpt, Device-in-Use — Findings. One record per property or setting per time point per visit or test date per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DU	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Expected in this domain as devices may have settings or uses that either may not involve subjects (e.g., diagnostic tools) or devices that are removed from the study prior to contact with a subject (e.g., device has malfunction).	Exp
SPDEVID	Applicant Device Identifier	Char		Identifier	Applicant-defined identifier for the device. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, or combination of identifiers).	Exp
DUSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of device records within subject records within a domain. May be any valid number. It should be unique within every subject/device combination.	Req
DUGRPID	Group ID	Char		Identifier	Identifier for a group or block of related records. Used to tie together a block of related records in a single domain for a subject or a group of subject related records (e.g., group records specifying all the settings for a specific imaging scan, such as field strength, repetition time and echo time).	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
DUREFID	Reference ID	Char		Identifier	Internal or external identifier. This could be a scan code or equivalent.	Perm
DUSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database.	Perm
DUTESTCD	Device-In-Use Test Short Name	Char	(DUTESTCD)	Topic	Short name of the measurement, test, or examination described in DUTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DUTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). DUTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "COILSTR", "CNTMEDIA".	Req
DUTEST	Device-In-Use Test Name	Char	(DUTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in DUTEST cannot be longer than 40 characters. Examples: "Coil Strength", "Contrast Media".	Req
DUCAT	Category for Device-In-Use	Char		Grouping Qualifier	Defines a category of related records. It can be used to define the type of device for which settings are recorded if the DI domain is not used (e.g., if the device is not under study); may also be used to record the type of setting (e.g., "HARDWARE" vs. "SOFTWARE").	Perm
DUSCAT	Subcategory for Device-In-Use	Char		Grouping Qualifier	A further categorization of a measurement or examination. For example, if DUCAT = "SOFTWARE", DUSCAT might be "NOMINAL" or "POST-ADJUSTMENT".	Perm
DUORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement as originally received or collected. DUORRES should contain the setting or other device condition in effect at the time the device was used.	Exp
DUORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for DUORRES. Examples: Tesla, mm.	Exp
DUSTRESC	Result or Finding in Standard Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from DUORRES in a standard format or standard units. DUSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in DUSTRESN. For example, if a test has results "NONE," "NEG," and "NEGATIVE" in DUORRES, and these results effectively have the same meaning, they could be represented in standard format in DUSTRESC as "NEGATIVE".	Exp
DUSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format. Copied in numeric format from DUSTRESC. DUSTRESN should store all numeric test results or findings.	Exp
DUSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for DUSTRESC and DUSTRESN. The unit for standardized results may or may not be the same as for the original results.	Exp
VISITNUM	Visit Number	Num		Timing	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics. This value is usually derived.	Perm
DUDTC	Date/Time Device Used with Test/Setting	Char	ISO 8601 datetime or interval	Timing	Date/time that the device was used with this setting. This is not the date/time that the setting was set on the device, but rather that date/time that a measurement or test was done using that setting.	Exp
DUDY	Study Day of Observation	Num		Timing	Study day of Device-In-Use measurement, measured as integer days. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in Demographics.	Perm

Assumptions

1. Definition: The Device In-Use (DU) domain represents properties of an ancillary device that are intentionally set when the device is used in the context of a study.
2. Tobacco products—including ENDS devices—are not considered ancillary devices and would not be represented here. An *ancillary device* is a device used within a study but which is not the target of the study (e.g., a smoking machine that performs a smoking regimen or a spirometer used in pulmonary function testing). If settings for an ancillary device in a study need to be recorded and the device needs to be identified in the data, DI must be used for that identification.
3. Unlike Device Properties (DO), which describes device characteristics that do not change for the device during the study, the DU domain captures characteristics and properties of a device that can vary from subject to subject or usage to usage over the course of a study. For example,
 - a. The full range of field strengths for a given MRI machine might be 0.5 to 3 tesla, and these values would be captured in DO. DU would record the specific settings used for a given subject (e.g., the field strength for the MRI scan for subject 123 was 0.5T for visit 1).
 - b. The software for a pacemaker may start at version 1, and be updated to version 2 during the study. This change can be captured here. It would not go in DO, as DO holds only characteristics that do not change during the study.
4. There are 2 primary identifiers in this domain, both Expected: USUBJID and SPDEVID. Either 1 or the other or both must be used. For example, a device under study will always have a SPDEVID, but may or may not have a USUBJID. An ancillary device (one not under study) for which in-use data are required may have a USUBJID but may or may not have SPDEVID. In all cases where SPDEVID is used, it must be defined in the DI domain.
5. This domain is not intended to capture manufacturer-set (i.e., nominal) settings, but rather the customized settings for a given usage.
6. Because any number of device settings (e.g., coil strength, placement of leads) can be reported in this domain, each setting is represented by a separate row and is defined in the topic variable DUTESTCD. The original result goes into DUORRES.
7. DUREFID is the identifier for a unique scan or other test result to link a group of settings (e.g., field strength or slice thickness in an MRI scan) to the results obtained from the reading or interpretation of the test (e.g., the MRI image).
8. The DUSPID variable can be used to link this domain to other domains if necessary, such as Adverse Events (AE), Exposure (EX), and/or Tobacco Product Device Events and Malfunctions (EM).
9. The following Qualifiers would not generally be used in DU: --MODIFY, --BODSYS, --POS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STNRNC, --NRIND, --RESCAT, --REASND, --XFN, --NAM, --LOINC, --SPEC, --SPCCND, --LOC, --METHOD, --FAST, --DRVFL, --EVAL, --TOX, --TOXGR, --SEV, --DTHREL, --LLOQ.

2.8.10.7 SDTM Device Properties (DO)

Description

A findings domain that contains the device characteristics that do not vary over the course of the study.

do.xpt, Device Properties — Findings. One record per property per device, Tabulation, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DO	Identifier	Two-character abbreviation for the domain.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
SPDEVID	Applicant Device Identifier	Char		Identifier	Applicant-defined identifier for the device. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, combination of identifiers).	Req
DOSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of device records within subject records within a domain. May be any valid number. It should be unique within every subject/device combination.	Req
DOGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a device.	Perm
Dorefid	Reference ID	Char		Identifier	Internal or external identifier. This could be a scan code or equivalent.	Perm
DOSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number.	Perm
DOTESTCD	Device Property Short Name	Char	(DOTESTCD)	Topic	Short name of the measurement, test, or examination described in DOTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DOTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). DOTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "SHLFLIFE", "INDC", "COMPOS".	Req
DOTEST	Device Property Test Name	Char	(DOTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in DOTEST cannot be longer than 40 characters. Examples: "Shelf Life", "Indication for use", "Composition" (of device).	Req
DOCAT	Category for Device In-Use	Char		Grouping Qualifier	Defines a category of related records. For example, it can be used to define the type of property being defined, such as "DIMENSIONS" versus "MATERIAL".	Perm
DOSCAT	Subcategory for Device In-Use	Char		Grouping Qualifier	A further categorization of a measurement or examination. For example, if DOCAT = "DIMENSION", DOSCAT might be "LENGTH" or "WIDTH" or "THICKNESS".	Perm
DOORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the device property as originally observed or collected. DOORRES should contain the result or value of the property defined in DOTEST. For example, if DOTEST is LIFE (shelf life), then DOORRES might be 6 (months).	Exp
DOORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for DOORRES. Examples: "MONTHS", "cm".	Exp

Assumptions

1. Definition: Device Properties (DO) is a Findings domain and defines important characteristics of a device that the applicant wishes to include in the submission but that do not form part of the unique applicant-defined identification of the device. If there are no non-identifier characteristics to submit, this domain may not be necessary.
2. Each property is identified using controlled terminology and is stored in DOTESTCD/DOTEST, which allows the property names to be values in DOTESTCD in an SDTM-based vertical (normalized) structure and variable names in a CDASH horizontal (non-normalized) structure, if necessary. The controlled terminology has not yet been identified.
3. There should be 1 record per device property.
4. Applicants define the properties and levels of granularity that are appropriate to include in this domain.
5. DO supports all device types (e.g., implantable, imaging, diagnostic), although implementation may vary by device type.
6. This domain does not define the relationships between tracked components and the overall device. This will be addressed in a future version of the standard.

7. DO should not contain characteristics that may change during the course of the study for a given device (e.g., dial settings on an imaging machine, software versions). As a result, the domain does not include Timing variables.
8. Applicants may choose whether to include in DO characteristics of approved products or components that are used in the study in accordance with the approved labeling.
9. The DO domain can contain data about devices that were not deployed, as there is no subject identifier in DO. It should contain only data that should be submitted with the clinical data; additional manufacturing and quality data may exist elsewhere in the submission and do not need to be included in DO unless the applicant has a specific reason to do so.
10. DO data would generally be assembled by a applicant, rather than by an investigative site. The data can be captured using a CRF, assembled on a worksheet to support entry of the information into the clinical database, derived manually, or derived electronically from data in other domains or elsewhere.
11. DOTESTCD values are limited to 8 characters and cannot begin with a number or underscore as they can be used as variable names when the dataset is transposed to a non-normalized structure.
12. Note that there are no examples currently included in the TIG for this domain.

2.8.10.8 SDTM Disposition (DS)

Description

An events domain that contains information encompassing and representing data related to subject disposition.

ds.xpt, Disposition — Events. One record per disposition status or protocol milestone per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
DSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
DSREFID	Reference ID	Char		Identifier	Internal or external identifier.	Perm
DSSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Line number on a Disposition page.	Perm
DSTERM	Reported Term for the Disposition Event	Char		Topic	Verbatim name of the event or protocol milestone. Some terms in DSTERM will match DSDECOD, but others, such as "Subject moved", will map to controlled terminology in DSDECOD, such as "LOST TO FOLLOW-UP".	Req
DSDECOD	Standardized Disposition Term	Char	(TNCOMPLT) (PROTMLST) (OTHEVENT)	Synonym Qualifier	Controlled terminology for the name of disposition event or protocol milestone. Examples of protocol milestones: "INFORMED CONSENT OBTAINED". There are separate codelists used for DSDECOD where the choice depends on the value of DSCAT. Codelist "NCOMPLT" is used for disposition events, codelist "PROTMLST" is used for protocol milestones, and codelist "OTHEVENT" is used for other events.	Req
DSCAT	Category for Disposition Event	Char	DSCAT	Grouping Qualifier	Used to define a category of related records.	Exp
DSSCAT	Subcategory for Disposition Event	Char	DSSCAT	Grouping Qualifier	A further categorization of DSCAT (e.g., "STUDY PARTICIPATION" when DSCAT = "DISPOSITION EVENT"). The variable may be subject to controlled terminology for other categories of disposition event records.	Perm
EPOCH	Epoch	Char	EPOCH	Timing	Epoch associated with the start date/time of the event.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
DSDTC	Date/Time of Collection	Char	ISO 8601 datetime or interval	Timing	Collection date and time of the disposition observation represented in ISO 8601 character format.	Perm
DSSTDTC	Start Date/Time of Disposition Event	Char	ISO 8601 datetime or interval	Timing	Start date/time of the disposition event in ISO 8601 character format.	Exp
DSDY	Study Day of Collection	Num		Timing	Study day of collection of event relative to the applicant-defined RFSTDTC.	Perm
DSSTDY	Study Day of Start of Disposition Event	Num		Timing	Study day of start of event relative to the applicant-defined RFSTDTC.	Exp

Assumptions

1. The Disposition (DS) dataset provides an accounting for all subjects who entered the study and may include protocol milestones, such as randomization, as well as the subject's completion status or reason for discontinuation for the entire study or each phase or segment of the study, including screening and follow-up. Applicants may choose which disposition events and milestones to submit for a study in alignment with regulatory requirements.
2. Categorization
 - a. DSCAT is used to distinguish between disposition events, protocol milestones, and other events. The controlled terminology for DSCAT consists of "DISPOSITION EVENT", "PROTOCOL MILESTONE", and "OTHER EVENT".
 - b. An event with DSCAT = "DISPOSITION EVENT" describes either disposition of study participation or of a product exposure. It describes whether subjects completed study participation or a product exposure and, if not, the reason they did not complete it. Dispositions may be described for each epoch (e.g., screening, initial exposure, washout, cross-over, follow-up) or for the study as a whole. If disposition events for both study participation and product exposure(s) are to be represented, then DSSCAT provides this distinction. For records with DSCAT = "DISPOSITION EVENT",
 - i. DSSCAT = "STUDY PARTICIPATION" is used to represent disposition of study participation.
 - ii. DSSCAT = "PRODUCT EXPOSURE" is used when a study has only a single product.
 - iii. If a study has multiple products, then DSSCAT should name the individual product.
 - c. DSSCAT may be used when DSCAT = "PROTOCOL MILESTONE" or "OTHER EVENT", but would be subject to additional CDISC Controlled Terminology.
 - d. An event with DSCAT = "PROTOCOL MILESTONE" is a protocol-specified, point-in-time event. Common protocol milestones include "INFORMED CONSENT OBTAINED" and "RANDOMIZED." DSSCAT may be used for subcategories of protocol milestones.
 - e. An event with DSCAT = "OTHER EVENT" is another important event that occurred during a study, but was not driven by protocol requirements and was not captured in another Events or Interventions class dataset.
3. DS description and coding
 - a. DSDECOD values are drawn from controlled terminology. The controlled terminology depends on the value of DSCAT.
 - b. When DSCAT = "DISPOSITION EVENT" DSTERM contains either "COMPLETED" or, if the subject did not complete, specific verbatim information about the reason for non-completion.
 - i. When DSTERM = "COMPLETED", DSDECOD is the term "COMPLETED" from the Controlled Terminology codelist NCOMPLT.
 - ii. When DSTERM contains verbatim text, DSDECOD will use the extensible Controlled Terminology codelist NCOMPLT. For example, DSTERM = "Subject moved" might be coded to DSDECOD = "LOST TO FOLLOW-UP".

- c. When DSCAT = "PROTOCOL MILESTONE", DSTERM contains the verbatim (as collected) and/or standardized text, DSDECOD will use the extensible Controlled Terminology codelist PROTMLST.
 - d. When DSCAT = "OTHER EVENT", DSDECOD uses applicant terminology.
 - i. If a reason for the event was collected, the reason for the event is in DSTERM and the DSDECOD is a term from applicant terminology.
 - ii. If no reason was collected, then DSTERM should be populated with the value in DSDECOD.
4. Timing variables
- a. DSSTDTC is expected and is used for the date/time of the disposition event. Events represented in the DS domain do not have end dates; disposition events do not span an interval, but rather occur at a single date/time (e.g., randomization date, disposition of study participation or product exposure).
 - b. DSSTDTC documents the date/time that a protocol milestone, disposition event, or other event occurred. For an event with DSCAT = "DISPOSITION EVENT" where DSTERM is not "COMPLETED", the reason for non-completion may be related to an observation reported in another dataset. DSSTDTC is the date/time that the epoch was completed and is not necessarily the same as the date/time, start date/time, or end date/time of the observation that led to discontinuation. For example, a subject reported severe vertigo on June 1, 2006 (AESTDTC). After ruling out other possible causes, the investigator decided to discontinue product exposure on June 6, 2006 (DSSTDTC). The subject reported that the vertigo had resolved on June 8, 2006 (AEENDTC).
 - c. EPOCH may be included as a timing variable as in other general observation-class domains. In DS, EPOCH is based on DSSTDTC. The values of EPOCH are drawn from the Trial Arms (TA) dataset.
5. Any identifier variables, timing variables, or Events general observation-class qualifiers may be added to the DS domain, but the following Qualifiers would generally not be used: --PRES, --OCCUR, --STAT, --REASND, --BODSYS, --LOC, --SEV, --SER, --ACN, --ACNOTH, --REL, --RELNST, --PATT, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE, --CONTRT, --TOXGR.

2.8.10.9 SDTM ECG Test Results (EG)

Description

A findings domain that contains ECG data, including position of the subject, method of evaluation, all cycle measurements and all findings from the ECG including an overall interpretation if collected or derived.

eg.xpt, ECG Test Results — Findings. One record per ECG observation per replicate per time point or one record per ECG observation per beat per visit per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	EG	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SPDEVID	Applicant Device Identifier	Char		Identifier	Applicant-defined identifier for a device.	Perm
EGSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
EGGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
EGREFID	ECG Reference ID	Char		Identifier	Internal or external ECG identifier. Example: "UUID".	Perm
EGSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Line number from the ECG page.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
EGBEATNO	ECG Beat Number	Num		Variable Qualifier	A sequence number that identifies the beat within an ECG.	Perm
EGTESTCD	ECG Test or Examination Short Name	Char	(EGTESTCD) (HETESTCD)	Topic	Short name of the measurement, test, or examination described in EGTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in EGTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). EGTESTCD cannot contain characters other than letters, numbers, or underscores. Examples : "PRAG", "QRSAG". Test codes are in 2 separate codelists, for tests based on regular 10-second ECGs (EGTESTCD) and for tests based on Holter monitoring (HETESTCD).	Req
EGTEST	ECG Test or Examination Name	Char	(EGTEST) (HETEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in EGTEST cannot be longer than 40 characters. Examples: "PR Interval, Aggregate", "QRS Duration, Aggregate". Test names are in 2 separate codelists, for tests based on regular 10-second ECGs (EGTEST) and for tests based on Holter monitoring (HETEST).	Req
EGCAT	Category for ECG	Char		Grouping Qualifier	Used to categorize ECG observations across subjects. Examples: "MEASUREMENT", "FINDING", "INTERVAL".	Perm
EGSCAT	Subcategory for ECG	Char		Grouping Qualifier	A further categorization of the ECG.	Perm
EGPOS	ECG Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".	Perm
EGORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the ECG measurement or finding as originally received or collected. Examples of expected values are "62" or "0.151" when the result is an interval or measurement, or "ATRIAL FIBRILLATION" or "QT PROLONGATION" when the result is a finding.	Exp
EGORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for EGORRES. Examples: "sec" or "msec".	Perm
EGSTRESC	Character Result/Finding in Std Format	Char	(EGSTRESC) (HESTRESC)	Result Qualifier	Contains the result value for all findings, copied or derived from EGORRES in a standard format or standard units. EGSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in EGSTRESN. For example, if a test has results of "NONE", "NEG", and "NEGATIVE" in EGORRES and these results effectively have the same meaning, they could be represented in standard format in EGSTRESC as "NEGATIVE". For other examples, see general assumptions. Additional examples of result data: "SINUS BRADYCARDIA", "ATRIAL FLUTTER", "ATRIAL FIBRILLATION". Test results are in 2 separate codelists, for tests based on regular 10-second ECGs (EGSTRESC) and for tests based on Holter monitoring (HESTRESC).	Exp
EGSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from EGSTRESC. EGSTRESN should store all numeric test results or findings.	Perm
EGSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized units used for EGSTRESC and EGSTRESN.	Perm
EGSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate an ECG was not done, or an ECG measurement was not taken. Should be null if a result exists in EGORRES.	Perm
EGREASND	Reason ECG Not Done	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: "BROKEN EQUIPMENT" or "SUBJECT REFUSED". Used in conjunction with EGSTAT when value is "NOT DONE".	Perm
EGXFN	ECG External File Path	Char		Record Qualifier	File name and path for the external ECG waveform file.	Perm
EGNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor who provided the test results.	Perm
EGMETHOD	Method of Test or Examination	Char	(EGMETHOD)	Record Qualifier	Method of the ECG test. Example: "12 LEAD STANDARD".	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
EGLEAD	Lead Location Used for Measurement	Char	(EGLEAD)	Record Qualifier	The lead used for the measurement. Examples: "LEAD 1", "LEAD 2", "LEAD 3", "LEAD rV2", "LEAD V1".	Perm
EGLOBXFL	Last Observation Before Exposure Flag	Char	(NY)	Record Qualifier	Operationally-derived indicator used to identify the last non-missing value prior to RFXSTDTC. The value should be "Y" or null.	Exp
EGEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain collected or derived data. Examples: "INVESTIGATOR", "ADJUDICATION COMMITTEE", "VENDOR".	Perm
EGEVALID	Evaluator Identifier	Char	(MEDEVAL)	Variable Qualifier	Used to distinguish multiple evaluators with the same role recorded in EGEVAL. Examples: "RADIOLOGIST 1" or "RADIOLOGIST 2".	Perm
EGREPNUM	Repetition Number	Num		Record Qualifier	The incidence number of a test that is repeated within a given timeframe for the same test. The level of granularity can vary (e.g., within a timepoint, within a visit). For example, multiple measurements of blood pressure or multiple analyses of a sample.	Perm
VISITNUM	Visit Number	Num		Timing	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm for the element in which the assessment was made.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the date/time at which the assessment was made.	Perm
EGDTC	Date/Time of ECG	Char	ISO 8601 datetime or interval	Timing	Date/Time of ECG.	Exp
EGDY	Study Day of ECG	Num		Timing	1. Study day of the ECG, measured as integer days. 2. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in Demographics.	Perm
EGTPT	Planned Time Point Name	Char		Timing	1. Text description of time when measurement should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See EGTPNUM and EGTPTRREF. Examples: "Start", "5 min post".	Perm
EGTPNUM	Planned Time Point Number	Num		Timing	Numerical version of EGTPT to aid in sorting.	Perm
EGELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601) relative to a fixed time point reference (EGTPTRREF). Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by EGTPTRREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by EGTPTRREF.	Perm
EGTPTRREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by EGELTM, EGTPNUM, and EGTPT.	Perm
EGRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/time for a fixed reference time point defined by EGTPTRREF.	Perm

Assumptions

1. EGREFID is intended to store an identifier (e.g., UUID) for the associated ECG tracing. EGXFN is intended to store the name of and path to the ECG waveform file when it is submitted.

2. There are separate codelists for tests and results based on regular 10-second ECGs and for tests and results based on Holter monitoring.
3. For non-individual ECG beat data and for aggregate ECG parameter results (e.g., "QT interval", "RR", "PR", "QRS"), EGREFID is populated for all unique ECGs, so that submitted SDTM data can be matched to the actual ECGs stored in the ECG warehouse. Therefore, this variable is expected for these types of records.
4. For individual-beat parameter results, waveform data will not be stored in the warehouse, so there will be no associated identifier for these beats.
5. The method for QT interval correction is specified in the test name by controlled terminology: EGTESTCD = "QTcFAG" and EGTEST = "QTcF Interval, Aggregate" is used for Fridericia's formula; EGTESTCD = "QTcBAG" and EGTEST = "QTcB Interval, Aggregate", is used for Bazett's formula.
6. EGBEATNO is used to differentiate between beats in beat-to-beat records.
7. EGREPNUM is used to differentiate between multiple repetitions of a test within a given time frame.
8. EGNRIND can be added to indicate where a result falls with respect to reference range defined by EGORNRL and EGORNRHI. Examples: "HIGH", "LOW".
9. When "QTcF Interval, Aggregate" or "QTcB Interval, Aggregate" is derived by the applicant, the derived flag (EGDRVFL) is set to "Y". However, when the "QTcF Interval, Aggregate" or "QTcB Interval, Aggregate" is received from a central provider or vendor, the value would go into EGORRES and EGDRVFL would be null.
10. If this domain is used in conjunction with the ECG QT Correction Model Data (QT) domain:
 - a. For each QT correction method used in the study, values of EGTESTCD and EGTEST are assigned at the study level.
 - b. The applicant should assign values for EGTESTCD/EGTEST appropriately with clear documentation on what each test code represents. For example, if the protocol calls for computing the top two best fit models, the applicant could choose to name the top best fit model QTCIAG1 and the second best fit model QTCIAG2, in rank order.
11. Any Identifiers, Timing variables, or Findings general observation class qualifiers may be added to the EG domain, but the following qualifiers would not generally be used in EG: --MODIFY, --BODSYS, --SPEC, -SPCCND, --FAST, --SEV. It is recommended that --LOINC not be used.

2.8.10.10 SDTM Exposure (EX)

Description

An interventions domain that contains the details of a subject's exposure to protocol-specified study products. A study product may be any intervention that is prospectively defined as a test material within a study, and is typically but not always supplied to the subject.

ex.xpt, Exposure — Interventions. One record per protocol-specified study product, constant-dosing interval, per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	EX	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
EXSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
EXGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
EXREFID	Reference ID	Char		Identifier	Internal or external identifier.	Perm
EXSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Line number on a CRF page.	Perm
EXLNKID	Link ID	Char		Identifier	Identifier used to link related records across domains.	Perm
EXLNKGRP	Link Group ID	Char		Identifier	Identifier used to link related, grouped records across domains.	Perm
EXTRT	Name of Product	Char		Topic	Name of the protocol-specified study product given during the dosing period for the observation.	Req
EXCAT	Category of Product	Char		Grouping Qualifier	Used to define a category of EXTTRT values.	Perm
EXSCAT	Subcategory of Product	Char		Grouping Qualifier	A further categorization of EXCAT values.	Perm
EXDOSE	Dose	Num		Record Qualifier	Amount of EXTTRT when numeric. Not populated when EXDOSTXT is populated.	Exp
EXDOSTXT	Dose Description	Char		Record Qualifier	Amount of EXTTRT when non-numeric. Dosing amounts or a range of dosing information collected in text form. Example: 200-400. Not populated when EXDOSE is populated.	Perm
EXDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for EXDOSE, EXDOSTOT, or EXDOSTXT representing protocol-specified values. Examples: "ng", "mg", "mg/kg", "mg/m2".	Exp
EXDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for EXTTRT.	Exp
EXDOSFRQ	Dosing Frequency per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of EXDOSE within a specific time period.	Perm
EXDOSRGM	Intended Dose Regimen	Char		Variable Qualifier	Text description of the intended schedule or regimen for the Intervention. Example: "TWO WEEKS ON, TWO WEEKS OFF".	Perm
EXROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for the intervention. Examples: "ORAL".	Perm
EXLOT	Lot Number	Char		Record Qualifier	Lot number of the intervention product.	Perm
EXLOC	Location of Dose Administration	Char	(LOC)	Record Qualifier	Specifies location of administration. Examples: "ARM", "LIP".	Perm
EXLAT	Laterality	Char	(LAT)	Variable Qualifier	Qualifier for anatomical location further detailing laterality of the intervention administration. Examples: "LEFT", "RIGHT".	Perm
EXDIR	Directionality	Char	(DIR)	Variable Qualifier	Qualifier for anatomical location further detailing directionality. Examples: "ANTERIOR", "LOWER", "PROXIMAL", "UPPER".	Perm
EXFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status. Examples: "Y", "N".	Perm
EXADJ	Reason for Dose Adjustment	Char		Record Qualifier	Describes reason or explanation of why a dose is adjusted.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Study epoch of the Exposure record. Examples: "RUN-IN", "FOLLOW-UP".	Perm
EXSTDTC	Start Date/Time of Exposure	Char	ISO 8601 datetime or interval	Timing	The date/time when administration of the product indicated by EXTTRT and EXDOSE began.	Exp
EXENDTC	End Date/Time of Exposure	Char	ISO 8601 datetime or interval	Timing	The date/time when administration of the product indicated by EXTTRT and EXDOSE ended. For administrations considered given at a point in time, where only an administration date/time is collected, EXSTDTC should be copied to EXENDTC as the standard representation.	Exp
EXSTDY	Study Day of Start of Exposure	Num		Timing	Study day of EXSTDTC relative to DM.RFSTDTC.	Perm
EXENDY	Study Day of End of Exposure	Num		Timing	Study day of EXENDTC relative to DM.RFSTDTC.	Perm
EXDUR	Duration of Exposure	Char	ISO 8601 duration	Timing	Collected duration of administration. Used only if collected on the CRF and not derived from start and end date/times.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
EXTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when administration should occur. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See EXTPTNUM and EXTPTREF.	Perm
EXTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of EXTPT to aid in sorting.	Perm
EXELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time relative to the planned fixed reference (EXTPTREF). This variable is useful where there are repetitive measures. Not a clock time.	Perm
EXTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by EXELTM, EXTPTNUM, and EXTPT. Examples: PREVIOUS DOSE.	Perm
EXRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/time for a fixed reference time point defined by EXTPTREF.	Perm

Assumptions

1. EX Structure and Usage
 - a. Examples of protocol-specified product administrations represented in the EX domain include but are not limited to placebo, active comparators, and investigational products. Products that are not protocol-specified should be represented in the Concomitant Medication (CM) or another Interventions domain as appropriate.
 - b. The EX domain is recognized in most cases as a derived dataset where EXDOSU reflects the protocol-specified unit per study product dose. Collected data points (e.g., number of tablets, total volume infused) along with additional inputs (e.g., randomization file, concentration, dosage strength, product accountability) are used to derive records in the EX domain.
 - c. The EX domain is required for all studies that include protocol-specified study product. Exposure records may be directly or indirectly determined; metadata should describe how the records were derived. Common methods for determining exposure (from most direct to least direct) include the following:
 - i. Derived from actual observation of the administration of product by the investigator
 - ii. Derived from automated dispensing device that records administrations
 - iii. Derived from subject recall
 - iv. Derived from product accountability data
 - v. Derived from the protocol

When a study is still masked and protocol-specified study product doses cannot yet be reflected in the protocol-specified unit due to blinding requirements, then the EX domain is not expected to be populated.
 - d. The EX domain should contain 1 record per constant-dosing interval per subject. "Constant-dosing interval" is applicant defined, and may include any period of time that can be described in terms of a known product given at a consistent dose, frequency, infusion rate, etc. For example, for a study with once-a-week administration of a standard dose for 6 weeks, exposure may be represented as one of the following:
 - i. If information about each dose is not collected, there would be a single record per subject, spanning the entire 6-week product administration phase.
 - ii. If the applicant monitors each product administration, there could be up to six records (one for each weekly administration).
2. Exposure Product Description

- a. EXTRT captures the name of the protocol-specified study product and is the topic variable. It is a Required variable and must have a value. EXTRT must include only the product name and must not include dosage, formulation, or other qualifying information. For example, "4mg Nicotine Lozenge" is not a valid value for EXTRT. This example should be expressed as EXTRT = "Nicotine", EXDOSE = "4", EXDOSU = "mg", and EXDOSFRM = "LOZENGE".
 - b. Doses of placebo should be represented by EXTRT = "PLACEBO" and EXDOSE = "0" (indicating 0 mg of active ingredient was taken or administered).
3. Categorization and Grouping
 - a. EXCAT and EXSCAT may be used when appropriate to categorize products into categories and subcategories. For example, if a study contains several active comparator medications, EXCAT may be set to "ACTIVE COMPARATOR". Such categorization may not be useful in all studies, so these variables are permissible.
 4. Timing Variables
 - a. The timing of exposure to study product is captured by the start/end date and start/end time of each constant-dosing interval. If the subject is only exposed to study medication within a clinical encounter (e.g., if an injection is administered at the clinic), VISITNUM may be added to the domain as an additional Timing variable. VISITDY and VISIT would then also be permissible Qualifiers. However, if the beginning and end of a constant-dosing interval is not confined within the time limits of a clinical encounter (e.g., if a subject takes pills at home), then it is not appropriate to include VISITNUM in the EX domain. This is because EX is designed to capture the timing of exposure to product, not the timing of dispensing product. Furthermore, VISITNUM should not be used to indicate that product exposure began at a particular visit and continued for a period of time. The SDTM does not have any provision for recording "start visit" and "end visit" of exposure.
 - b. For administrations considered given at a point in time (e.g., oral tablet, pre-filled syringe injection), where only an administration date/time is collected, EXSTDTC should be copied to EXENDTC as the standard representation.
 5. Collected exposure data points are to be represented in the EC domain. When the relationship between EC and EX records can be described in RELREC, then it should be defined. EX derivations must be described in the Define-XML document.
 6. Additional Interventions Qualifiers
 - a. EX contains medications received; the inclusion of administrations not taken, not given or missed is under evaluation.
 - b. --DOSTOT is under evaluation for potential deprecation and replacement with a mechanism to describe total dose over any interval of time (e.g., day, week, month). Applicants considering use of EXDOSTOT may want to consider using other dose amount variables (EXDOSE or EXDOSTXT) in combination with frequency (EXDOSFRQ) and timing variables to represent the data.
 - c. When the EC domain is implemented in conjunction with the EX domain, EXVAMT and EXVAMTU should not be used in EX; collected values instead would be represented in ECDOSE and ECDOSE.
 - d. Any Identifier variables, Timing variables, or Findings general-observation-class qualifiers may be added to the EX domain, but the following qualifiers would generally not be used in EX: --PRES, --OCCUR, --STAT, and --REASND.

2.8.10.11 SDTM Exposure as Collected (EC)

Description

An interventions domain that contains information about protocol-specified study product administrations, as collected.

ec.xpt, Exposure as Collected — Interventions. One record per protocol-specified study product, collected-dosing interval, per subject, per mood, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	EC	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
ECSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
ECGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
ECREFID	Reference ID	Char		Identifier	Internal or external identifier (e.g., kit number, bottle label, vial identifier).	Perm
ECSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Line number on a CRF page.	Perm
ECLNKID	Link ID	Char		Identifier	Identifier used to link related records across domains.	Perm
ECLNKGRP	Link Group ID	Char		Identifier	Identifier used to link related, grouped records across domains.	Perm
ECTRT	Name of Product	Char		Topic	Name of the product known to the subject and/or administrator.	Req
ECMOOD	Mood	Char	(BRDGMOOD)	Record Qualifier	Mode or condition of the record specifying whether the intervention (activity) is intended to happen or has happened. Values align with BRIDG pillars (e.g., scheduled context, performed context) and HL7 activity moods (e.g., intent, event). Examples: "SCHEDULED", "PERFORMED".	Perm
ECCAT	Category of Product	Char		Grouping Qualifier	Used to define a category of related ECTRT values.	Perm
ECSCAT	Subcategory of Product	Char		Grouping Qualifier	A further categorization of ECCAT values.	Perm
ECPRESP	Pre-Specified	Char	(NY)	Variable Qualifier	Used when a specific intervention is prespecified. Values should be "Y" or null.	Perm
ECOCCUR	Occurrence	Char	(NY)	Record Qualifier	Used to indicate whether an exposure occurred when information about the occurrence is solicited. ECOCCUR = "N" when a product was not taken, not given, or missed.	Perm
ECDOSE	Dose	Num		Record Qualifier	Amount of ECTRT when numeric. Not populated when ECDOSTXT is populated.	Exp
ECDOSTXT	Dose Description	Char		Record Qualifier	Amount of ECTRT when non-numeric. Dosing amounts or a range of dosing information collected in text form. Example: "200-400". Not populated when ECDOSE is populated.	Perm
ECDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for ECDOSE, ECDOSTOT, or ECDOSTXT.	Exp
ECDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for ECTRT.	Exp
ECDOSFRQ	Dosing Frequency per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of ECDOSE within a specific time period. Examples: "Q2H", "QD", "BID".	Perm
ECDOSTOT	Total Daily Dose	Num		Record Qualifier	Total daily dose of ECTRT using the units in ECDOSU. Used when dosing is collected as Total Daily Dose.	Perm
ECDOSRGM	Intended Dose Regimen	Char		Variable Qualifier	Text description of the intended schedule or regimen for the Intervention. Example: "TWO WEEKS ON", "TWO WEEKS OFF".	Perm
ECROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for the intervention. Examples: "ORAL".	Perm
ECLOT	Lot Number	Char		Record Qualifier	Lot Number of the ECTRT product.	Perm
ECLOC	Location of Dose Administration	Char	(LOC)	Record Qualifier	Specifies location of administration. Example: "ARM", "LIP".	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
ECLAT	Laterality	Char	(LAT)	Variable Qualifier	Qualifier for anatomical location further detailing laterality of the intervention administration. Examples: "LEFT", "RIGHT".	Perm
ECDIR	Directionality	Char	(DIR)	Variable Qualifier	Qualifier for anatomical location further detailing directionality. Examples: "ANTERIOR", "LOWER", "PROXIMAL", "UPPER".	Perm
ECPORTOT	Portion or Totality	Char	(PORTOT)	Variable Qualifier	Qualifier for anatomical location further detailing distribution, which means arrangement of, apportioning of. Examples: "ENTIRE", "SINGLE", "SEGMENT".	Perm
ECPSTRG	Pharmaceutical Strength	Num		Record Qualifier	Amount of an active ingredient expressed quantitatively per dosage unit, per unit of volume, or per unit of weight, according to the pharmaceutical dose form.	Perm
ECPSTRGU	Pharmaceutical Strength Units	Char		Variable Qualifier	Unit for ECPSTRG. Examples: "mg/TABLET", "mg/mL".	Perm
ECADJ	Reason for Dose Adjustment	Char		Record Qualifier	Describes reason or explanation of why a dose is adjusted.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Trial epoch of the Exposure as Collected record. Examples: "RUN-IN".	Perm
ECSTDTC	Start Date/Time of Exposure	Char	ISO 8601 datetime or interval	Timing	The date/time when administration of the product indicated by ECTRT and ECDOSE began.	Exp
ECENDTC	End Date/Time of Exposure	Char	ISO 8601 datetime or interval	Timing	The date/time when administration of the product indicated by ECTRT and ECDOSE ended. For administrations considered given at a point in time (e.g., oral tablet, pre-filled syringe injection), where only an administration date/time is collected, ECSTDTC should be copied to ECENDTC as the standard representation.	Exp
ECSTDY	Study Day of Start of Exposure	Num		Timing	Study day of ECSTDTC relative to the applicant-defined DM.RFSTDTC.	Perm
ECENDY	Study Day of End Exposure	Num		Timing	Study day of ECENDTC relative to the applicant-defined DM.RFSTDTC.	Perm
ECDUR	Duration of Exposure	Char	ISO 8601 duration	Timing	Collected duration of administration. Used only if collected on the CRF and not derived from start and end date/times.	Perm
ECTPT	Planned Time Point Name	Char		Timing	Text description of time when administration should occur. This may be represented as an elapsed time relative to a fixed reference point (e.g., time of last dose). See ECTPTNUM and ECTPTREF.	Perm
ECTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of ECTPT to aid in sorting.	Perm
ECELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time relative to the planned fixed reference (ECTPTREF). This variable is useful where there are repetitive measures. Not a clock time.	Perm
ECTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by ECELTM, ECTPTNUM, and ECTPT. Examples: PREVIOUS DOSE.	Perm
ECRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/time for a fixed reference time point defined by ECTPTREF.	Perm

Assumptions

1. EC Definition
 - a. The Exposure as Collected domain model reflects protocol-specified study product administrations, as collected.
 - i. EC should be used in all cases where collected exposure information cannot or should not be directly represented in EX. For example, administrations collected in mL but protocol-specified unit is mg, or administrations collected in LOZENGE but protocol-specified unit is mg. Product accountability details (e.g., amount dispensed, amount returned) are represented in DA and not in EC.

- ii. Collected exposure data are in most cases represented in a combination of one or more of EC, Drug Accountability (DA), or Findings About (FA) domains. If the entire EC dataset is an exact duplicate of the entire Exposure (EX) dataset, then EC is optional and at the applicant's discretion.
 - b. Collected exposure log data points descriptive of administrations typically reflect amounts at the product-level (e.g., number of tablets, number of mL).
2. Product Description
- a. ECTRT is applicant defined and should reflect how the protocol-specified study product is known or referred to in data collection. In an open-label study, ECTRT should store the product name. In a masked study, if product is collected and known as product A to the subject or administrator, then ECTRT = "PRODUCT A". If in a masked study the product is not known by a synonym and the data are to be exchanged between applicants, partners and/or regulatory agency(s), then assign ECTRT the value of "MASKED".
3. ECMOOD is permissible; when implemented, it must be populated for all records.
- a. Values of ECMOOD, to date, include:
 - i. "SCHEDULED" (for collected subject-level intended dose records)
 - ii. "PERFORMED" (for collected subject-level actual dose records)
 - b. Qualifier variables should be populated with equal granularity across scheduled and performed records when known. For example, if ECDOSU and ECDOSFRQ are known at scheduling and administration, then the variables would be populated on both records. If ECLOC is determined at the time of administration, then it would be populated on the performed record only.
 - c. Appropriate Timing variable(s) should be populated. Note: Details on scheduled records may describe timing at a higher level than performed records.
 - d. ECOCCUR is generally not applicable for scheduled records.
 - e. An activity may be rescheduled or modified multiple times before being performed. Representation of scheduled records is dependent on the collected, available data. If each rescheduled or modified activity is collected, then multiple scheduled records may be represented. If only the final scheduled activity is collected, then it would be the only scheduled record represented.
4. Doses Not Taken, Not Given, or Missed
- a. The record qualifier --OCCUR, with value of "N", is available in domains based on the Interventions and Events General Observation Classes as the standard way to represent whether an intervention or event did not happen. In the EC domain, ECOCCUR value of "N" indicates a dose was not taken, not given, or missed. For example, if 0 tablets are taken within a timeframe or 0 mL is infused at a visit, then ECOCCUR = "N" is the standard representation of the collected doses not taken, not given, or missed. Dose amount variables (e.g., ECDOSE, ECDOSTXT) must not be set to zero (0) as an alternative method for indicating doses not taken, not given, or missed.
 - b. The population of Qualifier variables (e.g., Grouping, Record, Variable) and additional Timing variables (e.g., date of collection, visit, timepoint) for records representing information collected about doses not taken, not given, or missed should be populated with equal granularity as administered records, when known and/or applicable. Qualifiers that indicate dose amount (e.g., ECDOSE, ECDOSTXT) may be populated with positive (non-zero) values in cases where the applicant feels it is necessary and/or appropriate to represent specific dose amounts not taken, not given, or missed.
5. Timing Variables
- a. Timing variables in the EC domain should reflect administrations by the intervals they were collected (e.g., constant-dosing intervals, visits, targeted dates like first dose, last dose).
 - b. For administrations considered given at a point in time (e.g., oral tablet, pre-filled syringe injection), where only an administration date/time is collected, ECSTDTC should be copied to ECENDTC.

6. The degree of summarization of records from EC to EX is applicant defined to support study purpose and analysis. When the relationship between EC and EX records can be described in RELREC, then it should be defined.
7. Additional Interventions Qualifiers
 - a. --DOSTOT is under evaluation for potential deprecation and replacement with a mechanism to describe total dose over any interval of time (e.g., day, week, month). Applicants considering ECDOSTOT may want to consider using other dose amount variables (ECDOSE or ECDOSTXT) in combination with frequency (ECDOSFRQ) and timing variables to represent the data.
 - b. Any Identifier variables, Timing variables, or Findings general-observation-class qualifiers may be added to the EC domain, but the following qualifiers would generally not be used in EC: --STAT, --REASND, --VAMT, and --VAMTU.

2.8.10.12 SDTM Findings About Events or Interventions (FA)

Description

A findings domain that contains the findings about an event or intervention that cannot be represented within an events or interventions domain record or as a supplemental qualifier.

fa.xpt, Findings About Events or Interventions — Findings About. One record per finding, per object, per time point, per visit per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	FA	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
FASEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
FAGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
FASPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Line number on a CRF.	Perm
FATESTCD	Findings About Test Short Name	Char	(FATESTCD)	Topic	Short name of the measurement, test, or examination described in FATEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in FATESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). FATESTCD cannot contain characters other than letters, numbers, or underscores. Example: "OCCUR". Note that controlled terminology is in a FATESTCD general codelist and in several therapeutic area-specific codelists.	Req
FATEST	Findings About Test Name	Char	(FATEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in FATEST cannot be longer than 40 characters. Example: "Occurrence". Note that controlled terminology is in a FATEST general codelist and in several therapeutic area-specific codelists.	Req
FAOBJ	Object of the Observation	Char		Record Qualifier	Used to describe the object or focal point of the findings observation that is represented by --TEST. Examples: the term (e.g., "Acne") describing a clinical sign or symptom that is being measured by a severity test; an event (e.g., "VOMIT", where the volume of vomit is being measured by a VOLUME test).	Req
FACAT	Category for Findings About	Char		Grouping Qualifier	Used to define a category of related records. Examples: "GERD", "PRE-SPECIFIED AE".	Perm
FASCAT	Subcategory for Findings About	Char		Grouping Qualifier	A further categorization of FACAT.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
FAORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the test as originally received or collected.	Exp
FAORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for FAORRES.	Perm
FASTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from FAORRES in a standard format or standard units. FASTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in FASTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in FAORRES, and these results effectively have the same meaning; they could be represented in standard format in FASTRESC as "NEGATIVE".	Exp
FASTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from FASTRESC. FASTRESN should store all numeric test results or findings.	Perm
FASTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for FASTRESC and FASTRESN.	Perm
FASTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that the measurement was not done. Should be null if a result exists in FAORRES.	Perm
FAAREASND	Reason Not Performed	Char		Record Qualifier	Describes why a question was not answered. Example: "Subject refused". Used in conjunction with FASTAT when value is "NOT DONE".	Perm
FALOC	Location of the Finding About	Char	(LOC)	Record Qualifier	Used to specify the location of the clinical evaluation. Example: "ARM".	Perm
FALAT	Laterality	Char	(LAT)	Variable Qualifier	Qualifier for anatomical location or specimen further detailing laterality. Examples: "RIGHT", "LEFT", "BILATERAL".	Perm
FALOBXFL	Last Observation Before Exposure Flag	Char	(NY)	Record Qualifier	Operationally-derived indicator used to identify the last non-missing value prior to RFSTDTC. The value should be "Y" or null.	Perm
FAEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain collected or derived data. Examples: "INVESTIGATOR", "ADJUDICATION COMMITTEE", "VENDOR".	Perm
VISITNUM	Visit Number	Num		Timing	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the date/time of the observation. Examples: "SCREENING", "PRODUCT EXPOSURE", "FOLLOW-UP".	Perm
FADTC	Date/Time of Collection	Char	ISO 8601 datetime or interval	Timing	Collection date and time of findings assessment represented in ISO 8601 character format.	Exp
FADY	Study Day of Collection	Num		Timing	1. Study day of collection, measured as integer days. 2. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in Demographics. This formula should be consistent across the submission.	Perm

Assumptions

1. The Findings About domain shares all qualities and conventions of findings observations.
2. Some variables in the events and interventions domains (e.g., OCCUR) represent findings about the whole of the event or intervention. When FA is used to represent findings about a part of the event or intervention (i.e., the assessment has different timing from the event as a whole), the FATEST and FATESTCD values

should be the same as the variable name and variable label in the corresponding event or intervention domain.

3. When data collection establishes a relationship between FA records and an events or interventions record, the relationship should be represented in RELREC.
 - a. The FAOBJ variable alone is not sufficient to establish a relationship, because an events or interventions dataset may have multiple records for the same topic (e.g., --TERM or --DECOD, --TRT or --DECOD).
4. Any Identifier variables, Timing variables, or Findings general observation-class qualifiers may be added to the FA domain, but the following qualifiers should generally not be used: --BODSYS, --MODIFY, --SEV, --TOXGR.

2.8.10.13 SDTM Inclusion/Exclusion Criteria Not Met (IE)

Description

A findings domain that contains those criteria that cause the subject to be in violation of the inclusion/exclusion criteria.

ie.xpt, Inclusion/Exclusion Criteria Not Met — Findings. One record per inclusion/exclusion criterion not met per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	IE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
IESEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
IESPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Inclusion or exclusion criteria number from CRF.	Perm
IETESTCD	Inclusion/Exclusion Criterion Short Name	Char		Topic	Short name of the criterion described in IETEST. The value in IETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). IETESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "IN01", "EX01".	Req
IETEST	Inclusion/Exclusion Criterion	Char		Synonym Qualifier	Verbatim description of the inclusion or exclusion criterion that was the exception for the subject within the study. IETEST cannot be longer than 200 characters.	Req
IECAT	Inclusion/Exclusion Category	Char	(IECAT)	Grouping Qualifier	Used to define a category of related records across subjects.	Req
IESCAT	Inclusion/Exclusion Subcategory	Char		Grouping Qualifier	A further categorization of the exception criterion. Can be used to distinguish criteria for a sub-study or for to categorize as a major or minor exceptions. Examples: "MAJOR", "MINOR".	Perm
IEORRES	I/E Criterion Original Result	Char	(NY)	Result Qualifier	Original response to Inclusion/Exclusion Criterion question, i.e., whether the inclusion or exclusion criterion was met.	Req
IESTRESC	I/E Criterion Result in Std Format	Char	(NY)	Result Qualifier	Response to inclusion/exclusion criterion result in standard format.	Req
VISITNUM	Visit Number	Num		Timing	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Perm
VISIT	Visit Name	Char		Timing	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics (DM).	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm for the element in which the assessment was made.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the observation date/time of the inclusion/exclusion finding.	Perm
IEDTC	Date/Time of Collection	Char	ISO 8601 datetime or interval	Timing	Collection date and time of the inclusion/exclusion criterion represented in ISO 8601 character format.	Perm
IEDY	Study Day of Collection	Num		Timing	1. Study day of collection of the inclusion/exclusion exceptions, measured as integer days. 2. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in DM. This formula should be consistent across the submission.	Perm

Assumptions

1. The intent of the domain model is to collect responses to only those criteria that the subject did not meet, and not the responses to all criteria. The complete list of Inclusion/Exclusion criteria can be found in the Trial Inclusion/Exclusion Criteria (TI) dataset.
2. This domain should be used to document the exceptions to inclusion or exclusion criteria at the time that eligibility for study entry is determined (e.g., at the end of a run-in period or immediately before randomization). This domain should not be used to collect protocol deviations/violations incurred during the course of the study, typically after randomization or start of study medication.
3. ITEST is to be used only for the verbatim description of the inclusion or exclusion criteria. If the text is no more than 200 characters, it goes in ITEST; if the text is more than 200 characters, put meaningful text in ITEST and describe the full text in the study metadata.
4. Additional findings qualifiers: The following Qualifiers would generally not be used in IE: --MODIFY, --POS, --BODSYS, --ORRESU, --ORNRLO, --ORNRHI, --STRESN, --STRESU, --STNRLO, --STNRHI, --STNRC, --NRIND, --RESCAT, --XFN, --NAM, --LOINC, --SPEC, --SPCCND, --LOC, --METHOD, --BLFL, --LOBXFL, --FAST, --DRVFL, --TOX, --TOXGR, --SEV, --STAT.

2.8.10.14 SDTM Laboratory Test Results (LB)

Description

A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.

Ib.xpt, Laboratory Test Results — Findings. One record per lab test per time point per visit per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	LB	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
LBSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
LBGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
LBREFID	Specimen ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
LBSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Line number on the Lab page.	Perm
LBTESTCD	Lab Test or Examination Short Name.	Char	(LBTESTCD)	Topic	Short name of the measurement, test, or examination described in LBTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in LBTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). LBTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "ALT", "LDH".	Req
LBTEST	Lab Test or Examination Name	Char	(LBTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. Note: Any test normally performed by a clinical laboratory is considered a lab test. The value in LBTEST cannot be longer than 40 characters. Examples: "Alanine Aminotransferase", "Lactate Dehydrogenase".	Req
LBCAT	Category for Lab Test	Char		Grouping Qualifier	Used to define a category of related records across subjects. Examples: "HEMATOLOGY", "URINALYSIS", "CHEMISTRY".	Exp
LBSCAT	Subcategory for Lab Test	Char		Grouping Qualifier	A further categorization of a test category such as "DIFFERENTIAL", "COAGULATION", "LIVER FUNCTION", "ELECTROLYTES".	Perm
LBORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
LBORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for LBORRES. Example: "g/L".	Exp
LBORNRLO	Reference Range Lower Limit in Orig Unit	Char		Variable Qualifier	Lower end of reference range for continuous measurement in original units. Should be populated only for continuous results.	Exp
LBORNRHI	Reference Range Upper Limit in Orig Unit	Char		Variable Qualifier	Upper end of reference range for continuous measurement in original units. Should be populated only for continuous results.	Exp
LBSTRESC	Character Result/Finding in Std Format	Char	(LBSTRESC)	Result Qualifier	Contains the result value for all findings, copied or derived from LBORRES in a standard format or standard units. LBSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in LBSTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in LBORRES and these results effectively have the same meaning, they could be represented in standard format in LBSTRESC as "NEGATIVE".	Exp
LBSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from LBSTRESC. LBSTRESN should store all numeric test results or findings.	Exp
LBSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for LBSTRESC or LBSTRESN.	Exp
LBSTNRLO	Reference Range Lower Limit-Std Units	Num		Variable Qualifier	Lower end of reference range for continuous measurements for LBSTRESC/LBSTRESN in standardized units. Should be populated only for continuous results.	Exp
LBSTNRHI	Reference Range Upper Limit-Std Units	Num		Variable Qualifier	Upper end of reference range for continuous measurements in standardized units. Should be populated only for continuous results.	Exp
LBSTNRC	Reference Range for Char Rslt-Std Units	Char		Variable Qualifier	For normal range values that are character in ordinal scale or if categorical ranges were supplied (e.g., "-1 to +1", "NEGATIVE TO TRACE").	Perm
LBSTREFC	Reference Result in Standard Format	Char		Variable Qualifier	Reference value for the result or finding copied or derived from LBORREF in a standard format.	Exp
LBNRIND	Reference Range Indicator	Char	(NRIND)	Variable Qualifier	1. Indicates where the value falls with respect to reference range defined by LBORNRL and LBORNRI, LBSTNRLO and LBSTNRHI, or by	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					LBSTNRC. Examples: "NORMAL", "ABNORMAL", "HIGH", "LOW". 2. Should not be used to indicate clinical significance.	
LBSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate exam not done. Should be null if a result exists in LBORRES.	Perm
LBREASND	Reason Test Not Done	Char		Record Qualifier	Describes why a measurement or test was not performed, e.g., "BROKEN EQUIPMENT", "SUBJECT REFUSED", or "SPECIMEN LOST". Used in conjunction with LBSTAT when value is "NOT DONE".	Perm
LBNAM	Vendor Name	Char		Record Qualifier	The name or identifier of the laboratory that performed the test.	Perm
LBLOINC	LOINC Code	Char		Synonym Qualifier	Code for the lab test from the LOINC code system.	Perm
LBSPEC	Specimen Type	Char	(SPECTYPE)	Record Qualifier	Defines the type of specimen used for a measurement. Examples: "SERUM", "PLASMA", "URINE", "DNA", "RNA".	Perm
LBSPCCND	Specimen Condition	Char	(SPECCOND)	Record Qualifier	Free or standardized text describing the condition of the specimen, e.g., "HEMOLYZED", "ICTERIC", "LIPEMIC".	Perm
LBMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Examples: "EIA" (Enzyme Immunoassay), "ELECTROPHORESIS", "DIPSTICK".	Perm
LBLOBXFL	Last Observation Before Exposure Flag	Char	(NY)	Record Qualifier	Operationally-derived indicator used to identify the last non-missing value prior to RFXSTDTC. The value should be "Y" or null.	Exp
LBFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status such as "Y", "N", "U", or null if not relevant.	Perm
LBTOX	Toxicity	Char		Variable Qualifier	Description of toxicity quantified by LBTOXGR.	Perm
LBTOXGR	Standard Toxicity Grade	Char		Record Qualifier	Records toxicity grade value using a standard toxicity scale (e.g., NCI CTCAE). If value is from a numeric scale, represent only the number (e.g., "2", not "Grade 2").	Perm
LBLLOQ	Lower Limit of Quantitation	Num		Variable Qualifier	The lowest threshold for reliably quantifying the amount of substance measured by a specific test, in standardized units.	Perm
LBULOQ	Upper Limit of Quantitation	Num		Variable Qualifier	The highest threshold for reliably detecting the result of a specific test in standardized units.	Perm
VISITNUM	Visit Number	Num		Timing	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the observation, or the date/time of collection if start date/time is not collected.	Perm
LBDTC	Date/Time of Specimen Collection	Char	ISO 8601 datetime or interval	Timing	Date/time of specimen collection represented in ISO 8601 character format.	Exp
LBENDTC	End Date/Time of Specimen Collection	Char	ISO 8601 datetime or interval	Timing	End date/time of specimen collection represented in ISO 8601 character format.	Perm
LBDY	Study Day of Specimen Collection	Num		Timing	1. Study day of specimen collection, measured as integer days. 2. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in Demographics (DM). This formula should be consistent across the submission.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
LBENDY	Study Day of End of Observation	Num		Timing	Actual study day of end of observation expressed in integer days relative to the applicant-defined RFSTDTC in DM.	Perm
LBTPT	Planned Time Point Name	Char		Timing	1. Text description of time when specimen should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See LBPTNUM and LBPTREF. Examples: "Start", "5 min post".	Perm
LBPTNUM	Planned Time Point Number	Num		Timing	Numerical version of LBTPT to aid in sorting.	Perm
LBELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601) relative to a planned fixed reference (LBPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date/time variable. Represented as ISO 8601 duration. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by LBPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by LBPTREF.	Perm
LBPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by LBELTM, LBPTNUM, and LBTPT.	Perm
LBRTDTC	Date/Time of Reference Time Point	CharSDTM-754	ISO 8601 datetime or interval	Timing	Date/time of the reference timepoint, LBPTREF.	Perm

Assumptions

1. The LB domain captures laboratory data collected on the CRF or received from a central provider or vendor.
2. For lab tests that do not have continuous numeric results (e.g., urine protein as measured by dipstick, descriptive tests such as urine color), LBSTNRC could be populated either with normal range values that are a range of character values for an ordinal scale (e.g., "NEGATIVE to TRACE") or a delimited set of values that are considered to be normal (e.g., "YELLOW", "AMBER"). LBORNRL, LBORNRI, LBSTNRLO, and LBSTNRHI should be null for these types of tests.
3. LBNRIND can be added to indicate where a result falls with respect to reference range defined by LBORNRL and LBORNRI. Examples: "HIGH", "LOW". Clinical significance would be represented as a record in SUPPLB with a QNAM of LBCLSIG.
4. For lab tests where the specimen is collected over time (e.g., 24-hour urine collection), the start date/time of the collection goes into LBDTC and the end date/time of collection goes into LBENDTC.
5. Any Identifiers, Timing variables, or Findings general-observation class qualifiers may be added to the LB domain, but the following Qualifiers would not generally be used in LB: --BODSYS, --SEV.
6. A value derived by a central lab according to their procedures is considered collected rather than derived.
7. The variable LBORRESU uses the UNIT codelist. This means that applicants should be submitting a term from the CDISC Submission Value column in the published Controlled Terminology List (available at <https://www.cdisc.org/standards/terminology/controlled-terminology>). When applicants have units that are not in this column, they should first check to see if their unit is mathematically synonymous with an existing unit and submit their lab values using that unit. For example, "g/L" and "mg/mL" are mathematically synonymous, but only "g/L" is in the CDISC Unit codelist. If this is not the case, then a New-Term Suggestion form (<https://ncitermform.nci.nih.gov/ncitermform/>) should be submitted.

2.8.10.15 SDTM Medical History (MH)

Description

An events domain that contains data that includes the subject's prior medical history at the start of the trial.

mh.xpt, Medical History — Events. One record per medical history event per subject, Tabulation.**Specification****Domain Specification Table**

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	MH	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
MHSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MHGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
MHREFID	Reference ID	Char		Identifier	Internal or external medical history identifier.	Perm
MHSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Line number on a Medical History CRF page.	Perm
MHTERM	Reported Term for the Medical History	Char		Topic	Verbatim or preprinted CRF term for the medical condition or event.	Req
MHMODIFY	Modified Reported Term	Char		Synonym Qualifier	If MHTERM is modified to facilitate coding, then MHMODIFY will contain the modified text.	Perm
MHDECOD	Dictionary-Derived Term	Char		Synonym Qualifier	Dictionary-derived text description of MHTERM or MHMODIFY. Equivalent to the Preferred Term (PT in MedDRA).	Perm
MHEVDTYP	Medical History Event Date Type	Char	(MHEDTTYP)	Variable Qualifier	Specifies the aspect of the medical condition or event by which MHSTDTC and/or the MHENDTC is defined. Examples: "DIAGNOSIS", "SYMPTOMS", "RELAPSE", "INFECTION".	Perm
MHCAT	Category for Medical History	Char		Grouping Qualifier	Used to define a category of related records. Examples: "CARDIAC", "GENERAL".	Perm
MHSCAT	Subcategory for Medical History	Char		Grouping Qualifier	A further categorization of the condition or event.	Perm
MHPRESP	Medical History Event Pre-Specified	Char	(NY)	Variable Qualifier	A value of "Y" indicates that this medical history event was prespecified on the CRF. Values are null for spontaneously reported events (i.e., those collected as free-text verbatim terms).	Perm
MHOCCUR	Medical History Occurrence	Char	(NY)	Record Qualifier	Used when the occurrence of specific medical history conditions is solicited, to indicate whether ("Y"/"N") a medical condition (MHTERM) had ever occurred. Values are null for spontaneously reported events.	Perm
MHSTAT	Completion Status	Char	(ND)	Record Qualifier	The status indicates that the prespecified question was not asked/answered.	Perm
MHREASND	Reason Medical History Not Collected	Char		Record Qualifier	Describes the reason why data for a prespecified condition was not collected. Used in conjunction with MHSTAT when value is "NOT DONE".	Perm
MHBODSYS	Body System or Organ Class	Char		Record Qualifier	Dictionary-derived. Body system or organ class that is involved in an event or measurement from a standard hierarchy (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the applicant's analyses and summary tables which may not necessarily be the primary SOC.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm for the element in which the assessment was made.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the medical history event.	Perm
MHDTC	Date/Time of History Collection	Char	ISO 8601 datetime or interval	Timing	Collection date and time of the medical history observation represented in ISO 8601 character format.	Perm
MHSTDTC	Start Date/Time of Medical History Event	Char	ISO 8601 datetime or interval	Timing	Start date/time of the medical history event represented in ISO 8601 character format.	Perm
MHENDTC	End Date/Time of Medical History Event	Char	ISO 8601 datetime or interval	Timing	End date/time of the medical history event.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
MHDY	Study Day of History Collection	Num		Timing	Study day of medical history collection, measured as integer day. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in Demographics. This formula should be consistent across the submission.	Perm
MHENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the event relative to the applicant-defined reference period. The applicant-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics).	Perm
MHENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the event as being before or after the reference time point defined by variable MHENTPT.	Perm
MHENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by MHENTPT. Examples: "2003-12-25", "VISIT 2".	Perm

Assumptions

1. Prior interventions, including prior medications and procedures, should be submitted in an appropriate dataset from the Interventions class (e.g., Concomitant/Prior Medications (CM), Procedures (PR)).
2. MH description and coding
 - a. MHTERM is the topic variable and captures the verbatim term collected for the condition or event or the prespecified term used to collect information about the occurrence of any of a group of conditions or events. MHTERM is a required variable and must have a value.
 - b. MHMODIFY is a permissible variable and should be included if the applicant's procedure permits modification of a verbatim term for coding. The modified term is listed in MHMODIFY. The variable should be populated as per the applicant's procedures; null values are permitted.
 - c. If the applicant codes the reported term (MHTERM) using a standard dictionary, then MHDECOD will be populated with the preferred term derived from the dictionary.
 - d. MHBODSYS is the system organ class (SOC) from the coding dictionary associated with the adverse event by the applicant. This value may differ from the primary SOC designated in the coding dictionary's standard hierarchy.
 - e. If a CRF collects medical history by prespecified body systems and the applicant also codes reported terms using a standard dictionary, then MHDECOD and MHBODSYS are populated using the standard dictionary. MHCAT and MHSCAT should be used for the prespecified body systems.
3. Additional categorization and grouping
 - a. MHCAT and MHSCAT may be populated with the applicant's predefined categorization of medical history events, which are often prespecified on the CRF. Note that even if the applicant uses the body system terminology from the standard dictionary, MHBODSYS and MHCAT may differ; MHBODSYS is derived from the coding system, whereas MHCAT is effectively assigned when the investigator records a condition under the prespecified category.
 - i. This categorization should not group all records (within the MH domain) into one generic group such as "Medical History" or "General Medical History" because this is redundant information with the domain code. If no smaller categorization can be applied, then it is not necessary to include or populate this variable.
 - ii. Examples of MHCAT could include "General Medical History" (see above assumption; if "General Medical History" is an MHCAT value, then there should be other MHCAT values), "Allergy Medical History," and "Reproductive Medical History".
 - b. MHGRPID may be used to link (or associate) different records together to form a block of related records at the subject level within the MH domain. It should not be used in place of MHCAT or MHSCAT, which are used to group data across subjects. For example, if a group of syndromes reported for a subject were related to a particular disease, then the MHGRPID variable could be populated with the appropriate text.

4. Prespecified terms; presence or absence of events
- Information on medical history is generally collected in 2 different ways, either by recording free text or using a prespecified list of terms. The solicitation of information on specific medical history events may affect the frequency at which they are reported; therefore, the fact that a specific medical history event was solicited may be of interest to reviewers. MHPRESP and MHOCCUR are used together to indicate whether the condition in MHTERM was prespecified and whether it occurred, respectively. A value of "Y" in MHPRESP indicates that the term was prespecified.
 - MHOCCUR is used to indicate whether a prespecified medical condition occurred; a value of "Y" indicates that the event occurred and "N" indicates that it did not.
 - If a medical history event was reported using free text, the values of MHPRESP and MHOCCUR should be null. MHPRESP and MHOCCUR are permissible fields and may be omitted from the dataset if all medical history events were collected as free text.
 - MHSTAT and MHREASND provide information about prespecified medical history questions for which no response was collected. MHSTAT and MHREASND are permissible fields and may be omitted from the dataset if all medications were collected as free text or if all prespecified conditions had responses in MHOCCUR.

Situation	Value of MHPRESP	Value of MHOCCUR	Value of MHSTAT
Spontaneously reported event occurred			
Prespecified event occurred	Y	Y	
Prespecified event did not occur	Y	N	
Prespecified event has no response	Y		NOT DONE

- When medical history events are collected with the recording of free text, a record may be entered into the data management system to indicate "no medical history" for a specific subject or prespecified body system category (e.g., gastrointestinal). For these subjects or categories within subject, do not include a record in the MH dataset to indicate that there were no events.
5. Timing variables
- Relative timing assessments such as "Ongoing" or "Active" are common in the collection of MH information. MHENRF may be used when this relative timing assessment is coincident with the start of the study reference period for the subject represented in the Demographics (DM) dataset (RFSTDTC). MHENTPT and MHENTPPT may be used when "Ongoing" is relative to another date such as the screening visit date.
 - Additional timing variables (e.g., MHSTRF) may be used when appropriate.
6. MH event date type
- MHEVDTYP is a domain-specific variable that can be used to indicate the aspect of the event that is represented in the event start and/or end date/times (MHSTDTC and/or MHENDTC). If a start date and/or end date is collected without further specification of what constitutes the start or end of the event, then MHEVDTYP is not needed. However, when data collection specifies how the start or end date is to be reported, MHEVDTYP can be used to provide this information. For example, when collecting the date of diagnosis, it would be used to populate MHSTDTC; MHEVDTYP would be populated with "DIAGNOSIS". If MHEVDTYP is not needed for any collected data, it need not be included in the dataset. If MHEVDTYP is included in the dataset, it should be populated only when the data collection specifies the aspect of the event that is to be used to populate the start and/or end date; otherwise, it should be null.
 - When data collected about an event includes 2 different dates that could be considered the start or end of an event, then an MH record will be created for each. For example, if data collection included both a date of onset of symptoms and a date of diagnosis, there would be 2 records for the event, one with MHSTDTC the date of onset of symptoms and MHEVDTYP = "SYMPTOMS" and a second with MHSTDTC the date of diagnosis and MHEVDTYP = "DIAGNOSIS". In such a case, it is recommended that the 2 records be linked by means such as a common value of MHSPID or MHGRPID.

7. Any identifiers, timing variables, or Events general observation-class qualifiers may be added to the MH domain, but the following Qualifiers would generally not be used: --SER, --ACN, --ACNOTH, --REL, --RELNST, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE.

2.8.10.16 SDTM Pharmacokinetics Concentrations (PC)

Description

A findings domain that contains concentrations of drugs or metabolites in fluids or tissues as a function of time.

pc.xpt, Pharmacokinetics Concentrations — Findings. One record per sample characteristic or time-point concentration per reference time point or per analyte per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	PC	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Unique subject identifier within the submission.	Req
PCSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
PCGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain to support relationships within the domain and between domains.	Perm
PCREFID	Reference ID	Char		Identifier	Internal or external specimen identifier.	Perm
PCSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number.	Perm
PCTESTCD	Pharmacokinetic Test Short Name	Char		Topic	Short name of the analyte or specimen characteristic. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PCTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PCTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "ASA", "VOL", "SPG".	Req
PCTEST	Pharmacokinetic Test Name	Char		Synonym Qualifier	Name of the analyte or specimen characteristic. Note any test normally performed by a clinical laboratory is considered a lab test. The value in PCTEST cannot be longer than 40 characters. Examples: "Acetylsalicylic Acid", "Volume", "Specific Gravity".	Req
PCCAT	Test Category	Char		Grouping Qualifier	Used to define a category of related records. Examples: "ANALYTE", "SPECIMEN PROPERTY".	Perm
PCSCAT	Test Subcategory	Char		Grouping Qualifier	A further categorization of a test category.	Perm
PCORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
PCORRESU	Original Units	Char	(PKUNIT)	Variable Qualifier	Original units in which the data were collected. The unit for PCORRES. Example: "mg/L".	Exp
PCSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from PCORRES in a standard format or standard units. PCSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in PCSTRESPN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in PCORRES, and these results effectively have the same meaning, they could be represented in standard format in PCSTRESC as "NEGATIVE". For other examples, see general assumptions.	Exp
PCSTRESPN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from PCSTRESC. PCSTRESPN should store all numeric test results or findings.	Exp
PCSTRESU	Standard Units	Char	(PKUNIT)	Variable Qualifier	Standardized unit used for PCSTRESC and PCSTRESPN.	Exp
PCSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a result was not obtained. Should be null if a result exists in PCORRES.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
PCREASND	Reason Test Not Done	Char		Record Qualifier	Describes why a result was not obtained, such as "SPECIMEN LOST". Used in conjunction with PCSTAT when value is "NOT DONE".	Perm
PCNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor who provides the test results.	Exp
PCSPEC	Specimen Material Type	Char	(SPECTYPE)	Record Qualifier	Defines the type of specimen used for a measurement. Examples: "SERUM", "PLASMA", "URINE".	Exp
PCSPCCND	Specimen Condition	Char	(SPECCOND)	Record Qualifier	Free or standardized text describing the condition of the specimen, e.g., "HEMOLYZED", "ICTERIC", "LIPEMIC".	Perm
PCMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Examples: "HPLC/MS", "ELISA". This should contain sufficient information and granularity to allow differentiation of various methods that might have been used within a study.	Perm
PCFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status.	Perm
PCLLOQ	Lower Limit of Quantitation	Num		Variable Qualifier	Indicates the lower limit of quantitation for an assay. Units should be those used in PCSTRESU.	Exp
PCULQO	Upper Limit of Quantitation	Num		Variable Qualifier	Indicates the upper limit of quantitation for an assay. Units should be those used in PCSTRESU.	Perm
VISITNUM	Visit Number	Num		Timing	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the observation, or the date/time of collection if start date/time is not collected.	Perm
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601 datetime or interval	Timing	Date/time of specimen collection represented in ISO 8601-character format. If there is no end time, then this will be the collection time.	Exp
PCENDTC	End Date/Time of Specimen Collection	Char	ISO 8601 datetime or interval	Timing	End date/time of specimen collection represented in ISO 8601-character format. If there is no end time, the collection time should be stored in PCDTC, and PCENDTC should be null.	Perm
PCDY	Actual Study Day of Specimen Collection	Num		Timing	1. Study day of specimen collection, measured as integer days. 2. Algorithm for calculations must be relative to the applicant defined RFSTDTC variable in Demographics.	Perm
PCENDY	Study Day of End of Observation	Num		Timing	Actual study day of end of observation expressed in integer days relative to the applicant defined RFSTDTC in Demographics.	Perm
PCTPT	Planned Time Point Name	Char		Timing	1. Text description of time when specimen should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last exposure. See PCTPTNUM and PCTPTREF. Examples: "Start", "5 min post".	Perm
PCTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of PCTPT to aid in sorting.	Perm
PCELT	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601) relative to a planned fixed reference (PCTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable.	Perm
PCTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point used as a basis for PCTPT, PCTPTNUM, and PCELT. Example: "Most Recent Dose".	Perm
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601 datetime or interval	Timing	Date/time of the reference time point described by PCTPTREF.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
PCEVLINT	Evaluation Interval	Char	ISO 8601 duration or interval	Timing	Evaluation Interval associated with a PCTEST record represented in ISO 8601-character format. Example: "-PT2H" to represent an interval of 2 hours prior to a PCTPT.	Perm

Assumptions

1. This domain can be used to represent specimen properties associated with concentration measurements.
2. Any Identifiers, Timing variables, or Findings general observation class qualifiers may be added to the PC domain, but the following Qualifiers would not generally be used in PC: --BODSYS, --SEV.

2.8.10.17 SDTM Pharmacokinetics Parameters (PP)

Description

A findings domain that contains pharmacokinetic parameters derived from pharmacokinetic concentration-time (PC) data.

pp.xpt, Pharmacokinetics Parameters — Findings. One record per PK parameter per time-concentration profile per modeling method per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	PP	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Unique subject identifier within the submission.	Req
PPSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
PPGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain to support relationships within the domain and between domains.	Perm
PPTESTCD	Parameter Short Name	Char	(PKPARMCD)	Topic	Short name of the pharmacokinetic parameter. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PPTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PPTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "AUCALL", "TMAX", "CMAX".	Req
PPTEST	Parameter Name	Char	(PKPARM)	Synonym Qualifier	Name of the pharmacokinetic parameter. The value in PPTEST cannot be longer than 40 characters. Examples: "AUC All", "Time of CMAX", "Max Conc".	Req
PPCAT	Parameter Category	Char		Grouping Qualifier	Used to define a category of related records. For PP, this should be the name of the analyte in PCTEST whose profile the parameter is associated with.	Exp
PPSCAT	Parameter Subcategory	Char		Grouping Qualifier	Categorization of the model type used to calculate the PK parameters. Examples: "COMPARTMENTAL", "NON-COMPARTMENTAL".	Perm
PPORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
PPORRESU	Original Units	Char	(PKUNIT) (PKUWG) (PKUWKG) (PKUDMG) (PKUDUG)	Variable Qualifier	Original units in which the data were collected. The unit for PPORRES.	Exp
PPSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from PPORRES in a standard format or standard units. PPSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in PPSTRESN.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
PPSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from PPSTRESC. PPSTRESN should store all numeric test results or findings.	Exp
PPSTRESU	Standard Units	Char	(PKUNIT) (PKUWG) (PKUWKG) (PKUDMG) (PKUDUG)	Variable Qualifier	Standardized unit used for PPSTRESC and PPSTRESN.	Exp
PPSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a parameter was not calculated. Should be null if a result exists in PPORRES.	Perm
PPREASND	Reason Parameter Not Calculated	Char		Record Qualifier	Describes why a parameter was not calculated, such as "INSUFFICIENT DATA". Used in conjunction with PPSTAT when value is "NOT DONE".	Perm
PPSPEC	Specimen Material Type	Char	(SPECTYPE)	Record Qualifier	Defines the type of specimen used for a measurement. If multiple specimen types are used for a calculation (e.g., serum and urine for renal clearance), then this field should be left blank. Examples: "SERUM", "PLASMA", "URINE".	Exp
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the Element within the Arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the observation, or the date/time of collection if start date/time is not collected.	Perm
PPDTC	Date/Time of Parameter Calculations	Char	ISO 8601 datetime or interval	Timing	Nominal date/time of parameter calculations.	Perm
PPDY	Study Day of Parameter Calculations	Num		Timing	Study day of the collection, in integer days. The algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
PPRFTDTC	Date/Time of Reference Point	Char	ISO 8601 datetime or interval	Timing	Date/time of the reference time point from the PC records used to calculate a parameter record. The values in PPRFTDTC should be the same as that in PCRFTDTC for related records.	Exp
PPSTINT	Planned Start of Assessment Interval	Char	ISO 8601 duration	Timing	The start of a planned evaluation or assessment interval relative to the Time Point Reference.	Perm
PPENINT	Planned End of Assessment Interval	Char	ISO 8601 duration	Timing	The end of a planned evaluation or assessment interval relative to the Time Point Reference.	Perm

Assumptions

1. It is recognized that PP is a derived dataset, and may be produced from an analysis dataset with a different structure.
2. Information pertaining to all parameters (e.g., number of exponents, model weighting) should be submitted in the SUPPPP dataset.
3. There are separate codelists used for PPORRESU/PPSTRESU where the choice depends on whether the value of the pharmacokinetic parameter is normalized.
 - a. Codelist "PKUNIT" is used for non-normalized parameters.
 - b. Codelists "PKUDMG" and "PKUDUG" are used when parameters are normalized by dose amount in milligrams or micrograms respectively.
 - c. Codelists "PKUWG" and "PKUWKG" are used when parameters are normalized by weight in grams or kilograms respectively.

Multiple subset codelists were created for the unique unit expressions of the same concept across codelists, this approach allows study-context appropriate use of unit values for PK analysis subtypes.
4. Any Identifiers, Timing variables, or Findings general observation class qualifiers may be added to the PP domain, but the following qualifiers would not generally be used in PP: --BODSYS, --SEV.

2.8.10.18 SDTM Product Accountability (DA)

Description

A findings domain that contains the accountability of study product, such as information on the receipt, dispensing, return, and packaging.

da.xpt, Product Accountability — Findings. One record per product accountability finding per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study within the submission.	Req
DOMAIN	Domain Abbreviation	Char	DA	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Unique subject identifier within the submission.	Req
DASEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DAGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
DAREFID	Reference ID	Char		Identifier	Internal or external identifier such as label number.	Perm
DASPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Examples: Line number on the Product Accountability page, product label code.	Perm
DATESTCD	Short Name of Accountability Assessment	Char	(DATESTCD)	Topic	Short character value for DATEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters and cannot begin with a number or contain characters other than letters, numbers, or underscores. Example: "DISPAMT", "RETAMT".	Req
DATEST	Name of Accountability Assessment	Char	(DATEST)	Synonym Qualifier	Verbatim name, corresponding to the topic variable, of the test or examination used to obtain the product accountability assessment. The value in DATEST cannot be longer than 40 characters. Example: "Dispensed Amount", "Returned Amount".	Req
DACAT	Category	Char		Grouping Qualifier	Used to define a category of topic-variable values (e.g., "STUDY PRODUCT").	Perm
DASCAT	Subcategory	Char		Grouping Qualifier	Used to define a further categorization level for a group of related records.	Perm
DAORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the product accountability assessment as originally received or collected.	Exp
DAORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Unit for DAORRES.	Perm
DASTRESC	Result or Finding in Standard Format	Char		Result Qualifier	Contains the result value for all product accountability assessments, copied or derived from DAORRES in a standard format or in standard units. DASTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in DASTRESN.	Exp
DASTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from DASTRESC. DASTRESN should store all numeric test results or findings.	Perm
DASTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized units used for DASTRESC and DASTRESN.	Perm
DASTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a product accountability assessment was not done. Should be null or have a value of "NOT DONE".	Perm
DAREASND	Reason Not Done	Char		Record Qualifier	Reason not done. Used in conjunction with DASTAT when value is "NOT DONE".	Perm
VISITNUM	Visit Number	Num		Timing	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
VISIT	Visit Name	Char		Timing	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit, based upon RFSTDTC in Demographics.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the observation, or the date/time of collection if start date/time is not collected.	Perm
DADTC	Date/Time of Collection	Char	ISO 8601 datetime or interval	Timing	Date and time of the product accountability assessment represented in ISO 8601 character format.	Exp
DADY	Study Day of Visit/Collection/Exam	Num		Timing	1. Study day of product accountability assessment, measured in integer days. 2. Algorithm for calculations must be relative to the applicant-defined RFSTDTC in Demographics.	Perm

Assumptions

- One way an applicant may choose to differentiate different types of products, (e.g., study product, comparator product) is to use DACAT.
- DAREFID and DASPID are both available for capturing label information.
- Any Identifiers, Timing variables, or Findings general observation class qualifiers may be added to the DA domain, but the following Qualifiers would not generally be used in DA: --MODIFY, --POS, --BODSYS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHII, --STNRC, --NRIND, --RESCAT, --XFN, --NAM, --LOINC, --SPEC, --SPCCND, --METHOD, --BLFL, --FAST, --DRVFL, --TOX, --TOXGR, --SEV.

2.8.10.19 SDTM Protocol Deviations (DV)

Description

An events domain that contains protocol violations and deviations during the course of the study.

dv.xpt, Protocol Deviations — Events. One record per protocol deviation per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DV	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
DVSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DVREFID	Reference ID	Char		Identifier	Internal or external identifier.	Perm
DVSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Line number on a CRF page.	Perm
DVTERM	Protocol Deviation Term	Char		Topic	Verbatim name of the protocol deviation criterion. Example: "IVRS PROCESS DEVIATION - NO DOSE CALL PERFORMED". DVTERM values will map to the controlled terminology in DVDECOD (e.g., "STUDY PRODUCT ASSIGNMENT DEVIATION").	Req
DVDECOD	Protocol Deviation Coded Term	Char		Synonym Qualifier	Controlled terminology for the name of the protocol deviation. Examples: "STUDY PRODUCT ASSIGNMENT	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					DEVIATION", "EXCLUDED CONCOMITANT MEDICATION".	
DVCAT	Category for Protocol Deviation	Char		Grouping Qualifier	Category of the protocol deviation criterion.	Perm
DVSCAT	Subcategory for Protocol Deviation	Char		Grouping Qualifier	A further categorization of the protocol deviation.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the deviation. Examples: "PRODUCT EXPOSURE", "SCREENING", "FOLLOW-UP".	Perm
DVSTDTC	Start Date/Time of Deviation	Char	ISO 8601 datetime or interval	Timing	Start date/time of deviation represented in ISO 8601 character format.	Perm
DVENDTC	End Date/Time of Deviation	Char	ISO 8601 datetime or interval	Timing	End date/time of deviation represented in ISO 8601 character format.	Perm
DVSTDY	Study Day of Start of Deviation Event	Num		Timing	Study day of start of event relative to the applicant-defined RFSTDTC.	Perm
DVENDY	Study Day of End of Deviation Event	Num		Timing	Study day of end of event relative to the applicant-defined RFSTDTC.	Perm

Assumptions

- The DV domain is an Events model for collected protocol deviations and not for derived protocol deviations that are more likely to be part of analysis. Events typically include what the event was, captured in --TERM (the topic variable), and when it happened (captured in its start and/or end dates). The intent of the domain model is to capture protocol deviations that occurred during the course of the study (see ICH E3, Section 10.2; https://database.ich.org/sites/default/files/E3_Guideline.pdf).
- This domain should not be used to collect entry-criteria information. Violated inclusion/exclusion criteria are stored in IE. The DV domain is for more general deviation data. A protocol may indicate that violating an inclusion/exclusion criterion during the course of the study (after first exposure) is a protocol violation. In this case, this information would go into DV.
- Any identifier variables, timing variables, or Events general observation-class qualifiers may be added to the DV domain, but the following qualifiers would generally not be used: --PRES, --OCCUR, --STAT, --REASND, --BODSYS, --LOC, --SEV, --SER, --ACN, --ACNOTH, --REL, --RELNST, --PATT, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE, --CONTRT, --TOXGR.

2.8.10.20 SDTM Questionnaires (QS)

Description

A findings domain that contains data for named, stand-alone instruments designed to provide an assessment of a concept. Questionnaires have a defined standard structure, format, and content; consist of conceptually related items that are typically scored; and have documented methods for administration and analysis.

qs.xpt, Questionnaires — Findings. One record per questionnaire per question per time point per visit per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	QS	Identifier	Two-character abbreviation for the domain.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
QSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
QSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
QSSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Question number on a questionnaire.	Perm
QTESTCD	Question Short Name	Char		Topic	Topic variable for QS. Short name for the value in QTEST, which can be used as a column name when converting the dataset from a vertical format to a horizontal format. The value in QTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). QTESTCD cannot contain characters other than letters, numbers, or underscores. Controlled terminology for QTESTCD is published in separate codelists for each questionnaire. Examples: "ADCCMD01", "BPR0103".	Req
QTEST	Question Name	Char		Synonym Qualifier	Verbatim name of the question or group of questions used to obtain the measurement or finding. The value in QTEST cannot be longer than 40 characters. Controlled terminology for QTEST is published in separate codelists for each questionnaire. Example: "BPR01 - Emotional Withdrawal".	Req
QSCAT	Category of Question	Char	(QSCAT)	Grouping Qualifier	Used to specify the questionnaire in which the question identified by QTEST and QTESTCD was included. Examples: "ADAS-COG", "MDS-UPDRS".	Req
QSSCAT	Subcategory for Question	Char		Grouping Qualifier	A further categorization of the questions within the category. Examples: "MENTAL HEALTH", "DEPRESSION", "WORD RECALL".	Perm
QSORRES	Finding in Original Units	Char		Result Qualifier	Finding as originally received or collected (e.g., "RARELY", "SOMETIMES"). When applicants apply codelist to indicate that code values are statistically meaningful standardized scores (which are defined by applicants or by valid methodologies, e.g., SF36 questionnaires), QSORRES will contain the decode format; QSSTRESC and QSSTRESN may contain the standardized code values or scores.	Exp
QSORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for QSORRES, such as minutes or seconds or the units associated with a visual analog scale.	Perm
QSSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the finding for all questions or subscores copied or derived from QSORRES, in a standard format or standard units. QSSTRESC should store all findings in character format; if findings are numeric, they should also be stored in numeric format in QSSTRESN. If question scores are derived from the original finding, then the standard format is the score. Examples: "0", "1". When applicants apply codelist to indicate the code values are statistically meaningful standardized scores (which are defined by applicants or by valid methodologies, e.g., SF36 questionnaires), QSORRES will contain the decode format; QSSTRESC and QSSTRESN may contain the standardized code values or scores.	Exp
QSSTRESN	Numeric Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric findings in standard format; copied in numeric format from QSSTRESC. QSSTRESN should store all numeric results or findings.	Perm
QSSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for QSSTRESC or QSSTRESN.	Perm
QSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a question was not done or was not answered. Should be null if a result exists in QSORRES.	Perm
QSREASND	Reason Not Performed	Char		Record Qualifier	Describes why a question was not answered. Used in conjunction with QSSTAT when value is "NOT DONE". Example: "SUBJECT REFUSED".	Perm
QSMETHOD	Method of Test or Examination	Char	(QRSMTHOD)	Record Qualifier	Method of the test or examination.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
QSLOBXFL	Last Observation Before Exposure Flag	Char	(NY)	Record Qualifier	Operationally derived indicator used to identify the last non-missing value prior to RFXSTDTC. Should be "Y" or null.	Exp
QSBFLF	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. Should be "Y" or null. Note that QSBFLF is retained for backward compatibility. The authoritative baseline for statistical analysis is in an ADaM dataset.	Perm
QSDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be "Y" or null. Records that represent the average of other records or questionnaire subscores that do not come from the CRF are examples of records that would be derived for the submission datasets. If QSDRVFL = "Y", then QSORRES may be null with QSSTRESC and (if numeric) QSSTRESN having the derived value.	Perm
VISITNUM	Visit Number	Num		Timing	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm for the element in which the assessment was made.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the observation date/time of the physical exam finding.	Perm
QSDTC	Date/Time of Finding	Char	ISO 8601 datetime or interval	Timing	Date of questionnaire.	Exp
QSDY	Study Day of Finding	Num		Timing	Study day of finding collection, measured as integer days. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in Demographics.	Perm
QSTPT	Planned Time Point Name	Char		Timing	Text description of time when questionnaire should be administered. This may be represented as an elapsed time relative to a fixed reference point (e.g., "TIME OF LAST DOSE"). See QSTPTNUM and QSTPTREF.	Perm
QSTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of QSTPT to aid in sorting.	Perm
QSELTIM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601) relative to a planned fixed reference (QSTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by QSTPTREF, "PT8H" to represent the period of 8 hours after the reference point indicated by QSTPTREF.	Perm
QSTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by QSELTIM, QSTPTNUM, and QSTPT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".	Perm
QSRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/time of the reference time point, QSTPTREF.	Perm
QSEVLINT	Evaluation Interval	Char	ISO 8601 duration or interval	Timing	Evaluation interval associated with a QTEST question represented in ISO 8601 character format. Example: "-P2Y" to represent an interval of 2 years in the question "Have you experienced any episodes in the past 2 years?"	Perm
QSEVINTX	Evaluation Interval Text	Char		Timing	Evaluation interval associated with an observation, where the interval is not able to be represented in ISO 8601 format. Examples: "LIFETIME", "LAST NIGHT", "RECENTLY", "OVER THE LAST FEW WEEKS".	Perm

Assumptions

There are no additional QS-specific assumptions; all are included in Section 2.8.7.2, [Questionnaires, Ratings, and Scales \(QRS\)](#).

2.8.10.21 SDTM Related Records (RELREC)

Description

A dataset used to describe relationships between records for a subject within or across domains, and relationships of records across datasets.

relrec.xpt, Related Records — Relationship. One record per related record, group of records or dataset, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
RDOMAIN	Related Domain Abbreviation	Char	(DOMAIN)	Identifier	Abbreviation for the domain of the parent record(s).	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Exp
IDVAR	Identifying Variable	Char		Identifier	Name of the identifying variable in the general-observation-class dataset that identifies the related record(s). Examples: --SEQ and --GRPID.	Req
IDVARVAL	Identifying Variable Value	Char		Identifier	Value of identifying variable described in IDVAR. If --SEQ is the variable being used to describe this record, then the value of --SEQ would be entered here.	Exp
RELTYP	Relationship Type	Char	(RELTYP)	Record Qualifier	Identifies the hierarchical level of the records in the relationship. Values should be either "ONE" or "MANY". Used only when identifying a relationship between datasets.	Exp
RELID	Relationship Identifier	Char		Record Qualifier	Unique value within USUBJID that identifies the relationship. All records for the same USUBJID that have the same RELID are considered "related/associated." RELID can be any value the applicant chooses, and is only meaningful within the RELREC dataset to identify the related/associated domain records.	Req

Assumptions

There are no additional RELREC-specific assumptions; all are included in Section 2.8.5.2, [Relating Subject Records and Datasets](#). See also Section 2.6, [Guidance for Datasets](#), Tabulation Datasets table Row 9.

2.8.10.22 SDTM Respiratory System Findings (RE)

Description

A findings domain that contains physiological and morphological findings related to the respiratory system, including the organs that are involved in breathing such as the nose, throat, larynx, trachea, bronchi and lungs.

re.xpt, Respiratory System Findings — Findings. One record per finding or result per time point per visit per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	RE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SPDEVID	Applicant Device Identifier	Char		Identifier	Applicant-defined identifier for a device.	Perm
RESEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness of records within a dataset for a subject. May be any valid number (including decimals) and does not have to start at 1.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
REGRPID	Group ID	Char		Identifier	Optional group identifier, used to link together a block of related records within a subject in a domain.	Perm
REREFID	Reference ID	Char		Identifier	Optional internal or external procedure identifier.	Perm
RESPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined identifier. Perhaps preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database.	Perm
RELNKID	Link ID	Char		Identifier	Identifier used to link related records across domains. This may be a one-to-one or a one-to-many relationship.	Perm
RELNKGRP	Link Group	Char		Identifier	Identifier used to link related records across domains. This will usually be a many-to-one relationship.	Perm
RETESTCD	Short Name of Respiratory Test	Char	(RETESTCD)	Topic	Short name of the measurement, test, or examination. It can be used as a column name when converting a dataset from a vertical format to a horizontal format. The value in RETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). RETESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "FEV1", "FVC".	Req
RETEST	Name of Respiratory Test	Char	(RETEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in RETEST cannot be longer than 40 characters. Examples: "Forced Expiratory Volume in 1 Second", "Forced Vital Capacity".	Req
RECAT	Category for Respiratory Test	Char		Grouping Qualifier	Used to categorize observations across subjects.	Perm
RESCAT	Subcategory for Respiratory Test	Char		Grouping Qualifier	A further categorization.	Perm
REPOS	Position of Subject During Observation	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".	Perm
REORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the procedure measurement or finding as originally received or collected.	Exp
REORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for REORRES and REORREF.	Perm
REORREF	Reference Result in Original Units	Char		Variable Qualifier	Reference result for continuous measurements in original units. Should be collected only for continuous results.	Perm
RESTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from REORRES in a standard format or in standard units. RESTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in RESTRESN.	Exp
RESTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from RESTRESC. RESTRESN should store all numeric test results or findings.	Perm
RESTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for RESTRESC, RESTRESN and RESTREFN.	Perm
RESTREFC	Character Reference Result	Char		Variable Qualifier	Reference value for the result or finding copied or derived from --ORREF in a standard format.	Perm
RESTREFN	Numeric Reference Result in Std Units	Num		Variable Qualifier	Reference result for continuous measurements in standard units. Should be populated only for continuous results.	Perm
RESTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a test was not done or a measurement was not taken. Should be null if a result exists in REORRES.	Perm
REREASND	Reason Not Done	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: "BROKEN EQUIPMENT", "SUBJECT REFUSED". Used in conjunction with RESTAT when value is "NOT DONE".	Perm
RELOC	Location Used for the Measurement	Char	(LOC)	Record Qualifier	Anatomical location of the subject relevant to the collection of the measurement. Examples: "LUNG", "BRONCHUS".	Perm
RELAT	Laterality	Char	(LAT)	Variable Qualifier	Side of the body used to collect measurement. Examples: "RIGHT", "LEFT".	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
REDIR	Directionality	Char	(DIR)	Variable Qualifier	Qualifier for anatomical location or specimen further detailing directionality. Examples: "ANTERIOR", "LOWER", "PROXIMAL".	Perm
REMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method used to create the result.	Perm
RELOBXFL	Last Observation Before Exposure Flag	Char	(NY)	Record Qualifier	Operationally derived indicator used to identify the last non-missing value prior to RFXSTDTC. The value should be "Y" or null.	Exp
REEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Examples: "ADJUDICATION COMMITTEE", "INDEPENDENT ASSESSOR", "RADIOLOGIST".	Perm
REEVALID	Evaluator Identifier	Char	(MEDEVAL)	Variable Qualifier	Used to distinguish multiple evaluators with the same role recorded in REEVAL. Examples: "RADIOLOGIST1" or "RADIOLOGIST2".	Perm
REREPNUM	Repetition Number	Num		Record Qualifier	The instance number of a test that is repeated within a given time frame for the same test. The level of granularity can vary, e.g., within a timepoint or within a visit. For example, multiple measurements of pulmonary function.	Perm
VISITNUM	Visit Number	Num		Timing	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics (DM).	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm for the element in which the assessment was made.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the date/time at which the assessment was made.	Perm
REDTCT	Date/Time of Collection	Char	ISO 8601 datetime or interval	Timing	Date/time of procedure or test.	Exp
REDY	Study Day of Visit/Collection/Exam	Num		Timing	Actual study day of visit/collection/exam expressed in integer days relative to the applicant-defined RFSTDTC in DM.	Perm
RETPT	Planned Time Point Name	Char		Timing	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See RETPTNUM and RETPTREF. Examples: "Start", "5 minutes post".	Perm
RETPTNUM	Planned Time Point Number	Num		Timing	Numeric version of RETPT to aid in sorting.	Perm
REELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time relative to a planned fixed reference (RETPTREF). Not a clock time or a date/time variable, but an interval, represented as ISO duration. Examples: "-PT15M" to represent 15 minutes prior to the reference timepoint indicated by RETPTREF, or "PT8H" to represent 8 hours after the reference timepoint represented by RETPTREF.	Perm
RETPTREF	Time Point Reference	Char		Timing	Description of the fixed reference point referred to by REELTM, RETPTNUM, and RETPT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".	Perm
RERFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/time for a fixed reference timepoint defined by RETPTREF.	Perm

Assumptions

1. This domain is used to represent the results/findings of a respiratory diagnostic procedure (e.g., spirometry).

2. Many respiratory assessments require the use of a device. When data about the device used for an assessment or additional information about its use in the assessment are collected, SPDEVID should be included in the record.
3. Any Identifier variables, Timing variables, or Findings general observation class qualifiers may be added to the RE domain, but the following qualifiers would generally not be used in the RE domain: --MODIFY, --BODSYS, and --FAST.

2.8.10.23 SDTM Subject Characteristics (SC)

Description

A findings domain that contains subject-related data not collected in other domains.

sc.xpt, Subject Characteristics — Findings. One record per characteristic per visit per subject., Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SC	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SCSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
SCGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
SCSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database.	Perm
SCTESTCD	Subject Characteristic Short Name	Char	(SCTESTCD)	Topic	Short name of the measurement, test, or examination described in SCTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in SCTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). SCTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "MARISTAT", "NATORIG".	Req
SCTEST	Subject Characteristic	Char	(SCTEST)	Synonym Qualifier	Vernbatim name of the test or examination used to obtain the measurement or finding. The value in SCTEST cannot be longer than 40 characters. Examples: "Marital Status", "National Origin".	Req
SCCAT	Category for Subject Characteristic	Char		Grouping Qualifier	Used to define a category of related records.	Perm
SCSCAT	Subcategory for Subject Characteristic	Char		Grouping Qualifier	A further categorization of the subject characteristic.	Perm
SCORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the subject characteristic as originally received or collected.	Exp
SCORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original unit in which the data were collected. The unit for SCORRES.	Perm
SCSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings copied or derived from SCORRES, in a standard format or standard units. SCSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in SCSTRESPN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in SCORRES, and these results effectively have the same meaning, they could be represented in standard format in SCSTRESC as "NEGATIVE".	Exp
SCSTRESPN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from SCSTRESC. SCSTRESPN should store all numeric test results or findings.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
SCSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for SCSTRESC or SCSTRESN.	Perm
SCSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that the measurement was not done. Should be null if a result exists in SCORRES.	Perm
SCREASND	Reason Not Performed	Char		Record Qualifier	Describes why the observation has no result. Example: "Subject refused". Used in conjunction with SCSTAT when value is "NOT DONE".	Perm
VISITNUM	Visit Number	Num		Timing	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Perm
VISIT	Visit Name	Char		Timing	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics (DM).	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time at which the assessment was made.	Perm
SCDTC	Date/Time of Collection	Char	ISO 8601 datetime or interval	Timing	Collection date and time of the subject characteristic represented in ISO 8601 character format.	Perm
SCDY	Study Day of Examination	Num		Timing	Study day of collection, measured as integer days. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in DM.	Perm

Assumptions

1. The structure of subject characteristics is based on the Findings general observation class and is an extension of the demographics data, including socioeconomic or other broad characteristics. The structure for demographic data is fixed and includes date of birth, age, sex, race, ethnicity, and country. Subject characteristics may be collected periodically over time. Some examples of subject characteristics include education level, marital status, and national origin.
2. Any Identifiers, Timing variables, or Findings general observation class qualifiers may be added to the SC domain, but the following qualifiers would generally not be used in SC: --MODIFY, --POS, --BODSYS, --ORNRL, --ORNRLH, --STNRLO, --STNRHI, --STNRHC, --NRIND, --RESCAT, --XFN, --NAM, --LOINC, --SPEC, --SPCCND, --BLFL, --LOBXFL, --FAST, --DRVFL, --TOX, --TOXGR, --SEV.

2.8.10.24 SDTM Subject Elements (SE)

Description

A special-purpose domain that contains the actual order of elements followed by the subject, together with the start date/time and end date/time for each element.

se.xpt, Subject Elements — Special-Purpose. One record per actual Element per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SESEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. Should be assigned to be consistent chronological order.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
ETCD	Element Code	Char		Topic	1. ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that ETCD will need to serve as a variable name. 2. If an encountered element differs from the planned element to the point that it is considered a new element, then use "UNPLAN" as the value for ETCD to represent this element.	Req
ELEMENT	Description of Element	Char		Synonym Qualifier	The name of the element. If ETCD has a value of "UNPLAN", then ELEMENT should be null.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the subject's assigned trial arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the element in the planned sequence of elements for the arm to which the subject was assigned.	Perm
SESTDTC	Start Date/Time of Element	Char	ISO 8601 datetime or interval	Timing	Start date/time for an element for each subject.	Req
SEENDTC	End Date/Time of Element	Char	ISO 8601 datetime or interval	Timing	End date/time for an element for each subject.	Exp
SESTDY	Study Day of Start of Element	Num		Timing	Study day of start of element relative to the applicant-defined RFSTDTc.	Perm
SEENDY	Study Day of End of Element	Num		Timing	Study day of end of element relative to the applicant-defined RFSTDTc.	Perm
SEUPDES	Description of Unplanned Element	Char		Synonym Qualifier	Description of what happened to the subject during an unplanned element. Used only if ETCD has the value of "UNPLAN".	Perm

Assumptions

The SE domain allows the submission of data on the timing of the trial elements a subject actually passed through in their participation in the trial.

- For any particular subject, the dates in the SE table are the dates when the transition events identified in the Trial Elements (TE) table occurred. Judgment may be needed to match actual events in a subject's experience with the definitions of transition events (i.e., events that mark the start of new elements) in the TE table; actual events may vary from the plan.
- Judgment will also have to be used in deciding how to represent a subject's experience if an element does not proceed or end as planned.
- If the applicant decides that the subject's experience for a particular period of time cannot be represented with one of the planned elements, then that period of time should be represented as an unplanned element. The value of ETCD for an unplanned element is "UNPLAN" and SEUPDES should be populated with a description of the unplanned element.
- The values of SESTDTC provide the chronological order of the actual subject elements. SESEQ should be assigned to be consistent with the chronological order. Note that the requirement that SESEQ be consistent with chronological order is more stringent than in most other domains, where --SEQ values need only be unique within subject.
- When TAETORD is included in the SE domain, it represents the planned order of an element in an arm. This should not be confused with the actual order of the elements, which will be represented by their chronological order and SESEQ. TAETORD will not be populated for subject elements that are not planned for the arm to which the subject was assigned. Thus, TAETORD will not be populated for any element with an ETCD value of "UNPLAN". TAETORD also will not be populated if a subject passed through an element that, although defined in the TE dataset, was out of place for the arm to which the subject was assigned.
- For subjects who follow the planned sequence of elements for the arm to which they were assigned, the values of EPOCH in the SE domain will match those associated with the elements for the subject's arm in

the TA dataset. The applicant will have to decide what value, if any, of EPOCH to assign SE records for unplanned elements and in other cases where the subject's actual elements deviate from the plan.

7. Because there are, by definition, no gaps between elements, the value of SEENDTC for one element will always be the same as the value of SESTDTC for the next element.
8. Note that SESTDTC is required, although --STDTC is not required in any other subject-level dataset. The purpose of the dataset is to record the elements a subject actually passed through. If it is known that a subject passed through a particular element, then there must be some information (perhaps imprecise) on when it started. Thus, SESTDTC may not be null, although some records may not have all the components (e.g., year, month, day, hour, minute) of the date/time value collected.
9. The following identifier variables are permissible and may be added as appropriate: --GRPID, --REFID, --SPID.
10. Care should be taken in adding additional timing variables:
 - a. The purpose of --DTC and --DY is to record the date and study day on which data was collected. Elements are generally “derived” in the sense that they are a secondary use of data collected elsewhere; it is not generally useful to know when those date/times were recorded.
 - b. --DUR could be added only if the duration of an element was collected, not derived.
 - c. It would be inappropriate to add the variables that support time points (--TPT, --TPTNUM, --ELTM, --TPTREF, and --RFTDTC), because the topic of this dataset is elements.

2.8.10.25 SDTM Subject Visits (SV)

Description

A special-purpose domain that contains information for each subject's actual and planned visits and contact events.

sv.xpt, Subject Visits — Special-Purpose. One record per actual or planned visit per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SV	Identifier	Two-character abbreviation for the domain most relevant to the observation. The domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VISITNUM	Visit Number	Num		Topic	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Req
VISIT	Visit Name	Char		Synonym Qualifier	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
SVPRESP	Pre-specified	Char	(NY)	Variable Qualifier	Used to indicate whether the visit was planned (i.e., visits specified in the TV domain). Value is "Y" for planned visits, null for unplanned visits.	Exp
SVOCCUR	Occurrence	Char	(NY)	Record Qualifier	Used to record whether a planned visit occurred. The value is null for unplanned visits.	Exp
SVREASOC	Reason for Occur Value	Char		Record Qualifier	The reason for the value in SVOCCUR. If SVOCCUR="N", SVREASOC is the reason the visit did not occur.	Perm
SVCNTMOD	Contact Mode	Char	(CNTMODE)	Record Qualifier	The way in which the visit was conducted. Examples: "IN PERSON", "TELEPHONE CALL", "IVRS".	Perm
SVEPCHGI	Epi/Pandemic Related Change Indicator	Char	(NY)	Record Qualifier	Indicates whether the visit was changed due to an epidemic or pandemic.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of VISIT. Should be an integer.	Perm
SVSTDTC	Start Date/Time of Observation	Char	ISO 8601 datetime or interval	Timing	Start date/time of an observation represented in ISO 8601 character format.	Exp
SVENDTC	End Date/Time of Observation	Char	ISO 8601 datetime or interval	Timing	End date/time of the observation represented in ISO 8601 character format.	Exp
SVSTDY	Study Day of Start of Observation	Num		Timing	Actual study day of start of observation expressed in integer days relative to the applicant-defined RFSTDTC in Demographics.	Perm
SVENDY	Study Day of End of Observation	Num		Timing	Actual study day of end of observation expressed in integer days relative to the applicant-defined RFSTDTC in Demographics.	Perm
SVUPDES	Description of Unplanned Visit	Char		Record Qualifier	Description of what happened to the subject during an unplanned visit. Only populated for unplanned visits.	Perm

Assumptions

1. The Subject Visits domain allows the submission of data on the timing of the trial visits for a subject, including both those visits they actually passed through in their participation in the trial and those visits that did not occur.
2. Subjects can have 1 and only 1 record per VISITNUM.
3. Subjects who screen fail, withdraw, die, or otherwise discontinue study participation will not have records for planned visits subsequent to their final disposition event.
4. Planned and unplanned visits with a subject, whether or not they are physical visits to the site, are represented in this domain.
 - a. SVPRESP = "Y" identifies rows for planned visits.
 - b. For planned visits, SVOCCUR indicates whether the visit occurred.
 - c. For unplanned visits, SVPRESP and SVOCCUR are null.
5. The identification of an actual visit with a planned visit sometimes calls for judgment. In general, data collection forms are prepared for particular visits, and the fact that data was collected on a form labeled with a planned visit is sufficient to make the association. Occasionally, the association will not be so clear, and the applicant will need to make decisions about how to label actual visits.
6. Records for unplanned visits should be included in the SV dataset. For unplanned visits, SVUPDES can be populated with a description of the reason for the unplanned visit. Some judgment may be required to determine what constitutes an unplanned visit. When data are collected outside a planned visit, that act of collecting data may or may not be described as a "visit." The encounter should generally be treated as a visit if data from the encounter are included in any domain for which VISITNUM is included; a record with a missing value for VISITNUM is generally less useful than a record with VISITNUM populated. If the occasion is considered a visit, its date/times must be included in the SV table and a value of VISITNUM must be assigned.
7. The variable SVCNTMOD is used to record the way in which the visit was conducted. For example, for visits to a clinic, SVCNTMOD = "IN PERSON", visits conducted remotely might have values such as "TELEPHONE", "REMOTE AUDIO VIDEO", or "IVRS".
8. The planned study day of visit variable (VISITDY) should not be populated for unplanned visits.
9. If SVSTDY is included, it is the actual study day corresponding to SVSTDTC. In studies for which VISITDY has been populated, it may be desirable to populate SVSTDY, as this will facilitate the comparison of planned (VISITDY) and actual (SVSTDY) study days for the start of a visit.
10. If SVENDY is included, it is the actual day corresponding to SVENDTC.
11. For many studies, all visits are assumed to occur within 1 calendar day, and only 1 date is collected for the visit. In such a case, the values for SVENDTC duplicate values in SVSTDTC. However, if the data for a visit is actually collected over several physical visits and/or over several days, then SVSTDTC and SVENDTC should reflect this fact. Note that it is fairly common for screening data to be collected over

several days, but for the data to be treated as belonging to a single planned screening visit, even in studies for which all other visits are single-day visits.

12. Differentiating between planned and unplanned visits may be challenging if unplanned assessments (e.g., repeat labs) are performed during the time period of a planned visit.
13. Algorithms for populating SVSTDTC and SVENDTC from the dates of assessments performed at a visit may be particularly challenging for screening visits, since baseline values collected at a screening visit are sometimes historical data from tests performed before the subject started screening for the trial. Therefore dates prior to informed consent are not part of the determination of SVSTDTC.
14. The following Identifier variables are permissible and may be added as appropriate: --SEQ, --GRPID, --REFID, and --SPID.
15. Care should be taken in adding additional timing variables:
 - a. If TAETORD and/or EPOCH are added, then the values must be those at the start of the visit.
 - b. The purpose of --DTC and --DY in other domains with start and end dates (Event and Intervention Domains) is to record the date on which data was collected. For a visit that occurred, it is not necessary to submit the date on which information about the visit was recorded. When SVPRESP = "Y" and SVOCCUR = "N", --DTC and --DY are available for use to represent the date on which it was recorded that the visit did not take place.
 - c. --DUR could be added if the duration of a visit was collected.
 - d. It would be inappropriate to add the variables that support time points (--TPT, --TPTNUM, --ELTM, --TPTREF, and --RFTDTC), because the topic of this dataset is visits.
 - e. --STRF and --ENRF could be used to say whether a visit started and ended before, during, or after the study reference period, although this seems unnecessary.
 - f. --STRTPT, --STTPT, --ENRTPT, and --ENTPT could be used to say that a visit started or ended before or after particular dates, although this seems unnecessary.
16. SVOCCUR = "N" records are only to be created for planned visits that were expected to occur before the end of the subject's participation.

2.8.10.26 SDTM Substance Use (SU)

Description

An interventions domain that contains information on the use of recreational products such as caffeine, alcohol, tobacco/nicotine, and other recreational drugs that may be of interest to the study.

su.xpt, Substance Use — Interventions. One record per substance type per reported occurrence per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SU	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SUSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
SUGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
SUSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database. Example: Line number on a Tobacco & Alcohol Use CRF page.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
SUTRT	Reported Name of Substance	Char		Topic	Substance name. Examples: "CIGARETTES", "COFFEE".	Req
SUMODIFY	Modified Substance Name	Char		Synonym Qualifier	If SUTRT is modified, then the modified text is placed here.	Perm
SUDECOD	Standardized Substance Name	Char		Synonym Qualifier	Standardized or dictionary-derived text description of SUTRT or SUMODIFY if the applicant chooses to code the substance use.	Perm
SUCAT	Category for Substance Use	Char		Grouping Qualifier	Used to define a category of related records. Examples: "TOBACCO", "ALCOHOL", or "CAFFEINE".	Perm
SUSCAT	Subcategory for Substance Use	Char		Grouping Qualifier	A further categorization of substance use. Examples: "CIGARS", "CIGARETTES", "BEER", "WINE".	Perm
SUPRESP	SU Pre-Specified	Char	(NY)	Variable Qualifier	Used to indicate whether ("Y"/null) information about the use of a specific substance was solicited on the CRF.	Perm
SUOCCUR	SU Occurrence	Char	(NY)	Record Qualifier	When the use of specific substances is solicited, SUOCCUR is used to indicate whether ("Y"/"N") a particular prespecified substance was used. Values are null for substances not specifically solicited.	Perm
SUSTAT	Completion Status	Char	(ND)	Record Qualifier	When the use of prespecified substances is solicited, the completion status indicates that there was no response to the question about the prespecified substance. When there is no prespecified list on the CRF, then the completion status indicates that substance use was not assessed for the subject.	Perm
SUREASND	Reason Substance Use Not Collected	Char		Record Qualifier	Describes the reason substance use was not collected. Used in conjunction with SUSTAT when value of SUSTAT is "NOT DONE".	Perm
SUCLAS	Substance Use Class	Char		Variable Qualifier	Substance use class. May be obtained from coding. When coding to a single class, populate with class value. If using a dictionary and coding to multiple classes, then follow Section 2.8.7.3, Adhering to Dataset Record Structure , or omit SUCLAS.	Perm
SUCLASCD	Substance Use Class Code	Char		Variable Qualifier	Code corresponding to SUCLAS. May be obtained from coding.	Perm
SUDOSE	Substance Use Consumption	Num		Record Qualifier	Amount of SUTRT consumed. Not populated if SUDOSTXT is populated.	Perm
SUDOSTXT	Substance Use Consumption Text	Char		Record Qualifier	Substance use consumption amounts or a range of consumption information collected in text form. Not populated if SUDOSE is populated.	Perm
SUDOSU	Consumption Units	Char	(UNIT)	Variable Qualifier	Units for SUDOSE, SUDOSTOT, or SUDOSTXT. Examples: "oz", "CIGARETTE", "PACK", "g".	Perm
SUDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for SUTRT. Examples: "INJECTABLE", "LIQUID", "POWDER".	Perm
SUDOSFRQ	Use Frequency Per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of SUDOSE within a specific time period. Example: "Q24H" (every day).	Perm
SUDOSTOT	Total Daily Consumption	Num		Record Qualifier	Total daily use of SUTRT using the units in SUDOSU. Used when dosing is collected as total daily dose. If an applicant needs to aggregate the data over a period other than daily, then the aggregated total could be recorded in a supplemental qualifier variable.	Perm
SURROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for SUTRT. Examples: "ORAL", "INTRAVENOUS".	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm for the element in which the substance use started. Null for substances that started before study participation.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the substance use. Null for substances that started before study participation.	Perm
SUSTDTC	Start Date/Time of Substance Use	Char	ISO 8601 datetime or interval	Timing	Start date/time of the substance use represented in ISO 8601 character format.	Perm
SUENDTC	End Date/Time of Substance Use	Char	ISO 8601 datetime or interval	Timing	End date/time of the substance use represented in ISO 8601 character format.	Perm
SUSTDY	Study Day of Start of Substance Use	Num		Timing	Study day of start of substance use relative to the applicant-defined RFSTDTC.	Perm
SUENDY	Study Day of End of Substance Use	Num		Timing	Study day of end of substance use relative to the applicant-defined RFSTDTC.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
SUDUR	Duration of Substance Use	Char	ISO 8601 duration	Timing	Collected duration of substance use in ISO 8601 format. Used only if collected on the CRF and not derived from start and end date/times.	Perm
SUSTRF	Start Relative to Reference Period	Char	(STENRF)	Timing	Describes the start of the substance use relative to the applicant-defined reference period. The applicant-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR" was collected, this information may be translated into SUSTRF.	Perm
SUENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the substance use with relative to the applicant-defined reference period. The applicant-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). If information such as "PRIOR", "ONGOING", or "CONTINUING" was collected, this information may be translated into SUENRF.	Perm
SUSTRTPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the start of the substance as being before or after the reference time point defined by variable SUSTTPT.	Perm
SUSTTPT	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by SUSTRTPT. Examples: "2003-12-15", "VISIT 1".	Perm
SUENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the substance as being before or after the reference time point defined by variable SUENTPT.	Perm
SUENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by SUENRTPT. Examples: "2003-12-25", "VISIT 2".	Perm

Assumptions

1. Substance use information may be independent of planned study evaluations, or may be a key outcome (e.g., planned evaluation) of a clinical study.
 - a. In many clinical studies, detailed substance use information as provided for in the domain model above may not be required (e.g., the only information collected may be a response to the question "Have you ever smoked tobacco?"); in such cases, many of the qualifier variables would not be submitted.
 - b. SU may contain responses to questions about use of prespecified substances as well as records of substance use collected as free text.
2. SU description and coding
 - a. SUTRT captures the verbatim or the prespecified text collected for the substance. It is the topic variable for the SU dataset. SUTRT is a required variable and must have a value.
 - b. SUMODIFY is a permissible variable and should be included if coding is performed and the applicant's procedure permits modification of a verbatim substance use term for coding. The modified term is listed in SUMODIFY. The variable may be populated as per the applicant's procedures.
 - c. SUDECOD is the preferred term derived by the applicant from the coding dictionary if coding is performed. It is a permissible variable. Where deemed necessary by the applicant the verbatim term (SUTRT) should be coded using a standard dictionary such as WHO Drug. The applicant is expected to provide the dictionary name and version used to map the terms utilizing the external codelist element in the Define-XML document.
3. Additional categorization and grouping
 - a. SUCAT and SUSCAT should not be redundant with the domain code or dictionary classification provided by SUDECOD, or with SUTRT. That is, they should provide a different means of defining or classifying SU records. For example, an applicant may be interested in identifying all substances that the investigator feels might represent opium use, and to collect such use on a separate CRF page. This categorization might differ from the categorization derived from the coding dictionary.

- b. SUGRPID may be used to link (or associate) different records together to form a block of related records within SU at the subject level). It should not be used in place of SUCAT or SUSCAT.
4. Timing variables
- a. SUSTDTC and SUENDTC may be populated as required.
 - b. If substance use information is collected more than once within the CRF (indicating that the data are visit-based) then VISITNUM would be added to the domain as an additional timing variable. VISITDY and VISIT would then be permissible variables.
5. Any additional qualifiers from the Interventions class may be added to the SU domain, but the following qualifiers would generally not be used: --MOOD, --LOT.

2.8.10.27 SDTM Supplemental Qualifiers (SUPP--)

Description

A relationship dataset used to describe nonstandard variables and their association to parent records in general-observation class datasets.

supp--.xpt, Supplemental Qualifiers for [domain name] — Relationship. One record per supplemental qualifier per related parent domain record(s), Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Study identifier of the parent record(s).	Req
RDOMAIN	Related Domain Abbreviation	Char	(DOMAIN)	Identifier	Two-character abbreviation for the domain of the parent record(s).	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Unique subject identifier of the parent record(s).	Req
IDVAR	Identifying Variable	Char		Identifier	Identifying variable in the dataset that identifies the related record(s). Examples: --SEQ, --GRPID.	Exp
IDVARVAL	Identifying Variable Value	Char		Identifier	Value of identifying variable of the parent record(s).	Exp
QNAM	Qualifier Variable Name	Char		Topic	The short name of the Qualifier variable, which is used as a column name in a domain view with data from the parent domain. The value in QNAM cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). QNAM cannot contain characters other than letters, numbers, or underscores. This will often be the column name in the applicant's operational dataset.	Req
QLABEL	Qualifier Variable Label	Char		Synonym Qualifier	This is the long name or label associated with QNAM. The value in QLABEL cannot be longer than 40 characters. This will often be the column label in the applicant's original dataset.	Req
QVAL	Data Value	Char		Result Qualifier	Result of, response to, or value associated with QNAM. A value for this column is required; no records can be in SUPP-- with a null value for QVAL.	Req
QORIG	Origin	Char		Record Qualifier	Since QVAL can represent a mixture of collected (on a CRF), derived, or assigned items, QORIG is used to indicate the origin of this data.	Req
QEVAL	Evaluator	Char		Record Qualifier	Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain objectively collected or derived data. Examples: "ADJUDICATION COMMITTEE", "STATISTICIAN", "DATABASE ADMINISTRATOR", "CLINICAL COORDINATOR".	Exp

Assumptions

There are no additional SUPPQUAL-specific assumptions; all are included in Section 2.8.5.3, [Relating NSVs and Attributions to a Domain](#).

2.8.10.28 SDTM Tobacco Product Events and Malfunctions (EM)

Description

An events domain for representing tobacco product device events, issues, and malfunctions that may occur during its use or testing. Since events may or may not be associated with a subject, USUBJID is a permissible variable.

em.xpt, Tobacco Product Events and Malfunctions — Events. One record per event or malfunction per tobacco product device, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	EM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Permissible rather than required because events may happen to or with a tobacco product device that do not involve subjects, and may even be before the tobacco product device was in contact with a subject. Should be used when the malfunction is associated with a subject's use or possession of the tobacco product device.	Perm
SPTOBID	Applicant-Defined Tobacco Product ID	Char		Identifier	Identifier used to uniquely identify a tobacco product across all studies for all applications/submissions involving the product.	Req
EMSEQ	Device Events Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of records.	Req
EMSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. Perhaps defined in the applicant's operational database. Note that it does not have to be numeric.	Perm
EMTERM	Reported Term for Device Event	Char		Topic	Verbatim name of the observed event. Examples: "Battery malfunction", "Overheating".	Req
EMMODIFY	Modified Device Event Name	Char		Synonym Qualifier	The modified text for EMTERM. If EMTERM is modified, then the modified text is placed here.	Perm
EMDECOD	Device Events Dictionary-Derived Term	Char		Synonym Qualifier	Dictionary-derived text description of EMTERM or EMMODIFY. Note: CDISC does not prescribe what standardized or dictionary-derived text should be used. The name and version of the dictionary used to map terms must be provided to reviewers.	Perm
EMCAT	Category of Device Event	Char		Grouping Qualifier	Used to define a categorization level for events. For example, "MALFUNCTION" vs. "CALIBRATION".	Perm
EMSCAT	Subcategory of Device Event	Char		Grouping Qualifier	Used to define a further category level for events.	Perm
EMPRESP	Pre-Specified Device Event	Char	(NY)	Record Qualifier	Used to indicate whether (Y/null) information about a specific event was solicited on the CRF. For example, EMTERM could contain a list of malfunctions that are being specifically evaluated. EMPRESP would identify those (Y), whereas any spontaneous events would have EMPRESP null.	Perm
EMOCCUR	Device Event Occurrence	Char	(NY)	Record Qualifier	When information about specific events is solicited, EMOCCUR is used to indicate whether or not (Y/N) a particular pre-specified event occurred. Values are null for events not specifically solicited.	Perm
EMSTAT	Device Event Collection Status	Char	(ND)	Record Qualifier	The status indicates that the pre-specified question was not answered. For example, if equipment operation requires checking, such as checking an event log to detect events. Capturing that the checks were not completed may be relevant to interpreting the study data.	Perm
EMREASND	Reason Device Event Not Collected	Char		Record Qualifier	Reason EMSTAT was "NOT DONE". This variable should only be used if there are prespecified events.	Perm
EMSEV	Device Event Severity	Char		Record Qualifier	Describes the severity of the event, (e.g, the severity of a malfunction).	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
EMACNDEV	Action Taken with Device	Char		Record Qualifier	Describes action taken with respect to the tobacco product device (e.g., tobacco product device replacement, battery replacement).	Perm
EMPATT	Pattern of Device Event	Char		Record Qualifier	A characterization of the temporal pattern of occurrences of the tobacco product device event or malfunction.	Perm
VISITNUM	Visit Number	Num		Timing	Clinical encounter number. Numeric version of VISIT, used for sorting.	Perm
VISIT	Visit Name	Char		Timing	Protocol-defined description of clinical encounter. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics. This value is usually derived.	Perm
EMDTC	Date of Device Event Data Collection	Char	ISO 8601 datetime or interval	Timing	Date the tobacco product device event information was collected. This may be reported if the event (e.g., malfunction) is discovered on a different date from the event.	Perm
EMSTDTC	Start Date/Time of Device Event	Char	ISO 8601 datetime or interval	Timing	Start date/time of the tobacco product device event. If the event happened at a single point in time, EMSTDTC is used.	Perm
EMENDTC	End Date/Time of Device Event	Char	ISO 8601 datetime or interval	Timing	End date/time of the tobacco product device event. If an event lasted over a period of time, EMENDTC can be used to capture the end date/time.	Perm
EMDY	Study Day of Start of Tracking Event	Num		Timing	Study day of tobacco product device event observation, measured as integer days. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in Demographics.	Perm
EMSTDY	Study Day of Device Event Start	Num		Timing	Study day of start of tobacco product device event, measured as integer days. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in Demographics.	Perm
EMENDY	Study Day of Device Event End	Num		Timing	Study day of end of tobacco product device event, measured as integer days. Algorithm for calculations must be relative to the applicant-defined RFENDTC variable in Demographics.	Perm

Assumptions

1. EM captures information about a variety of activities (e.g., malfunctions, calibrations, parts replacement) that can occur to or with tobacco product devices. It is an optional domain, to be used only if the applicant has events that should be reported or that they otherwise want to track. Records are specific to an individual device (SPTOBID). The entries may or may not be related to a study subject. EM is not to be used for non-tobacco-product device events.
2. Events represented in the EM domain will be consistent with scientific and regulatory requirements. It is the applicant's responsibility to define an event and the appropriate collection period for events. This definition may vary based on product characterization and reporting of product safety. In consultation with regulatory authorities, applicants may extend or limit the scope of event collection.
3. USUBJID is Permissible in this domain, but should only be populated if the device event is associated with a subject's use of the product. See the CDISC Notes column in the specification for further explanation.
4. If a malfunction or other event results in an adverse experience for a subject, then that information should be recorded in the AE domain. See Section 2.8.10.1, [Adverse Events \(AE\)](#), for more information on how to represent subject adverse experiences. See also Section 2.8.5.2, [Relating Subject Records and Datasets](#), for information on how to relate the records between EM and AE.
5. EMSTDTC is the date/time of the device event. EMENDTC (end date/time) can be used, for example, if a malfunction occurs during a deployment and it is repaired later.
6. If this domain is used to capture device malfunctions and a controlled terminology coding dictionary is used to code the event, then any codes beyond the value shown in EMDECOD can be included as NSVs.

2.8.10.29 SDTM Trial Arms (TA)

Description

A trial design domain that contains each planned arm in the trial.

ta.xpt, Trial Arms — Trial Design. One record per planned Element per Arm, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TA	Identifier	Two-character abbreviation for the domain.	Req
ARMCD	Planned Arm Code	Char		Topic	ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than that for other "short" variables to accommodate the kind of values that are likely to be needed for crossover studies/trials. For example, if ARMCD values for a 7-period crossover were constructed using 2-character abbreviations for each product and separating hyphens, the length of ARMCD values would be 20.	Req
ARM	Description of Planned Arm	Char		Synonym Qualifier	Name given to an arm or exposure group.	Req
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the order of the element within the arm.	Req
ETCD	Element Code	Char		Record Qualifier	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that ETCD will need to serve as a variable name.	Req
ELEMENT	Description of Element	Char		Synonym Qualifier	The name of the element. The same element may occur more than once within an arm.	Perm
TABRANCH	Branch	Char		Rule	Condition subject met, at a "branch" in the study/trial design at the end of this element, to be included in this arm (e.g., "Randomization to PRODUCT X").	Exp
TATRANS	Transition Rule	Char		Rule	If the study/trial design allows a subject to transition to an element other than the next element in sequence, then the conditions for transitioning to those other elements, and the alternative element sequences, are specified in this rule (e.g., "Responders go to washout").	Exp
EPOCH	Epoch	Char	(EPOCH)	Timing	Name of the epoch with which this element of the arm is associated.	Req

Assumptions

1. TAETORD is an integer. In general, the value of TAETORD is 1 for the first element in each arm, 2 for the second element in each arm, and so on. Occasionally, it may be convenient to skip some values (see Example Trial 6). Although the values of TAETORD need not always be sequential, their order must always be the correct order for the elements in the arm path.
2. Elements in different arms with the same value of TAETORD may or may not be at the same time, depending on the design of the trial. The example trials illustrate a variety of possible situations. The same element may occur more than once within an arm.
3. TABRANCH describes the outcome of a branch decision point in the trial design for subjects in the arm. A branch decision point takes place between epochs, and is associated with the element that ends at the decision point. For instance, if subjects are assigned to an arm where they receive product A through a randomization at the end of element X, the value of TABRANCH for element X would be "Randomized to A."
4. Branch decision points may be based on decision processes other than randomizations (e.g., clinical evaluations of disease response, subject choice).
5. There is usually some gap in time between the performance of a randomization and the start of randomized product. However, in many trials this gap in time is small and it is highly unlikely that subjects will leave

the trial between randomization and product. In these circumstances, the trial does not need to be modeled with this time period between randomization and start of product as a separate element.

6. Some trials include multiple paths that are closely enough related so that they are all considered to belong to 1 arm. In general, this set of paths will include a "complete" path along with shorter paths that skip some elements. The sequence of elements represented in the trial arms should be the complete, longest path. TATRANS describes the decision points that lead to a shortened path within the arm.
7. If an element does not end with a decision that could lead to a shortened path within the arm, then TATRANS will be blank. If there is such a decision, TATRANS will be in a form like, "If condition X is true, then go to epoch Y" or "If condition X is true, then go to element with TAETORD = 'Z'".
8. EPOCH is not strictly necessary for describing the sequence of elements in an arm path, but it is the conceptual basis for comparisons between arms and also provides a useful way to talk about what is happening in a blinded trial while it is blinded. During periods of blinded product, blinded participants will not know which arm and element a subject is in, but EPOCH should provide a description of the time period that does not depend on knowing arm.
9. EPOCH should be assigned in such a way that elements from different arms with the same value of EPOCH are "comparable" in some sense. The degree of similarity across arms varies considerably in different trials, as illustrated in the examples.
10. EPOCH values for multiple similar epochs:
 - a. When a study design includes multiple epochs with the same purpose (e.g., multiple similar product epochs), it is recommended that the EPOCH values be terms from controlled terminology, but with numbers appended. For example, multiple product epochs could be represented using "PRODUCT 1", "PRODUCT 2", and so on. Because the codelist is extensible, this convention allows multiple similar epochs to be represented without adding numbered terms to the CDISC Controlled Terminology for epoch. The inclusion of multiple numbered terms in the EPOCH codelist is not considered to add value.
 - b. Note that the controlled terminology does include some more granular terms for distinguishing between epochs that differ in ways other than mere order, and these terms should be used where applicable, as they are more informative.
11. Note that study cells are not explicitly defined in the TA dataset. A set of records with a common value of both ARMCD and EPOCH constitute the description of a study cell. Transition rules within this set of records are also part of the description of the study cell.
12. EPOCH may be used as a timing variable in other datasets, such as Exposure (EX) and Disposition (DS), and values of EPOCH must be different for different epochs. For instance, in a crossover trial with 3 product epochs, each must be given a distinct name; all 3 cannot be called "PRODUCT".

2.8.10.30 SDTM Trial Elements (TE)

Description

A trial design domain that contains the element code that is unique for each element, the element description, and the rules for starting and ending an element.

te.xpt, Trial Elements — Trial Design. One record per planned Element, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TE	Identifier	Two-character abbreviation for the domain.	Req
ETCD	Element Code	Char		Topic	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					programming, but it is not expected that ETCD will need to serve as a variable name.	
ELEMENT	Description of Element	Char		Synonym Qualifier	The name of the element.	Req
TESTRL	Rule for Start of Element	Char		Rule	Describes condition for beginning element.	Req
TEENRL	Rule for End of Element	Char		Rule	Describes condition for ending element. Either TEENRL or TEDUR must be present for each element.	Perm
TEDUR	Planned Duration of Element	Char	ISO 8601 duration	Timing	Planned duration of element in ISO 8601 format. Used when the rule for ending the element is applied after a fixed duration.	Perm

Assumptions

1. There are no gaps between elements. The instant one element ends, the next element begins. A subject spends no time “between” elements.
2. The ELEMENT (Description of the Element) variable usually indicates the product being administered during an element, or, if no product is being administered, the other activities that are the purpose of this period of time (e.g., "Screening", "Follow-up", "Washout"). In some cases, this time period may be quite passive (e.g., "Rest"; "Wait, for disease episode").
3. The TESTRL (Rule for Start of Element) variable identifies the event that marks the transition into this element. For elements that involve product, this is the start of product administration.
4. For elements that do not involve product, TESTRL can be more difficult to define. For washout and follow-up elements, which always follow product exposure elements, the start of the element may be defined relative to the end of a preceding product administration. For example, a washout period might be defined as starting 24 or 48 hours after the last dose of product for the preceding product exposure element or epoch. This definition is not totally independent of the TA dataset, because it relies on knowing where in the study/trial design the element is used, and that it always follows a product exposure element. Defining a clear starting point for the start of a non-product exposure element that always follows another non-product exposure element can be particularly difficult. The transition may be defined by a decision-making activity such as enrollment or randomization. For example, every arm of a study/trial that involves treating disease episodes might start with a screening element followed by an element that consists of waiting until a disease episode occurs. The activity that marks the beginning of the wait element might be randomization.
5. TESTRL for a product exposure element may be thought of as “active” whereas the start rule for a non-product exposure element—particularly a follow-up or washout element—may be “passive.” The start of a product exposure element will not occur until a dose is given, no matter how long that dose is delayed. Once the last dose is given, the start of a subsequent non-product exposure element is inevitable, as long as another dose is not given.
6. Note that the date/time of the event described in TESTRL will be used to populate the date/times in the Subject Elements (SE) dataset, so the date/time of the event should be captured in the CRF.
7. Specifying TESTRL for an element that serves the first element of an arm in the TA dataset involves defining the start of the study/trial. In the examples in this document, obtaining informed consent has been used as "Trial Entry."
8. TESTRL should be expressed without referring to arm. If the element appears in more than 1 arm in the TA dataset, then the element description (ELEMENT) **must not** refer to any arms.
9. TESTRL should be expressed without referring to epoch. If the element appears in more than 1 epoch in the TA dataset, then the Element description (ELEMENT) **must not** refer to any epochs.
10. For a blinded study/trial, it is useful to describe TESTRL in terms that separate the properties of the event that are visible to blinded participants from the properties that are visible only to those who are unblinded. For product exposure elements in blinded studies/trials, wording such as the following is suitable: "First dose of study product for an exposure epoch, where study product is X."

11. Element end rules are rather different from element start rules. The actual end of one element is the beginning of the next element. Thus, the element end rule does not give the conditions under which an element does end, but the conditions under which it *should* end or is *planned to* end.
12. At least 1 of TEENRL and TEDUR must be populated. Both may be populated.
13. TEENRL describes the circumstances under which a subject should leave this element. Element end rules may depend on a variety of conditions. The TA dataset, not the TE dataset, describes where the subject moves next, so TEENRL must be expressed without referring to arm.
14. TEDUR serves the same purpose as TEENRL for the special (but very common) case of an element with a fixed duration. TEDUR is expressed in ISO 8601. For example, a TEDUR value of P6W is equivalent to a TEENRL of "6 weeks after the start of the element."
15. Note that elements that have different start and end rules are different elements and must have different values of ELEMENT and ETCD. For instance, elements that involve the same product but have different durations are different elements. The same applies to non-product exposure elements. For instance, a washout with a fixed duration of 14 days is different from a washout that is to end after 7 days if product cannot be detected in a blood sample, or after 14 days otherwise.

2.8.10.31 SDTM Trial Inclusion/Exclusion Criteria (TI)

Description

A trial design domain that contains one record for each of the inclusion and exclusion criteria for the trial. This domain is not subject oriented.

ti.xpt, Trial Inclusion/Exclusion Criteria — Trial Design. One record per I/E criterion, Tabulation

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TI	Identifier	Two-character abbreviation for the domain.	Req
IETESTCD	Incl/Excl Criterion Short Name	Char		Topic	Short name IETEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in IETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). IETESTCD cannot contain characters other than letters, numbers, or underscores. The prefix "IE" is used to ensure consistency with the IE domain.	Req
IETEST	Inclusion/Exclusion Criterion	Char		Synonym Qualifier	Full text of the inclusion or exclusion criterion. The prefix "IE" is used to ensure consistency with the IE domain.	Req
IECAT	Inclusion/Exclusion Category	Char	(IECAT)	Grouping Qualifier	Used for categorization of the inclusion or exclusion criteria.	Req
IESCAT	Inclusion/Exclusion Subcategory	Char		Grouping Qualifier	A further categorization of the exception criterion. Can be used to distinguish criteria for a sub-study or to categorize as major or minor exceptions. Examples: "MAJOR", "MINOR".	Perm
TIRL	Inclusion/Exclusion Criterion Rule	Char		Rule	Rule that expresses the criterion in computer-executable form.	Perm
TIVERS	Protocol Criteria Versions	Char		Record Qualifier	The number of this version of the inclusion/exclusion criteria. May be omitted if there is only 1 version.	Perm

Assumptions

1. If inclusion/exclusion criteria were amended during the trial, then each complete set of criteria must be included in the TI domain. TIVERS is used to distinguish between the versions.
2. Protocol version numbers should be used to identify criteria versions, although there may be more versions of the protocol than versions of the inclusion/exclusion criteria. For example, a protocol might have versions 1, 2, 3, and 4, but if the inclusion/exclusion criteria in version 1 were unchanged through versions 2 and 3, and changed only in version 4, then there would be 2 sets of inclusion/exclusion criteria in TI: one for version 1 and one for version 4.

3. Individual criteria do not have versions. If a criterion changes, it should be treated as a new criterion, with a new value for IETESTCD. If criteria have been numbered and values of IETESTCD are generally of the form INCL00n or EXCL00n, and new versions of a criterion have not been given new numbers, separate values of IETESTCD might be created by appending letters (e.g., INCL003A, INCL003B).
4. IETEST contains the text of the inclusion/exclusion criterion. However, because entry criteria are rules, the variable TIRL has been included in anticipation of the development of computer-executable rules.
5. If a criterion text is <200 characters, it goes in IETEST; if the text is >200 characters, put meaningful text in IETEST and describe the full text in the study metadata.

2.8.10.32 SDTM Trial Summary (TS)

Description

A trial design domain that contains one record for each trial summary characteristic. This domain is not subject oriented.

ts.xpt, Trial Summary — Trial Design. One record per trial summary parameter value, Tabulation

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TS	Identifier	Two-character abbreviation for the domain.	Req
TSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a parameter. Allows inclusion of multiple records for the same TSPARMCD.	Req
TSGRPID	Group ID	Char		Identifier	Used to tie together a group of related records.	Perm
TSPARMCD	Trial Summary Parameter Short Name	Char	(TSPARMCD)	Topic	TSPARMCD (the companion to TSPARM) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that TSPARMCD will need to serve as variable names. Examples: "AGEMIN", "AGEMAX".	Req
TSPARM	Trial Summary Parameter	Char	(TSPARM)	Synonym Qualifier	Term for the trial summary parameter. The value in TSPARM cannot be longer than 40 characters. Examples: "Planned Minimum Age of Subjects", "Planned Maximum Age of Subjects".	Req
TSVAL	Parameter Value	Char		Result Qualifier	Value of TSPARM. Example: "ASTHMA" when TSPARM value is "Trial Indication". TSVAL can only be null when TSVALNF is populated. Text over 200 characters can be added to additional columns TSVAL1-TSVALn.	Exp
TSVALNF	Parameter Value Null Flavor	Char	ISO 21090 NullFlavor	Result Qualifier	Null flavor for the value of TSPARM, to be populated only if TSVAL is null.	Perm
TSVALCD	Parameter Value Code	Char		Result Qualifier	This is the code of the term in TSVAL. For example, "6CW7F3G59X" is the code for gabapentin; "C49488" is the code for Y. The length of this variable can be longer than 8 to accommodate the length of the external terminology.	Exp
TSVCDREF	Name of the Reference Terminology	Char	(DICTNAM)	Result Qualifier	The name of the reference terminology from which TSVALCD is taken. For example; CDISC CT, SNOMED, ISO 8601.	Exp
TSVCDVER	Version of the Reference Terminology	Char		Result Qualifier	The version number of the reference terminology, if applicable.	Exp

Assumptions

1. The intent of this dataset is to provide a summary of study/trial information. This is not subject-level data.
2. Recipients may specify their requirements for which study/trial summary parameters should be included under which circumstances.
3. The order of parameters in the examples of TS datasets should not be taken as a requirement. There are no requirements or expectations about the order of parameters within the TS dataset.

4. The method for treating text >200 characters in TS is similar to that used for the Comments (CO) special-purpose domain. If TSVAL is >200 characters, then it should be split into multiple variables, TSVAL-TSVALn.
5. A list of values for TSPARM and TSPARMCD can be found in CDISC Controlled Terminology.
6. Controlled terminology for TSPARM is extensible. The meaning of any added parameters should be explained in the metadata for the TS dataset.
7. For a particular study/trial summary parameter, responses (values in TSVAL) may be numeric, datetimes or amounts of time represented in ISO8601 format, or text. For some parameters, textual responses may be taken from controlled terminology; for others, responses may be free text.
8. For some study/trial summary parameters, CDISC Controlled Terminology includes codelists for use with TSVAL. Recipients may also specify controlled terminology for TSVAL. These specifications may be for study/trial summary parameters for which there is no CDISC Controlled Terminology or they may replace CDISC Controlled Terminology for a study/trial summary parameter.
9. There is a code value for TSVALCD only when there is controlled terminology for TSVAL. For example, when TSPARMCD = "PLANSUB" (Planned Number of Subjects) or TSPARMCD = "TITLE" (Trial Title), then TSVALCD will be null.
10. TSVALNF contains a “null flavor,” a value that provides additional coded information when TSVAL is null. For example, for TSPARM = "AGEMAX" (Planned Maximum Age of Subjects), there is no value if a study does not specify a maximum age. In this case, the appropriate null flavor is "PINF", which stands for "positive infinity." In a clinical pharmacology study conducted in healthy volunteers for a drug where indications are not yet established, the appropriate null flavor for TSPARM = "INDIC" (Trial Disease/Condition Indication) would be "NA" (i.e., not applicable). TSVALNF can also be used in a case where the value of a particular parameter is unknown.
11. Some codelists used for TSVAL include terms which are also null flavors. For example, the Pharmaceutical Dosage Form codelist includes the values "UNKNOWN" and "NOT APPLICABLE". In such cases, TSVAL should have the term from the codelist and TSVALNF should be null.
12. For some studies/trials, there will be multiple records in the TS dataset for a single parameter. For example, a study/trial that addresses both safety and usability testing could have 2 records with TSPARMCD = "TTYPE" (Trial Type), one with the TSVAL = "SAFETY" and the other with TSVAL = "USABILITY TESTING". TSSEQ has a different value for each record for the same parameter.

Note that this is different from datasets that contain subject data, where the --SEQ variable has a different value for each record for the same subject.

13. TS does not contain subject-level data, so there is no restriction analogous to the requirement in subject-level datasets that the blocks bound by TSGRPID are within a subject. TSGRPID can be used to tie together any block of records in the dataset. TSGRPID is most likely to be used when the TS dataset includes multiple records for the same parameter.

For example, if a trial compared administration of a total daily dose given once a day to that dose split over 2 administrations, the TS dataset might include the following records. There are 2 records each for TSPARMCD = "Dose" and TSPARMCD = "DOSFREQ". Records with the same TSGRPID are associated with each other. In this example, dose units are the same for both administration schedules, so only 1 record for DOSU is needed.

TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL
1	A	DOSE	Dose per Administration	50
1	A	DOSFREQ	Dosing Frequency	BID
2	B	DOSE	Dose per Administration	100
2	B	DOSFREQ	Dosing Frequency	Q24H
1		DOSU	Dose Units	mg

14. Protocols vary in how they describe objectives. If the protocol does not provide information about which objectives meet the definition of TSPARM = "OBJPRIM" (Trial Primary Objective; i.e., the principal purpose of the study/trial), then the objectives should be provided as values of TSPARM = "OBJPRIM".

Consult the controlled terminology for trial/study summary parameters for appropriate parameter values for representing other objective designations (e.g., secondary, exploratory).

15. As per the definitions, the primary outcome measure is associated with the primary objective, the secondary outcome measure is associated with the secondary objective, and the exploratory outcome measure is associated with the exploratory objective. It is possible for the same outcome measure to be associated with more than 1 objective. For example, 2 objectives could use the same outcome measure at different time points, or using different analysis methods.
16. If a primary objective is assessed by means of multiple outcome measures, then all of these outcome measures should be provided as values of TSPARM = "OUTMSPR" (Primary Outcome Measure). Similarly, all outcome measures used to assess secondary objectives should be provided as values of TSPARM = "OUTMSSEC" (Secondary Outcome Measure), and all outcome measures used to assess exploratory objectives should be provided as values of TSPARM = "OUTMSEXP" (Exploratory Outcome Measure). Additional key measures of a study that are not designated as primary, secondary, or exploratory should be provided as values of TSPARM = "OUTMSADD" (Additional Outcome Measure).
17. Trial indication: Values for TSVAL when TSPARMCD = "INDIC" would indicate the condition, disease, or disorder the study/trial is intended to investigate or address. A vaccine study of healthy subjects, with the intended purpose of preventing influenza infection, would have TSVAL = "Influenza". A clinical pharmacology study of healthy volunteers, with the purpose of collecting pharmacokinetic data, would have no trial indication; TSVAL would be null and TSVALNF = "NA" if TS contains a row where TSPARMCD = "INDIC".
18. Values for TSVAL when TSPARMCD = "REGID" (Registry Identifier) will be identifiers assigned by the registry (e.g., ClinicalTrials.gov, EudraCT).

2.8.10.33 SDTM Trial Visits (TV)

Description

A trial design domain that contains the planned order and number of visits in the study within each arm.

tv.xpt, Trial Visits — Trial Design. One record per planned Visit per Arm, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TV	Identifier	Two-character abbreviation for the domain.	Req
VISITNUM	Visit Number	Num		Topic	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Req
VISIT	Visit Name	Char		Synonym Qualifier	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Req
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of VISIT. Due to its sequential nature, used for sorting.	Perm
ARMCD	Planned Arm Code	Char		Record Qualifier	1. ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a 7-period crossover were constructed using 2-character abbreviations for each product and separating hyphens, the length of ARMCD values would be 20. 2. If the timing of visits for a trial does not depend on which arm a subject is in, then ARMCD should be null.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
ARM	Description of Planned Arm	Char		Synonym Qualifier	1. Name given to an arm or product exposure group. 2. If the timing of visits for a trial does not depend on which arm a subject is in, then Arm should be left blank.	Perm
TVSTRL	Visit Start Rule	Char		Rule	Rule describing when the visit starts, in relation to the sequence of elements.	Req
TVENRL	Visit End Rule	Char		Rule	Rule describing when the visit ends, in relation to the sequence of elements.	Perm

Assumptions

1. Although the general structure of the Trial Visits (TV) dataset is 1 record per planned visit per arm, for many clinical studies—particularly blinded clinical studies—the schedule of visits is the same for all arms, and the structure of the TV dataset will be 1 record per planned visit. If the schedule of visits is the same for all arms, ARMCD should be left blank for all records in the TV dataset. For studies with study visits that are different for different arms, ARMCD and ARM should be populated for all records. If some visits are the same for all arms, and some visits differ by arm, then ARMCD and ARM should be populated for all records, to ensure clarity, even though this will mean creating near-duplicate records for visits that are the same for all arms.
2. A visit may start in one element and end in another. This means that a visit may start in one epoch and end in another. For example, if one of the activities planned for a visit is the administration of the first dose of study product, the visit might start in the screen epoch and end in a product exposure epoch.
3. TVSTRL describes the scheduling of the visit and should reflect the wording in the protocol. In many studies, all visits are scheduled relative to the study's day 1 (RFSTDTC). In such studies, it is useful to include VISITDY, which is, in effect, a special case representation of TVSTRL.
4. Note that there is a subtle difference between the following 2 examples. In the first case, if visit 3 were delayed for some reason, visit 4 would be unaffected. In the second case, a delay to visit 3 would result in visit 4 being delayed as well.
 - a. Case 1: Visit 3 starts 2 weeks after RFSTDTC. Visit 4 starts 4 weeks after RFSTDTC.
 - b. Case 2: Visit 3 starts 2 weeks after RFSTDTC. Visit 4 starts 2 weeks after visit 3.
5. Many protocols do not give any information about visit ends because visits are assumed to end on the same day they start. In such a case, TVENRL may be left blank to indicate that the visit ends on the same day it starts. Care should be taken to assure that this is appropriate; common practice may be to record data collected over more than 1 day as occurring within a single visit. Screening visits may be particularly prone to collection of data over multiple days. The examples for this domain show how TVENRL could be populated.
6. The values of VISITNUM in the TV dataset are the valid values of VISITNUM for planned visits. Any values of VISITNUM that appear in subject-level datasets that are not in the TV dataset are assumed to correspond to unplanned visits. There will be a one-to-one relationship between values of VISIT and VISITNUM in TV. If a subject-level dataset includes both VISITNUM and VISIT, then records that include values of VISITNUM that appear in the TV dataset should also include the corresponding values of VISIT from the TV dataset.

2.8.10.34 SDTM Vital Signs (VS)

Description

A findings domain that contains measurements including but not limited to blood pressure, temperature, respiration, body surface area, body mass index, height and weight.

vs.xpt, Vital Signs — Findings. One record per vital sign measurement per time point per visit per subject, Tabulation.

Specification

Domain Specification Table

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	VS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
VSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
VSSPID	Applicant-Defined Identifier	Char		Identifier	Applicant-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the applicant's operational database.	Perm
VTESTCD	Vital Signs Test Short Name	Char	(VTESTCD)	Topic	Short name of the measurement, test, or examination described in VTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). VTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "SYSBP", "DIABP", "BMI".	Req
VTEST	Vital Signs Test Name	Char	(VTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in VTEST cannot be longer than 40 characters. Examples: "Systolic Blood Pressure", "Diastolic Blood Pressure", "Body Mass Index".	Req
VSCAT	Category for Vital Signs	Char		Grouping Qualifier	Used to define a category of related records.	Perm
VSSCAT	Subcategory for Vital Signs	Char		Grouping Qualifier	A further categorization of a measurement or examination.	Perm
VSPOS	Vital Signs Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".	Perm
VSORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the vital signs measurement as originally received or collected.	Exp
VSORRESU	Original Units	Char	(VSRESU)	Variable Qualifier	Original units in which the data were collected. The unit for VSORRES. Examples: "in", "LB", "beats/min".	Exp
VSSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from VSORRES in a standard format or standard units. VSSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in VSSTRESPN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in VSORRES, and these results effectively have the same meaning, they could be represented in standard format in VSSTRESC as "NEGATIVE".	Exp
VSSTRESPN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from VSSTRESC. VSSTRESPN should store all numeric test results or findings.	Exp
VSSTRESU	Standard Units	Char	(VSRESU)	Variable Qualifier	Standardized unit used for VSSTRESC and VSSTRESPN.	Exp
VSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a vital sign measurement was not done. Should be null if a result exists in VSORRES.	Perm
VSREASND	Reason Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: "BROKEN EQUIPMENT", "SUBJECT REFUSED". Used in conjunction with VSSTAT when value is "NOT DONE".	Perm
VSLOC	Location of Vital Signs Measurement	Char	(LOC)	Record Qualifier	Location relevant to the collection of vital signs measurement. Example: "ARM" for blood pressure.	Perm
VSLAT	Laterality	Char	(LAT)	Result Qualifier	Qualifier for anatomical location or specimen further detailing laterality. Examples: "RIGHT", "LEFT", "BILATERAL".	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
VSLOBXFL	Last Observation Before Exposure Flag	Char	(NY)	Record Qualifier	Operationally derived indicator used to identify the last non-missing value prior to RFXSTDTC. Should be "Y" or null.	Exp
VSTOX	Toxicity	Char		Variable Qualifier	Description of toxicity quantified by VSTOXGR.	Perm
VSTOXGR	Standard Toxicity Grade	Char		Record Qualifier	Records toxicity grade value using a standard toxicity scale (e.g., NCI CTCAE). If value is from a numeric scale, represent only the number (e.g., "2", not "Grade 2").	Perm
VSCLSIG	Clinically Significant, Collected	Char	(NY)	Record Qualifier	Used to indicate whether a collected observation is clinically significant based on judgment.	Perm
VISITNUM	Visit Number	Num		Timing	1. An assigned numeric identifier that aligns to the chronological order of an encounter. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. The label for a protocol-defined encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the element within the arm.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time at which the assessment was made.	Perm
VSDTC	Date/Time of Measurements	Char	ISO 8601 datetime or interval	Timing	Date and time of the vital signs assessment represented in ISO 8601 character format.	Exp
VSDY	Study Day of Vital Signs	Num		Timing	Study day of vital signs measurements, measured as integer days. Algorithm for calculations must be relative to the applicant-defined RFSTDTC variable in Demographics.	Perm
VSTPT	Planned Time Point Name	Char		Timing	Text description of time when measurement should be taken. This may be represented as an elapsed time relative to a fixed reference point (e.g., time of last dose). See VSTPTNUM and VSTPTREF. Examples: "START", "5 MIN POST".	Perm
VSTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of VSTPT to aid in sorting.	Perm
VSELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Planned elapsed time (in ISO 8601) relative to a planned fixed reference (VSTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 Duration. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by VSTPTREF, "PT8H" to represent the period of 8 hours after the reference point indicated by VSTPTREF.	Perm
VSTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by VSELTM, VSTPTNUM, and VSTPT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".	Perm
VSRTFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Date/time of the reference time point, VSTPTREF.	Perm

Assumptions

1. In cases where the LOINC dictionary is used for vital sign tests, the permissible variable VSLOINC may be used.
2. If a reference range is available for a vital signs test, the variables VSORNRLO, VSORNRHI, VSNRIND from the Findings observation class may be added to the domain. VSORNRLO and VSORNRHI would represent the reference range, and VSNRIND would be used to indicate where a result falls with respect to the reference range (e.g., "HIGH", "LOW"). If toxicity grading is available, values would be represented in the variables VSTOX and VSTOXGR. Clinical significance would be represented in VSCLSIG.
3. Any Identifiers, Timing variables, or Findings general observation class qualifiers may be added to the VS domain, but the following qualifiers would not generally be used: --BODSYS, --XFN, --SPEC, --SPCCND, --FAST.

2.9 Standards for Analysis

ADaM establishes a standard way to build datasets that support analysis needs and the efficient generation, replication, and review of analysis results. Guidance in this section implements ADaM for the TIG Product Description, Product Impact on Individual Health, and Product Impact on Population Health use cases and provides:

- Fundamental principles that apply to all analysis datasets
- Dataset structures
- Metadata for data and results

The TIG covers the fundamentals describing ADaM as well as dataset examples that are typically created to support analyses performed for tobacco submissions.

2.9.1 How to Use Analysis Data Structures

Analysis dataset structures in this guide provide a standard way to build analysis datasets. These structures are captured in the "CLASS OF DATASET" field in the ADaM metadata. Currently ADaM has 3 structures: the Subject-level Analysis Dataset (ADSL), the Basic Data Structure (BDS), and the Structure for Occurrence Data (OCCDS). Analysis datasets that follow the ADaM fundamental principles and other ADaM conventions but do not follow one of these 3 defined structures are considered to be ADaM datasets with a class of ADAM OTHER. Current ADaM standards do not cover non-subject data. A REFERENCE dataset structure has been developed for the TIG and will be considered for inclusion in future versions of ADaM.

For the TIG Product Description use case, ADaM fundamental principles will be followed with identifiers in addition to the currently allowed USUBJID and SPEVID. Current ADaM principles and standards are implemented for the Product Impact on Individual Health use case. For the Product Impact on Population Health use case, the REFERENCE dataset structure addresses reference data which captures historic trends and results that are used as input for study analyses.

The following table describes ADaM dataset structures applicable to TIG use cases.

Use Case	Dataset Structure(s)	Implementation
Product description	ADAM OTHER	Follows ADaM fundamental principles but is not subject based
Product impact on individual health	ADSL, BDS, and OCCDS	Follows ADaM fundamental principles and current ADaM structures
Product impact on population health	REFERENCE	Follows ADaM fundamental principles and the new dataset structure developed for the TIG

Analysis dataset specifications list standard ADaM variables and define the required characteristics of standard variables (columns) that are frequently needed in ADaM datasets. ADaM requires that these variable names be used when a variable that contains the content defined in the predefined ADaM variables sections is included in any ADaM dataset, regardless of dataset class. It also requires these ADaM standard variables be used for the purposes indicated, even if the content of an ADaM variable is a copy of the content of an SDTM dataset variable.

The columns in an ADaM dataset specification table are:

Row	Dataset Specification Column	Purpose of Column Content
1	Variable Name	Specifies the name of the variable in the resulting dataset
2	Variable Label	Specifies a descriptive label for the variable
3	Type	Specifies the data type of the variable. Values for in this column are: <ul style="list-style-type: none"> • Num for numeric data • Char for character or alphanumeric data
4	Controlled Terms, Codelist, or Format	Specifies applicable controlled terminology or formats with which to populate the variable. Values in this column are: <ul style="list-style-type: none"> • Names of one or more CDISC Controlled Terminology codelists, with each codelist name in parentheses • Short references to external terminology (e.g., MedDRA) • The name of an external ISO 8601 format

5	Core	<p>Specifies expectations for inclusion of the variable in the resulting dataset. Values in this column are:</p> <ul style="list-style-type: none"> Req for variables which are Required and must be included in the resulting dataset. However, unlike SDTM a required variable may be null for any record. Cond for variables which must be included in the dataset in certain circumstances Perm for variables for which it is Permissible to include or exclude the variable from the resulting dataset
6	CDISC Notes	<p>Provides additional context for the intended use of the variable and may include:</p> <ul style="list-style-type: none"> A description of the purpose of the variable and/or what the variable means Guidelines for variable use including rules for when or how the variable should be populated, or how the contents should be formatted Example values which could appear in the variable. Such values are intended to support understanding and are not intended to influence decisions regarding what values must be captured in the variable.

2.9.1.1 ADSL Dataset Structure

Data Structure Name	Data Structure Description	Class of Dataset	CDISC Notes
ADSL	Subject-Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET	<p>The label of the ADSL dataset is "Subject-Level Analysis Dataset." In a study, there is only 1 dataset in the class "SUBJECT LEVEL ANALYSIS DATASET", and its name is ADSL. Any other datasets with 1 record per subject would be members of other classes (e.g., the "BASIC DATA STRUCTURE" and "ADAM OTHER" classes).</p> <p>ADSL contains variables such as subject-level population flags, planned and actual product variables, demographic information, randomization factors, subgrouping variables, stratification factors, and important dates. ADSL is used to provide key facts about the subject that are analysis-enabling or which facilitate interpretation of analysis. ADSL is a source for subject-level variables used in other ADaM datasets, such as population flags and product variables. The process for adding ADSL variables into BDS datasets is set by the producer of the datasets.</p> <p><i>It should be noted that although the ADSL contains subject-level variables that are also important in other datasets, there is no requirement that every ADSL variable be present in other analysis datasets.</i> However, at a minimum, any ADSL variable needed to enable analysis (e.g., statistical model covariates, population flags, subgrouping variables) should appear in the analysis dataset. Other ADSL variables may also be included for traceability or other reasons. A variable that is present in both ADSL and any other ADaM dataset must have the same values, type, and label.</p>

2.9.1.2 BDS Dataset Structure

Data Structure Name	Data Structure Description	Class of Dataset	CDISC Notes
BDS	CDISC Basic Data Structure	BASIC DATA STRUCTURE	A BDS dataset contains 1 or more records per subject, per analysis parameter, per analysis timepoint. Analysis timepoint is conditionally required, depending on the analysis. In situations where there is no analysis timepoint, the structure is 1 or more records per subject per analysis parameter.

2.9.1.3 OCCDS Dataset Structure

Data Structure Name	Data Structure Description	Class of Dataset	CDISC Notes
OCCDS	Occurrence Data Structure	OCCURRENCE DATA STRUCTURE	Generally, 1 record per record in SDTM domain (optional: per coding path, per analysis period and/or phase). See Section 1.1, Purpose , for examples of when the analysis data structure might not be 1 record per record in SDTM domain.

2.9.1.4 REFERENDS Dataset Structure

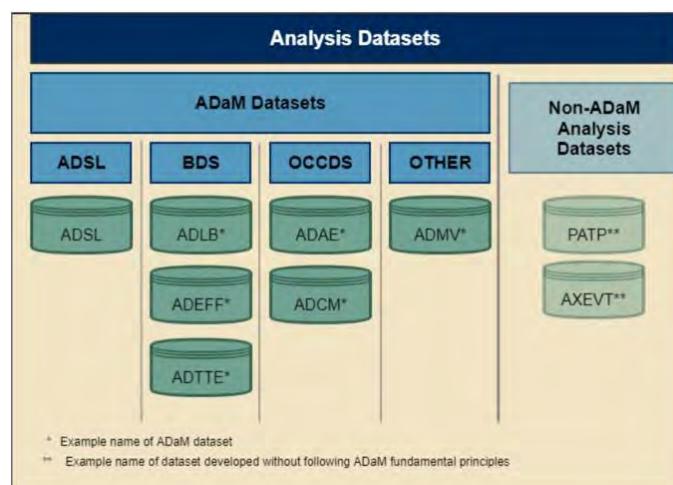
Data Structure Name	Data Structure Description	Class of Dataset	CDISC Notes
REFERENDS	Reference Data Structure	REFERENCE DATA STRUCTURE	Reference dataset names must begin with RF and can contain up to 6 additional characters

2.9.2 Considerations for Designing Analysis Datasets

An ADaM dataset is a particular type of analysis dataset that either:

1. is compliant with one of the ADaM defined structures and follows the ADaM fundamental principles, or
2. follows the ADaM fundamental principles defined in ADaM and adheres as closely as possible to TIG analysis variable naming and other conventions.

The Analysis Dataset Structure



Fundamental Principles

ADaM datasets must adhere to certain fundamental principles:

- ADaM datasets and associated metadata must clearly and unambiguously communicate the content and source of the datasets supporting the statistical analyses performed in a study following ADaM.
- ADaM datasets and associated metadata must provide traceability to show the source or derivation of a value or a variable (i.e., the data's lineage or relationship between a value and its predecessor(s)). The metadata must identify when and how analysis data have been derived or imputed.
- ADaM datasets must be readily usable with commonly available software tools.
- ADaM datasets must be associated with metadata to facilitate clear and unambiguous communication. Ideally the metadata are machine-readable.
- ADaM datasets should have a structure and content that allow statistical analyses to be performed with minimal programming. Such datasets are described as "analysis-ready."
- ADaM datasets contain the data needed for the review and re-creation of specific statistical analyses. It is not necessary to collate data into analysis-ready datasets solely to support data listings or other non-analytical displays.

Traceability

To assist review, ADaM datasets and metadata must clearly communicate how the datasets were created. The verification of derivations in an ADaM dataset requires having at hand the input data used to create the ADaM dataset. A CDISC-conformant submission includes both SDTM and ADaM datasets; therefore, it follows that the

relationship between SDTM and ADaM must be clear. This requirement highlights the importance of traceability between the analyzed data (ADaM) and its input data (SDTM).

Traceability is built by clearly establishing the path between an element and its immediate predecessor. The full path is traced by going from one element to its predecessors, then on to their predecessors, and so on, back to the SDTM datasets, and ultimately to the data collection instrument.

Traceability establishes across-dataset relationships as well as within-dataset relationships. For example, the metadata for supportive variables within the ADaM dataset facilitates the understanding of how (and perhaps why) derived records were created.

There are 2 levels of traceability:

1. **Metadata traceability** facilitates the understanding of the relationship of the analysis variable to its source dataset(s) and variable(s) and is required for ADaM compliance. This traceability is established by describing (via metadata) the algorithm used or steps taken to derive or populate an analysis variable from its immediate predecessor. Metadata traceability is also used to establish the relationship between an analysis result and ADaM dataset(s).
2. **Datapoint traceability** points directly to the specific predecessor record(s) and should be implemented if practical and feasible. This level of traceability can be very helpful when trying to trace a complex data manipulation path. This traceability is established by providing clear links in the data (e.g., by use of a --SEQ variable) to the specific data values used as input for an analysis value. The BDS and OCCDS structures were designed to enable datapoint traceability back to predecessor data.

Traceability would then involve several steps. The analysis results would be linked by appropriate metadata to the data which supports the analytical procedure, those data would be linked to the intermediate analysis data, and the intermediate data would in turn be linked to the source SDTM data. When traceability is successfully implemented, it is possible to identify:

- Information in the ADaM datasets that comes from the SDTM data
- Information that is derived or imputed within the ADaM dataset
- The method used to create derived or imputed data
- Information used for analyses, in contrast to information that is not used for analyses yet is included to support traceability or future analysis

2.9.3 How to Create Analysis Variables

The following sections describe how to create analysis variables in a manner that is conformant to the ADaM standard.

2.9.3.1 General Variable Conventions

Num	Convention
1	To ensure compliance with SAS Version 5 transport file format and Oracle constraints, all ADaM variable names must be no more than 8 characters in length, start with a letter (not underscore), and be composed only of letters (A-Z), underscore (_), and numerals (0-9). All ADaM variable labels must be no more than 40 characters in length. All ADaM character variables must be no more than 200 characters in length.
2	The lower-case letters "w", "xx", "y", and "zz" that appear in a variable name or label in this document must be replaced in the actual variable name or label using the following conventions: <ul style="list-style-type: none"> • The lower-case letter "w" in a variable name (e.g., PHwSDT, PxxSwSDT) is an index for the wth variable where "w" is replaced with a single digit [1-9]. • The letters "xx" in a variable name (e.g., TRTxP, APxxSDT) refer to a specific period where "xx" is replaced with a zero-padded two-digit integer [01-99]. The use of "xx" within a variable name is restricted to the concept of a period, and "xx" is not considered an index. • The lower-case letter "y" in a variable name (e.g., SITEGRy) refers to a grouping or other categorization scheme, an analysis criterion, or an analysis range, and is replaced with an integer [1-99, not zero-padded]. Truncation of the original variable name may be necessary in rare situations when a two-digit index is needed and causes the length of the variable name to exceed 8 characters. In these situations, it is recommended that the same truncation be used for both the character and numeric versions of the variables in a variable pair.

Num	Convention
	<ul style="list-style-type: none"> The lower-case letters "zz" in a variable name (e.g., ANLzzFL) are an index for the zzth variable where "zz" is replaced with a zero-padded two-digit integer [01-99]. Note that the "zz" convention represents a simple counter, while the "xx" convention represents a specific period. If an indexed variable is included in a dataset, there is no requirement that the preceding variable(s) in the sequence be included. For example, a dataset might include ANL02FL but not ANL01FL.
3	Any variable in an ADaM dataset whose name is the same as an SDTM variable, and its label, meaning, and values must not be modified. ADaM adheres to a principle of harmonization known as "same name, same meaning, same values." However, to optimize file size, it is permissible that the length of the variables differ (e.g., trailing blanks may be removed). In many cases it makes sense to copy over a variable from an SDTM dataset. For example, the SDTM variable --SEQ may be useful for traceability. However, in other cases, it is also perfectly acceptable, and might be much better, to create an ADaM variable with a meaningful variable name and clear and unambiguous metadata. An SDTM variable may be somewhat meaningless when removed from its SDTM context. For example, the meaning of the SDTM variable DSDECOD may depend on other SDTM variables such as DSCAT and DSSCAT, and ultimately on how the data were collected and mapped to SDTM in a particular study; thus it may be better to create a clearly defined ADaM variable. In any case, whenever values are modified in any way, it is mandatory to do so in an ADaM variable, and it is prohibited to do so in a variable whose name is that of an SDTM variable.
4	When an ADaM standard variable name has been defined for a specific concept, the ADaM standard variable name must be used, even if the content of an ADaM variable is a direct copy of the content of an SDTM variable. For example, in the creation of an ADaM dataset based on an SDTM LB dataset, even if AVAL is just a copy of LBSTRESN, the dataset must contain AVAL.
5	For variable pairs designated as having a one-to-one relationship within a specified scope (e.g., within a parameter, within a study), if both variables are present in the dataset and there exists a row in that scope on which both variables are populated, then there must be a one-to-one relationship between the two variables on all rows within the scope on which both variables are populated. The scope noted in this document should be considered the minimum level for the mapping; it does not preclude the producer from using a broader level of scope. For example, if a one-to-one relationship is specified as within a PARAM, the producer may elect to use the same one-to-one relationship across all PARAMs within the dataset or study. In addition, note that "within a parameter" means "within a parameter within a dataset."
6	In a pair of corresponding variables (e.g., TRTP and TRTPN), the primary or most commonly used variable does not have the suffix or extension (i.e., N for numeric or C for character). The relevant suffix is used only on the name of the secondary member of the variable pair. For example, in the (TRTP, TRTPN) pair, the primary variable, TRTP, is character, but it is not named TRTPC. Similarly in the (APERIOD, APERIODC) pair, the primary variable, APERIOD, is numeric, but it is not named APERIODN. When a secondary variable is included in the dataset, then the primary variable must also be included. If both variables of a variable pair are present, there must be a one-to-one relationship between the values of the two variables, as described in Item 5 above.
7	In general, if an SDTM character variable is converted to a numeric variable in an ADaM dataset, then it should be named as it is in the SDTM dataset with an "N" suffix added. For example, the numeric version of the DM variable SEX is SEXN in an ADaM dataset, and a numeric version of RACE is RACEN. As stated in item 6, the secondary variable of the variable pair cannot be present in the dataset unless the primary variable is also present. Applying Item 6 to the variable pairs being described in Item 7, the numeric equivalent of the variable cannot be present in the dataset unless the character version is also present. If necessary to keep within the eight-character variable name length limit, the last character may be removed prior to appending the N. Note that this naming scheme applies only to numeric variables whose values have a one-to-one relationship to the values of the equivalent character variables. Note also that this convention does not apply to SDTM date/time ISO8601-formatted character variables converted to ADaM numeric *DT, *TM, and *DTM variables.
8	Variables whose names end in FL are character flag (or indicator) variables with at most two possible non-missing values, Y or N (i.e., yes or no). The name of the corresponding numeric flag (or indicator) variable ends in FN. If the flag is included in an ADaM dataset, the character version (*FL) is required but the corresponding numeric version (*FN) can also be included. If both versions of the flag are included, there must be a one-to-one relationship between the values of the two variables, as described in Section 3.1.4, Flag Variable Conventions.
9	Variables whose names end in GRy, Gy, or CATy are grouping variables, where "y" refers to the grouping scheme or algorithm (not the category within the grouping). For example, SITEGR3 is the name of a variable containing site group (pooled site) names, where the grouping has been done according to the third site-grouping algorithm; SITEGR3 does not mean the third group of sites. Within this document, CATy is the suffix used for categorization of ADaM-specified analysis variables (e.g., CHGCATy categorizes CHG).
10	It is recommended that producer-defined grouping or categorization variables begin with the name of the variable being grouped and end in GRy (e.g., variable ABCGRy is a character description of a grouping or categorization of the values from the ABC variable for analysis purposes). If any grouping of values from an SDTM variable is done, the name of the derived ADaM character grouping variable should begin with the SDTM variable name and end in GRy (GRyN for the numeric equivalent) where y is an integer [1-99, not zero-padded] representing a grouping scheme. For example, if a character analysis variable is created to contain values of Caucasian and Non-Caucasian from the SDTM RACE variable, then it should be named RACEGRy and its numeric equivalent should be named RACEGRyN (e.g., RACEGR1, RACEGR1N). Gy can be used as an abbreviated form of GRy when the use of GRy would create a variable name longer than 8 characters. Truncation of the original variable name may be necessary when appending suffix fragments GRy, GRyN, Gy, or GyN.

2.9.3.2 Timing Variable Conventions

Num	Convention
1	Numeric date, time, and datetime variables should be formatted so as to be human-readable with no loss of precision.
2	Variables whose names end in DT are numeric dates.
3	Variables whose names end in DTM are numeric datetimes.
4	Variables whose names end in TM are numeric times.

Num	Convention
5	If a *DTM and associated *TM variable exist, then the *TM value must match the time part of the *DTM value when the *DTM variable is populated. If a *DTM and associated *DT variable exist, then the *DT value must match the date part of the *DTM value when the *DTM variable is populated.
6	Names of timing start variables end with an S followed by the characters indicating the type of timing (i.e., SDT, STM, SDTM), unless otherwise specified elsewhere in the predefined ADaM variables sections.
7	Names of timing end variables end with an E followed by the characters indicating the type of timing (i.e., EDT, ETM, EDTM), unless otherwise specified elsewhere in the predefined ADaM variables sections.
8	Variables whose names end in DY are relative day variables. In the ADaM as in the SDTM, there is no day 0. If there is a need to create a relative day variable that includes day 0, then its name must not end in DY.
9	ADaM relative day variables need not be anchored by DM.RFSTDTC. The anchor (i.e., reference) date variable must be indicated in the variable-level metadata for the relative day variable. The anchor date variable should also be included in ADSL or the current ADaM dataset to facilitate traceability. Similarly, anchor time variables used to calculate values for ADaM relative time variables must be indicated in the variable-level metadata for the relative time variable, and must be included in ADSL or the current ADaM dataset. Note that it is possible to have different definitions for a relative day (or time) variable (e.g., ADY) in separate datasets, using different anchor dates (or times). For example, the derivation of ADY for product evaluation datasets might be different from that for safety datasets.
10	Section 2.9.3.5, Variable Naming Fragments , presents standard suffix naming conventions for producer-defined supportive variables containing numeric dates, times, datetimes, and relative days, as well as date and time imputation flags. These conventions are applicable to all ADaM datasets. The asterisk that appears in a variable name in the table must be replaced by a suitable character string, so that the actual variable name is meaningful and complies with the restrictions noted in Section 2.9.3.1, General Variable Conventions .
11	The reader is cautioned that the root or prefix (represented by *) of such producer-specified supportive ADaM date, time, and datetime variable names must be chosen with care, to prevent unintended conflicts among other such names and standard numeric versions of possible SDTM variable names. In particular, potentially problematic values for producer-defined roots/prefixes (*) include: <ul style="list-style-type: none"> One-letter prefixes. For an example of the problem, if * is Q, then a date *DT would be QDT; however, a starting date *SDT would be QSDT, which would potentially be confusing if the producer intended QSDT to be something other than the numeric date version of the SDTM variable QSDTC. Two-letter prefixes, except when intentionally chosen to refer explicitly to a specific SDTM domain and its --DTC, --STDTC, and/or --ENDTC variables. For an example of an appropriate intentional use of a 2-letter prefix, if * is LB, then *DT is LBDT, the numeric date version of SDTM variable LBDTC. For an example of the problem, if * is QQ, then a date *DT would be QQDT, which would potentially be confusing if the producer intended QQDT to be something other than the numeric date version of a potential SDTM variable QQDTC. Three-letter prefixes ending in S or E. For an example of the problem, if * is QQS, then a date *DT would be QQS DT, which would potentially be confusing if the producer intended QQS DT to be something other than the numeric date version of a potential SDTM variable QQS DT.
12	In general, all 3 of *DT, *TM, *DTM are not required. Include only the *DT, *TM, and *DTM variables needed for analysis or review. However, when a *DTM variable exists, it is good practice to include a corresponding *DT variable. For more information regarding date and time variable conventions, refer to Section 2.9.6.3, Timing Variables for BDS Datasets .

2.9.3.3 Date and Time Imputation Flag Variables

When a date or time is imputed, it is required that the variable containing the imputed value be accompanied by a date or time imputation flag variable. The variable fragments to be used for these variables are DTF and TMF, as defined in ADaMIG Table 3.1.5.1 (<https://www.cdisc.org/standards/foundational/adam>). DF and TF can be used as abbreviated forms of DTF and TMF, respectively, when the use of DTF or TMF would create a variable name longer than 8 characters. These additional imputation flag variables are conditionally required. The root, identified by "/*", of the names of each pair of variables, *DT and *DTF (or *DF), should be identical. The same is true for the corresponding time and imputation flag variables *TM and *TMF (or *TF). Thus it is good practice to limit roots to 5 characters in length.

Section 2.9.5.6, [Product Timing Variables for ADSL Datasets](#), contains sets of timing variables which share a common prefix, such as TRTSDT, TRTSTM, and TRTSSTM. It should be noted that in many instances in Section 2.9.5.6 [Predefined Standard Variables for ADSL](#), specific DTF and TMF flags are defined within sets of timing variables. However, imputation flags should be created for all date or time variables when imputation has been performed, even if there is not a specific imputation flag variable mentioned in Section 2.9.5.6 [Predefined Standard Variables for ADSL](#). For example, the imputation flag variable has not been listed for EOSDT, but EOSDTF must be present if date imputation was performed.

- As described in Section 2.9.3.5, [Variable Naming Fragments](#), variables whose names end in DTF are date imputation flags. *DTF variables represent the highest level of imputation of the *DT variable based on the source SDTM dataset DTC variable. *DTF = Y if the year is imputed. *DTF = M if year is present and month is imputed. *DTF = D if only day is imputed. *DTF = null if *DT equals the SDTM dataset DTC

variable date part equivalent. If a date was imputed, *DTF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of imputation in *DTM if imputation was done.

2. As described in Section 2.9.3.5, [Variable Naming Fragments](#), variables whose names end in TMF are time imputation flags. *TMF variables represent the level of imputation of the *TM (and *DTM) variable based on the source SDTM dataset DTC variable. *TMF = H if the entire time is imputed. *TMF = M if minutes and seconds are imputed. *TMF = S if only seconds are imputed. *TMF = null if *TM equals the SDTM DTC variable time part equivalent. For a given SDTM DTC variable, if only hours and minutes are ever collected, and seconds are imputed in *DTM as 00, then it is not necessary to set *TMF to "S". However if seconds are generally collected but are missing in a given value of the DTC variable and imputed as 00, or if a collected value of seconds is changed in the creation of *DTM, then *TMF should be set to "S". If a time was imputed *TMF must be populated and is required. Both *DTF and *TMF may be needed to describe the level of imputation in *DTM if imputation was done.

Note that using SDTM --DTC source variables for comparison purposes in analysis algorithms may be problematic in the presence of missing date or time elements. SDTM --DTC variables containing date, time, and datetime values are character strings that, in the presence of missing elements (i.e., year, month, day, hour, minute, second), sort or compare in a manner that may be equivalent to imputation of missing elements with the lowest possible value. For example, if in a given --DTC variable in a dataset, dates are present on all records but time is missing on some records, then within any given date, the records with missing time may sort or compare before the records that contain a value of time. Thus the --DTC variable would sort or compare in a manner that is equivalent to imputing midnight when time is missing. The sort or comparison may work mechanically, but imputing midnight may not be the most appropriate thing to do for statistical analysis. Further, the effective imputation of midnight would be hidden and not made explicit. It is important to consider the implications of implicit or explicit imputation whenever dates, times, or datetimes are compared or sorted.

2.9.3.4 Flag Variable Conventions

Num	Convention
1	The terms "flag" and "indicator" are used interchangeably within this document, and "flag variables" are sometimes referred to simply as "flags."
2	Population flags must be included in a dataset if the dataset is analyzed by the given population. At least 1 population flag is required for datasets used for analysis. A character indicator variable is required for every population that is defined in the SAP. All applicable subject-level population flags must be present in ADSL.
3	Character and numeric subject-level population flag names end in FL and FN, respectively. Similarly, parameter-level population flag names end in PFL and PFN, and record-level population flag names end in RFL and RFN. Please also refer to Section 2.9.3.1, General Variable Conventions .
4	For subject-level character population flag variables: N = no (not included in the population), Y = yes (included). Null values are not allowed.
5	For subject-level numeric population flag variables: 0 = no (not included in the population), 1 = yes (included). Null values are not allowed.
6	For parameter-level and record-level character population flag variables: N = no (not included), Y = yes (included). Null values are allowed.
7	For parameter-level and record-level numeric population flag variables, 0 = no (not included), 1 = yes (included). Null values are allowed.
8	In addition to the population flag variables defined in 2.9.5.3, Population Indicator Variables for ADSL Datasets , other population flag variables may be added to ADaM datasets as needed, and must comply with these conventions.
9	For character flags with variable names that end in FL and that are not population flags, a scheme of Y/N/null, or Y/null may be specified. As indicated in Section 2.9.6.6, Analysis Parameter Criteria Variables for BDS Datasets , and Section 2.9.6.10, Indicator Variables for BDS Datasets , some common character flags use the scheme Y/null. The choice of Y/N/null vs Y/null is dependent on analysis needs. Y/N/null should be used when N and null values need to be analyzed differently. Y/null can be used when the need is to analyze just the Y values. Corresponding 1/0/null and 1/null schemes apply to numeric flags with variable names that end in FN and which are not population indicators.
10	Additional flags may be added if their names and values comply with these conventions.

2.9.3.5 Variable Naming Fragments

There are 2 types of reserved variable fragments described in ADaM: those that are reserved as variable suffix fragments and those that may be used in naming ADaM variables. The suffix variables must be used as listed; if they appear at the end of a variable name, then the variable must match the fragment definition. The other fragments

listed should be used in variable naming if possible but this does not preclude these fragments appearing in a variable name that has a different meaning.

Required Suffix Fragments for Use in Naming ADaM Variables

The following table lists standard suffix fragments (i.e., variable name fragments used as the last part of a variable name) that are required when naming variables in ADaM datasets, as defined in Section 2.9.5, [Predefined Standard Variables for ADSL](#); Section 2.9.6, [Predefined Standard Variables for BDS](#); and Section 2.9.7, [Predefined Standard Variables for OCCDS](#). For these fragments, it is a requirement that the appropriate fragment be used whenever the concept applies and that the fragment is reserved to be used only for the corresponding concept. For example, a variable whose name ends in DT must contain a numeric date, and a variable created to contain a numeric date must have a name ending in DT.

Num	Fragment	CDISC Notes
1	GRy	Suffix used in names of grouping variables, where "y" refers to the grouping scheme or algorithm (not the category within the grouping). Note that GRy can be abbreviated to Gy when necessary to comply with the variable name length limit of 8 characters. The corresponding numeric version of the variable will use the suffix GRyN (or GyN if the Gy abbreviation is used). For more information on grouping variables see Section 2.9.3.1, General Variable Conventions .
2	FL	Suffix used in names of character flag variables, when the valid values of the variable are Y/null or Y/N/null. The corresponding numeric version of the variable will use the suffix FN. For more information on flag variables, see Section 2.9.3.1, General Variable Conventions , and Section 2.9.3.4, Flag Variable Conventions
3	DT	Suffix used in names of numeric date variables. For more information on timing variables, see Section 2.9.3.2, Timing Variable Conventions , and Section 2.9.6.3, Timing Variables for BDS Datasets
4	TM	Suffix used in names of numeric time variables. For more information on timing variables, see Section 2.9.3.2, Timing Variable Conventions , and Section 2.9.6.3, Timing Variables for BDS Datasets , for examples of timing variables. Note that although ADaM variable ARELTM ends in TM, it is an exception, and is not a numeric time variable. In addition, the SDTM variables -- ELTM are not numeric time variables.
5	DTM	Suffix used in names of numeric datetime variables. For more information on timing variables, see Section 2.9.3.2, Timing Variable Conventions , and Section 2.9.6.3, Timing Variables for BDS Datasets , for examples of timing variables.
6	DTF	Suffix used in names of date imputation flag variables. Note that DTF can be abbreviated to DF to comply with the variable name length limit of 8 characters. For more information, see Section 2.9.6.3, Timing Variables for BDS Datasets , for examples of timing imputation variables.
7	TMF	Suffix used in names of time imputation flag variables. Note that TMF can be abbreviated to TF to comply with the variable name length limit of 8 characters. For more information, see Section 2.9.6.3, Timing Variables for BDS Datasets , for examples of timing imputation variables.
8	DY	Suffix used in names of relative day variables that do not include day 0. For more information on timing variables, see Section 2.9.3.2, Timing Variable Conventions , and Section 2.9.6.3, Timing Variables for BDS Datasets .

Additional Fragments that May Be Used in Naming ADaM Variables

The following table lists additional standard reserved fragments to use as a guide when naming variables in ADaM datasets. This list should be used in addition to the list of timing fragments defined in Section 2.9.6.3, [Timing Variables for BDS Datasets](#), and the fragments defined in the CDISC NSV Registry. It should be noted that some concepts have slightly different fragments in ADaM than in the TIG; the ADaM fragment takes precedence when creating an ADaM variable. When using fragments, the general rule is to use the fragment(s) that best conveys the meaning of the variable within the 8-character limit. This list of fragments is provided as a guideline, not as a requirement.

Num	Fragment	CDISC Notes
1	BL	Baseline. The position of this fragment within the variable name is dependent on the purpose of the variable. Not to be used to support more than 1 baseline definition for AVAL in BDS datasets.
2	CHG	Change. As described below, the position of this fragment within the variable name is dependent on the purpose of the variable. Not to be used to support change from more than one baseline for AVAL in BDS datasets.
3	FU	Follow-up. As described below, the position of this fragment within the variable name is dependent on the purpose of the variable.
4	RU	Run-in. The position of this fragment within the variable name is dependent on the purpose of the variable.
5	SC	Screening. The position of this fragment within the variable name is dependent on the purpose of the variable.
6	TA	Taper. The position of this fragment within the variable name is dependent on the purpose of the variable.
7	TI	Titer. The position of this fragment within the variable name is dependent on the purpose of the variable.
8	U	Units. The position of this fragment is at the end of the variable, as a suffix.

Num	Fragment	CDISC Notes
		To identify the units for a variable, a separate variable can be created, using the name of the original variable with a "U" suffix added. To keep within the 8-character variable name length limit, some truncation may be necessary prior to appending the U. In situations where the units do not vary within the ADaM dataset, it may be preferable to simply include the units in the variable's label and metadata. The approach taken will be determined by the producer, based on the requirements of the analysis and review of the dataset. Note that there is no separate units variable for BDS variables PARAM or AVAL, since the units of AVAL will be included in the value of PARAM.
9	WA	Washout. The position of this fragment within the variable name is dependent on the purpose of the variable.

2.9.3.6 Additional Information

In general, the variable labels specified in Sections 2.9, [Predefined Standard Variables for REFERENCE](#), 2.9.5, [Predefined Standard Variables for ADSL](#), 2.9.6, [Predefined Standard Variables for BDS](#), and 2.9.7, [Predefined Standard Variables for OCCDS](#), are required. There are only 2 exceptions to this rule:

1. Descriptive text is allowed at the end of the labels of variables whose names contain indexes "y" or "zz."
2. Variable labels containing a word or phrase in curly brackets, e.g., {Time} (the label for *TM variables), should be replaced by the producer with appropriate text. The label must contain the bracketed word or phrase somewhere in the text. For example, *STM must use the phrase "Start Time" in the label, so labels such as "Start Time of Rescue Med" or "Rescue Med Start Time" are both valid.

It is important to note that:

- The standard variable labels by no means imply the use of standard derivation algorithms across studies and/or producers.
- When the CDISC Notes for a variable refer to another variable, it is understood that this means "on the same record or row." For example, "The numeric code for TRTP" is understood to mean "The numeric code for TRTP on the same record."

Controlled terminology has been developed for the values of certain ADaM variables. The most current CDISC terminology sets can be accessed at <http://www.cdisc.org/terminology>. In the tables in this section, the parenthesized external codelist name appears in the Codelist/Controlled Terms column, where relevant. Examples of controlled terms in this document should be considered examples only; the official source is the most current CDISC set available through the website.

Note that CDISC Controlled Terminology sets cannot represent null (absence of a value) in the list of valid terms because "null" is not a term. However, unless specified in the definition for a specific variable, null is allowed.

Additional variables not defined in this section may be necessary (e.g., to enable analysis, to support traceability, to facilitate presentation of the data), and may therefore be added to ADaM datasets, providing that they adhere to the ADaM naming conventions and rules as defined in this document.

2.9.4 How to Describe Analysis Metadata

The underlying assumptions, statistical methods, transformations, derivations and imputations performed in the analysis of a clinical study should be communicated clearly and in such a manner that the values and results can be easily replicated. ADaM metadata facilitates this communication by providing specification of details and links between the general description of the analysis (as found in the protocol's data analysis section, SAP, or the reported analysis methods), the analysis results, the data used in the analysis, and the SDTM domains. The following sections describe in detail the components of the ADaM metadata.

The metadata structures described for the analysis dataset metadata and the analysis variable metadata are based on the Case Report Tabulation Data Definition Specification Standard, version 1.0.0 (CRT-DDS). Refer to that document for additional details.

The examples of metadata included in this document are for illustration only and are not intended to dictate or recommend presentation style, format or process. In addition, the italicized rows included in some of the illustrations are only for reference, as a reminder of the field definitions. It is not intended that this row be included by applicants in metadata.

2.9.4.1 Analysis Dataset Metadata

Analysis dataset metadata provide information about the analysis dataset, including a description of the contents of the dataset. Best practices strongly recommend that every analysis dataset be described using the metadata fields described below.

Num	Analysis Dataset Metadata Field	Description
1	DATASET NAME	The file name of the dataset, hyperlinked to the corresponding analysis dataset variable descriptions (i.e., the data definition table) within the define file.
2	DATASET DESCRIPTION	A short descriptive summary of the contents of the dataset
3	DATASET LOCATION	The folder and filename where the dataset can be found, ideally hyperlinked to the actual dataset (i.e., XPT file)
4	DATASET STRUCTURE	The level of detail represented by individual records in the dataset (e.g., "One record per subject," "One record per subject per visit," "One record per subject per event").
5	KEY VARIABLES OF DATASET	A list of variable names that parallels the structure, ideally uniquely identifies and indexes each record in the dataset.
6	CLASS OF DATASET	Identification of the general class of the dataset using the name of the ADaM structure (i.e., "ADSL," "BDS") or "OTHER" if not an ADaM-specified structure
7	DOCUMENTATION	Description of the source data, processing steps, and analysis decisions pertaining to the creation of the dataset. Software code of various levels of functionality and complexity, such as pseudo-code or actual code fragments may be provided. Links or references to external documents (e.g., protocol, statistical analysis plan, software code) may be used.

2.9.4.2 Analysis Variable Metadata

The analysis variable metadata describe each variable in the analysis dataset, including the variable attributes and definition. The metadata fields used to provide these descriptions are listed below. Best practices strongly recommend that every analysis variable be described using these metadata fields. ADaM-compliant analysis datasets must be described by these analysis variable metadata fields.

How to capture analysis metadata is described in the Define-XML specification (available at <https://www.cdisc.org/standards/data-exchange/define-xml>).

Num	Analysis Variable Metadata Field	Description
1	DATASET NAME	The file name of the analysis dataset
2	VARIABLE NAME	The name of the variable
3	LABEL/DESCRIPTION	A brief description of the variable
4	VARIABLE TYPE	The variable type. Valid values are as defined in the Define-XML specification (e.g., "text", "integer", "float", "date", "datetime").
5	DISPLAY FORMAT	The variable display information (i.e., the format used for the variable in a tabular or graphical presentation of results). It is suggested that the syntax be consistent with the format terminology incorporated in the software package used for analysis (e.g., \$16 or 3.1 if using SAS).
6	CODELIST / CONTROLLED TERMS	A list of valid values or allowable codes and their corresponding decodes for the variable. The field can include a reference to an external codelist (identified by name and version) or a hyperlink to a list of the values in the codelist/controlled terms section of the define file.
7	SOURCE / DERIVATION	<ul style="list-style-type: none"> • Provides details about the variable's lineage—what was the predecessor, where the variable came from in the source data (SDTM or other analysis dataset), or how the variable was derived. This field is used to identify the immediate predecessor source and/or a brief description of the algorithm or process applied to that source and can contain hyperlinked text that refers readers to additional information. • The source/derivation can be as simple as a 2-level name (e.g., ADSL.AGEGR) identifying the data file and variable that is the source of the variable (i.e., a variable copied with no change). It can be a simple description of a derivation and the variable used in the derivation (e.g., "categorization of ADSL.BMI"). It can also be a complex algorithm, where the element contains a complete description of the derivation algorithm and/or a link to a document containing it and/or a link to the analysis dataset creation program.

2.9.4.3 Analysis Parameter Value-Level Metadata

An analysis dataset that follows ADaM BDS (i.e., an analysis dataset of the BDS class) can contain multiple analysis parameters. In a BDS analysis dataset, the variable PARAM contains a unique description for every analysis parameter included in that dataset. The variable PARAMCD contains the short name of the analysis

parameter in PARAM, with a one-to-one mapping between the 2 variables. Each value of PARAM identifies a set of 1 or more rows in the dataset.

The metadata for the columns (variables) in the dataset often depend on the values of PARAM/PARAMCD. This concept is analogous to that of value-level metadata for a single variable in SDTM, but in the BDS it is quite common that the metadata of several variables vary by PARAM/PARAMCD. To describe how variable metadata vary by PARAM/PARAMCD, the metadata element PARAMETER IDENTIFIER is required in variable-level metadata for a BDS analysis dataset. This PARAMETER IDENTIFIER metadata element identifies which variables have metadata that vary depending on PARAM/PARAMCD, and links the metadata for a variable to the appropriate value of PARAM/PARAMCD.

Controlled terminology reduces the need to enter the same metadata for a variable for multiple values of PARAM/PARAMCD:

- The use of “*ALL*” in the PARAMETER IDENTIFIER for a variable indicates that the metadata for that variable is the same for all values of PARAM/PARAMCD in the analysis dataset.
- The use of “*DEFAULT*” in the PARAMETER IDENTIFIER for a variable indicates that the specified metadata for that variable should be considered the metadata for all values of PARAM/PARAMCD in the analysis dataset unless otherwise specified.

A particular value of PARAMCD in the PARAMETER IDENTIFIER for a variable indicates that the specified metadata for that variable should be considered the metadata applicable to the particular PARAMCD, overriding the specified *DEFAULT* metadata, if any.

How to capture analysis metadata is described in the Define-XML specification.

Num	Analysis Variable Metadata Field	Description
1	PARAMETER IDENTIFIER	<p>Contains either:</p> <ul style="list-style-type: none"> the value of PARAMCD that identifies the analysis parameter to which the variable metadata applies; or controlled terminology to indicate groupings of analysis parameters: <ul style="list-style-type: none"> *ALL* - Used when the variable metadata applies to all analysis parameters in the dataset. *DEFAULT* - Used when the variable metadata applies to all analysis parameters in the dataset except for those specifically listed within the metadata.

By referencing the codelist for PARAMCD, the user of the dataset can determine the unique analysis parameter values found in the dataset and is able to determine the analysis parameter-specific attributes and derivation algorithms for each variable when PARAMCD is a specific value.

Note that for the PARAMCD variable, the parameter identifier is “PARAMCD.” The list of values that exist for the variable also serves as an index of the analysis parameters and parameter identifiers included in the analysis dataset.

2.9.4.4 Analysis Results Metadata

Analysis results metadata provide traceability from a result used in a statistical display to the data in the analysis datasets. Although not required, best practice is that this metadata be provided to assist the reviewer by identifying the critical analyses; providing links between results, documentation, and datasets; and documenting the analyses performed.

Analysis results include statistical displays (e.g., text, tabular, or graphical presentation of results) or inferential statements (e.g., *p* values, estimates of product effect). Analysis results metadata provide a link between analysis results and the data used to generate it in a standard format and a predictable location. This allows reviewers to link from an analysis result to important information describing the analysis (e.g., the reason for performing the analysis) and the dataset and selection criteria used to generate the analysis.

Analysis results metadata are not needed or even advisable for every analysis included in a clinical study report or submission. The applicant determines which analyses should have analysis results metadata. For example, the applicant might elect to provide analysis results metadata only for the primary safety analysis and the secondary safety analyses being considered for a marketing claim.

Analysis results metadata describe the major attributes of a specified analysis result found in a CSR or submission. The metadata fields to be used to describe an analysis result are listed in the following table. The word “display” is used instead of “table” as it is more generic, referring to tabular or graphical presentation of results.

Num	Analysis Results Metadata Field	Description
1	DISPLAY IDENTIFIER	A unique identifier for the specific analysis display (e.g., a table or figure number)
2	DISPLAY NAME	Title of display, including additional information if needed to describe and identify the display (e.g., analysis population)
3	RESULT IDENTIFIER	Identifies the specific analysis result within a display. For example, if there are multiple <i>p</i> values on a display and the analysis results metadata specifically refers to 1 of them, this field identifies the <i>p</i> value of interest. When combined with the display identifier, provides a unique identification of a specific analysis result.
4	PARAM	The analysis parameter in the BDS analysis dataset that is the focus of the analysis result. Does not apply if the result is not based on a BDS analysis dataset.
5	PARAMCD	Corresponds to PARAM in the BDS analysis dataset. Does not apply if the result is not based on a BDS analysis dataset.
6	ANALYSIS VARIABLE	The analysis variable being analyzed
7	REASON	The rationale for performing this analysis. It indicates when the analysis was planned (e.g., “Pre-specified in Protocol,” “Pre-specified in SAP,” “Data Driven,” “Requested by Regulatory Agency”) and the purpose of the analysis within the body of evidence (e.g., “Safety”). The terminology used is applicant defined. An example of a reason is “Safety Analysis as Prespecified in Protocol.”
8	DATASET	The name of the dataset used to generate the analysis result. In most cases, this is a single dataset. However, if multiple datasets are used, they are all listed here.
9	SELECTION CRITERIA	Specific and sufficient selection criteria for analysis subset and/or numerator—a complete list of the variables and their values used to identify the records selected for the analysis. Though the syntax is not ADaM-specified, the expectation is that the information could easily be included in a WHERE clause or something equivalent to ensure selecting the exact set of records appropriate for an analysis. This information is required if the analysis does not include every record in the analysis dataset.
10	DOCUMENTATION	Textual description of the analysis performed. This information could be a text description, pseudo code, a link to another document such as the protocol or SAP, or a link to an analysis generation program (i.e., a statistical software program used to generate the analysis result). The contents of the documentation metadata element contains depends on the level of detail required to describe the analysis itself, whether or not the applicant is providing a corresponding analysis generation program, and applicant-specific requirements and standards. This documentation metadata element will remain free form, meaning it will not become subject to a rigid structure or controlled terminology.
11	PROGRAMMING STATEMENTS	The software programming code used to perform the specific analysis. This includes, for example, the model statement (using the specific variable names) and all technical specifications needed for reproducing the analysis (e.g., covariance structure). The name and version of the applicable software package should be specified either as part of this metadata element or in another document (e.g., reviewer’s guide).

2.9.5 Predefined Standard Variables for ADSL

An ADaM-compliant ADSL dataset and its related metadata are required in a CDISC-based submission of data from a clinical study even if no other ADaM datasets are submitted. The structure of the ADSL is 1 record per subject, regardless of the type of study design. The label of the ADSL dataset is "Subject-Level Analysis Dataset." In a study, there is only 1 dataset in the class "SUBJECT LEVEL ANALYSIS DATASET", and its name is ADSL. Any other datasets with 1 record per subject would be members of other classes (e.g., the BDS, "ADAM OTHER" class).

This section lists standard ADSL variables. Within a given study, USUBJID is the key variable that links the ADSL to other datasets (both SDTM and ADaM).

For ADSL variables, the scope is "within the study." For example, the definition of SITEGR1 is consistent for all datasets within a study. It is acknowledged that the scope of USUBJID extends beyond the study, as defined in the SDTM.

There may be situations where highly derived variables are to be included in the ADSL yet the derivation of these variables may better be performed in another ADaM dataset. For example, consider the analysis need to include the baseline value of a derived parameter that is a composite score based on up to seven other parameters. These individual parameters and composite parameter may best be created in a separate analysis dataset. Different programming processes can be employed to address this analysis need, and ADaM does not dictate process.

One possible solution includes the creation of a "pre-ADSL" dataset that is used as input into subsequent analysis datasets. The final ADSL is created and collates variables as needed from any analysis dataset including the pre-

ADSL dataset. If this process is employed, the pre-ADSL dataset should follow ADaM principles but may not contain all required ADSL variables.

2.9.5.1 Identifier Variables for ADSL Datasets

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	Char		Req	DM.STUDYID
USUBJID	Unique Subject Identifier	Char		Req	DM.USUBJID
SUBJID	Subject Identifier for the Study	Char		Req	DM.SUBJID. SUBJID is required in ADSL, but permissible in other datasets.
SITEID	Study Site Identifier	Char		Req	DM.SITEID. SITEID is required in ADSL, but permissible in other datasets.
SITEGRy	Pooled Site Group y	Char		Perm	Character description of a grouping or pooling of clinical sites for analysis purposes. For example, SITEGR3 is the name of a variable containing site group (pooled site) names, where the grouping has been done according to the third site grouping algorithm, defined in variable metadata; SITEGR3 does not mean the third group of sites.
SITEGRyN	Pooled Site Group y (N)	Num		Perm	Numeric representation of SITEGRy. There must be a one-to-one relationship between SITEGRyN and SITEGRy within a study. SITEGRyN cannot be present unless SITEGRy is also present. When SITEGRy and SITEGRyN are present, then on a given record, either both must be populated or both must be null.
REGIONy	Geographic Region y	Char		Perm	Character description of geographical region. For example, REGION1 might have values of "Asia", "Europe", "North America", "Rest of World"; REGION2 might have values of "United States", "Rest of World".
REGIONyN	Geographic Region y (N)	Num		Perm	Numeric representation of REGIONy. Orders REGIONy for analysis and reporting. There must be a one-to-one relationship between REGIONyN and REGIONy within a study. REGIONyN cannot be present unless REGIONy is also present. When REGIONy and REGIONyN are present, then on a given record, either both must be populated or both must be null.

2.9.5.2 Subject Demographics Variables for ADSL Datasets

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
AGE	Age	Num		Req	DM.AGE. If analysis needs require a derived age that does not match DM.AGE, then AAGE must be added
AGEU	Age Units	Char	(AGEU)	Req	DM.AGEU
AGEGRy	Pooled Age Group y	Char		Perm	Character description of a grouping or pooling of the subject's age for analysis purposes. For example, AGEGR1 might have values of "<18", "18-65", and ">65"; AGEGR2 might have values of "Less than 35 y old" and "At least 35 y old".
AGEGRyN	Pooled Age Group y (N)	Num		Perm	Numeric representation of AGEGRy. Orders the grouping or pooling of subject age for analysis and reporting. There must be a one-to-one relationship between AGEGRyN and AGEGRy within a study. AGEGRyN cannot be present unless AGEGRy is also present. When AGEGRy and AGEGRyN are present, then on a given record, either both must be populated or both must be null.
AAGE	Analysis Age	Num		Cond	Age used for analysis that may be derived differently than DM.AGE. AAGE is required if age is calculated differently than DM.AGE.
SEX	Sex	Char	(SEX)	Req	DM.SEX.
RACE	Race	Char	(RACE)	Req	DM.RACE.
RACEGRy	Pooled Race Group y	Char		Perm	Character description of a grouping or pooling of the subject's race for analysis purposes.
RACEGRyN	Pooled Race Group y (N)	Num		Perm	Numeric representation of RACEGRy. Orders the grouping or pooling of subject race for analysis and reporting. There must be a one-to-one relationship between RACEGRyN and RACEGRy within a study. RACEGRyN cannot be present unless RACEGRy is also present. When RACEGRy and RACEGRyN are present, then on a given record, either both must be populated or both must be null.

2.9.5.3 Population Indicator Variables for ADSL Datasets

These flags identify whether the subject is included in the specified population. A minimum of 1 subject-level population flag variable is required in ADSL.

Not all of the indicators listed here need to be included in ADSL. As stated in Section 2.9.3.4, [Flag Variable Conventions](#), only those indicators corresponding to populations defined in the statistical analysis plan or populations used as a basis for analysis need be included in ADSL.

This list of flags is not meant to be all-inclusive. Additional population flags may be added.

The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0 = No and 1 = Yes) of the population flag can also be included. Please also refer to Section 2.9.3.4, [Flag Variable Conventions](#).

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
FASFL	Full Analysis Set Population Flag	Char	Y, N	Cond	Must be included if FASFL is defined and required per the SAP
SAFFL	Safety Population Flag	Char	Y, N	Cond	Must be included if SAFFL is defined and required per the SAP
PPROTFL	Per-Protocol Population Flag	Char	Y, N	Cond	Must be included if PPROTFL is defined and required per the SAP
COMPLFL	Completers Population Flag	Char	Y, N	Cond	Must be included if COMPLFL is defined and required per the SAP
RANDFL	Randomized Population Flag	Char	Y, N	Cond	Must be included if RANDFL is defined and required per the SAP
ENRLFL	Enrolled Population Flag	Char	Y, N	Cond	Must be included if ENRLFL is defined and required per the SAP

2.9.5.4 Product Variables for ADSL Datasets

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ARM	Description of Planned Arm	Char		Req	DM.ARM
ACTARM	Description of Actual Arm	Char		Perm	DM.ACTARM
TRTxP	Planned Product for Period xx	Char		Req	Subject-level identifier that represents the planned product for period xx. In a one-period randomized trial, TRT01P would be the product to which the subject was randomized. TRTxP might be derived from the SDTM DM variable ARM. At least TRT01P is required. The xx in TRTxP must be populated in numeric order such that if TRTxP is present then TRT{xx-1}P must also be present (with the exception of TRT01P where TRT00P cannot be present).
TRTxPN	Planned Product for Period xx (N)	Num		Perm	Numeric representation of TRTxP. There must be a one-to-one relationship between TRTxPN and TRTxP within a study. TRTxPN cannot be present unless TRTxP is also present. When TRTxP and TRTxPN are present, then on a given record, either both must be populated or both must be null.
TRTxA	Actual Product for Period xx	Char		Cond	Subject-level identifier that represents the actual product for the subject for period xx. Required when actual product does not match planned and there is an analysis of the data as treated. If TRTxA is present then TRTxP must also be present.
TRTxAN	Actual Product for Period xx (N)	Num		Perm	Numeric representation of TRTxA. There must be a one-to-one relationship between TRTxAN and TRTxA within a study. TRTxAN cannot be present unless TRTxA is also present. When TRTxA and TRTxAN are present, then on a given record, either both must be populated or both must be null.
TRTSEQP	Planned Sequence of Products	Char		Cond	Required when there is an analysis based on the sequence of products, for example in a crossover design. TRTSEQP is not necessarily equal to ARM, for example if ARM contains elements that are not relevant to analysis of products or ARM is not fully descriptive (e.g., "GROUP 1," "GROUP 2"). When analyzing based on the sequence of products, TRTSEQP is required even if identical to ARM.
TRTSEQPN	Planned Sequence of Products (N)	Num		Perm	Numeric representation of TRTSEQP. There must be a one-to-one relationship between TRTSEQPN and TRTSEQP within a study. TRTSEQPN cannot be present unless TRTSEQP is also present. When TRTSEQP and TRTSEQPN are present, then on a given record, either both must be populated or both must be null.
TRTSEQA	Actual Sequence of Products	Char		Cond	TRTSEQA is required if a situation occurred in the conduct of the trial where a subject received a sequence of products other than what was planned and there is an analysis based on the sequence of products.
TRTSEQAN	Actual Sequence of Products (N)	Num		Perm	Numeric representation of TRTSEQA. There must be a one-to-one relationship between TRTSEQAN and TRTSEQA within a study.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
					TRTSEQAN cannot be present unless TRTSEQA is also present. When TRTSEQA and TRTSEQAN are present, then on a given record, either both must be populated or both must be null.
TRxxPGy	Planned Pooled Product y for Period xx	Char		Perm	Planned pooled product y for period xx. Useful when planned products (TRTxxP) in the specified period xx are pooled together for analysis according to pooling algorithm y. For example when in period 2 the first pooling algorithm dictates that all doses of Drug A (TR02PG1="All doses of Drug A") are pooled together for comparison to all doses of Drug B (TR02PG1="All doses of Drug B"). Each value of TRTxxP is pooled within at most one value of TRxxPGy.
TRxxPGyN	Planned Pooled Trt y for Period xx (N)	Num		Perm	Numeric representation of TRxxPGy. There must be a one-to-one relationship between TRxxPGyN and TRxxPGy within a study. TRxxPGyN cannot be present unless TRxxPGy is also present. When TRxxPGy and TRxxPGyN are present, then on a given record, either both must be populated or both must be null.
TRxxAGy	Actual Pooled Product y for Period xx	Char		Cond	Actual pooled product y for period xx. Required when TRxxPGy is present and TRTxxA is present.
TRxxAGyN	Actual Pooled Trt y for Period xx (N)	Num		Perm	Numeric representation of TRxxAGy. There must be a one-to-one relationship between TRxxAGyN and TRxxAGy within a study. TRxxAGyN cannot be present unless TRxxAGy is also present. When TRxxAGy and TRxxAGyN are present, then on a given record, either both must be populated or both must be null.
TSEQPGy	Planned Pooled Product Sequence y	Char		Perm	Planned pooled product sequence y. Useful when planned product sequences (TRTSEQP) are pooled together for analysis according to pooling algorithm y. For example, this might be used in an analysis of an extension study when the analysis is based on what the subject received in the parent study as well as in the extension study.
TSEQPGyN	Planned Pooled Product Sequence y (N)	Num		Perm	Numeric representation of TSEQPGy. There must be a one-to-one relationship between TSEQPGyN and TSEQPGy within a study. TSEQPGyN cannot be present unless TSEQPGy is also present. When TSEQPGy and TSEQPGyN are present, then on a given record, either both must be populated or both must be null.
TSEQAGy	Actual Pooled Product Sequence y	Char		Cond	Actual pooled product sequence y. Required when TSEQPGy is present and TRTSEQA is present.
TSEQAGyN	Actual Pooled Product Sequence y (N)	Num		Perm	Numeric representation of TSEQAGy. There must be a one-to-one relationship between TSEQAGyN and TSEQAGy within a study. TSEQAGyN cannot be present unless TSEQAGy is also present. When TSEQAGy and TSEQAGyN are present, then on a given record, either both must be populated or both must be null.

2.9.5.5 Dose Variables for ADSL Datasets

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
DOSExxP	Planned Product Dose for Period xx	Num		Perm	Subject-level identifier that represents the planned product dosage for period xx.
DOSExxA	Actual Product Dose for Period xx	Num		Perm	Subject-level identifier that represents the actual product dosage for period xx.
DOSExxU	Units for Dose for Period xx	Char		Perm	The units for DOSExxP and DOSExxA. It is permissible to use suffixes such as "P" and "A" if needed, with labels modified accordingly.

2.9.5.6 Product Timing Variables for ADSL Datasets

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
TRTSdt	Date of First Exposure to Product	Num		Cond	Date of first exposure to product for a subject in a study. TRTSdt and/or TRTSDTM are required if there is an investigational product. Note that TRTSdt is not required to have the same value as the SDTM DM variable RFXSTDTC. While both of these dates reflect the concept of first exposure, the ADAm date may be derived to support the analysis which may not necessarily be the very first date in the SDTM EX domain.
TRTSTM	Time of First Exposure to Product	Num		Perm	Time of first exposure to product for a subject in a study.
TRTSDTM	Datetime of First Exposure to Product	Num		Cond	Datetime of first exposure to product for a subject in a study. TRTSdt and/or TRTSDTM are required if there is an investigational product.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
TRTSDF	Date of First Exposure Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of date of first exposure to product. If TRTSDF (or the date part of TRTSDTM) was imputed, TRTSDF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
TRTSTMF	Time of First Exposure Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of time of first exposure to product. If TRTSTM (or the time part of TRTSDTM) was imputed, TRTSTM must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
TRTEDT	Date of Last Exposure to Product	Num		Cond	Date of last exposure to product for a subject in a study. TRTEDT and/or TRTEDTM are required if there is an investigational product. Note that TRTEDT is not required to have the same value as the SDTM DM variable RFXENDTC. While both of these dates reflect the concept of last exposure, the ADaM date may be derived to support the analysis which may not necessarily be the very last date in the SDTM EX domain.
TRTEM	Time of Last Exposure to Product	Num		Perm	Time of last exposure to product for a subject in a study.
TRTEDTM	Datetime of Last Exposure to Product	Num		Cond	Datetime of last exposure to product for a subject in a study. TRTEDT and/or TRTEDTM are required if there is an investigational product.
TRTEDTF	Date of Last Exposure Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of date of last exposure to product. If TRTEDT (or the date part of TRTEDTM) was imputed, TRTEDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
TRTETMF	Time of Last Exposure Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of time of last exposure to product. If TRTEM (or the time part of TRTEDTM) was imputed, TRTETMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
TRxxSDT	Date of First Exposure in Period xx	Num		Cond	Date of first exposure to product in period xx. TRxxSDT and/or TRxxSDTM are only required in trial designs where multiple product periods are defined (i.e., required when there is a TRTxP other than TRT01P). Examples include crossover designs or designs where multiple periods exist for the same product.
TRxxSTM	Time of First Exposure in Period xx	Num		Cond	Starting time of exposure to product in period xx. TRxxSTM and/or TRxxSDTM are only required in trial designs where starting time is important to the analysis and multiple product periods are defined (i.e., required when there is a TRTxP other than TRT01P).
TRxxSDTM	Datetime of First Exposure in Period xx	Num		Cond	Datetime of first exposure to product in period xx. TRxxSDTM is only required in trial designs where multiple product periods are defined (i.e., required when there is a TRTxP other than TRT01P).
TRxxSDTF	Date 1st Exposure Period xx Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of date of first exposure to product in period xx. If TRxxSDT (or the date part of TRxxSDTM) was imputed, TRxxSDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
TRxxSTMF	Time 1st Exposure Period xx Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of time of first exposure to product in period xx. If TRxxSTM (or the time part of TRxxSDTM) was imputed, TRxxSTMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
TRxxEDT	Date of Last Exposure in Period xx	Num		Cond	Date of last exposure to product in period xx. TRxxEDT and/or TRxxEDTM are only required in trial designs where multiple product periods are defined (i.e., required when there is a TRTxP other than TRT01P).
TRxxETM	Time of Last Exposure in Period xx	Num		Cond	Ending time of exposure to product in period xx. TRxxETM and/or TRxxEDTM are only required in trial designs where ending time is important to the analysis and multiple product periods are defined (i.e., required when there is a TRTxP other than TRT01P).
TRxxEDTM	Datetime of Last Exposure in Period xx	Num		Cond	Datetime of last exposure to product in period xx. TRxxEDTM is only required in trial designs where multiple product periods are defined (i.e., required when there is a TRTxP other than TRT01P).
TRxxEDTF	Date Last Exposure Period xx Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of date of last exposure to product in period xx. If TRxxEDT (or the date part of TRxxEDTM) was imputed, TRxxEDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
TRxxETMF	Time Last Exposure Period xx Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of time of last exposure to product in period xx. If TRxxETM (or the time part of TRxxEDTM) was imputed, TRxxETMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .

Additional timing variables can be included for phase, period, and subperiod (APHASE, APERIOD, and ASPER, defined in Section 2.9.6.3, [Timing Variables for BDS Datasets](#)). Section 2.9.5.7, [Subject-Level Period, Subperiod, and Phase Timing Variables for ADSL Datasets](#), provides the subject-level variables for these timing elements.

The following provisions apply to the inclusion or exclusion of sets of pairs of subject-level analysis timing variables in ADSL. A set of pairs of subject-level analysis timing variable is the set of start and end variables for an

analysis timing element, such as phase, period, or subperiod. For example, for analysis period, the set consists of APxxSDT and APxxEDT for all of the analysis periods xx in the study. The set of timing variables for a specific phase, period, or subperiod includes only those variables from Section 2.9.5.7, [Subject-Level Period, Subperiod, and Phase Timing Variables for ADSL Datasets](#), that are applicable to the study. For example, although the period start time is defined, it should be included in the set of analysis period timing variables only if needed for the study.

1. A set of analysis timing variables can be included in ADSL only if the definitions for all of the variables in the set are fixed across the study (i.e., the definitions of the start and end of each timing element for a given subject do not change based on endpoint or data type). The first such set consists of all of the analysis period timing variables defined in Section 2.9.5.7, [Subject-Level Period, Subperiod, and Phase Timing Variables for ADSL Datasets](#). The second set consists of all of the subperiod timing variables in that table. The third set consists of all of the phase timing variables in that table.
2. If period timing variables are not included in ADSL, then subperiod timing variables must be excluded from ADSL.
3. If any of the definitions of the variables in the set do vary, for example, when analysis period start or stop date definitions differ for different types of analyses, then none of the variables in the set can be included in ADSL.
4. If all of the variable definitions in the set are the same across all datasets, then they can be included in Section 2.9.6.3, [Timing Variables for BDS Datasets](#), specifies variables to be used in the other datasets when definitions differ by dataset.

2.9.5.7 Subject-Level Period, Subperiod, and Phase Timing Variables for ADSL Datasets

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
APxxSDT	Period xx Start Date	Num		Perm	The starting date of period xx.
APxxSTM	Period xx Start Time	Num		Perm	The starting time of period xx.
APxxSDTM	Period xx Start Datetime	Num		Perm	The starting datetime of period xx.
APxxSDTF	Period xx Start Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of period xx start date. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
APxxSTMF	Period xx Start Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of period xx start time. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
APxxEDT	Period xx End Date	Num		Perm	The ending date of period xx.
APxxETM	Period xx End Time	Num		Perm	The ending time of period xx.
APxxEDTM	Period xx End Datetime	Num		Perm	The ending datetime of period xx.
APxxEDTF	Period xx End Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of period xx end date. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
APxxETMF	Period xx End Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of period xx end time. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
PxxSw	Description of Period xx Subperiod w	Char		Perm	Description of analysis subperiod w within period xx.
PxxSwSDT	Period xx Subperiod w Start Date	Num		Perm	The starting date of subperiod w within period xx.
PxxSwSTM	Period xx Subperiod w Start Time	Num		Perm	The starting time of subperiod w within period xx.
PxxSwSDM	Period xx Subperiod w Start Datetime	Num		Perm	The starting datetime of subperiod w within period xx.
PxxSwSDF	Period xx Subper w Start Date Imput Flag	Char	(DATEFL)	Cond	The level of imputation of the start date for subperiod w within period xx. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
PxxSwSTF	Period xx Subper w Start Time Imput Flag	Char	(TIMEFL)	Cond	The level of imputation of the start time for subperiod w within period xx. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
PxxSwEDT	Period xx Subperiod w End Date	Num		Perm	The ending date of subperiod w within period xx.
PxxSwETM	Period xx Subperiod w End Time	Num		Perm	The ending time of subperiod w within period xx.
PxxSwEDM	Period xx Subperiod w End Datetime	Num		Perm	The ending datetime of subperiod w within period xx.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
PxxSwEDF	Period xx Subper w End Date Imput Flag	Char	(DATEFL)	Cond	The level of imputation of the end date for subperiod w within period xx. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
PxxSwETF	Period xx Subper w End Time Imput Flag	Char	(TIMEFL)	Cond	The level of imputation of the end time for subperiod w within period xx. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
APHASEw	Description of Phase w	Char		Perm	Description of analysis phase w. Analysis phase is independent of TRTxP within ADSL, and may be populated for spans of time where a subject is not on product.
PHwSDT	Phase w Start Date	Num		Perm	The starting date of phase w.
PHwSTM	Phase w Start Time	Num		Perm	The starting time of phase w.
PHwSDTM	Phase w Start Datetime	Num		Perm	The starting datetime of phase w.
PHwSDTF	Phase w Start Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of the start date for phase w. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
PHwSTMF	Phase w Start Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of the start time for phase w. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
PHwEDT	Phase w End Date	Num		Perm	The ending date of phase w.
PHwETM	Phase w End Time	Num		Perm	The ending time of phase w.
PHwEDTM	Phase w End Datetime	Num		Perm	The ending datetime of phase w.
PHwEDTF	Phase w End Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of the end date for phase w. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
PHwETMF	Phase w End Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of the end time for phase w. See Section 2.9.3.3, Date and Time Imputation Flag Variables .

Additional timing variables can be included for phase, period, and subperiod (APHASE, APERIOD, and ASPER, defined in Section 2.9.6.3, [Timing Variables for BDS Datasets](#)). Section 2.9.5.7, [Subject-Level Period, Subperiod, and Phase Timing Variables for ADSL Datasets](#), provides the subject-level variables for these timing elements.

The following provisions apply to the inclusion or exclusion of sets of pairs of subject-level analysis timing variables in ADSL. A set of pairs of subject-level analysis timing variable is the set of start and end variables for an analysis timing element (e.g., phase, period, subperiod). For example, for analysis period, the set consists of APxxSDT and APxxEDT for all of the analysis periods xx in the study. The set of timing variables for a specific phase, period, or subperiod includes only those variables from ADaMIG Table 3.2.7 that are applicable to the study. For example, although the period start time is defined in Table 3.2.7, it should be included in the set of analysis period timing variables only if needed for the study.

1. A set of analysis timing variables can be included in ADSL only if the definitions for all of the variables in the set are fixed across the study (i.e., the definitions of the start and end of each timing element for a given subject do not change based on endpoint or data type). The first such set consists of all of the analysis period timing variables defined in Section 2.9.5.7, [Subject-Level Period, Subperiod, and Phase Timing Variables for ADSL Datasets](#). The second set consists of all of the subperiod timing variables in that table. The third set consists of all of the phase timing variables in that table.
2. If period timing variables are not included in ADSL, then subperiod timing variables must be excluded from ADSL.
3. If any of the definitions of the variables in the set vary (e.g., analysis period start or stop date definitions differ for different types of analyses), then none of the variables in the set can be included in ADSL.
4. If all of the variable definitions in the set are the same across all datasets, then they can be included in ADSL. Section 2.9.6.3, [Timing Variables for BDS Datasets](#), specifies variables to be used in the other datasets when definitions differ by dataset.

2.9.5.8 Subject-Level Trial Experience Variables for ADSL Datasets

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
EOSSTT	End of Study Status	Char	(SBJTSTAT)	Perm	The subject's status as of the end of study or data cutoff. Examples: COMPLETED, DISCONTINUED, ONGOING.
EOSDT	End of Study Date	Num		Perm	Date subject ended the study—either date of completion or date of discontinuation or data cutoff date for interim analyses.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
DCSREAS	Reason for Discontinuation from Study	Char		Perm	Reason for subject's discontinuation from study. The source would most likely be the SDTM DS dataset. Null for subjects who completed the study.
DCSREASP	Reason Spec for Discont from Study	Char		Perm	Additional detail regarding subject's discontinuation from study (e.g., description of "other").
EOTSTT	End of Product Status	Char	(SBJTSTAT)	Perm	The subject's status as of the end of product or data cutoff. Examples: COMPLETED, DISCONTINUED, ONGOING.
DCTREAS	Reason for Discontinuation of Product	Char		Perm	If a subject discontinued product in the study, then this variable indicates the reason for discontinuation. This is for discontinuation of product in the overall study and not to be used for discontinuation reason within individual product periods.
DCTREASP	Reason Specify for Discont of Product	Char		Perm	Additional detail regarding subject's discontinuation from product (e.g., description of "other").
EOTxxSTT	End of Product Status in Period xx	Char	(SBJTSTAT)	Perm	The subject's product status as of the end of period xx, or data cutoff if within period xx. Examples: COMPLETED, DISCONTINUED, ONGOING.
DCTxxRS	Reason for Discont of Prd in Period xx	Char		Perm	Reason for discontinuing product in period xx.
DCTxxRSP	Reason Spec for Disc of Prd in Period xx	Char		Perm	Additional detail regarding subject's discontinuation of product in period xx (e.g., description of "other").
EOPxxSTT	End of Period xx Status	Char	(SBJTSTAT)	Perm	The subject's status as of the end of period xx, or data cutoff if within period xx. Examples: COMPLETED, DISCONTINUED, ONGOING.
DCPxxRS	Reason for Discont from Period xx	Char		Perm	Reason for discontinuing analysis period xx.
DCPxxRSP	Reason Spec for Discont from Period xx	Char		Perm	Additional detail regarding subject's discontinuation from period xx (e.g., description of "other").
RFICDT	Date of Informed Consent	Num		Perm	Date subject gave informed consent. Generally equivalent to DM.RFICDT.
ENRLDT	Date of Enrollment	Num		Perm	Date of subject's enrollment into trial.
RANDDT	Date of Randomization	Num		Cond	Required in randomized trials.
RFICyDT	Date of Informed Consent y	Num		Perm	This variable may be used in the case where there are multiple consent dates within a study. This date does not need to repeat the date in RFICDT. "y" can start with 1 but it is not required to start with 1.
ENRLyDT	Date of Enrollment y	Num		Perm	This variable may be used in the case where there are multiple enrollment dates within a study. This date does not need to repeat the date in ENRLDT. "y" can start with 1 but it is not required to start with 1.
RANDyDT	Date of Randomization y	Num		Perm	This variable may be used in the case where there are multiple randomization dates within a study. This date does not need to repeat the date in RANDDT. "y" can start with 1 but it is not required to start with 1.
LSTALVDT	Date Last Known Alive	Num		Perm	If this variable is included in ADSL, the best practice is to populate it for everyone. If the derivation for subjects who died differs from the derivation for subjects who are not known to have died, the differences should be noted in metadata.
TRCMP	Product Compliance (%)	Num		Perm	Overall percent compliance with product in the trial. TRCMP may be useful for inclusion in ADSL for reasons such as defining subgroups and/or populations.
TRCMPGy	Product Compliance (%) Group y	Char		Perm	Grouping "y" of TRCMP, product compliance percentage.
TRCMPGyN	Product Compliance (%) Group y (N)	Num		Perm	Numeric representation of product compliance (%) grouping "y". There must be a one-to-one relationship between TRCMPGyN and TRCMPGy within a study. TRCMPGyN cannot be present unless TRCMPGy is also present. When TRCMPGy and TRCMPGyN are present, then on a given record, either both must be populated or both must be null.
TRxxDURD	Product Duration in Period xx (Days)	Num		Perm	Product duration for period xx as measured in days. More than one of TRxxDURD, TRxxDURM, and TRxxDURY can be populated, but each represents the entire duration in its respective units.
TRxxDURM	Product Duration in Period xx (Months)	Num		Perm	Product duration for period xx, as measure in months. More than one of TRxxDURD, TRxxDURM, and TRxxDURY can be populated, but each represents the entire duration in its respective units.
TRxxDURY	Product Duration in Period xx (Years)	Num		Perm	Product duration for period xx, as measured in years. More than one of TRxxDURD, TRxxDURM, and TRxxDURY can be populated, but each represents the entire duration in its respective units.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
TRTDURD	Total Product Duration (Days)	Num		Perm	Total product duration, as measured in days. More than one of TRTDURD, TRTDURM, and TRTDURY can be populated, but each represents the entire duration in its respective units.
TRTDURM	Total Product Duration (Months)	Num		Perm	Total product duration, as measured in months. More than one of TRTDURD, TRTDURM, and TRTDURY can be populated, but each represents the entire duration in its respective units.
TRTDURY	Total Product Duration (Years)	Num		Perm	Total product duration, as measured in years. More than one of TRTDURD, TRTDURM, and TRTDURY can be populated, but each represents the entire duration in its respective units.
DTHDT	Date of Death	Num		Perm	Date of subject's death. Derived from DM.DTHDTC.
DTHDTF	Date of Death Imputation Flag	Char	(DATEFL)	Cond	Imputation flag for date of subject's death. If DTHDT was imputed, DTHDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
DTHCAUS	Cause of Death	Char		Perm	Cause of Death.
DTHCAUSN	Cause of Death (N)	Num		Perm	Numeric representation of cause of death. There must be a one-to-one relationship between DTHCAUSN and DTHCAUS within a study. DTHCAUSN cannot be present unless DTHCAUS is also present. When DTHCAUS and DTHCAUSN are present, then on a given record, either both must be populated or both must be null.
DTHCGy	Cause of Death Group y	Char		Perm	Grouping "y" of DTHCAUS, the subject's cause of death.
DTHCGyN	Cause of Death Group y (N)	Num		Perm	Numeric representation of grouping "y" of the subject's cause of death. There must be a one-to-one relationship between DTHCGyN and DTHCGy within a study. DTHCGyN cannot be present unless DTHCGy is also present. When DTHCGy and DTHCGyN are present, then on a given record, either both must be populated or both must be null.

2.9.5.9 Stratification Variables for ADSL Datasets

Stratified randomization is used to ensure balance of product assignments across 1 or more prognostic factors. A *prognostic factor* is an aspect of the disease or a characteristic of the subject that may influence product effect. The prognostic factors used to stratify the randomization are specified in the protocol. As a simple example, suppose age group (<50, >=50) and gender (male, female) are considered important prognostic factors. When a subject is deemed eligible for randomization, their individual values of these factors are determined at the site and used as input to the randomization process to determine their product assignment. The situation may occur where the value of a factor used for randomization is later discovered to be in error. For example, suppose a subject was randomized according to the age group of <50 and male. Later, it was discovered that the subject was actually 54 and therefore should have been randomized according to the age group of >=50 and male. If this situation happens too often, the balance in product assignments across these factors is in question, which may then result in the use of sensitivity analyses. Therefore, there is an analysis need to have 2 sets of values to describe the stratification factors. In this document, these 2 sets of values are referred to the “as-randomized” values and the “as-verified” values. As-verified values are derived using source documentation.

At present, there is no standard method for representing the randomization strata factors and values in SDTM-based datasets. Depending on the randomization process, it might be unnecessary to represent variables and values specific to stratification in SDTM-based datasets if the information can be found within an appropriate domain. For example, if age and sex were used as stratification factors, then the Demographics (DM) variables AGE and SEX should appropriately reflect values used for randomization. However, more sophisticated randomizations or more complicated derivations of prognostic factors, such as whether a subject had ever used a particular concomitant medication for a given length of time, may be harder to identify or document in SDTM-based datasets. If using an interactive voice response system (IVRS), the values used for randomization would be captured by the system and would correspond to the values that are represented on the randomization schedule. As-verified values are typically derived by comparing the values used for randomization against the data that is in the SDTM dataset, whether it be a simple match with a single data point such as sex or the reprogramming of more complex factors such as previous products.

The following table provides a set of variables to allow maximum flexibility in representing the description of the prognostic factors. To illustrate the interrelationships of the variables, the examples for every variable in the CDISC Notes column use the combination of 3 stratification factors: age group (“<50” or “>=50”), prior product status (“Product naïve”, “Product experienced”), and hypertension (“Y” or “N”).

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
STRATAR	Strata Used for Randomization	Char		Perm	STRATAR contains the combination of values of the individual stratification factors used for randomization. The exact format should be determined by the applicant. This variable is intended for studies that use stratified randomization. For example, ">=50, Product experienced, N"
STRATARN	Strata Used for Randomization (N)	Num		Perm	Numeric representation of STRATAR. For example, STRATARN=3 when STRATAR=>=50, Product experienced, N". There must be a one-to-one relationship between STRATARN and STRATAR within a study. STRATARN cannot be present unless STRATAR is also present. When STRATAR and STRATARN are present, then on a given record, either both must be populated or both must be null.
STRATwD	Description of Stratification Factor w	Char		Perm	STRATwD is a full text description of the stratification factor "w". This text description will remain constant for all subjects. These descriptive variables are included to quickly and clearly communicate critical study design information as well as to facilitate integration. For example, STRAT3D="Hypertension"
STRATwR	Strat Factor w Value Used for Rand	Char		Perm	STRATwR is the subject-level value of the "w'th" stratification factor used for randomization. For example, STRAT3R="N"
STRATwRN	Strat Factor w Value Used for Rand (N)	Num		Perm	Numeric representation of STRATwR. For example, STRAT3RN=0 when STRAT3R="N". There must be a one-to-one relationship between STRATwRN and STRATwR within a study. STRATwRN cannot be present unless STRATwR is also present. When STRATwR and STRATwRN are present, then on a given record, either both must be populated or both must be null.
STRATAV	Strata from Verification Source	Char		Perm	STRATAV contains the entire string value represents the combination of values of the individual stratification factors that should have been used and represents the "as verified" value. The STRATAV variables are based on the source documentation and are determined after randomization. If the values used for the randomization of a given subject were all correct, then STRATAV will equal STRATAR. Otherwise, one or more components of the text string for STRATAR and STRATAV will be different. The exact format should be determined by the applicant. For example, ">=50, Product experienced, Y"
STRATAVN	Strata from Verification Source (N)	Num		Perm	Numeric representation of STRATAV. For example, STRATAVN=4 when STRATVR=>=50, Product experienced, Y". There must be a one-to-one relationship between STRATAVN and STRATAV within a study. STRATAVN cannot be present unless STRATAV is also present. When STRATAV and STRATAVN are present, then on a given record, either both must be populated or both must be null.
STRATwV	Strat Factor w Value from Verif Source	Char		Perm	STRATwV is the "as verified" subject-level value of the "w'th" stratification factor. If the value based on randomization was correct, then STRATwV will equal STRATwR. For example, STRAT3V="Y"
STRATwVN	Strat Fact w Val from Verif Source (N)	Num		Perm	Numeric representation of STRATwV. For example, STRAT3VN=1 when STRAT3V="Y". There must be a one-to-one relationship between STRATwVN and STRATwV within a study. STRATwVN cannot be present unless STRATwV is also present. When STRATwV and STRATwVN are present, then on a given record, either both must be populated or both must be null.

2.9.6 Predefined Standard Variables for BDS

A BDS dataset contains 1 or more records per subject, per analysis parameter, per analysis timepoint. An analysis timepoint is conditionally required, depending on the analysis. In situations where there is no analysis timepoint, the structure is 1 or more records per subject per analysis parameter. Typically there are several BDS datasets in a study. This section of the TIG defines the standard variables used in BDS datasets. See Section 2.9.5, [Predefined Standard Variables for ADSL](#), for ADSL variables, any of which may also be included in BDS datasets to support traceability or enable analysis.

In this section, "within a given study, subject, and dataset" is implied, unless otherwise stated. For example, the description of ABLFL defines it as a variable that indicates baseline record for each parameter, or, if there is more than 1 baseline definition, for each parameter and baseline type (BASETYPE). It should be understood that the baseline record is for the subject identified by USUBJID. In addition, note that "within a parameter" means "within a parameter within a dataset."

2.9.6.1 Identifier Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	Char		Req	DM.STUDYID, ADSL STUDYID, and/or STUDYID from another ADaM or SDTM dataset appropriate to the analysis.
USUBJID	Unique Subject Identifier	Char		Req	DM.USUBJID, ADSL.USUBJID, and/or USUBJID from another ADaM or SDTM dataset appropriate to the analysis.
SUBJID	Subject Identifier for the Study	Char		Perm	DM.SUBJID, ADSL.SUBJID, and/or SUBJID from another ADaM dataset appropriate to the analysis. SUBJID is required in ADSL, but permissible in other datasets.
SITEID	Study Site Identifier	Char		Perm	DM.SITEID, ADSL.SITEID, and/or SITEID from another ADaM dataset appropriate to the analysis. SITEID is required in ADSL, but permissible in other datasets.
ASEQ	Analysis Sequence Number	Num		Perm	Sequence number given to ensure uniqueness of subject records within an ADaM dataset. As long as values are unique within a subject within the dataset, any valid number can be used for ASEQ. ASEQ uniquely indexes records within a subject within an ADaM dataset. ASEQ is useful for traceability when the dataset is used as input to another ADaM dataset. To refer to a record in a predecessor ADaM dataset, set SRCDOM to the name of the predecessor dataset, and set SRCSEQ to the value of ASEQ in the predecessor dataset.

2.9.6.2 Record-Level Product and Dose Variables for BDS Datasets

At least 1 product variable is required in a BDS dataset. This requirement is satisfied by any of the subject-level product variables (e.g., TRTxP) or record- level product variables (e.g., TRTP). All product variables defined in ADaMIG Table 3.3.2.1 are record level, meaning that the values contained in the variable may vary by record within a subject. Subject-level product variables are described in Section 2.9.5.4, [Product Variables for ADSL Datasets](#).

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
TRTP	Planned Product	Char		Cond	TRTP is a record-level identifier that represents the planned product attributed to a record for analysis purposes. TRTP indicates how product varies by record within a subject and enables analysis of crossover and other designs. Though there is no requirement that TRTP will correspond to the TRTxP as defined by the record's value of APERIOD, if populated, TRTP must match at least one value of the character planned product variables in ADSL (e.g., TRTxP, TRTSEQP, TRxxPGy). At least 1 product variable is required even in non-randomized trials. This requirement is satisfied by any subject-level or record-level product variables (e.g., TRTxP, TRTP, TRTA). Even if not used for analysis, any ADSL product variable may be included in the BDS dataset.
TRTPN	Planned Product (N)	Num		Perm	Numeric representation of TRTP. There must be a one-to-one relationship between TRTPN and TRTP within a study. TRTPN cannot be present unless TRTP is also present. When TRTP and TRTPN are present, then on a given record, either both must be populated or both must be null.
TRTA	Actual Product	Char		Cond	TRTA is a record-level identifier that represents the actual product attributed to a record for analysis purposes. TRTA indicates how product varies by record within a subject and enables analysis of crossover and other multi-period designs. Though there is no requirement that TRTA will correspond to the TRTxA as defined by the record's value of APERIOD, TRTA must match at least one value of the character actual product variables in ADSL (e.g., TRTxP, TRTSEQA, TRxxAGy). At least 1 product variable is required. This requirement is satisfied by any subject-level or record-level product variables (e.g., TRTxP, TRTP, TRTA). Even if not used for analysis, any ADSL product variable may be included in the BDS dataset.
TRTAN	Actual Product (N)	Num		Perm	Numeric representation of TRTA. There must be a one-to-one relationship between TRTAN and TRTA within a study. TRTAN cannot be present unless TRTA is also present. When TRTA and TRTAN are present, then on a given record, either both must be populated or both must be null.
TRTPGy	Planned Pooled Product y	Char		Perm	TRTPGy is the planned pooled product y attributed to a record for analysis purposes; "y" represents an integer [1-99, not zero-padded] corresponding to a particular pooling scheme. Useful when planned products (TRTP) are pooled together for analysis, for example when all doses of drug A (TRTPG1=All doses of Drug A) are compared to all doses of drug B (TRTPG1=All doses of Drug B). Each value of TRTP is pooled within at most 1 value of TRTPGy.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
TRTPGyN	Planned Pooled Product y (N)	Num		Perm	Numeric representation of TRTPGy. There must be a one-to-one relationship between TRTPGyN and TRTPGy within a study. TRTPGyN cannot be present unless TRTPGy is also present. When TRTPGy and TRTPGyN are present, then on a given record, either both must be populated or both must be null.
TRTAGy	Actual Pooled Product y	Char		Cond	TRTAGy is the actual pooled product y attributed to a record for analysis purposes; "y" represents an integer [1-99, not zero-padded] corresponding to a particular pooling scheme. Required when TRTPGy is present and TRTA is present.
TRTAGyN	Actual Pooled Product y (N)	Num		Perm	Numeric representation of TRTAGy. There must be a one-to-one relationship between TRTAGyN and TRTAGy within a study. TRTAGyN cannot be present unless TRTAGy is also present. When TRTAGy and TRTAGyN are present, then on a given record, either both must be populated or both must be null.

All dose variables defined in the following table are record level. This means that the values contained in the variable may vary by record within a subject. These record-level dose variables, plus ADSL subject-level dose variables, can be used in addition to—but not instead of—record-level product variables.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
DOSEP	Planned Product Dose	Num		Perm	DOSEP represents the planned product dosage associated with the record.
DOSCUMP	Cumulative Planned Product Dose	Num		Perm	Cumulative planned dosage of product for the subject at the point in time of the record (e.g., ADT).
DOSEA	Actual Product Dose	Num		Perm	DOSEA represents the actual product dosage associated with the record.
DOSCUMA	Cumulative Actual Product Dose	Num		Perm	Cumulative actual dosage of product for the subject at the point in time of the record (e.g., ADT).
DOSEU	Product Dose Units	Char		Perm	The units for DOSEP, DOSCUMP, DOSEA, and DOSCUMA. It is permissible to use suffixes such as "P" and "A" if needed, with labels modified accordingly.

2.9.6.3 Timing Variables for BDS Datasets

Any SDTM timing variable (including, but not limited to EPOCH, --DTC, --DY, VISITNUM, VISIT, and VISITDY) may be copied into ADaM datasets when it supports data traceability and/or shows how ADaM timing variables contrast with SDTM timing data. If a dataset contains more than 1 record within a parameter and within a subject, then an SDTM or ADaM relative timing variable must be present (eg, ADY, ASTDY, AENDY, AVISIT, ATPT).

ADaMIG Table 3.3.3.1 defines analysis timing variables for BDS datasets. The timing variables whose names start with the letter *A* are the timing variables directly associated with the AVAL and AVALC variables in the ADaM dataset.

A variable for relative day of measurement or event, along with timing variables for visit, should be included when an ADaM dataset contains multiple records per subject (i.e., repeated measures data).

Timing variables not directly characterizing AVAL (e.g., *DT) should be prefixed by a character string instead of the placeholder asterisk shown in ADaMIG Table 3.3.3.3, so that their actual names comply with the variable naming conventions described in Section 2.9.3.1, [General Variable Conventions](#). In many cases, the prefix for these date and time variables would match that of an SDTM --DTC, --STDTC or --ENDTC variable name. For example, if a numeric date variable were created from --STDTC, then it would be named --SDT. However, if --DTC or --STDTC is the date that is associated with AVAL and AVALC, its numeric equivalent should be named ADT or ASTDT, as appropriate. The timing variable conventions documented in Section 2.9.3.2, [Timing Variable Conventions](#), apply here as well.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
ADT	Analysis Date	Num		Cond	The date associated with AVAL and/or AVALC in numeric format.
ATM	Analysis Time	Num		Cond	The time associated with AVAL and/or AVALC in numeric format.
ADTM	Analysis Datetime	Num		Cond	The datetime associated with AVAL and/or AVALC in numeric format.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ADY	Analysis Relative Day	Num		Cond	The relative day of AVAL and/or AVALC. The number of days from an anchor date (not necessarily DM.RFSTDTC) to ADT. See Section 2.9.3.2, Timing Variable Conventions . If a dataset contains more than one record per parameter per subject, then an SDTM or ADaM relative timing variable must be present (ADY would meet this requirement).
ADTF	Analysis Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of analysis date. If ADT (or the date part of ADTM) was imputed, ADTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
ATMF	Analysis Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of analysis time. If ATM (or the time part of ADTM) was imputed, ATMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
ASTDT	Analysis Start Date	Num		Cond	The start date associated with AVAL and/or AVALC. ASTDT and AENDT may be useful for traceability when AVAL summarizes data collected over an interval of time, or when AVAL is a duration.
ASTTM	Analysis Start Time	Num		Cond	The start time associated with AVAL and/or AVALC. ASTTM and AENTM may be useful for traceability when AVAL summarizes data collected over an interval of time, or when AVAL is a duration.
ASTDTM	Analysis Start Datetime	Num		Cond	The start datetime associated with AVAL and/or AVALC. ASTDTM and AENDTM may be useful for traceability when AVAL summarizes data collected over an interval of time, or when AVAL is a duration.
ASTDY	Analysis Start Relative Day	Num		Cond	The number of days from an anchor date (not necessarily DM.RFSTDTC) to ASTDT. See Section 2.9.3.2, Timing Variable Conventions . If a dataset contains more than one record per parameter per subject then, an SDTM or ADaM relative timing variable must be present (ASTDY would meet this requirement).
ASTDTF	Analysis Start Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of analysis start date. If ASTDT (or the date part of ASTDTM) was imputed, ASTDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
ASTTMF	Analysis Start Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of analysis start time. If ASTTM (or the time part of ASTDTM) was imputed, ASTTMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
AENDT	Analysis End Date	Num		Cond	The end date associated with AVAL and/or AVALC. See also ASTDT. If both ASTDT and AENDT are populated then ASTDT must less than or equal to AENDT.
AENTM	Analysis End Time	Num		Cond	The end time associated with AVAL and/or AVALC. See also ASTTM.
AENDTM	Analysis End Datetime	Num		Cond	The end datetime associated with AVAL and/or AVALC. See also ASTDTM. If both ASTDTM and AENDTM are populated then ASTDTM must less than or equal to AENDTM.
AENDY	Analysis End Relative Day	Num		Cond	The number of days from an anchor date (not necessarily DM.RFSTDTC) to AENDT. See Section 2.9.3.2, Timing Variable Conventions . If a dataset contains more than 1 record per parameter per subject, then an SDTM or ADaM relative timing variable must be present (AENDY would meet this requirement). If both ASTDY and AENDY are populated then ASTDY must be less than or equal to AENDY
AENDTF	Analysis End Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of analysis end date. If AENDT (or the date part of AENDTM) was imputed, AENDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
AENTMF	Analysis End Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of analysis end time. If AENTM (or the time part of AENDTM) was imputed, AENTMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
AVISIT	Analysis Visit	Char		Cond	The analysis visit description; required if an analysis is done by nominal, assigned or analysis visit. AVISIT may contain the visit names as observed (i.e., from SDTM VISIT), derived visit names, time window names, conceptual descriptions (such as Average, Endpoint, etc.), or a combination of any of these. AVISIT is a derived field and does not have to map to VISIT from the SDTM. AVISIT represents the analysis visit of the record, but it does not mean that the record was analyzed. There are often multiple records for the same subject and parameter that have the same value of AVISIT. ANLzzFL and other variables may be needed to identify the records selected for any given analysis. See Section 2.9.6.10, Indicator Variables for BDS Datasets , for information about flag variables. AVISIT should be unique for a given analysis visit window. In the event that a record does not fall within any predefined analysis timepoint window, AVISIT can be populated in any way that the producer chooses to indicate this fact (e.g., blank or "Not Windowed"). The way that AVISIT is calculated, including the variables used in its derivation, should be indicated in

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
					<p>the variable metadata for AVISIT. The values and the rules for deriving AVISIT may be different for different parameters within the same dataset. Values of AVISIT are producer-defined, and are often directly usable in Clinical Study Report displays. If a dataset contains more than one record per parameter per subject, then an SDTM or ADaM relative timing variable must be present (AVISIT could meet this requirement).</p>
AVISITN	Analysis Visit (N)	Num		Perm	<p>Numeric representation of AVISIT. Since study visits are usually defined by certain timepoints, defining AVISITN so that it represents the timepoint associated with the visit can facilitate plotting and interpretation of the values. Alternatively, AVISITN may be a protocol visit number, a cycle number, an analysis visit number, or any other number logically related to AVISIT or useful for sorting that is needed for analysis.</p> <p>There must be a one-to-one relationship between AVISITN and AVISIT (i.e., AVISITN has the same value for each distinct AVISIT) within a parameter. A best practice is to extend the one-to-one relationship to within a study, but this is not an ADaM requirement. In the event that a record does not fall within any predefined analysis timepoint window, AVISITN can be populated in any way that the producer chooses to indicate this fact (e.g., may be null). Values of AVISITN are producer-defined.</p> <p>AVISITN cannot be present unless AVISIT is also present. On a given record, AVISITN cannot be populated if AVISIT is null. AVISITN can be null when AVISIT is populated, as long as the one-to-one relationship is maintained within a parameter on all rows on which both variables are populated.</p>
ATPT	Analysis Timepoint	Char		Cond	<p>The analysis timepoint description; required if an analysis is done by nominal, assigned or analysis timepoint (instead of or in addition to by-visit). Timepoints are relative to ATPTREF. ATPT may contain the timepoint names as observed (i.e., from SDTM –TPT), derived timepoint names, time window names, conceptual descriptions (such as Average, Endpoint, etc.), or a combination of any of these. This variable is often used in conjunction with AVISIT. ATPT represents the analysis timepoint of the record.</p> <p>ATPT can be within an analysis visit (e.g., blood pressure assessments at 10 min, 20 min, and 30 min post-dose at AVISIT=Week 1) or can be unrelated to AVISIT (e.g., migraine symptoms 30 min, 60 min, and 120 min post-dose for attack 1).</p> <p>The way that ATPT is calculated, including the variables used in its derivation, should be indicated in the variable metadata for ATPT. The values and the rules for deriving ATPT may be different for different parameters within the same dataset. Values of ATPT are producer-defined, and are often directly usable in Clinical Study Report displays.</p> <p>If a dataset contains more than one record per parameter per subject, then an SDTM or ADaM relative timing variable must be present (ATPT could meet this requirement).</p>
ATPTN	Analysis Timepoint (N)	Num		Perm	<p>Numeric representation of ATPT. Defining ATPTN so that its values represent the planned timepoints (e.g., minutes or hours after dosing) is not required but can facilitate plotting and interpretation of the values. There must be a one-to-one relationship between ATPTN and ATPT within a parameter. (Best practice would dictate that the mapping would be one-to-one within a study, but that is not an ADaM requirement.)</p> <p>ATPTN cannot be present unless ATPT is also present. When ATPT and ATPTN are present, then on a given record, either both must be populated or both must be null.</p>
ATPTREF	Analysis Timepoint Reference	Char		Perm	Description of the fixed reference point referred to by ATPT/ATPTN (e.g., time of dose).
APHASE	Phase	Char		Perm	APHASE is a categorization of timing within a study, for example a higher-level categorization of APERIOD or an analysis epoch. For example, APHASE could describe spans of time for SCREENING, ON PRODUCT, and FOLLOW-UP. APHASE may be used alone or in addition to APERIOD. APHASE is independent of TRTxxP within ADSL. APHASE may be populated for spans of time where a subject is not on product. The value of APHASE (if populated) must be one of the values found in the ADSL APHASEw variables.
APHASEN	Phase (N)	Num		Perm	<p>Numeric representation of APHASE. The value of APHASEN (if populated) must be one of the w values found in the ADSL APHASEw variable names.</p> <p>There must be a one-to-one relationship between APHASEN and APHASE within a study, which must be the same as the one-to-one mapping between w and APHASEw in ADSL.</p> <p>APHASEN cannot be present unless APHASE is also present. When APHASE and APHASEN are present, then on a given record, either both must be populated or both must be null.</p>
APERIOD	Period	Num		Cond	APERIOD is a record-level timing variable that represents the analysis period within the study associated with the record for analysis purposes. The value of

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
					APERIOD (if populated) must be one of the xx values found in the ADSL TRTxxP variable names. APERIOD is required if ASPER is present. APERIOD must be populated on all records where ASPER is populated.
APERIODC	Period (C)	Char		Perm	Text characterizing to which analysis period the record belongs. There must be a one-to-one relationship between APERIODC and APERIOD within a study. APERIODC cannot be present unless APERIOD is also present. When APERIOD and APERIODC are present, then on a given record, either both must be populated or both must be null.
ASPER	Subperiod within Period	Num		Perm	The numeric value characterizing a sublevel within APERIOD to which the record belongs. Within each APERIOD, the first ASPER is 1 (i.e., it resets to 1 when the APERIOD value changes). The value of ASPER (if populated) must be one of the w values found in the ADSL PxxSw variable names.
ASPERC	Subperiod within Period (C)	Char		Perm	Text characterizing to which subperiod the record belongs. There must be a one-to-one relationship between ASPERC and ASPER within a value of APERIOD, which must be the same as the one-to-one mapping between PxxSw and w in ADSL, where xx is equal to the value of APERIOD. The value of ASPERC (if populated) must be one of the values found in the ADSL PxxSw variables. ASPERC cannot be present unless ASPER is also present. When ASPER and ASPERC are present, then on a given record, either both must be populated or both must be null.
ARELTM	Analysis Relative Time	Num		Perm	The time relative to an anchor time. The amount of time from an anchor time to ATM. When ARELTM is present, the anchor time variable and ARELTMU must also be included in the dataset, and the anchor time variable must be identified in the metadata for ARELTM.
ARELTMU	Analysis Relative Time Unit	Char		Perm	The units of ARELTM. For example, "HOURS" or "MINUTES." ARELTMU is required if ARELTM is present.

Period, Subperiod, and Phase Start and End Timing Variables

Additional timing variables can be included for phase, period, and subperiod. The values of period, subperiod, and phase start (and end) timing variables must be consistent with their subject-level counterparts from ADSL.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
APERSDT	Period Start Date	Num		Perm	The starting date for the period defined by APERIOD.
APERSTM	Period Start Time	Num		Perm	The starting time for the period defined by APERIOD.
APERSDTM	Period Start Datetime	Num		Perm	The starting datetime for the period defined by APERIOD.
APERSDTF	Period Start Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of period start date. If APERSDT (or the date part of APERSDTM) was imputed, APERSDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
APERSTMF	Period Start Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of period start time. If APERSTM (or the time part of APERSDTM) was imputed, APERSTMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
APEREDT	Period End Date	Num		Perm	The ending date for the period defined by APERIOD.
APERETM	Period End Time	Num		Perm	The ending time for the period defined by APERIOD.
APEREDTM	Period End Datetime	Num		Perm	The ending datetime for the period defined by APERIOD.
APEREDTF	Period End Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of period end date. If APEREDT (or the date part of APEREDTM) was imputed, APEREDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
APERETMF	Period End Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of period end time. If APERETM (or the time part of APEREDTM) was imputed, APERETMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
ASPRSDT	Subperiod Start Date	Num		Perm	The starting date for the subperiod defined by ASPER.
ASPRSTM	Subperiod Start Time	Num		Perm	The starting time for the subperiod defined by ASPER.
ASPRSDTM	Subperiod Start Datetime	Num		Perm	The starting datetime for the subperiod defined by ASPER.
ASPRSDTF	Subperiod Start Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of subperiod start date. If ASPRSRT (or the date part of ASPRSDTM) was imputed, ASPRSRTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
ASPRSTMF	Subperiod Start Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of subperiod start time. If ASPRSTM (or the time part of ASPRSRTM) was imputed, ASPRSTMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
ASPREDT	Subperiod End Date	Num		Perm	The ending date for the subperiod defined by ASPER.
ASPRETM	Subperiod End Time	Num		Perm	The ending time for the subperiod defined by ASPER.
ASPREDTM	Subperiod End Datetime	Num		Perm	The ending datetime for the subperiod defined by ASPER.
ASPREDTF	Subperiod End Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of subperiod end date. If ASPREDT (or the date part of ASPREDTM) was imputed, ASPREDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
ASPRETMF	Subperiod End Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of subperiod end time. If ASPRETM (or the time part of ASPREDTM) was imputed, ASPRETMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
PHSDT	Phase Start Date	Num		Perm	The starting date for the phase defined by APHASE.
PHSTM	Phase Start Time	Num		Perm	The starting time for the phase defined by APHASE.
PHSDTM	Phase Start Datetime	Num		Perm	The starting datetime for the phase defined by APHASE.
PHSDTF	Phase Start Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of phase start date. If PHSDT (or the date part of PHSDTM) was imputed, PHSDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
PHSTMF	Phase Start Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of phase start time. If PHSTM (or the time part of PHSDTM) was imputed, PHSTMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
PHEDT	Phase End Date	Num		Perm	The ending date for the phase defined by APHASE.
PHETM	Phase End Time	Num		Perm	The ending time for the phase defined by APHASE.
PHEDTM	Phase End Datetime	Num		Perm	The ending datetime for the phase defined by APHASE.
PHEDTF	Phase End Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of phase end date. If PHEDT (or the date part of PHEDTM) was imputed, PHEDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
PHETMF	Phase End Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of phase end time. If PHETM (or the time part of PHEDTM) was imputed, PHETMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .

Suffixes for Producer-defined Timing Variables in BDS Datasets

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
*DT	{Date}	Num		Perm	Analysis date not directly characterizing AVAL and/or AVALC in numeric format.
*TM	{Time}	Num		Perm	Analysis time not directly characterizing AVAL and/or AVALC in numeric format.
*DTM	{Datetime}	Num		Perm	Analysis datetime not directly characterizing AVAL and/or AVALC in numeric format.
*ADY	{Relative Day}	Num		Perm	Analysis relative day not directly characterizing AVAL and/or AVALC.
*DTF	{Date Imputation Flag}	Char	(DATEFL)	Cond	The level of imputation of *DT. If *DT (or the date part of *DTM) was imputed, *DTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
*TMF	{Time Imputation Flag}	Char	(TIMEFL)	Cond	The level of imputation of *TM. If *TM (or the time part of *DTM) was imputed, *TMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
*SDT	{Start Date}	Num		Perm	Starting analysis date not directly characterizing AVAL and/or AVALC in numeric format.
*STM	{Start Time}	Num		Perm	Starting analysis time not directly characterizing AVAL and/or AVALC in numeric format.
*SDTM	{Start Datetime}	Num		Perm	Starting analysis datetime not directly characterizing AVAL and/or AVALC in numeric format.
*SDY	{Relative Start Day}	Num		Perm	Starting analysis relative day not directly characterizing AVAL and/or AVALC.
*SDTF	{Start Date Imputation Flag}	Char	(DATEFL)	Cond	The level of imputation of *SDT. If *SDT (or the date part of *SDTM) was imputed, *SDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
*STMF	{Start Time Imputation Flag}	Char	(TIMEFL)	Cond	The level of imputation of *STM. If *STM (or the time part of *SDTM) was imputed, *STM must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
*EDT	{End Date}	Num		Perm	Ending analysis date not directly characterizing AVAL and/or AVALC in numeric format. If both *SDT and *EDT are populated then *SDT must be less than or equal to *EDT.
*ETM	{End Time}	Num		Perm	Ending analysis time not directly characterizing AVAL and/or AVALC in numeric format.
*EDTM	{End Datetime}	Num		Perm	Ending analysis datetime not directly characterizing AVAL and/or AVALC in numeric format. If both *SDTM and *EDTM are populated then *SDTM must be less than or equal to *EDTM.
*EDY	{Relative End Day}	Num		Perm	Ending analysis relative day not directly characterizing AVAL and/or AVALC. If both *SDY and *EDY are populated then *SDY must be less than or equal to *EDY
*EDTF	{End Date Imputation Flag}	Char	(DATEFL)	Cond	The level of imputation of *EDT. If *EDT (or the date part of *EDTM) was imputed, *EDTF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
*ETMF	{End Time Imputation Flag}	Char	(TIMEFL)	Cond	The level of imputation of *ETM. If *ETM (or the time part of *EDTM) was imputed, *ETMF must be populated and is required. See Section 2.9.3.3, Date and Time Imputation Flag Variables .

2.9.6.4 Analysis Parameter Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
PARAM	Parameter	Char		Req	<p>The description of the analysis parameter. PARAM must include all descriptive and qualifying information relevant to the analysis purpose of the parameter. Some examples are: "Supine Systolic Blood Pressure (mm Hg)", "Log10 (Weight (kg))", "Time to First Hypertension Event (Days)", and "Estimated Tumor Growth Rate". PARAM should be sufficient to describe unambiguously the contents of AVAL and/or AVALC.</p> <p>Examples of qualifying information that might be relevant to analysis, and are therefore candidates for inclusion in PARAM, are units, specimen type, location, position, machine type, and transformation function. There is no need to include qualifiers that are not relevant to the analysis of PARAM. In contrast to SDTM --TEST, no additional variable is needed to further qualify PARAM. PARAM is restricted to a maximum of 200 characters. If the value of PARAM will be used as a variable label in a transposed dataset, then the producer may wish to limit the value of PARAM to 40 characters. Such limitation to 40 characters should not compromise the integrity of the description.</p> <p>PARAM is often directly usable in clinical study report displays. Note that in the ADaMIG, "parameter" is a synonym of "analysis parameter."</p> <p>PARAM must be present and populated on every record in a BDS dataset.</p>
PARAMCD	Parameter Code	Char		Req	<p>The short name of the analysis parameter in PARAM. The values of PARAMCD must be no more than 8 characters in length, start with a letter (not underscore), and be composed only of letters (A-Z), underscore (_), and numerals (0-9). These constraints allow for a BDS dataset to be transposed in such a way that the values of PARAMCD can be used as valid ADaM variable names per Section 2.9.3.1, General Variable Conventions. There must be a one-to-one relationship between PARAM and PARAMCD within a dataset.</p> <p>PARAMCD must be present and populated on every record in a BDS dataset.</p>
PARAMN	Parameter (N)	Num		Perm	<p>Numeric representation of PARAM. Useful for ordering and programmatic manipulation. There must be a one-to-one relationship between PARAM and PARAMN within a dataset for all parameters where PARAMN is populated. If PARAMN is populated on any record for a PARAM, it must be populated on every record for that PARAM.</p>
PARCATy	Parameter Category y	Char		Perm	<p>A categorization of PARAM within a dataset. For example, values of PARCAT1 might group the parameters having to do with a particular questionnaire, lab specimen type, or area of investigation. Note that PARCATy is not a qualifier for PARAM. PARAM to PARCATy is a many-to-one mapping; any given PARAM may be associated with at most one level of PARCATy (e.g., one level of PARCAT1 and one level of PARCAT2).</p>
PARCATyN	Parameter Category y (N)	Num		Perm	<p>Numeric representation of PARCATy. Useful for the ordering of values of PARCATy or for other purposes. There must be a one-to-one relationship between PARCATy and PARCATyN within a dataset.</p> <p>PARCATyN cannot be present unless PARCATy is also present. When PARCATy and PARCATyN are present, then on a given record, either both must be populated or both must be null.</p>

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
AVAL	Analysis Value	Num		Cond	Numeric analysis value described by PARAM. On a given record, it is permissible for AVAL, AVALC, or both to be null. AVAL is required if AVALC is not present, since either AVAL or AVALC must be present in the dataset.
AVALC	Analysis Value (C)	Char		Cond	Character analysis value described by PARAM. AVALC can be a character string mapping to AVAL, but if so there must be a one-to-one relationship between AVAL and AVALC within a given PARAM. AVALC should not be used to categorize the values of AVAL. Within a given parameter, if there exists a row on which both AVALC and AVAL are populated, then there must be a one-to-one relationship between AVALC and AVAL on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either AVAL or AVALC be included when determining whether the one-to-one relationship requirement is satisfied.) On a given record, it is permissible for AVAL, AVALC, or both to be null. AVALC is required if AVAL is not present, since either AVAL or AVALC must be present in the dataset.
AVALCATy	Analysis Value Category y	Char		Perm	A categorization of AVAL or AVALC within a parameter. Not necessarily a one-to-one mapping to AVAL and/or AVALC. For example, if PARAM is "Headache Severity" and AVAL has values 0, 1, 2, or 3, AVALCAT1 can categorize AVAL into "None or Mild" (for AVAL 0 or 1) and "Moderate or Severe" (for AVAL 2 or 3). AVALCATy is parameter variant.
AVALCAYN	Analysis Value Category y (N)	Num		Perm	Numeric representation of AVALCATy. Useful for ordering of values of AVALCATy or for other purposes. There must be a one-to-one relationship between AVALCAYN and AVALCATy within a parameter. AVALCAYN cannot be present unless AVALCATy is also present. When AVALCATy and AVALCAYN are present, then on a given record, either both must be populated or both must be null.
BASE	Baseline Value	Num		Cond	The subject's baseline analysis value for a parameter and baseline definition (i.e., BASETYPE) if present. BASE contains the value of AVAL copied from a record within the parameter on which ABLFL = "Y". Required if dataset supports analysis or review of numeric baseline value or functions of numeric baseline value. If BASE is populated for a parameter, and BASE is non-null for a subject for that parameter, then there must be a record flagged by ABLFL for that subject and parameter. Note that a baseline record may be derived (e.g., it may be an average) in which case DTYPY must be populated on the baseline record.
BASEC	Baseline Value (C)	Char		Perm	The subject's baseline value of AVALC for a parameter and baseline definition (i.e., BASETYPE) if present. May be needed when AVALC is of interest. BASEC contains the value of AVALC copied from a record within the parameter on which ABLFL = "Y". If both AVAL and AVALC are populated within a parameter, the baseline record for AVALC must be the same record as that for AVAL. Within a given parameter, if there exists a row on which both BASEC and BASE are populated, then there must be a one-to-one relationship between BASEC and BASE on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either BASE or BASEC be included when determining whether the one-to-one relationship requirement is satisfied.) On a given record, it is permissible for BASE, BASEC, or both to be null.
BASECATy	Baseline Category y	Char		Perm	A categorization of BASE or BASEC within a parameter. Not necessarily a one-to-one mapping to BASE or BASEC. For example, if PARAM is "Headache Severity" and AVAL has values 0, 1, 2, or 3, BASECAT1 can categorize BASE into "None or Mild" (for BASE 0 or 1) and "Moderate or Severe" (for BASE 2 or 3).
BASECAYN	Baseline Category y (N)	Num		Perm	Numeric representation of BASECATy. Useful for ordering of values of BASECATy or for other purposes. There must be a one-to-one relationship between BASECAYN and BASECATy within a parameter. BASECAYN cannot be present unless BASECATy is also present. When BASECATy and BASECAYN are present, then on a given record, either both must be populated or both must be null.
BASETYPE	Baseline Type	Char		Cond	Producer-defined text describing the definition of baseline relevant to the value of BASE on the current record. Required when there are multiple ways that baseline is defined. If used for any PARAM within a dataset, it must be non-null for all records for that PARAM within that dataset where either BASE or BASEC are also non-null.
CHG	Change from Baseline	Num		Perm	Change from baseline analysis value. Equal to AVAL-BASE. If used for a given PARAM, should be populated for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of CHG is left to producer choice.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
CHGCATy	Change from Baseline Category y	Char		Perm	A categorization of CHG within a parameter. Not necessarily a one-to-one mapping to CHG. The definition of CHGCATy may vary by PARAM. For example, CHGCAT1 may be used to categorize CHG with respect to ranges of change in SYSBP; "-10 to -5 mm Hg", "-5 to 0 mm Hg" categories.
CHGCATyN	Change from Baseline Category y (N)	Num		Perm	Numeric representation of CHGCATy. Useful for ordering of values of CHGCATy or for other purposes. There must be a one-to-one relationship between CHGCATyN and CHGCATy within a parameter. CHGCATyN cannot be present unless CHGCATy is also present. When CHGCATy and CHGCATyN are present, then on a given record, either both must be populated or both must be null.
PCHG	Percent Change from Baseline	Num		Perm	Percent change from baseline analysis value. Equal to ((AVAL-BASE)/BASE)*100. If used for a given PARAM, should be populated (when calculable) for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of PCHG is left to producer choice.
PCHGCATy	Percent Chg from Baseline Category y	Char		Perm	A categorization of PCHG within a parameter. Not necessarily a one-to-one mapping to PCHG. The definition of PCHGCATy may vary by PARAM. For example, PCHGCAT1 may be used to categorize PCHG with respect to ranges of change in SYSBP; ">5%", ">10%" categories.
PCHGCAYN	Percent Chg from Baseline Category y (N)	Num		Perm	Numeric representation of PCHGCATy. Useful for ordering of values of PCHGCATy or for other purposes. There must be a one-to-one relationship between PCHGCAYN and PCHGCATy within a parameter. PCHGCAYN cannot be present unless PCHGCATy is also present. When PCHGCATy and PCHGCAYN are present, then on a given record, either both must be populated or both must be null.
R2BASE	Ratio to Baseline	Num		Perm	Ratio to the baseline value. Equal to AVAL / BASE. If used for a given PARAM, should be populated for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of R2BASE is left to producer choice.
R2AyLO	Ratio to Analysis Range y Lower Limit	Num		Perm	Ratio to the lower limit of the analysis range y. Equal to AVAL / AyLO. AyLO must exist in the ADaM dataset. If used for a given PARAM, should be populated for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of R2AyLO is left to producer choice.
R2AyHI	Ratio to Analysis Range y Upper Limit	Num		Perm	Ratio to the upper limit of the analysis range y. Equal to AVAL / AyHI. AyHI must exist in the ADaM dataset. If used for a given PARAM, should be populated for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of R2AyHI is left to producer choice.
SHIFTy	Shift y	Char		Perm	A shift in values depending on the defined pairing for group y within a parameter. SHIFTy can only be based on the change in value of any of the following pairs (BASECATy, AVALCATy), (BNRIND, ANRIND), (ByIND, AyIND), (BTOXGR, ATOXGR), (BTOXGRL, ATOXGRL), (BTOXGRH, ATOXGRH), (BASE, AVAL) or (BASEC, AVALC). Useful for shift tables. For example, "NORMAL to HIGH". If used for a given PARAM, should be populated (when calculable) for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate baseline and pre-baseline values of SHIFTy is left to producer choice.
SHIFTyN	Shift y (N)	Num		Perm	Numeric representation of SHIFTy. There must be a one-to-one relationship between SHIFTyN and SHIFTy within a parameter. SHIFTyN cannot be present unless SHIFTy is also present. When SHIFTy and SHIFTyN are present, then on a given record, either both must be populated or both must be null. If SHIFTyN is used for a given PARAM, SHIFTy and SHIFTyN should be populated (when calculable) for all post-baseline records of that PARAM regardless of whether that record is used for analysis.
BCHG	Change to Baseline	Num		Perm	Change to baseline analysis value. Equal to BASE-AVAL. If used for a given PARAM, should be populated for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of BCHG is left to producer choice.
BCHGCATy	Change to Baseline Category y	Char		Perm	A categorization of BCHG within a parameter. Not necessarily a one-to-one mapping to BCHG. The definition of BCHGCATy may vary by PARAM. For example, BCHGCAT1 may be used to categorize BCHG with respect to ranges of change in SYSBP; "-10 to -5 mm Hg", "-5 to 0 mm Hg" categories.
BCHGCAYN	Change to Baseline Category y (N)	Num		Perm	Numeric representation of BCHGCATy. Useful for ordering of values of BCHGCATy or for other purposes. There must be a one-to-one relationship between BCHGCAYN and BCHGCATy within a parameter. BCHGCAYN cannot be present unless BCHGCATy is also present. When BCHGCATy and BCHGCAYN are present, then on a given record, either both must be populated or both must be null.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
PBCHG	Percent Change to Baseline	Num		Perm	Percent change to baseline analysis value. Equal to ((BASE-AVAL)/AVAL)*100. If used for a given PARAM, should be populated (when calculable) for all post-baseline records of that PARAM regardless of whether that record is used for analysis. The decision on how to populate pre-baseline and baseline values of PBCHG is left to producer choice
PBCHGCAy	Percent Change to Baseline Category y	Char		Perm	A categorization of PBCHG within a parameter. Not necessarily a one-to-one mapping to PBCHG. The definition of PBCHGCAy may vary by PARAM. For example, PBCHGCA1 may be used to categorize PBCHG with respect to ranges of change in SYSBP, ">5%", ">10%" categories.
PBCHGCyN	Percent Change to Baseline Category y (N)	Num		Perm	Numerical representation of PBCHGCAy. Useful for ordering of values of PBCHGCAy or for other purposes. There must be a one-to-one relationship between PBCHGCyN and PBCHGCAy within a parameter. PBCHGCyN cannot be present unless PBCHGCAy is also present. When PBCHGCAy and PBCHGCyN are present, then on a given record, either both must be populated or both must be null.

2.9.6.5 PARAM, AVAL, and AVALC

It is important to understand a key difference in approach between the SDTM Findings class variable --TEST and the ADaM BDS variable PARAM. SDTM --TEST is designed to work in conjunction with other variables called "qualifiers" (e.g., specimen type, machine type, body position) in order to describe the collected result. In contrast, the ADaM BDS variable PARAM does not have any accompanying qualifier variables. PARAM is the only variable that describes AVAL or AVALC. Qualifiers are not allowed.

PARAM is created to meet an analysis need, not just because something was collected. PARAM may describe an analysis value that is highly derived from subject data from any combination of SDTM domains of any class or classes, and/or any ADaM dataset. PARAM describes what is in AVAL or AVALC.

For most parameters, only AVAL or AVALC will be populated, not both. That both --STRESC and --STRESN are present and populated in SDTM Findings class domains does not imply that both AVAL and AVALC must be present and populated in BDS datasets. AVAL and AVALC have a different purpose than --STRESN and --STRESC. For example, for parameters corresponding to numeric tests in SDTM Findings class domains, it is not recommended to copy SDTM --STRESC into AVALC, because there is no analysis need for a character value. Further, doing so may result in breaking the one-to-one mapping requirement in some cases. If it is desired for traceability or listing purposes to bring the value of --STRESC into the ADaM dataset, the variable --STRESC may be copied as is without renaming it.

AVAL and AVALC are both populated only when one-to-one mapping may be useful, for example:

- When PARAM describes the numeric score of an individual question from a questionnaire, AVAL contains the score, and AVALC can be populated with the question answer text. Populating AVALC with the question answer text is supportive of review, and may help the consumer understand the meaning of the numeric score that is the subject of the Within the parameter, there is a one-to-one relationship between AVAL and AVALC on the rows on which both are populated.
- When PARAM describes a character-valued response from a set of possible values, the result is contained in If desired for ordering or other reasons, AVAL can also be populated, as long as the result of populating both AVAL and AVALC for the parameter is that they are a one-to-one map on the rows on which both are populated.

2.9.6.6 Analysis Parameter Criteria Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
CRITy	Analysis Criterion y	Char		Perm	A text string identifying a prespecified criterion within a parameter (e.g., SYSBP > 90). Required if CRITyFL is present. In some cases, the presence of the text string indicates that the criterion is satisfied on this record and CRITyFL is set to "Y", while a null value indicates that the criterion is not satisfied or is not evaluable and is accompanied by a null value in CRITyFL. In other cases, the text string identifies the criterion being evaluated and is populated on every row for the parameter; whether the criterion is satisfied is indicated by the value of the variable CRITyFL. See CRITyFL and CRITyFN. Refer to Section 2.9.9.4, Identification of Records Used for Analysis , for additional discussion of CRITy, CRITyFL and CRITyFN.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
CRITyFL	Criterion y Evaluation Result Flag	Char	Y or Y, N	Cond	Character flag variable indicating whether the criterion defined in CRITy was met by the data on the record. See CRITy for more information regarding how to use CRITy and CRITyFL to indicate whether a criterion is met. Required if CRITy is present. Refer to Section 2.9.9.4, Identification of Records Used for Analysis , for additional discussion.
CRITyFN	Criterion y Evaluation Result Flag (N)	Num	1 or 1, 0	Perm	Numeric representation of CRITyFL. There must be a one-to-one relationship between CRITyFN and CRITyFL within a parameter. CRITyFN cannot be present unless CRITyFL is also present. When CRITyFL and CRITyFN are present, then on a given record, either both must be populated or both must be null.
MCRITy	Analysis Multi-Response Criterion y	Char		Perm	A text string identifying a prespecified criterion within a parameter, where the criterion can have multiple responses (as opposed to CRITy which has binary responses). Required if MCRITyML is present. For example, the grade of a lab analyte is compared to the baseline grade, with the possible conditions being 0 to 1, 0 to 2, etc. The text string identifies the criterion being evaluated (e.g., "Grade increase") and is populated on every row for the parameter; which level of the criterion is satisfied is indicated by the value of the variable MCRITyML (e.g., "0 to 1", "0 to 2"). See MCRITyML and MCRITyMN, and Section 2.9.9.4, Identification of Records Used for Analysis , for additional discussion of MCRITy, MCRITyML, and MCRITyMN.
MCRITyML	Multi-Response Criterion y Evaluation	Char		Cond	Character variable indicating which level of the criterion defined in MCRITy was met by the data on the record. See MCRITy for more information regarding how to use MCRITy and MCRITyML to indicate whether a criterion was met. Content is applicant-defined. Required if MCRITy is present.
MCRITyMN	Multi-Response Criterion y Eval (N)	Num		Perm	Numeric representation of MCRITyML. There must be a one-to-one relationship between MCRITyMN and MCRITyML within a parameter. Content is applicant-defined. MCRITyMN cannot be present unless MCRITyML is also present. When MCRITyML and MCRITyMN are present, then on a given record, either both must be populated or both must be null.

2.9.6.7 Analysis Descriptor Variables for BDS Datasets

For a given parameter within a BDS dataset, it is important (1) to be able to distinguish analysis values that are special cases of AVAL/AVALC (those for which the value is determined differently than the other analysis values within the parameter), and (2) to understand what method or algorithm was used to populate each special case. The variable DTYPe is to be used to identify records within a given parameter that contain these special-case analysis values. The value of DTYPe indicates the method used for populating the analysis value; a null value of DTYPe indicates the analysis value was not a special case. The metadata for AVAL (or AVALC) will give further information about the details of any algorithm or statistical method used to derive or impute these values. When the analysis value on a record within a parameter has been imputed or modified, DTYPe will indicate the method used to populate the analysis value. DTYPe would be used if there are special cases within the new parameter that should be identified. If a parameter is wholly derived (e.g., a time-to-event parameter), then it is a misapplication to populate DTYPe for all records in that parameter because, by definition, all records are derived using the same method.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
DTYPe	Derivation Type	Char	(DTYPe)	Cond	<p>Analysis value derivation method. DTYPe is used to denote, and must be populated, when the value of AVAL or AVALC has been imputed or derived differently than the other analysis values within the parameter. DTYPe is required to be populated even if AVAL and AVALC are null on the derived record.</p> <p>Three common situations when DTYPe should be populated:</p> <ul style="list-style-type: none"> • A new row is added within a parameter with the analysis value populated based on other rows within the parameter. • A new row is added within a parameter with the analysis value populated based on a constant value or data from other subjects. • An analysis value (AVAL or AVALC) on an existing record is being replaced with a value based on a pre-specified algorithm. <p>DTYPe is used to denote analysis values that are "special cases" within a parameter. For each value of DTYPe, the precise derivation algorithm must be defined in analysis variable metadata, even for DTYPe values in the CDISC Controlled Terminology. The controlled terminology for DTYPe is extensible. Some examples of DTYPe values:</p>

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
					<ul style="list-style-type: none"> • LOCF = last observation carried forward • WOOF = worst observation carried forward • AVERAGE = average of values

If analysis timepoints are defined by relative day or hour windows, then the variables in the following table may be used along with ADY or ARELTM to clarify how the record representing each analysis timepoint was chosen from among the possible candidates. The record chosen is indicated by the analyzed record flag ANLzzFL (see Section 2.9.6.10, [Indicator Variables for BDS Datasets](#)). Note that the variables in this table may not be applicable in all situations and are presented as an option.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
AWRANGE	Analysis Window Valid Relative Range	Char		Perm	The range of values that are valid for a given analysis timepoint (a given value of AVISIT). For example, "5-9 DAYS".
AWTARGET	Analysis Window Target	Num		Perm	The target or most desired analysis relative day (ADY) value or analysis relative time (ARELTM) value for a given value of AVISIT.
AWTDIFF	Analysis Window Diff from Target	Num		Perm	Absolute difference between ADY or ARELTM and AWTARGET. It will be necessary to adjust for the fact that there is no day 0 in the event that ADY and AWTARGET are not of the same sign. If the sign of the difference is important, then AWTDIFF might have to be used in conjunction with ADY or ARELTM and possibly AWTARGET when choosing among records.
AWLO	Analysis Window Beginning Timepoint	Num		Perm	The value of the beginning timepoint (inclusive) needs to be used in conjunction to AWRANGE. For example, if AWRANGE is "5-9 DAYS", then AWLO is "5".
AWHI	Analysis Window Ending Timepoint	Num		Perm	The value of the ending timepoint (inclusive) needs to be used in conjunction to AWRANGE. For example, if AWRANGE is "5-9 DAYS", then AWHI is "9".
AWU	Analysis Window Unit	Char		Perm	Unit used for AWTARGET, AWTDIFF, AWLO and AWHI. Examples: DAYS, HOURS.

2.9.6.8 Time-to-Event Variables for BDS Datasets

The following table describes variables useful for time-to-event analysis. The ADaM Basic Data Structure for Time-to-Event Analyses (available at <https://www.cdisc.org/standards/foundational/adam>) provides discussion and examples of the use of these variables and other ADaM variables to support time-to-event analyses. For example, the document describes using AVAL for the length of time from the start of the at-risk period to the event of interest, ADT for the date of event or censoring, and AVISIT for the analysis visit where event or censoring occurred.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
STARTDT	Time-to-Event Origin Date for Subject	Num		Perm	The original date of risk for the time-to-event analysis. This is generally the point at which a subject is first at risk for the event of interest evaluation (as defined in the protocol or SAP). For example, this may be the randomization date or the date of first study therapy exposure.
STARTDTM	Time-to-Event Origin Datetime	Num		Perm	The original datetime of risk for the time-to-event analysis. This is generally the point at which a subject is first at risk for the event of interest evaluation (as defined in the protocol or SAP). For example, this may be the randomization datetime or the datetime of first study therapy exposure.
STARTDTF	Origin Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of the start date. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
STARTTMF	Origin Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of the start time. See Section 2.9.3.3, Date and Time Imputation Flag Variables .
CNSR	Censor	Num		Cond	Defines whether the event was censored for the subject within the parameter (period of observation truncated prior to event being observed). It is strongly recommended to use 0 as an event indicator and positive integers as censoring indicators. It is also recommended that unique positive integers be used to indicate coded descriptions of censoring reasons. CNSR is required for time-to-event parameters.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
EVNTDESC	Event or Censoring Description	Char		Perm	Description of the event of interest or censoring reason for the subject within the parameter.
CNSSTDSC	Censor Date Description	Char		Perm	Describes the circumstance represented by the censoring date if different from the event date that warrants censoring.

2.9.6.9 Toxicity and Range Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
ATOXGR	Analysis Toxicity Grade	Char		Perm	Toxicity grade of AVAL or AVALC for analysis; may be based on SDTM --TOXGR or an imputed or assigned value.
ATOXGRN	Analysis Toxicity Grade (N)	Num		Perm	Numeric representation of ATOXGR. There must be a one-to-one relationship between ATOXGRN and ATOXGR within a parameter. ATOXGRN cannot be present unless ATOXGR is also present. When ATOXGR and ATOXGRN are present, then on a given record, either both must be populated or both must be null.
BTOXGR	Baseline Toxicity Grade	Char		Perm	ATOXGR of the baseline record identified by ABLFL.
BTOXGRN	Baseline Toxicity Grade (N)	Num		Perm	Numeric representation of BTOXGR. There must be a one-to-one relationship between BTOXGRN and BTOXGR within a parameter. BTOXGRN cannot be present unless BTOXGR is also present. When BTOXGR and BTOXGRN are present, then on a given record, either both must be populated or both must be null.
ANRIND	Analysis Reference Range Indicator	Char		Perm	Indicates where AVAL or AVALC falls with respect to the normal reference range for analysis; may be based on SDTM --NRIND or an imputed or assigned value.
BNRIND	Baseline Reference Range Indicator	Char		Perm	ANRIND of the baseline record identified by ABLFL.
ANRLO	Analysis Normal Range Lower Limit	Num		Perm	Normal range lower limit for analysis; may be based on SDTM --NRLO or an imputed or assigned value.
ANRLOC	Analysis Normal Range Lower Limit (C)	Char		Perm	Character analysis normal range lower limit. ANRLOC can be a character string mapping to ANRLO, but if so there must be a one-to-one relationship between ANRLO and ANRLOC within a given PARAM. ANRLOC should not be used to categorize the values of ANRLO. Within a given parameter, if there exists a row on which both ANRLOC and ANRLO are populated, then there must be a one-to-one relationship between ANRLOC and ANRLO on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either ANRLO or ANRLOC be included when determining whether the one-to-one relationship requirement is satisfied.) On a given record, it is permissible for ANRLO, ANRLOC, or both to be null.
ANRHI	Analysis Normal Range Upper Limit	Num		Perm	Normal range upper limit for analysis; may be based on SDTM --NRHI or an imputed or assigned value.
ANRHIC	Analysis Normal Range Upper Limit (C)	Char		Perm	Character analysis normal range upper limit. ANRHIC can be a character string mapping to ANRHI, but if so there must be a one-to-one relationship between ANRHI and ANRHIC within a given PARAM. ANRHIC should not be used to categorize the values of ANRHI. Within a given parameter, if there exists a row on which both ANRHIC and ANRHI are populated, then there must be a one-to-one relationship between ANRHIC and ANRHI on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either ANRHI or ANRHIC be included when determining whether the one-to-one relationship requirement is satisfied.) On a given record, it is permissible for ANRHI, ANRHIC, or both to be null.
AyLO	Analysis Range y Lower Limit	Num		Cond	AyLO and/or AyHI are used for analysis ranges other than the normal range. AyLO and/or AyHI are created to capture the different levels of cutoff values used to determine whether an analysis is within a clinically acceptable value range or outside that value range. AyLO and/or AyHI are usually but not necessarily constants, parameter-specific constants, or subject-specific constants. AyLO must be included if R2AyLO is included in the dataset.
AyLOC	Analysis Range y Lower Limit (C)	Char		Perm	Character analysis range y lower limit.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
					AyLOC can be a character string mapping to AyLO, but if so there must be a one-to-one relationship between AyLO and AyLOC within a given PARAM. AyLOC should not be used to categorize the values of AyLO. Within a given parameter, if there exists a row on which both AyLOC and AyLO are populated, then there must be a one-to-one relationship between AyLOC and AyLO on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either AyLO or AyLOC be included when determining whether the one-to-one relationship requirement is satisfied.) On a given record, it is permissible for AyLO, AyLOC, or both to be null.
AyHI	Analysis Range y Upper Limit	Num		Cond	See AyLO. For example, if ECG QTc values are summarized based on values >450, values >480, and values >500, there is a need for 3 "hi value" range variables against which to compare values: A1HI=450, A2HI=480, A3HI=500. AyHI must be included if R2AyHI is included in the dataset.
AyHIC	Analysis Range y Upper Limit (C)	Char		Perm	Character analysis range y upper limit. AyHIC can be a character string mapping to AyHI, but if so there must be a one-to-one relationship between AyHI and AyHIC within a given PARAM. AyHIC should not be used to categorize the values of AyHI. Within a given parameter, if there exists a row on which both AyHIC and AyHI are populated, then there must be a one-to-one relationship between AyHIC and AyHI on all rows on which both variables are populated. (In other words, there is no requirement that records with a null value in either AyHI or AyHIC be included when determining whether the one-to-one relationship requirement is satisfied.) On a given record, it is permissible for AyHI, AyHIC, or both to be null.
AyIND	Analysis Range y Indicator	Char		Perm	Indicates relationship of AVAL to the analysis range variables AyLO and/or AyHI, or the relationship of AVALC to the analysis range variables AyLOC and/or AyHIC.
ByIND	Baseline Analysis Range y Indicator	Char		Perm	AyIND of the baseline record identified by ABLFL.
ATOXGRL	Analysis Toxicity Grade Low	Char		Perm	Low toxicity grade of AVAL or AVALC for analysis; may be based on SDTM --TOXGR or an imputed or assigned value. Used to assess when a subject's lab value falls within the low toxicity range.
ATOXGRLN	Analysis Toxicity Grade Low (N)	Num		Perm	Numeric representation of ATOXGRL. There must be a one-to-one relationship between ATOXGRLN and ATOXGRL within a parameter. ATOXGRLN cannot be present unless ATOXGRL is also present. When ATOXGRL and ATOXGRLN are present, then on a given record, either both must be populated or both must be null.
ATOXGRH	Analysis Toxicity Grade High	Char		Perm	High toxicity grade of AVAL or AVALC for analysis; may be based on SDTM --TOXGR or an imputed or assigned value. Used to assess when a subject's lab value falls within the high toxicity range.
ATOXGRHN	Analysis Toxicity Grade High (N)	Num		Perm	Numeric representation of ATOXGRH. There must be a one-to-one relationship between ATOXGRHN and ATOXGRH within a parameter. ATOXGRHN cannot be present unless ATOXGRH is also present. When ATOXGRH and ATOXGRHN are present, then on a given record, either both must be populated or both must be null.
BTOXGRL	Baseline Toxicity Grade Low	Char		Perm	ATOXGRL of the baseline record identified by ABLFL.
BTOXGRLN	Baseline Toxicity Grade Low (N)	Num		Perm	Numeric representation of BTOXGRL. There must be a one-to-one relationship between BTOXGRLN and BTOXGRL within a parameter. BTOXGRLN cannot be present unless BTOXGRL is also present. When BTOXGRL and BTOXGRLN are present, then on a given record, either both must be populated or both must be null.
BTOXGRH	Baseline Toxicity Grade High	Char		Perm	ATOXGRH of the baseline record identified by ABLFL.
BTOXGRHN	Baseline Toxicity Grade High (N)	Num		Perm	Numeric representation of BTOXGRH. There must be a one-to-one relationship between BTOXGRHN and BTOXGRH within a parameter.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
					BTOXGRHN cannot be present unless BTOXGRH is also present. When BTOXGRH and BTOXGRHN are present, then on a given record, either both must be populated or both must be null.
ATOXDSCL	Analysis Toxicity Description Low	Char		Perm	The analysis toxicity term used to describe toxicity in the low direction. ATOXDSCL is only populated if AVAL is populated and the PARAM is evaluated for toxicity in the low direction. There is a one-to-one relationship between ATOXDSCL and PARAM within a subject. The intent of this variable is to describe the type of toxicity being evaluated and not the level of toxicity on the specific record.
ATOXDSCH	Analysis Toxicity Description High	Char		Perm	The analysis toxicity term used to describe toxicity in the high direction. ATOXDSCH is only populated if AVAL is populated and the PARAM is evaluated for toxicity in the high direction. There is a one-to-one relationship between ATOXDSCH and PARAM within a subject. The intent of this variable is to describe the type of toxicity being evaluated and not the level of toxicity on the specific record.

2.9.6.10 Indicator Variables for BDS Datasets

For flag variables, values of only "Y" or null are used when a value of "N" is unimportant to the analysis (i.e., "N" and null are treated the same in the analysis). Flag values of "Y", "N", or null should be used when "N" and null are treated differently in the analysis. The values shown in the Codelist/Controlled Terms column support common statistical needs. If required, the codelist/controlled terms values can be changed from "Y" to "Y, N".

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
ABLFL	Baseline Record Flag	Char	Y	Cond	Character indicator to identify the baseline record for each subject, parameter, and baseline type (BASETYPE) combination. See Section 2.9.6.4, Analysis Parameter Variables for BDS Datasets . ABLFL is required if BASE is present in the dataset. A baseline record may be derived (e.g., may be an average), in which case DTYP must also be populated. If BASE is populated for a parameter, and BASE is non-null for a subject for that parameter, then there must be a record flagged by ABLFL for that subject and parameter.
ABLFN	Baseline Record Flag (N)	Num	1	Perm	Numeric representation of ABLFL. There must be a one-to-one relationship between ABLFN and ABLFL. ABLFN cannot be present unless ABLFL is also present. When ABLFL and ABLFN are present, then on a given record, either both must be populated or both must be null.
ANLzzFL	Analysis Flag zz	Char	Y	Cond	as SITEGRY, and others. The lower-case letter "zz" in the variable name is an index for the zz th record selection algorithm where "zz" is replaced with a zero-padded two-digit integer [01-99]. Every record selection algorithm "zz" (i.e., every algorithm for populating an ANLzzFL) must be defined in variable metadata. When the set of records that the algorithm "zz" operates on is pre-filtered by application of other criteria, such as a record-level population flag, then the selection algorithm definition in the metadata must so specify. Note that the ANLzzFL value of Y indicates that the record fulfilled the requirements of the algorithm, but does not necessarily imply that the record was actually used in one or more analyses, as whether or not a record is used also depends on the other selection variables applied. The ANLzzFL flag is useful in many circumstances; an example is when there is more than one record for an analysis timepoint within a subject and parameter, as it can be used to identify the record chosen to represent the timepoint for an analysis. "zz" is an index for a record selection algorithm, such as "record closest to target relative day for the AVISIT, with ties broken by the latest record, for each AVISIT within <list of AVISITS>." Note that it is not required that a specific ANLzzFL variable has the same definition across a project or even across datasets within a study. There is also no requirement that the ANLzzFL variables in a dataset or study be used in numerical order; e.g. ANL02FL might occur in a dataset or study without ANL01FL present in the same dataset or study.
ANLzzFN	Analysis Flag zz (N)	Num	1	Perm	Numeric representation of ANLzzFL. There must be a one-to-one relationship between ANLzzFN and ANLzzFL within a dataset. ANLzzFN cannot be present unless ANLzzFL is also present. When ANLzzFL and ANLzzFN are present, then on a given record, either both must be populated or both must be null.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ONTRTFL	On Product Record Flag	Char	Y	Perm	Character indicator of whether the observation occurred while the subject was on product. ONTRTFL is producer-defined, and its definition may vary across datasets in a study based on analysis needs.
ONTRTFN	On Product Record Flag (N)	Num	1	Perm	Numeric representation of ONTRTFL. There must be a one-to-one relationship between ONTRTFN and ONTRTFL within a dataset. ONTRTFN cannot be present unless ONTRTFL is also present. When ONTRTFL and ONTRTFN are present, then on a given record, either both must be populated or both must be null.
LVOTFL	Last Value On Product Record Flag	Char	Y	Perm	Character indicator of the subject's last non-missing value on product for each parameter.
LVOTFN	Last Value On Product Record Flag (N)	Num	1	Perm	Numeric representation of LVOTFL. There must be a one-to-one relationship between LVOTFN and LVOTFL within a dataset. LVOTFN cannot be present unless LVOTFL is also present. When LVOTFL and LVOTFN are present, then on a given record, either both must be populated or both must be null.

2.9.6.11 Datapoint Traceability Variables for BDS Datasets

Variables to support datapoint traceability should be included whenever practical and feasible. Primary candidates for datapoint traceability, when used in conjunction with USUBJID, include the dataset or domain name, the name of the source variable, and the relevant sequence number (SDTM domain --SEQ value or the ADaM ASEQ value). The ADaM ASEQ variable (see Section 2.9.6.1, [Identifier Variables for BDS Datasets](#)) facilitates datapoint traceability by providing sequence numbers that are unique within a subject within an ADaM dataset, ensuring uniqueness of a record when used in combination with USUBJID.

The following table defines additional variables useful in certain situations to facilitate datapoint traceability. These variables are useful in situations where a single ADaM dataset or multiple SDTM datasets and/or ADaM datasets were used to create an ADaM dataset. Section 2.9.9.3, [Inclusion of Input Data that Are Not Analyzed but that Support a Derivation in the ADaM Dataset](#), contains an example of how to use these variables.

Variables used for datapoint traceability may also include any other variables that facilitate transparency and clarity of derivations and analysis.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
SRCDOM	Source Data	Char		Perm	The SDTM domain name or ADaM dataset name that relates to the analysis value (i.e., AVAL or AVALC in a BDS dataset). If the source data is a supplemental qualifier in SDTM, this variable will contain the value of RDOMAIN in SUPP-- or SUPPQUAL.
SRCVAR	Source Variable	Char		Perm	The name of the column (in the domain or dataset identified by SRCDOM) that relates to the analysis value (i.e., AVAL or AVALC in a BDS dataset). In the event that SRCDOM is a SUPPQUAL, then SRCVAR will be populated with the value of the related QNAM.
SRCSEQ	Source Sequence Number	Num		Perm	The sequence number --SEQ or ASEQ of the row (in the domain or dataset identified by SRCDOM) that relates to the analysis value (i.e., AVAL or AVALC in a BDS dataset). In the event that SRCDOM is a SUPPQUAL, then this variable will contain the sequence number of the relevant related domain record.

If the value of AVAL or AVALC in the ADaM dataset is taken from another ADaM dataset, SRCDOM, SRCVAR, and SRCSEQ will contain the name of the source ADaM dataset, the variable name, and the ASEQ value of the row where the source datapoint is located, respectively. If the source SDTM dataset is a supplemental qualifier dataset, the 2-letter domain prefix of --SEQ in the ADaM dataset will be the related domain abbreviation (the value of RDOMAIN in SUPP-- or SUPPQUAL), and SRCVAR will contain the value of QNAM.

SRCDOM, SRCVAR, and SRCSEQ are permissible and, if included in a dataset, do not all need to be populated on every row. For example, if the value of AVAL or AVALC is a summary of multiple rows from a single ADaM or SDTM dataset, then SRCDOM will be populated, SRCVAR will be populated if the same variable is summarized across all of the rows, and SRCSEQ will be left blank. In another example, if multiple SDTM and/or ADaM datasets are used to create AVAL or AVALC, then SRCDOM, SRCVAR, and SRCSEQ will all be left blank.

If all values of AVAL or AVALC in the ADaM dataset are taken from a single SDTM domain, all records in the ADaM dataset would have the same value for SRCDOM and SRCVAR. Instead of using SRCDOM, SRCVAR, and SRCSEQ in that case, the producer may elect to simply include the --SEQ variable from the source SDTM domain, which is sufficient to provide the needed traceability within a subject.

2.9.7 Predefined Standard Variables for OCCDS

As stated previously, OCCDS is different from the BDS. There is no PARAM nor AVAL, for example. The more standardized variables commonly occurring in the ADaM OCCDS are described here in tabular format. In general, include all variables from the SDTM dataset and corresponding supplemental qualifiers that are needed for analysis or traceability. For traceability when copying variables from SUPPQUAL, it is recommended to use variable names that exactly match the corresponding SUPPQUAL.QNAM values. Additional study- or therapeutic-area-specific variables may be added as needed but should follow the standard variable-naming conventions described in ADaMIG v1.2 Section 3.3, ADaM Basic Data Structure (BDS) Variables. For example, variables with the 2-letter SDTM prefix are most commonly those that are copied from the SDTM or transposed SUPPQUAL dataset, or the numeric version of the SDTM variable, but not analysis versions of SDTM variables. Choose variable names with care to prevent unintended conflicts with standard names.

As described in ADaM, the 3 rightmost columns of the table (i.e., Core, SubClass ADVERSE EVENT Core, CDISC Notes) provide information about the variables to assist users in preparing their datasets. These columns are not meant to be metadata submitted in define.xml. The Core column describes whether a variable is required (Req), conditionally required (Cond), or permissible (Perm) in the OCCURRENCE DATA STRUCTURE Class. The SubClass ADVERSE EVENT Core column describes whether a variable is required (Req), conditionally required (Cond), permissible (Perm), or not used (Not used) in the ADVERSE EVENT SubClass. The CDISC Notes column provides more information about the variable. In addition, the Type column is being used to define whether the variable is character (Char) or numeric value (Num). More specific information will be provided in metadata.

SubClass ADVERSE EVENT Variables

OCCDS variables are described later in this section. Variables in an OCCDS dataset that is of SubClass ADVERSE EVENT can include:

- Any variable copied unchanged from ADSL
- Any variable copied unchanged from SDTM AE
 - SubClass ADVERSE EVENT should include all SDTM AE variables with the SDTM core value of Required or Expected.
- Any variable copied or derived from SDTM F
 - When FA is used as input to the ADVERSE EVENT SubClass dataset, a unique identifier variable, such as FASEQ or FASPID, is required for traceability.
- Any variable copied from content in SDTM SUPPAE
 - It is recommended to use SUPPAE QNAM as the ADVERSE EVENT SubClass dataset variable name, SUPPAE QLABEL as the ADVERSE EVENT SubClass dataset variable label, and SUPPAE QVAL as the ADVERSE EVENT SubClass variable content.
- Derived variables, such as numeric timing variables, TRTEMFL and other indicators, analysis versions of descriptive variables, and other variables derived using the naming conventions described in Section 2.9.7.11, [User-specified Variable Naming Conventions](#)

2.9.7.1 ADSL Variables in OCCDS

Merge any subject-level variables needed for analysis or reference.

Be aware that only subjects with a record in an input SDTM domain would have a record in the analysis dataset. For this reason, it is recommended that population indicators and denominator counts for percentages be derived from ADSL and not from the occurrence analysis dataset.

2.9.7.2 Identifier Variables in OCCDS

OCCDS Identifier Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	Char		Req	XX.STUDYID
USUBJID	Unique Subject Identifier	Char		Req	XX.USUBJID
SUBJID	Subject Identifier for the Study	Char		Perm	ADSL.SUBJID
SITEID	Study Site Identifier	Char		Perm	ADSL.SITEID

In addition to the above identifiers, row identifiers are included to support datapoint traceability. The combination of dataset or domain name and the relevant sequence number, when used in conjunction with USUBJID, provide datapoint traceability. There are 2 row identifier options: --SEQ or the combination of SRCDOM + SRCSEQ.

Commonly, rows in an OCCDS dataset are created from a single SDTM domain. In this case, --SEQ provides all of the row identifier (and thus datapoint traceability) information: The 2-letter prefix of the variable name is the SDTM domain name, and the content is the relevant sequence number.

Less commonly, rows in an OCCDS dataset are from multiple SDTM domains or from 1 or more ADaM datasets. Either the --SEQ variable from each domain can be added, or the variables SRCDOM and SRCSEQ can be used to identify the input rows.

For the ADVERSE EVENT SubClass, when data from FA is used in the ADVERSE EVENT SubClass, a unique identifier variable, such as FASEQ or FASPID, is also required for traceability.

Row Identifier Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
--SEQ	Sequence Number	Num		Cond	XX.--SEQ Identifies the sequence number in SDTM domain XX that is the source for this row. This variable would be copied unchanged from the SDTM domain XX. Required for traceability back to SDTM when rows in the dataset are created from a single SDTM domain. This may be missing for derived rows. For SubClass ADVERSE EVENT, use AESEQ, copied from SDTM AE.AESEQ.
SRCDOM	Source Data	Char		Perm	Identifies the name of the domain or dataset that is the source for this row. If the source data is a supplemental qualifier in SDTM, this variable will contain the value of RDOMAIN in SUPP-- or SUPPQUAL. Used when rows in the OCCDS dataset are from multiple SDTM domains or from one or more ADaM datasets. Not to be used in conjunction with --SEQ. This may be missing for derived rows. For SubClass ADVERSE EVENT, AESEQ is used rather than SRCDOM and SRCSEQ.
SRCSEQ	Source Sequence Number	Num		Perm	Identifies the sequence number that is the source for this row. If SRCDOM is a SUPPQUAL, then this variable will contain the sequence number of the relevant related domain record. Used when rows in the OCCDS dataset are from multiple SDTM domains or from one or more ADaM datasets. Not to be used in conjunction with --SEQ. This may be missing for derived rows. For SubClass ADVERSE EVENT, AESEQ is used rather than SRCDOM and SRCSEQ.
ASEQ	Analysis Sequence Number	Num		Perm	Sequence number given to ensure uniqueness of subject records within an ADaM dataset. ASEQ is useful for traceability when the OCCDS dataset is used as input to another ADaM dataset and the --SEQ variable is not included or unique. ASEQ is described in more detail in ADaMIG v1.2, Section 3.3.1, Identifier Variables for BDS Datasets.

2.9.7.3 Dictionary Coding and Categorization Variables

Dictionary coding and categorization variables provided in the SDTM should be included as needed for analysis, review, or traceability. Common coding variables are provided in this section. If other coding variables are included in the SDTM and pertinent for analysis, these should be included in ADaM using a similar naming convention as shown here. For any public versioned dictionary, the metadata for each coding variable should include both the name and version of the dictionary.

2.9.7.3.1 MedDRA Dictionary Coding Variables

MedDRA coding is typically used for adverse events and medical history. Copy the needed MedDRA terms and codes from SDTM to the analysis dataset.

For the SubClass ADVERSE EVENT, it is required that all levels of terms for the primary path in the MedDRA hierarchy—System Organ Class (SOC), High Level Group Term (HLGT), High Level Term (HLT), Lowest Level Term (LLT), and Preferred Term (PT)—be included. For other OCCDS datasets, these variables are recommended (they are frequently useful in further analyses of events), but not required.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
--TERM	Reported Term	Char		Req	Copied from XX.--TERM This variable label differs depending on the SDTM domain. See SDTM v1.7 Section 2.2.2, The Events Observation Class, and SDTMIG v3.3 Section 6.2, Models for Events Domains, for details. Required for adverse event data.
--DECOD	Dictionary-Derived Term	Char	MedDRA	Cond	Copied from XX.--DECOD This variable is typically one of the primary variables used in an analysis and would be brought in from the SDTM domain. Equivalent to the MedDRA PT. All other SDTM domain variables and supplemental qualifiers needed for analysis or traceability should also be included. Include the dictionary version in the metadata. Conditional on whether coded and used for analysis. Required for adverse event data.
--BODSYS	Body System or Organ Class	Char	MedDRA	Cond	Copied from XX.--BODSYS Include the dictionary version in the metadata. Conditional on whether coded and used for analysis. Required for adverse event data.
--BDSYCD	Body System or Organ Class Code	Num	MedDRA	Perm	Copied from XX.--BDSYCD or the supplemental qualifier This would be copied from the SDTM domain XX or supplemental qualifier dataset. Include the dictionary version in the metadata. Required for adverse event data.
--LLT	Lowest Level Term	Char	MedDRA	Cond	Copied from XX.--LLT or the supplemental qualifier Include the dictionary version in the metadata. Conditional on whether coded and used for analysis. Required for adverse event data.
--LLTCD	Lowest Level Term Code	Num	MedDRA	Perm	Copied from XX.--LLTCD or the supplemental qualifier Include the dictionary version in the metadata. Required for adverse event data.
--PTCD	Preferred Term Code	Num	MedDRA	Perm	Copied from XX.--PTCD or the supplemental qualifier Include the dictionary version in the metadata. Required for adverse event data.
--HLT	High Level Term	Char	MedDRA	Cond	Copied from XX.--HLT or the supplemental qualifier Include the dictionary version in the metadata. Conditional on whether used for analysis. Required for adverse event data.
--HLTCD	High Level Term Code	Num	MedDRA	Perm	Copied from XX.--HLTCD or the supplemental qualifier Include the dictionary version in the metadata. Required for adverse event data.
--HLGTT	High Level Group Term	Char	MedDRA	Cond	Copied from XX.--HLGTT or the supplemental qualifier Include the dictionary version in the metadata. Conditional on whether used for analysis. Required for adverse event data.
--HLGTCD	High Level Group Term Code	Num	MedDRA	Perm	Copied from XX.--HLGTCD or the supplemental qualifier Include the dictionary version in the metadata. Required for adverse event data.
--SOC	Primary System Organ Class	Char	MedDRA	Cond	Copied from XX.--SOC or the supplemental qualifier Include the dictionary version in the metadata. Conditional on whether a secondary SOC was used for analysis. Required for adverse event data.
--SOCCD	Primary System Organ Class Code	Num	MedDRA	Perm	Copied from XX.--SOCCD or the supplemental qualifier Include the dictionary version in the metadata. Required for adverse event data.

2.9.7.3.2 WHO Drug Dictionary Coding Variables

WHODrug coding is typically used for concomitant medications. Copy to the analysis dataset the needed WHODrug terms and codes from SDTM CM and SUPPCM.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
CMTRT	Reported Name of Drug, Med, or Therapy	Char		Req	CM.CMTRT
CMDECOD	Standardized Medication Name	Char	WHO Drug	Cond	CM.CMDECOD This is typically one of the primary variables used in CM analysis and would be copied from the SDTM CM domain. Include the dictionary version in the variable metadata.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
					Conditional on whether coded and used for analysis.
CMCLAS	Medication Class	Char		Perm	CM.CMCLAS Include the dictionary version in the metadata.
CMCLASCD	Medication Class Code	Char		Perm	CM.CMCLASCD Include the dictionary version in the metadata.
ATCy	ATC Level y Text	Char	WHO Drug	Cond	Corresponds to the ATC Level Text for WHO Drug. Include the dictionary version in the variable metadata. Conditional, based on analysis at multiple levels (y)
ATCyCD	ATC Level y Code	Char	WHO Drug	Cond	Corresponds to the ATC Level Code for WHO Drug. Include the dictionary version in the variable metadata. Conditional, based on analysis at multiple levels (y)

2.9.7.3.3 Other Categorization Variables

When categories are used for the intended analysis, instead of or in addition to MedDRA or WHO Drug, these generic categorization variables are commonly used:

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
--CAT	Category	Char		Perm	Copied from XX.--CAT This variable label differs depending on the SDTM domain.
--SCAT	Subcategory	Char		Perm	Copied from XX.--SCAT This variable label differs depending on the SDTM domain.
ACATy	Analysis Category y	Char		Perm	Category used in analysis. May be derived from --CAT and/or --SCAT. Examples include records of special interest (e.g., prohibited medications), concomitant medications taken during an infusion reaction, growth factors, antimicrobial medications, and other such categories not defined elsewhere or present in SDTM domains.

2.9.7.4 Timing Variables

Timing variables are copied from the SDTM and derived within ADaM. Common timing variables are provided in this section. If other timing variables are collected in SDTM and pertinent for analysis, these should be included in ADaM. Additional timing variables, such as those for period start and end dates, can be included. For more details on timing variables, see Section 2.9.6.3, [Timing Variables for BDS Datasets](#).

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
--STDTC	Start Date/Time of Observation	Char	ISO 8601 datetime or interval	Cond	Copied from XX.--STDTC Conditional on whether start date is pertinent for study and is populated in SDTM This variable label differs depending on the SDTM domain. AESTDT is required for adverse event data.
ASTDT	Analysis Start Date	Num		Cond	Created from converting XX.--STDTC from character ISO 8601 format to numeric date format, applying imputation rules if specified in the statistical analysis plan (SAP) or metadata Conditional on whether start date is pertinent for study and is populated in SDTM. Required for adverse event data.
ASTTM	Analysis Start Time	Num		Cond	Created from converting XX.--STDTC from character ISO 8601 format to numeric time format, applying imputation rules if specified in the SAP or metadata Conditional on whether start time is pertinent for study and is populated in SDTM
ASTDTM	Analysis Start Datetime	Num		Cond	Created from converting XX.--STDTC from character ISO 8601 format to numeric datetime format, applying imputation rules if specified in the SAP or metadata Conditional on whether start datetime is pertinent for study and is populated in SDTM
ASTDTF	Analysis Start Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of analysis start date. Imputation flags are described in ADaMIG v1.2 Section 3.1.3, Date and Time Imputation Flag Variables. Conditional on whether ASTDT (or the date part of ASTDTM) was imputed
ASTTMF	Analysis Start Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of analysis start time. Imputation flags are described in ADaMIG v1.2 Section 3.1.3, Date and Time Imputation Flag Variables. Conditional on whether ASTTM (or the time part of ASTDTM) was imputed

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
--ENDTC	End Date/Time of Observation	Char	ISO 8601 datetime or interval	Cond	Copied from XX.--ENDTC Conditional on whether end date is pertinent for study and is populated in SDTM This variable label differs depending on the SDTM domain. AEENDTC is required for adverse event data.
AENDT	Analysis End Date	Num		Cond	Created from converting XX.--ENDTC from character ISO 8601 format to numeric date format, applying imputation rules if specified in the SAP or metadata. If both ASTDT and AENDT are populated then ASTDT must less than or equal to AENDT. Conditional on whether end date is pertinent for study and is populated in SDTM. Required for adverse event data.
AENTM	Analysis End Time	Num		Cond	Created from converting XX.--ENDTC from character ISO 8601 format to numeric time format, applying imputation rules if specified in the SAP or metadata Conditional on whether end time is pertinent for study and is populated in SDTM
AENDTM	Analysis End Datetime	Num		Cond	Created from converting XX.--ENDTC from character ISO 8601 format to numeric datetime format, applying imputation rules if specified in the SAP or metadata. If both ASTDTM and AENDTM are populated then ASTDTM must less than or equal to AENDTM. Conditional on whether end datetime is pertinent for study and is populated in SDTM
AENDTF	Analysis End Date Imputation Flag	Char	(DATEFL)	Cond	The level of imputation of analysis end date. Imputation flags are described in Section 2.9.3.3, Date and Time Imputation Flag Variables . Conditional on whether AENDT (or the date part of AENDTM) was imputed
AENTMF	Analysis End Time Imputation Flag	Char	(TIMEFL)	Cond	The level of imputation of analysis end time. Imputation flags are described in Section 2.9.3.3, Date and Time Imputation Flag Variables . Conditional on whether AENTM (or the date part of AENDTM) was imputed
ASTDY	Analysis Start Relative Day	Num		Cond	The number of days from an anchor date (not necessarily DM.RFSTDTC) to ASTDT Example derivation: ASTDT - ADSL.TRTSDT + 1 if ASTDT >= ADSL.TRTSDT, else ASTDT - ADSL.TRTSDT if ASTDT < ADSL.TRTSDT This variable may instead be copied from --STDY. Conditional on whether analysis start relative day is pertinent to the study. Required for adverse event data.
--STDY	Study Day of Start of Observation*	Num		Perm	Copied from XX.--STDY ASTDY may differ from --STDY due to date imputation and the option in ADaM to use a reference date other than SDTM's RFSTDTC. Including XX.--STDY in addition to ASTDY adds traceability. For SubClass ADVERSE EVENT, conditional on whether the AEASTDY variable is in the SDTM AE dataset
AENDY	Analysis End Relative Day	Num		Perm	The number of days from an anchor date (not necessarily DM.RFSTDTC) to AENDT Example derivation: AENDT - ADSL.TRTSDT + 1 if AENDT >= ADSL.TRTSDT, else AENDT - ADSL.TRTSDT if AENDT < ADSL.TRTSDT This variable may instead be copied from --ENDY. If both ASTDY and AENDY are populated then ASTDY must be less than or equal to AENDY. Required for adverse event data.
--ENDY	Study Day of End of Observation*	Num		Perm	Copied from XX.--ENDY AENDY may differ from --ENDY due to date imputation and the option in ADaM to use a reference date other than SDTM's RFSTDTC. Including XX.--ENDY in addition to AENDY adds traceability. If both --STDY and --ENDY are populated then --STDY must be less than or equal to --ENDY For SubClass ADVERSE EVENT, conditional on whether the AEENDY variable is in the SDTM AE dataset
ADURN	Analysis Duration (N)	Num		Perm	Derive from ASTDT (or ASTDTM) and AENDT (or AENDTM).
ADURU	Analysis Duration Units	Char	(UNIT)	Cond	Conditional on whether ADURN is included
--DUR	Duration of XX	Char	ISO 8601 duration	Cond	Copied from XX.--DUR Because --DUR is a collected field and ADURN is derived, the values will often differ. Including XX.--DUR in addition to ADURN adds traceability. For SubClass ADVERSE EVENT, conditional on whether the AEADUR variable is in the SDTM AE dataset.
APERIOD	Period	Num		Perm	APERIOD is a record-level timing variable that represents the analysis period within the study associated with the record for analysis purposes. The value of APERIOD (if populated) must be one of the xx values found in

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
					the ADSL TRTxxP variables. See Section 2.9.6.3, Timing Variables for BDS Datasets , for more information on this variable.
APERIODC	Period (C)	Char		Perm	Text characterizing to which period the record belongs. One-to-one map to APERIOD.
APHASE	Phase	Char		Perm	APHASE is a categorization of timing within a study, for example a higher-level categorization of APERIOD or an analysis epoch. For example, APHASE could describe spans of time for SCREENING, ON PRODUCT, and FOLLOW-UP.

2.9.7.5 Indicator Variables

Although some indicator variables can be copied from the SDTM, others are derived within ADaM. If indicator variables other than those shown in this section are included in the SDTM and pertinent for analysis, these should be copied to ADaM. Other indicator analysis variables that are needed for analysis can also be added.

SDTM Indicator Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
--OCCUR	XX Occurrence	Char	(NY)	Cond	Copied from XX.--OCCUR Conditional on whether this content is pertinent for analysis and is populated in SDTM SDTM does not allow variable AEOCUR, so this variable is not available to include in ADaM.
--PRESP	XX Pre-Specified	Char	(NY)	Cond	Copied from XX.--PRESP Conditional on whether this content is pertinent for analysis and is populated in SDTM

OCCDS Indicator Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ANLzzFL	Analysis Flag zz	Char	Y	Cond	The ANLzzFL flag is useful in many circumstances; an example is when more than 1 coding path is included for analysis, in which case separate analysis flags could be used to denote primary coding path or the records used for analysis from each coding path. A codelist of Y, N, null may be used as described in ADaMIG v1.2 Section 3.3.8, Indicator Variables for BDS Datasets. This variable is conditional on whether analysis records flags are needed for analysis.

Adverse Events Indicator Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
TRTEMFL	Product Emergent Analysis Flag	Char	Y	Cond	Product-emergent flag as defined for analysis. Example derivation: If ADSL.TRTSDT<=ASTDT<=ADSL.TRTEDT + x days then TRTEMFL="Y" The number x in this derivation is defined by the producer and often incorporates the known half-life of the drug. For datasets other than SubClass ADVERSE EVENT, this variable is conditional on whether the concept of product emergent is a key feature of the analysis.
TREMxxFL	Product Emergent Period xx Flag	Char	Y	Cond	This variable is required if there are multiple periods where product emergence is a key feature of the analysis for each period. If TREMxxFL is included, TRTEMFL is defined as the overall product-emergent flag.
TRTEMwFL	Product Emergent Analysis w Flag	Char	Y	Perm	This variable is used if there are other analysis needs (e.g., different cut-offs) where product emergence is a key feature of the analysis. If TREMwFL is included, TRTEMFL is defined as the overall product-emergent flag.
AETRTEM	Product Emergent Flag	Char	(NY)	Perm	Product-emergent flag from SDTM, if available. Derivation: SUPPAE.QVAL where QNAM="AETRTEM" TRTEMFL may differ from AETRTEM due to different definitions, date imputation, and other analysis rules. Including AETRTEM in addition to TRTEMFL will add traceability. For SubClass ADVERSE EVENT, conditional on whether the AETRTEM variable is in the SDTM AE dataset and populated.

Concomitant Medications Indicator Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ONTRTFL	On Product Record Flag	Char	Y	Cond	Character indicator of whether the observation occurred while the subject was on product. A codelist of Y, N, null may be used as described in ADaMIG Section 3.3.8, Indicator Variables for BDS Datasets. Example derivation: If ADSL.TRTSDT <= ASTDT <= ADSL.TRTEDT then ONTRTFL = "Y" This variable is conditional on whether the concept of on product is a feature of the study and used in analysis.
ONTRxxFL	On Product Period xx Flag	Char	Y	Perm	This variable is used if there are multiple periods where on product is a key feature of the analysis for each period. If ONTRxxFL is included, ONTRTFL is defined as the overall on-product flag.
ONTRTwFL	On Product Record w Flag	Char	Y	Perm	This variable is used if there are other analysis needs (e.g., different cut-offs) where on product is a key feature of the analysis. If ONTRTwFL is included, ONTRTFL is defined as the overall on-product flag.

Adverse Event and Concomitant Medications Indicator Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
PREFL	Pre-product Flag	Char	Y	Cond	Character indicator of whether the observation occurred before the subject started product Example derivation: If ASTDT < ADSL.TRTSDT then PREFL="Y" This variable is conditional on whether the concept of pre-product is a feature of the study and used in analysis.
FUPFL	Follow-up Flag	Char	Y	Cond	Character indicator of whether the observation occurred while the subject was on follow-up Example derivation: If ASTDT > ADSL.TRTEDT then FUPFL="Y" This variable is conditional on whether the concept of follow-up is a feature of the study and used in analysis.

2.9.7.6 Occurrence Flag Variables

Occurrence flags can be used to prepare data for analysis. They are typically created by sorting the data in the required order and then flagging the first product-emergent record. The use of the word “first” in this section does not necessarily mean chronological, although that is an option. The more common occurrence flags and a structure for additional flags are shown below

OCCDS Occurrence Flag Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
AOCCFL	1st Occurrence within Subject Flag	Char	Y	Perm	Character indicator for the first occurrence of any event/intervention/finding within the subject Example derivation: Sort the data in the required order and flag the first product emergent record for each subject.
AOCCPFL	1st Occurrence of Preferred Term Flag	Char	Y	Perm	Character indicator for the first occurrence of the preferred term within the subject Example derivation: Sort the data in the required order and flag the first product emergent record for each --DECOD for each subject.
AOCCIFL	1st Max Sev./Int. Occurrence Flag	Char	Y	Perm	Character indicator for the first occurrence of the event/intervention/finding with the maximum severity/intensity within the subject Example derivation: Sort the data in the required order and flag the first product emergent record for maximum severity for each subject.
AOCCPIFL	1st Max Sev./Int. Occur Within PT Flag	Char	Y	Perm	Character indicator for the first occurrence of the maximum severity/intensity within the subject and preferred term Example derivation: Sort the data in the required order and flag the first product emergent record for maximum severity within preferred term for each subject.
AOCCzzFL	1st Occurrence of ...	Char	Y	Perm	Additional flag variables as needed for analysis. Derivation rules for these flags need to be described in the metadata.

MedDRA Occurrence Flag Variables

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
AOCCSFL	1st Occurrence of SOC Flag	Char	Y	Perm	Character indicator for the first occurrence of the system organ class within the subject Example derivation: Sort the data in the required order and flag the first product-emergent record for each body system for each subject.
AOCCSIFL	1st Max Sev./Int. Occur Within SOC Flag	Char	Y	Perm	Character indicator for the first occurrence of the maximum severity/intensity within the subject and system organ class Example derivation: Sort the data in the required order and flag the first product-emergent record for maximum severity within body system for each subject.

2.9.7.7 Product/Dose Variables

The product variable used for analysis must be included. Typically, this would be TRTP, TRTA, TRTxxP, or TRTxxA. See Section 2.9.5.5, [Dose Variables for ADSL Datasets](#), and Section 2.9.6.2, [Record-Level Product and Dose Variables for BDS Datasets](#), for more details on these variables. Additional dosing variables may also be included.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
DOSEON	Product Dose at Record Start	Num		Perm	Dose received at the point in time of the record start date. Example derivation: Obtained from EX.EXDOSE where --STDTC falls between the values of EX.EXSTDTC and EX.EXENDTC
DOSCUMA	Cumulative Actual Product Dose	Num		Perm	Cumulative actual study drug dosage at the point in time of the record start date
DOSEU	Product Dose Units	Char	(UNIT)	Cond	Conditional on whether DOSEON and/or DOSCUMA are included.

2.9.7.8 Descriptive Variables

Variables that describe the record are often used in analysis. Include these and any other SDTM variables if used in analysis. If the analysis version of the variable differs from the version in the SDTM, additional variables must be added using the conventions below and described in Section 2.9.3, [How to Create Analysis Variables](#).

The following table lists some common descriptive variables that are often included in ADAE. Any other SDTM variables should be included as appropriate (e.g. AEOUT, AESDTH).

Adverse Event Descriptive Variables

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
--SER	Serious Event	Char	(NY)	Perm	XX.--SER AESER is required for adverse event data.
--SEV	Severity/Intensity	Char	(AESEV) or (SEVRs)	Perm	XX.--SEV For SubClass ADVERSE EVENT, conditional on whether the --SEV variable is in the SDTM AE dataset. Note that either --SEV or --TOXGR should be included in SDTM.
--SEVN	Severity/Intensity (N)	Num	1, 2, 3	Perm	Code XX.--SEV to numeric Low intensity should correspond to low value
ASEV	Analysis Severity/Intensity	Char		Perm	Apply imputation rules for missing severity of adverse events as specified in the SAP or metadata. May change case of text, such as from all uppercase in --SEV to mixed case in ASEV.
ASEVN	Analysis Severity/Intensity (N)	Num	1, 2, 3	Perm	Code ASEV to numeric Low intensity should correspond to low value
SEVGRy	Pooled Severity Group y	Char		Perm	Pooled grouping of AE severity for analysis (e.g., mild/moderate, severe)
SEVGRyN	Pooled Severity Group y (N)	Num		Perm	Code SEVGRy to numeric Low intensity should correspond to low value
--REL	Causality	Char		Perm	XX.--REL
--RELN	Causality (N)	Num		Perm	Code XX.--REL to numeric Low relation should correspond to low value
AREL	Analysis Causality	Char		Perm	Apply imputation rules for missing causality of study drug as specified in the SAP or metadata. May change case of text, such as from all uppercase in --REL to mixed case in AREL.
ARELN	Analysis Causality (N)	Num		Perm	Code AREL to numeric

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
RELGRy	Pooled Causality Group y	Char		Perm	Pooled grouping of causality of study drug for analysis (e.g. related, not related)
RELGRyN	Pooled Causality Group y (N)	Num		Perm	Code of RELGRy to numeric Low relation should correspond to low value
--TOXGR	Standard Toxicity Grade	Char		Perm	XX.--TOXGR For SubClass ADVERSE EVENT, conditional on whether the --TOXGR variable is in the SDTM AE dataset. Note that either --SEV or --TOXGR should be included in SDTM.
--TOXGRN	Standard Toxicity Grade (N)	Num		Perm	Code --TOXGR to numeric Low toxicity should correspond to low value
ATOXGR	Analysis Toxicity Grade	Char		Perm	Toxicity grade for analysis. May be based on --TOXGR or an imputed or assigned value. May change case of text, such as from all uppercase in --TOXGR to mixed case in ATOXGR.
ATOXGRN	Analysis Toxicity Grade (N)	Num		Perm	Code ATOXGR to numeric Low toxicity should correspond to low value
TOXGGRy	Pooled Toxicity Grade Group y	Char		Perm	Pooled grouping of toxicity grade for analysis
TOXGGRyN	Pooled Toxicity Grade Group y (N)	Num		Perm	Code of TOXGGRy to numeric Low toxicity should correspond to low value
--ACN	Action Taken with Study Product	Char	(TPACN)	Perm	XX.--ACN Required if XX.--ACN is present and populated

Medical history data typically does not contain descriptive variables. If needed for analysis, use variables as shown above for adverse events, replacing the prefix “AE” with “MH”.

Concomitant Medications Descriptive Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
--STAT	Completion Status	Char		Perm	XX.--STAT
--INDC	Indication	Char		Perm	XX.--INDC
--DOSE	Dose per Administration	Num		Perm	XX.--DOSE
--DOSFRM	Dose Form	Char		Perm	XX.--DOSFRM
--DOSRGM	Intended Dose Regimen	Char		Perm	XX.--DOSRGM
--ROUTE	Route of Administration	Char		Perm	XX.--ROUTE

2.9.7.9 Standardized MedDRA Query Variables

Standardized MedDRA queries (SMQs) are becoming increasingly common in clinical study safety evaluations, particularly when known or suspected safety issues are associated with experimental compounds. In addition, customized queries (CQs) are often used to modify an SMQ or identify records of special interest. The following table lists variables used to identify SMQs and CQs, where zz is replaced with a zero-padded 2-digit integer (01-99) for each SMQ or CQ of interest. This ordering can be based on importance or some other producer-defined criteria. It is recommended that ordering be consistent across studies within a development program, but it is recognized that there may be situations where this is not possible or practical.

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
SMQzzNAM	SMQ zz Name	Char		Cond	The Standardized MedDRA query name. Would be blank for terms that are not in the SMQ. Therefore this variable could be blank for all records if no terms within the study were included in the SMQ. Conditional on whether SMQ analysis is done
SMQzzCD	SMQ zz Code	Num		Perm	The SMQ number code
SMQzzSC	SMQ zz Scope	Char	BROAD, NARROW	Cond	The search strategy for SMQs can be narrow or broad. The preferred terms that are narrow in scope have high specificity for identifying events of interest, whereas the broad terms have high sensitivity. By definition, all narrow terms are also considered within the broad scope. Therefore, to summarize all broad terms, terms with either narrow <i>or</i> broad would be considered. Will be null for terms that do not meet the criteria. Conditional on whether SMQ analysis is done
SMQzzSCN	SMQ zz Scope (N)	Num	1, 2	Perm	Will be null for terms that do not meet the criteria
CQzzNAM	Customized Query zz Name	Char		Cond	The CQ name or name of the adverse event of special interest category based on a grouping of terms. Would be blank for terms that are not in the CQ. Conditional on whether CQ analysis is done Examples: “DERMATOLOGICAL EVENTS” “CARDIAC EVENTS”, “IARS (INFUSION ASSOCIATED REACTIONS)”

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
ADECODY	Analysis Dictionary-Derived Term y	Char		Perm	The terms used for the analysis when combining multiple CQs or multiple SMQs and the original MedDRA terms under 1 variable Although designed for MedDRA queries, this variable could be used for other OCCDS analysis needs.

2.9.7.10 Original or Prior Coding Variables

Keeping original coding variables is not common, but there are a couple of instances where it might be helpful:

- When a study is mapped to one version of a mapping dictionary for an interim analysis and another for final analysis
- When studies using different versions of a mapping dictionary are pooled together for an integrated analysis

Because the dictionary-coded values may change with each version, counts for study tables can differ between versions for the same study. Therefore, keeping the original variables provides traceability to original (or prior) analysis(es).

The variables described below provide traceability to original (or prior) analysis(es). The suffix “w” represents an integer (1-9) corresponding to a previous version. Include the dictionary name and version as part of the metadata for each variable. These variable names at this time are recommendations only. Additional prior or original variables needed for traceability may be added following the same conventions. There is an ADaM subteam working on integration, and this group may create different naming conventions for that type of analysis.

Original or Prior MedDRA Coding Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
DECDORGw	PT in Original Dictionary w	Char	MedDRAw	Perm	Original preferred term coding of XX.--TERM using MedDRA or other dictionary version X.X
BDSYORGw	SOC in Original Dictionary w	Char	MedDRAw	Perm	Original body system coding of XX.--TERM using MedDRA or other dictionary version X.X
HLGTORGw	HLGT in Original Dictionary w	Char	MedDRAw	Perm	Original HLGT coding of XX.--TERM using MedDRA or other dictionary version X.X
HLTORGw	HLT in Original Dictionary w	Char	MedDRAw	Perm	Original HLT coding of XX.--TERM using MedDRA or other dictionary version X.X
LLTORGw	LLT in Original Dictionary w	Char	MedDRAw	Perm	Original LLT coding of XX.--TERM using MedDRA or other dictionary version X.X
LLTNORGw	LLT Code in Original Dictionary w	Char	MedDRAw	Perm	Original LLT code of XX.--TERM using MedDRA or other dictionary version X.X

Original or Prior WHODrug Coding Variables

Variable Name	Variable Label	Type	Codelist/ Controlled Terms	Core	CDISC Notes
DECDORGw	Standardized Med Name in Orig Dict w	Char	WHODRUGw	Perm	Original standardized medication name of CM.CMTRT using WHODrug version X.X
CLASORGw	Medication Class in Orig Dictionary w	Char	WHODRUGw	Perm	Original medication class of CM.CMTRT using WHODrug version X.X
CLCDORGw	Medication Class Code in Orig Dict w	Char	WHODRUGw	Perm	Original medication class code of CM.CMTRT using WHODrug version X.X
ATyCORGw	ATC Level y Code in Orig Dictionary w	Char	WHODRUGw	Perm	Original ATC Level y code of CM.CMTRT using WHODrug version X.X
ATyTORGw	ATC Level y Text in Orig Dictionary w	Char	WHODRUGw	Perm	Original ATC Level y text of CM.CMTRT using WHODrug version X.X

2.9.7.11 User-specified Variable Naming Conventions

ADaM allows for user-specified variable names when creating additional variables not specified in this document or the ADaMIG. The ADaMIG has variable name fragments and other conventions, which are often needed with ADSL and BDS datasets. OCCDS datasets may have fewer derived variables, but there are some conventions and fragments described here to help build easily understood variable names.

Many variables from SDTM data are copied to ADaM with no change to the variable name, label, or content. ADaM follows a principle of harmonization (same name, same meaning, same values). This means that when an SDTM variable name is in an ADaM dataset, the values within that variable are exactly the same as the SDTM data.

Many times, a modified version of an SDTM variable is needed, such as when missing data is imputed. As shown in Section 2.9.7.8, [Descriptive Variables](#), when creating an analysis version of an SDTM descriptive variable, the prefix "A" (for "analysis") replaces the 2-letter SDTM domain code. This same convention can be used to create analysis versions of variables not specified in Section 2.9.7.8. For example, if changes needed to be made to AEBODSYS for analysis, the variable name ABODSYS (with a prefix of "A" instead of "AE") would convey that it is the analysis version of the AEBODSYS variable, and that the value of ABODSYS may not be the same as AEBODSYS on some records.

When variable content remains unmodified but the name of the SDTM variable cannot be used in the analysis dataset, the prefix "U" (for "unmodified") can be used instead of the 2-letter SDTM domain code. For example, if combining records from Adverse Events (AE) and Medical History (MH) into an analysis dataset, it would likely not be analysis-ready to have body-system information spread across 2 variables, AEBODSYS on the rows from the AE dataset and MHBODSYS on the rows from the MH dataset. Instead, a single variable that contains the value from AEBODSYS or MHBODSYS is needed. Using the "A" prefix and calling the variable ABODSYS implies that it is an analysis version of a variable, and that the value of ABODSYS may not be the same as AEBODSYS and MHBODSYS on some records. If no changes are made to AEBODSYS and MHBODSYS, using instead a "U" prefix allows for a single column called UBODSYS but makes it clear that no modifications to the content of the SDTM variables were made.

2.9.8 Predefined Standard Variables for REFERENCE

The reference specifications introduce the Reference Dataset Structure. A Reference Dataset Structure dataset contains 1 record per combination of stratum values. At least 1 stratum variable is required and up to 99 stratum variables can be present in a reference dataset. There may be several reference datasets in a study. This section of the TIG defines the standard variables used in reference datasets.

Reference dataset names must have a prefix of RF. There are then up to 6 characters that should be used to make dataset name meaningful. However, in the ADaM standard there are currently no predefined dataset names besides for ADSL.

- Proposed names for the datasets in the example section are:
 - RFBR (Reference Data for Birthrate)
 - RFIP (Reference Data for Initial Population)
 - RFMIGRAT (Reference Data for Migration Rates)
 - RFMORT (Reference Data for Mortality Rates)
 - RFTRANS (Reference Data for Transition Prob)

The identifier variables associated with the reference values are captured in the STRTMy (Stratum y) variables. The actual values of the STRTMy variables are captured in the STRVALy (Stratum y Value) variables. As many identifiers as necessary based on the source data should be captured in the reference dataset. The order of the stratum variables has no inherent meaning, so ordering is not defined in this section. The convention of y is used as an index value indicating an integer with a value of 1-99. There is no requirement that the stratum variables start with 1, nor must the variables use consecutive values. Some examples of stratum variables are Year, Sex, Race, Age, Transition type, and Product.

The source file may change over time so capturing the name of the source file either in the dataset or the define.xml file allows for traceability back to the source. If the source name is captured in the dataset, then REFSRCE (Reference Data Source) is the variable to use.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
STRTMy	Stratum y	Char		Req	Indicates stratification factors used when calculating the value of the input parameter. At least one STRTMy column must be present and populated.
STRVALy	Stratum y Value	Char		Req	Identifies the stratum with which the input parameter is associated. At least one STRVALy column must be present and populated.
INPRM	Input Parameter	Char		Req	Indicate the calculated input parameter for the stratum or strata.
INPRMVAL	Input Parameter Value	Num		Req	This is the value of the input parameter.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
INPRMU	Input Parameter Unit	Char		Perm	Unit associated with the input parameter value.
REFSRCE	Reference Data Source	Char		Perm	Information identifying the source of the reference data - this may be captured in the dataset or in the define file

2.9.9 Implementation Issues, Standard Solutions, and Examples

The ADaM standard variables (columns) have been described in previous sections. However, there is more to ADaM than just using ADaM standard variables. The purpose of this section is to provide additional guidance on how to implement ADaM standard datasets correctly.

2.9.9.1 Creation of Derived Columns Versus Creation of Derived Rows

This section provides specific rules to use in building a BDS dataset. These rules are essential, because they ensure the BDS dataset is analysis-focused, with all analysis-enabling variables and supportive variables included in a predictable structure, while preventing a "horizontalization" of the dataset.

The rows (i.e., records) in the ADaM BDS represent subject data for analysis parameters and timepoints (as applicable). There may be multiple rows within a given combination of subject, parameter, and timepoint, depending on the number of observations collected or derived, baseline definition, and so on.

The ADaM BDS structure contains a central set of columns (i.e., variables) that represent the data being analyzed. These variables include the value being analyzed (e.g., AVAL) and the description of the value being analyzed (e.g., PARAM). Other columns in the dataset provide more information about the value being analyzed (e.g., the subject identification) or describe and trace its derivation (e.g., DTYPY) or support its analysis (e.g., product variables, covariates). Standard columns exist for a variety of purposes, such as SDTM record identifiers for traceability, population, and other record selection flags; analysis values; and some standard functions of analysis values. Permissible columns are not limited to those whose variable names are specified in Section 2.9.5, [Predefined Standard Variables for ADSL](#); Section 2.9.6, [Predefined Standard Variables for BDS](#); and Section 2.9.7, [Predefined Standard Variables for OCCDS](#), and may include study-specific analysis model covariates, subgrouping variables, variables supportive of traceability, and other variables needed for analysis or useful for review.

The BDS is flexible in that derived data can be added to the collected data as additional rows and columns that support the analyses and provide traceability. However, there are some constraints on how to incorporate derived data in the BDS dataset. This section addresses when derived data that are functions of analysis values should be added as additional columns, and when they should be added as additional rows.

The precise sequence of steps involved in creating a BDS dataset varies according to operational and study-specific needs. For the purposes of this discussion, it is useful to consider 2 fundamental steps.

1. Create an initial dataset from the source datasets. The first step is to create a set of rows and columns more or less directly derived from or loaded from input datasets (primarily SDTM datasets and other ADaM datasets) into their appropriate places. This step will include creation and population of columns containing analysis parameter (PARAM), analysis timepoint (e.g., AVISIT), and analysis values (e.g., AVAL, AVALC). It would also include adding columns containing identifiers (e.g., STUDYID, USUBJID, SUBJID, SITEID) and other SDTM variables for traceability (e.g., VISIT, --SEQ).
2. Add additional derived data as needed for the analysis. The second step consists of adding derived rows and columns based on the initial set of ADaM dataset records and columns. The rules below govern this step. These rules are further described and illustrated in the remaining subsections of this section.

Num	Rules	Implementation
1	Rule 1: A parameter-invariant function of AVAL and BASE on the same row that does not involve a transform of BASE should be added as a new column.	<p>The 3 conditions of rule 1 for when a function of AVAL and BASE should be added as a column (i.e., a function column) are:</p> <ol style="list-style-type: none"> 1. the function is of AVAL and, optionally, BASE, on the same row; 2. the function is parameter-invariant; and 3. the function does not involve a transform of BASE. <p>The remainder of the discussion of this rule is devoted to explaining these conditions. PARAM uniquely describes the contents of AVAL or AVALC. Often, AVAL itself is not the value that is needed for analysis. For example, in a change from baseline analysis, it is the</p>

Num	Rules	Implementation
		<p>change from baseline CHG that is analyzed. The change from baseline column CHG should be created according to rule 1 because it satisfies the 3 conditions:</p> <ol style="list-style-type: none"> 1. CHG is derived from AVAL and BASE on the same row. 2. The same calculation applies on all rows in the dataset on which CHG is populated (the function CHG=AVAL-BASE does not vary according to PARAM). This second condition is known as the "property of parameter-invariance"; unless listed in Section 2.9.5, Predefined Standard Variables for ADSL; Section 2.9.6, Predefined Standard Variables for BDS; or Section 2.9.7, Predefined Standard Variables for OCCDS, a function of AVAL (and optionally BASE) may not be derived as a column if it is parameter-variant (i.e., is calculated differently for different parameters). 3. In the function CHG=AVAL-BASE, BASE is not transformed. <p>The intent is to use the standard columns as much as possible, to keep the structure as standard as possible, and avoid undue "horizontalization," while still permitting efficient use of function columns.</p>
2	Rule 2: A transformation of AVAL that does not meet the conditions of rule 1 should be added as a new parameter, and AVAL should contain the transformed value.	<ul style="list-style-type: none"> • If the intention is to redefine AVAL, BASE, CHG, and so on in terms of a transform of AVAL, then a new parameter must be added in which PARAM describes the transform. The creation of a new parameter results, by definition, in the creation of a new set of rows. • For example, as described in the discussion of rule 1, in a change from baseline analysis of the logarithm of weight, AVAL should contain the log of weight, BASE should contain the baseline value of the log of weight, and CHG should contain the difference between the 2. PARAM should contain a description of the transformed data contained in AVAL (e.g., "Log10 (Weight (kg))"). In this way, the ADaM standard accommodates an analysis of transformed data in the standard columns without creating a multiplicity of new special-purpose columns. • A related application of rule 2 is the case where it is necessary to support analysis and reporting in 2 different systems of units. In SDTM Findings domains (e.g., LB, QS, EG), the --STRESN column is the only numeric result column, and is also the only standardized numeric result column. The --ORRES column contains a character representation of the collected result, in the collected units specified in the --ORRESU column. The --ORRES column is not standardized. So for example, if data are typically collected in conventional units, SDTM cannot accommodate standardized data in both conventional units and the International System of Units (SI). In SDTM, for any given --TEST, a producer can standardize in 1 system of units but not 2. If one wishes to be able to analyze standardized results in both conventional units and in SI units, a transform in an ADaM dataset is needed. In each such case, a new parameter must be created in order to accommodate standardized data in the other system of units. • The description in the PARAM column must contain the units, as well as any other information (e.g., location, specimen type) that is needed to ensure that PARAM uniquely describes what is in AVAL, and differentiates between parameters as needed. PARAM cannot be the same for different units. • When a record is derived from a single record in the dataset, retain on the derived record any variable values from the original record that do not change and that make sense in the context of the new record (e.g., --SEQ, VISIT, VISITNUM, --TPT, covariates).
3	Rule 3: A function of 1 or more rows within the same parameter for the purpose of creating an analysis timepoint should be added as a new row for the same parameter.	<ul style="list-style-type: none"> • For analysis purposes, there is often a need to impute missing data, or to create a derived conceptual timepoint. Such derivations should result in the creation of new derived records within the same parameter. • As a general rule, when a record is derived from a single record in the dataset, retain on the derived record any variable values from the original record that do not change and that make sense in the context of the new record (e.g., --SEQ, VISIT, VISITNUM, --TPT, covariates). When a record is derived from multiple records, retain on the derived record all variable values that are constant across the original records, that do not change, and which make sense in the context of the new record. Note that there are situations when retention of values from an original record or records would make no sense on the derived record; in such cases, do not retain those values. • For example, suppose that the analysis endpoint value is defined as the average of the last two available post-baseline values. In this case, a new row should be added, with a corresponding description in AVISIT, and the DTYPE (derivation type) column should contain a description on that row such as "AVERAGE" to indicate both that the row was derived, and also the derivation method. The metadata associated with AVISIT=Endpoint should adequately describe which records are used in the definition of the average. Note that even though the set of records for the log transformation of weight are derived, DTYPE is not populated for every row. DTYPE should be used to indicate rows that are derived within a given value of PARAM and is not to be used as an indication of whether the record exists in SDTM. • An extension of rule 3 is necessary in the case where there is record-level population flagging. For example, assume the SAP states that if the subject is off drug for 7 days prior to a visit, the measurement collected at that visit is not included in the per-protocol

Num	Rules	Implementation
		analysis. Then, for some subjects, the last 2 available values may be different for intent-to-treat and for per-protocol analyses, so that the calculated endpoint averages would be different. For such subjects, 2 distinct derived endpoint rows would be needed, the appropriate row for each analysis indicated by the record-level population flags ITTRFL and PPROTRFL.
4	Rule 4: A function of multiple rows within a parameter should be added as a new parameter.	Rule 4 is a special case of rule 2. The functions covered by this rule violate the second condition of rule 1 (they are not same-row functions of AVAL), and may also violate the first and third conditions.
5	Rule 5: A function of more than 1 parameter should be added as a new parameter.	<ul style="list-style-type: none"> There is often a need to derive for analysis a parameter that was not collected. Such parameters may be quite complex functions of data from multiple SDTM domains and domain classes. Rule 5 addresses the case where a parameter is derived from other parameters already present in the dataset. For example, a questionnaire total domain score is calculated as a function of more than 1 observed question. The total domain score should be added as a new parameter, with its corresponding set of derived rows. For this derived parameter, the value of PARAM could be "Total Domain Score", and the value of the total domain score would be stored in the standard AVAL column, the baseline value would be stored in the standard BASE column, change from baseline would be stored in CHG, as usual.
6	Rule 6: When there is more than 1 definition of baseline, each additional definition of baseline requires the creation of its own set of rows.	In case there is more than 1 definition of baseline in an ADaM dataset, new rows must be created for each additional alternative definition of baseline. There will therefore be multiple sets of rows, where each set of rows corresponds to a particular definition of baseline. Whenever there is more than 1 definition of baseline, the BASETYPE column is required. BASETYPE identifies the definition of baseline that corresponds to the value of BASE in each row. There is only 1 BASE column, and only 1 column for each qualifying function of AVAL and BASE.

2.9.9.2 Inclusion of All Observed and Derived Records for a Parameter Versus the Subset of Records Used for Analysis

The ADaM methodology is to include all observed and derived rows for a given analysis parameter. The inclusion of all the rows in the ADaM dataset, including those not used in the analysis, requires a way to identify the rows used in the specified analysis. The advantage of this approach is that the inclusion of all rows makes it easier to verify that the selection and derived timepoint processing was done correctly, thus providing useful traceability. In addition, the data are also then available to enable other analyses, including sensitivity analyses. However, this approach increases the size of the dataset; it also introduces a risk that the appropriate selection criteria will not be used, producing incorrect analysis results.

Regulatory reviewers prefer that the path followed in creating and/or selecting analysis rows be clearly delineated and traceable all the way back to the originating rows in the SDTM dataset, if possible and within reason. Simply including the algorithm in the metadata is often not sufficient, as any complicated data manipulations may not be clearly identified (e.g., how missing pieces of the input data were handled). Retaining in 1 dataset all the observed and derived rows for the analysis parameter provides the clearest traceability in the most flexible manner within the standard BDS. The resulting dataset also provides the most flexibility for testing the robustness of an analysis (e.g., using a different imputation method).

2.9.9.3 Inclusion of Input Data that Are Not Analyzed but that Support a Derivation in the ADaM Dataset

ADaM datasets are developed to facilitate intended analyses. The original data sources for ADaM datasets are SDTM datasets, even when ADaM datasets are derived from other ADaM datasets. ADaM has features that enable traceability from analysis results to ADaM datasets and from ADaM datasets to SDTM datasets.

The ADaM methodology to achieve the expected traceability is to describe the derivation algorithms in the metadata and, if practical and feasible, to include supportive rows as appropriate for traceability. To include the input data as rows in the ADaM dataset, columns should be added where feasible to indicate the source of the input data. Although this methodology increases both the size of the dataset and the complexity of selecting the appropriate rows for analysis, it also provides input data in an immediately accessible manner. In addition, intermediate values can be retained if appropriate flags are used to distinguish them.

In general, it is strongly recommended to include as much supporting data as is needed for traceability. However, there are situations in which this may not be practical. For example, if an analyzed parameter is a summary derived

from a very large number of raw e-diary input records, it may be neither useful nor practical to include all of the raw e-diary records as rows in the ADaM dataset.

The remainder of this section addresses cases where the ADaM datasets contain not only the analysis data but also input data that are necessary to provide clearer traceability of the algorithms used to derive the analysis data. In addition to the actual values used in the analysis, the dataset may include rows not used in the analysis, rows containing input data, and rows containing intermediate values computed during the derivation of the analysis data. Flags or other columns are used to distinguish the various data types as well as to provide a traceable path from the input data to the value used in the analysis. The analysis results metadata specify how the appropriate rows are identified (by a specific selection clause). The identification of rows used in an analysis is addressed in Section 2.9.9.4, [Identification of Records Used for Analysis](#).

Unless the input data are already present as column(s) on the row (e.g., as covariate(s) or supportive variable(s)), the input data will be retained as rows in the ADaM dataset. The analysis value column (AVAL and/or AVALC) on the retained input data row will contain a value for the analysis parameter. Not all columns from the input dataset are carried into the ADaM dataset; instead, additional variables will be included indicating the source of the input data—domain, variable name, and sequence number. This approach allows the inclusion of input data from multiple domains. If the input data are already included in columns on the analysis parameter row (e.g., as covariates or supportive information), there is no need to include additional rows for those input data. The decision regarding keeping the input data as rows or columns will therefore be dictated by the types of input data and whether they are used for other purposes in the ADaM dataset.

Retaining in 1 dataset all data used in the determination of the analysis parameter value will provide the clearest traceability in the most flexible manner within the standard ADaM BDS. This large dataset also provides the most flexibility for testing the robustness of an analysis.

If it is determined that this large dataset is too cumbersome, the producer can choose to provide 2 datasets: 1 that contains all rows and another that is a subset of the first, containing only the rows used in the specified analysis. To ensure traceability, the metadata for the subset ADaM dataset will refer back to the full ADaM dataset as the immediate predecessor. This approach provides the needed traceability along with a dataset that can be used in an analysis without specifying a selection clause. The producer will need to ensure consistency is maintained between the 2 datasets. There also may be potential confusion about which dataset supported an analysis, if analysis results metadata is not provided for that analysis.

2.9.9.4 Identification of Records Used for Analysis

This section addresses how to identify the records of an ADaM dataset that are used for analysis. The specific issues addressed include

1. identification of the records used in an LOCF analysis;
2. identification of the record containing the baseline value;
3. identification of post-baseline conceptual timepoint records, such as endpoint, minimum, maximum, or average; and
4. identification of specific records used in an analysis.

Num	Identification	Implementation
1	Records used in a timepoint imputation analysis	<ul style="list-style-type: none"> • This section considers the issue of how to identify records used in a timepoint-related imputation analysis as well as how to represent data imputed for missing timepoints in an ADaM dataset. LOCF (last observation carried forward) is commonly used in timepoint-related imputation analyses and is therefore specifically mentioned. However, the methodology is general and is not restricted to LOCF analysis. WOOF (worst observation carried forward) analysis is also mentioned to emphasize generalizability. • When an analysis timepoint is missing, the ADaM methodology is to create a new record in the ADaM dataset to represent the missing timepoint and identify these imputed records by populating the derivation type variable DTTYPE. • For example, when an LOCF/WOOF analysis is being performed, create LOCF/WOOF records when the LOCF/WOOF analysis timepoints are missing, and identify these imputed records by populating the derivation type variable DTTYPE with values LOCF or WOOF. All of the original records would have null values in DTTYPE. It would be very simple to select the appropriate records for analysis by selecting DTTYPE = null for DAO (data as observed) analysis, DTTYPE = null or LOCF for LOCF analysis, and DTTYPE = null or WOOF for WOOF analysis. This approach would require understanding and communicating that if the DTTYPE flag were not referenced correctly, the analysis would default to using

Num	Identification	Implementation
		all records, including the DAO records, plus the records derived by LOCF and WOCF. To perform a correct DAO analysis, one would need to explicitly select DTTYPE = null.
2	Baseline records	<ul style="list-style-type: none"> Many statistical analyses require the identification of a baseline value. This section describes how a record used as a baseline is identified. The ADaM methodology is to create a baseline flag column to indicate the record used as baseline (the record whose value of AVAL is used to populate the BASE variable). This method does not require duplication of records in the event that the baseline record is not derived. Although a baseline record flag variable ABLFL is created and used to identify the record that is the baseline record, this does not prohibit also providing a record with a unique value of AVISIT (e.g., "Baseline"), designating the baseline record used for analysis, even if redundant with another record. For more complicated baseline definitions (functions of multiple records), a derived baseline record would have to be created as described in Section 2.9.9.1, Creation of Derived Columns Versus Creation of Derived Rows. This methodology requires that clear metadata be provided for the baseline record variable so that the value can be reproduced accurately.
3	Post-baseline conceptual timepoint records	<ul style="list-style-type: none"> When analysis involves cross-timepoint derivations (e.g., endpoint, minimum, maximum, average post-baseline), questions such as "Should distinct records with unique value of AVISIT always be created even if redundant with an observed value record?" or "Should these records just be flagged?" need to be considered. The ADaM methodology is to create a new record with a unique value of AVISIT in cases where analysis is based on AVISIT. The advantage of this approach is that it is simple and analysis-friendly. It is recognized that such new records might be redundant with observed records for some kinds of conceptual timepoint definitions. Always creating a record with a unique value of AVISIT designating the record used for analysis (e.g., "Endpoint," "Post-Baseline Minimum," "Post-Baseline Maximum") has the advantage that once the AVISIT values are understood, producers, consumers, and software can rely on these values of AVISIT. This approach represents the general case because any such cross-timepoint derivation can be represented in a new record with a unique AVISIT description. The disadvantage is that the dataset would contain more records, and conventions would have to be communicated and understood. In cases where analysis is not based on AVISIT, either solution is valid. It is recognized that in cases where the AVISIT values are not defined in the analysis documentation, adding a flag may be more appropriate. Which methodology is appropriate for situations where an "analysis visit" value is not defined can be driven by how the analysis will be performed. In cases where only a subset of data is analyzed (e.g., only on product minimum values), then flagging the values that qualify for analysis might be a better choice than creating an additional record to contain the minimum value. However, where the subset of data is analyzed within the context of a greater pool of data, creating an additional record to contain the minimum value would help facilitate analysis-ready usage and review.
4	Records used for analysis—general case	<ul style="list-style-type: none"> It is important to identify the records used in or excluded from analysis. Should records used in the analysis be identified via flags or by unique values of analysis timepoint window description AVISIT? The ADaM methodology is to use an analysis flag (ANLzzFL) to indicate the records that fulfill specific requirements for 1 or more analyses. For example, ANLzzFL = Y indicates records meeting the requirements for analysis and is blank (null) in other records, such as a duplicate record that was not the one selected for analysis, or prespecified post-study timepoints not included in the analysis. This allows multiple records within a parameter with the same value of AVISIT. However, it also requires flags to be added to the dataset to be used in selecting appropriate records for analysis. Understanding of the flags is required for correct analysis results to be generated. In addition to ANLzzFL, additional flags might also be required, such as record-based population flags (e.g., ITTRFL, PPROTRFL). Note that there can be multiple ANLzzFL variables. In this case, it will be imperative to have clear and robust metadata to indicate the basis for the creation and population of each ANLzzFL variable.
5	Population-specific analyzed records	<ul style="list-style-type: none"> It is not uncommon in the statistical analysis of clinical studies to conduct analyses based on multiple populations of interest. The population of interest can be defined either at the subject level, the record (measurement) level, or both. For example, when defining an analysis population, a subject may be included in one analysis population (e.g., intent-to-treat), but excluded from another analysis population (e.g., per-protocol). Analysis populations may also be defined using characteristics of individual measurements. For example, a measurement that was assessed outside of a prespecified time window for a particular visit may not be included in a per-protocol visit-level population. In this section, it is assumed that the definition of a record-level analysis population is dependent on the definition of the subject-level population. In other words, if a subject is excluded from the subject-level per-protocol population, then none of that subject's records would be candidates for inclusion within the record-level per-protocol population. Given the variety of possible population definitions, the same record in an analysis dataset could be included in one analysis and excluded from another, depending on characteristics of the subject as a whole and the characteristics of the individual measurement. Therefore, the issue becomes how best to select records for each analysis. The ADaM methodology for this analysis issue is to create a single ADaM dataset that can be used to perform multiple analyses using population flag variables to identify records that are used for each type of analysis. An advantage of this approach is that this single ADaM dataset can be used for multiple analyses. Flag variables obviate the need to replicate records for each type of analysis. This approach promotes efficiency in the operational aspects of electronic submissions, clarity of analyses, and ease in comparing selected values for each population. This approach does, however, require that clear

Num	Identification	Implementation
		metadata be provided for the flag variables so that each specific analysis can be reproduced accurately.
6	Records which satisfy a predefined criterion for analysis purposes	<p>For analysis purposes, criteria are often defined to group results based on the collected value's relationship to one or more algorithmic condition—for example, subjects who had a result greater than 5 times the upper limit of the normal range or subjects who had a systolic blood pressure value >160 mmHg with at least a 25-point increase from the BASE value. In addition to creating subgroups of subjects, the categorization of the presence or absence of a criterion is often used in listings, tabular displays, or statistical modeling (as a covariate or a response variable).</p> <p>When the criterion has binary responses,</p> <ul style="list-style-type: none"> • ADaM methodology provides an analysis criterion variable, CRITy, paired with a criterion evaluation result flag, CRITYFL, to identify whether a criterion is met. These variables are defined in 2.9.6.4, Analysis Parameter Variables for BDS Datasets. The variables MCRITY and MCRITYML are defined in Section 2.9.6.6, Analysis Parameter Criteria Variables for BDS Datasets, for use in situations where the criterion can have multiple responses (as opposed to CRITy, which has binary responses). <ul style="list-style-type: none"> ◦ CRITY is populated with a text description defining the conditions necessary to satisfy the presence of the criterion. The definition of CRITY can use any variable(s) located on the row, and the definition must stay constant across all rows within the same value of PARAM. A complex criterion which draws from multiple rows (different parameters or multiple rows for a single parameter) will require a new PARAM be created. ◦ CRITYFL (Criterion Evaluation Result Flag) is the character indicator of whether the criterion described in CRITY was met. Variable CRITYFL must be present on the dataset if variable CRITY is present. CRITYFN is permitted if a numeric result flag is needed. • ADaM methodology allows the option of only populating CRITY on a row if the CRITY criterion is met for that row. In that case, CRITYFL is set to "Y" only if CRITY is populated and is null otherwise. If this option is not used and CRITY is populated on all rows within the parameter, then CRITYFL is set to "Y" or "N" or null. The choice of populating CRITY on only the rows where the criteria is met versus on all rows is dependent on the analysis need. ◦ CRITY and CRITYFL facilitate subgroup analyses. The ADaM methodology does not preclude the addition of rows (in contrast to the addition of multiple CRITY and CRITYFL columns) to the BDS for the criterion CRITY. However, CRITY must be kept constant (if populated) across all rows within the same value of PARAM. ◦ CRITY, CRITYFL, and CRITYFN are not parameter-invariant in that CRITY can vary across parameters within a dataset, as can the controlled terminology used for the corresponding CRITYFL and CRITYFN. In other words, CRITY for one parameter can be different than CRITY for a different parameter in the same dataset. <p>When the criterion has multiple responses,</p> <ul style="list-style-type: none"> • ADaM methodology provides an analysis criterion variable, MCRITY, paired with a criterion evaluation result flag, MCRITYML (Multi-Response Criterion y Evaluation), to identify which level of a multiple response criterion is met. These variables are defined in Section 2.9.6.6, Analysis Parameter Criteria Variables for BDS Datasets. <ul style="list-style-type: none"> ◦ MCRITY is populated with a text description identifying the criterion being evaluated. The definition of MCRITY can use any variable(s) located on the row and the definition must stay constant across all rows within the same value of PARAM. A complex criterion which draws from multiple rows (different parameters or multiple rows for a single parameter) will require a new PARAM be created. ◦ MCRITYML is the character flag variable that indicates which level of the criterion defined in MCRITY was met. Variable MCRITYML must be present on the dataset if variable MCRITY is present. ◦ MCRITYMN is permitted if a numeric result flag is needed. ◦ MCRITY and MCRITYML facilitate subgroup analyses. The ADaM methodology does not preclude the addition of rows (in contrast to the addition of multiple MCRITY and MCRITYML columns) to the BDS for the criterion MCRITY. However, MCRITY must be kept constant (if populated) across all rows within the same value of PARAM. ◦ MCRITY, MCRITYML, and MCRITYMN are not parameter-invariant in that MCRITY can vary across parameters within a dataset, as can the Controlled Terminology used for the corresponding MCRITYML and MCRITYMN. In other words, MCRITY for one parameter can be different than MCRITY for a different parameter in the same dataset.

2.10 Standards for Data Exchange

Standards for data exchange support sharing of structured metadata and data between parties and across different information systems. Standards referenced in this section support exchange of CDASH-compliant CRFs for data collection and exchange of tabulation and analysis datasets through provision of data-definition documents to describe datasets. Standards referenced in this section are supported by the CDISC Operational Data Model (ODM, available at <https://www.cdisc.org/standards/data-exchange/odm>). ODM is a vendor-neutral, platform-independent format for exchanging and archiving research data, along with their associated metadata, administrative data, reference data, and audit information.

Accessing CDASH-compliant CRFs

The CDISC eCRF Portal (<https://www.cdisc.org/kb/ecrf>) is a platform from which to download standard CRFs including metadata standardized per ODM. All example CRFs in Section 3.3, [Product Impact on Individual Health](#), may be downloaded in ODM format and loaded into applicable EDC tools. Once loaded into an EDC tool, standard CRFs may then be used as-is or modified per the TIG and related CDISC standards to support needs.

CDISC Library

The CDISC Library (<https://www.cdisc.org/cdisc-library>) is a free community resource from which TIG v1.0 standards may be browsed, searched, and downloaded for electronic use. The Library is a cloud-based metadata repository used to support efficient and controlled development, management, reuse, and electronic publication of all applicable CDISC standards. It consolidates standards within a single user interface and enables the export of standards in multiple formats for ease of implementation into software solutions. Additionally, the Library can be accessed via an API to deliver CDISC standards metadata to software applications that automate standards-based processes.

Creating Data Definition Documents to Support Data Submission

Version 2.1 of the CDISC Define-XML standard (available at <https://www.cdisc.org/standards/data-exchange/define-xml/>) supports creation of data-definition files which describe the structure and contents of tabulation and analysis datasets. Define-XML documents provide both a machine-readable format for use by various software applications and, through the provision of an XSL stylesheet, a browser-based rendition describing the metadata attributes of tabulation and analysis datasets. The Define-XML model is implemented using extensions to the ODM-XML schema.

3 Examples

The TIG provides examples to demonstrate the intended use of CDISC standards for tobacco product data and to support further understanding of implementation guidance in Section 2, [Standards for Tobacco Product Data](#). The examples in this guide reflect use cases for data inherent to studies of tobacco products. Use cases selected present concepts identified by one or more stakeholders as important in the context of tobacco product studies and are organized in the following sections:

- Section 3.1, [Product Description](#)
- Section 3.2, [Nonclinical](#)
- Section 3.3, [Product Impact on Individual Health](#)
- Section 3.4, [Product Impact on Population Health](#)

Examples in this guide are intended to show collection and/or representation of data using CDISC standards and are not intended to influence decisions regarding what data to collect or represent. For guidance on the selection of data to collect or represent, please refer to the appropriate regulatory authorities.

3.1 Product Description

The examples in this section do not illustrate the various concepts described below for all categories and subcategories of tobacco products. Concepts are illustrated primarily using cigarettes, ENDS devices, and/or smokeless tobacco products. The data modeling of the concepts illustrated would work the same for all other tobacco product categories as well (i.e., the same datasets and variables would be used the same way as illustrated in the examples shown).

Users of this guide should be also be aware that the examples included here do not necessarily show exhaustive lists of the various tests and parameters that would be required for the tobacco products that are illustrated. Additional terminology to support creation of CDISC-conformant datasets representing the various parameters and analytes applicable to all tobacco products will be developed in an ongoing basis independent of the publication of this guide. For more information on controlled terminology, see Section 2.3, [How to Use Controlled Terminology and Formats](#).

This section illustrates how to use CDISC standards to represent various aspects of the identification, descriptive characteristics, product design, and testing of tobacco products that occur separately from product testing in human or nonclinical studies. The concepts illustrated in the examples include:

- How to uniquely identify a tobacco product under study, or a predicate/comparator product using the Applicant-defined Tobacco Product Identifier (SPTOBID) variable, which is used in any applicable dataset throughout the product development lifecycle to identify the tobacco product that is a focal point of a record or records
- How to represent tobacco product identifying and descriptive parameters using the Tobacco Product Identifiers and Descriptors (TO) domain
- How to represent product design parameter specifications using the Product Design Parameters (PD) domain, and the results of testing for conformance to those specifications using the Tobacco Product Testing (PT) domain
- How to represent and quantify tobacco ingredients, non-tobacco ingredients, and additives using the Tobacco Ingredients (IT) domain, the Non-Tobacco Ingredients (IN) domain, and the Ingredient Quantities by Component (IQ) domain
- How to represent tobacco product testing for HPHC content using the Tobacco Product Testing (PT) domain
- How to represent smoking machines and smoking / vaping regimens using the Device Identifiers (DI) domain and the Device In-Use Properties (DU) domain, and how to relate those to measurements of analytes using the DURERFID and PTREFID variables

- How to represent stability study results using the PT domain
- How to represent storage conditions (used in stability studies) using the Environmental Storage Conditions (ES) domain, and how to relate the parameters of those conditions to the stability study results using the STOCONID variable

The Tobacco Product Identifiers and Descriptors example is applicable to *all* studies of tobacco products. Users should review this example first before proceeding to other examples.

The variable PTCAT (Category of Test) in the PT domain is a Required variable (and therefore *must* be populated in submitted PT datasets). This variable will be necessary to group and differentiate records coming from the many types of tests that are represented in this domain, some of which will contain the same analytes collected under different contexts. The use of PTCAT makes the context of the analyte data collection explicit.

3.1.1 Tobacco Product Identifiers and Descriptors – New, Predicate, Original, and Comparison Products (TO)

Tobacco Product Identifiers and Descriptors (TO) is a study reference dataset that provides a mechanism for uniquely identifying a tobacco product. It is the origin of the applicant-defined tobacco product identifier (SPTOBID). This identifier is additionally used in any dataset containing records that pertain to the product at all stages of the product development lifecycle, including nonclinical testing and testing in human subjects. See Section 2.8.8.1., [SDTM Tobacco Product Identifiers and Descriptors \(TO\)](#), for a detailed description and specification table for this dataset.

The example in this section demonstrates how to identify both a new product and a predicate product. Subsequent examples in this guide focus only on *new* products, in order to keep the tables concise and easier to review. In reality, many of the examples in this guide would contain data on both the new and predicate product, and the SPTOBID for both products would be used with every dataset on any record that pertains to the associated product.

Each unique new product and each unique predicate, original, or comparison product would be assigned a unique SPTOBID value which would be associated with a block of records for their identifying and descriptive characteristics in the TO dataset.

This example illustrates TO concepts using a cigarette product and its predicate product for demonstration purposes. Section 3.1.2, [Product Design Parameters and Conformance Testing](#), demonstrates this dataset for an ENDS product and a portioned snus product.

- Rows 1-10:** Show the identifying and descriptive parameters for a new product. Note that the category variable (TOCAT) is "NEW PRODUCT" for these records. The applicant chose to further subcategorize each parameter as either an identifying or descriptive parameter in the variable TOSCAT.
- Rows 1-4:** Show the records for the product identifiers for the tobacco product identified in SPTOBID.
- Rows 11-21:** Show the records for the product descriptors for a predicate tobacco product identified in SPTOBID. Note that the category variable (TOCAT) is "PREDICATE PRODUCT" for these records. The applicant chose to further subcategorize each parameter as either an identifying or descriptive parameter in the variable TOSCAT.
- Row 13:** Shows the FDA submission tracking number (STN) associated with the predicate product. This parameter should be included for all products for which an FDA STN is available.

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Row	STUDYID	DOMAIN	SPTOBID	TOSEQ	TOPARMCD	TOPARM	TOCAT	TOSCAT	TOVAL	TOVALU
1	TOB07	TO	CIG01a	1	TBPRDCAT	Tobacco Product Category	NEW PRODUCT	PRODUCT IDENTIFIER	Cigarettes	
2	TOB07	TO	CIG01a	2	TBPRSCAT	Tobacco Product Subcategory	NEW PRODUCT	PRODUCT IDENTIFIER	Filtered	
3	TOB07	TO	CIG01a	3	MANUF	Manufacturer	NEW PRODUCT	PRODUCT IDENTIFIER	Joes Cigs USA	

Row	STUDYID	DOMAIN	SPTOBID	TOSEQ	TOPARMCD	TOPARM	TOCAT	TOSCAT	TOVAL	TOVALU
4	TOB07	TO	CIG01a	4	TRADENAM	Trade Name	NEW PRODUCT	PRODUCT IDENTIFIER	Treetop Menthol King Size	
5	TOB07	TO	CIG01a	5	PACKTYP	Package Type	NEW PRODUCT	PRODUCT DESCRIPTOR	HARD PACK	
6	TOB07	TO	CIG01a	6	PRDQUAN	Product Quantity	NEW PRODUCT	PRODUCT DESCRIPTOR	20	CIGARETTE
7	TOB07	TO	CIG01a	7	LENGTH	Length	NEW PRODUCT	PRODUCT DESCRIPTOR	86.0	mm
8	TOB07	TO	CIG01a	8	CIRCUMF	Circumference	NEW PRODUCT	PRODUCT DESCRIPTOR	26.0	mm
9	TOB07	TO	CIG01a	9	VENTLTOT	Total Ventilation	NEW PRODUCT	PRODUCT DESCRIPTOR	10.0	%
10	TOB07	TO	CIG01a	10	CHARFLAV	Characterizing Flavor	NEW PRODUCT	PRODUCT DESCRIPTOR	MENTHOL	
11	TOB07	TO	CIG064	1	TBPRDCAT	Tobacco Product Category	PREDICATE PRODUCT	PRODUCT IDENTIFIER	Cigarette	
12	TOB07	TO	CIG064	2	TBPRSCAT	Tobacco Product Subcategory	PREDICATE PRODUCT	PRODUCT IDENTIFIER	Filtered	
13	TOB07	TO	CIG064	3	FDASTN	FDA Submission Tracking Number	PREDICATE PRODUCT	PRODUCT IDENTIFIER	SE0212345	
14	TOB07	TO	CIG064	4	MANUF	Manufacturer	PREDICATE PRODUCT	PRODUCT IDENTIFIER	Joes Cigs USA	
15	TOB07	TO	CIG064	5	TRADENAM	Trade Name	PREDICATE PRODUCT	PRODUCT IDENTIFIER	Treetop Menthol King Size	
16	TOB07	TO	CIG064	6	PACKTYP	Package Type	PREDICATE PRODUCT	PRODUCT DESCRIPTOR	HARD PACK	
17	TOB07	TO	CIG064	7	PRDQUAN	Product Quantity	PREDICATE PRODUCT	PRODUCT DESCRIPTOR	20	CIGARETTE
18	TOB07	TO	CIG064	8	LENGTH	Length	PREDICATE PRODUCT	PRODUCT DESCRIPTOR	86.5	mm
19	TOB07	TO	CIG064	9	CIRCUMF	Circumference	PREDICATE PRODUCT	PRODUCT DESCRIPTOR	26.1	mm
20	TOB07	TO	CIG064	10	VENTLTOT	Total Ventilation	PREDICATE PRODUCT	PRODUCT DESCRIPTOR	12.0	%
21	TOB07	TO	CIG064	11	CHARFLAV	Characterizing Flavor	PREDICATE PRODUCT	PRODUCT DESCRIPTOR	MENTHOL	

3.1.2 Product Design Parameters and Conformance Testing

The examples in this section illustrate how to represent lists of design parameter specifications and testing for conformance to those specifications using three tobacco product categories: cigarettes (Example 1), ENDS devices (Example 2), and smokeless tobacco products (Example 3). Each example starts with a TO dataset, followed by a Product Design Parameters (PD) dataset and a Tobacco Product Testing (PT) dataset.

Note that tobacco product testing for conformance to design parameters would typically require multiple replicates for each parameter being tested. In SDTM, each replicate would be represented in its own record, differentiated by using the PTREPNUM variable (repetition number), which would be set to values of 1 through n (where n = the total number of replicates being tested). For simplicity of review, each example uses the PTREPNUM variable, but only for 1 record (1 repetition). In reality, if only 1 record for a given parameter or analyte is collected, the PTREPNUM variable would not be used.

Example 1

This example illustrates the representation of a cigarette product's identifiers and descriptors using the TO domain. Note that this example uses TOSCAT (Subcategory of Tobacco Prod ID Element, a permissible variable) to emphasize and differentiate the 2 distinct types of parameters represented in TO: tobacco product identifiers and tobacco product descriptors.

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Row	STUDYID	DOMAIN	SPTOBID	TOSEQ	TOPARMCD	TOPARM	TOCAT	TOSCAT	TOVAL	TOVALU
1	TOB07	TO	CIG01a	1	TBPRDCAT	Tobacco Product Category	NEW PRODUCT	PRODUCT IDENTIFIER	Cigarettes	
2	TOB07	TO	CIG01a	2	TBPRSCAT	Tobacco Product Subcategory	NEW PRODUCT	PRODUCT IDENTIFIER	Filtered	
3	TOB07	TO	CIG01a	3	MANUF	Manufacturer	NEW PRODUCT	PRODUCT IDENTIFIER	Joes Cigs USA	
4	TOB07	TO	CIG01a	4	TRADENAM	Trade Name	NEW PRODUCT	PRODUCT IDENTIFIER	Treetop Menthol King Size	
5	TOB07	TO	CIG01a	5	PACKTYP	Package Type	NEW PRODUCT	PRODUCT DESCRIPTOR	HARD PACK	
6	TOB07	TO	CIG01a	6	PRDQUAN	Product Quantity	NEW PRODUCT	PRODUCT DESCRIPTOR	20	CIGARETTE
7	TOB07	TO	CIG01a	7	LENGTH	Length	NEW PRODUCT	PRODUCT DESCRIPTOR	86.0	mm
8	TOB07	TO	CIG01a	8	CIRCUMF	Circumference	NEW PRODUCT	PRODUCT DESCRIPTOR	26.0	mm
9	TOB07	TO	CIG01a	9	VENTLTOT	Total Ventilation	NEW PRODUCT	PRODUCT DESCRIPTOR	10.0	%
10	TOB07	TO	CIG01a	10	CHARFLAV	Characterizing Flavor	NEW PRODUCT	PRODUCT DESCRIPTOR	MENTHOL	

The manufacturing parameter specifications of the cigarette tobacco product as intended for use are represented in the PD domain. The following example shows the target, minimum, and maximum values associated with each of 23 separate design parameters. These parameters are defined manufacturing specifications, not characteristics that are determined experimentally.

Note the use of the variable IGDCMPID (Ingredient or Component Identifier) in rows 5-6. This tobacco product had 2 tobacco ingredients with 2 different tobacco cut sizes. IGDCMPID identifies to which tobacco ingredient the cut size applies. IGDCMPID originates in the IT (Tobacco Ingredients) and IN (Non-Tobacco Ingredients) domains. See Section 3.1.3.1, [Ingredients and Additives](#), for more information.

pd.xpt

Row	STUDYID	DOMAIN	SPTOBID	IGDCMPID	PDSEQ	PDPARMCD	PDPARM	PDVALTRG	PDVALMIN	PDVALMAX	PDVALU
1	TOB07	PD	CIG01a		1	LENGTH	Length	84	83.5	84.5	mm
2	TOB07	PD	CIG01a		2	CIRCUMF	Circumference	24.8	24.6	25	mm
3	TOB07	PD	CIG01a		3	TBFILMASS	Tobacco Filler Mass	783	753	814	mg
4	TOB07	PD	CIG01a		4	MOISTURE	Moisture	13	12	14	%
5	TOB07	PD	CIG01a	Burley tobacco	5	TOCUTSIZ	Tobacco Cut Size	22	20	24	cuts/in
6	TOB07	PD	CIG01a	Reconstituted tobacco	6	TOCUTSIZ	Tobacco Cut Size	27	25	29	mm
7	TOB07	PD	CIG01a		7	VENTLFLT	Filter Ventilation	30	23	37	%
8	TOB07	PD	CIG01a		8	TPNPLGTH	Tipping Paper Length	31	30	32	mm
9	TOB07	PD	CIG01a		9	CBPPOR	Cigarette Base Paper Porosity	50	45	55	Cu
10	TOB07	PD	CIG01a		10	CBPPERM	Cigarette Base Paper Permeability	50	45	55	Cu
11	TOB07	PD	CIG01a		11	CPBPOR	Cigarette Paper Band Porosity	10	0.2	13	Cu
12	TOB07	PD	CIG01a		12	CPBPERM	Cigarette Paper Band Permeability	10	0.2	13	Cu
13	TOB07	PD	CIG01a		13	CPBDIFF	Cigarette Paper Band Diffusivity	0.05	0.001	0.100	cm ² /s
14	TOB07	PD	CIG01a		14	CPBWID	Cigarette Paper Band Width	7	6.7	7.3	mm
15	TOB07	PD	CIG01a		15	CPBSPC	Cigarette Paper Band Space	20	19.8	20.2	mm
16	TOB07	PD	CIG01a		16	FLTREFF	Filter Efficiency	30	25	35	%
17	TOB07	PD	CIG01a		17	DPF	Denier Per Filament	4	3.6	4.4	
18	TOB07	PD	CIG01a		18	TDENIER	Total Denier	30000	29100	30900	g/9000m
19	TOB07	PD	CIG01a		19	FLTRDEN	Filter Density	0.1234	0.105	0.1419	g/cm ³
20	TOB07	PD	CIG01a		20	FLTRLGTH	Filter Length	25	24.5	25.5	mm
21	TOB07	PD	CIG01a		21	FLTPRDRP	Filter Pressure Drop	60	51	69	mm H ₂ O
22	TOB07	PD	CIG01a		22	TORODDEN	Tobacco Rod Density	0.2678	0.2437	0.2919	g/cm ³
23	TOB07	PD	CIG01a		23	CIGPLGTH	Cigarette Paper Length	53	52	54	mm

Finally, the PT domain is used to represent the actual results of testing the manufactured cigarette product for conformance to the tobacco product design parameters shown in PD above. PTCAT is a Required variable and is set to "DESIGN PARAMETER TESTING" for all records here. As described in the PD example, IGDCMPID is also used here to differentiate 2 records of the same test performed on each of 2 different types of tobacco that are ingredients of the

tobacco product. Typically, applicants would submit data on each parameter in multiple replicates. For simplicity of review, only 1 replicate per parameter is shown. Note that PTREPNUM (repetition number) = 1 for all rows.

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Row	STUDYID	DOMAIN	SPTOBID	IGDCMPID	PTSEQ	PTTESTCD	PTTEST	PTCAT	PTTORRES	PTTORRESU	PTSTRESC	PTSTRESN	PTSTRESU	PTMETHOD	PTREPNUM
1	TOB07	PT	CIG01a		1	LENGTH	Length	DESIGN PARAMETER TESTING	83.9	mm	83.9	83.9	mm		1
2	TOB07	PT	CIG01a		2	CIRCUMF	Circumference	DESIGN PARAMETER TESTING	24.9	mm	24.9	24.9	mm		1
3	TOB07	PT	CIG01a		3	TBFLMASS	Tobacco Filler Mass	DESIGN PARAMETER TESTING	779	mg	779	779	mg		1
4	TOB07	PT	CIG01a		4	MOISTURE	Moisture	DESIGN PARAMETER TESTING	13.1	%	13.1	13.1	%		1
5	TOB07	PT	CIG01a	Burley tobacco	5	TOCUTSIZ	Tobacco Cut Size	DESIGN PARAMETER TESTING	22	cuts/in	22	22	cuts/in		1
6	TOB07	PT	CIG01a	Reconstituted tobacco	6	TOCUTSIZ	Tobacco Cut Size	DESIGN PARAMETER TESTING	27	mm	27	27	mm		1
7	TOB07	PT	CIG01a		7	VENTLFLT	Filter Ventilation	DESIGN PARAMETER TESTING	35	%	35	35	%		1
8	TOB07	PT	CIG01a		8	TPNPLGTH	Tipping Paper Length	DESIGN PARAMETER TESTING	30	mm	30	30	mm		1
9	TOB07	PT	CIG01a		9	CBPPOR	Cigarette Base Paper Porosity	DESIGN PARAMETER TESTING	48	Cu	48	48	Cu		1
10	TOB07	PT	CIG01a		10	CBPPERM	Cigarette Base Paper Permeability	DESIGN PARAMETER TESTING	50	Cu	50	50	Cu		1
11	TOB07	PT	CIG01a		11	CPBPOR	Cigarette Paper Band Porosity	DESIGN PARAMETER TESTING	9.8	Cu	9.8	9.8	Cu		1
12	TOB07	PT	CIG01a		12	CPBPERM	Cigarette Paper Band Permeability	DESIGN PARAMETER TESTING	10	Cu	10	10	Cu		1
13	TOB07	PT	CIG01a		13	CPBDIFF	Cigarette Paper Band Diffusivity	DESIGN PARAMETER TESTING	0.06	cm ² /s	0.06	0.06	cm ² /s		1
14	TOB07	PT	CIG01a		14	CPBWID	Cigarette Paper Band Width	DESIGN PARAMETER TESTING	7.1	mm	7.1	7.1	mm		1
15	TOB07	PT	CIG01a		15	CPBSPC	Cigarette Paper Band Space	DESIGN PARAMETER TESTING	19.9	mm	19.9	19.9	mm		1
16	TOB07	PT	CIG01a		16	FLTREFF	Filter Efficiency	DESIGN PARAMETER TESTING	28	%	28	28	%		1
17	TOB07	PT	CIG01a		17	DPF	Denier Per Filament	DESIGN PARAMETER TESTING	4.1		4.1	4.1			1
18	TOB07	PT	CIG01a		18	TDENIER	Total Denier	DESIGN PARAMETER TESTING	29900	g/9000m	29900	29900	g/9000m		1

Row	STUDYID	DOMAIN	SPTOBID	IGDCMPID	PTSEQ	PTTESTCD	PTTEST	PTCAT	PTORRES	PTORRESU	PTSTRESC	PTSTRESN	PTSTRESU	PTMETHOD	PTREPNUM
19	TOB07	PT	CIG01a		19	FLTRDEN	Filter Density	DESIGN PARAMETER TESTING	0.1112	g/cm3	0.1112	0.1112	g/cm3		1
20	TOB07	PT	CIG01a		20	FLTRLGTH	Filter Length	DESIGN PARAMETER TESTING	25	mm	25	25	mm		1
21	TOB07	PT	CIG01a		21	FLTPRDRP	Filter Pressure Drop	DESIGN PARAMETER TESTING	62	mm H2O	62	62	mm H2O		1
22	TOB07	PT	CIG01a		22	TORODDEN	Tobacco Rod Density	DESIGN PARAMETER TESTING	0.2701	g/cm3	0.2701	0.2701	g/cm3		1
23	TOB07	PT	CIG01a		23	CIGPLGTH	Cigarette Paper Length	DESIGN PARAMETER TESTING	53	mm	53	53	mm		1

References:

- International Organization for Standardization. *ISO 9512:2019(en) - Cigarettes — Determination of ventilation — Definitions and measurement principles*. ISO; June 2019. Accessed October 15, 2023. <https://www.iso.org/obp/ui/#iso:std:iso:9512:ed-3:v1:en>
- Song M-A, Benowitz NL, Berman M, et al. Cigarette filter ventilation and its relationship to increasing rates of lung adenocarcinoma. *J Natl Cancer Inst.* 2017;109(12):dix075. <https://doi.org/10.1093/jnci/dix075>

Example 2

The following example illustrates the representation of an ENDS tobacco product's identifiers and descriptors using the TO domain. Note that this example uses TOSCAT to emphasize and differentiate the 2 distinct types of parameters represented in TO: tobacco product identifiers and tobacco product descriptors.

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Row	STUDYID	DOMAIN	SPTOBID	TOSEQ	TOPARMCD	TOPARM	TOCAT	TOSCAT	TOVAL	TOVALU
1	TOB09	TO	VAPE-Z27	1	TBPRDCAT	Tobacco Product Category	NEW PRODUCT	PRODUCT IDENTIFIER	Electronic Nicotine Delivery Systems (ENDS) (Vapes)	
2	TOB09	TO	VAPE-Z27	2	TBPRSCAT	Tobacco Product Subcategory	NEW PRODUCT	PRODUCT IDENTIFIER	Closed E-Cigarette	
3	TOB09	TO	VAPE-Z27	3	MANUF	Manufacturer	NEW PRODUCT	PRODUCT IDENTIFIER	Joes Vapes USA	
4	TOB09	TO	VAPE-Z27	4	TRADENAM	Trade Name	NEW PRODUCT	PRODUCT IDENTIFIER	Everyday Rich Tobacco	
5	TOB09	TO	VAPE-Z27	5	PACKTYP	Package Type	NEW PRODUCT	PRODUCT DESCRIPTOR	BOX	
6	TOB09	TO	VAPE-Z27	6	PRDQUAN	Product Quantity	NEW PRODUCT	PRODUCT DESCRIPTOR	1	E-CIGARETTE
7	TOB09	TO	VAPE-Z27	7	LENGTH	Length	NEW PRODUCT	PRODUCT DESCRIPTOR	107.2	mm
8	TOB09	TO	VAPE-Z27	8	DIAMETER	Diameter	NEW PRODUCT	PRODUCT DESCRIPTOR	9	mm
9	TOB09	TO	VAPE-Z27	9	NICTNCNC	Nicotine Concentration	NEW PRODUCT	PRODUCT DESCRIPTOR	2	mg/L
10	TOB09	TO	VAPE-Z27	10	PRPYLGLY	Propylene Glycol	NEW PRODUCT	PRODUCT DESCRIPTOR	50	%
11	TOB09	TO	VAPE-Z27	11	VEGGLY	Vegetable Glycerin	NEW PRODUCT	PRODUCT DESCRIPTOR	50	%
12	TOB09	TO	VAPE-Z27	12	CHARFLAV	Characterizing Flavor	NEW PRODUCT	PRODUCT DESCRIPTOR	Tobacco	
13	TOB09	TO	VAPE-Z27	13	ELQDVOL	E-Liquid Volume	NEW PRODUCT	PRODUCT DESCRIPTOR	1	mL
14	TOB09	TO	VAPE-Z27	14	BATCAPC	Battery Capacity	NEW PRODUCT	PRODUCT DESCRIPTOR	600	mAh
15	TOB09	TO	VAPE-Z27	15	DSCRTIND	Disposable Cartridge Indicator	NEW PRODUCT	PRODUCT DESCRIPTOR	Y	

The manufacturing parameter specifications of the ENDS product as intended for use are represented in the PD domain. The following example shows the target, minimum, and maximum values associated with each of 33 separate design parameters. These parameters are defined manufacturing specifications, not characteristics that are determined experimentally.

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Row	STUDYID	DOMAIN	SPTOBID	PDSEQ	PDPARMCD	PDPARM	PDVALTRG	PDVALMIN	PDVALMAX	PDVALU
1	TOB09	PD	VAPE-Z27	1	DRWRST	Draw Resistance	90.0	80.0	120.0	mm H2O
2	TOB09	PD	VAPE-Z27	2	PUFCNT	Puff Count	300	290	310	
3	TOB09	PD	VAPE-Z27	3	CRTVOL	Cartridge Volume	3	1	5	mL
4	TOB09	PD	VAPE-Z27	4	HTELNUM	Number of Heating Elements	1	1	1	
5	TOB09	PD	VAPE-Z27	5	HTELGTH	Heating Element Length	3	2.7	3.3	mm
6	TOB09	PD	VAPE-Z27	6	HTEDIAM	Heating Element Diameter	3	2.9	3.2	mm
7	TOB09	PD	VAPE-Z27	7	HTELrst	Heating Element Resistance	0.75	0.25	1.5	ohm
8	TOB09	PD	VAPE-Z27	8	HTELrng	Heating Element Range	175	100	250	C
9	TOB09	PD	VAPE-Z27	9	HTELcfg	Heating Element Configuration	SPIRAL	SPIRAL	SPIRAL	
10	TOB09	PD	VAPE-Z27	10	BTVLORG	Battery Voltage Operating Range	4.5	3	6	V
11	TOB09	PD	VAPE-Z27	11	BTCRTORG	Battery Current Operating Range	1000	650	1600	mAh
12	TOB09	PD	VAPE-Z27	12	BATCAPC	Battery Capacity	1100	800	3000	mAh
13	TOB09	PD	VAPE-Z27	13	BATNOMV	Battery Nominal Voltage	4.2	4.0	4.5	V
14	TOB09	PD	VAPE-Z27	14	BTCCRTRT	Battery Current Rating	2500	2000	2800	mA
15	TOB09	PD	VAPE-Z27	15	BTCHTPL	Battery Charging Temperature Limits	200	100	315	C
16	TOB09	PD	VAPE-Z27	16	BTDCTMPL	Battery Discharge Temperature Limits	20	-20	60	C
17	TOB09	PD	VAPE-Z27	17	BTENDCV	Battery End of Discharge Voltage	3.0	2.0	3.5	V
18	TOB09	PD	VAPE-Z27	18	BTMXCHC	Battery Maximum Charging Current	24	20	30	mA
19	TOB09	PD	VAPE-Z27	19	BTMXDCC	Battery Maximum Discharging Current	2700	2400	3000	mA
20	TOB09	PD	VAPE-Z27	20	BTULCHV	Battery Upper Limits Charging Voltage	4.2	4.1	4.3	V
21	TOB09	PD	VAPE-Z27	21	PDUVOR	PDU Voltage Operating Range	3.7	3.2	4.2	V
22	TOB09	PD	VAPE-Z27	22	PDUCOR	PDU Current Operating Range	1200	850	1800	mA
23	TOB09	PD	VAPE-Z27	23	PDUTCTOF	PDU Temperature Cut-off	70	55	65	C
24	TOB09	PD	VAPE-Z27	24	AIRFLRT	Airflow Rate	720	700	740	L/min
25	TOB09	PD	VAPE-Z27	25	PDUCRCOF	PDU Current Cut-off	35	20	50	mA
26	TOB09	PD	VAPE-Z27	26	INHAERT	Inhaled Aerosol Temperature	37	35	40	C
27	TOB09	PD	VAPE-Z27	27	VENTLTOT	Total Ventilation	50	40	60	%
28	TOB09	PD	VAPE-Z27	28	ELQDVISC	E-Liquid Viscosity	500	75	1130	mPa/s
29	TOB09	PD	VAPE-Z27	29	ELQDVOL	E-liquid Volume	60	10	120	mL
30	TOB09	PD	VAPE-Z27	30	PNUMCNC	Particle Number Concentration	500	108	1010	/cm3
31	TOB09	PD	VAPE-Z27	31	CTMDDIAM	Count Median Diameter	200	150	250	nm
32	TOB09	PD	VAPE-Z27	32	PM2.5	Particulate Matter 2.5	25	12	35	ug/m3

Finally, the PT domain is used to represent the actual results of testing the manufactured ENDS product for conformance to the tobacco product design parameters shown in PD. PTCAT is a Required variable and is set to "DESIGN PARAMETER TESTING" for all records here. Typically, applicants would submit data on each parameter in multiple replicates. For simplicity of review, only 1 replicate per parameter is shown. Note that PTREPNUM (repetition number) = 1 for all rows.

pt.xpt

Row	STUDYID	DOMAIN	SPTOBID	PTSEQ	PTREFID	PTTESTCD	PTTEST	PTTSTCND	PTCAT	PTSCAT	PTTRESU	PTTRESL	PTSTRESU	PTSTRESL	PTREPNUM	
1	TOB09	PT	VAPE-Z27	1		DRWRST	Draw Resistance		DESIGN PARAMETER TESTING		91	mm H2O	91	91	mm H2O	1
2	TOB09	PT	VAPE-Z27	2		PUFCNT	Puff Count		DESIGN PARAMETER TESTING		309		309	309		1
3	TOB09	PT	VAPE-Z27	3		CRTVOL	Cartridge Volume		DESIGN PARAMETER TESTING		3.09	mL	3.09	3.09	mL	1
4	TOB09	PT	VAPE-Z27	4		HTELNUM	Number of Heating Elements		DESIGN PARAMETER TESTING		1		1	1		1

Row	STUDYID	DOMAIN	SPTOBID	PTSEQ	PTREFID	PTTESTCD	PTTEST	PTTSTCND	PTCAT	PTSCAT	PTORRES	PTORRESU	PTSTRESC	PTSTRESN	PTSTRESU	PTREPNUM
5	TOB09	PT	VAPE-Z27	5		HTELGTH	Heating Element Length		DESIGN PARAMETER TESTING		2.97	mm	2.97	2.97	mm	1
6	TOB09	PT	VAPE-Z27	6		HTEDIAM	Heating Element Diameter		DESIGN PARAMETER TESTING		3.05	mm	3.05	3.05	mm	1
7	TOB09	PT	VAPE-Z27	7		HTELRST	Heating Element Resistance		DESIGN PARAMETER TESTING		0.77	ohm	0.77	0.77	ohm	1
8	TOB09	PT	VAPE-Z27	8		HTELRNG	Heating Element Range		DESIGN PARAMETER TESTING		174	C	174	174	C	1
9	TOB09	PT	VAPE-Z27	9		HTELCFG	Heating Element Configuration		DESIGN PARAMETER TESTING		SPIRAL		SPIRAL	SPIRAL		1
10	TOB09	PT	VAPE-Z27	10		BTVLTORG	Battery Voltage Operating Range		DESIGN PARAMETER TESTING		4.6	V	4.6	4.6	V	1
11	TOB09	PT	VAPE-Z27	11		BTCRTORG	Battery Current Operating Range		DESIGN PARAMETER TESTING		997	mAh	997	997	mAh	1
12	TOB09	PT	VAPE-Z27	12		BATCAPC	Battery Capacity		DESIGN PARAMETER TESTING		1112	mAh	1112	1112	mAh	1
13	TOB09	PT	VAPE-Z27	13		BATNOMV	Battery Nominal Voltage		DESIGN PARAMETER TESTING		4.18	V	4.18	4.18	V	1
14	TOB09	PT	VAPE-Z27	14		BTCRTTRT	Battery Current Rating		DESIGN PARAMETER TESTING		2488	mA	2488	2488	mA	1
15	TOB09	PT	VAPE-Z27	15		BTCHTPL	Battery Charging Temperature Limits		DESIGN PARAMETER TESTING		198	C	198	198	C	1
16	TOB09	PT	VAPE-Z27	16		BTDCTMPL	Battery Discharge Temperature Limits		DESIGN PARAMETER TESTING		19	C	19	19	C	1
17	TOB09	PT	VAPE-Z27	17		BTENDCV	Battery End of Discharge Voltage		DESIGN PARAMETER TESTING		3.03	V	3.03	3.03	V	1
18	TOB09	PT	VAPE-Z27	18		BTMXCHC	Battery Maximum Charging Current		DESIGN PARAMETER TESTING		23.5	mA	23.5	23.5	mA	1
19	TOB09	PT	VAPE-Z27	19		BTMXDCC	Battery Maximum Discharging Current		DESIGN PARAMETER TESTING		2696	mA	2696	2696	mA	1
20	TOB09	PT	VAPE-Z27	20		BTULCHV	Battery Upper Limits Charging Voltage		DESIGN PARAMETER TESTING		4.21	V	4.21	4.21	V	1
21	TOB09	PT	VAPE-Z27	21		PDUVOR	PDU Voltage Operating Range		DESIGN PARAMETER TESTING		3.65	V	3.65	3.65	V	1
22	TOB09	PT	VAPE-Z27	22		PDUCOR	PDU Current Operating Range		DESIGN PARAMETER TESTING		1202	mA	1202	1202	mA	1

Row	STUDYID	DOMAIN	SPTOBID	PTSEQ	PTREFID	PTTESTCD	PTTEST	PTTSTCND	PTCAT	PTSCAT	PTORRES	PTORRESU	PTSTRESC	PTSTRESN	PTSTRESU	PTREPNUM
23	TOB09	PT	VAPE-Z27	23		PDUTCTOF	PDU Temperature Cut-off		DESIGN PARAMETER TESTING		69.9	C	69.9	69.9	C	1
24	TOB09	PT	VAPE-Z27	24		AIRFLRT	Airflow Rate		DESIGN PARAMETER TESTING		727	L/min	727	727	L/min	1
25	TOB09	PT	VAPE-Z27	25		PDUCRCOF	PDU Current Cut-off		DESIGN PARAMETER TESTING		34.8	mA	34.8	34.8	mA	1
26	TOB09	PT	VAPE-Z27	26		INHAERT	Inhaled Aerosol Temperature		DESIGN PARAMETER TESTING		36.9	C	36.9	36.9	C	1
27	TOB09	PT	VAPE-Z27	27		VENTLTOT	Total Ventilation		DESIGN PARAMETER TESTING		51	%	51	51	%	1
28	TOB09	PT	VAPE-Z27	28		ELQDVISC	E-Liquid Viscosity	Test performed at 20 degrees Celsius	DESIGN PARAMETER TESTING		496	mPa/s	496	496	mPa/s	1
29	TOB09	PT	VAPE-Z27	29		ELQDVOL	E-liquid Volume		DESIGN PARAMETER TESTING		60.1	mL	60.1	60.1	mL	1
30	TOB09	PT	VAPE-Z27	30		PNUMCNC	Particle Number Concentration		DESIGN PARAMETER TESTING		511	/cm3	511	511	/cm3	1
31	TOB09	PT	VAPE-Z27	31		CTMDDIAM	Count Median Diameter		DESIGN PARAMETER TESTING		202	nm	202	202	nm	1
32	TOB09	PT	VAPE-Z27	32		PM2.5	Particulate Matter 2.5		DESIGN PARAMETER TESTING		24.4	ug/m3	24.4	24.4	ug/m3	1

Example 3

The following example illustrates the representation of a smokeless tobacco product's (portioned snus) identifiers and descriptors using the TO domain. Note that this example uses TOSCAT to emphasize and differentiate the 2 distinct types of parameters represented in TO: tobacco product identifiers and tobacco product descriptors.

to.xpt

Row	STUDYID	DOMAIN	SPTOBID	TOSEQ	TOPARMCD	TOPARM	TOCAT	TOSCAT	TOVAL	TOVALU
1	TOB17	TO	SNUS-77	1	TBPRDCAT	Tobacco Product Category	NEW PRODUCT	PRODUCT IDENTIFIER	Smokeless Tobacco Products	
2	TOB17	TO	SNUS-77	2	TBPRSCAT	Tobacco Product Subcategory	NEW PRODUCT	PRODUCT IDENTIFIER	Portioned Snus	
3	TOB17	TO	SNUS-77	3	MANUF	Manufacturer	NEW PRODUCT	PRODUCT IDENTIFIER	Joes Smokeless	
4	TOB17	TO	SNUS-77	4	TRADENAM	Trade Name	NEW PRODUCT	PRODUCT IDENTIFIER	Happy Dog Snus	
5	TOB17	TO	SNUS-77	5	PACKTYP	Package Type	NEW PRODUCT	PRODUCT DESCRIPTOR	Plastic Can with Lid	
6	TOB17	TO	SNUS-77	6	PACKQUAN	Package Quantity	NEW PRODUCT	PRODUCT DESCRIPTOR	24	g
7	TOB17	TO	SNUS-77	7	PRTMASS	Portion Mass	NEW PRODUCT	PRODUCT DESCRIPTOR	1	g
8	TOB17	TO	SNUS-77	8	PORTCONT	Portion count	NEW PRODUCT	PRODUCT DESCRIPTOR	24	
9	TOB17	TO	SNUS-77	9	PRTLENG	Portion length	NEW PRODUCT	PRODUCT DESCRIPTOR	30	mm
10	TOB17	TO	SNUS-77	10	PRTWDTH	Portion width	NEW PRODUCT	PRODUCT DESCRIPTOR	10	mm
11	TOB17	TO	SNUS-77	11	PRTTHICK	Portion thickness	NEW PRODUCT	PRODUCT DESCRIPTOR	5	mm
12	TOB17	TO	SNUS-77	12	CHARFLAV	Characterizing Flavor	NEW PRODUCT	PRODUCT DESCRIPTOR	Flavored	

The manufacturing parameter specifications of the portioned snus tobacco product as intended for use are represented in the PD domain. The following example shows the target, minimum, and maximum values associated with each of 10 separate design parameters. These parameters are defined manufacturing specifications, not characteristics that are determined experimentally.

pd.xpt

Row	STUDYID	DOMAIN	SPTOBID	PDSEQ	PDPARMCD	PDPARM	PDVALTRG	PDVALMIN	PDVALMAX	PDVALU
1	TOB17	PD	SNUS-77	1	TOCUTSIZ	Tobacco Cut Size	70	65	75	cuts/in
2	TOB17	PD	SNUS-77	1	TOPRTSIZ	Tobacco Particle Size	70	65	75	mm
3	TOB17	PD	SNUS-77	2	TOMOISTR	Tobacco Moisture	32.2	31	34	%
4	TOB17	PD	SNUS-77	3	PRTLENG	Portion Length	38	36.5	39.5	mm
5	TOB17	PD	SNUS-77	4	PRTWDTH	Portion Width	16	15	17	mm
6	TOB17	PD	SNUS-77	5	PRTMASS	Portion Mass	1000	900	1100	mg
7	TOB17	PD	SNUS-77	6	PRTTHICK	Portion Material Thickness	0.06	0.055	0.065	mm
8	TOB17	PD	SNUS-77	7	PRTMWGT	Pouch Material Basis Weight	16	15	17	g/m ²
9	TOB17	PD	SNUS-77	8	PRTMPOR	Pouch Material Porosity	1850	1600	2200	L/m ² /s
10	TOB17	PD	SNUS-77	9	NICTDSRT	Nicotine Dissolution Rate	15	5	22	%/min

Finally, the PT domain is used to represent the actual results of testing the manufactured portioned snus product for conformance to the tobacco product design parameters shown in PD. PTCAT is a Required variable and is set to "DESIGN PARAMETER TESTING" for all records here. Typically, applicants would submit data on each parameter in multiple replicates. For simplicity of review, only 1 replicate per parameter is shown. Note that PTREPNUM (repetition number) = 1 for all rows.

pt.xpt

Row	STUDYID	DOMAIN	SPTOBID	PTSEQ	PTTESTCD	PTTEST	PTCAT	PTTRESR	PTTRESU	PTSTRESC	PTSTRESN	PTSTRESU	PTREPNUM
1	TOB17	PT	SNUS-77	1	TOCUTSIZ	Tobacco Cut Size	DESIGN PARAMETER TESTING	70	cuts per inch	70	70	cuts/in	1
2	TOB17	PT	SNUS-77	1	TOPRTSIZ	Tobacco Particle Size	DESIGN PARAMETER TESTING	70	mm	70	70	mm	1
3	TOB17	PT	SNUS-77	2	TOMOISTR	Tobacco Moisture	DESIGN PARAMETER TESTING	31.8	%	31.8	31.8	%	1
4	TOB17	PT	SNUS-77	3	PRTMASS	Portion Mass	DESIGN PARAMETER TESTING	998	mg	998	998	mg	1
5	TOB17	PT	SNUS-77	4	PRTMWGT	Pouch Material Basis Weight	DESIGN PARAMETER TESTING	15.3	g/m ²	15.3	15.3	g/m ²	1
6	TOB17	PT	SNUS-77	5	PRTMPOR	Pouch Material Porosity	DESIGN PARAMETER TESTING	1900	L/m ² /s	1900	1900	L/m ² /s	1
7	TOB17	PT	SNUS-77	6	NICTDSRT	Nicotine Dissolution Rate	DESIGN PARAMETER TESTING	18	%/min	18	18	%/min	1

3.1.3 Ingredients, Additives, and Constituents Module

This section illustrates how to create CDISC-conformant datasets on

- listing of tobacco and non-tobacco ingredients,
- quantifying tobacco and non-tobacco ingredients by component and stating their function within the product, and
- testing for HPHC.

According to the PMTA rule,

"Ingredient" means tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing.

"Additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco, or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

"Constituent" means any chemical or chemical compound in a tobacco product that is or potentially is inhaled, ingested, or absorbed into the body, any chemical or chemical compound in an emission (e.g., smoke, aerosol, droplets) from a tobacco product, that either transfers from any component or part of the tobacco product to the emission or that is formed by the product, including through combustion or heating of tobacco, additives, or other components of the tobacco product.

Reference:

Premarket tobacco product applications and recordkeeping requirements. *Fed Regist.* 2021;86 FR 55300:55300-55439. Codified at 21 CFR §1100.

<https://www.federalregister.gov/d/2021-21011/p-17>

3.1.3.1 Ingredients and Additives

This following example illustrates how the ingredients of a tobacco product would be represented and quantified using 3 datasets:

- Tobacco Ingredients (IT) is used for representing the tobacco ingredients and their attributes within the tobacco product under study.
- Non-tobacco Ingredients (IN) is used for representing other ingredients/additives and their attributes as used in the tobacco product under study.
- Ingredient Quantities by Component (IQ) is used for representing the quantity and function of each ingredient (both tobacco and non-tobacco) by component of the tobacco product in which they are included. These values represent the design/formulation specification of the product, not experimentally determined values (as the latter would be represented in the Product Testing (PT) dataset, not shown here).

All 3 datasets use the SPTOBID variable to identify the tobacco product under study, and the IGDCMPID (ingredient or component identifier) variable to represent the ingredient name. IGDCMPID must be assigned by applicants to be unique with regard to the attributes that describe it. For instance, if the same ingredient varies on 1 or more attribute (e.g., 2 different manufacturers supplied the same ingredient that is used in 2 different components of the product), IGDCMPID must be unique for each use to reflect this difference, even if they share the same common name, and/or the same IUPAC name and CAS registry number. See IT dataset example, which illustrates this, below.

Example 1

The IT example shows tobacco filler and the types of tobacco of which it is composed, each listed as tobacco ingredients in the variable IGDCMPID (ingredient or component identifier) for the tobacco product CIG01A (SPTOBID). The variable ITSPECIF shows the specification/variety of the first 3 tobaccos. ITIGDPLX (Ingredient Complexity) is used to indicate that the tobacco filler and the reconstituted tobacco are complex ingredients (i.e., have 2 or more subcomponents). The details of which single tobacco ingredients compose these complex ingredients is made explicit in the IQ dataset example. ITCURMTH indicates the cure method. ITCIGIND (applicant-customized ingredient indicator) is used to indicate whether complex ingredients were made to the applicant's specification. TPMF indicates the Tobacco Product Master File name/number, which should be provided in the data if the component manufacturer has made it available. Note that there are 2 varieties of burley tobacco in this tobacco product; each is given a unique IGDCMPID value (Burley Tobacco and Burley Tobacco 2).

it.xpt

Row	DOMAIN	STUDYID	SPTOBID	IGDCMPID	TPMF	ITSPECIF	ITIGDPLX	ITCURMTH	ITCIGIND
1	IT	TOB07	CIG01A	Tobacco Filler			COMPLEX INGREDIENT		
2	IT	TOB07	CIG01A	Burley Tobacco	MF5555555	NC 7LC	SINGLE INGREDIENT	Air	

Row	DOMAIN	STUDYID	SPTOBID	IGDCMPID	TPMF	ITSPECIF	ITIGDPLX	ITCURMTH	ITCIGIND
3	IT	TOB07	CIG01A	Bright Tobacco		CC 1063	SINGLE INGREDIENT	Flue	
4	IT	TOB07	CIG01A	Oriental Tobacco		USDA Nicotiana Collection PI 552747	SINGLE INGREDIENT	Sun	
5	IT	TOB07	CIG01A	Reconstituted Tobacco			COMPLEX INGREDIENT		N
6	IT	TOB07	CIG01A	Burley Tobacco 2		KT215LC	SINGLE INGREDIENT	Air	

The IN dataset example shows the list of non-tobacco ingredients used in the tobacco product identified as CIG01A. Each unique ingredient is listed in IGDCMPID. Where applicable, IUPAC name and CAS number are listed (IUPACNAM and CASNO variables, respectively). INIGDPLX is used to indicate whether an ingredient is a single ingredient or a complex ingredient. INCIGIND indicates whether complex ingredients were made to the applicant's specification. Grade, purity, manufacturer name, ingredient unique item number, and the Tobacco Product Master File number complete the dataset.

in.xpt

Row	DOMAIN	STUDYID	SPTOBID	IGDCMPID	INMANUF	INMANUIN	TPMF	IUPACNAM	CASNO	UNII	INIGDPLX	INCIGIND	INGRAGE	INPURTY
1	IN	TOB07	CIG01A	Cocoa Extract	Flavor House A	FLVR1234	MF5555555				COMPLEX INGREDIENT	N	FOOD	
2	IN	TOB07	CIG01A	Butyric Acid				butanoic acid	107-92-6		SINGLE INGREDIENT		USP	≥99%
3	IN	TOB07	CIG01A	Cellulose Filter A	MFR A	FIL789			-		COMPLEX INGREDIENT	N	USP	
4	IN	TOB07	CIG01A	Cellulose Acetate				cellulose acetate	9004-35-7		SINGLE INGREDIENT			99%
5	IN	TOB07	CIG01A	Triacetin				1,3-diacetylxypropan-2-yl acetate	102-76-1		SINGLE INGREDIENT		USP	
6	IN	TOB07	CIG01A	FSC Paper B	MFR B	FSC123	MF5678910				COMPLEX INGREDIENT	N		
7	IN	TOB07	CIG01A	Cellulose Pulp				cellulose pulp	65996-61-4		SINGLE INGREDIENT			≥99%
8	IN	TOB07	CIG01A	Calcium Carbonate				calcium carbonate	471-34-1		SINGLE INGREDIENT		USP	
9	IN	TOB07	CIG01A	Sodium Alginate				sodium;3,4,5,6-tetrahydroxyxane-2-carboxylate	9005-38-3		SINGLE INGREDIENT		FOOD	
10	IN	TOB07	CIG01A	Trisodium Citrate				trisodium;2-hydroxypropane-1,2,3-tricarboxylate	6132-04-3		SINGLE INGREDIENT			≥98%
11	IN	TOB07	CIG01A	Cationic Starch				starch, 2-hydroxy-3-(trimethylammonio)propyl ether, chloride	56780-58-6		SINGLE INGREDIENT		FOOD	
12	IN	TOB07	CIG01A	Seam Adhesive	MFR C	ADV123	MF2345678				COMPLEX INGREDIENT	N		
13	IN	TOB07	CIG01A	Methylcellulose					9004-67-5		SINGLE INGREDIENT		FOOD	
14	IN	TOB07	CIG01A	1,3-Butanediol				Butane-1,3-diol	34844-08-1		SINGLE INGREDIENT		USP	≥99%

Finally, the IQ domain is used to represent the quantity (target, minimum, and maximum) of each ingredient identified in IGDCMPID that the product (SPTOBID) is designed to contain, with the units for these values represented in IQUNIT. The function of each ingredient is described in IQFUNCT. Note: Ingredients that appear in more than 1 component of the tobacco product are quantified separately for each component. IQPARENT identifies a component or complex ingredient composed of the subcomponents/ingredients shown in IDGCMPIID. IQLEVEL is used to identify at what level in the overall hierarchy that subcomponent/ingredient appears.

The following implementation rules apply, as described in more detail in Section 2.8.8.6, [SDTM Ingredient Quantities by Component \(IQ\)](#), Assumptions:

- IQPARENT must correspond to a value of IGDCMPID in the same dataset. If parent is null, the ingredient is considered a top-level component and is assigned an IQLEVEL value of "1".

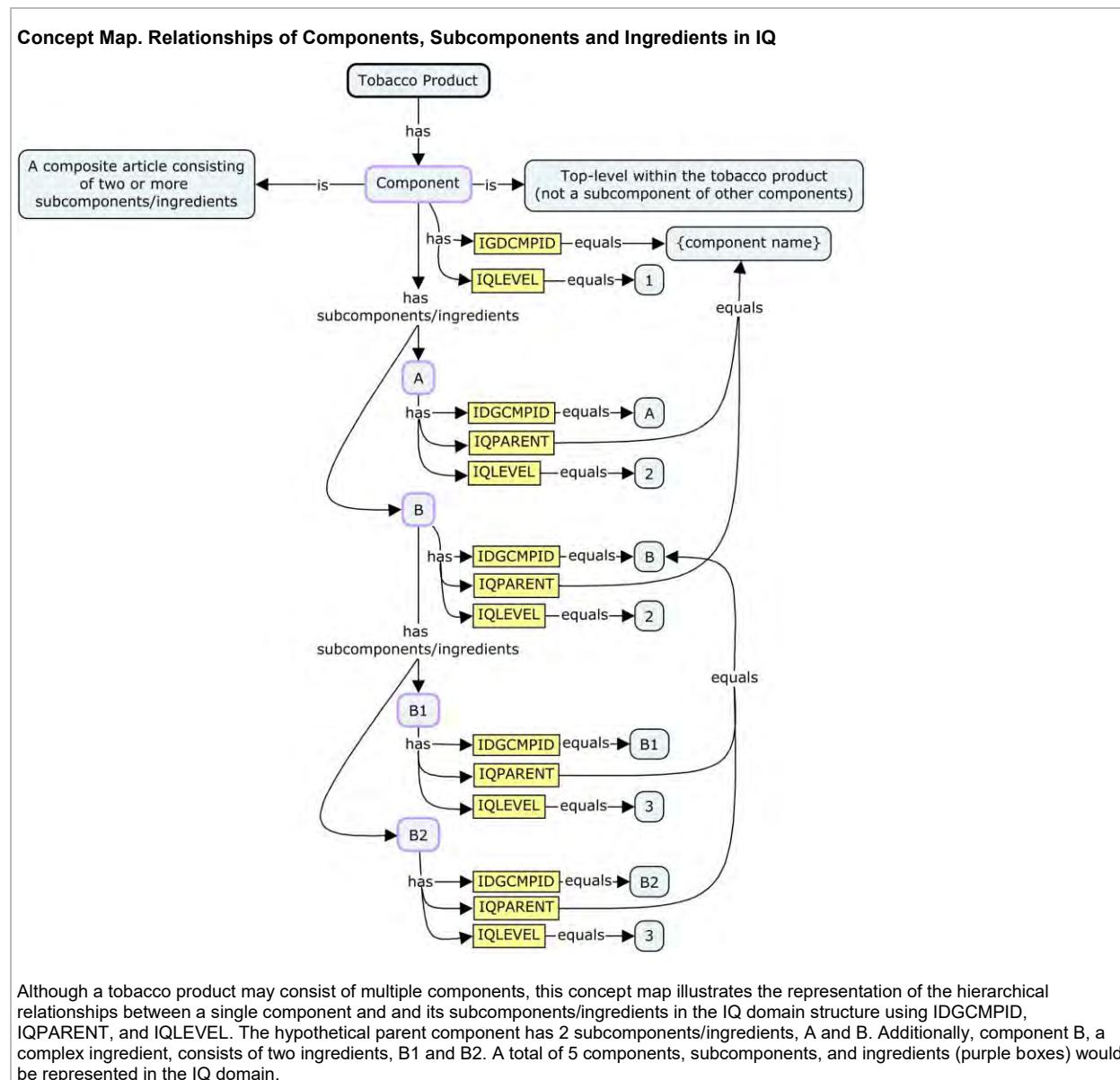
- Records describing subcomponents/ingredients that compose a parent component listed in the dataset will have IQPARENT value equal to the IGDCMPID of that parent component. IQLEVEL will be set to $n + 1$, where n = the parent record's value of IQLEVEL
- Every value of IGDCMPID used in the IQ dataset must have a matching value of IGDCMPID:
 - In the IT dataset (when IQCAT=TOBACCO INGREDIENT), or

In the IN dataset (when IQCAT=NON-TOBACCO INGREDIENT)

Therefore, IQCAT is required to relate ingredient quantity records in IQ to the associated ingredient attributes described in either IT or IN.

The use of IQPARENT and IQLEVEL help make explicit the relationship between complex ingredients or components and the subcomponents/ingredients of which they are composed, and can assist when totaling the quantities of an ingredient that appears in multiple components of a tobacco product.

This concept map illustrates the representation of the hierarchical relationships between a component and its subcomponents/ingredients in the IQ domain structure.



The IQ dataset example illustrates these principles, using a cigarette tobacco product:

- Rows 1, 13, 16:** Show 3 top-level components of a cigarette product: tobacco filler, filter, and cigarette paper, respectively. Their target, minimum, and maximum quantities expressed in units of mg/cigarette are shown in IQVALTRG, IQVALMIN, IQVALMAX and IQUNIT. Because there is no parent component other than the finished product itself, IQPARENT is null, and IQLEVEL=1, indicating that these are top-level ingredients/components of the finished product.
- Rows 2-5:** Show the quantities of 4 types of tobacco used in the product. IQPARENT=Tobacco Filler and IQLEVEL=2, together indicating that these are subcomponents/ingredients in the tobacco filler, a top level-component of the cigarette product.
- Rows 6-8:** Show the 3 tobacco ingredients that compose reconstituted tobacco in row 5 (IQPARENT=Reconstituted Tobacco). The quantities of these tobaccos pertain to the quantity at which they appear in the reconstituted tobacco ONLY. IQLEVEL=3 to show that these ingredients are at the third level of the hierarchy (subcomponents/ingredients in Reconstituted Tobacco, which has IQLEVEL=2). Therefore, the total quantity of the individual tobaccos used in this tobacco product is the sum of these 3 rows plus the sum of the quantities shown in rows 2-4.
- Rows 9-10:** Show the quantities of 2 non-tobacco ingredients, methylcellulose and 1,3-butanediol, which are further subcomponents/ingredients in Reconstituted Tobacco, as indicated by IQPARENT. IQFUNCT shows that methylcellulose functions as a binder and 1,3-butanediol functions as a humectant. IQLEVEL=3 to show that these ingredients are at the third level of the hierarchy.
- Rows 11-12:** Show the quantities of 2 subcomponents/ingredients that both function as a flavorant in the tobacco filler (as indicated by IQFUNCT= Flavor and IQPARENT=Tobacco Filler).
- Rows 14-15:** Show the quantities of 2 subcomponents/ingredients that function as filtration and plasticizer, respectively, in the filter portion of the cigarette (cellulose filter A, a top-level component shown in row 13).
- Rows 17-22:** Show the quantities and functions of 6 subcomponents/ingredients in the top-level component FSC paper B (the cigarette paper shown in row 16).

iq.xpt

Row	DOMAIN	STUDYID	SPTOBID	IGDCMPID	IQCAT	IQPARENT	IQLEVEL	IQFUNCT	IQVALTRG	IQVALMIN	IQVALMAX	IQUNIT
1	IQ	TOB07	CIG01A	Tobacco Filler	TOBACCO INGREDIENT		1		672.5	661.3	683.7	mg/cigarette
2	IQ	TOB07	CIG01A	Burley Tobacco	TOBACCO INGREDIENT	Tobacco Filler	2		19	17	21	mg/cigarette
3	IQ	TOB07	CIG01A	Bright Tobacco	TOBACCO INGREDIENT	Tobacco Filler	2		300	295	305	mg/cigarette
4	IQ	TOB07	CIG01A	Oriental Tobacco	TOBACCO INGREDIENT	Tobacco Filler	2		115	113	117	mg/cigarette
5	IQ	TOB07	CIG01A	Reconstituted Tobacco	TOBACCO INGREDIENT	Tobacco Filler	2		231	229	233	mg/cigarette
6	IQ	TOB07	CIG01A	Burley Tobacco 2	TOBACCO INGREDIENT	Reconstituted Tobacco	3		19	18	20	mg/cigarette
7	IQ	TOB07	CIG01A	Bright Tobacco	TOBACCO INGREDIENT	Reconstituted Tobacco	3		103	101	105	mg/cigarette
8	IQ	TOB07	CIG01A	Oriental Tobacco	TOBACCO INGREDIENT	Reconstituted Tobacco	3		65	63	67	mg/cigarette
9	IQ	TOB07	CIG01A	Methylcellulose	NON-TOBACCO INGREDIENT	Reconstituted Tobacco	3	Binder	20	19	21	mg/cigarette
10	IQ	TOB07	CIG01A	1,3-Butanediol	NON-TOBACCO INGREDIENT	Reconstituted Tobacco	3	Humectant	24	23	25	mg/cigarette
11	IQ	TOB07	CIG01A	Cocoa Extract	NON-TOBACCO INGREDIENT	Tobacco Filler	2	Flavor	7	6.75	7.25	mg/cigarette
12	IQ	TOB07	CIG01A	Butyric Acid	NON-TOBACCO INGREDIENT	Tobacco Filler	2	Flavor	0.5	0.55	0.45	mg/cigarette
13	IQ	TOB07	CIG01A	Cellulose Filter A	NON-TOBACCO INGREDIENT		1	Filter	164	163	165	mg/cigarette
14	IQ	TOB07	CIG01A	Cellulose Acetate	NON-TOBACCO INGREDIENT	Cellulose Filter A	2	Filtration	155	154	156	mg/cigarette
15	IQ	TOB07	CIG01A	Triacetin	NON-TOBACCO INGREDIENT	Cellulose Filter A	2	Plasticizer	9	8	10	mg/cigarette
16	IQ	TOB07	CIG01A	FSC Paper B	NON-TOBACCO INGREDIENT		1	Cigarette Paper (Wrapper)	50	49	51	mg/cigarette

Row	DOMAIN	STUDYID	SPTOBID	IGDCMPID	IQCAT	IQPARENT	IQLEVEL	IQFUNCT	IQVALTRG	IQVALMIN	IQVALMAX	IQUNIT
17	IQ	TOB07	CIG01A	Cellulose Pulp	NON-TOBACCO INGREDIENT	FSC Paper B	2	Fiber	30	29	31	mg/cigarette
18	IQ	TOB07	CIG01A	Calcium Carbonate	NON-TOBACCO INGREDIENT	FSC Paper B	2	Filler	15	14	16	mg/cigarette
19	IQ	TOB07	CIG01A	Sodium Alginate	NON-TOBACCO INGREDIENT	FSC Paper B	2	Reduced ignition propensity	2	1.75	2.25	mg/cigarette
20	IQ	TOB07	CIG01A	Trisodium Citrate	NON-TOBACCO INGREDIENT	FSC Paper B	2	Combustion Modifier	0.5	0.45	0.55	mg/cigarette
21	IQ	TOB07	CIG01A	Cationic Starch	NON-TOBACCO INGREDIENT	FSC Paper B	2	Binder	0.5	0.45	0.55	mg/cigarette
22	IQ	TOB07	CIG01A	Seam Adhesive	NON-TOBACCO INGREDIENT	FSC Paper B	2	Adhesive	2	1.75	2.25	mg/cigarette

3.1.3.2 HPHCs, Other Constituents, and Smoking/Vaping Regimens

Harmful and potentially harmful constituents (HPHC) are a subset of tobacco product constituents which may cause direct and indirect harm to product users. These compounds may be found in the tobacco product, tobacco smoke, or aerosol.

Example 1

Tobacco product HPHC testing results are represented in the PT domain. This example illustrates HPHC testing and smoking regimens for a cigarette product. The example assumes testing at a single time point, not serial testing over multiple timepoints as in stability studies. See Section 3.1.4, Stability Studies, for more information and examples illustrating how to represent those data.

This example only shows test results for each constituent for 1 replicate of 1 sample of 1 product that was tested (PTREPNUM = 1 for all records). Details of the sampling and testing plan, including the number of samples of the products tested, are determined by the applicant or by regulatory requirement. Applicants would likely have multiple product samples tested in multiple replicates, and those would be distinguished in the dataset by values of PTREPNUM being set to 1 through n, where n = the number of replicates being performed.

Note the use of the PTXFN (external file name) to indicate that the lab methodology was submitted as separate documentation.

- Rows 1-17:** Show HPHC testing performed in smoke produced by a smoking machine from the tobacco product identified in SPTOBID (CIG01a). Note of the use of SPDEVID as the device identifier for the smoking machine and the use of PTREFID to identify the smoking regimen (non-intense regimen). PTSPEC=SMOKE to indicate the specimen type is smoke.
- Row 18:** Shows 1 analyte was tested with a different smoking regimen (PTREFID=INTENSE REGIMEN) using the same smoking machine.
- Row 19:** Shows 1 analyte was tested in the tobacco filler (PTSPEC). Thus SPDEVID and PTREFID are null.

pt.xpt

Row	STUDYID	DOMAIN	SPTOBID	SPDEVID	PTSEQ	PTREFID	PTTESTCD	PTTEST	PTCAT	PTSCAT	PTORRES	PTORRESU	PTSTRESC	PTSTRESN	PTSTRESU	PTXFN	PTNAM	PTSPEC	PTRENUM	PTDTC
1	TOB07	PT	CIG01a	PUFFMASTER3K	1	NON-INTENSE REGIMEN	ACTALD	Acetaldehyde	HPHC TESTING	HPHC	522	ug/cigarette	522	522	ug/cigarette	TL001_V5.pdf	TPT LABCO	SMOKE	1	2022-09-30
2	TOB07	PT	CIG01a	PUFFMASTER3K	2	NON-INTENSE REGIMEN	ACROLEIN	Acrolein	HPHC TESTING	HPHC	43	ug/cigarette	43	43	ug/cigarette	TL002_V3.6.pdf	TPT LABCO	SMOKE	1	2022-09-30
3	TOB07	PT	CIG01a	PUFFMASTER3K	3	NON-INTENSE REGIMEN	ACRYNTRL	Acrylonitrile	HPHC TESTING	HPHC	7	ug/cigarette	7	7	ug/cigarette	TL006_V6.pdf	TPT LABCO	SMOKE	1	2022-09-30
4	TOB07	PT	CIG01a	PUFFMASTER3K	4	NON-INTENSE REGIMEN	ABP4	4-Aminobiphenyl	HPHC TESTING	HPHC	1.2	ng/cigarette	1.2	1.2	ng/cigarette	TL008_V3.pdf	TPT LABCO	SMOKE	1	2022-09-30
5	TOB07	PT	CIG01a	PUFFMASTER3K	5	NON-INTENSE REGIMEN	AMNPHTH1	1-Aminonaphthalene	HPHC TESTING	HPHC	14	ng/cigarette	14	14	ng/cigarette	TL003_V1.4.pdf	TPT LABCO	SMOKE	1	2022-09-30
6	TOB07	PT	CIG01a	PUFFMASTER3K	6	NON-INTENSE REGIMEN	AMNPHTH2	2-Aminonaphthalene	HPHC TESTING	HPHC	8	ng/cigarette	8	8	ng/cigarette	TL003_V1.4.pdf	TPT LABCO	SMOKE	1	2022-09-30
7	TOB07	PT	CIG01a	PUFFMASTER3K	7	NON-INTENSE REGIMEN	AMMONIA	Ammonia	HPHC TESTING	HPHC	9	ug/cigarette	9	9	ug/cigarette	TL020_V4.pdf	TPT LABCO	SMOKE	1	2022-09-30
8	TOB07	PT	CIG01a	PUFFMASTER3K	8	NON-INTENSE REGIMEN	BENZENE	Benzene	HPHC TESTING	HPHC	33	ug/cigarette	33	33	ug/cigarette	TL017_V1.1.pdf	TPT LABCO	SMOKE	1	2022-09-30
9	TOB07	PT	CIG01a	PUFFMASTER3K	9	NON-INTENSE REGIMEN	BZAPYR	Benzo[a]pyrene	HPHC TESTING	HPHC	6.8	ng/cigarette	6.8	6.8	ng/cigarette	TL017_V1.1.pdf	TPT LABCO	SMOKE	1	2022-09-30
10	TOB07	PT	CIG01a	PUFFMASTER3K	10	NON-INTENSE REGIMEN	CMONOX	Carbon Monoxide	HPHC TESTING	HPHC	10.1	mg/cigarette	10.1	10.1	mg/cigarette	TL019_V3.pdf	TPT LABCO	SMOKE	1	2022-09-30
11	TOB07	PT	CIG01a	PUFFMASTER3K	11	NON-INTENSE REGIMEN	CROTNALD	Crotonaldehyde	HPHC TESTING	HPHC	11	ug/cigarette	11	11	ug/cigarette	TL001_V5.pdf	TPT LABCO	SMOKE	1	2022-09-30
12	TOB07	PT	CIG01a	PUFFMASTER3K	12	NON-INTENSE REGIMEN	FORMALD	Formaldehyde	HPHC TESTING	HPHC	27	ug/cigarette	27	27	ug/cigarette	TL001_V5.pdf	TPT LABCO	SMOKE	1	2022-09-30
13	TOB07	PT	CIG01a	PUFFMASTER3K	13	NON-INTENSE REGIMEN	ISOPRENE	Isoprene	HPHC TESTING	HPHC	320	ug/cigarette	320	320	ug/cigarette	TL041_V1.pdf	TPT LABCO	SMOKE	1	2022-09-30
14	TOB07	PT	CIG01a	PUFFMASTER3K	14	NON-INTENSE REGIMEN	NICOTINE	Nicotine	HPHC TESTING	HPHC	0.721	mg/cigarette	0.721	0.721	mg/cigarette	TL007_V2.1.pdf	TPT LABCO	SMOKE	1	2022-09-30
15	TOB07	PT	CIG01a	PUFFMASTER3K	15	NON-INTENSE REGIMEN	NNK	Nicotine-Derived Nitrosamine Ketone	HPHC TESTING	HPHC	71	ng/cigarette	71	71	ng/cigarette	TL026_V12.2.pdf	TPT LABCO	SMOKE	1	2022-09-30
16	TOB07	PT	CIG01a	PUFFMASTER3K	16	NON-INTENSE REGIMEN	NNN	N-Nitrosonomonicotine	HPHC TESTING	HPHC	85	ng/cigarette	85	85	ng/cigarette	TL026_V12.2.pdf	TPT LABCO	SMOKE	1	2022-09-30
17	TOB07	PT	CIG01a	PUFFMASTER3K	17	NON-INTENSE REGIMEN	TOLUENE	Toluene	HPHC TESTING	HPHC	53	ug/cigarette	53	53	ug/cigarette	TL011_V3.3.pdf	TPT LABCO	SMOKE	1	2022-09-30
18	TOB07	PT	CIG01a	PUFFMASTER3K	18	INTENSE REGIMEN	ACTALD	Acetaldehyde	HPHC TESTING	HPHC	1552	ug/cigarette	1552	1552	ug/cigarette	TL009_V4.3.pdf	TPT LABCO	SMOKE	1	2022-09-30
19	TOB07	PT	CIG01a		19		AMMONIA	Ammonia	HPHC TESTING	HPHC	956	ug/g	956	956	ug/cigarette	TL016_V1.2.pdf	TPT LABCO	TOBACCO FILLER	1	2022-09-30

The identifying characteristics of the smoking machine are represented in the Device Identifiers reference dataset. DI is the source of the applicant-defined device ID variable (SPDEVID) used in the PT dataset to indicate the smoking machine used to perform the smoking regimen.

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	TOB07	DI	PUFFMASTER3K	1	DEVTYPE	Device Type	Smoking Machine
2	TOB07	DI	PUFFMASTER3K	2	MANUF	Manufacturer	Acme
3	TOB07	DI	PUFFMASTER3K	3	TRADEFAM	Trade Name	PuffMaster 3000

Details of the smoking regimen performed by the smoking machine are represented as device in-use properties (such as settings) of the smoking machine. They are linked to the HPHC testing results in PT by matching values of PTREFID/DUREFID.

Rows 1-9: Show the parameters of the non-intense smoking regimen.

Rows 8-9: Note the use of DUGRPID to group these records together to indicate that puff pause and puff pause interval are related records. Taken together, they indicate that this smoking regimen pauses for 60 seconds every 10 puffs.

Rows 10-18: Show the parameters of the intense smoking regimen.

Rows 17-18: Note the use of DUGRID to group these records together to indicate that puff pause and puff pause interval are related records. Taken together, they indicate that this smoking regimen pauses for 30 seconds every 10 puffs.

du.xpt

Row	STUDYID	DOMAIN	SPDEVID	DUSEQ	DUREFID	DUGRID	DUTESTCD	DUTEST	DUORRES	DUORRESU	DUSTRESC	DUSTRESN	DUSTRESU
1	TOB07	DU	PUFFMASTER3K	1	NON-INTENSE REGIMEN		PUFFPROF	Puff Profile	SQUARE		SQUARE		
2	TOB07	DU	PUFFMASTER3K	2	NON-INTENSE REGIMEN		PUFFDUR	Puff Duration	1.25	sec	1.25	1.25	sec
3	TOB07	DU	PUFFMASTER3K	3	NON-INTENSE REGIMEN		PUFFINT	Puff Interval	3	PUFF/min	3	3	PUFF/min
4	TOB07	DU	PUFFMASTER3K	4	NON-INTENSE REGIMEN		PUFFBLCK	Puff Block	25	%	25	25	%
5	TOB07	DU	PUFFMASTER3K	5	NON-INTENSE REGIMEN		PUFFNUM	Number of Puffs	200	PUFF	200	200	PUFF
6	TOB07	DU	PUFFMASTER3K	6	NON-INTENSE REGIMEN		PUFFVOL	Puff Volume	10	mL	10	10	mL
7	TOB07	DU	PUFFMASTER3K	7	NON-INTENSE REGIMEN		PUFFRNG	Puff Range	100-200		100-200		
8	TOB07	DU	PUFFMASTER3K	8	NON-INTENSE REGIMEN	1	PUFFPAUS	Puff Pause	60	s	60	60	s
9	TOB07	DU	PUFFMASTER3K	9	NON-INTENSE REGIMEN	1	PUFFPINT	Puff Pause Interval	10	PUFF	10	10	PUFF
10	TOB07	DU	PUFFMASTER3K	1	INTENSE REGIMEN		PUFFPROF	Puff Profile	SQUARE		SQUARE		
11	TOB07	DU	PUFFMASTER3K	2	INTENSE REGIMEN		PUFFDUR	Puff Duration	2.25	sec	2.25	2.25	sec
12	TOB07	DU	PUFFMASTER3K	3	INTENSE REGIMEN		PUFFINT	Puff Interval	3	PUFF/min	3	3	PUFF/min
13	TOB07	DU	PUFFMASTER3K	4	INTENSE REGIMEN		PUFFBLCK	Puff Block	30	%	30	30	%
14	TOB07	DU	PUFFMASTER3K	5	INTENSE REGIMEN		PUFFNUM	Number of Puffs	100	PUFF	100	100	PUFF
15	TOB07	DU	PUFFMASTER3K	6	INTENSE REGIMEN		PUFFVOL	Puff Volume	20	mL	20	20	mL
16	TOB07	DU	PUFFMASTER3K	7	INTENSE REGIMEN		PUFFRNG	Puff Range	50-150		50-150		
17	TOB07	DU	PUFFMASTER3K	8	INTENSE REGIMEN	2	PUFFPAUS	Puff Pause	30	s	30	30	s
18	TOB07	DU	PUFFMASTER3K	9	INTENSE REGIMEN	2	PUFFPINT	Puff Pause Interval	10	PUFF	10	10	PUFF

This example illustrates HPHC testing and vaping regimens for an ENDS product.

Example 2

Tobacco product HPHC testing results are represented in the PT domain. This example shows HPHC testing with an ENDS device. HPHC testing is conducted on samples of the product of interest, and (if applicable) samples of comparison products. Each product tested would have its own unique applicant-defined value for SPTOBID to identify the product.

Row 1: Shows the HPHC testing performed for acetaldehyde from a sample of e-Liquid (as indicated by PTSPEC=E-LIQUID).

Rows 2-4: Show the HPHC testing performed for 3 analytes from aerosol produced using the non-intense regimen on a smoking machine. PTSPEC=AEROSOL, SPDEVID indicates the smoking machine used to produce the aerosol, and PTREFID indicates the vaping regimen.

Rows 5-7: Show the HPHC testing performed for 3 analytes using the intense regimen on the same smoking machine (PTREFID=INTENSE REGIMEN).

pt.xpt

Row	STUDYID	DOMAIN	SPTOBID	SPDEVID	PTSEQ	PTREFID	PTTESTCD	PTTEST	PTCAT	PTSCAT	PTORRES	PTORRESU	PTSTRESC	PTSTRESN	PTSTRESU	PTSPEC	PTREPNUM	PTDTC
1	TOB08	PT	ENDS02a		1		ACTALD	Acetaldehyde	HPHC TESTING	HPHC	7.9	µg/mL	7.9	7.9	µg/mL	E-LIQUID	1	2022-09-30
2	TOB08	PT	ENDS02a	PUFFMASTER3K	2	NON-INTENSE REGIMEN	NICOTINE	Nicotine	HPHC TESTING	HPHC	53.5	µg/puff	53.5	53.5	µg/puff	AEROSOL	1	2022-09-30
3	TOB08	PT	ENDS02a	PUFFMASTER3K	3	NON-INTENSE REGIMEN	ACTALD	Acetaldehyde	HPHC TESTING	HPHC	34.7	ng/puff	34.7	34.7	ng/puff	AEROSOL	1	2022-09-30
4	TOB08	PT	ENDS02a	PUFFMASTER3K	4	NON-INTENSE REGIMEN	BNZOICAC	Benzoic Acid	HPHC TESTING	Other	43.3	µg/puff	43.3	43.3	µg/puff	AEROSOL	1	2022-09-30
5	TOB08	PT	ENDS02a	PUFFMASTER3K	5	INTENSE REGIMEN	NICOTINE	Nicotine	HPHC TESTING	HPHC	105	µg/puff	105	105	µg/puff	AEROSOL	2	2022-09-30
6	TOB08	PT	ENDS02a	PUFFMASTER3K	6	INTENSE REGIMEN	ACTALD	Acetaldehyde	HPHC TESTING	HPHC	43.5	ng/puff	43.5	43.5	ng/puff	AEROSOL	2	2022-09-30
7	TOB08	PT	ENDS02a	PUFFMASTER3K	7	INTENSE REGIMEN	BNZOICAC	Benzoic Acid	HPHC TESTING	Other	84.1	µg/puff	84.1	84.1	µg/puff	AEROSOL	2	2022-09-30

The identifying characteristics of the smoking machine are represented in the DI reference dataset.

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	TOB07	DI	PUFFMASTER3K	1	DEVTYPE	Device Type	Smoking Machine
2	TOB07	DI	PUFFMASTER3K	2	MANUF	Manufacturer	Acme
3	TOB07	DI	PUFFMASTER3K	3	TRADENAM	Trade Name	PuffMaster 3000

Details of the vaping regimen performed by the smoking machine are represented as device in-use properties, linked to the HPHC testing results in PT by matching values of PTREFID/DUREFID.

Rows 1-9: Show the parameters of the non-intense vaping regimen.

Rows 8-9: Note the use of DUGRID to group these records together to indicate that puff pause and puff pause interval are related records. Taken together, they indicate that this vaping regimen pauses for 60 seconds every 10 puffs.

Rows 10-18: Show the parameters of the intense vaping regimen.

Rows 17-18: Note the use of DUGRID to group these records together to indicate that puff pause and puff pause interval are related records. Taken together, they indicate that this vaping regimen pauses for 30 seconds every 10 puffs.

du.xpt

Row	STUDYID	DOMAIN	SPDEVID	DUSEQ	DUREFID	DUGRID	DUTESTCD	DUTEST	DUORRES	DUORRESU	DUSTRESC	DUSTRESN	DUSTRESU
1	TOB07	DU	PUFFMASTER3K	1	NON-INTENSE REGIMEN		PUFFPROF	Puff Profile	SQUARE		SQUARE		
2	TOB07	DU	PUFFMASTER3K	2	NON-INTENSE REGIMEN		PUFFDUR	Puff Duration	1.25	sec	1.25	1.25	sec
3	TOB07	DU	PUFFMASTER3K	3	NON-INTENSE REGIMEN		PUFFINT	Puff Interval	7	PUFF/min	7	7	PUFF/min
4	TOB07	DU	PUFFMASTER3K	4	NON-INTENSE REGIMEN		PUFFBLCK	Puff Block	25	%	25	25	%
5	TOB07	DU	PUFFMASTER3K	5	NON-INTENSE REGIMEN		PUFFNUM	Number of Puffs	200	PUFF	200	200	PUFF
6	TOB07	DU	PUFFMASTER3K	6	NON-INTENSE REGIMEN		PUFFVOL	Puff Volume	10	mL	10	10	mL
7	TOB07	DU	PUFFMASTER3K	7	NON-INTENSE REGIMEN		PUFFRNG	Puff Range	100-200		100-200		
8	TOB07	DU	PUFFMASTER3K	8	NON-INTENSE REGIMEN	1	PUFFPAUS	Puff Pause	60	s	60	60	s
9	TOB07	DU	PUFFMASTER3K	9	NON-INTENSE REGIMEN	1	PUFFPINT	Puff Pause Interval	10	PUFF	10	10	PUFF
10	TOB07	DU	PUFFMASTER3K	1	INTENSE REGIMEN		PUFFPROF	Puff Profile	SQUARE		SQUARE		
11	TOB07	DU	PUFFMASTER3K	2	INTENSE REGIMEN		PUFFDUR	Puff Duration	3.25	sec	3.25	3.25	sec
12	TOB07	DU	PUFFMASTER3K	3	INTENSE REGIMEN		PUFFINT	Puff Interval	10	PUFF/min	10	10	PUFF/min
13	TOB07	DU	PUFFMASTER3K	4	INTENSE REGIMEN		PUFFBLCK	Puff Block	25	%	25	25	%
14	TOB07	DU	PUFFMASTER3K	5	INTENSE REGIMEN		PUFFNUM	Number of Puffs	300	PUFF	300	300	PUFF
15	TOB07	DU	PUFFMASTER3K	6	INTENSE REGIMEN		PUFFVOL	Puff Volume	25	mL	25	25	mL
16	TOB07	DU	PUFFMASTER3K	7	INTENSE REGIMEN		PUFFRNG	Puff Range	100-400		100-400		
17	TOB07	DU	PUFFMASTER3K	8	INTENSE REGIMEN	2	PUFFPAUS	Puff Pause	10	s	10	10	s
18	TOB07	DU	PUFFMASTER3K	9	INTENSE REGIMEN	2	PUFFPINT	Puff Pause Interval	30	PUFF	30	30	PUFF

Reference:

US Food and Drug Administration. *Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List*. April 2012. Accessed October 16, 2023. <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/>

3.1.4 Stability Studies (Including Analysis Dataset)

Tobacco product stability studies are conducted to assess changes in the properties, characteristics, and constituents of a product over the course of the shelf life after manufacture. Any changes of a product over time may affect the health risks of product use.

Measures of stability may include microbial stability, chemical stability, product component stability (e.g., battery), and container closure stability (e.g., leachability).

Stability studies of tobacco products typically require testing for constituents and parameters in multiple replicates over multiple timepoints throughout a study, and possibly under multiple different sets of storage conditions. Such studies result in datasets that can be quite large. In order to demonstrate the concepts in more concise datasets, the SDTM examples here illustrate stability studies in 2 parts: (1) a dataset that shows results from testing of multiple constituents at 1 replicate, 1 timepoint, under 1 set of environmental storage conditions; and (2) a dataset that shows what the results would look like for testing of 1 constituent at 3 replicates, 3 timepoints, and 2 different sets of storage conditions. The examples demonstrate these concepts for an ENDS tobacco product (Example 1) and a smokeless tobacco product (Example 2). Additionally, an analysis dataset example is provided for the smokeless tobacco product to illustrate the representation of some common statistics using the CDISC ADaM standard.

Example 1

The following example illustrates stability study results for an ENDS tobacco product. Stability study results are represented in the Tobacco Product Testing (PT) domain, with PTCAT = STABILITY TESTING.

The first pt.xpt dataset shows 22 constituents and parameters each as a single replicate (PTREPNUM=1), at 1 time point (PTTPT=Week 0 / PTTPTNUM=1) and from 1 set of storage conditions (STOCONID= Condition 1) in order to illustrate the variables and terminology required to construct an SDTM-conformant PT dataset for a stability study. Some constituent names (values of PTTESTCD/PTTEST) appear twice because they are tested separately in both e-liquid and aerosol (as indicated by PTSPEC). Note that the constituent names shown do not represent an exhaustive list of the controlled terminology that will be developed to support representation of stability studies in SDTM.

- The use of SPDEVID and PTREFID in this example on records where PTSPEC=AEROSOL indicates that a smoking machine (shown in SPDEVID) was used to perform the vaping regimen (shown in PTREFID) to produce the aerosol from the e-liquid product on records where PTSPEC=AEROSOL. Details of the smoking machine and vaping regimen are not shown in this example. For examples illustrating how to represent these concepts in SDTM, see Section 3.1.3.2, [PHHCs, Other Constituents, and Smoking / Vaping Regimens](#).
- PTXFN (External File Path) is used to document the location or file name within the submission that contains the lab methodology protocol used to assay the associated constituent when such methodology is too complex for the single PTMETHOD variable.
- STOCONID is used to identify the storage conditions of the e-liquid product for the testing performed. Details of these conditions are represented in the Environmental Storage Conditions (ES) dataset example that follows the 2 PT dataset examples.
- In this example, the applicant chose to subcategorize some constituents and parameters using the permissible variable PTSCAT (Sub-Category of Test).

Rows 1, 3, 5, 7, 9, 10, 15, 17-19, 22, 24, 25, 27-31: Show the results of testing for constituents in samples of e-liquid product (PTSPEC=E-LIQUID).

Rows 2, 4, 6, 8, 11-14, 16, 20, 21, 23, 26: Show the results of testing for constituents/parameters in aerosol produced from the e-liquid product. The smoking machine is shown in SPDEVID and the regimen is shown in PTREFID.

pt.xpt

Row	STUDYID	DOMAIN	SPTOBID	SPDEVID	STOCONDID	PTSEQ	PTREFID	PTTESTCD	PTTEST	PTCAT	PTSCAT	PTTRES	PTTRESU
1	TOB07	PT	111		Condition 1	1		NICOTINE	Nicotine	STABILITY TESTING		35.94	mg/g
2	TOB07	PT	111	PUFFMASTER3K	Condition 1	2	NON-INTENSE REGIMEN	NICOTINE	Nicotine	STABILITY TESTING		0.1039	mg/PUFF
3	TOB07	PT	111		Condition 1	3		NORNCTN	Nornicotine	STABILITY TESTING	Nicotine Degradant	25.76	ug/g
4	TOB07	PT	111	PUFFMASTER3K	Condition 1	4	NON-INTENSE REGIMEN	NORNCTN	Nornicotine	STABILITY TESTING	Nicotine Degradant	0.0392	ug/PUFF
5	TOB07	PT	111		Condition 1	5		GLYCRL	Glycerol	STABILITY TESTING	Primary Ingredient	615.68	mg/g
6	TOB07	PT	111	PUFFMASTER3K	Condition 1	6	NON-INTENSE REGIMEN	GLYCRL	Glycerol	STABILITY TESTING	Primary Ingredient	1.81	mg/PUFF
7	TOB07	PT	111		Condition 1	7		PRPYLGLY	Propylene Glycol	STABILITY TESTING	Primary Ingredient	218.21	mg/g
8	TOB07	PT	111	PUFFMASTER3K	Condition 1	8	NON-INTENSE REGIMEN	PRPYLGLY	Propylene Glycol	STABILITY TESTING	Primary Ingredient	0.8565	mg/PUFF
9	TOB07	PT	111		Condition 1	9		BNZOICAC	Benzoic Acid	STABILITY TESTING	Acid	42.2	ug/PUFF
10	TOB07	PT	111		Condition 1	10		MENTHOL	Menthol	STABILITY TESTING	Flavorant	37.53	mg/g
11	TOB07	PT	111	PUFFMASTER3K	Condition 1	11	NON-INTENSE REGIMEN	MENTHOL	Menthol	STABILITY TESTING	Flavorant	0.5881	mg/PUFF
12	TOB07	PT	111	PUFFMASTER3K	Condition 1	12	NON-INTENSE REGIMEN	GLYCDOL	Glycidol	STABILITY TESTING	Stabilizer	NOT DETECTED	
13	TOB07	PT	111	PUFFMASTER3K	Condition 1	13	NON-INTENSE REGIMEN	FRMLDHD	Formaldehyde	STABILITY TESTING		0.0728	ug/PUFF
14	TOB07	PT	111	PUFFMASTER3K	Condition 1	14	NON-INTENSE REGIMEN	ACROLN	Acrolien	STABILITY TESTING		DETECTED, BELOW LLOQ	
15	TOB07	PT	111		Condition 1	15		LACTICAC	Lactic Acid	STABILITY TESTING		40.44	ug/g
16	TOB07	PT	111	PUFFMASTER3K	Condition 1	16	NON-INTENSE REGIMEN	LACTICAC	Lactic Acid	STABILITY TESTING		29.71	ug/PUFF
17	TOB07	PT	111		Condition 1	17		VANLLN	Vanillin	STABILITY TESTING	Flavorant	1.12	ug/g
18	TOB07	PT	111		Condition 1	18		NNK	Nicotine-Derived Nitrosamine Ketone	STABILITY TESTING	HPHC	0.0711	ug/g
19	TOB07	PT	111		Condition 1	19		NNN	N-Nitrosonornicotine	STABILITY TESTING	HPHC	0.0852	ug/g
20	TOB07	PT	111	PUFFMASTER3K	Condition 1	20	NON-INTENSE REGIMEN	NNK	Nicotine-Derived Nitrosamine Ketone	STABILITY TESTING	HPHC	0.0577	ug/PUFF
21	TOB07	PT	111	PUFFMASTER3K	Condition 1	21	NON-INTENSE REGIMEN	NNN	N-Nitrosonornicotine	STABILITY TESTING	HPHC	0.0742	ug/PUFF
22	TOB07	PT	111		Condition 1	22		NICKEL	Nickel	STABILITY TESTING	Extractables / Leachables	0.0897	ug/g
23	TOB07	PT	111	PUFFMASTER3K	Condition 1	23	NON-INTENSE REGIMEN	MASS	Mass	STABILITY TESTING		3.87	mg/PUFF
24	TOB07	PT	111		Condition 1	24		CHROMIUM	Chromium	STABILITY TESTING		NOT DETECTED	
25	TOB07	PT	111		Condition 1	25		PH	pH	STABILITY TESTING		7.15	

Row	STUDYID	DOMAIN	SPTOBID	SPDEVID	STOCONDID	PTSEQ	PTREFID	PTTESTCD	PTTEST	PTCAT	PTSCAT	PTORRES	PTORRESU
26	TOB07	PT	111	PUFFMASTER3K	Condition 1	26	NON-INTENSE REGIMEN	PH	pH	STABILITY TESTING		7.24	
27	TOB07	PT	111		Condition 1	27		ENDTXN	Endotoxin	STABILITY TESTING	Toxins	NOT DETECTED	
28	TOB07	PT	111		Condition 1	28		AEBCT	Aerobic Colony Count	STABILITY TESTING	Microbiological	<1	CFU/mL
29	TOB07	PT	111		Condition 1	29		YSTMLDCT	Yeast and/or Mold Colony Count	STABILITY TESTING	Microbiological	1	CFU/mL
30	TOB07	PT	111		Condition 1	30		ACTALD	Acetaldehyde	STABILITY TESTING	Aldehyde	7.8	ug/mL
31	TOB07	PT	111		Condition 1	31		ACTPROPBN	Acetyl Propionyl	STABILITY TESTING	Diketone	32.4	ug/mL
Row	PTLLOD	PTSTRESC	PTSTRESN	PTSTRESU	PTNAM	PTXFN	PTSPEC	PTLLOQ	PTREPNUM	PTDTC	PTTPT	PTTPTNUM	
1		35.94	35.94	mg/g	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
2		0.1039	0.1039	mg/PUFF	TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
3		25.76	25.76	ug/g	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
4		0.0392	0.0392	ug/PUFF	TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
5		615.68	615.68	mg/g	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
6	0.00144	1.81	1.81	mg/PUFF	TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
7		218.21	218.21	mg/g	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
8	0.00024	0.8565	0.8565	mg/PUFF	TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
9		42.2	42.2	ug/PUFF	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
10		37.53	37.53	mg/g	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
11	0.00024	0.5881	0.5881	mg/PUFF	TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
12	0.00011	NOT DETECTED			TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
13	0.00549	0.0728	0.0728	ug/PUFF	TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
14	0.00928	DETected, BELOW LLOQ			TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
15		40.44	40.44	ug/g	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
16	0.284	29.71	29.71	ug/PUFF	TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
17		1.12	1.12	ug/g	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
18		0.0711	0.0711	ug/g	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
19		0.0852	0.0852	ug/g	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
20		0.0577	0.0577	ug/PUFF	TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
21		0.0742	0.0742	ug/PUFF	TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
22		0.0897	0.0897	ug/g	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
23	0.0071	3.87	3.87	mg/PUFF	TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
24		NOT DETECTED			TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
25		7.15	7.15		TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
26		7.24	7.24		TPT LABCO	TLAE01 v2.1.pdf	AEROSOL	0.001	1	02-01-2023	Week 0	1	
27		NOT DETECTED			TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
28		<1		CFU/mL	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
29		1	1	CFU/mL	TPT LABCO	TLAE01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
30		7.8	7.8	ug/mL	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	
31		32.4	32.4	ug/mL	TPT LABCO	TLEL01 v1.5.pdf	E-LIQUID	0.001	1	02-01-2023	Week 0	1	

The second PT dataset shows testing for just 1 constituent (nicotine), performed in 3 replicates (note the values of PTREPNUM), at the first 3 time points of the study (as shown in PTTPT/PTTPTNUM), from 3 sets of storage conditions (STOCONDID), in samples of e-liquid and aerosol (PTSPEC) in order to illustrate how those variables are used to represent their associated concepts in a stability study.

- As in the first PT dataset, the details of the smoking machine and vaping regimen are not shown in this example. For examples illustrating how to represent these concepts in SDTM, see Section 3.1.3.2, [HPHCs, Other Constituents, and Smoking/Vaping Regimens](#).
- Details of the 3 conditions are represented in the ES dataset example that follows.

pt.xpt

Row	STUDYID	DOMAIN	SPTOBID	SPDEVID	STOCONID	PTSEQ	PTREFID	PTTESTCD	PTTEST	PTORRES	PTSTRESU	PTSTRESC	PTSTRESN	PTSTRESU	PTNAME	PTXFN	PTSPEC	PTREPNUM	PTDTC	PTTPT	PTTPNUM	
1	TOB07	PT	111			Condition 1	211		NICOTINE	Nicotine	35.94	mg/g	35.94	35.94	mg/g	TPT LABCO	TLEL01_v1.5.pdf	E-LIQUID	1	02-01-2023	Week 0	1
2	TOB07	PT	111			Condition 1	212		NICOTINE	Nicotine	35.46	mg/g	35.46	35.46	mg/g	TPT LABCO	TLEL01_v1.5.pdf	E-LIQUID	2	02-01-2023	Week 0	1
3	TOB07	PT	111			Condition 1	213		NICOTINE	Nicotine	35.97	mg/g	35.97	35.97	mg/g	TPT LABCO	TLEL01_v1.5.pdf	E-LIQUID	3	02-01-2023	Week 0	1
4	TOB07	PT	111			Condition 1	214		NICOTINE	Nicotine	35.55	mg/g	35.55	35.55	mg/g	TPT LABCO	TLEL01_v1.5.pdf	E-LIQUID	1	03-29-2023	Week 8	2
5	TOB07	PT	111			Condition 1	215		NICOTINE	Nicotine	35.88	mg/g	35.88	35.88	mg/g	TPT LABCO	TLEL01_v1.5.pdf	E-LIQUID	2	03-29-2023	Week 8	2
6	TOB07	PT	111			Condition 1	216		NICOTINE	Nicotine	35.67	mg/g	35.67	35.67	mg/g	TPT LABCO	TLEL01_v1.5.pdf	E-LIQUID	3	03-29-2023	Week 8	2
7	TOB07	PT	111			Condition 1	217		NICOTINE	Nicotine	36.11	mg/g	36.11	36.11	mg/g	TPT LABCO	TLEL01_v1.5.pdf	E-LIQUID	1	07-19-2023	Week 24	3
8	TOB07	PT	111			Condition 1	218		NICOTINE	Nicotine	35.72	mg/g	35.72	35.72	mg/g	TPT LABCO	TLEL01_v1.5.pdf	E-LIQUID	2	07-19-2023	Week 24	3
9	TOB07	PT	111			Condition 1	219		NICOTINE	Nicotine	35.54	mg/g	35.54	35.54	mg/g	TPT LABCO	TLEL01_v1.5.pdf	E-LIQUID	3	07-19-2023	Week 24	3
10	TOB07	PT	111	PUFFMASTER3K	Condition 2	220	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1039	mg/PUFF	0.1039	0.1039	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	1	02-01-2023	Week 0	1	
11	TOB07	PT	111	PUFFMASTER3K	Condition 2	221	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1142	mg/PUFF	0.1142	0.1142	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	2	02-01-2023	Week 0	1	
12	TOB07	PT	111	PUFFMASTER3K	Condition 2	222	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1282	mg/PUFF	0.1282	0.1282	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	3	02-01-2023	Week 0	1	
13	TOB07	PT	111	PUFFMASTER3K	Condition 2	223	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1242	mg/PUFF	0.1242	0.1242	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	1	03-29-2023	Week 8	2	
14	TOB07	PT	111	PUFFMASTER3K	Condition 2	224	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1084	mg/PUFF	0.1084	0.1084	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	2	03-29-2023	Week 8	2	
15	TOB07	PT	111	PUFFMASTER3K	Condition 2	225	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1174	mg/PUFF	0.1174	0.1174	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	3	03-29-2023	Week 8	2	
16	TOB07	PT	111	PUFFMASTER3K	Condition 2	226	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1374	mg/PUFF	0.1374	0.1374	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	1	07-19-2023	Week 24	3	
17	TOB07	PT	111	PUFFMASTER3K	Condition 2	227	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1364	mg/PUFF	0.1364	0.1364	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	2	07-19-2023	Week 24	3	
18	TOB07	PT	111	PUFFMASTER3K	Condition 2	228	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1264	mg/PUFF	0.1264	0.1264	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	3	07-19-2023	Week 24	3	
19	TOB07	PT	111	PUFFMASTER3K	Condition 2	229	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1256	mg/PUFF	0.1256	0.1256	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	1	02-01-2023	Week 0	1	
20	TOB07	PT	111	PUFFMASTER3K	Condition 3	230	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1236	mg/PUFF	0.1236	0.1236	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	2	02-01-2023	Week 0	1	
21	TOB07	PT	111	PUFFMASTER3K	Condition 3	231	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1126	mg/PUFF	0.1126	0.1126	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	3	02-01-2023	Week 0	1	
22	TOB07	PT	111	PUFFMASTER3K	Condition 3	232	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1334	mg/PUFF	0.1334	0.1334	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	1	03-29-2023	Week 8	2	
23	TOB07	PT	111	PUFFMASTER3K	Condition 3	233	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1134	mg/PUFF	0.1134	0.1134	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	2	03-29-2023	Week 8	2	
24	TOB07	PT	111	PUFFMASTER3K	Condition 3	234	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1125	mg/PUFF	0.1125	0.1125	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	3	03-29-2023	Week 8	2	

Row	STUDYID	DOMAIN	SPTOBID	SPDEVID	STOCONID	PTSEQ	PTREFID	PTTESTCD	PTTEST	PTORRES	PTORRESU	PTSTRESC	PTSTRESN	PTSTRESU	PTNAM	PTXFN	PTSPEC	PTREPNUM	PTDTC	PTTPT	PTTPNUM
25	TOB07	PT	111	PUFFMASTER3K	Condition 3	235	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1156	mg/PUFF	0.1156	0.1156	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	1	07-19-2023	Week 24	3
26	TOB07	PT	111	PUFFMASTER3K	Condition 3	236	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1145	mg/PUFF	0.1145	0.1145	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	2	07-19-2023	Week 24	3
27	TOB07	PT	111	PUFFMASTER3K	Condition 3	237	NON-INTENSE REGIMEN	NICOTINE	Nicotine	0.1157	mg/PUFF	0.1157	0.1157	mg/puff	TPT LABCO	TLAE01_v2.1.pdf	AEROSOL	3	07-19-2023	Week 24	3

Details of the storage conditions are represented in the ES dataset. The variable STOCONID/Storage Condition ID represents the storage condition and links to the PT datasets by matching values of STOCONID there. Each of the parameters defining that storage condition are represented in ESPARMCD/ESPARM, with values and units shown in ESVAL/ESVALU. The ES dataset shows all 3 sets of storage conditions used across both of the PT dataset examples.

es.xpt

Row	STUDYID	DOMAIN	STOCONID	ESSEQ	ESPARMCD	ESPARM	ESVAL	ESVALU
1	TOB07	ES	Condition 1	1	HUMID	Humidity	37	%
2	TOB07	ES	Condition 1	2	TEMP	Temperature	24	C
3	TOB07	ES	Condition 2	1	HUMID	Humidity	60	%
4	TOB07	ES	Condition 2	2	TEMP	Temperature	27	C
5	TOB07	ES	Condition 3	1	HUMID	Humidity	95	%
6	TOB07	ES	Condition 3	2	TEMP	Temperature	31	C

Example 2 demonstrates stability studies using constituents/parameters applicable to a smokeless tobacco product.

Example 2

The first PT dataset shows 7 constituents/parameters, each as a single replicate (PTREPNUM=1), at 1 time point (PTTPT=Week 0 / PTTPNUM=1) and from 1 set of storage conditions (STOCONID= Condition 1) in order to illustrate the variables and terminology required to construct an SDTM-conformant PT dataset for a stability study of a smokeless product. Some constituent names (Values of PTTESTCD/PTTEST) appear twice because their results are reported two separate ways: once for the result as tested and once where the result is expressed as dry weight basis (the latter is indicated by PTTSTDTL = DRY WEIGHT BASIS). Note that the constituent/parameter names shown do not represent an exhaustive list of the controlled terminology that will be developed to support representation of stability studies in SDTM.

- STOCONID is used to identify the storage conditions of the e-liquid product for the testing performed. Details of these conditions are represented in the ES dataset example that follows the 2 PT dataset examples.
- PTXFN (External File Path) is used to document the location or file name within the submission that contains the lab methodology protocol used to assay the associated constituent/parameter when such methodology is too complex for the single PTMETHOD variable.

Row 1: Shows the PTTEST of Moisture Content, which reflects the percentage of moisture in the substance for the condition noted in STOCONID (i.e., Condition 1). Moisture Content is used in chemistry stability studies. For microbial stability studies, Water Activity should be used, not Moisture Content (see row 3).

Rows 4, 6: Show the NNK and NNN tests with the results from the tobacco product as tested.

Rows 5, 7: Show the NNK and NNN test results as dry weight basis (DWB). Note the use of PTTSTDTL = "DRY WEIGHT BASIS"

Rows 2-3, 8-9: Show the other analytes measured in testing.

pt.xpt

Row	STUDYID	DOMAIN	SPTOBID	STOCONID	PTSEQ	PTTESTCD	PTTEST	PTTSTDTL	PTCAT	PTORRES	PTORRESU	PTLLOD
1	TOB07	PT	Smokeless01	Condition 1	1	MOISTCTT	Moisture Content		STABILITY TESTING	52.0	%	0.1
2	TOB07	PT	Smokeless01	Condition 1	2	PH	pH		STABILITY TESTING	8.06		
3	TOB07	PT	Smokeless01	Condition 1	3	H2OACT	Water Activity		STABILITY TESTING	0.86		0.01
4	TOB07	PT	Smokeless01	Condition 1	4	NNK	Nicotine-Derived Nitrosamine Ketone		STABILITY TESTING	1.0225	ug/g	0.01
5	TOB07	PT	Smokeless01	Condition 1	5	NNK	Nicotine-Derived Nitrosamine Ketone	DRY WEIGHT BASIS	STABILITY TESTING	0.4908	ug/g	0.01
6	TOB07	PT	Smokeless01	Condition 1	6	NNN	N-Nitrosornicotine		STABILITY TESTING	4.4633	ug/g	0.01
7	TOB07	PT	Smokeless01	Condition 1	7	NNN	N-Nitrosornicotine	DRY WEIGHT BASIS	STABILITY TESTING	2.1424	ug/g	0.01
8	TOB07	PT	Smokeless01	Condition 1	8	AEBCT	Aerobic Colony Count		STABILITY TESTING	154000	CFU/g	1
9	TOB07	PT	Smokeless01	Condition 1	9	YSTMLDCT	Yeast and/or Mold Colony Count		STABILITY TESTING	<10	CFU/g	1

Row	PTSTRESC	PTSTRESN	PTSTRESU	PTXFN	PTNAM	PTSPEC	PTLLOQ	PTREPNUM	PTDTC	PTTPT	PTTPTNUM
1	52.0	52.0	%	TLT07 V1	TPT LABCO	TOBACCO	0.12	1	02-01-2023	Week 0	1
2	8.06	8.06		TL009 V1	TPT LABCO	TOBACCO		1	02-01-2023	Week 0	1
3	0.86	0.86		TLPH01 V1	TPT LABCO	TOBACCO	0.05	1	02-01-2023	Week 0	1
4	1.0225	1.0225	ug/g	TL026 V12.2	TPT LABCO	TOBACCO	0.05	1	02-01-2023	Week 0	1
5	0.4908	0.4908	ug/g	TL026 V12.2	TPT LABCO	TOBACCO	0.05	1	02-01-2023	Week 0	1
6	4.4633	4.4633	ug/g	TL026 V12.2	TPT LABCO	TOBACCO	0.05	1	02-01-2023	Week 0	1
7	2.1424	2.1424	ug/g	TL026 V12.2	TPT LABCO	TOBACCO	0.05	1	02-01-2023	Week 0	1
8	154000	154000	CFU/g	TLMB V1.1	TPT LABCO	TOBACCO	1	1	02-01-2023	Week 0	1
9	<10		CFU/g	TLMB V1.1	TPT LABCO	TOBACCO	1	1	02-01-2023	Week 0	1

The second PT dataset shows testing for just 1 parameter (Moisture Content), performed in 3 replicates (note the values of PTREPNUM), at the first 3 time points of the study (as shown in PTTPT/PTTPTNUM), from 2 sets of storage conditions (STOCONID), in samples of both dried and as-is tobacco (PTSPEC, PTSPCCND) in order to illustrate how those variables are used to represent their associated concepts in a stability study.

- Details of the storage conditions are represented in the ES dataset example that follows.

Rows 1-9: Show the results of testing Moisture Content in 3 replicates (PTREPNUM) at 3 timepoints (weeks 0, 8, and 24) under the storage "Condition 1" (STOCONID).

Rows 10-18: Show the results of testing Moisture Content in 3 replicates (PTREPNUM) at 3 timepoints (weeks 0, 8, and 24) under the storage "Condition 2" (STOCONID).

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Row	STUDYID	DOMAIN	SPTOBID	STOCONID	PTSEQ	PTTESTCD	PTTEST	PTORRES	PTORRESU	PTLLOD	PTSTRESC	PTSTRESN
1	TOB07	PT	Smokeless01	Condition 1	111	MOISTCTT	Moisture Content	51.93	%	0.1	51.93	51.93
2	TOB07	PT	Smokeless01	Condition 1	112	MOISTCTT	Moisture Content	51.96	%	0.1	51.96	51.96
3	TOB07	PT	Smokeless01	Condition 1	113	MOISTCTT	Moisture Content	51.98	%	0.1	51.98	51.98
4	TOB07	PT	Smokeless01	Condition 1	114	MOISTCTT	Moisture Content	51.75	%	0.1	51.75	51.75
5	TOB07	PT	Smokeless01	Condition 1	115	MOISTCTT	Moisture Content	51.75	%	0.1	51.75	51.75
6	TOB07	PT	Smokeless01	Condition 1	116	MOISTCTT	Moisture Content	51.67	%	0.1	51.67	51.67
7	TOB07	PT	Smokeless01	Condition 1	117	MOISTCTT	Moisture Content	52.05	%	0.1	52.05	52.05
8	TOB07	PT	Smokeless01	Condition 1	118	MOISTCTT	Moisture Content	52.68	%	0.1	52.68	52.68
9	TOB07	PT	Smokeless01	Condition 1	119	MOISTCTT	Moisture Content	52.21	%	0.1	52.21	52.21
10	TOB07	PT	Smokeless01	Condition 2	120	MOISTCTT	Moisture Content	51.93	%	0.1	51.93	51.93
11	TOB07	PT	Smokeless01	Condition 2	121	MOISTCTT	Moisture Content	51.96	%	0.1	51.96	51.96
12	TOB07	PT	Smokeless01	Condition 2	122	MOISTCTT	Moisture Content	51.98	%	0.1	51.98	51.98

Row	STUDYID	DOMAIN	SPTOBID	STOCONID	PTSEQ	PTTESTCD	PTTEST	PTTRES	PTTRESU	PTLLOD	PTSTRESC	PTSTRESN
13	TOB07	PT	Smokeless01	Condition 2	123	MOISTCTT	Moisture Content	51.80	%	0.1	51.80	51.80
14	TOB07	PT	Smokeless01	Condition 2	124	MOISTCTT	Moisture Content	51.77	%	0.1	51.77	51.77
15	TOB07	PT	Smokeless01	Condition 2	125	MOISTCTT	Moisture Content	51.84	%	0.1	51.84	51.84
16	TOB07	PT	Smokeless01	Condition 2	126	MOISTCTT	Moisture Content	52.18	%	0.1	52.18	52.18
17	TOB07	PT	Smokeless01	Condition 2	127	MOISTCTT	Moisture Content	52.21	%	0.1	52.21	52.21
18	TOB07	PT	Smokeless01	Condition 2	128	MOISTCTT	Moisture Content	51.87	%	0.1	51.87	51.87

Row	PTSTRESU	PTXFN	PTNAM	PTSPEC	PTSPCCND	PTLLOQ	PTREPNM	PTDTC	PTTP	PTTPNUM
1	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	1	02-01-2023	Week 0	1
2	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	2	02-01-2023	Week 0	1
3	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	3	02-01-2023	Week 0	1
4	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	1	03-29-2023	Week 8	2
5	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	2	03-29-2023	Week 8	2
6	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	3	03-29-2023	Week 8	2
7	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	1	07-19-2023	Week 24	3
8	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	2	07-19-2023	Week 24	3
9	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	3	07-19-2023	Week 24	3
10	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	1	02-01-2023	Week 0	1
11	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	2	02-01-2023	Week 0	1
12	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	3	02-01-2023	Week 0	1
13	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	1	03-29-2023	Week 8	2
14	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	2	03-29-2023	Week 8	2
15	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	3	03-29-2023	Week 8	2
16	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	1	07-19-2023	Week 24	3
17	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	2	07-19-2023	Week 24	3
18	%	TLT07_V1	TPT LABCO	TOBACCO	AS-IS	0.12	3	07-19-2023	Week 24	3

Details of the storage conditions are represented in the Environmental Storage Conditions (ES) dataset. The variable STOCONID/Storage Condition ID represents the storage condition and links to the PT datasets by matching values of STOCONID there. Each of the parameters defining that storage condition are represented in ESPARMCD/ESPARM, with values and units shown in ESVAL/ESVALU. The ES dataset shows both sets of storage conditions used across both of the PT dataset examples.

es.xpt

Row	STUDYID	DOMAIN	STOCONID	ESSEQ	ESPARMCD	ESPARM	ESVAL	ESVALU
1	TOB07	ES	Condition 1	1	HUMID	Humidity	37	%
2	TOB07	ES	Condition 1	2	TEMP	Temperature	24	C
3	TOB07	ES	Condition 2	1	HUMID	Humidity	85	%
4	TOB07	ES	Condition 2	2	TEMP	Temperature	27	C

Example 3

The following example illustrates calculation of some of the statistics typically calculated on product stability measures.

adpt.xpt

Row	STUDYID	PRODSTID	SPTOBID	STOCONID	PARQUAL	PARAM	PARAMCD	AVAL	ATPT	ATPTN
1	TOB07	Smokeless01/Condition 1	Smokeless01	Condition 1	Product Moisture (%)	Average	AVERAGE	51.95667	Week 0	1
2	TOB07	Smokeless01/Condition 1	Smokeless01	Condition 1	Product Moisture (%)	S.D.	STD	0.025166	Week 0	1
3	TOB07	Smokeless01/Condition 1	Smokeless01	Condition 1	Product Moisture (%)	% RSD	PCTRSD	0.048437	Week 0	1
4	TOB07	Smokeless01/Condition 1	Smokeless01	Condition 1	Product Moisture (%)	Average	AVERAGE	51.72333	Week 8	2
5	TOB07	Smokeless01/Condition 1	Smokeless01	Condition 1	Product Moisture (%)	S.D.	STD	0.046188	Week 8	2
6	TOB07	Smokeless01/Condition 1	Smokeless01	Condition 1	Product Moisture (%)	% RSD	PCTRSD	0.089298	Week 8	2
7	TOB07	Smokeless01/Condition 1	Smokeless01	Condition 1	Product Moisture (%)	Average	AVERAGE	52.31333	Week 24	3
8	TOB07	Smokeless01/Condition 1	Smokeless01	Condition 1	Product Moisture (%)	S.D.	STD	0.327465	Week 24	3
9	TOB07	Smokeless01/Condition 1	Smokeless01	Condition 1	Product Moisture (%)	% RSD	PCTRSD	0.625969	Week 24	3
10	TOB07	Smokeless01/Condition 2	Smokeless01	Condition 2	Product Moisture (%)	Average	AVERAGE	51.95667	Week 0	1
11	TOB07	Smokeless01/Condition 2	Smokeless01	Condition 2	Product Moisture (%)	S.D.	STD	0.025166	Week 0	1
12	TOB07	Smokeless01/Condition 2	Smokeless01	Condition 2	Product Moisture (%)	% RSD	PCTRSD	0.048437	Week 0	1
13	TOB07	Smokeless01/Condition 2	Smokeless01	Condition 2	Product Moisture (%)	Average	AVERAGE	51.80333	Week 8	2
14	TOB07	Smokeless01/Condition 2	Smokeless01	Condition 2	Product Moisture (%)	S.D.	STD	0.035119	Week 8	2
15	TOB07	Smokeless01/Condition 2	Smokeless01	Condition 2	Product Moisture (%)	% RSD	PCTRSD	0.067793	Week 8	2
16	TOB07	Smokeless01/Condition 2	Smokeless01	Condition 2	Product Moisture (%)	Average	AVERAGE	52.08667	Week 24	3
17	TOB07	Smokeless01/Condition 2	Smokeless01	Condition 2	Product Moisture (%)	S.D.	STD	0.188237	Week 24	3
18	TOB07	Smokeless01/Condition 2	Smokeless01	Condition 2	Product Moisture (%)	% RSD	PCTRSD	0.361393	Week 24	3

ADPT Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADPT	Product Stability Analysis Dataset	ADAM OTHER	one record per product stability identifier per parameter qualifier per parameter per analysis timepoint	Analysis	PRODSTID, PARQUAL, PARAM, ATPT	adpt.xpt	NA

ADPT Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	Char		Req	PT.STUDYID
PRODSTID	Product Stability Identifier	Char		Req	Concatenate SPTOBID with STOCONID separated with '/'
SPTOBID	Applicant-Defined Tobacco Product ID	Char		Perm	PT.SPTOBID
STOCONID	Applicant-Defined Storage Conditions ID	Char		Perm	PT.STOCONID
PARQUAL	Parameter Qualifier	Char		Cond	Set to the item being tested
PARAM	Parameter	Char		Req	Set to the parameter being captured
PARAMCD	Parameter Code	Char		Req	Set to the parameter code associated with the parameter
AVAL	Analysis Value	Num		Req	Calculated statistic
ATPT	Analysis Timepoint	Char		Cond	PT.PTTPT
ATPTN	Analysis Timepoint (N)	Num		Cond	PT.PTTPTNUM

3.2 Nonclinical

Nonclinical tobacco product studies are conducted to assess the biological, toxicological, pharmacological, and behavioral impacts tobacco products and their constituents have within in vitro and in vivo test systems. This section provides examples for representing data from nonclinical tobacco product research using the SDTM, including:

- Guidance on the use of domains and variables
- Examples of SDTM datasets, with text describing the situational context and pointing out records of note
- Descriptions and examples of trial design datasets for use with both in vitro and in vivo studies
- Additional trial design datasets needed to fully describe in vivo study designs

3.2.1 Nonclinical Trial Design

This section includes example trials, which illustrate the intended implementation of Trial Design datasets.

3.2.1.1 In vivo and in vitro Trial Summary (TS) Domain Model

The Trial Summary (TS) dataset allows the applicant to submit a summary of the study in a structured format. The TS dataset contains information about the planned study characteristics, identical for all study subjects, which is usually found in the protocol. Each record in the TS dataset contains the value of a parameter, a characteristic of the study, or study level information.

Example 1: Simple Parallel Design With Recovery

In this example, the dataset includes many informational fields that may provide context for the study. TSPARMCD = "GLPTYP" is included twice in this example, since both GLP types apply for this study. Also, TSGRPID has been used to link records (name, location, country) related to the test facility (TSGRPID = "1") and records related to the test site (TSGRPID = "2"). The study director is associated with the test facility and the principal investigator is associated with the test site. Finally, the primary treatment CAS registry number is not known; this is recorded as an empty TSVAL and UNKNOWN in the corresponding TSVALNF.

ts.xpt

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF
1	XYZ	TS	1		SSTYP	Study Type	REPEAT DOSE TOXICITY	
2	XYZ	TS	1		SPECIES	Species	RAT	
3	XYZ	TS	1		STRAIN	Strain/Substrain	FISCHER 344	
4	XYZ	TS	1		SBSTRAIN	Strain/Substrain Details	NON-DIABETIC OBESE RAT	
5	XYZ	TS	1		SPLRNM	Test Subject Supplier	Example Supplier	
6	XYZ	TS	1		SDESIGN	Study Design	PARALLEL	
7	XYZ	TS	1		ROUTE	Route of Administration	ORAL	
8	XYZ	TS	1		GLPTYP	Good Laboratory Practice Type	FDA	
9	XYZ	TS	2		GLPTYP	Good Laboratory Practice Type	OECD	
10	XYZ	TS	1		EXPSTDTC	Experimental Start Date	2008-01-01	
11	XYZ	TS	1		EXPENDTC	Experimental End Date	2008-02-13	
12	XYZ	TS	1		DOSDUR	Dosing Duration	P28D	
13	XYZ	TS	1		STITLE	Study Title	Example of a 4-week Repeat-Dose Toxicity Study in Rats with a 1-week Recovery	
14	XYZ	TS	1		SNDIGVER	SEND Implementation Guide Version	SEND Implementation Guide Version 3.1.1	
15	XYZ	TS	1		SNDCTVER	SEND Controlled Terminology Version	SEND Terminology 2023-06-30	
16	XYZ	TS	1		STCAT	Study Category	TOX	
17	XYZ	TS	1		APPLCNT	Applicant	Example Applicant Inc.	
18	XYZ	TS	1	1	TSTFNAM	Test Facility Name	Example Contract Lab Name	
19	XYZ	TS	1	1	TSTFLOC	Test Facility Location	1000 Anywhere Street, Honolulu, HI 11111	
20	XYZ	TS	1	1	TFCNTRY	Test Facility Country	USA	
21	XYZ	TS	1	2	TSNAM	Test Site Name	Example Subcontract Lab Name	
22	XYZ	TS	1	2	TSLOC	Test Site Location	1000 Allen Street Omaha, NE 88888	
23	XYZ	TS	1	2	TSCNTRY	Test Site Country	USA	
24	XYZ	TS	1		STSTDTC	Study Start Date	2007-12-30	
25	XYZ	TS	1		STENDTC	Study End Date	2008-06-01	
26	XYZ	TS	1		AGETXT	Age Text	6-8	
27	XYZ	TS	1		AGEU	Age Unit	WEEKS	
28	XYZ	TS	1	1	STDIR	Study Director	Dr. H. Someone	
29	XYZ	TS	1	2	PINV	Principal Investigator	G. Person	
30	XYZ	TS	1		TRT	Investigational Therapy or Treatment	Example Compound Name	
31	XYZ	TS	1		TRTV	Treatment Vehicle	SALINE	
32	XYZ	TS	1		GLPFL	GLP Flag	Y	
33	XYZ	TS	1		TRTCAS	Primary Treatment CAS Registry Number		UNKNOWN

3.2.1.2 In vivo and in vitro Trial Sets (TX) Domain Model

Example 1: Simple Parallel Design, No Recovery

This example assumes a simple parallel design in which the applicant-defined protocol specifies the following information. All subjects are to be screened for 7 days prior to randomization into 3 protocol groups:

- Group 1 is a control group of 20 subjects, 10 male and 10 female, dosed with vehicle once per day for 28 days.
- Group 2 is a low-dose group of 20 subjects, 10 male and 10 female, dosed at 100 mg/kg once per day for 28 days.

- Group 3 is a high-dose group of 20 subjects, 10 male and 10 female, dosed at 500 mg/kg once per day for 28 days.

There are no other experimental factors of interest specified in the study design. There are only 3 trial sets in this scenario, because there are no nontreatment factors to consider. In this example, the applicant has chosen to provide a small amount of additional information about each trial set, including the associated arm code, applicant-defined protocol group number, control group type, group label, and dose level and units, and the applicant has made the assumption that male and female animals will be compared separately when relevant.

tx.xpt

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
1	EXP1	TX	1	Control Group, Vehicle Control once daily	1	ARMCD	Arm Code	1
2	EXP1	TX	1	Control Group, Vehicle Control once daily	2	SPGRPCD	Applicant-Defined Group Code	1
3	EXP1	TX	1	Control Group, Vehicle Control once daily	3	TCTRL	Control Type	VEHICLE CONTROL
4	EXP1	TX	1	Control Group, Vehicle Control once daily	4	GRPLBL	Group Label	Group 1, Control
5	EXP1	TX	1	Control Group, Vehicle Control once daily	5	TRTDOS	Dose Level	0
6	EXP1	TX	1	Control Group, Vehicle Control once daily	6	TRTDOSU	Dose Units	mg/kg/day
7	EXP1	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily	7	ARMCD	Arm Code	2
8	EXP1	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily	8	SPGRPCD	Applicant-Defined Group Code	2
9	EXP1	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily	9	GRPLBL	Group Label	Group 2, 100 mg/kg/day
10	EXP1	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily	10	TRTDOS	Dose Level	100
11	EXP1	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily	11	TRTDOSU	Dose Units	mg/kg/day
12	EXP1	TX	3	High-Dose Group, 500 mg/kg Drug a once daily	12	ARMCD	Arm Code	3
13	EXP1	TX	3	High-Dose Group, 500 mg/kg Drug a once daily	13	SPGRPCD	Applicant-Defined Group Code	3
14	EXP1	TX	3	High-Dose Group, 500 mg/kg Drug a once daily	14	GRPLBL	Group Label	Group 3, 500 mg/kg/day
15	EXP1	TX	3	High-Dose Group, 500 mg/kg Drug a once daily	15	TRTDOS	Dose Level	500
16	EXP1	TX	3	High-Dose Group, 500 mg/kg Drug a once daily	16	TRTDOSU	Dose Units	mg/kg/day

See also Section 3.2.1.5, [Additional Examples of In Vivo Trial Designs](#).

3.2.1.3 In vivo Trial Arms (TA) Domain Model

Example 1: Simple Parallel Design, No Recovery

This example assumes a simple parallel design in which the applicant-defined protocol specifies the following information. All subjects are to be screened for 7 days prior to randomization into 3 protocol groups:

- Group 1 is a control group of 20 subjects, 10 male and 10 female, dosed with vehicle once per day for 28 days.
- Group 2 is a low-dose group of 20 subjects, 10 male and 10 female, dosed at 100 mg/kg once per day for 28 days.
- Group 3 is a high-dose group of 20 subjects, 10 male and 10 female, dosed at 500 mg/kg once per day for 28 days.

There are no other experimental factors of interest specified in the study design. In this case, the design consists of 3 trial arms, because there are 3 distinct sequences of elements, depicted as follows:

ta.xpt

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	EPOCH
1	EXP1	TA	1	Control	1	SCRN	Screen	Randomized to Group 1	PRE-EXPOSURE
2	EXP1	TA	1	Control	2	TRT01	Vehicle Control		EXPOSURE
3	EXP1	TA	2	100 mg/kg	1	SCRN	Screen	Randomized to Group 2	PRE-EXPOSURE
4	EXP1	TA	2	100 mg/kg	2	TRT02	100 mg/kg Drug A		EXPOSURE
5	EXP1	TA	3	500 mg/kg	1	SCRN	Screen	Randomized to Group 3	PRE-EXPOSURE
6	EXP1	TA	3	500 mg/kg	2	TRT03	500 mg/kg Drug A		EXPOSURE

3.2.1.4 In vivo Trial Elements (TE) Domain Model

Example 1: Simple Parallel Design

This is a simple study design example, including element start (TESTRL) and end (TEENRL) rules as well as element duration (TEDUR).

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	EXP1	TE	SCRN	Screen	Start of Pretreatment	1 week after start of Element	P7D
2	EXP1	TE	TRT01	Vehicle Control	First day of dosing with vehicle control	28 days after start of Element	P28D
3	EXP1	TE	TRT02	100 mg/kg Drug A, once daily	First day of dosing with 100 mg/kg Drug A	28 days after start of Element	P28D
4	EXP1	TE	TRT03	500 mg/kg Drug A, once daily	First day of dosing with 500 mg/kg Drug A	28 days after start of Element	P28D

Example 2: Study with a Nonfixed Duration Element

This example includes the nonfixed duration for pretest phase where the end rule is not a definite time, but when the subject achieves a specified body weight. In order to completely understand the experimental design of a trial, the TA and TS datasets are needed.

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	EXP7	TE	PRETEST	Pretreatment Feeding Period	Start of pre-exposure period	When subject's body weight is at least 750 g	
2	EXP7	TE	CONTROL	Control Period	After completion of PRETEST Element	30 days after start of Element	P30D
3	EXP7	TE	TREAT2	100 mg/kg Drug A, once daily	After completion of PRETEST Element	30 days after start of Element	P30D
4	EXP7	TE	TREAT3	200 mg/kg Drug A, once daily	After completion of PRETEST Element	30 days after start of Element	P30D
5	EXP7	TE	TREAT4	300 mg/kg Drug A, once daily	After completion of PRETEST Element	30 days after start of Element	P30D
6	EXP7	TE	TREAT5	100 mg/kg Drug B, twice daily doses of 50 mg/kg each	After completion of PRETEST Element	30 days after start of Element	P30D
7	EXP7	TE	TREAT6	200 mg/kg Drug B, twice daily doses of 100 mg/kg each	After completion of PRETEST Element	30 days after start of Element	P30D
8	EXP7	TE	TREAT7	400 mg/kg Drug B, twice daily doses of 200 mg/kg each	After completion of PRETEST Element	30 days after start of Element	P30D
9	EXP7	TE	RECOVERY	Recovery Period	After last dose with product or vehicle control	14 days after start of Element	P14D

3.2.1.5 Additional Examples of In Vivo Trial Designs

This section includes additional examples of in vivo trial designs, which illustrate the intended implementation of Trial Design datasets.

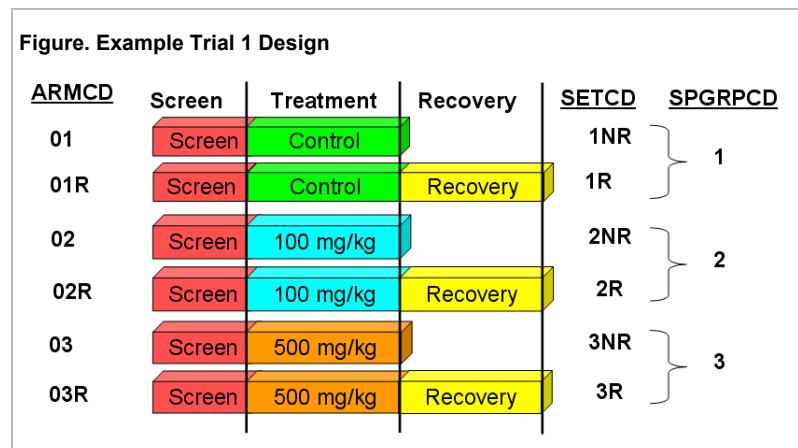
3.2.1.5.1 Parallel Design With Some Subjects Moving To Recovery

This example assumes a design in which the applicant-defined protocol specifies the following information. All subjects are to be screened for 7 days prior to randomization into 3 protocol groups:

- Group 1 is a control group of 20 subjects, 10 male and 10 female, dosed with vehicle once per day for 28 days. After 28 days, 5 subjects/sex will be terminated and the other half will go on to a 7-day recovery period prior to termination.
- Group 2 is a low-dose group of 20 subjects, 10 male and 10 female, dosed at 100 mg/kg once per day for 28 days. After 28 days, 5 subjects/sex will be terminated and the other half will go on to a 7-day recovery period prior to termination.
- Group 3 is a high-dose group of 20 subjects, 10 male and 10 female, dosed at 500 mg/kg once per day for 28 days. After 28 days, 5 subjects/sex will be terminated and the other half will go on to a 7-day recovery period prior to termination.

Group Number	Group Label	Dose Level	Number of Animals (Both Sexes Combined)	
			Nonrecovery	Recovery
1	Group 1, Control	Vehicle Control	10	10
2	Group 2, 100 mg/kg	100 mg/kg/day	10	10
3	Group 3, 500 mg/kg	500 mg/kg/day	10	10

There are no other experimental factors of interest specified in the study design. In this case, the design consists of 6 trial arms, because there are 6 distinct sequences of elements, as depicted in the following figure.



Trial Elements

This example includes the start and end rule for the recovery element starting after last dose of the drug or vehicle.

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	TDM1	TE	SCRN	Screen	Start of Pre-exposure	1 week after start of Element	P7D
2	TDM1	TE	TRT01	Vehicle Control	First day of dosing with vehicle control	28 days after start of Element	P28D
3	TDM1	TE	TRT02	100 mg/kg Drug A, once daily	First day of dosing with 100 mg/kg Drug A	28 days after start of Element	P28D
4	TDM1	TE	TRT03	500 mg/kg Drug A, once daily	First day of dosing with 500 mg/kg Drug A	28 days after start of Element	P28D
5	TDM1	TE	RECO	Recovery	First day of Recovery	7 days after start of Element	P7D

Trial Arms

The 6 trial arms of this study can be depicted as follows:

ta.xpt

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	EPOCH
1	TDM1	TA	01	Control	1	SCRN	Screen	Randomized to Group 1	PRE-EXPOSURE
2	TDM1	TA	01	Control	2	TRT01	Vehicle Control		EXPOSURE
3	TDM1	TA	01R	Control w/ Recovery	1	SCRN	Screen	Randomized to Group 1, planned for recovery	PRE-EXPOSURE
4	TDM1	TA	01R	Control w/ Recovery	2	TRT01	Vehicle Control		EXPOSURE
5	TDM1	TA	01R	Control w/ Recovery	3	RECO	Recovery		RECOVERY
6	TDM1	TA	02	Low Dose	1	SCRN	Screen	Randomized to Group 2	PRE-EXPOSURE
7	TDM1	TA	02	Low Dose	2	TRT02	100 mg/kg Drug A		EXPOSURE
8	TDM1	TA	02R	Low Dose w/ Recovery	1	SCRN	Screen	Randomized to Group 2, planned for recovery	PRE-EXPOSURE
9	TDM1	TA	02R	Low Dose w/ Recovery	2	TRT02	100 mg/kg Drug A		EXPOSURE
10	TDM1	TA	02R	Low Dose w/ Recovery	3	RECO	Recovery		RECOVERY
11	TDM1	TA	03	High Dose	1	SCRN	Screen	Randomized to Group 3	PRE-EXPOSURE
12	TDM1	TA	03	High Dose	2	TRT03	500 mg/kg Drug A		EXPOSURE
13	TDM1	TA	03R	High Dose w/ Recovery	1	SCRN	Screen	Randomized to Group 3, planned for recovery	PRE-EXPOSURE
14	TDM1	TA	03R	High Dose w/ Recovery	2	TRT03	500 mg/kg Drug A		EXPOSURE
15	TDM1	TA	03R	High Dose w/ Recovery	3	RECO	Recovery		RECOVERY

Trial Sets

As noted, there are 6 distinct trial sets. The experimental factors of interest are the dose level to be received during the exposure period and whether the subjects are planned for termination on day 28 or will enter a recovery period.

In this example, the applicant is providing the arm code, applicant-defined group code, group label, set label, dose level and units, control type, and planned number of males and females for each set.

tx.xpt

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
1	TDM1	TX	1NR	Control Group, Vehicle Control once daily, Nonrecovery	1	ARMCD	Arm Code	01
2	TDM1	TX	1NR	Control Group, Vehicle Control once daily, Nonrecovery	2	SPGRPCD	applicant-Defined Group Code	1
3	TDM1	TX	1NR	Control Group, Vehicle Control once daily, Nonrecovery	3	GRPLBL	Group Label	Group 1, Control
4	TDM1	TX	1NR	Control Group, Vehicle Control once daily, Nonrecovery	4	SETLBL	Set Label	Group 1, Control - Nonrec
5	TDM1	TX	1NR	Control Group, Vehicle Control once daily, Nonrecovery	5	TRTDOS	Dose Level	0
6	TDM1	TX	1NR	Control Group, Vehicle Control once daily, Nonrecovery	6	TRTDOSU	Dose Units	mg/kg/day
7	TDM1	TX	1NR	Control Group, Vehicle Control once daily, Nonrecovery	7	TCNTRL	Control Type	VEHICLE CONTROL
8	TDM1	TX	1NR	Control Group, Vehicle Control once daily, Nonrecovery	8	PLANMSUB	Planned Number of Male Subjects	5
9	TDM1	TX	1NR	Control Group, Vehicle Control once daily, Nonrecovery	9	PLANFSUB	Planned Number of Female Subjects	5
10	TDM1	TX	1R	Control Group, Vehicle Control once daily, Recovery	10	ARMCD	Arm Code	01R
11	TDM1	TX	1R	Control Group, Vehicle Control once daily, Recovery	11	SPGRPCD	Applicant-Defined Group Code	1
12	TDM1	TX	1R	Control Group, Vehicle Control once daily, Recovery	12	GRPLBL	Group Label	Group 1, Control
13	TDM1	TX	1R	Control Group, Vehicle Control once daily, Recovery	13	SETLBL	Set Label	Group 1, Control - Rec
14	TDM1	TX	1R	Control Group, Vehicle Control once daily, Recovery	14	TRTDOS	Dose Level	0
15	TDM1	TX	1R	Control Group, Vehicle Control once daily, Recovery	15	TRTDOSU	Dose Units	mg/kg/day
16	TDM1	TX	1R	Control Group, Vehicle Control once daily, Recovery	16	TCNTRL	Control Type	VEHICLE CONTROL
17	TDM1	TX	1R	Control Group, Vehicle Control once daily, Recovery	17	PLANMSUB	Planned Number of Male Subjects	5
18	TDM1	TX	1R	Control Group, Vehicle Control once daily, Recovery	18	PLANFSUB	Planned Number of Female Subjects	5
19	TDM1	TX	2NR	Low-Dose Group, 100 mg/kg Drug a once daily, Nonrecovery	19	ARMCD	Arm Code	02
20	TDM1	TX	2NR	Low-Dose Group, 100 mg/kg Drug a once daily, Nonrecovery	20	SPGRPCD	Applicant-Defined Group Code	2
21	TDM1	TX	2NR	Low-Dose Group, 100 mg/kg Drug a once daily, Nonrecovery	21	GRPLBL	Group Label	Group 2, 100 mg/kg
22	TDM1	TX	2NR	Low-Dose Group, 100 mg/kg Drug a once daily, Nonrecovery	22	SETLBL	Set Label	Group 2, 100 mg/kg - Nonrec
23	TDM1	TX	2NR	Low-Dose Group, 100 mg/kg Drug a once daily, Nonrecovery	23	TRTDOS	Dose Level	100
24	TDM1	TX	2NR	Low-Dose Group, 100 mg/kg Drug a once daily, Nonrecovery	24	TRTDOSU	Dose Units	mg/kg/day
25	TDM1	TX	2NR	Low-Dose Group, 100 mg/kg Drug a once daily, Nonrecovery	25	PLANMSUB	Planned Number of Male Subjects	5
26	TDM1	TX	2NR	Low-Dose Group, 100 mg/kg Drug a once daily, Nonrecovery	26	PLANFSUB	Planned Number of Female Subjects	5
27	TDM1	TX	2R	Low-Dose Group, 100 mg/kg Drug a once daily, Recovery	27	ARMCD	Arm Code	02R
28	TDM1	TX	2R	Low-Dose Group, 100 mg/kg Drug a once daily, Recovery	28	SPGRPCD	Applicant-Defined Group Code	2
29	TDM1	TX	2R	Low-Dose Group, 100 mg/kg Drug a once daily, Recovery	29	GRPLBL	Group Label	Group 2, 100 mg/kg
30	TDM1	TX	2R	Low-Dose Group, 100 mg/kg Drug a once daily, Recovery	30	SETLBL	Set Label	Group 2, 100 mg/kg - Rec
31	TDM1	TX	2R	Low-Dose Group, 100 mg/kg Drug a once daily, Recovery	31	TRTDOS	Dose Level	100
32	TDM1	TX	2R	Low-Dose Group, 100 mg/kg Drug a once daily, Recovery	32	TRTDOSU	Dose Units	mg/kg/day
33	TDM1	TX	2R	Low-Dose Group, 100 mg/kg Drug a once daily, Recovery	33	PLANMSUB	Planned Number of Male Subjects	5
34	TDM1	TX	2R	Low-Dose Group, 100 mg/kg Drug a once daily, Recovery	34	PLANFSUB	Planned Number of Female Subjects	5
35	TDM1	TX	3NR	High-Dose Group, 500 mg/kg Drug a once daily, Nonrecovery	35	ARMCD	Arm Code	03
36	TDM1	TX	3NR	High-Dose Group, 500 mg/kg Drug a once daily, Nonrecovery	36	SPGRPCD	Applicant-Defined Group Code	3
37	TDM1	TX	3NR	High-Dose Group, 500 mg/kg Drug a once daily, Nonrecovery	37	GRPLBL	Group Label	Group 3, 500 mg/kg
38	TDM1	TX	3NR	High-Dose Group, 500 mg/kg Drug a once daily, Nonrecovery	38	SETLBL	Set Label	Group 3, 500 mg/kg - Nonrec

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
39	TDM1	TX	3NR	High-Dose Group, 500 mg/kg Drug a once daily, Nonrecovery	39	TRTDOS	Dose Level	500
40	TDM1	TX	3NR	High-Dose Group, 500 mg/kg Drug a once daily, Nonrecovery	40	TRTDOSU	Dose Units	mg/kg/day
41	TDM1	TX	3NR	High-Dose Group, 500 mg/kg Drug a once daily, Nonrecovery	41	PLANMSUB	Planned Number of Male Subjects	5
42	TDM1	TX	3NR	High-Dose Group, 500 mg/kg Drug a once daily, Nonrecovery	42	PLANFSUB	Planned Number of Female Subjects	5
43	TDM1	TX	3R	High-Dose Group, 500 mg/kg Drug a once daily, Recovery	43	ARMCD	Arm Code	03R
44	TDM1	TX	3R	High-Dose Group, 500 mg/kg Drug a once daily, Recovery	44	SPGRPCD	Applicant-Defined Group Code	3
45	TDM1	TX	3R	High-Dose Group, 500 mg/kg Drug a once daily, Recovery	45	GRPLBL	Group Label	Group 3, 500 mg/kg
46	TDM1	TX	3R	High-Dose Group, 500 mg/kg Drug a once daily, Recovery	46	SETLBL	Set Label	Group 3, 500 mg/kg - Rec
47	TDM1	TX	3R	High-Dose Group, 500 mg/kg Drug a once daily, Recovery	47	TRTDOS	Dose Level	500
48	TDM1	TX	3R	High-Dose Group, 500 mg/kg Drug a once daily, Recovery	48	TRTDOSU	Dose Units	mg/kg/day
49	TDM1	TX	3R	High-Dose Group, 500 mg/kg Drug a once daily, Recovery	49	PLANMSUB	Planned Number of Male Subjects	5
50	TDM1	TX	3R	High-Dose Group, 500 mg/kg Drug a once daily, Recovery	50	PLANFSUB	Planned Number of Female Subjects	5

3.2.1.5.2 In Vivo Study With Tk Subjects in Separate Protocol Groups

This example assumes a design in which the applicant-defined protocol specifies the following information. All subjects are to be screened for 7 days prior to randomization into 6 protocol groups:

- Group 1 is a control group of 20 subjects, 10 male and 10 female, dosed with vehicle once per day for 28 days.
- Group 2 is a low-dose group of 20 subjects, 10 male and 10 female, dosed at 100 mg/kg with compound A once per day for 14 days and 100 mg/kg with compound B once per day for 14 days.
- Group 3 is a high-dose group of 20 subjects, 10 male and 10 female, dosed at 500 mg/kg with compound A once per day for 14 days and 500 mg/kg with compound B once per day for 14 days.
- Group 4 is a control group of 6 subjects, 3 male and 3 female, dosed with vehicle once per day for 28 days. This group will be subjected to blood sampling for the purpose of TK analysis, with samples taken on days 14, 21, and 28.
- Group 5 is a low-dose group of 6 subjects, 3 male and 3 female, dosed at 100 mg/kg with compound A once per day for 14 days and 100 mg/kg with compound B once per day for 14 days. This group will be subjected to blood sampling for the purpose of toxicokinetic (TK) analysis, with samples taken on days 14, 21, and 28.
- Group 6 is a high-dose group of 6 subjects, 3 male and 3 female, dosed at 500 mg/kg with compound A once per day for 14 days and 500 mg/kg with compound B once per day for 14 days. This group will be subjected to blood sampling for the purpose of TK analysis, with samples taken on days 14, 21, and 28.

Group Number	Group Label	Dose Level	Number of Animals (both sexes combined)	
			Non-Toxicokinetic	Toxicokinetic
1	Group 1, Control	Vehicle Control	20	-
2	Group 2, 100 mg/kg A, B	100 mg/kg/day A, B	20	-
3	Group 3, 500 mg/kg A, B	500 mg/kg/day A, B	20	-
4	Group 4, Control	Vehicle Control	-	6
5	Group 5, 100 mg/kg A, B	100 mg/kg/day A, B	-	6
6	Group 6, 500 mg/kg A, B	500 mg/kg/day A, B	-	6

There are no other experimental factors of interest specified in the study design.

Figure. Example Trial 3 Design

<u>ARMCD</u>	<u>Screen</u>	<u>Treatment</u>	<u>SETCD</u>	<u>SPGRPCD</u>
1	Screen	Control	1	1
	Screen	Control	4	4
2	Screen	100 mg/kg Drug A	2	2
	Screen	100 mg/kg Drug A	5	5
3	Screen	500 mg/kg Drug A	3	3
	Screen	500 mg/kg Drug A	6	6

Trial Elements

The TK blood collection has no effect on the structure of the dosing elements.

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	TDM3	TE	SCRN	Screen	Start of Preexposure	1 week after start of Element	P7D
2	TDM3	TE	TRT01	Vehicle Control	First day of dosing with vehicle control	28 days after start of Element	P28D
3	TDM3	TE	TRT02A	100 mg/kg Compound A, once daily	First day of dosing with 100 mg/kg Compound A	14 days after start of Element	P14D
4	TDM3	TE	TRT02B	100 mg/kg Compound B, once daily	First day of dosing with 100 mg/kg Compound B	14 days after start of Element	P14D
5	TDM3	TE	TRT03A	500 mg/kg Compound A, once daily	First day of dosing with 500 mg/kg Compound A	14 days after start of Element	P14D
6	TDM3	TE	TRT03B	500 mg/kg Compound B, once daily	First day of dosing with 500 mg/kg Compound B	14 days after start of Element	P14D

Trial Arms

There are 3 trial arms on this study. The fact that some subjects are being selected for blood sampling is an experimental factor that is separate from the dosing; see the TS example. The applicant-defined protocol group numbering is also not addressed in the TA domain. Therefore, the TA dataset for this design is similar to that for Example 1, although the "branching" rule differs, due to the randomization procedure employed. In this case, the applicant considers all exposure elements for the study to be part of a single exposure epoch.

ta.xpt

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	EPOCH
1	TDM3	TA	1	Control	1	SCRN	Screen	Randomized to Group 1 or Group 4	PRE-EXPOSURE
2	TDM3	TA	1	Control	2	TRT01	Vehicle Control		EXPOSURE
3	TDM3	TA	2	100 mg/kg	1	SCRN	Screen	Randomized to Group 2 or Group 5	PRE-EXPOSURE
4	TDM3	TA	2	100 mg/kg	2	TRT02A	100 mg/kg Compound A, once daily		EXPOSURE
5	TDM3	TA	2	100 mg/kg	3	TRT02B	100 mg/kg Compound B, once daily		EXPOSURE
6	TDM3	TA	3	500 mg/kg	1	SCRN	Screen	Randomized to Group 3 or Group 5	PRE-EXPOSURE
7	TDM3	TA	3	500 mg/kg	2	TRT03A	500 mg/kg Compound A, once daily		EXPOSURE
8	TDM3	TA	3	500 mg/kg	3	TRT03B	500 mg/kg Compound B, once daily		EXPOSURE

Trial Sets

In this case, there are 6 trial sets, corresponding to the following experimental factors: dosing level (3 separate dose levels) and whether the subjects will be used for TK analysis.

The applicant has chosen to provide the associated arm code, applicant-defined group code, group label, set label, dose level and units, control type, toxicokinetic description, and planned number of males and females for each set.

tx.xpt

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
1	TDM3	TX	1	Control Group, Vehicle Control, once daily	1	ARMCD	Arm Code	1
2	TDM3	TX	1	Control Group, Vehicle Control, once daily	2	SPGRPCD	Applicant-Defined Group Code	1
3	TDM3	TX	1	Control Group, Vehicle Control, once daily	3	GRPLBL	Group Label	Group 1, Control
4	TDM3	TX	1	Control Group, Vehicle Control, once daily	4	SETLBL	Set Label	Group 1, Control
5	TDM3	TX	1	Control Group, Vehicle Control, once daily	5	TRTDOS	Dose Level	0
6	TDM3	TX	1	Control Group, Vehicle Control, once daily	6	TRTDOSU	Dose Units	mg/kg/day
7	TDM3	TX	1	Control Group, Vehicle Control, once daily	7	TCNTRL	Control Type	VEHICLE CONTROL
8	TDM3	TX	1	Control Group, Vehicle Control, once daily	8	TKDESC	Toxicokinetic Description	NON-TK
9	TDM3	TX	1	Control Group, Vehicle Control, once daily	9	PLANMSUB	Planned Number of Male Subjects	10
10	TDM3	TX	1	Control Group, Vehicle Control, once daily	10	PLANFSUB	Planned Number of Female Subjects	10
11	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	11	ARMCD	Arm Code	2
12	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	12	SPGRPCD	Applicant-Defined Group Code	2
13	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	13	GRPLBL	Group Label	Group 2, 100 mg/kg A, B
14	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	14	SETLBL	Set Label	Group 2, 100 mg/kg/day
15	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	15	TRTDOS	Dose Level	100
16	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	16	TRTDOSU	Dose Units	mg/kg/day
17	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	17	TKDESC	Toxicokinetic Description	NON-TK
18	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	18	PLANMSUB	Planned Number of Male Subjects	10
19	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	19	PLANFSUB	Planned Number of Female Subjects	10
20	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	20	ARMCD	Arm Code	3
21	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	21	SPGRPCD	Applicant-Defined Group Code	3
22	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	22	GRPLBL	Group Label	Group 3, 500 mg/kg A, B
23	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	23	SETLBL	Set Label	Group 3, 500 mg/kg/day
24	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	24	TRTDOS	Dose Level	500
25	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	25	TRTDOSU	Dose Units	mg/kg/day
26	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	26	TKDESC	Toxicokinetic Description	NON-TK
27	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	27	PLANMSUB	Planned Number of Male Subjects	10
28	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	28	PLANFSUB	Planned Number of Female Subjects	10
29	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	29	ARMCD	Arm Code	1
30	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	30	SPGRPCD	Applicant-Defined Group Code	4
31	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	31	GRPLBL	Group Label	Group 4, Control
32	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	32	SETLBL	Set Label	Group 4, Control - TK
33	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	33	TRTDOS	Dose Level	0
34	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	34	TRTDOSU	Dose Units	mg/kg/day
35	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	35	TCNTRL	Control Type	VEHICLE CONTROL
36	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	36	TKDESC	Toxicokinetic Description	TK
37	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	37	PLANMSUB	Planned Number of Male Subjects	3
38	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	38	PLANFSUB	Planned Number of Female Subjects	3
39	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	39	ARMCD	Arm Code	2
40	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	40	SPGRPCD	Applicant-Defined Group Code	5
41	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	41	GRPLBL	Group Label	Group 5, 100 mg/kg A, B
42	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	42	SETLBL	Set Label	Group 5, 100 mg/kg/day - TK
43	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	43	TRTDOS	Dose Level	100
44	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	44	TRTDOSU	Dose Units	mg/kg/day

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
44	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	45	TKDESC	Toxicokinetic Description	TK
45	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	46	PLANMSUB	Planned Number of Male Subjects	3
46	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	47	PLANFSUB	Planned Number of Female Subjects	3
47	TDM3	TX	6	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily, TK	48	ARMCD	Arm Code	3
48	TDM3	TX	6	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily, TK	49	SPGRPCD	Applicant-Defined Group Code	6
49	TDM3	TX	6	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily, TK	50	GRPLBL	Group Label	Group 6, 500 mg/kg A, B
50	TDM3	TX	6	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily, TK	51	SETLBL	Set Label	Group 6, 500 mg/kg/day - TK
51	TDM3	TX	6	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily, TK	52	TRTDOS	Dose Level	500
52	TDM3	TX	6	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily, TK	53	TRTDOSU	Dose Units	mg/kg/day
53	TDM3	TX	6	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily, TK	54	TKDESC	Toxicokinetic Description	TK
54	TDM3	TX	6	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily, TK	55	PLANMSUB	Planned Number of Male Subjects	3
55	TDM3	TX	6	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily, TK	56	PLANFSUB	Planned Number of Female Subjects	3

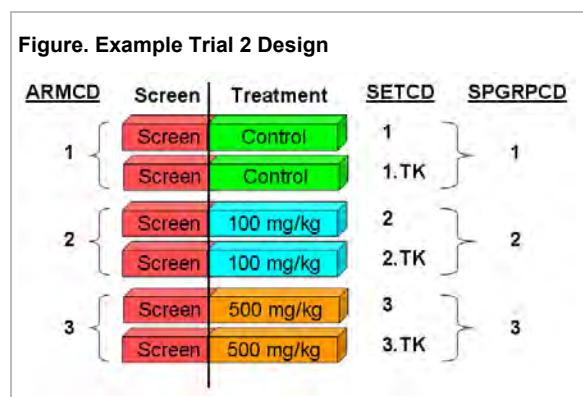
3.2.1.5.3 In Vivo Study With TK Subjects Within Same Protocol Group and Scheduled Necropsy

This example assumes a design in which the applicant-defined protocol specifies the following information. All subjects are to be screened for 7 days prior to randomization into 3 protocol groups:

- Group 1 is a control group of 20 subjects, 10 male and 10 female, dosed with vehicle once per day for 28 to 30 days. Three subjects of each sex will be subject to blood sampling for the purpose of toxicokinetic (TK) analysis and all remaining animals will be scheduled for necropsy.
- Group 2 is a low-dose group of 20 subjects, 10 male and 10 female, dosed at 100 mg/kg once per day for 28 to 30 days. Three subjects of each sex will be subject to blood sampling for the purpose of TK analysis and all remaining animals will be scheduled for necropsy.
- Group 3 is a high-dose group of 20 subjects, 10 male and 10 female, dosed at 500 mg/kg once per day for 28 to 30 days. Three subjects of each sex will be subject to blood sampling for the purpose of TK analysis and all remaining animals will be scheduled for necropsy.

Group Number	Group Label	Dose Level	Number of Animals (Both Sexes Combined)	
			Non-Toxicokinetic	Toxicokinetic
1	Group 1, Control	Vehicle Control	14	6
2	Group 2, 100 mg/kg	100 mg/kg/day	14	6
3	Group 3, 500 mg/kg	500 mg/kg/day	14	6

There are no other experimental factors of interest specified in the study design. In this case the design consists of 3 trial arms, depicted in the following figure.



Trial Elements

In this study, dosing started on one date and the necropsy is scheduled, for an individual animal, after 28 to 30 days of dosing. The necropsy for a subset of animals per exposure group per day will be staggered over a 3-day period.

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	TDM2	TE	SCRN	Screen	Start of Pre-exposure	1 week after start of Element	P7D
2	TDM2	TE	TRT01	Vehicle Control	First day of dosing with vehicle control	Date of necropsy: 28 to 30 days after start of Element	
3	TDM2	TE	TRT02	100 mg/kg Drug A, once daily	First day of dosing with 100 mg/kg Drug A	Date of necropsy: 28 to 30 days after start of Element	
4	TDM2	TE	TRT03	500 mg/kg Drug A, once daily	First day of dosing with 500 mg/kg Drug A	Date of necropsy: 28 to 30 days after start of Element	

Trial Arms

There are 3 trial arms in this study. The fact that some subjects are being selected for blood sampling is an experimental factor that is separate from the dosing being received; this is described in the TS example.

ta.xpt

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	EPOCH
1	TDM2	TA	1	Control	1	SCRN	Screen	Randomized to Group 1	PRE-EXPOSURE
2	TDM2	TA	1	Control	2	TRT01	Vehicle Control		EXPOSURE
3	TDM2	TA	2	100 mg/kg	1	SCRN	Screen	Randomized to Group 2	PRE-EXPOSURE
4	TDM2	TA	2	100 mg/kg	2	TRT02	100 mg/kg Drug A		EXPOSURE
5	TDM2	TA	3	500 mg/kg	1	SCRN	Screen	Randomized to Group 3	PRE-EXPOSURE
6	TDM2	TA	3	500 mg/kg	2	TRT03	500 mg/kg Drug A		EXPOSURE

Trial Sets

Assuming that the protocol also specifies that subjects with blood sampling for TK analysis are experimentally distinct, the factors of interest are the dosing levels and whether the subject is sampled for TK analysis; this leads to 6 trial sets.

The applicant has chosen to provide the associated arm code, applicant-defined group code, group label, set label, dose level and units, control type, whether the trial set is being sampled for TK analysis, and planned number of males and females for each set.

tx.xpt

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
1	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	1	ARMCD	Arm Code	1
2	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	2	SPGRPCD	Applicant-Defined Group Code	1
3	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	3	GRPLBL	Group Label	Group 1, Control
4	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	4	SETLBL	Set Label	Group 1, Control
5	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	5	TRTDOS	Dose Level	0
6	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	6	TRTDOSU	Dose Units	mg/kg/day
7	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	7	TCNTRL	Control Type	VEHICLE CONTROL
8	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	8	TKDESC	Toxicokinetic Description	NON-TK
9	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	9	PLANMSUB	Planned Number of Male Subjects	7
10	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	10	PLANFSUB	Planned Number of Female Subjects	7
11	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	11	ARMCD	Arm Code	1
12	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	12	SPGRPCD	Applicant-Defined Group Code	1
13	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	13	GRPLBL	Group Label	Group 1, Control
14	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	14	SETLBL	Set Label	Group 1, Control - TK
15	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	15	TRTDOS	Dose Level	0
16	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	16	TRTDOSU	Dose Units	mg/kg/day
17	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	17	TCNTRL	Control Type	VEHICLE CONTROL
18	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	18	TKDESC	Toxicokinetic Description	TK

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
19	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	19	PLANMSUB	Planned Number of Male Subjects	3
20	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	20	PLANFSUB	Planned Number of Female Subjects	3
21	TDM2	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily, Non-TK	21	ARMCD	Arm Code	2
22	TDM2	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily, Non-TK	22	SPGRPCD	Applicant-Defined Group Code	2
23	TDM2	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily, Non-TK	23	GRPLBL	Group Label	Group 2, 100 mg/kg/day
24	TDM2	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily, Non-TK	24	SETLBL	Set Label	Group 2, 100 mg/kg/day
25	TDM2	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily, Non-TK	25	TRTDOS	Dose Level	100
26	TDM2	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily, Non-TK	26	TRTDOSU	Dose Units	mg/kg/day
27	TDM2	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily, Non-TK	27	TKDESC	Toxicokinetic Description	NON-TK
28	TDM2	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily, Non-TK	28	PLANMSUB	Planned Number of Male Subjects	7
29	TDM2	TX	2	Low-Dose Group, 100 mg/kg Drug a once daily, Non-TK	29	PLANFSUB	Planned Number of Female Subjects	7
30	TDM2	TX	2.TK	Low-Dose Group, 100 mg/kg Drug a once daily, TK	30	ARMCD	Arm Code	2
31	TDM2	TX	2.TK	Low-Dose Group, 100 mg/kg Drug a once daily, TK	31	SPGRPCD	Applicant-Defined Group Code	2
32	TDM2	TX	2.TK	Low-Dose Group, 100 mg/kg Drug a once daily, TK	32	GRPLBL	Group Label	Group 2, 100 mg/kg/day
33	TDM2	TX	2.TK	Low-Dose Group, 100 mg/kg Drug a once daily, TK	33	SETLBL	Set Label	Group 2, 100 mg/kg/day - TK
34	TDM2	TX	2.TK	Low-Dose Group, 100 mg/kg Drug a once daily, TK	34	TRTDOS	Dose Level	100
35	TDM2	TX	2.TK	Low-Dose Group, 100 mg/kg Drug a once daily, TK	35	TRTDOSU	Dose Units	mg/kg/day
36	TDM2	TX	2.TK	Low-Dose Group, 100 mg/kg Drug a once daily, TK	36	TKDESC	Toxicokinetic Description	TK
37	TDM2	TX	2.TK	Low-Dose Group, 100 mg/kg Drug a once daily, TK	37	PLANMSUB	Planned Number of Male Subjects	3
38	TDM2	TX	2.TK	Low-Dose Group, 100 mg/kg Drug a once daily, TK	38	PLANFSUB	Planned Number of Female Subjects	3
39	TDM2	TX	3	High-Dose Group, 500 mg/kg Drug a once daily, Non-TK	39	ARMCD	Arm Code	3
40	TDM2	TX	3	High-Dose Group, 500 mg/kg Drug a once daily, Non-TK	40	SPGRPCD	Applicant-Defined Group Code	3
41	TDM2	TX	3	High-Dose Group, 500 mg/kg Drug a once daily, Non-TK	41	GRPLBL	Group Label	Group 3, 500 mg/kg/day
42	TDM2	TX	3	High-Dose Group, 500 mg/kg Drug a once daily, Non-TK	42	SETLBL	Set Label	Group 3, 500 mg/kg/day
43	TDM2	TX	3	High-Dose Group, 500 mg/kg Drug a once daily, Non-TK	43	TRTDOS	Dose Level	500
44	TDM2	TX	3	High-Dose Group, 500 mg/kg Drug a once daily, Non-TK	44	TRTDOSU	Dose Units	mg/kg/day
45	TDM2	TX	3	High-Dose Group, 500 mg/kg Drug a once daily, Non-TK	45	TKDESC	Toxicokinetic Description	NON-TK
46	TDM2	TX	3	High-Dose Group, 500 mg/kg Drug a once daily, Non-TK	46	PLANMSUB	Planned Number of Male Subjects	7
47	TDM2	TX	3	High-Dose Group, 500 mg/kg Drug a once daily, Non-TK	47	PLANFSUB	Planned Number of Female Subjects	7
48	TDM2	TX	3.TK	High-Dose Group, 500 mg/kg Drug a once daily, TK	48	ARMCD	Arm Code	3
49	TDM2	TX	3.TK	High-Dose Group, 500 mg/kg Drug a once daily, TK	49	SPGRPCD	Applicant-Defined Group Code	3
50	TDM2	TX	3.TK	High-Dose Group, 500 mg/kg Drug a once daily, TK	50	GRPLBL	Group Label	Group 3, 500 mg/kg/day
51	TDM2	TX	3.TK	High-Dose Group, 500 mg/kg Drug a once daily, TK	51	SETLBL	Set Label	Group 3, 500 mg/kg/day - TK
52	TDM2	TX	3.TK	High-Dose Group, 500 mg/kg Drug a once daily, TK	52	TRTDOS	Dose Level	500
53	TDM2	TX	3.TK	High-Dose Group, 500 mg/kg Drug a once daily, TK	53	TRTDOSU	Dose Units	mg/kg/day
54	TDM2	TX	3.TK	High-Dose Group, 500 mg/kg Drug a once daily, TK	54	TKDESC	Toxicokinetic Description	TK
55	TDM2	TX	3.TK	High-Dose Group, 500 mg/kg Drug a once daily, TK	55	PLANMSUB	Planned Number of Male Subjects	3
56	TDM2	TX	3.TK	High-Dose Group, 500 mg/kg Drug a once daily, TK	56	PLANFSUB	Planned Number of Female Subjects	3

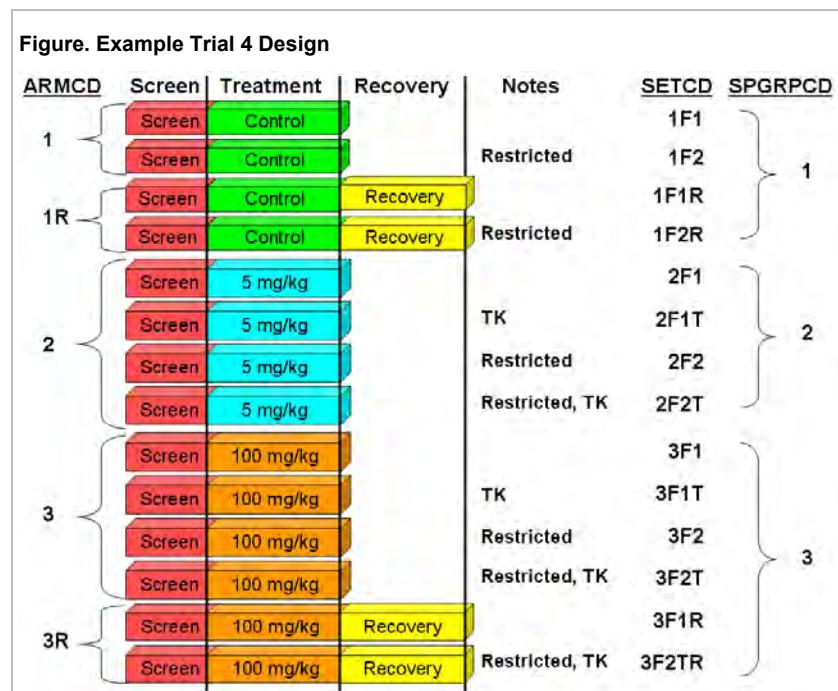
3.2.1.5.4 In Vivo Study With Multiple Experimental Factors

The example depicts a complex multifactorial trial design. The applicant-defined protocol specifies the following information: All subjects are to be screened for 7 days prior to randomization into 3 protocol groups:

- Group 1 is a control group of 40 subjects, 20 male and 20 female, dosed with vehicle once per day for 30 days. Of this group, 10 males and 10 females will be fed ad libitum, while the remainder will be subject to a restricted diet. Half of the subjects will be terminated after 30 days, while the other half will be subject to a 14-day recovery period; the subjects selected for recovery will be divided equally among animals fed ad libitum and those subject to restricted feeding (i.e., 5 males and 5 females with ad libitum feeding will move to recovery, and 5 males and 5 females with restricted diet will also move to recovery).
- Group 2 is a low-dose group of 40 subjects, 20 male and 20 female, dosed at 5 mg/kg once per day for 30 days. Of this group, 10 males and 10 females will be fed ad libitum, while the remainder will be subject to a restricted diet. Three subjects of each sex and feeding pattern will be subject to blood sampling for the purpose of TK analysis (i.e., 3 males and 3 females from those fed ad libitum and 3 males and 3 females from those receiving a restricted diet)
- Group 3 is a high-dose group of 40 subjects, 20 male and 20 female, dosed at 100 mg/kg once per day for 30 days. Of this group, 10 males and 10 females will be fed ad libitum, while the remainder will be subject to a restricted diet. Of those subjects fed ad libitum, 3 males and 3 females will be subject to blood sampling for the purpose of TK analysis and terminated on day 30; 3 males and 3 females (other than those selected for TK analysis) will be subject to a 14-day recovery period, and the remaining subjects will be terminated on day 30. Of the subjects given a restricted diet, 6 males and 6 females will be subject to blood sampling for the purpose of TK analysis; half of these subjects will be terminated on day 30 while the others are subject to a 14-day recovery period before termination. The balance of the subjects receiving a restricted diet will be terminated at the end of the dosing period (day 30).

Group Number	Group Label	Dose Level	Number of Animals (Both Sexes Combined)							
			Fed Ad Libitum				Restricted Feeding			
			Non-toxicokinetic		Toxicokinetic		Non-toxicokinetic		Toxicokinetic	
			Nonrecovery	Recovery	Nonrecovery	Recovery	Nonrecovery	Recovery	Nonrecovery	Recovery
1	Group 1, Control	Vehicle Control	10	10	0	0	10	10	0	0
2	Group 2, 5 mg/kg	5 mg/kg/day	14	0	6	0	14	0	6	0
3	Group 3, 100 mg/kg	100 mg/kg/day	8	6	6	0	8	0	6	6

There are no other experimental factors of interest specified in the study design.



Trial Elements

The variety of feeding and TK analysis factors do not affect the TE dataset, which deals only with dosing. The fact that only some of the dosing elements are combined with the recovery element is only captured in the TA dataset.

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	TDM4	TE	SCRN	Screen	Start of screening period	7 days after start of Element	P7D
2	TDM4	TE	CONTROL	Control	At completion of SCRN Element	30 days after start of Element	P30D
3	TDM4	TE	T5	5 mg/kg Drug A	At completion of SCRN Element	30 days after start of Element	P30D
4	TDM4	TE	T100	100 mg/kg Drug A	At completion of SCRN Element	30 days after start of Element	P30D
5	TDM4	TE	RECO	Recovery	1 day after last dose with product or vehicle control	14 days after start of Element	P14D

Trial Arms

Despite the complex description in the study protocol, there are only 5 trial arms in this study. All subjects experience a screening element. Based upon the result of randomization, they then receive 1 of 3 different exposure levels; some of the subjects receiving the vehicle control or the high dose are subject to a recovery period post-exposure. This can be depicted as follows.

ta.xpt

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	EPOCH
1	TDM4	TA	1	Control	1	SCRN	Screen	Randomized to Group 1	PRE-EXPOSURE
2	TDM4	TA	1	Control	2	CONTROL	Control		EXPOSURE
3	TDM4	TA	1R	Control + Recovery	1	SCRN	Screen	Randomized to Group 1 with Recovery	PRE-EXPOSURE
4	TDM4	TA	1R	Control + Recovery	2	CONTROL	Control		EXPOSURE
5	TDM4	TA	1R	Control + Recovery	3	RECO	Recovery		RECOVERY
6	TDM4	TA	2	Low Dose	1	SCRN	Screen	Randomized to Group 2	PRE-EXPOSURE
7	TDM4	TA	2	Low Dose	2	T5	5 mg/kg Drug A		EXPOSURE
8	TDM4	TA	3	High Dose	1	SCRN	Screen	Randomized to Group 3	PRE-EXPOSURE
9	TDM4	TA	3	High Dose	2	T100	100 mg/kg Drug A		EXPOSURE
10	TDM4	TA	3R	High Dose + Recovery	1	SCRN	Screen	Randomized to Group 3 with Recovery	PRE-EXPOSURE
11	TDM4	TA	3R	High Dose + Recovery	2	T100	100 mg/kg Drug A		EXPOSURE
12	TDM4	TA	3R	High Dose + Recovery	3	RECO	Recovery		RECOVERY

Trial Sets

In this study there are multiple experimental factors of interest: the dosing level given during the exposure epoch (3 levels), the feeding regimen of the subjects (ad libitum vs. restricted feeding), whether the subjects are to be used for TK analysis, and whether the subjects will be terminated at the end of the dosing period or experience a recovery period. The combination of these factors ($3 \times 2 \times 2 \times 2$) could lead to up to 24 possible combinations or sets; however, upon careful reading of the description there are 14 sets that will actually be part of the study:

1. Vehicle Control + Fed Ad Libitum + No Recovery + No TK analysis
2. Vehicle Control + Restricted Feeding + No Recovery + No TK analysis
3. Vehicle Control + Fed Ad Libitum + Recovery + No TK analysis
4. Vehicle Control + Restricted Feeding + Recovery + No TK analysis
5. Low Dose + Fed Ad Libitum + No Recovery + No TK analysis
6. Low Dose + Restricted Feeding + No Recovery + No TK analysis
7. Low Dose + Fed Ad Libitum + No Recovery + TK analysis
8. Low Dose + Restricted Feeding + No Recovery + TK analysis
9. High Dose + Fed Ad Libitum + No Recovery + No TK analysis
10. High Dose + Fed Ad Libitum + Recovery + No TK analysis
11. High Dose + Fed Ad Libitum + No Recovery + TK analysis
12. High Dose + Restricted Feeding + No Recovery + TK analysis

13. High Dose + Restricted Feeding + Recovery + TK analysis

14. High Dose + Restricted Feeding + No Recovery + No TK analysis

This can be represented in the TS domain as follows. The applicant is providing the following information for each set: arm code, applicant-defined group code, group label, dose level and units, control type, feeding regimen, toxicokinetic description, and planned number of subjects (not broken out by sex).

tx.xpt

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
1	TDM4	TX	1F1	Control Group, Control Article Name once daily, Fed Ad Libitum	1	ARMCD	Arm Code	1
2	TDM4	TX	1F1	Control Group, Control Article Name once daily, Fed Ad Libitum	2	SPGRPCD	Applicant-Defined Group Code	1
3	TDM4	TX	1F1	Control Group, Control Article Name once daily, Fed Ad Libitum	3	GRPLBL	Group Label	Group 1, Control
4	TDM4	TX	1F1	Control Group, Control Article Name once daily, Fed Ad Libitum	4	TRTDOS	Dose Level	0
5	TDM4	TX	1F1	Control Group, Control Article Name once daily, Fed Ad Libitum	5	TRTDOSU	Dose Units	mg/kg/day
6	TDM4	TX	1F1	Control Group, Control Article Name once daily, Fed Ad Libitum	6	TCNTRL	Control Type	VEHICLE CONTROL
7	TDM4	TX	1F1	Control Group, Control Article Name once daily, Fed Ad Libitum	7	FEEDREG	Feeding Regimen	Ad Libitum
8	TDM4	TX	1F1	Control Group, Control Article Name once daily, Fed Ad Libitum	8	TKDESC	Toxicokinetic Description	NON-TK
9	TDM4	TX	1F1	Control Group, Control Article Name once daily, Fed Ad Libitum	9	SPLANSUB	Planned Number of Subjects	10
10	TDM4	TX	1F1R	Control Group, Control Article Name once daily, Fed Ad Libitum, Recovery animals	10	ARMCD	Arm Code	1R
11	TDM4	TX	1F1R	Control Group, Control Article Name once daily, Fed Ad Libitum, Recovery animals	11	SPGRPCD	Applicant-Defined Group Code	1
12	TDM4	TX	1F1R	Control Group, Control Article Name once daily, Fed Ad Libitum, Recovery animals	12	GRPLBL	Group Label	Group 1, Control
13	TDM4	TX	1F1R	Control Group, Control Article Name once daily, Fed Ad Libitum, Recovery animals	13	TRTDOS	Dose Level	0
14	TDM4	TX	1F1R	Control Group, Control Article Name once daily, Fed Ad Libitum, Recovery animals	14	TRTDOSU	Dose Units	mg/kg/day
15	TDM4	TX	1F1R	Control Group, Control Article Name once daily, Fed Ad Libitum, Recovery animals	15	TCNTRL	Control Type	VEHICLE CONTROL
16	TDM4	TX	1F1R	Control Group, Control Article Name once daily, Fed Ad Libitum, Recovery animals	16	FEEDREG	Feeding Regimen	Ad Libitum
17	TDM4	TX	1F1R	Control Group, Control Article Name once daily, Fed Ad Libitum, Recovery animals	17	TKDESC	Toxicokinetic Description	NON-TK
18	TDM4	TX	1F1R	Control Group, Control Article Name once daily, Fed Ad Libitum, Recovery animals	18	SPLANSUB	Planned Number of Subjects	10
19	TDM4	TX	1F2	Control Group, Control Article Name once daily, Restricted Diet	19	ARMCD	Arm Code	1
20	TDM4	TX	1F2	Control Group, Control Article Name once daily, Restricted Diet	20	SPGRPCD	Applicant-Defined Group Code	1
21	TDM4	TX	1F2	Control Group, Control Article Name once daily, Restricted Diet	21	GRPLBL	Group Label	Group 1, Control
22	TDM4	TX	1F2	Control Group, Control Article Name once daily, Restricted Diet	22	TRTDOS	Dose Level	0
23	TDM4	TX	1F2	Control Group, Control Article Name once daily, Restricted Diet	23	TRTDOSU	Dose Units	mg/kg/day
24	TDM4	TX	1F2	Control Group, Control Article Name once daily, Restricted Diet	24	TCNTRL	Control Type	VEHICLE CONTROL
25	TDM4	TX	1F2	Control Group, Control Article Name once daily, Restricted Diet	25	FEEDREG	Feeding Regimen	Restricted Diet (50g/animal/day)
26	TDM4	TX	1F2	Control Group, Control Article Name once daily, Restricted Diet	26	TKDESC	Toxicokinetic Description	NON-TK
27	TDM4	TX	1F2	Control Group, Control Article Name once daily, Restricted Diet	27	SPLANSUB	Planned Number of Subjects	10
28	TDM4	TX	1F2R	Control Group, Control Article Name once daily, Restricted Diet, Recovery animals	28	ARMCD	Arm Code	1R
29	TDM4	TX	1F2R	Control Group, Control Article Name once daily, Restricted Diet, Recovery animals	29	SPGRPCD	Applicant-Defined Group Code	1
30	TDM4	TX	1F2R	Control Group, Control Article Name once daily, Restricted Diet, Recovery animals	30	GRPLBL	Group Label	Group 1, Control
31	TDM4	TX	1F2R	Control Group, Control Article Name once daily, Restricted Diet, Recovery animals	31	TRTDOS	Dose Level	0
32	TDM4	TX	1F2R	Control Group, Control Article Name once daily, Restricted Diet, Recovery animals	32	TRTDOSU	Dose Units	mg/kg/day
33	TDM4	TX	1F2R	Control Group, Control Article Name once daily, Restricted Diet, Recovery animals	33	TCNTRL	Control Type	VEHICLE CONTROL
34	TDM4	TX	1F2R	Control Group, Control Article Name once daily, Restricted Diet, Recovery animals	34	FEEDREG	Feeding Regimen	Restricted Diet (50g/animal/day)
35	TDM4	TX	1F2R	Control Group, Control Article Name once daily, Restricted Diet, Recovery animals	35	TKDESC	Toxicokinetic Description	NON-TK

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
36	TDM4	TX	1F2R	Control Group, Control Article Name once daily, Restricted Diet, Recovery animals	36	SPLANSUB	Planned Number of Subjects	10
37	TDM4	TX	2F1	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum	37	ARMCD	Arm Code	2
38	TDM4	TX	2F1	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum	38	SPGRPCD	Applicant-Defined Group Code	2
39	TDM4	TX	2F1	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum	39	GRPLBL	Group Label	Group 2, 5 mg/kg/day
40	TDM4	TX	2F1	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum	40	TRTDOS	Dose Level	5
41	TDM4	TX	2F1	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum	41	TRTDOSU	Dose Units	mg/kg/day
42	TDM4	TX	2F1	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum	42	FEEDREG	Feeding Regimen	Ad Libitum
43	TDM4	TX	2F1	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum	43	TKDESC	Toxicokinetic Description	NON-TK
44	TDM4	TX	2F1	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum	44	SPLANSUB	Planned Number of Subjects	14
45	TDM4	TX	2F1T	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	45	ARMCD	Arm Code	2
46	TDM4	TX	2F1T	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	46	SPGRPCD	Applicant-Defined Group Code	2
47	TDM4	TX	2F1T	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	47	GRPLBL	Group Label	Group 2, 5 mg/kg/day
48	TDM4	TX	2F1T	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	48	TRTDOS	Dose Level	5
49	TDM4	TX	2F1T	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	49	TRTDOSU	Dose Units	mg/kg/day
50	TDM4	TX	2F1T	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	50	FEEDREG	Feeding Regimen	Ad Libitum
51	TDM4	TX	2F1T	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	51	TKDESC	Toxicokinetic Description	TK
52	TDM4	TX	2F1T	Low-Dose Group, 5 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	52	SPLANSUB	Planned Number of Subjects	6
53	TDM4	TX	2F2	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet	53	ARMCD	Arm Code	2
54	TDM4	TX	2F2	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet	54	SPGRPCD	Applicant-Defined Group Code	2
55	TDM4	TX	2F2	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet	55	GRPLBL	Group Label	Group 2, 5 mg/kg/day
56	TDM4	TX	2F2	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet	56	TRTDOS	Dose Level	5
57	TDM4	TX	2F2	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet	57	TRTDOSU	Dose Units	mg/kg/day
58	TDM4	TX	2F2	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet	58	FEEDREG	Feeding Regimen	Restricted Diet (50g/animal/day)
59	TDM4	TX	2F2	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet	59	TKDESC	Toxicokinetic Description	NON-TK
60	TDM4	TX	2F2	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet	60	SPLANSUB	Planned Number of Subjects	14
61	TDM4	TX	2F2T	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet, TK animals	61	ARMCD	Arm Code	2
62	TDM4	TX	2F2T	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet, TK animals	62	SPGRPCD	Applicant-Defined Group Code	2
63	TDM4	TX	2F2T	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet, TK animals	63	GRPLBL	Group Label	Group 2, 5 mg/kg/day
64	TDM4	TX	2F2T	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet, TK animals	64	TRTDOS	Dose Level	5
65	TDM4	TX	2F2T	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet, TK animals	65	TRTDOSU	Dose Units	mg/kg/day
66	TDM4	TX	2F2T	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet, TK animals	66	FEEDREG	Feeding Regimen	Restricted Diet (50g/animal/day)
67	TDM4	TX	2F2T	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet, TK animals	67	TKDESC	Toxicokinetic Description	TK
68	TDM4	TX	2F2T	Low-Dose Group, 5 mg/kg Compound A once daily, Restricted Diet, TK animals	68	SPLANSUB	Planned Number of Subjects	6
69	TDM4	TX	3F1	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum	69	ARMCD	Arm Code	3
70	TDM4	TX	3F1	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum	70	SPGRPCD	Applicant-Defined Group Code	3
71	TDM4	TX	3F1	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum	71	GRPLBL	Group Label	Group 3, 100 mg/kg/day
72	TDM4	TX	3F1	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum	72	TRTDOS	Dose Level	100
73	TDM4	TX	3F1	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum	73	TRTDOSU	Dose Units	mg/kg/day
74	TDM4	TX	3F1	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum	74	FEEDREG	Feeding Regimen	Ad Libitum
75	TDM4	TX	3F1	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum	75	TKDESC	Toxicokinetic Description	NON-TK
76	TDM4	TX	3F1	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum	76	SPLANSUB	Planned Number of Subjects	8

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
77	TDM4	TX	3F1R	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, Recovery animals	77	ARMCD	Arm Code	3R
78	TDM4	TX	3F1R	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, Recovery animals	78	SPGRPCD	Applicant-Defined Group Code	3
79	TDM4	TX	3F1R	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, Recovery animals	79	GRPLBL	Group Label	Group 3, 100 mg/kg/day
80	TDM4	TX	3F1R	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, Recovery animals	80	TRTDOS	Dose Level	100
81	TDM4	TX	3F1R	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, Recovery animals	81	TRTDOSU	Dose Units	mg/kg/day
82	TDM4	TX	3F1R	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, Recovery animals	82	FEEDREG	Feeding Regimen	Ad Libitum
83	TDM4	TX	3F1R	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, Recovery animals	83	TKDESC	Toxicokinetic Description	NON-TK
84	TDM4	TX	3F1R	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, Recovery animals	84	SPLANSUB	Planned Number of Subjects	6
85	TDM4	TX	3F1T	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	85	ARMCD	Arm Code	3
86	TDM4	TX	3F1T	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	86	SPGRPCD	Applicant-Defined Group Code	3
87	TDM4	TX	3F1T	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	87	GRPLBL	Group Label	Group 3, 100 mg/kg/day
88	TDM4	TX	3F1T	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	88	TRTDOS	Dose Level	100
89	TDM4	TX	3F1T	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	89	TRTDOSU	Dose Units	mg/kg/day
90	TDM4	TX	3F1T	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	90	FEEDREG	Feeding Regimen	Ad Libitum
91	TDM4	TX	3F1T	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	91	TKDESC	Toxicokinetic Description	TK
92	TDM4	TX	3F1T	High-Dose Group, 100 mg/kg Compound A once daily, Fed Ad Libitum, TK animals	92	SPLANSUB	Planned Number of Subjects	6
93	TDM4	TX	3F2	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet	93	ARMCD	Arm Code	3
94	TDM4	TX	3F2	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet	94	SPGRPCD	Applicant-Defined Group Code	3
95	TDM4	TX	3F2	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet	95	GRPLBL	Group Label	Group 3, 100 mg/kg/day
96	TDM4	TX	3F2	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet	96	TRTDOS	Dose Level	100
97	TDM4	TX	3F2	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet	97	TRTDOSU	Dose Units	mg/kg/day
98	TDM4	TX	3F2	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet	98	FEEDREG	Feeding Regimen	Restricted Diet (50g/animal/day)
99	TDM4	TX	3F2	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet	99	TKDESC	Toxicokinetic Description	NON-TK
100	TDM4	TX	3F2	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet	100	SPLANSUB	Planned Number of Subjects	8
101	TDM4	TX	3F2T	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK Nonrecovery animals	101	ARMCD	Arm Code	3
102	TDM4	TX	3F2T	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK Nonrecovery animals	102	SPGRPCD	Applicant-Defined Group Code	3
103	TDM4	TX	3F2T	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK Nonrecovery animals	103	GRPLBL	Group Label	Group 3, 100 mg/kg/day
104	TDM4	TX	3F2T	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK Nonrecovery animals	104	TRTDOS	Dose Level	100
105	TDM4	TX	3F2T	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK Nonrecovery animals	105	TRTDOSU	Dose Units	mg/kg/day
106	TDM4	TX	3F2T	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK Nonrecovery animals	106	FEEDREG	Feeding Regimen	Restricted Diet (50g/animal/day)
107	TDM4	TX	3F2T	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK Nonrecovery animals	107	TKDESC	Toxicokinetic Description	TK
108	TDM4	TX	3F2T	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK Nonrecovery animals	108	SPLANSUB	Planned Number of Subjects	6
109	TDM4	TX	3F2TR	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK w/Recovery animals	109	ARMCD	Arm Code	3R
110	TDM4	TX	3F2TR	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK w/Recovery animals	110	SPGRPCD	Applicant-Defined Group Code	3
111	TDM4	TX	3F2TR	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK w/Recovery animals	111	GRPLBL	Group Label	Group 3, 100 mg/kg/day

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
112	TDM4	TX	3F2TR	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK w/Recovery animals	112	TRTDOS	Dose Level	100
113	TDM4	TX	3F2TR	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK w/Recovery animals	113	TRTDOSU	Dose Units	mg/kg/day
114	TDM4	TX	3F2TR	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK w/Recovery animals	114	FEEDREG	Feeding Regimen	Restricted Diet (50g/animal/day)
115	TDM4	TX	3F2TR	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK w/Recovery animals	115	TKDESC	Toxicokinetic Description	TK
116	TDM4	TX	3F2TR	High-Dose Group, 100 mg/kg Compound A once daily, Restricted Diet, TK w/Recovery animals	116	SPLANSUB	Planned Number of Subjects	6

3.2.1.5.5 In Vivo Crossover Design (Latin Square)

This example assumes a crossover design in which the applicant-defined protocol specifies the following information. All subjects are to be screened for 10 days prior to randomization into 4 protocol groups:

- Group 1 is a control group of 20 subjects, 10 male and 10 female, which are to be dosed with vehicle once per day for 14 days, given a 7-day rest period, dosed again with vehicle once per day for 14 days, given a second 7-day rest period, and dosed with vehicle once per day for the final 14 days.
- Group 2 is a group of 20 subjects, 10 male and 10 female, which are to be dosed at 50 mg/kg of product/intervention article once per day for 14 days, given a 7-day rest period, dosed at 800 mg/kg once per day for 14 days, given a second 7-day rest period, and dosed at 400 mg/kg of product once per day for the final 14 days.
- Group 3 is a group of 20 subjects, 10 male and 10 female, which are to be dosed at 400 mg/kg of product/intervention article once per day for 14 days, given a 7-day rest period, dosed at 50 mg/kg of product once per day for 14 days, given a second 7-day rest period, and dosed at 800 mg/kg of product once per day for the final 14 days.
- Group 4 is a group of 20 subjects, 10 male and 10 female, which are to be dosed at 800 mg/kg of product/intervention article once per day for 14 days, given a 7-day rest period, dosed at 400 mg/kg of product once per day for 14 days, given a second 7-day rest period, and dosed at 50 mg/kg of product once per day for the final 14 days.

There are no other experimental factors of interest specified in the study design.

Figure. Example Trial 5 Design							
ARMCD	Screen	Trt 1	Rest 1	Trt 2	Rest 2	Trt 3	SETCD SPGRPCD
1	Screen	Ctrl	Rest	Ctrl	Rest	Ctrl	1 1
2	Screen	50 mg/kg	Rest	800 mg/kg	Rest	400 mg/kg	2 2
3	Screen	400 mg/kg	Rest	50 mg/kg	Rest	800 mg/kg	3 3
4	Screen	800 mg/kg	Rest	400 mg/kg	Rest	50 mg/kg	4 4

Trial Elements

This example shows the start and end rules and durations for the different exposure elements, indicating whether they follow an exposure or nonexposure element.

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	TDM5	TE	SCRN	Screen	Start of Preexposure	10 days after start of Element	P10D

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
2	TDM5	TE	CONTROL	Vehicle Control	First dosing with vehicle control following a nonexposure Element	14 days after start of Element	P14D
3	TDM5	TE	REST	Rest for 7 days	1 day after last dose in an exposure Element	7 days after start of Element	P7D
4	TDM5	TE	50A	50 mg/kg Drug A, once daily	First dosing with 50 mg/kg Drug a following a nonexposure Element	14 days after start of Element	P14D
5	TDM5	TE	400A	400 mg/kg Drug A, once daily	First dosing with 400 mg/kg Drug a following a nonexposure Element	14 days after start of Element	P14D
6	TDM5	TE	800A	800 mg/kg Drug A, once daily	First dosing with 800 mg/kg Drug a following a nonexposure Element	14 days after start of Element	P14D

Trial Arms

Based upon the description, there are 4 trial arms.

ta.xpt

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	EPOCH
1	TDM5	TA	1	Control	1	SCRN	Screen	Randomized to Group 1	PRE-EXPOSURE
2	TDM5	TA	1	Control	2	CONTROL	Vehicle Control		EXPOSURE
3	TDM5	TA	1	Control	3	REST	Rest for 7 days		WASHOUT
4	TDM5	TA	1	Control	4	CONTROL	Vehicle Control		EXPOSURE
5	TDM5	TA	1	Control	5	REST	Rest for 7 days		WASHOUT
6	TDM5	TA	1	Control	6	CONTROL	Vehicle Control		EXPOSURE
7	TDM5	TA	2	50-800-400	1	SCRN	Screen	Randomized to Group 2	PRE-EXPOSURE
8	TDM5	TA	2	50-800-400	2	50A	50 mg/kg Drug A		EXPOSURE
9	TDM5	TA	2	50-800-400	3	REST	Rest for 7 days		WASHOUT
10	TDM5	TA	2	50-800-400	4	800A	800 mg/kg Drug A		EXPOSURE
11	TDM5	TA	2	50-800-400	5	REST	Rest for 7 days		WASHOUT
12	TDM5	TA	2	50-800-400	6	400A	400 mg/kg Drug A		EXPOSURE
13	TDM5	TA	3	400-50-800	1	SCRN	Screen	Randomized to Group 3	PRE-EXPOSURE
14	TDM5	TA	3	400-50-800	2	400A	400 mg/kg Drug A		EXPOSURE
15	TDM5	TA	3	400-50-800	3	REST	Rest for 7 days		WASHOUT
16	TDM5	TA	3	400-50-800	4	50A	50 mg/kg Drug A		EXPOSURE
17	TDM5	TA	3	400-50-800	5	REST	Rest for 7 days		WASHOUT
18	TDM5	TA	3	400-50-800	6	800A	800 mg/kg Drug A		EXPOSURE
19	TDM5	TA	4	800-400-50	1	SCRN	Screen	Randomized to Group 4	PRE-EXPOSURE
20	TDM5	TA	4	800-400-50	2	800A	800 mg/kg Drug A		EXPOSURE
21	TDM5	TA	4	800-400-50	3	REST	Rest for 7 days		WASHOUT
22	TDM5	TA	4	800-400-50	4	400A	400 mg/kg Drug A		EXPOSURE
23	TDM5	TA	4	800-400-50	5	REST	Rest for 7 days		WASHOUT
24	TDM5	TA	4	800-400-50	6	50A	50 mg/kg Drug A		EXPOSURE

Trial Sets

In this example, there are 4 trial sets. The experimental factors considered are type of exposure (vehicle control or product) and sequencing of exposure levels. The applicant is providing the arm code, applicant-defined group code, group label, control type, dose level and units, and planned number of subjects (total) only.

tx.xpt

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
1	TDM5	TX	1	Group 1, (Vehicle Control Name) once daily for each of 3 dosing periods of 14 days each with 7-day rests between	1	ARMCD	Arm Code	1
2	TDM5	TX	1	Group 1, (Vehicle Control Name) once daily for each of 3 dosing periods of 14 days each with 7-day rests between	2	SPGRPCD	Applicant-Defined Group Code	1
3	TDM5	TX	1	Group 1, (Vehicle Control Name) once daily for each of 3 dosing periods of 14 days each with 7-day rests between	3	GRPLBL	Group Label	Group 1, Control
4	TDM5	TX	1	Group 1, (Vehicle Control Name) once daily for each of 3 dosing periods of 14 days each with 7-day rests between	4	TCNTRL	Control Type	VEHICLE CONTROL
5	TDM5	TX	1	Group 1, (Vehicle Control Name) once daily for each of 3 dosing periods of 14 days each with 7-day rests between	5	TRTDOS	Dose Level	0
6	TDM5	TX	1	Group 1, (Vehicle Control Name) once daily for each of 3 dosing periods of 14 days each with 7-day rests between	6	TRTDOSU	Dose Units	mg/kg/day
7	TDM5	TX	1	Group 1, (Vehicle Control Name) once daily for each of 3 dosing periods of 14 days each with 7-day rests between	7	SPLANSUB	Planned Number of Subjects	20
8	TDM5	TX	2	Group 2, (Intervention Name) once daily dosing in sequence: 50-800-400 mg/kg (14 days each) with 7-day rests between	8	ARMCD	Arm Code	2
9	TDM5	TX	2	Group 2, (Intervention Name) once daily dosing in sequence: 50-800-400 mg/kg (14 days each) with 7-day rests between	9	SPGRPCD	Applicant-Defined Group Code	2

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
10	TDM5	TX	2	Group 2, (Intervention Name) once daily dosing in sequence: 50-800-400 mg/kg (14 days each) with 7-day rests between	10	GRPLBL	Group Label	Group 2, 50-800-400 mg/kg/day
11	TDM5	TX	2	Group 2, (Intervention Name) once daily dosing in sequence: 50-800-400 mg/kg (14 days each) with 7-day rests between	11	ITVCONC	Concentration of Intervention Article	SEE PROTOCOL
12	TDM5	TX	2	Group 2, (Intervention Name) once daily dosing in sequence: 50-800-400 mg/kg (14 days each) with 7-day rests between	12	ITVCONCU	Concentration Unit for Intervention Article	SEE PROTOCOL
13	TDM5	TX	2	Group 2, (Intervention Name) once daily dosing in sequence: 50-800-400 mg/kg (14 days each) with 7-day rests between	13	SPLANSUB	Planned Number of Subjects	20
14	TDM5	TX	3	Group 3, (Intervention Name) once daily dosing in sequence: 400-50-800 mg/kg (14 days each) with 7-day rests between	14	ARMCD	Arm Code	3
15	TDM5	TX	3	Group 3, (Intervention Name) once daily dosing in sequence: 400-50-800 mg/kg (14 days each) with 7-day rests between	15	SPGRPCD	Applicant-Defined Group Code	3
16	TDM5	TX	3	Group 3, (Intervention Name) once daily dosing in sequence: 400-50-800 mg/kg (14 days each) with 7-day rests between	16	GRPLBL	Group Label	Group 3, 400-50-800 mg/kg/day
17	TDM5	TX	3	Group 3, (Intervention Name) once daily dosing in sequence: 400-50-800 mg/kg (14 days each) with 7-day rests between	17	ITVCONC	Concentration of Intervention Article	SEE PROTOCOL
18	TDM5	TX	3	Group 3, (Intervention Name) once daily dosing in sequence: 400-50-800 mg/kg (14 days each) with 7-day rests between	18	ITVCONCU	Concentration Unit for Intervention Article	SEE PROTOCOL
19	TDM5	TX	3	Group 3, (Intervention Name) once daily dosing in sequence: 400-50-800 mg/kg (14 days each) with 7-day rests between	19	SPLANSUB	Planned Number of Subjects	20
20	TDM5	TX	4	Group 4, (Intervention Name) once daily dosing in sequence: 800-400-50 mg/kg (14 days each) with 7-day rests between	20	ARMCD	Arm Code	4
21	TDM5	TX	4	Group 4, (Intervention Name) once daily dosing in sequence: 800-400-50 mg/kg (14 days each) with 7-day rests between	21	SPGRPCD	Applicant-Defined Group Code	4
22	TDM5	TX	4	Group 4, (Intervention Name) once daily dosing in sequence: 800-400-50 mg/kg (14 days each) with 7-day rests between	22	GRPLBL	Group Label	Group 4, 800-400-50 mg/kg/day
23	TDM5	TX	4	Group 4, (Intervention Name) once daily dosing in sequence: 800-400-50 mg/kg (14 days each) with 7-day rests between	23	ITVCONC	Concentration of Intervention Article	SEE PROTOCOL
24	TDM5	TX	4	Group 4, (Intervention Name) once daily dosing in sequence: 800-400-50 mg/kg (14 days each) with 7-day rests between	24	ITVCONCU	Concentration Unit for Intervention Article	SEE PROTOCOL
25	TDM5	TX	4	Group 4, (Intervention Name) once daily dosing in sequence: 800-400-50 mg/kg (14 days each) with 7-day rests between	25	SPLANSUB	Planned Number of Subjects	20

3.2.2 In vivo Studies

In vivo studies are conducted in tobacco product research to address research activities that cannot be addressed using alternative approaches such as in vitro. Such studies may focus on tobacco product effects on biological processes such as inhalation, pharmacological behavior, toxicity, and dose ranging.

3.2.2.1 Demographics (DM)

The following examples illustrate typical scenarios in the DM domain. Example 1 is a general DM example showing a study of 6 animals with different arms recorded.

Example 1: General Demographics

1. The animal number given in this study is the SUBJID. In this example, STUDYID and SUBJID have been concatenated to create the USUBJID. This is to ensure that this particular animal is referred to in a unique way throughout an entire submission, which one might expect to be composed of several studies where each study contains an animal number with SUBJID = "1." **Note:** USUBJID does not need necessarily to be created by concatenating STUDYID and SUBJID, but it must be a unique identifying value for a subject across all studies within the submission.
2. This is a simple study where ARMCD represents dose groups, which is not always the case. This study has 3 groups (ARMCD values 1-3): ARMCD = "1" is the control animals, ARMCD = "2" is the low-dose animals, and ARMCD = "3" is the high-dose animals.
3. The actual birth dates of the animals were recorded; therefore, the age of the animals was calculated and recorded.

4. In this example, the variable "SPECIES" has been omitted because this information is within the Trial Summary (TS) domain.

Rows 1-6: Show demographics records for 6 subjects. Note that the subjects possess birthdates (BRTHDTC) and ages (AGE, AGEU).

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	BRTHDTC	AGE	AGEU	SEX	ARMCD	ARM	SETCD
1	ABC	DM	ABC-1	1	2006-01-01	2006-03-10	2005-12-01	31	DAYS	M	1	Control	1
2	ABC	DM	ABC-2	2	2006-01-01	2006-02-28	2005-12-01	31	DAYS	M	1	Control	1
3	ABC	DM	ABC-3	3	2006-01-01	2006-03-19	2005-12-01	31	DAYS	M	2	Low	2
4	ABC	DM	ABC-4	4	2006-01-01	2006-03-10	2005-12-01	31	DAYS	F	2	Low	2
5	ABC	DM	ABC-5	5	2006-01-01	2006-03-31	2005-12-15	17	DAYS	F	3	High	3
6	ABC	DM	ABC-6	6	2006-01-01	2006-04-05	2005-12-16	16	DAYS	F	3	High	3

Example 2: Unknown Birth Date

In this example, the exact birth date of the animal is not known, but there is an age range, so the AGETXT in conjunction with the AGEU is used. This study has some animals where the sex of the animals is either unknown or undifferentiated.

Row 1: Shows an example of a subject with a known age range of 2 to 4 weeks and an unknown sex.

Row 2: Shows an example of a subject with a known age range of 2 to 4 weeks and an undifferentiated sex.

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	AGETXT	AGEU	SEX	ARMCD	ARM	SETCD
1	DCB	DM	DCB-1	1	2006-01-01	2006-03-10	2-4	WEEKS	U	1	Low	1
2	DCB	DM	DCB-2	2	2006-01-01	2006-03-10	2-4	WEEKS	UNDIFFERENTIATED	2	High	2

Example 3: Species, Strains, and Substrains

Rows 1-3: Show an example of a study with the same SPECIES and different STRAIN and SBSTRAIN.

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	AGETXT	AGEU	SEX	SPECIES	STRAIN	SBSTRAIN	ARMCD	SETCD
1	ABC	DM	ABC-101	101	2006-03-01	2006-04-16	8-9	WEEKS	M	RAT	FISCHER 344	Surgically ovariectomized	1	RFIS2
2	ABC	DM	ABC-102	102	2006-03-01	2006-04-16	8-9	WEEKS	M	RAT	FISCHER 344	Surgically ovariectomized	1	RFIS2
3	ABC	DM	ABC-103	103	2006-03-01	2006-04-16	8-9	WEEKS	M	RAT	ZUCKER	Zuker Diabetic Fatty; obese; Type 2 diabetic; ZDF.GmiCrl-fa/fa	2	RZDF3

3.2.2.2 Comments (CO)

Example 1

Rows 1-6: Show comments related to parent records in the Body Weights (BW), Laboratory Test Results (LB), Clinical Observations (CL), and Food and Water Consumption (FW) domains.

Row 1: Shows a comment related to a single BW record having its BWSEQ = 1.

Row 2: Shows a comment related to a single LB record having its LBSEQ = 2516.

Row 3: Shows a comment related to a single CL record having its CLSEQ = 5642.

Row 4: Shows a comment related to a single CL record having its CLSEQ = 7541.

Row 5: Shows a comment related to a single FW record having its FWSEQ = 6542.

Row 6: Shows a comment related to a single FW record having its FWSEQ = 5621.

Row 7: Shows how to incorporate comments that are longer than 200 characters.

Row 8: Shows a comment related to the entire study (no particular domain); note that RDOMAIN is null and USUBJID is null.

Row 9: Shows how to add a comment from a logbook not related to a domain; IDVAR and IDVARVAL are null and COREF is populated.

Row 10: Shows how to add a comment related to a specific domain, but unrelated to a specific subject or record; USUBJID, IDVAR, and IDVARVAL are null.

co.xpt

Row	STUDYID	DOMAIN	RDOMAIN	USUBJID	COSEQ	IDVAR	IDVARVAL	COREF	COVAL	COVAL1	COVAL2	COEVAL	CODTC	CODY
1	ABC123	CO	BW	ABC123-1001	1	BWSEQ	1		animal reweighed			TECH		
2	ABC123	CO	LB	ABC123-1001	3	LBSEQ	2516		sample taken peri-mortem					
3	ABC123	CO	CL	ABC123-1001	4	CLSEQ	5642		during mortality check					
4	ABC123	CO	CL	ABC123-1003	5	CLSEQ	7541		fur wet pre-rx					
5	ABC123	CO	FW	ABC123-1001	6	FWSEQ	6542		100g warm water add to 400g of pmi certified 5007					
6	ABC123	CO	FW	ABC123-1002	7	FWSEQ	5621		food supplement					
7	ABC123	CO	TF	ABC123-1002	8	TFSEQ	88530		Interstitial fibrosis and inflammatory infiltrates and dilated tubules filled with protein casts. Pigment and mineralization is seen in tubular epithelial cells. The glomerulus shows an increased mesangial proliferation with basement membrane thickening and adhesions are present between the glomerular tuft and capsular wall. There is a slight increase in the size and number of parietal cells	mesangial proliferation with basement membrane thickening and adhesions are present between the glomerular tuft and capsular wall. There is a slight increase in the size and number of parietal cells	in Bowman's capsule.			
8	ABC123	CO			11				HVAC failure so the animals didn't have cooling			TECH	2006-07-19T08:30	84
9	ABC123	CO			12			Logbook page 650	Comment for logbook.			STUDY DIRECTOR	2006-07-19	84
10	ABC123	CO	BW		13				The scale was not calibrated as scheduled in week 2			TECH	2007-05-11	15

3.2.2.3 Subject Elements (SE)

Example 1: Parallel Design

In this example, subjects ABC1-001, ABC1-021, and ABC1-041 all experienced their planned sequence of elements. The SE dataset documents the start and end dates of each element.

se.xpt

Row	STUDYID	DOMAIN	USUBJID	SESEQ	ETCD	ELEMENT	SESTDTC	SEENDTC
1	ABC1	SE	ABC1-001	1	SCRN	Screen	2008-01-08	2008-01-14
2	ABC1	SE	ABC1-001	2	GP 01	Control	2008-01-15	2008-01-27
3	ABC1	SE	ABC1-021	1	SCRN	Screen	2008-01-08	2008-01-14
4	ABC1	SE	ABC1-021	2	GP 02	100 mg/kg Product A	2008-01-15	2008-01-27
5	ABC1	SE	ABC1-041	1	SCRN	Screen	2008-01-08	2008-01-14
6	ABC1	SE	ABC1-041	2	GP 03	500 mg/kg Product A	2008-01-15	2008-01-27

The following table is the corresponding Trial Arms (TA) dataset outlining the planned arms and elements for the same study. This is provided to assist with understanding how the actual experienced elements (SE dataset) relate to the planned arms defined here.

ta.xpt

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	EPOCH
1	ABC1	TA	01	Control	1	SCRN	Screen	Randomized to Group 01	Screen
2	ABC1	TA	01	Control	2	GP 01	Control		Exposure
3	ABC1	TA	02	100 mg/kg	1	SCRN	Screen	Randomized to Group 02	Screen
4	ABC1	TA	02	100 mg/kg	2	GP 02	100 mg/kg Product A		Exposure
5	ABC1	TA	03	500 mg/kg	1	SCRN	Screen	Randomized to Group 03	Screen
6	ABC1	TA	03	500 mg/kg	2	GP 03	500 mg/kg Product A		Exposure

Note: This is a simple design where ARMCD relates directly to dose groups. In more complex designs, a separation between arms and groups may be required in naming conventions (e.g., "Randomized to Exposure 1").

Example 2: High Dose Changed from 900 mg/kg to 700 mg/kg

In this example, the high-dose group originally scheduled to get 900 mg/kg was intentionally changed to 700 mg/kg after 1 week of the study. Prior to this change, a protocol amendment was created that altered the plan; therefore, this element would appear in TA, Trial Elements (TE), and SE.

se.xpt

Row	STUDYID	DOMAIN	USUBJID	SESEQ	ETCD	ELEMENT	SESTDTC	SEENDTC
1	CDF2	SE	CDF2-001	1	PRETEST	Screen	2008-01-08	2008-01-14T07:00
2	CDF2	SE	CDF2-001	2	TREATA	Control	2008-01-14T07:00	2008-01-27T09:00
3	CDF2	SE	CDF2-001	3	RECOVERY	Rest	2008-01-27T09:00	2008-02-02T07:00
4	CDF2	SE	CDF2-010	1	PRETEST	Screen	2008-01-08	2008-01-14T07:00
5	CDF2	SE	CDF2-010	2	TREATB	100 mg/kg Product A	2008-01-14T07:00	2008-01-27T09:30
6	CDF2	SE	CDF2-010	3	RECOVERY	Rest	2008-01-27T09:30	2008-02-02T07:00
7	CDF2	SE	CDF2-020	1	PRETEST	Screen	2008-01-08	2008-01-14T07:00
8	CDF2	SE	CDF2-020	2	TREATC	300 mg/kg Product A	2008-01-14T07:00	2008-01-27T10:30
9	CDF2	SE	CDF2-020	3	RECOVERY	Rest	2008-01-27T10:30	2008-02-02T07:00
10	CDF2	SE	CDF2-030	1	PRETEST	Screen	2008-01-08	2008-01-14T07:00
11	CDF2	SE	CDF2-030	2	TREATD	900 mg/kg Product A	2008-01-14T07:00	2008-01-21T07:00
12	CDF2	SE	CDF2-030	3	TREATD2	700 mg/kg Product A	2008-01-21T07:00	2008-01-27T09:30
13	CDF2	SE	CDF2-030	4	RECOVERY	Rest	2008-01-27T09:30	2008-02-02T07:00
14	CDF2	SE	CDF2-040	1	PRETEST	Screen	2008-01-08	2008-01-14T07:00
15	CDF2	SE	CDF2-040	2	TREATE	Positive Control Product XY	2008-01-14T07:00	2008-01-27T10:30

3.2.2.4 Disposition (DS)

Example 1

This example shows a typical DS dataset; subjects were sacrificed by exsanguination. The date values are entered in ISO 8601 format and include the time of sacrifice.

Rows 1-3: The original value of "Exsanguinated" was recorded in the DSTERM column and mapped to the controlled term "TERMINAL SACRIFICE" in the DSDECOD column. Because the records are intended to be reported together, DSNOMDY is the same for each record.

ds.xpt

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSSTDTC	DSSTDY	DSNOMDY
1	840515	DS	xx-xx75	1	Exsanguinated	TERMINAL SACRIFICE	1996-07-30T08:13:00	29	28
2	840515	DS	xx-xx76	1	Exsanguinated	TERMINAL SACRIFICE	1996-07-30T08:40:00	29	28
3	840515	DS	xx-xx77	1	Exsanguinated	TERMINAL SACRIFICE	1996-07-29T08:13:00	28	28

Example 2

This example shows a more complex DS dataset, and illustrates how to handle different days that subjects were disposed. The applicant has included the label under which the deaths were grouped in the study report.

Rows 1-3: The date values are entered in ISO 8601 format and include the time of disposition. DSNOMDY is the same for all 3 records; however, DSNOMLBL is different for row 1, which indicates the records would not be grouped together.

Row 1: The original value of "Animal escaped/Found dead" was recorded in the DSTERM column and mapped to the controlled term "ACCIDENTAL DEATH" in the DSDECOD column. The DSUSCHFL is "Y" because this is an unscheduled disposition.

Rows 2-3: The original value of "Final Phase Sacrifice" was recorded in the DSTERM column and mapped to the controlled term "TERMINAL SACRIFICE" in the DSDECOD column.

ds.xpt

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSUSCHFL	DSSTDTC	DSSTDY	DSNOMDY	DSNOMLBL
1	840516	DS	xx-xx82	1	Animal escaped/Found dead	ACCIDENTAL DEATH	Y	1996-03-01T08:10	28	28	Unscheduled Death
2	840516	DS	xx-xx83	1	Final Phase sacrifice	TERMINAL SACRIFICE		1996-03-02T17:40	29	28	Terminal Sacrifice
3	840516	DS	xx-xx84	1	Final Phase sacrifice	TERMINAL SACRIFICE		1996-03-01T08:13	28	28	Terminal Sacrifice

3.2.2.5 Exposure (EX)

Example 1: Inhalation Study

This is an example of an EX dataset for selected animals from a nonclinical inhalation study in rats. Subjects were randomized to 1 of 4 dose groups with the test article at dose levels of 0.7, 2.1, and 7.1 mg/kg/day and 1 control group receiving vehicle. The study included 13 weeks of dosing. However, due to severe clinical signs, the dose level for group 4 animals was reduced from 7.1 to 5 during week 6. The other groups remained on the same dose level throughout the study. The animals were placed in inhalation chambers each day for 60 minutes over the 13 weeks period. Prior to first dose and during the study exposure levels were measured by placing a filter for a given time or a set amount of air passing in a port hole in the inhalation chamber. However, the EXDOSE in this inhalation study contain the planned dose level.

Rows 1-5: Each animal had 1 record for each exposure period. Volume delivered per porthole is not available so EXVAMT/EXVAMTU variables are not populated. EXDUR was populated with the time the animals are exposed per exposure incident.

Rows 4-5: Animal 12345-004 had dose reduced from 7.1 to 5 mg on day 41 due to clinical signs as explained in the EXADJ variable.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXLOT	EXFAST	EXTRTV	EXVAMT	EXVAMTU	EXADJ	EXSTDTC	EXENDTC	EXSTDY	EXENDY	EXDUR
1	12345	EX	12345-001	1	CX2345	0	mg/kg/day	AEROSOL	RESPIRATORY (INHALATION)		Y	5% (w/v) of D-Mannitol in deionized water				2021-06-01	2021-09-01	1	91	PT60M
2	12345	EX	12345-002	2	CX2345	0.7	mg/kg/day	AEROSOL	RESPIRATORY (INHALATION)	AB789.1	Y	5% (w/v) of D-Mannitol in deionized water				2021-06-01	2021-09-01	1	91	PT60M
3	12345	EX	12345-003	3	CX2345	2.1	mg/kg/day	AEROSOL	RESPIRATORY (INHALATION)	AB789.1	Y	5% (w/v) of D-Mannitol in deionized water				2021-06-01	2021-09-01	1	91	PT60M
4	12345	EX	12345-004	4	CX2345	7.1	mg/kg/day	AEROSOL	RESPIRATORY (INHALATION)	AB789.1	Y	5% (w/v) of D-Mannitol in deionized water				2021-06-01	2021-08-15	1	40	PT60M
5	12345	EX	12345-004	5	CX2345	5	mg/kg/day	AEROSOL	RESPIRATORY (INHALATION)	AB789.1	Y	5% (w/v) of D-Mannitol in deionized water			Reduced due to toxicity	2021-08-15	2021-09-01	41	91	PT60M

Example 2: Oral Dosing Reported with 1 Record for Multiple Days of Dosing

This is an example of an EX dataset for selected animals from a typical nonclinical study. In this example, subjects were randomized to 1 of 4 dose groups: the test article at dose levels of 20, 40, and 100 mg/kg/day (single daily administration), and 1 control. The study included 13 weeks of dosing. However, due to severe clinical signs, the dose level for subject 12345004 was reduced from 100 to 75 during week 6. The other subjects remained on the same dose level throughout the study. With respect to timing of doses, the applicant only collected the start and stop dates of uninterrupted periods of dosing.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXTRTV	EXADJ	EXSTDTC	EXENDTC	EXSTDY	EXENDY
1	12345	EX	12345001	1	CX2345	0	mg/kg	SUSPENSION	QD	ORAL GAVAGE		CMC		2007-01-08	2007-04-08	1	91
2	12345	EX	12345002	2	CX2345	20	mg/kg	SUSPENSION	QD	ORAL GAVAGE	AB789.1	CMC		2007-01-08	2007-04-08	1	91
3	12345	EX	12345003	3	CX2345	40	mg/kg	SUSPENSION	QD	ORAL GAVAGE	AB789.1	CMC		2007-01-08	2007-04-08	1	91
4	12345	EX	12345004	4	CX2345	100	mg/kg	SUSPENSION	QD	ORAL GAVAGE	AB789.1	CMC		2007-01-08	2007-02-16	1	40
5	12345	EX	12345004	5	CX2345	75	mg/kg	SUSPENSION	QD	ORAL GAVAGE	AB789.1	CMC	Reduced due to toxicity	2007-02-17	2007-04-09	41	91

Example 3: Oral Gavage - 1 Record per Dosing with Multiple Treatments

This is an example of an EX dataset for selected animals from a toxicology study using 2 product exposures and a vehicle control with once-weekly oral administration. Subjects were randomized to 1 of 5 groups. In this example, results are shown for 5 animals, 1 in each group, with 1 record each for the first 2 weeks. For the control group, the EXTRT is listed as the 2 product substances, concatenated with a pipe and zero dose.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXTRTV	EXVAMT	EXVAMTU	EXSTDTC	EXSTDY
1	12345	EX	12345001	1	RP187 RP188	0	mg/kg	SOLUTION	1 TIME PER WEEK	ORAL GAVAGE		Saline	5	mL	2013-08-20	1
2	12345	EX	12345002	2	RP187	10	mg/kg	SOLUTION	1 TIME PER WEEK	ORAL GAVAGE	Ta.1308	Saline	5	mL	2013-08-20	1
3	12345	EX	12345003	3	RP187	100	mg/kg	SOLUTION	1 TIME PER WEEK	ORAL GAVAGE	Ta.1308	Saline	5	mL	2013-08-20	1
4	12345	EX	12345004	4	RP188	10	mg/kg	SOLUTION	1 TIME PER WEEK	ORAL GAVAGE	Ta.2212	Saline	5	mL	2013-08-20	1
5	12345	EX	12345005	5	RP188	100	mg/kg	SOLUTION	1 TIME PER WEEK	ORAL GAVAGE	Ta.2212	Saline	5	mL	2013-08-20	1
6	12345	EX	12345001	6	RP187 RP188	0	mg/kg	SOLUTION	1 TIME PER WEEK	ORAL GAVAGE		Saline	5	mL	2013-08-27	8
7	12345	EX	12345002	7	RP187	10	mg/kg	SOLUTION	1 TIME PER WEEK	ORAL GAVAGE	Ta.1308	Saline	5	mL	2013-08-27	8
8	12345	EX	12345003	8	RP187	100	mg/kg	SOLUTION	1 TIME PER WEEK	ORAL GAVAGE	Ta.1308	Saline	5	mL	2013-08-27	8
9	12345	EX	12345004	9	RP188	10	mg/kg	SOLUTION	1 TIME PER WEEK	ORAL GAVAGE	Ta.2212	Saline	5	mL	2013-08-27	8
10	12345	EX	12345005	10	RP188	100	mg/kg	SOLUTION	1 TIME PER WEEK	ORAL GAVAGE	Ta.2212	Saline	5	mL	2013-08-27	8

3.2.2.6 Body Weight (BW)***Example 1***

This example shows body weights collected at weekly intervals, including some records showing when the collection was not done. In addition, some records were marked as excluded from all calculations due to being out of the normal range for the test.

Row 1: The "Y" in BWBLFL is an example of the use of baseline flag.

Rows 1-11: Show records for body weight for subject ABC-001-001 at weekly intervals.

Row 4: Shows that the subject was fasted in error prior to the body weight being taken. The value was excluded from calculations.

Row 7: Shows a record that was excluded due to faulty equipment; the exclusion flag is "Y" and a reason for exclusion is included.

Row 9: Shows proper use of the BWSTAT variable to indicate "NOT DONE", where a reason was collected when a test was not done.

Row 12: Shows TERMBW collected along with an indication that the animal was fasted prior to collection.

Row 13: Shows that subject ABC-001-010's body weight was taken on day 15, but this was not scheduled (reflected by the use of BWUSCHFL).

bw.xpt

Row	STUDYID	DOMAIN	USUBJID	BWSEQ	BWTESCD	BWTEST	BWORRES	BWORRESU	BWSTRESC	BWSTRESN	BWSTRESU	BWSTAT	BWREASND	BWBLFL	BWFAST	BWXCLFL	BWREASEX	BWUSCHFL	BWDTC	BWDY	BWNOMDY	BWNOMLBL
1	ABC	BW	ABC-001-001	1	BW	Body Weight	250	g	250	250	g			Y					1999-06-19	1	1	Week 1
2	ABC	BW	ABC-001-001	2	BW	Body Weight	240	g	240	240	g								1999-06-26	8	8	Week 2
3	ABC	BW	ABC-001-001	3	BW	Body Weight	280	g	280	280	g								1999-07-03	15	15	Week 3
4	ABC	BW	ABC-001-001	4	BW	Body Weight	190	g	190	190	g				Y	Y	FASTING BY HUMAN ERROR		1999-07-10	22	22	Week 4
5	ABC	BW	ABC-001-001	5	BW	Body Weight	225	g	225	225	g								1999-07-17	29	29	Week 5
6	ABC	BW	ABC-001-001	6	BW	Body Weight	245	g	245	245	g								1999-07-24	36	36	Week 6

Row	STUDYID	DOMAIN	USUBJID	BWSEQ	BWTESTCD	BWTEST	BWORRES	BWORRESU	BWSTRESC	BWSTRESN	BWSTRESU	BWSTAT	BWREASND	BWBFL	BWFAST	BWXCLFL	BWREASEX	BWUSCHFL	BWDTC	BWDY	BWNOMDY	BWNOMLBL
7	ABC	BW	ABC-001-001	7	BW	Body Weight	50	g	50	50	g					Y	FAULTY EQUIPMENT		1999-07-31	43	43	Week 7
8	ABC	BW	ABC-001-001	8	BW	Body Weight	260	g	260	260	g								1999-08-07	50	50	Week 8
9	ABC	BW	ABC-001-001	9	BW	Body Weight						NOT DONE	TECHNICIAN OVERSIGHT						1999-08-14	57	57	Week 9
10	ABC	BW	ABC-001-001	10	BW	Body Weight	229	g	229	229	g								1999-08-21	64	64	Week 10
11	ABC	BW	ABC-001-001	11	BW	Body Weight	243	g	243	243	g								1999-08-28	71	71	Week 11
12	ABC	BW	ABC-001-001	12	TERMBW	Terminal Body Weight	225	g	225	225	g					Y			1999-09-04	78	78	
13	ABC	BW	ABC-001-010	1	BW	Body Weight	237	g	237	237	g							Y	1999-07-03	15	15	Unscheduled

3.2.2.7 Clinical Observations (CL)

Example 1

This example shows clinical signs captured in the collection system using categorization by CLCAT or CLTEST. CLCAT is "CLINICAL SIGNS". CLTESTCD and CLTEST are used to capture the collection system's breakdown of observations. A comment record was included to clarify the time period for the tremors.

Rows 1-3: CLTESTCD and CLTEST are used to describe different tests whose results were recorded during the examination.

Row 5: CLORRES includes a duration of >10 minutes, which indicates that the technician saw tremors while cageside and did not see them end. A comment recorded in CO was included to clarify the time period for the tremors.

Row 6: This row includes an example of a "normal" observation for the animal.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	CLLOC	CLDTC	CLDY	CLNOMDY
1	13456	CL	13456-01	1	AG	Activity/Gait	CLINICAL SIGNS	Difficulty Walking	Difficulty Walking		2003-01-20T15:44:42	7	7
2	13456	CL	13456-01	2	AC	Appearance and Condition	CLINICAL SIGNS	Pale			2003-01-20T15:45:39	7	7
3	13456	CL	13456-01	3	EY	Eyes	CLINICAL SIGNS	Squinting			2003-01-20T15:45:55	7	7
4	13456	CL	13456-02	1	GO	General Observations	CLINICAL SIGNS	Salivation			2003-01-28T15:44:42	15	15
5	13456	CL	13456-02	2	GO	General Observations	CLINICAL SIGNS	Tremors; >10 mins			2003-01-28T15:44:42	15	15
6	13456	CL	13456-03	1	GO	General Observations	CLINICAL SIGNS	Normal			2003-01-28T15:48:09	15	15

Row 1: COVAL explains the time modifier used in the CLORRES in row 5 above.

co.xpt

Row	STUDYID	DOMAIN	RDOMAIN	USUBJID	COSEQ	IDVAR	IDVARVAL	COVAL	CODTC
1	13456	CO	CL	13456-02	1	CLSEQ	2	Tremors did not cease while the technician was at the cage, which was a period of 10 minutes.	

Example 2

This example shows clinical signs captured in the collection system using no categorization by CLCAT or CLTEST. CLTESTCD and CLTEST are also recorded as simply clinical signs.

Rows 1-5: All CLORRES values reflect a clinical sign.

Row 6: This row includes an example of a NORMAL observation. The originally recorded result was "NAD" (no abnormalities detected), which is mapped to NORMAL in CLSTREC.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTREC	CLLOC	CLDTc	CLDY	CLNOMDy
1	13456	CL	13456-01	1	CS	Clinical Sign	CLINICAL SIGNS	Difficulty Walking	Difficulty Walking		2003-01-20T15:44:42	7	7
2	13456	CL	13456-01	2	CS	Clinical Sign	CLINICAL SIGNS	Pale	Pale		2003-01-20T15:45:39	7	7
3	13456	CL	13456-01	3	CS	Clinical Sign	CLINICAL SIGNS	Squinting	Squinting	Both Eyes	2003-01-20T15:45:55	7	7
4	13456	CL	13456-02	1	CS	Clinical Sign	CLINICAL SIGNS	Salivation	Salivation		2003-01-28T15:44:42	15	15
5	13456	CL	13456-02	2	CS	Clinical Sign	CLINICAL SIGNS	Tremors	Tremors		2003-01-28T15:44:42	15	15
6	13456	CL	13456-03	1	CS	Clinical Sign	CLINICAL SIGNS	NAD	NORMAL		2003-01-28T15:44:42	15	15

Example 3

This example shows clinical signs captured in the collection system using no categorization by CLCAT or CLTEST and having result categorization applied after collection for reporting purposes. CLTESTCD and CLTEST are recorded as simply "Clinical Sign", and CLRESCAT is used to categorize each result.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTREC	CLRESCAT	CLLOC	CLDTc	CLDY	CLNOMDy
1	13456	CL	13456-01	1	CS	Clinical Sign	CLINICAL SIGNS	Difficulty Walking	Difficulty Walking	CNS		2003-01-20T15:44:42	7	7
2	13456	CL	13456-01	2	CS	Clinical Sign	CLINICAL SIGNS	Pale	Pale	Color		2003-01-20T15:45:39	7	7
3	13456	CL	13456-01	3	CS	Clinical Sign	CLINICAL SIGNS	Squinting	Squinting	Facial	Both Eyes	2003-01-20T15:45:55	7	7
4	13456	CL	13456-02	1	CS	Clinical Sign	CLINICAL SIGNS	Salivation	Salivation	Facial		2003-01-28T15:44:42	15	15
5	13456	CL	13456-02	2	CS	Clinical Sign	CLINICAL SIGNS	Tremors	Tremors	CNS		2003-01-28T15:44:42	15	15

Example 4

This example shows clinical signs captured in the collection system using categorization by CLTEST and having result categorization applied after collection for reporting purposes. CLTESTCD and CLTEST are used to capture the collection system's breakdown of observations and CLRESCAT is used to categorize each result.

Rows 1-3: CLTESTCD and CLTEST are used to describe different tests whose results were recorded during the examination.

Rows 1-5: CLRESCAT was used to categorize results during analysis for further categorization of data.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTREC	CLRESCAT	CLLOC	CLDTc	CLDY	CLNOMDy
1	13456	CL	13456-01	1	AG	Activity/Gait	CLINICAL SIGNS	Difficulty Walking	Difficulty Walking	CNS		2003-01-20T15:44:42	7	7
2	13456	CL	13456-01	2	AC	Appearance and Condition	CLINICAL SIGNS	Pale	Pale	Color		2003-01-20T15:45:39	7	7
3	13456	CL	13456-01	3	EY	Eyes	CLINICAL SIGNS	Squinting	Squinting	Facial	Both Eyes	2003-01-20T15:45:55	7	7
4	13456	CL	13456-02	1	GO	General Observations	CLINICAL SIGNS	Salivation	Salivation	Facial		2003-01-28T15:44:42	15	15
5	13456	CL	13456-02	2	GO	General Observations	CLINICAL SIGNS	Tremors	Tremors	CNS		2003-01-28T15:44:42	15	15

Example 5

This example shows clinical signs captured in the collection system using categorization by CLSCAT or CLTEST. CLTESTCD and CLTEST are used to capture the collection system's breakdown of observations. CLSCAT further categorizes tests in the collection system.

CLTESTCD and CLTEST are used to describe different tests whose results were recorded during the examination. CLSCAT is used to break tests into multiple categories as recorded during examination.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLSCAT	CLORRES	CLSTRESC	CLLOC	CLSEV	CLDTc	CLDY	CLNOMDy
1	13456	CL	13456-01	1	FE	Fur Examination	CLINICAL SIGNS	Whole Body Appearance	Piloerection, mild	Piloerection		Mild	2003-01-20T15:44:42	7	7
2	13456	CL	13456-01	2	FE	Fur Examination	CLINICAL SIGNS	Whole Body Appearance	Stained, yellow	Stained			2003-01-20T15:45:39	7	7
3	13456	CL	13456-01	3	EE	Eye Examination	CLINICAL SIGNS	Sensory Organ Appearance	Red	Red			2003-01-20T15:45:55	7	7
4	13456	CL	13456-02	1	FE	Fur Examination	CLINICAL SIGNS	Whole Body Appearance	Stained, yellow	Stained			2003-01-28T15:44:42	15	15
5	13456	CL	13456-02	2	OE	Oral Examination	CLINICAL SIGNS	Sensory Organ Appearance	Missing tooth, right, bicuspid	Missing tooth	Right bicuspid		2003-01-28T15:44:42	15	15

Example 6

This example shows clinical signs captured in the collection system using categorization with CLCAT. CLTESTCD and CLTEST are simply "Clinical Signs" for all entries in this example. Examples show results for 2 animals caged together, so POOLID and not USUBJID is populated. The POOLDEF table (see Section 2.8.9.21, [SEND Pool Definition \(POOLDEF\)](#)) is shown below.

Rows 1-7: CLCAT is used to categorize the clinical signs into a controlled list and CLSTRESC is used to enter only the finding without modifiers.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	POOLID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	CLLOC	CLSEV	CLDTc	CLDY	CLNOMDy
1	ABC1	CL		CAGE1	1	CS	Clinical Signs	CLINICAL SIGNS	Skin, Red, Pinna, Left	Skin, Red	Pinna, Left		2003-01-20T15:44:42	7	7
2	ABC1	CL		CAGE1	2	CS	Clinical Signs	CLINICAL SIGNS	Fur, Thin Cover, Hindpaw, Left	Fur, Thin Cover	Hindpaw, Left		2003-01-20T15:45:39	7	7
3	ABC1	CL		CAGE1	3	CS	Clinical Signs	CLINICAL SIGNS	Fur, Thin Cover, Hindpaw, Right	Fur, Thin Cover	Hindpaw, Right		2003-01-20T15:45:55	7	7
4	ABC1	CL		CAGE1	4	CS	Clinical Signs	CLINICAL SIGNS	Conjunctival Hyperemia, Moderate	Conjunctival Hyperemia	Eye	MODERATE	2003-01-28T15:44:42	15	15
5	ABC1	CL		CAGE1	5	CS	Clinical Signs	CLINICAL SIGNS	Feces, Watery	Feces, Watery			2003-01-28T15:44:42	15	15
6	ABC1	CL		CAGE1	6	CS	Clinical Signs	CLINICAL SIGNS	Feces, Mucoid	Feces, Mucoid			2003-01-28T15:44:42	15	15
7	ABC1	CL		CAGE1	7	CS	Clinical Signs	CLINICAL SIGNS	Feces, Liquid (TS),Slight	Feces, Liquid		SLIGHT	2003-01-28T15:44:42	15	15

pooldef.xpt

Row	STUDYID	POOLID	USUBJID
1	ABC1	CAGE1	ABC1-1001
2	ABC1	CAGE1	ABC1-1002

Example 7

This example shows clinical signs captured in the collection system using categorization. CLTESTCD and CLTEST are simply "Clinical Signs" for all entries in this example. Time points are included to indicate the signs that were taken for post-dose periods.

Rows 1-6: CLCAT is used to categorize the clinical signs into a controlled list. CLTPT is used to specify the observation session in which the observations were collected. CLELM was not included because this session was not specified in terms of elapsed time after dosing.

Row 6: CLUSCHFL is used to specify that the observation was unscheduled. Note that CLNOMDY was populated with the actual study day for tabulation. CLNOMLBL reflects the label that was used in the study report.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	CLLOC	CLUSCHFL	CLDTC	CLDY	CLNOMDY	CLNOMLBL	CLTPT	CLTPTNUM
1	ABC1	CL	ABC1-1001	1	CS	Clinical Signs	CLINICAL SIGNS	Skin, Red	Skin, Red	Pinna, Left		2004-07-19T07:21:39	7	7	Day 7	Postdose 1	1
2	ABC1	CL	ABC1-1001	2	CS	Clinical Signs	CLINICAL SIGNS	Fur, Thin Cover	Fur, Thin Cover	Hindpaw, Left		2004-07-19T07:16:57	7	7	Day 7	Postdose 1	1
3	ABC1	CL	ABC1-1002	1	CS	Clinical Signs	CLINICAL SIGNS	Fur, Thin Cover	Fur, Thin Cover	Hindpaw, Right		2004-07-19T07:27:01	7	7	Day 7	Postdose 1	1
4	ABC1	CL	ABC1-1001	3	CS	Clinical Signs	CLINICAL SIGNS	Skin, Red	Skin, Red	Pinna, Left		2004-07-19T02:21:39	7	7	Day 7	Postdose 2	2
5	ABC1	CL	ABC1-1001	4	CS	Clinical Signs	CLINICAL SIGNS	Fur, Thin Cover	Fur, Thin Cover	Hindpaw, Left		2004-07-19T02:16:57	7	7	Day 7	Postdose 2	2
6	ABC1	CL	ABC1-1002	2	CS	Clinical Signs	CLINICAL SIGNS	Fur, Thin Cover	Fur, Thin Cover	Hindpaw, Right	Y	2004-07-19T04:15:01	7	7	Day 7 Unscheduled		

Example 8

This example shows clinical signs categorized by CLTEST, with CLEVAL used to specify the role of the person who performed the examination. Physical examinations were captured in the collection system using categorization by CLTEST but not by CLCAT. CLTESTCD and CLTEST are used to capture the collection system's breakdown of observations.

Rows 1-5: All CLTESTCD and CLTEST values reflect a physical examination.

Rows 1-5: CLEVAL is used to specify that a veterinarian performed the examination.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	CLLOC	CLEVAL	CLSEV	CLDTC	CLDY	CLNOMDY
1	13456	CL	13456-01	1	OE	Oral Examination	PHYSICAL EXAM	Teeth broken	Teeth broken		VET		2005-12-15T09:15:16	1	1
2	13456	CL	13456-01	2	EA	External Appearance	PHYSICAL EXAM	Hordeolum, Mild, Right Eye	Hordeolum	Right Eye	VET	Mild	2005-12-15T09:20:42	1	1
3	13456	CL	13456-01	3	EA	External Appearance	PHYSICAL EXAM	Material around eyes, Red, Left Eye	Material around eyes, Red	Left Eye	VET		2005-12-15T09:22:51	1	1
4	13456	CL	13456-02	1	PS	Pelage/Skin	PHYSICAL EXAM	Skin discolored	Skin discolored		VET		2005-12-16T07:02:58	2	2
5	13456	CL	13456-02	2	RE	Respiration	PHYSICAL EXAM	Breathing difficult, Severe	Breathing difficult		VET	Severe	2005-12-16T07:02:58	2	2

Example 9

This example shows ophthalmoscopic examinations captured in the collection system using no result categorization applied after collection for reporting purposes.

Rows 1-5: CLTESTCD and CLTEST are also recorded as simply "Ophthalmoscopic Examination". CLEVAL is used to specify that an ophthalmologist performed the examination.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLRRS	CLSTREC	CLLOC	CLEVAL	CLSEV	CLDTC	CLDY	CLNOMDY
1	13456	CL	13456-01	1	OP	Ophthalmoscopic Examination	OPHTHALMOLOGY	Nictitating membrane protruding, Left Eye	Nictitating membrane protruding	Left Eye	OPHTHALMOLOGIST		2005-12-15T09:15:16	1	1
2	13456	CL	13456-01	2	OP	Ophthalmoscopic Examination	OPHTHALMOLOGY	Chorioretinal hypoplasia, Moderate, Both Eyes	Chorioretinal hypoplasia	Both Eyes	OPHTHALMOLOGIST	Moderate	2005-12-15T09:20:42	1	1
3	13456	CL	13456-01	3	OP	Ophthalmoscopic Examination	OPHTHALMOLOGY	Conjunctivitis, Mild, Right Eye	Conjunctivitis	Right Eye	OPHTHALMOLOGIST	Mild	2005-12-15T09:22:51	1	1
4	13456	CL	13456-02	1	OP	Ophthalmoscopic Examination	OPHTHALMOLOGY	Retinal atrophy, Severe, Left Eye	Retinal atrophy	Left Eye	OPHTHALMOLOGIST	Severe	2005-12-16T07:02:58	2	2
5	13456	CL	13456-02	2	OP	Ophthalmoscopic Examination	OPHTHALMOLOGY	Iritis, Mild, Both Eyes	Iritis	Both Eyes	OPHTHALMOLOGIST	Mild	2005-12-16T07:02:58	2	2

Example 10

This example shows clinical signs captured in the collection system using categorization. CLTESTCD and CLTEST are simply "Clinical Signs" for all entries in this example. Reference time points are included to indicate that the signs being taken are for a certain duration post-dose.

Rows 1-6: CLTPT is used to specify the observation session in which the observations were collected. CLELTM is included to signify that the measurements were planned at 15 minutes and 8 hours post-dose.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLRRS	CLSTREC	CLLOC	CLDTC	CLDY	CLNOMDY	CLTPT	CLTPTNUM	CLELTM	CLTPTREF	CLRFTDTC
1	ABC1	CL	ABC1-1001	1	CS	Clinical Signs	CLINICAL SIGNS	Skin, Red	Skin, Red	Pinna, Left	2004-07-19T07:21:39	1	1	15 minutes Postdose	1	PT15M	Day 1 Dose	2004-07-19T07:05:00
2	ABC1	CL	ABC1-1001	2	CS	Clinical Signs	CLINICAL SIGNS	Fur, Thin Cover	Fur, Thin Cover	Hindpaw, Left	2004-07-19T07:22:57	1	1	15 minutes Postdose	1	PT15M	Day 1 Dose	2004-07-19T07:05:00
3	ABC1	CL	ABC1-1002	1	CS	Clinical Signs	CLINICAL SIGNS	Fur, Thin Cover	Fur, Thin Cover	Hindpaw, Right	2004-07-19T07:27:01	1	1	15 minutes Postdose	1	PT15M	Day 1 Dose	2004-07-19T07:05:00
4	ABC1	CL	ABC1-1001	3	CS	Clinical Signs	CLINICAL SIGNS	Skin, Red	Skin, Red	Pinna, Left	2004-07-19T15:05:39	1	1	8 Hours Postdose	2	PT8H	Day 1 Dose	2004-07-19T07:05:00
5	ABC1	CL	ABC1-1001	4	CS	Clinical Signs	CLINICAL SIGNS	Fur, Thin Cover	Fur, Thin Cover	Hindpaw, Left	2004-07-19T15:05:57	1	1	8 Hours Postdose	2	PT8H	Day 1 Dose	2004-07-19T07:05:00
6	ABC1	CL	ABC1-1002	2	CS	Clinical Signs	CLINICAL SIGNS	Fur, Thin Cover	Fur, Thin Cover	Hindpaw, Right	2004-07-19T15:05:01	1	1	8 Hours Postdose	2	PT8H	Day 1 Dose	2004-07-19T07:05:00

Example 11

Clinical sign related to a finding in another domain. This example shows 2 unrelated clinical signs: thinning fur on the left hindpaw and swelling seen on the animal that then was determined to be a mass. A RELREC example is used to tie the record for the mass to an Macroscopic Findings (MA) record.

Row 1: CLSPID is used to identify the mass on the animal's jaw.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLSPID	CLTESTCD	CLTEST	CLCAT	CLRRS	CLSTREC	CLLOC	CLDTC	CLDY	CLNOMDY
1	PY001002	CL	AA-12012	1065	MASS1	CS	Clinical Signs	CLINICAL SIGNS	Swelling; Left Jaw	Swelling	Left Jaw	2004-07-19	42	42
2	PY001002	CL	AA-12012	1066		CS	Clinical Signs	CLINICAL SIGNS	Fur, Thin Cover; Left Hindpaw	Fur, Thin Cover	Left Hindpaw	2004-07-19	42	42

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	POOLID	IDVAR	IDVARVAL	RELTYPE	RELIID
1	PY001002	CL	AA-12012		CLSEQ	1065		62
2	PY001002	MA	AA-12012		MASEQ	233		62

Example 12

This example shows food consumption within the CL domain when it is collected as text and reported as a qualitative measure.

Row 1: Shows a record collected as an unscheduled observation when it is abnormal.

Row 2: Shows a record collected as part of the routine observations as defined in the protocol.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLSCAT	CLRRS	CLSTREC	CLLOC	CLUSCHFL	CLDTC	CLDY	CLNOMDY
1	654321	CL	654321 101	1	BEAC	BEHAVIOR/ACTIVITY	CLINICAL SIGNS	UNSCHEDULED	Inappetence	INAPPETENCE		Y	2013-06-14T13:41:18	141	141
2	654321	CL	654321 101	2	BEAC	BEHAVIOR/ACTIVITY	CLINICAL SIGNS	ROUTINE	Inappetence	INAPPETENCE			2013-06-15T08:01:10	142	142

3.2.2.8 Death Diagnosis and Details (DD)

Example 1

This example shows the use of additional permissible variables.

Rows 1-2: These rows include the use of the DDRESCAT variable to record a categorization performed after the finding collection. Values include "ACCIDENTAL" and "TREATMENT-RELATED". The DDEVAL variable records the evaluator of the death diagnosis.

dd.xpt

Row	STUDYID	DOMAIN	USUBJID	DDSEQ	DDTESTCD	DDTEST	DDORRES	DDSTRESC	DDRESCAT	DDEVAL	DDDTc	DDDY
1	840516	DD	xx-xx82	1	DEATHD	Death Diagnosis	Broken Neck	Spinal Column, Severed	ACCIDENTAL	NECROPSY SUPERVISOR	1996-02-06	329
2	840516	DD	xx-xx83	1	DEATHD	Death Diagnosis	Clonic Convulsions	Clonic Convulsions	TREATMENT RELATED	VETERINARIAN	1996-03-05	358

3.2.2.9 Food and Water Consumption (FW)

Example 1

This example shows when the data collection system stores the calculated food consumption and water consumption (FWORRES) as "g" and "mL", and FWSTRESC and FWSTRESN reflect results in the standardized unit per animal per day.

Rows 1-4: Show examples of food consumption records where the animals were housed together; therefore, USUBJID is null and POOLID is populated.

fw.xpt

Row	STUDYID	DOMAIN	USUBJID	POOLID	FWSEQ	FWTESTCD	FWTEST	FWORRES	FWORRESU	FWSTRESC	FWSTRESN	FWSTRESU	FWDTc	FWENDTC	FWDY	FWENDY
1	13456	FW		C1-101-102	1	FC	Food Consumption	400	g	28.6	28.6	g/animal/day	2003-01-20	2003-01-27	1	7
2	13456	FW		C1-201-202	2	FC	Food Consumption	300	g	21.4	21.4	g/animal/day	2003-01-20	2003-01-27	1	7
3	13456	FW		C1-101-102	3	WC	Water Consumption	210	mL	15.0	15.0	mL/animal/day	2003-01-20	2003-01-27	1	7
4	13456	FW		C1-201-202	4	WC	Water Consumption	276	mL	34.5	34.5	mL/animal/day	2003-01-23	2003-01-27	3	7

pooldef.xpt

Row	STUDYID	POOLID	USUBJID
1	13456	C1-101-102	ABC1-101
2	13456	C1-101-102	ABC1-102
3	13456	C1-201-202	ABC1-201
4	13456	C1-201-202	ABC1-202

Example 2

This example shows when the data collection system stores FWORRES as the total cage consumption, and FWSTRESC and FWSTRESN are populated with a calculation of g/animal/week. In this example, the pools are defined at the start of each collection interval.

Rows 1-2: Show examples of food consumption records where the animals were housed together; therefore, USUBJID is null and POOLID is populated.

Row 1: Shows the pool of the food consumption of the pooled animals for week 1.

Row 2: Shows that the POOLID value has changed for the following week, because 1 animal died during the first week.

fw.xpt

Row	STUDYID	DOMAIN	USUBJID	POOLID	FWSEQ	FWTESTCD	FWTEST	FWORRES	FWORRESU	FWSTRESC	FWSTRESN	FWSTRESU	FWDTC	FWENDTC	FWDY	FWENDY
1	13456	FW		C1-101-102-103	1	FC	Food Consumption	400	g	165	165	g/animal/week	2003-01-20T15:44:42	2003-01-27T15:44:47	1	7
2	13456	FW		C1-101-103	2	FC	Food Consumption	280	g	140	140	g/animal/week	2003-01-28T15:45:43	2003-02-04T15:45:48	8	15

Row 1: In the Comments domain, COVAL explains that the animal died mid-interval.

co.xpt

Row	STUDYID	DOMAIN	RDOMAIN	POOLID	COSEQ	IDVAR	IDVARVAL	COVAL
1	13456	CO	FW	C1-101-102-103	1	FWSEQ	1	Animal 102 died unscheduled during the week. Food consumption was calculated based upon the number of days the animal was alive.

pooldef.xpt

Row	STUDYID	POOLID	USUBJID
1	13456	C1-101-102-103	ABC1-101
2	13456	C1-101-102-103	ABC1-102
3	13456	C1-101-102-103	ABC1-103
4	13456	C1-101-103	ABC1-101
5	13456	C1-101-103	ABC1-103

Example 3

This is an example of food consumption records for single-housed subjects.

Rows 1, 3, 4: Show examples of food/water consumption.

Rows 2, 5: Show examples of food/water consumption relative to body weight.

Row 3: Shows that this animal's food consumption value should be excluded from all calculations because the food was found to be wet.

fw.xpt

Row	STUDYID	DOMAIN	USUBJID	FWSEQ	FWTESTCD	FWTEST	FWORRES	FWORRESU
1	123456	FW	12345-101	1	FC	Food Consumption	220	g
2	123456	FW	12345-101	2	FCRELBW	Food Consumption Relative to Body Wt	20.2	g/kg
3	123456	FW	12345-102	3	FC	Food Consumption	260	g
4	123456	FW	12345-101	4	WC	Water Consumption	220	mL
5	123456	FW	12345-101	5	WCRELBW	Water Consumption Relative to Body Wt	20.2	mL/kg

Row	FWSTRESC	FWSTRESN	FWSTRESU	FWEXCLFL	FWEXREASEX	FWDTC	FWENDTC	FWDY	FWENDY
1	220	220	g			2006-07-19T12:17:26	2006-07-19T16:05:47	1	1
2	20.2	20.2	g/kg			2006-12-29	2006-12-29	160	160
3	260	260	g	Y	FOOD WET	2006-07-19T12:17:26	2006-07-19T16:05:47	1	1
4	220	220	mL			2006-07-19T13:17:26	2006-07-19T17:05:47	1	1
5	20.2	20.2	mL/kg			2006-12-29	2006-12-29	160	160

3.2.2.10 Laboratory Test Results (LB)

Example 1

- Row 1:** Shows a value collected in 1 unit, but converted to selected standard unit.
- Rows 2-4:** Show 2 records for alkaline phosphatase that were collected 1 day apart and are expected to be reported together. Row 4 shows how to create a derived record (average of the rows 2 and 3) and flag it as derived (LBDRVFL = "Y") as well as the record to use as baseline (LBBFL = "Y").
- Rows 6-7:** Show a suggested use of the LBSCAT variable. It could be used to further classify types of tests within a laboratory panel (e.g., "DIFFERENTIAL").
- Row 9:** Shows the proper use of the LBSTAT variable to indicate "NOT DONE," when the fact that the test was done was documented.
- Row 12:** The subject had cholesterol measured. The normal range for this test is <200 mg/dL. The value <200 may not be used in the normal range variables LBORNRI or LBSTNRHI; however, an applicant may decide, for example, to enter "0" into LBORNRL and "199" in LBORNRI. The applicant must define the appropriate value for all of the normal range variables.
- Row 13:** Shows the use of LBUSCHFL to indicate that the test result was obtained from an unscheduled blood collection. In this case, the subject was moribund and a blood sample was taken prior to sacrifice.
- Rows 1, 6:** Use records in the SUPPLB dataset example to show biological significance assigned by the investigator for test results.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRLO
1	ABC	LB	ABC-001-001	1	ALB	Albumin	CLINICAL CHEMISTRY	LIVER FUNCTION	30	kg/m3	3.0	3	g/dL	3.5
2	ABC	LB	ABC-001-001	2	ALP	Alkaline Phosphatase	CLINICAL CHEMISTRY	GENERAL	398	U/L	398	398	U/L	40
3	ABC	LB	ABC-001-001	3	ALP	Alkaline Phosphatase	CLINICAL CHEMISTRY	GENERAL	350	U/L	350	350	U/L	40
4	ABC	LB	ABC-001-001	4	ALP	Alkaline Phosphatase	CLINICAL CHEMISTRY	GENERAL	374	U/L	374	374	U/L	40
5	ABC	LB	ABC-001-001	5	WBC	Leukocytes	HEMATOLOGY		5.9	10^9/L	5.9	5.9	10^9/L	4
6	ABC	LB	ABC-001-001	6	LYMLE	Lymphocytes/ Leukocytes	HEMATOLOGY	DIFFERENTIAL	6.7	%	6.7	6.7	%	25
7	ABC	LB	ABC-001-001	7	NEUT	Neutrophils	HEMATOLOGY	DIFFERENTIAL	5.1	10^9/L	5.1	5.1	10^9/L	2
8	ABC	LB	ABC-001-001	8	PH	pH	URINALYSIS		7.5		7.5	7.5		5.00
9	ABC	LB	ABC-001-001	9	ALB	Albumin	CLINICAL CHEMISTRY	LIVER FUNCTION						
10	ABC	LB	ABC-001-001	10	CREAT	Creatinine	CLINICAL CHEMISTRY		0.9	mg/dL	80	80	umol/L	44.201
11	ABC	LB	ABC-001-001	11	WBC	Leukocytes	HEMATOLOGY		5.9	10^9/L	5.9	5.9	10^9/L	4
12	ABC	LB	ABC-001-001	12	CHOL	Cholesterol	CLINICAL CHEMISTRY		229	mg/dL	229	229	mg/dL	0
13	ABC	LB	ABC-001-001	13	WBC	Leukocytes	HEMATOLOGY		9.8	10^9/L	9.8	9.8	10^9/L	4

Row	LBSTNRHI	LBNRIND	LBSTAT	LBREASND	LBSPEC	LBETHOD	LBBFL	LBFAST	LBDRVFL	LBUSCHFL	LBDTC	LBDY	LBNO MDY	LBNO MBL
1	5	LOW			SERUM		Y	Y			2006-07-19T08:30	1	1	Chemistry Day 1

Row	LBSTNRHI	LBNRIND	LBSTAT	LBREASND	LBSPEC	LBMETHOD	LBBLFL	LBFAST	LBDRVFL	LBUSCHFL	LBDTCT	LBDY	LBNO MDY	LBNO MBL
2	160				SERUM			Y			2006-07-19T08:30	1	1	Chemistry Day 1
3	160				SERUM			Y			2006-07-20T12:30	2	1	Chemistry Day 1
4	160				SERUM			Y	Y	Y	2006-07-19T08:30	1	1	Chemistry Day 1
5	11				WHOLE BLOOD			Y	Y		2006-07-19T08:30	1	1	Hematology Day 1
6	40	LOW			WHOLE BLOOD			Y	Y		2006-07-19T08:30	1	1	Hematology Day 1
7	8				WHOLE BLOOD			Y	Y		2006-07-19T08:30	1	1	Hematology Day 1
8	9.00				URINE			Y	Y		2006-07-19T08:30	1	1	Urinalysis Day 1
9		NOT DONE	Insufficient sample		SERUM						2006-07-24T09:00	6	6	Chemistry Day 6
10	114.9226				SERUM						2006-07-24T09:00	6	6	Chemistry Day 6
11	11				WHOLE BLOOD				Y		2006-07-24T09:00	6	6	Hematology Day 6
12	199	HIGH			SERUM						2006-07-24T09:00	6	6	Chemistry Day 6
13	11				WHOLE BLOOD					Y	2006-07-27T06:42	9	9	Unscheduled Hematology Day 9

supplb.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAME	QLABEL	QVAL	QORIG	QEVAL
1	ABC	LB	ABC-001-001	LBSEQ	1	BIOSIG	Biological Significance	N	OTHER	PRINCIPAL INVESTIGATOR
2	ABC	LB	ABC-001-001	LBSEQ	6	BIOSIG	Biological Significance	N	OTHER	PRINCIPAL INVESTIGATOR

Example 2**Rows 1-3:** Show urine analysis for glucose.**Row 1:** Shows an example of a predose urine collection interval (from 4 hours prior to dosing until 15 minutes prior to dosing) with a negative value for LBELTM that reflects the end of the interval in reference to dosing (LBTPTREF), the date of which is recorded in LBRFTDTC.**Rows 2-3:** Show an example of postdose urine collection intervals with values for LBELTM that reflect the end of the intervals in reference to the fixed reference LBTPTREF, the date of which is recorded in LBRFTDTC.**Row 4:** Shows an assessment of color was also included for the sample collected from 8 to 16 hours postdose.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRL	LBORNRI	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRLO
1	ABC	LB	ABC-001-001	1	GLUCOSE	Glucose	URINALYSIS	7	mg/dL	1	15	0.39	0.39	mmol/L	0.06
2	ABC	LB	ABC-001-001	2	GLUCOSE	Glucose	URINALYSIS	11	mg/dL	1	15	0.61	0.61	mmol/L	0.06
3	ABC	LB	ABC-001-001	3	GLUCOSE	Glucose	URINALYSIS	9	mg/dL	1	15	0.50	0.50	mmol/L	0.06
4	ABC	LB	ABC-001-001	4	COLOR	Color	URINALYSIS	YELLOW				YELLOW			

Row	LBSTNRHI	LBSPEC	LBMETHOD	LBBLFL	LBDTCT	LBENDTCT	LBDY	LBENDY	LBNO MDY	LBTPPT	LBTPNUM	LBELTM	LBTPTREF	LBRTFTDTC
1	0.83	URINE			2006-07-19T04:00	2006-07-19T07:45	1	1	1	Predose	1	-P15M	Day 1 dose	2006-07-19T08:00
2	0.83	URINE			2006-07-19T08:00	2006-07-19T16:00	1	1	1	0-8 hours after dosing	2	P8H	Day 1 dose	2006-07-19T08:00
3	0.83	URINE			2006-07-19T16:00	2006-07-20T00:00	1	2	1	8-16 hours after dosing	3	P16H	Day 1 dose	2006-07-19T08:00
4		URINE			2006-07-19T16:00	2006-07-20T00:00	1	2	1	8-16 hours after dosing	3	P16H	Day 1 dose	2006-07-19T08:00

Example 3

This is an example of urine glucose test records, 1 with a result and 1 with no result because the test was not performed due to sample being insufficient.

Row 1: Shows an example of a urine glucose test record that was originally recoded in the collection system as "-" (negative sign). Instead, the results show the text value associated with that code in both LBORRES and LBSTRESC.

Row 2: Shows an example of a serum glucose test that was not performed because the sample was exhausted, and the applicant felt it was necessary to report a record documenting the reason why the test was not performed.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSTAT	LBREASND	LBSPEC	LBMETHOD	LBBLFL	LBDTC	LBDY	LBNO MDY
1	ABC	LB	ABC-001-001	1	GLUCOSE	Glucose	URINALYSIS	NEGATIVE		NEGATIVE					URINE			2006-07-19T04:00	1	1
2	ABC	LB	ABC-001-002	1	GLUCOSE	Glucose	CLINICAL CHEMISTRY						NOT DONE	SAMPLE EXHAUSTED	SERUM			2006-07-24T08:00	5	5

Example 4

This is an example of albumin tests done for pooled subjects. Samples from subjects ABC-009, ABC-010, and ABC-011 were pooled, and their results were reported as pooled results. The associated POOLDEF rows follow, to illustrate the pool definition.

Rows 1-3: Show the results pooled from subjects ABC-009, ABC-010, and ABC-011, with POOLID of POOL001.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	POOLID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSPEC	LBMETHOD	LBBLFL	LBDTC	LBDY	LBNO MDY
1	ABC	LB		POOL001	1	ALB	Albumin	CLINICAL CHEMISTRY	3.0	g/dL	3.0	3.0	g/dL	SERUM			2006-07-19T04:00	1	1

pooldef.xpt

Row	STUDYID	POOLID	USUBJID
1	ABC	POOL001	ABC-009
2	ABC	POOL001	ABC-010
3	ABC	POOL001	ABC-011

Example 5

The following example shows cases of categorical data that cannot be considered as numeric, even though in some cases it appears that the data includes a number. The allowed values in these ranges should be defined in the data definition file. Samples were collected at 1 point and not over a given interval.

Rows 1-2: Show an example of urine ketones tests performed for 2 animals. The test's values are categorical, using a list (i.e., NEGATIVE, TRACE, SMALL, MODERATE, LARGE), the range of which is referenced in LBSTRNRC. LBSTRESN is left null.

Rows 3-4: Show an example of urine bilirubin tests performed for 2 animals. The test's values are categorical, using a list (i.e., NEGATIVE, 1+, 2+, 3+) which represents qualitative levels. Although the 1+, 2+, and 3+ values could be converted to numbers, the values represent a nonnumeric category based on an arbitrary scale; therefore, LBSTRESN is left blank.

Rows 5-6: Show an example of urine protein tests performed for 2 animals. The test's values are categorical, using a list (i.e., NEGATIVE, TRACE, 30, 100). Although the 30 and 100 values could be converted as numbers, the values represent a nonnumeric label of the result; therefore, LBSTRESN is left blank.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRC	LBSPEC	LBMETHOD	LBBLFL	LBDTC	LBDY	LBNO MDY
1	ABC	LB	ABC-001-001	1	KETONES	Ketones	URINALYSIS	SMALL		SMALL			NEGATIVE TO LARGE	URINE			2006-07-19	1	1
2	ABC	LB	ABC-001-002	2	KETONES	Ketones	URINALYSIS	LARGE		LARGE			NEGATIVE TO LARGE	URINE			2006-07-19	1	1
3	ABC	LB	ABC-001-001	3	BILI	Bilirubin	URINALYSIS	NEGATIVE		NEGATIVE			NEGATIVE TO 3+	URINE			2006-07-19	1	1
4	ABC	LB	ABC-001-002	4	BILI	Bilirubin	URINALYSIS	2+		2+			NEGATIVE TO 3+	URINE			2006-07-19	1	1

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRCC	LBSPEC	LBMETHOD	LBBLFL	LBDTCC	LBDY	LBNO
5	ABC	LB	ABC-001-001	5	PROT	Protein	URINALYSIS	TRACE		TRACE			NEGATIVE TO 100	URINE			2006-07-19	1	1
6	ABC	LB	ABC-001-002	6	PROT	Protein	URINALYSIS	30		30			NEGATIVE TO 100	URINE			2006-07-19	1	1

3.2.2.11 Macroscopic Findings (MA)

Example 1

This example demonstrates additional example findings.

Rows 1-4: These findings demonstrate original results with modifiers, including a severity, which is copied into MASEV. The base gross observations are entered into MASTRESC, and the remaining modifiers are submitted in MARESMOD supplemental qualifiers.

Row 3: The left lobe is not qualifying a part of the scheduled sampled specimen (LUNG), but qualifying the finding (as it is present in MAORRES) and, therefore, belongs as a result modifier in supplemental qualifier (MARESMOD) and not in MAANTREG.

Row 4: The finding demonstrates an original result with a comment that is copied into the Comments domain (see the CO dataset in this example).

Rows 5, 10: These findings demonstrate original results without modifiers.

Row 6: This finding demonstrates the use of specimen qualifiers (MAANTREG, MALAT, and MADIR).

Row 7: This is an example of a reason why a macroscopic evaluation was not done (MAREASND). Note that MAORRES is null and MASTAT is "NOT DONE".

Row 8: Represents a normal observation applied to all examined tissues for the subject. Note the MASPEC field's value of "ALL TISSUES".

Row 9: Represents a normal observation for the cecum.

ma.xpt

Row	STUDYID	DOMAIN	USUBJID	MASEQ	MASPID	MATESTCD	MATEST	MAORRES	MASTRESC	MASTAT	MAREASND	MASPEC	MAANTREG	MALAT	MADIR	MASEV	MADTC	MADY
1	123456	MA	123456-1001	1		GROSPATH	Gross Pathological Examination	Discoloration dark, mucosa	Discoloration			LARGE INTESTINE, CECUM					2011-03-23	365
2	123456	MA	123456-1001	2		GROSPATH	Gross Pathological Examination	Foci dark, mucosa	Foci			LARGE INTESTINE, COLON		DISTAL			2011-03-23	365
3	123456	MA	123456-1001	3		GROSPATH	Gross Pathological Examination	Congestion, left lobe moderate	Congestion			LUNG			MODERATE		2011-03-23	365
4	123456	MA	123456-1001	4		GROSPATH	Gross Pathological Examination	Bulla, right caudal lobe, 1 cm in diameter, one section	Bulla			LUNG					2011-03-23	365
5	123456	MA	123456-1001	5		GROSPATH	Gross Pathological Examination	Small	Small			THYMUS					2011-03-23	365
6	123456	MA	123456-1002	6	MASS 1	GROSPATH	Gross Pathological Examination	Mass, approximately 8 mm long, 6 mm wide, 4 mm thick, pale firm well defined	Mass			BONE, FEMUR	STIFLE	LEFT	MEDIAL		2011-03-23	365
7	123456	MA	123456-1002	7		GROSPATH	Gross Pathological Examination			NOT DONE	Tissue lost	GLAND, PITUITARY					2011-03-23	365
8	123456	MA	123456-1003	8		GROSPATH	Gross Pathological Examination	No necropsy observations noted.	UNREMARKABLE			ALL TISSUES					2011-03-23	365
9	123456	MA	123456-1004	9		GROSPATH	Gross Pathological Examination	Normal	UNREMARKABLE			LARGE INTESTINE, CECUM					2011-03-24	366
10	123456	MA	123456-1004	10		GROSPATH	Gross Pathological Examination	Adhesion	Adhesion			LUNG					2011-03-24	366

suppma.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAME	QLABEL	QVAL	QORIG
1	123456	MA	123456-1001	MASEQ	1	MARESMOD	Result Modifiers	dark; mucosa	COLLECTED
2	123456	MA	123456-1001	MASEQ	2	MARESMOD	Result Modifiers	dark; mucosa	COLLECTED
3	123456	MA	123456-1001	MASEQ	3	MARESMOD	Result Modifiers	left lobe	COLLECTED
4	123456	MA	123456-1001	MASEQ	4	MARESMOD	Result Modifiers	right caudal lobe; 1 cm in diameter	COLLECTED
5	123456	MA	123456-1001	MASEQ	6	MARESMOD	Result Modifiers	approximately 8 mm long, 6 mm wide, 4 mm thick; pale; firm; well defined	COLLECTED

This table demonstrates the representation of the comment which was included in MAORRES.

co.xpt

Row	STUDYID	DOMAIN	RDOMAIN	USUBJID	COSEQ	IDVAR	IDVARVAL	COVAL	COTDC	CODY
1	123456	CO	MA	123456-1001	1	MASEQ	4	one section	2011-03-23	365

Example 2

This example demonstrates the use of the domain to record clinical signs follow-up examinations performed at necropsy.

Rows 1-2: Represents examples of a follow-up of a clinical observation that could not be confirmed at necropsy.

Row 3: Represents an example of a follow-up of a clinical observation that was confirmed at necropsy.

ma.xpt

Row	STUDYID	DOMAIN	USUBJID	MASEQ	MATESTCD	MATEST	MAORRES	MASTRESC	MASPEC	MAANTREG	MADTC	MADY
1	999123	MA	999123-101	16	CLSFUP	Clinical Signs Follow-up	MASS NOT FOUND AT NECROPSY	MASS NOT FOUND AT NECROPSY			2000-01-31T14:33:21	365
2	999123	MA	999123-101	17	CLSFUP	Clinical Signs Follow-up	NOT PRESENT	NOT PRESENT			2000-01-31T14:33:21	365
3	999123	MA	999123-101	18	CLSFUP	Clinical Signs Follow-up	PRESENT	PRESENT			2000-01-31T14:33:21	365

This RELREC demonstrates a linking between a specific clinical observation (CLSEQ) and its corresponding clinical sign follow-up at necropsy (MASEQ).

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	POOLID	IDVAR	IDVARVAL	RELTYPE	RELID
1	999123	CL	123456		CLSEQ	47		62
2	999123	CL	123456		CLSEQ	49		63
3	999123	CL	123456		CLSEQ	51		64
4	999123	MA	123456		MASEQ	16		62
5	999123	MA	123456		MASEQ	17		63
6	999123	MA	123456		MASEQ	18		64

This example demonstrates a linking between findings across the Clinical Observations (CL), Palpable Masses (PM), MA, Microscopic Findings (MI), and Tumor Findings (TF) domains using RELREC. The mass was first identified as an abrasion over several weeks (grouped by CLGRPID = 5), graduating to a mass with several associated clinical findings (identified by a CLSPID of "MASS 2"). These clinical findings correspond to a set of findings in the PM domain, a clinical signs follow-up and gross pathological examination in the MA domain, a single microscopic finding from the MI domain, and a single tumor finding in the TF domain. Each of the findings in the PM, MA, MI, and TF are related by way of the --SPID field, with a value of "MASS 2".

Because all of these records are related, they are given the same RELID (in this case a value of 80).

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	POOLID	IDVAR	IDVARVAL	RELTYPE	RELID
1	PY001002	CL	AA-12540		CLGRPID	5		80
2	PY001002	CL	AA-12540		CLSPID	MASS 2		80
3	PY001002	PM	AA-12540		PMSPID	MASS 2		80
4	PY001002	MA	AA-12540		MASPID	MASS 2		80
5	PY001002	MI	AA-12540		MISPID	MASS 2		80
6	PY001002	TF	AA-12540		TFSPID	MASS 2		80

Example 3

These are example records of a macroscopic evaluation of injection sites (as indicated in FOCID).

ma.xpt

Row	STUDYID	DOMAIN	USUBJID	FOCID	MASEQ	MASPID	MASTESTCD	MATEST	MAORRES	MASTRESC	MASPEC	MAANTREG	MALAT	MADIR	MASEV
1	12345	MA	12345001	Injection site 1	1		GROSPATH	Gross Pathological Examination	Fur thin cover	Focal hair loss	SKIN		LEFT	DORSOCRANIAL	
2	12345	MA	12345001	Injection site 2	2		GROSPATH	Gross Pathological Examination	Unremarkable	UNREMARKABLE	SKIN		RIGHT	DORSOCRANIAL	
3	12345	MA	12345001	Injection site 3	3		GROSPATH	Gross Pathological Examination	Focal hemorrhage	Hemorrhage	SKIN		LEFT	DORSOCAUDAL	
4	12345	MA	12345001	Injection site 4	4	MASS 1	GROSPATH	Gross Pathological Examination	Mass, approximately 8 mm long, 4 mm thick, pale firm well defined	Mass	SKIN		RIGHT	DORSOCAUDAL	
5	12345	MA	12345002	Injection site 1	1		GROSPATH	Gross Pathological Examination	Unremarkable	UNREMARKABLE	SKIN		LEFT	DORSOCRANIAL	
6	12345	MA	12345002	Injection site 2	2		GROSPATH	Gross Pathological Examination	Discoloration; subcutaneous; red; slight	Discoloration	SKIN		RIGHT	DORSOCRANIAL	MILD
7	12345	MA	12345002	Injection site 3	3		GROSPATH	Gross Pathological Examination	Unremarkable	UNREMARKABLE	SKIN		LEFT	DORSOCAUDAL	
8	12345	MA	12345002	Injection site 4	4		GROSPATH	Gross Pathological Examination	Mucosal hemorrhage (about 2x2 cm), moderate	Hemorrhage	SKIN		RIGHT	DORSOCAUDAL	MODERATE

Note that the concept of "MASS 1" (in CLSPID) is different from "Injection site 1" (in FOCID), in that information in the FOCID variable is known prior to the examination, but the mass ID/applicant identifier is assigned as part of the examination. FOCID thereby qualifies the test, whereas CLSPID qualifies the result.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	FOCID	CLSEQ	CLSPID	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	CLLOC	CLSEV	CLDTC	CLDY	CLNOMDY
1	12345	CL	12345001	Injection site 1	1		SKINEX	Skin Examination	CLINICAL SIGNS	Fur, Thin Cover; Left Scapula	Fur, Thin Cover	Left Scapula		2004-07-19	42	42
2	12345	CL	12345001	Injection site 2	2		SKINEX	Skin Examination	CLINICAL SIGNS	No Abnormal Findings, Right Scapula	Unremarkable	Right Scapula		2004-07-19	42	42
3	12345	CL	12345001	Injection site 3	3		SKINEX	Skin Examination	CLINICAL SIGNS	No Abnormal Findings, Left Medial Back	Unremarkable	Left Medial Back		2004-07-19	42	42
4	12345	CL	12345001	Injection site 4	4	MASS 1	SKINEX	Skin Examination	CLINICAL SIGNS	Moderate Swelling, Right Medial Back	Swelling	Right Medial Back	MODERATE	2004-07-19	42	42
5	12345	CL	12345002	Injection site 1	1		SKINEX	Skin Examination	CLINICAL SIGNS	No Abnormal Findings, Left Scapula	Unremarkable	Left Scapula		2004-07-19	42	42

Row	STUDYID	DOMAIN	USUBJID	FOCID	CLSEQ	CLSPID	CLTESTCD	CLTEST	CLCAT	CLRRRES	CLSTRESC	CLLOC	CLSEV	CLDTG	CLDY	CLNOMDY
6	12345	CL	12345002	Injection site 2	2		SKINEX	Skin Examination	CLINICAL SIGNS	Slight Reddening, Right Scapula	Reddening	Right Scapula	MILD	2004-07-19	42	42
7	12345	CL	12345002	Injection site 3	3		SKINEX	Skin Examination	CLINICAL SIGNS	Abrasion, Left Medial Back	Abrasions	Left Medial Back		2004-07-19	42	42
8	12345	CL	12345002	Injection site 4	4		SKINEX	Skin Examination	CLINICAL SIGNS	Moderate Reddening, Right Medial Back	Reddening	Right Medial Back	MODERATE	2004-07-19	42	42

3.2.2.12 Microscopic Findings (MI)

Example 1

This example shows different types of histopathological findings for 6 different animals.

- Rows 1-2:** For these findings, the specimen consists of tissues from both the testis and the epididymis. Therefore, the list of tissues comprising the specimen becomes the SPEC value for each contributing tissue, noted by a slash, as is found in the controlled terminology list.
- Row 2:** For this finding, the base pathological process is inflammation, and is recorded in MISTRESC. The term "acute" is recorded in MICHRON using the controlled CHRNCTY codelist term ACUTE.
- Row 3:** For this finding, the specimen consists of skeletal muscle. The base pathological process is degeneration/regeneration and is represented in MISTRESC. The term "Myofiber" is recorded in MIRESMOD (SUPPMI example).
- Row 4:** This is an example of a reason why a microscopic evaluation of the mammary gland specimen was not performed. Note that MIORRES is null and MISTAT is "NOT DONE", the reason for the specimen not being evaluated is entered in MIREASND.
- Row 5:** This shows an example of a record where the specimen contained no pathologic process. A record should be included for every scheduled specimen that was without pathology. The controlled NONNEO term "UNREMARKABLE" is recorded in MISTRESC. **Note:** There is no MIRESCAT for "UNREMARKABLE" as there is no finding.
- Row 6:** In this record, the finding was the cause of death; therefore, MIDTHREL is "Y" (Yes).
- Row 7:** The base pathological process is hyperplasia, recorded into MISTRESC from the NONNEO controlled terminology list. The modifiers "endometrial" and "cystic" are recorded in MIRESMOD (SUPPMI example). Note that the 2 values for MIRESMOD are separated by a semicolon, as required in Section 6.3.8.
- Row 8:** For this finding, a mass identified as mass 1 (MISPID="MASS 1") is observed on the left ovary (MILAT = "LEFT"). This mass is considered benign (MIRESCAT). Note that MISTRESC contains controlled terminology for the tumor, which may include term(s) similar to characteristics and/or distribution as part of the base pathological process.
- Row 9:** This is an example of a malignant mass (MISPID = "MASS 2"). The malignancy of the mass is recorded as part of the original result (MIORRES) as well as the controlled term in MIRESCAT. This finding was not the cause of death of the subject (MIDTHREL= "N"). Note that MISTRESC contains only the finding without modifiers. This record is linked to row 11 (via the MIGRID value of 1) to relate the primary tumor with its metastasis in another tissue. The tumor origin described in MIORRES ("Primary") is associated to the MI records using the supplemental qualifier MIRESMOD (SUPPMI example).
- Row 10:** This shows an example of a metastasis found in the uterus. The primary site for this tumor is unknown, and the applicant decided to include row 13 ("SITE, UNCERTAIN PRIMARY") to represent the source tumor. This record is related to rows 12 and 13 via the MIGRID value of 2.

- Row 11:** This finding describes a mass (MISPID="MASS 3") that is a metastasis of a primary tumor, which is recorded in the original result (MIORRES). This specific finding did not cause the death of the animal (MIDTHREL="N"). This record is linked to row 9 via the MIGRID value of 1 to relate the metastasis to the finding at the primary site identified for the tumor.
- Row 12:** This record illustrates another metastasis row for the lymphoma found in multiple sites. This record is related to rows 10 and 13 via the MIGRID value of 2.
- Row 13:** This record is an example of how to represent an unknown primary site for the lymphoma found in the uterus and vagina (row 11). The applicant decided to include a row to represent the base tumor (TFSPEC="SITE, UNCERTAIN PRIMARY") related to the metastasis row via the MIGRID of 2, and defining it as the cause of death (MIDTHREL="Y"). Note: The use of "SITE, UNCERTAIN PRIMARY" is applicant-specific; an alternative (based on how the data are collected) would be to exclude this row and only include rows for each site at which the tumor was found.
- Rows 14-15:** These findings demonstrate an original result with modifiers, including a severity which is copied into MISEV. The base pathological process is entered into MISTRESC using the controlled terminology list and the remaining modifiers are recorded in MIRESMOD ("Mononuclear Cell" for line 14) and MIDISTR ("Multifocal" for line 15) in the SUPPMI example.
- Rows 16-17:** These findings demonstrate the use of specimen location qualifiers of MIANTREG, MILAT, and MIDIR.
- Row 18:** This finding demonstrates the use of finding qualifiers MICHRON, MIDISTR, and MIRESMOD, and the use of a semicolon to separate 2 terms in MIRESMOD (SUPPMI example).
- Row 19:** This record is an example of an incidental malignant neoplasm in the liver that has not metastasized. The MIDTHREL is "N" because the tumor is incidental.

mi.xpt

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MIGRID	MISPID	MITESTCD	MITEST	MIORRES	MISTRESC	MICHRON	MIDISTR	MIRESCAT
1	123	MI	123-01	1			GHISTXQL	General Histopathologic Exam, Qual	Amyloidosis, grade 2	AMYLOID			NON-NEOPLASTIC
2	123	MI	123-01	2			GHISTXQL	General Histopathologic Exam, Qual	Inflammation, acute, grade 2	INFLAMMATION	ACUTE		NON-NEOPLASTIC
3	123	MI	123-01	3			GHISTXQL	General Histopathologic Exam, Qual	Degeneration/regeneration, myofiber, grade 4	DEGENERATION/REGENERATION			NON-NEOPLASTIC
4	123	MI	123-01	4			GHISTXQL	General Histopathologic Exam, Qual					
5	123	MI	123-01	5			GHISTXQL	General Histopathologic Exam, Qual	Normal	UNREMARKABLE			
6	123	MI	123-02	6			GHISTXQL	General Histopathologic Exam, Qual	Inflammation, meninges, grade 5	INFLAMMATION			NON-NEOPLASTIC
7	123	MI	123-03	7			GHISTXQL	General Histopathologic Exam, Qual	Hyperplasia, endometrial cystic, grade 3	HYPERPLASIA			NON-NEOPLASTIC
8	123	MI	123-03	8		MASS 1	GHISTXQL	General Histopathologic Exam, Qual	Adenoma: tubulostromal (benign neoplasm), left	ADENOMA, TUBULOSTROMAL, BENIGN			BENIGN

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MIGRPID	MISPID	MTESTCD	MTEST	MIORRES	MISTRESC	MICHRON	MIDISTR	MIRESCAT
9	123	MI	123-03	9	1	MASS 2	GHISTXQL	General Histopathologic Exam, Qual	Sarcoma: endometrial stromal (malignant neoplasm), Primary	STROMAL SARCOMA, ENDOMETRIAL, MALIGNANT			MALIGNANT
10	123	MI	123-03	10	2		GHISTXQL	General Histopathologic Exam, Qual	Lymphoma: metastasis	LYMPHOMA, MALIGNANT			METASTATIC
11	123	MI	123-03	11	1	MASS 3	GHISTXQL	General Histopathologic Exam, Qual	Sarcoma: metastasis; Uterus was the primary site	SARCOMA, MALIGNANT			METASTATIC
12	123	MI	123-03	12	2		GHISTXQL	General Histopathologic Exam, Qual	Lymphoma: metastasis	LYMPHOMA, MALIGNANT			METASTATIC
13	123	MI	123-03	13	2		GHISTXQL	General Histopathologic Exam, Qual	Lymphoma: multicentric	LYMPHOMA, MALIGNANT			MALIGNANT
14	123	MI	123-04	14			GHISTXQL	General Histopathologic Exam, Qual	Infiltrate, mononuclear cell, grade 1	INFILTRATE			NON-NEOPLASTIC
15	123	MI	123-04	15			GHISTXQL	General Histopathologic Exam, Qual	Atrophy, multifocal, grade 2	ATROPHY		MULTIFOCAL	NON-NEOPLASTIC
16	123	MI	123-04	16			GHISTXQL	General Histopathologic Exam, Qual	Intra-alveolar hemorrhage, right, grade 2	HEMORRHAGE			NON-NEOPLASTIC
17	123	MI	123-04	17			GHISTXQL	General Histopathologic Exam, Qual	Cyst, right, anterior	CYST			NON-NEOPLASTIC
18	123	MI	123-05	18			GHISTXQL	General Histopathologic Exam, Qual	Inflammation, moderate, chronic, multifocal, mucosal, forestomach, grade 3	INFLAMMATION	CHRONIC	MULTIFOCAL	NON-NEOPLASTIC
19	123	MI	123-06	19			GHISTXQL	General Histopathologic Exam, Qual	Hepatocellular carcinoma (malignant neoplasm without metastasis), incidental	CARCINOMA, HEPATOCELLULAR, MALIGNANT			MALIGNANT

Row	MISTAT	MIREASND	MISPEC	MIANTREG	MISPCCND	MISPCUFL	MILAT	MIDIR	MISEV	MIDTHREL	MIDTC	MIDY
1			TESTIS/EPIDIDYMIS						MILD		2015-10-27	365
2			TESTIS/EPIDIDYMIS						MILD		2015-10-27	365
3			MUSCLE, SKELETAL						MARKED		2015-10-27	365
4	NOT DONE	Tissue not present for histologic examination no glandular tissue in section	GLAND, MAMMARY								2015-10-27	365
5			GLAND, PARATHYROID								2015-10-27	365
6			BRAIN						SEVERE	Y	2015-05-15	200
7			UTERUS						MODERATE		2015-10-27	365
8			OVARY				LEFT			N	2015-10-27	365
9			UTERUS							N	2015-10-27	365
10			UTERUS							U	2015-10-27	365
11			VAGINA							N	2015-10-27	365
12			VAGINA							U	2015-10-27	365

Row	MISTAT	MIREASND	MISPEC	MIANTREG	MISPCCND	MISPCUFL	MILAT	MIDIR	MISEV	MIDTHREL	MIDTC	MIDY
13			SITE, UNCERTAIN PRIMARY							Y	2015-10-27	365
14			MENINGES						MINIMAL		2015-10-27	365
15			TESTIS						MILD		2015-10-27	365
16			LUNG	CRANIAL LOBE			RIGHT		MILD		2015-10-27	365
17			KIDNEY				RIGHT	ANTERIOR			2015-10-27	365
18			STOMACH						MODERATE		2015-10-27	365
19			LIVER							N	2015-10-07	345

Rows 1-7: These rows show the supplemental qualifier records for the modifiers associated with the findings in Example 1. Via IDVAR and IDVARVAL, these records are linked to the MISEQ with the values 3, 7, 9, 13, 14, 16, and 18, respectively.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	123	MI	123-01	MISEQ	3	MIRESMOD	Result Modifiers	Myofiber	COLLECTED	PATHOLOGIST
2	123	MI	123-03	MISEQ	7	MIRESMOD	Result Modifiers	Endometrial; Cystic	COLLECTED	PATHOLOGIST
3	123	MI	123-03	MISEQ	9	MIRESMOD	Result Modifiers	Primary	COLLECTED	PATHOLOGIST
4	123	MI	123-03	MISEQ	13	MIRESMOD	Result Modifiers	Multicentric	COLLECTED	PATHOLOGIST
5	123	MI	123-04	MISEQ	14	MIRESMOD	Result Modifiers	Mononuclear Cell	COLLECTED	PATHOLOGIST
6	123	MI	123-04	MISEQ	16	MIRESMOD	Result Modifiers	Intraalveolar	COLLECTED	PATHOLOGIST
7	123	MI	123-05	MISEQ	18	MIRESMOD	Result Modifiers	Mucosal; Forestomach	COLLECTED	PATHOLOGIST

This comment table shows the representation of the comment that was included in MIORRES.

Row 1: Demonstrates the representation of the comment that was included in MIORRES.

Row 2: Shows how to represent a comment for an animal tissue that is not associated with any particular finding.

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Row	STUDYID	DOMAIN	RDOMAIN	USUBJID	COSEQ	IDVAR	IDVARVAL	COVAL	CODTC
1	123	CO	MI	123-03	1	MISEQ	11	Site of primary neoplasm: UTERUS	
2	123	CO	MI	123-01	2	MISPEC	GLAND, PARATHYROID	One of pair present	

Example 2

This example shows some multiple-base pathological processes, collected as if they were 1 finding.

The original descriptive text by the pathologist is repeated in the original result fields (MIORRES), because a finding should comprise only 1 base pathological process and its modifiers (severity, chronicity, or distribution, and the remaining in result modifiers as a supplemental qualifier record). Because there are 3 base processes described in MIORRES, there needs to be 3 records, each with 1 base process in MISTRESC.

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Row	STUDYID	DOMAIN	USUBJID	MISEQ	MIGRPID	MIREFID	MITESTCD	MITEST	MIORRES	MISTRESC	MICHRON	MIDISTR	MISPEC	MISPCCND	MISPCUFL	MISEV	MIDTC	MIDY
1	ABC	MI	ABC-101	1	1	101-A1	GHISTXQL	General Histopathologic Exam, Qual	Necrosis-hepatocytes in centrilobular area surrounded by slight acute inflammation with	NECROSIS			LIVER			1991-05-17	91	

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MIGRPID	MIREFID	MITESTCD	MITEST	MIORRES	MISTRESC	MICHRON	MIDISTR	MISPEC	MISPCCND	MISPCUFL	MISEV	MIDTC	MIDY
									moderate hemorrhage									
2	ABC	MI	ABC-101	2	1	101-A1	GHISTXQL	General Histopathologic Exam, Qual	Necrosis-hepatocytes in centrilobular area surrounded by slight acute inflammation with moderate hemorrhage	INFLAMMATION	ACUTE		LIVER			MILD	1991-05-17	91
3	ABC	MI	ABC-101	3	1	101-A1	GHISTXQL	General Histopathologic Exam, Qual	Necrosis-hepatocytes in centrilobular area surrounded by slight acute inflammation with moderate hemorrhage	HEMORRHAGE			LIVER			MODERATE	1991-05-17	91

This row shows the supplemental qualifier record for the modifiers associated with the findings in row 1.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	MI	ABC-101	MISEQ	3	MIRESMOD	Result Modifiers	Hepatocytes; Centrilobular	COLLECTED	PATHOLOGIST

Example 3

This example shows the result of a histopathological evaluation of 2 injection sites on 1 animal.

Rows 1-2: This shows 2 observations (base pathological processes) for injection site 1 (in FOCID). The finding is standardized when mapping to the controlled terminology in MISTRESC, MICHRON, MIDISTR, MISEV, and any additional modifiers in MIRESMOD (SUPPMI example).

Row 3: A second injection site (in FOCID) on the same animal was also examined.

mi.xpt

Row	STUDYID	DOMAIN	USUBJID	FOCID	MISEQ	MITESTCD	MITEST	MIORRES	MISTRESC	MICHRON	MIDISTR	MISPEC	MISPCCND	MISPCUFL	MISEV	MIDTC	MIDY
1	ABC	MI	ABC-101	Injection Site 1	1	GHISTXQL	General Histopathologic Exam, Qual	Subcutaneous Inflammation, Minimal	INFLAMMATION			SITE, INJECTION			MINIMAL	2015-10-27	42
2	ABC	MI	ABC-101	Injection Site 1	2	GHISTXQL	General Histopathologic Exam, Qual	Panniculus Muscle-Inflammation/Degeneration, Focal, Slight	INFLAMMATION/DEGENERATION		FOCAL	SITE, INJECTION			MILD	2015-10-27	42
3	ABC	MI	ABC-101	Injection Site 2	3	GHISTXQL	General Histopathologic Exam, Qual	Subcutaneous Hemorrhage, Minimal	HEMORRHAGE			SITE, INJECTION			MINIMAL	2015-10-27	42

This row shows the supplemental qualifier record for the modifiers associated with the findings in MI.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	MI	ABC-101	MISEQ	1	MIRESMOD	Result Modifiers	Subcutaneous	COLLECTED	PATHOLOGIST
2	ABC	MI	ABC-101	MISEQ	2	MIRESMOD	Result Modifiers	Panniculus Muscle	COLLECTED	PATHOLOGIST
3	ABC	MI	ABC-101	MISEQ	3	MIRESMOD	Result Modifiers	Subcutaneous	COLLECTED	PATHOLOGIST

Example 4

This example shows how to tabulate data for a bilateral organ, where both sides were examined and only 1 result was reported.

One side was unremarkable and the other side had a finding. "UNREMARKABLE" was not tabulated; only the finding was included. Per schedule, both sides of the kidney were examined, so MILAT is "BOTH". Because the finding is reported for 1 unspecified side (unilateral), this is the result location, consequently tabulated as a result modifier (see MIRESMOD example below).

mi.xpt

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MTESTCD	MTEST	MORRES	MISTRESC	MICHRON	MIDISTR	MISPEC	MISPCCN	MISPCUFL	MILAT	MIEV	MIDTC	MIDY
1	ABC	MI	ABC-101	1	GHISTXQL	General Histopathologic Exam, Qual	Acute focal glomerular hemorrhage, unilateral	HEMORRHAGE	ACUTE	FOCAL	KIDNEY			BOTH		2015-10-27	42

This row shows the supplemental qualifier record for the modifiers associated with the findings in MI.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	MI	ABC-101	MISEQ	1	MIRESMOD	Result Modifiers	glomerular; unilateral	COLLECTED	PATHOLOGIST

3.2.2.13 Organ Measurements (OM)

Example 1

The following example shows how an applicant would supply a domain containing organ weights and relative organ weights.

om.xpt

Row	STUDYID	DOMAIN	USUBJID	OMSEQ	OMTESTCD	OMTEST	OMORRES	OMORRESU	OMSTRESC	OMSTRESN	OMSTRESU	OMSTAT	OMREASND	OMSPEC	OMDTC	OMDY
1	MOCK	OM	SUB1	1	WEIGHT	Weight	10.0	g	10.0	10.0	g			LIVER	2006-10-08	5
2	MOCK	OM	SUB2	2	WEIGHT	Weight	9.8	g	9.8	9.8	g			LIVER	2006-10-08	5
3	MOCK	OM	SUB3	3	WEIGHT	Weight	10.3	g	10.3	10.3	g			LIVER	2006-10-08	5
4	MOCK	OM	SUB1	4	WEIGHT	Weight	11.0	g	11.0	11.0	g			BRAIN	2006-10-08	5
5	MOCK	OM	SUB2	5	WEIGHT	Weight	10.2	g	10.2	10.2	g			BRAIN	2006-10-08	5
6	MOCK	OM	SUB3	6	WEIGHT	Weight	10.3	g	10.3	10.3	g			BRAIN	2006-10-08	5
7	MOCK	OM	SUB1	7	WEIGHT	Weight	10.0	g	10.0	10.0	g			HEART	2006-10-08	5
8	MOCK	OM	SUB2	8	WEIGHT	Weight	9.8	g	9.8	9.8	g			HEART	2006-10-08	5
9	MOCK	OM	SUB3	9	WEIGHT	Weight	10.3	g	10.3	10.3	g			HEART	2006-10-08	5
10	MOCK	OM	SUB1	10	OWBW	Organ to Body Weight Ratio						NOT DONE	MISSING TERMINAL BODY WEIGHT	LIVER		
11	MOCK	OM	SUB2	11	OWBW	Organ to Body Weight Ratio	0.030	RATIO	0.030	0.03	RATIO			LIVER	2006-10-08	5
12	MOCK	OM	SUB3	12	OWBW	Organ to Body Weight Ratio	0.033	RATIO	0.033	0.033	RATIO			LIVER	2006-10-08	5
13	MOCK	OM	SUB1	16	OWBR	Organ to Brain Weight Ratio	0.909	RATIO	0.909	0.909	RATIO			LIVER	2006-10-08	5
14	MOCK	OM	SUB2	17	OWBR	Organ to Brain Weight Ratio	0.961	RATIO	0.961	0.961	RATIO			LIVER	2006-10-08	5
15	MOCK	OM	SUB3	18	OWBR	Organ to Brain Weight Ratio	1.000	RATIO	1.000	1	RATIO	OMSTAT		LIVER	2006-10-08	5

Row	STUDYID	DOMAIN	USUBJID	OMSEQ	OMTESTCD	OMTEST	OMRRES	OMRRESU	OMSTRESC	OMSTRESN	OMSTRESU	OMSTAT	OMREASND	OMSPEC	OMDTC	OMDY
16	MOCK	OM	SUB1	13	OWHT	Organ to Heart Weight Ratio	1.000	RATIO	1.000	1	RATIO			LIVER	2006-10-08	5
17	MOCK	OM	SUB2	14	OWHT	Organ to Heart Weight Ratio	1.000	RATIO	1.000	1	RATIO			LIVER	2006-10-08	5
18	MOCK	OM	SUB3	15	OWHT	Organ to Heart Weight Ratio	1.000	RATIO	1.000	1	RATIO			LIVER	2006-10-08	5

Example 2: Using Anatomical Regions

om.xpt

Row	STUDYID	DOMAIN	USUBJID	OMSEQ	OMTESTCD	OMTEST	OMRRES	OMRRESU	OMSTRESC	OMSTRESN	OMSTRESU	OMSPEC	OMANTREG	OMLAT	OMDTC	OMDY
1	MOCK	OM	SUB1	1	WEIGHT	Weight	5.0	g	5.0	5.0	g	KIDNEY	Cortex	LEFT	2006-10-08	5
2	MOCK	OM	SUB2	2	WEIGHT	Weight	4.3	g	4.3	4.3	g	KIDNEY	Cortex	LEFT	2006-10-08	5
3	MOCK	OM	SUB3	3	WEIGHT	Weight	5.2	g	5.2	5.2	g	KIDNEY	Cortex	LEFT	2006-10-08	5

3.2.2.14 Palpable Masses (PM)

Example 1

This example shows masses with additional tests collected.

Rows 1-10: Reflect the findings for the third mass of subject A0001043, observed on the lower abdomen.

Rows 11-20: Reflect the findings for the first mass of subject A0001201, observed on the mid tail.

pm.xpt

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMSPID	PMTESTCD	PMTEST	PMRRES	PMRRESU	PMSTRESC	PMSTRESN	PMSTRESU	PMLOC	PMDTC	PMDY	PMNOMDY
1	123456-A	PM	A0001043	102	MASS 3	SHAPE	Shape	Round		Round			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
2	123456-A	PM	A0001043	103	MASS 3	DEPTH	Depth	0.4	mm	0.4	0.4	mm	LOWER ABDOMEN	2001-09-16T09:59:04	42	42
3	123456-A	PM	A0001043	104	MASS 3	DIAMETER	Diameter	4.7	mm	4.7	4.7	mm	LOWER ABDOMEN	2001-09-16T09:59:04	42	42
4	123456-A	PM	A0001043	105	MASS 3	LENGTH	Length	1.6	mm	1.6	1.6	mm	LOWER ABDOMEN	2001-09-16T09:59:04	42	42
5	123456-A	PM	A0001043	106	MASS 3	WIDTH	Width	1.4	mm	1.4	1.4	mm	LOWER ABDOMEN	2001-09-16T09:59:04	42	42
6	123456-A	PM	A0001043	107	MASS 3	CONSIST	Consistency	Hard		Hard			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
7	123456-A	PM	A0001043	108	MASS 3	COLOR	Color	Yellow		Yellow			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
8	123456-A	PM	A0001043	109	MASS 3	HAIRCOV	Hair Cover	Y		Y			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
9	123456-A	PM	A0001043	110	MASS 3	ULCER	Ulceration	NON-ULCERATED		NON-ULCERATED			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
10	123456-A	PM	A0001043	111	MASS 3	DESCR	Description	Scabbed, Red		Scabbed, Red			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
11	123456-A	PM	A0001201	256	MASS 1	SHAPE	Shape	Oval		Oval			MID TAIL	2001-09-23T11:23:51	49	49
12	123456-A	PM	A0001201	257	MASS 1	DEPTH	Depth	1.0	mm	1.0	1	mm	MID TAIL	2001-09-23T11:23:51	49	49
13	123456-A	PM	A0001201	258	MASS 1	DIAMETER	Diameter	6.1	mm	6.1	6.1	mm	MID TAIL	2001-09-23T11:23:51	49	49
14	123456-A	PM	A0001201	259	MASS 1	LENGTH	Length	2.1	mm	2.1	2.1	mm	MID TAIL	2001-09-23T11:23:51	49	49
15	123456-A	PM	A0001201	260	MASS 1	WIDTH	Width	1.6	mm	1.6	1.6	mm	MID TAIL	2001-09-23T11:23:51	49	49

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMSPID	PMTESTCD	PMTEST	PMORRES	PMORRESU	PMSTRESC	PMSTRESN	PMSTRESU	PMLOC	PMDTC	PMDY	PMNOMDY
16	123456-A	PM	A0001201	261	MASS 1	CONSIST	Consistency	Soft		Soft			MID TAIL	2001-09-23T11:23:51	49	49
17	123456-A	PM	A0001201	262	MASS 1	COLOR	Color	Brown		Brown			MID TAIL	2001-09-23T11:23:51	49	49
18	123456-A	PM	A0001201	263	MASS 1	HAIRCOV	Hair Cover	No		N			MID TAIL	2001-09-23T11:23:51	49	49
19	123456-A	PM	A0001201	264	MASS 1	ULCER	Ulceration	ULCERATED		ULCERATED			MID TAIL	2001-09-23T11:23:51	49	49
20	123456-A	PM	A0001201	265	MASS 1	DESCR	Description	Scratch marks around base of mass.		Scratch marks around base of mass.			MID TAIL	2001-09-23T11:23:51	49	49

Example 2

This example shows tests where the observations were collected as single descriptions in the collection system.

- Row 1:** Reflects the finding for the first mass of subject ABC0013, observed on the left thoracic region. The collected result of the mass is the description of its size, along with additional information collected on the ulceration. Note that the PMORRES field contains all originally collected text, and that the PMSTRESC field has the location removed and submitted in PMLOC.
- Row 2:** Reflects the finding for the first mass of subject ABC0016, observed on the dorsal side of the tail. The collected result of the mass is a description of its size, along with some additional information collected on the color and ulceration.
- Row 3:** Reflects the finding for the second mass of subject ABC0016, observed on the right hind limb. The collected result of the mass is just a description of its size.

pm.xpt

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMSPID	PMTESTCD	PMTEST	PMORRES	PMORRESU	PMSTRESC	PMSTRESN	PMSTRESU	PMLOC	PMDTC	PMDY	PMNOMDY
1	ABC-123	PM	ABC0013	17	MASS 1	DESCR	Description	2.0 mm x 1.1 mm, Ulcerated, Left Thoracic Region		2.0 mm x 1.1 mm, Ulceration			LEFT THORACIC REGION	2000-03-11	42	42
2	ABC-123	PM	ABC0016	19	MASS 1	DESCR	Description	3.5 mm x 3.4 mm, Red, Ulcerated, Dorsal Tail		3.5 mm x 3.4 mm, Red, Moderate Ulceration			Dorsal TAIL	2000-03-12	43	43
3	ABC-123	PM	ABC0016	25	MASS 2	DESCR	Description	1.1 mm x 0.9 mm, Right Hind Limb		1.1 mm x 0.9 mm			RIGHT HIND LIMB	2000-03-14	45	45

Example 3

This example shows masses with additional tests collected.

Rows 1-10: Reflect the findings for the third mass of subject A0001043, observed on the lower abdomen.

Rows 11-20: Reflect the findings for the first mass of subject A0001201, observed on the mid tail.

pm.xpt

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMSPID	PMTESTCD	PMTEST	PMORRES	PMORRESU	PMSTRESC	PMSTRESN	PMSTRESU	PMLOC	PMDTC	PMDY	PMNOMDY
1	123456-A	PM	A0001043	102	MASS 3	SHAPE	Shape	Round		Round			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
2	123456-A	PM	A0001043	103	MASS 3	DEPTH	Depth	0.4	mm	0.4	0.4	mm	LOWER ABDOMEN	2001-09-16T09:59:04	42	42
3	123456-A	PM	A0001043	104	MASS 3	DIAMETER	Diameter	4.7	mm	4.7	4.7	mm	LOWER ABDOMEN	2001-09-16T09:59:04	42	42
4	123456-A	PM	A0001043	105	MASS 3	LENGTH	Length	1.6	mm	1.6	1.6	mm	LOWER ABDOMEN	2001-09-16T09:59:04	42	42

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMSPID	PMTESTCD	PMTEST	PMORRES	PMORRESU	PMSTRESC	PMSTRESN	PMSTRESU	PMLOC	PMDTC	PMDY	PMNOMDY
5	123456-A	PM	A0001043	106	MASS 3	WIDTH	Width	1.4	mm	1.4	1.4	mm	LOWER ABDOMEN	2001-09-16T09:59:04	42	42
6	123456-A	PM	A0001043	107	MASS 3	CONSIST	Consistency	Hard		Hard			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
7	123456-A	PM	A0001043	108	MASS 3	COLOR	Color	Yellow		Yellow			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
8	123456-A	PM	A0001043	109	MASS 3	HAIRCOV	Hair Cover	Y		Y			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
9	123456-A	PM	A0001043	110	MASS 3	ULCER	Ulceration	NON-ULCERATED		NON-ULCERATED			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
10	123456-A	PM	A0001043	111	MASS 3	DESCR	Description	Scabbed, Red		Scabbed, Red			LOWER ABDOMEN	2001-09-16T09:59:04	42	42
11	123456-A	PM	A0001201	256	MASS 1	SHAPE	Shape	Oval		Oval			MID TAIL	2001-09-23T11:23:51	49	49
12	123456-A	PM	A0001201	257	MASS 1	DEPTH	Depth	1.0	mm	1.0	1	mm	MID TAIL	2001-09-23T11:23:51	49	49
13	123456-A	PM	A0001201	258	MASS 1	DIAMETER	Diameter	6.1	mm	6.1	6.1	mm	MID TAIL	2001-09-23T11:23:51	49	49
14	123456-A	PM	A0001201	259	MASS 1	LENGTH	Length	2.1	mm	2.1	2.1	mm	MID TAIL	2001-09-23T11:23:51	49	49
15	123456-A	PM	A0001201	260	MASS 1	WIDTH	Width	1.6	mm	1.6	1.6	mm	MID TAIL	2001-09-23T11:23:51	49	49
16	123456-A	PM	A0001201	261	MASS 1	CONSIST	Consistency	Soft		Soft			MID TAIL	2001-09-23T11:23:51	49	49
17	123456-A	PM	A0001201	262	MASS 1	COLOR	Color	Brown		Brown			MID TAIL	2001-09-23T11:23:51	49	49
18	123456-A	PM	A0001201	263	MASS 1	HAIRCOV	Hair Cover	No		N			MID TAIL	2001-09-23T11:23:51	49	49
19	123456-A	PM	A0001201	264	MASS 1	ULCER	Ulceration	ULCERATED		ULCERATED			MID TAIL	2001-09-23T11:23:51	49	49
20	123456-A	PM	A0001201	265	MASS 1	DESCR	Description	Scratch marks around base of mass.		Scratch marks around base of mass.			MID TAIL	2001-09-23T11:23:51	49	49

Example 4

This example demonstrates a case where masses converge and diverge.

Rows 1-15: Reflect a case where subject 00540101 has 2 masses at day 7. The next week, these are observed as a single mass ("MASS 3"). The following week, the masses separate and are again observed as 2 single masses. All of the records are given a PMGRPID of 1, to establish their association.

Rows 1-6: Reflect the findings for mass 1 and mass 2 on the first week of the study, observed on the mid tail. Rows 1-3 list the findings for mass 1, and rows 4-6 list the findings for mass 2.

Rows 7-9: Reflect the findings for mass 3 (the convergence of mass 1 and mass 2 from the previous week) on the second week of the study.

Rows 10-15: Reflect the findings for mass 4 and mass 5 (the divergence of mass 3 from the previous week) on the third week of the study.

pm.xpt

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMGRPID	PMSPID	PMTESTCD	PMTEST	PMORRES	PMORRESU	PMSTRESC	PMSTRESN	PMSTRESU	PMLOC	PMDTC	PMDY	PMNOMDY
1	1A412-Z	PM	00540101	23	1	MASS 1	LENGTH	Length	2.1	mm	2.1	2.1	mm	MID TAIL		7	7
2	1A412-Z	PM	00540101	24	1	MASS 1	WIDTH	Width	2.1	mm	2.1	2.1	mm	MID TAIL		7	7
3	1A412-Z	PM	00540101	25	1	MASS 1	ULCER	Ulceration	NON-ULCERATED					MID TAIL		7	7

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMGRPID	PMSPID	PMTESTCD	PMTEST	PMORRES	PMORRESU	PMSTRESC	PMSTRESN	PMSTRESU	PMLOC	PMDTC	PMDY	PMNOMDY
4	1A412-Z	PM	00540101	65	1	MASS 2	LENGTH	Length	1.3	mm	1.3	1.3	mm	MID TAIL		7	7
5	1A412-Z	PM	00540101	66	1	MASS 2	WIDTH	Width	0.9	mm	0.9	0.9	mm	MID TAIL		7	7
6	1A412-Z	PM	00540101	67	1	MASS 2	ULCER	Ulceration	ULCERATED					MID TAIL		7	7
7	1A412-Z	PM	00540101	91	1	MASS 3	LENGTH	Length	3.3	mm	3.3	3.3	mm	MID TAIL		14	14
8	1A412-Z	PM	00540101	92	1	MASS 3	WIDTH	Width	3.1	mm	3.1	3.1	mm	MID TAIL		14	14
9	1A412-Z	PM	00540101	93	1	MASS 3	ULCER	Ulceration	NON-ULCERATED					MID TAIL		14	14
10	1A412-Z	PM	00540101	155	1	MASS 4	LENGTH	Length	1.9	mm	1.9	1.9	mm	MID TAIL		21	21
11	1A412-Z	PM	00540101	156	1	MASS 4	WIDTH	Width	1.8	mm	1.8	1.8	mm	MID TAIL		21	21
12	1A412-Z	PM	00540101	157	1	MASS 4	ULCER	Ulceration	NON-ULCERATED					MID TAIL		21	21
13	1A412-Z	PM	00540101	170	1	MASS 5	LENGTH	Length	1.5	mm	1.5	1.5	mm	MID TAIL		21	21
14	1A412-Z	PM	00540101	171	1	MASS 5	WIDTH	Width	1.2	mm	1.2	1.2	mm	MID TAIL		21	21
15	1A412-Z	PM	00540101	172	1	MASS 5	ULCER	Ulceration	ULCERATED					MID TAIL		21	21

This example demonstrates relating palpable mass findings to other domains, such as in the case of tumor findings.

- Rows 1-5:** Reflect a relationship between the PM, CL, MA, MI, and TF domains, specifying that subject 001-0329's findings are related for matching --SPID values across the domains. This example would be defined for each animal and relevant domain where the --SPID field has been populated.
- Rows 6-10:** Reflect an example where the related clinical signs for a mass were not a mass observation (e.g., a lump, a swelling). In this case, the clinical signs are grouped under a CLGRPID of 44 and related to the other domains --SPID of "MASS 2".
- Rows 11-12:** Reflect an example of a relationship set up to relate a tumor finding (TFSEQ = "43") with its onset record (PMSEQ = "104").
- Rows 13-19:** Reflect an example of a relationship between a number of specific observations across the domains. For example, the 2 tumor findings referenced (TFSEQ="23" and TFSEQ="24") pertain to 2 convergent tumors (similar to Example 4), so a collection of findings from palpable masses and clinical findings are related, with 1 macroscopic finding.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	F012-007	PM	001-0329	PMSPID	MASS 3		34
2	F012-007	CL	001-0329	CLGRPID	MASS 3		34
3	F012-007	MA	001-0329	MASPID	MASS 3		34
4	F012-007	MI	001-0329	MISPID	MASS 3		34
5	F012-007	TF	001-0329	TFSPID	MASS 3		34
6	F012-007	PM	001-0450	PMSPID	MASS 2		76
7	F012-007	CL	001-0450	CLGRPID	44		76
8	F012-007	MA	001-0450	MASPID	MASS 2		76
9	F012-007	MI	001-0450	MISPID	MASS 2		76
10	F012-007	TF	001-0450	TFSPID	MASS 2		76
11	F012-007	PM	001-0501	PMSEQ	104		89
12	F012-007	TF	001-0501	TFSEQ	43		89
13	F012-007	PM	001-0563	PMGRPID	17		91
14	F012-007	CL	001-0563	CLGRPID	7		91

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
15	F012-007	MA	001-0563	MASEQ	26		91
16	F012-007	MI	001-0563	MISEQ	47		91
17	F012-007	MI	001-0563	MISEQ	48		91
18	F012-007	TF	001-0563	TFSEQ	23		91
19	F012-007	TF	001-0563	TFSEQ	24		91

3.2.2.15 Pharmacokinetics Concentrations (PC)

Example 1

This example illustrates a PC record for an unscheduled sample collection. This is for a study with a weekly dosing regimen. The subject was dosed on days 1 and 8, and on day 11 was found to be moribund.

PCTPT, PCTPTNUM, and PCELTM were not populated because this was unscheduled.

Note that PCNOMDY was populated with the actual study day for tabulation. PCNOMLBL reflects the label that was used in the study report. PCUSCHFL was populated with "Y" to indicate that this sample collection was unscheduled.

pc.xpt

Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCTESTCD	PCTEST	PCCAT	PCSCAT	PCORRES	PCORRESU	PCSTRESC	PCSTRESN	PCSTRESU	PCNAM
1	ABC-123	PC	ABC-123-1002	1	XYZ123	XYZ-123	ANALYTE	PARENT	458.07	ng/mL	458.07	458.07	ng/mL	BIOANALYSIS LAB X
Row	PCSPEC	PCMETHOD	PCLLOQ	PCUSCHFL	PCDTC	PCDY	PCNOMDY	PCNOMLBL	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC	
1	PLASMA	LC/MS/MS	0.6	Y	2017-06-23T10:49:00	11	11	Day 11 Unscheduled				Day 8 Dose	2017-06-20T09:49:39	

3.2.2.16 Pharmacokinetics Parameters (PP)

Example 1

This example illustrates several tests for area under the curve, demonstrating the different ways of qualifying these tests. This study had a dosing interval of 24 hours, last dose on day 28, and TK sampling until at least 72 hours.

Rows 1, 4-5: AUCINT is qualified by the planned elapsed time from dosing to the start and the end of the interval using the specific planned elapsed time variables for intervals: PPSTINT and PPENINT.

Rows 2, 6: AUCLST is the area under the curve from time of dose to the last measurable concentration.

Rows 3, 7: TLST is the observed time of the last measurable concentration. This parameter was included because it qualifies the AUCLST.

pp.xpt

Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPTESTCD	PPTEST	PPCAT	PPSCAT	PPORRES	PPORRESU	PPSTRESC
1	ABC-123	PP	ABC-123-1001	1	AUCINT	AUC from T1 to T2	XYZ-123		271	h*ng/mL	271
2	ABC-123	PP	ABC-123-1001	2	AUCLST	AUC to Last Nonzero Conc	XYZ-123		271	h*ng/mL	271
3	ABC-123	PP	ABC-123-1001	3	TLST	Time of Last Nonzero Conc	XYZ-123		24	h	24
4	ABC-123	PP	ABC-123-1001	4	AUCINT	AUC from T1 to T2	XYZ-123		270	h*ng/mL	270
5	ABC-123	PP	ABC-123-1001	5	AUCINT	AUC from T1 to T2	XYZ-123		324	h*ng/mL	324
6	ABC-123	PP	ABC-123-1001	6	AUCLST	AUC to Last Nonzero Conc	XYZ-123		324	h*ng/mL	324
7	ABC-123	PP	ABC-123-1001	7	TLST	Time of Last Nonzero Conc	XYZ-123		72	h	72
Row	PPSTRESN	PPSTRESU	PPSTAT	PPREASND	PPSPEC	PPNOMLBL	PPTPTREF	PPRFTDTC	PPSTINT	PPENINT	
1	271	h*ng/mL			PLASMA	1	Day 1 Dose	2018-01-01T09:50:36	PT0H	PT24H	
2	271	h*ng/mL			PLASMA	1	Day 1 Dose	2018-01-01T09:50:36			
3	24	h			PLASMA	1	Day 1 Dose	2018-01-01T09:50:36			

Row	PPSTRESN	PPSTRESU	PPSTAT	PPREASND	PPSPEC	PPNOMLBL	PPTPTREF	PPRFTDTC	PPSTINT	PPENINT
4	270	h*ng/mL			PLASMA	28	Day 28 Dose	2018-01-28T09:55:14	PT0H	PT24H
5	324	h*ng/mL			PLASMA	28	Day 28 Dose	2018-01-28T09:55:14	PT0H	PT72H
6	324	h*ng/mL			PLASMA	28	Day 28 Dose	2018-01-28T09:55:14		
7	72	h			PLASMA	28	Day 28 Dose	2018-01-28T09:55:14		

3.2.2.17 Subject Characteristics (SC)

Example 1

This example shows data that are collected once per subject and which do not fit into the Demographics (DM) domain; these can be represented in SC. For this study, the hair coat color and physical markings were collected.

sc.xpt

Row	STUDYID	DOMAIN	USUBJID	SCSEQ	SCTESTCD	SCTEST	SCORRES	SCSTRESC	SCDTC	SCDY
1	DOG1	SC	DOG1-001	1	HAIRCOLR	Hair Coat Color	Bluetick	Bluetick	2008-01-19	1
2	DOG1	SC	DOG1-001	2	PHYMARK	Physical Marking	Neutered	Neutered	2008-01-19	1
3	DOG1	SC	DOG1-002	1	HAIRCOLR	Hair Coat Color	Tri-Color	Tri-Color	2008-01-19	1
4	DOG1	SC	DOG1-002	2	PHYMARK	Physical Marking	Non-USDA Tattoo #	Non-USDA Tattoo #	2008-01-19	1
5	DOG1	SC	DOG1-003	1	HAIRCOLR	Hair Coat Color	Redtick	Redtick	2008-01-19	1
6	DOG1	SC	DOG1-003	2	PHYMARK	Physical Marking	Undershot Bite	Undershot Bite	2008-01-19	1
7	DOG1	SC	DOG1-004	1	HAIRCOLR	Hair Coat Color	Orange/ White	Orange/ White	2008-01-19	1
8	DOG1	SC	DOG1-004	2	PHYMARK	Physical Marking	Tail Bobbed	Tail Bobbed	2008-10-19	1

3.2.2.18 Vital Signs (VS)

Example 1

This example shows vital signs collected for subject ABC-001-001.

Rows 1-2: Show 2 temperatures taken at study day 1 (VSDY="1"). Row 2 has a "Y" in the VSBLFL to indicate it was used as the baseline measurement.

Row 3: Shows a value collected in 1 unit but converted to selected standard unit, reflected in VSSTRESC, VSSTRESN, and VSSTRESU.

Row 4: Shows the proper use of the VSSTAT variable to indicate "NOT DONE" where a test was not done.

vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VTESTCD	VTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSSTAT	VSREASND	VSLOC	VSBLFL	VSDTC	VSDY	VSNOMDY
1	ABC	VS	ABC-001-001	8	TEMP	Temperature	34.7	C	34.7	34.7	C			RECTAL		1999-06-19T08:45	1	1
2	ABC	VS	ABC-001-001	9	TEMP	Temperature	36.2	C	36.2	36.2	C			RECTAL	Y	1999-06-19T09:00	1	1
3	ABC	VS	ABC-001-001	14	TEMP	Temperature	97.2	F	36.2	36.2	C			RECTAL		1999-07-21T9:04	33	33
4	ABC	VS	ABC-001-001	15	TEMP	Temperature						NOT DONE	Equipment failure			1999-07-31	43	43

Example 2

This example shows a collection of vital signs for subject ABC-001-001, where the time was not collected. The dosing regimen is once-weekly administration, which is why the first dose of the study (VSTPTREF) is on study day 1 (VSDY) and the second dose is on study day 8.

Rows 1-8: VSELTM show planned elapsed times after the first dose and after the second dose for a series of vital signs measurements.

Rows 4, 8: The study plan stated that the last measurement should be performed 4 to 6 hours post dosing (shown in VSTPT). The applicant chose to show this as a planned elapsed time of 4 hours in VSELTm.

vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VTESTCD	VTEST	VSORRES	VSORRESU	VSSTRESC
1	ABC	VS	ABC-001-001	1	TEMP	Temperature	34.7	C	34.7
2	ABC	VS	ABC-001-001	2	TEMP	Temperature	36.2	C	36.2
3	ABC	VS	ABC-001-001	3	TEMP	Temperature	37.1	C	37.1
4	ABC	VS	ABC-001-001	4	TEMP	Temperature	34.3	C	34.3
5	ABC	VS	ABC-001-001	5	TEMP	Temperature	35.2	C	35.2
6	ABC	VS	ABC-001-001	6	TEMP	Temperature	35.9	C	35.9
7	ABC	VS	ABC-001-001	7	TEMP	Temperature	36.5	C	36.5
8	ABC	VS	ABC-001-001	8	TEMP	Temperature	34.9	C	34.9

Row	VSSTRESN	VSSTRESU	VSLBLFL	VSDTC	VSDY	VSNOMDY	VSTPT	VSTPTNUM	VSELTm	VSTPTREF
1	34.7	C	Y	2012-10-25	1	1	PREDOSE	1	PT0H	Day 1 Dose
2	36.2	C		2012-10-25	1	1	30 MIN	2	PT0.5H	Day 1 Dose
3	37.1	C		2012-10-25	1	1	1H	3	PT1H	Day 1 Dose
4	34.3	C		2012-10-25	1	1	4H-6H	4	PT4H	Day 1 Dose
5	35.2	C		2012-11-01	8	8	PREDOSE	1	PT0H	Day 2 Dose
6	35.9	C		2012-11-01	8	8	30 MIN	2	PT0.5H	Day 2 Dose
7	36.5	C		2012-11-01	8	8	1H	3	PT1H	Day 2 Dose
8	34.9	C		2012-11-01	8	8	4H-6H	4	PT4H	Day 2 Dose

3.2.2.19 Respiratory Test Results (RE)

The Cardiovascular Test Results (CV), ECG Results (EG), and RE domains are very similar in structure. Note that the examples provided in this section represent uses of timing variables, which could apply to any of these domains, regardless of study type or design.

Example 1

This example shows measurements for 2 animals. At each time point (baseline, 30 minutes, 60 minutes, 90 minutes, 2 hours, 4 hours), the previous 15 minutes of data are aggregated to represent a result.

- Row 1:** Shows a case where 15 minutes prior to dose (REELTM = -PT15M and RETPTREF = "Day 1 Dose"), the previous 15 minutes (evaluation interval -PT30M to -PT15M) are aggregated.
- Row 2:** Shows a case where at the 30-minute mark post-dose (REELTM = PT30M and RETPTREF = "Day 1 Dose"), the previous 15 minutes (evaluation interval PT15M to PT30M) are aggregated.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	RESEQ	RETESTCD	RETEST	REPOS	REORRES	REORRESU	RESTRESC	RESTRESN	RESTRESU	REMETHOD
1	AA1111	RE	AA111-3	1	RESPRATE	Respiratory Rate	SITTING	115.25	breaths/min	115.25	115.25	breaths/min	plethysmograph
2	AA1111	RE	AA111-3	2	RESPRATE	Respiratory Rate	SITTING	127.11	breaths/min	127.11	127.11	breaths/min	plethysmograph
3	AA1111	RE	AA111-3	3	RESPRATE	Respiratory Rate	SITTING	111.57	breaths/min	111.57	111.57	breaths/min	plethysmograph
4	AA1111	RE	AA111-3	4	RESPRATE	Respiratory Rate	SITTING	140.28	breaths/min	140.28	140.28	breaths/min	plethysmograph
5	AA1111	RE	AA111-3	5	RESPRATE	Respiratory Rate	SITTING	109.87	breaths/min	109.87	109.87	breaths/min	plethysmograph
6	AA1111	RE	AA111-3	6	RESPRATE	Respiratory Rate	SITTING	85.84	breaths/min	85.84	85.84	breaths/min	plethysmograph
7	AA1111	RE	AA111-3	7	TIDALVOL	Tidal Volume	SITTING	1.48	mL	1.48	1.48	mL	plethysmograph
8	AA1111	RE	AA111-3	8	TIDALVOL	Tidal Volume	SITTING	1.46	mL	1.46	1.46	mL	plethysmograph
9	AA1111	RE	AA111-3	9	TIDALVOL	Tidal Volume	SITTING	1.34	mL	1.34	1.34	mL	plethysmograph
10	AA1111	RE	AA111-3	10	TIDALVOL	Tidal Volume	SITTING	1.11	mL	1.11	1.11	mL	plethysmograph
11	AA1111	RE	AA111-3	11	TIDALVOL	Tidal Volume	SITTING	1.29	mL	1.29	1.29	mL	plethysmograph

Row	STUDYID	DOMAIN	USUBJID	RESEQ	RETESTCD	RETEST	REPOS	REORRES	REORRESU	RESTRESC	RESTRESN	RESTRESU	REMETHOD
12	AA1111	RE	AA111-3	12	TIDALVOL	Tidal Volume	SITTING	1.58	mL	1.58	1.58	ml	plethysmograph
13	AA1111	RE	AA111-3	13	MV	Minute Volume	SITTING	170.43	mL/min	170.43	170.43	mL/min	plethysmograph
14	AA1111	RE	AA111-3	14	MV	Minute Volume	SITTING	184.98	mL/min	184.98	184.98	mL/min	plethysmograph
15	AA1111	RE	AA111-3	15	MV	Minute Volume	SITTING	149.27	mL/min	149.27	149.27	mL/min	plethysmograph
16	AA1111	RE	AA111-3	16	MV	Minute Volume	SITTING	155.19	mL/min	155.19	155.19	mL/min	plethysmograph
17	AA1111	RE	AA111-3	17	MV	Minute Volume	SITTING	141.95	mL/min	141.95	141.95	mL/min	plethysmograph
18	AA1111	RE	AA111-3	18	MV	Minute Volume	SITTING	135.34	mL/min	135.34	135.34	mL/min	plethysmograph
19	AA1111	RE	AA111-7	19	RESPRATE	Respiratory Rate	SITTING	123.06	breaths/min	123.06	123.06	breaths/min	plethysmograph
20	AA1111	RE	AA111-7	20	RESPRATE	Respiratory Rate	SITTING	149.42	breaths/min	149.42	149.42	breaths/min	plethysmograph
21	AA1111	RE	AA111-7	21	RESPRATE	Respiratory Rate	SITTING	122.17	breaths/min	122.17	122.17	breaths/min	plethysmograph
22	AA1111	RE	AA111-7	22	RESPRATE	Respiratory Rate	SITTING	140.47	breaths/min	140.47	140.47	breaths/min	plethysmograph
23	AA1111	RE	AA111-7	23	RESPRATE	Respiratory Rate	SITTING	117.75	breaths/min	117.75	117.75	breaths/min	plethysmograph
24	AA1111	RE	AA111-7	24	RESPRATE	Respiratory Rate	SITTING	116.00	breaths/min	116.00	116	breaths/min	plethysmograph
25	AA1111	RE	AA111-7	25	TIDALVOL	Tidal Volume	SITTING	1.24	mL	1.24	1.24	ml	plethysmograph
26	AA1111	RE	AA111-7	26	TIDALVOL	Tidal Volume	SITTING	1.33	mL	1.33	1.33	ml	plethysmograph
27	AA1111	RE	AA111-7	27	TIDALVOL	Tidal Volume	SITTING	1.45	mL	1.45	1.45	ml	plethysmograph
28	AA1111	RE	AA111-7	28	TIDALVOL	Tidal Volume	SITTING	1.27	mL	1.27	1.27	ml	plethysmograph
29	AA1111	RE	AA111-7	29	TIDALVOL	Tidal Volume	SITTING	1.42	mL	1.42	1.42	ml	plethysmograph
30	AA1111	RE	AA111-7	30	TIDALVOL	Tidal Volume	SITTING	1.50	mL	1.50	1.5	ml	plethysmograph
31	AA1111	RE	AA111-7	31	MV	Minute Volume	SITTING	153.09	mL/min	153.09	153.09	mL/min	plethysmograph
32	AA1111	RE	AA111-7	32	MV	Minute Volume	SITTING	198.06	mL/min	198.06	198.06	mL/min	plethysmograph
33	AA1111	RE	AA111-7	33	MV	Minute Volume	SITTING	176.67	mL/min	176.67	176.67	mL/min	plethysmograph
34	AA1111	RE	AA111-7	34	MV	Minute Volume	SITTING	178.20	mL/min	178.20	178.2	mL/min	plethysmograph
35	AA1111	RE	AA111-7	35	MV	Minute Volume	SITTING	167.47	mL/min	167.47	167.47	mL/min	plethysmograph
36	AA1111	RE	AA111-7	36	MV	Minute Volume	SITTING	174.18	mL/min	174.18	174.18	mL/min	plethysmograph

Row	RECSTATE	REBLFL	REDTA	REDY	RENOMDY	RETPPT	RETPPTNUM	REELTM	RETPTREF	RERFTDTC	RESTINT	REENINT
1	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
2	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
3	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
4	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
5	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
6	CONSCIOUS		2005-12-15	1	1	4 Hours	16	PT4H	Day 1 Dose	2005-12-15T10:00	P225M	PT4H
7	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
8	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
9	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
10	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
11	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
12	CONSCIOUS		2005-12-15	1	1	4 Hours	16	PT4H	Day 1 Dose	2005-12-15T10:00	P225M	PT4H
13	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
14	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
15	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
16	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
17	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
18	CONSCIOUS		2005-12-15	1	1	4 Hours	16	PT4H	Day 1 Dose	2005-12-15T10:00	P225M	PT4H
19	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
20	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
21	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
22	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
23	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
24	CONSCIOUS		2005-12-15	1	1	4 Hours	16	PT4H	Day 1 Dose	2005-12-15T10:00	P225M	PT4H
25	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
26	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
27	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
28	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
29	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
30	CONSCIOUS		2005-12-15	1	1	4 Hours	16	PT4H	Day 1 Dose	2005-12-15T10:00	P225M	PT4H

Row	RECSTATE	REBLFL	REDTC	REDY	RENOMDY	RETPT	RETPTNUM	REELTM	RETPTREF	RERFTDTC	RESTINT	REENINT
31	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
32	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
33	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
34	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
35	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
36	CONSCIOUS		2005-12-15	1	1	4 Hours	16	PT4H	Day 1 Dose	2005-12-15T10:00	P225M	PT4H

Example 2

This example shows measurements for 2 animals with continuous collection summarized into 1-hour measurements. The protocol defines the individual timepoints as the start of the assessment interval relative to the dosing. The REELTM shows the start of the planned assessment interval relative to the RETPTREF (day 1 dose).

- Row 1:** Shows a case where the assessment interval starts 1 hour prior to dose (REELTM = -PT1H and RETPTREF = "Day 1 Dose"). All the data during the 1 hour leading up to the dose (evaluation interval -PT1H to PT0H) is aggregated and labeled as the "Predose" timepoint.
- Row 2:** Shows a case where the assessment interval starts with the dose (REELTM = PT0H and RETPTREF = "Day 1 Dose"). All the data during the first hour post-dose (evaluation interval PT0H to PT1H) is aggregated and labeled as the "0 hour" timepoint.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	RESEQ	RETESTCD	RETEST	REPOS	REORRES	REORRESU	RESTRESC	RESTRESN	RESTRESU	REMETHOD
1	XY123	RE	XY123_101	1	RESPRATE	Respiratory Rate	UNCONSTRAINED	115.25	breaths/min	115.25	115.25	breaths/min	plethysmograph
2	XY123	RE	XY123_101	2	RESPRATE	Respiratory Rate	UNCONSTRAINED	127.11	breaths/min	127.11	127.11	breaths/min	plethysmograph
3	XY123	RE	XY123_101	3	RESPRATE	Respiratory Rate	UNCONSTRAINED	111.57	breaths/min	111.57	111.57	breaths/min	plethysmograph
4	XY123	RE	XY123_101	4	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.48	mL	1.48	1.48	mL	plethysmograph
5	XY123	RE	XY123_101	5	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.46	mL	1.46	1.46	mL	plethysmograph
6	XY123	RE	XY123_101	6	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.34	mL	1.34	1.34	mL	plethysmograph
7	XY123	RE	XY123_101	7	MV	Minute Volume	UNCONSTRAINED	170.43	mL/min	170.43	170.43	mL/min	plethysmograph
8	XY123	RE	XY123_101	8	MV	Minute Volume	UNCONSTRAINED	184.98	mL/min	184.98	184.98	mL/min	plethysmograph
9	XY123	RE	XY123_101	9	MV	Minute Volume	UNCONSTRAINED	149.27	mL/min	149.27	149.27	mL/min	plethysmograph
10	XY123	RE	XY123_102	10	RESPRATE	Respiratory Rate	UNCONSTRAINED	123.06	breaths/min	123.06	123.06	breaths/min	plethysmograph
11	XY123	RE	XY123_102	11	RESPRATE	Respiratory Rate	UNCONSTRAINED	149.42	breaths/min	149.42	149.42	breaths/min	plethysmograph
12	XY123	RE	XY123_102	12	RESPRATE	Respiratory Rate	UNCONSTRAINED	122.17	breaths/min	122.17	122.17	breaths/min	plethysmograph
13	XY123	RE	XY123_102	13	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.24	mL	1.24	1.24	mL	plethysmograph
14	XY123	RE	XY123_102	14	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.33	mL	1.33	1.33	mL	plethysmograph
15	XY123	RE	XY123_102	15	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.45	mL	1.45	1.45	mL	plethysmograph
16	XY123	RE	XY123_102	16	MV	Minute Volume	UNCONSTRAINED	153.09	mL/min	153.09	153.09	mL/min	plethysmograph
17	XY123	RE	XY123_102	17	MV	Minute Volume	UNCONSTRAINED	198.06	mL/min	198.06	198.06	mL/min	plethysmograph
18	XY123	RE	XY123_102	18	MV	Minute Volume	UNCONSTRAINED	176.67	mL/min	176.67	176.67	mL/min	plethysmograph

Row	RECSTATE	REBLFL	REDTC	REDY	RENOMDY	RETPT	RETPTNUM	REELTM	RETPTREF	RERFTDTC	RESTINT	REENINT
1	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:32:58	-PT1H	PT0H
2	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:32:58	PT0H	PT1H
3	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:32:58	PT1H	PT2H
4	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:32:58	-PT1H	PT0H
5	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:32:58	PT0H	PT1H
6	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:32:58	PT1H	PT2H
7	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:32:58	-PT1H	PT0H
8	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:32:58	PT0H	PT1H
9	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:32:58	PT1H	PT2H
10	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:33:02	-PT1H	PT0H
11	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:33:02	PT0H	PT1H
12	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:33:02	PT1H	PT2H
13	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:33:02	-PT1H	PT0H

Row	RECSTATE	REBLFL	REDTC	REDY	RENOMDY	RETPT	RETPTNUM	REELTM	RETPTREF	RERFTDTC	RESTINT	REENINT
14	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:33:02	PT0H	PT1H
15	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:33:02	PT1H	PT2H
16	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:33:02	-PT1H	PT0H
17	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:33:02	PT0H	PT1H
18	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:33:02	PT1H	PT2H

3.2.2.20 PC PP Multi-domain Examples

The following sections provide cross-domain examples for pharmacokinetic data. These examples demonstrate the relationship between concentration data and their relevant parameters. Each example takes a study and shows how the Exposure (EX), PC, PP, supplemental qualifiers, and Pool Definition (POOLDEF) domains would work together for that study. The examples demonstrate both individual sampling and sparse sampling but do not address Latin square study designs, which may require different implementation of certain timing variables.

3.2.2.20.1 PC PP Multi-domain Example 1

This example shows data for 1 animal subject, where all timing variables are populated as the information was readily available electronically. The subject was dosed daily and sampled for 2 profiles, starting day 1 and day 7. A full profile was obtained from the subject on both occasions and analyzed for parent compound (PCTESTCD = XYZ123) and 2 metabolites (PCTESTCD = XYZ345 and XYZ456).

PC PP Cross-domain Example 1: EX

The Exposure (EX) records are provided to show the relationship between the time recorded in the dosing records (EXSTDTC) and the PCRFDTDC and PPRFTDTC.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXRTV	EXVAMT	EXVAMTU	EXSTDTC	EXSTDY
1	ABC-123	EX	ABC-123-1001	1	XYZ-123	2.6	mg	SOLUTION	QD	ORAL Gavage	XYZ123-01	Saline	5	mL	2017-06-20T09:49:39	1
2	ABC-123	EX	ABC-123-1001	2	XYZ-123	2.6	mg	SOLUTION	QD	ORAL Gavage	XYZ123-01	Saline	5	mL	2017-06-21T09:36:08	2
3	ABC-123	EX	ABC-123-1001	3	XYZ-123	2.6	mg	SOLUTION	QD	ORAL Gavage	XYZ123-01	Saline	5	mL	2017-06-22T09:24:26	3
4	ABC-123	EX	ABC-123-1001	4	XYZ-123	2.7	mg	SOLUTION	QD	ORAL Gavage	XYZ123-01	Saline	5	mL	2017-06-23T09:55:14	4
5	ABC-123	EX	ABC-123-1001	5	XYZ-123	2.7	mg	SOLUTION	QD	ORAL Gavage	XYZ123-01	Saline	5	mL	2017-06-24T09:42:59	5
6	ABC-123	EX	ABC-123-1001	6	XYZ-123	2.7	mg	SOLUTION	QD	ORAL Gavage	XYZ123-01	Saline	5	mL	2017-06-25T09:15:16	6
7	ABC-123	EX	ABC-123-1001	7	XYZ-123	2.6	mg	SOLUTION	QD	ORAL Gavage	XYZ123-01	Saline	5	mL	2017-06-26T09:08:40	7

PC PP Cross-domain Example 1: PC

In this example, the applicant chose to populate PCTPTNUM with a value representing the number of hours postdose. The applicant populated PCCAT with ANALYTE and PCSCAT to differentiate between PARENT and METABOLITE.

Rows 1, 9-10, 19-20: Show that when a measurement is identified as being below a limit of quantitation threshold in PCSTRES, PCLLOQ should be populated, and PCSTRESU must be populated.

Rows 2-8, 11-18, 21-36: Show measurements where all result variables (PCORRES, PCSTRES, PCSTRESN) are populated because they are not below the limit of quantitation. Although these values are not below the lower limit of quantitation, PCLLOQ is populated.

pc.xpt

Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCTESTCD	PCTEST	PCCAT	PCSCAT	PCORRES	PCORRESU	PCSTRESC	PCSTRESN	PCSTRESU	PCNAM	PCSPEC	PCMETHOD	PCLLOQ	PCDTC	PCDY	PCNOMDY	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
1	ABC-123	PC	ABC-123-1001	1	XYZ123	XYZ-123	ANALYTE	PARENT	<LLOQ	ng/mL	BLQ		ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T09:49:00	1	1	Predose	0	PT0H	Day 1 Dose	2017-06-20T09:49:39
2	ABC-123	PC	ABC-123-1001	2	XYZ123	XYZ-123	ANALYTE	PARENT	0.700	ng/mL	0.700	0.7	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T10:04:00	1	1	0.25 hour postdose	0.25	PT0.25H	Day 1 Dose	2017-06-20T09:49:39
3	ABC-123	PC	ABC-123-1001	3	XYZ123	XYZ-123	ANALYTE	PARENT	8.1	ng/mL	8.1	8.1	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T10:19:00	1	1	0.5 hour postdose	0.5	PT0.5H	Day 1 Dose	2017-06-20T09:49:39
4	ABC-123	PC	ABC-123-1001	4	XYZ123	XYZ-123	ANALYTE	PARENT	44.0	ng/mL	44.0	44	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T10:44:00	1	1	1 hour postdose	1	PT1H	Day 1 Dose	2017-06-20T09:49:39
5	ABC-123	PC	ABC-123-1001	5	XYZ123	XYZ-123	ANALYTE	PARENT	108	ng/mL	108	108	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T11:52:00	1	1	2 hours postdose	2	PT2H	Day 1 Dose	2017-06-20T09:49:39
6	ABC-123	PC	ABC-123-1001	6	XYZ123	XYZ-123	ANALYTE	PARENT	32.3	ng/mL	32.3	32.3	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T13:56:00	1	1	4 hours postdose	4	PT4H	Day 1 Dose	2017-06-20T09:49:39
7	ABC-123	PC	ABC-123-1001	7	XYZ123	XYZ-123	ANALYTE	PARENT	4.75	ng/mL	4.75	4.75	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T17:53:00	1	1	8 hours postdose	8	PT8H	Day 1 Dose	2017-06-20T09:49:39
8	ABC-123	PC	ABC-123-1001	8	XYZ123	XYZ-123	ANALYTE	PARENT	2.01	ng/mL	2.01	2.01	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T21:27:00	1	1	12 hours postdose	12	PT12H	Day 1 Dose	2017-06-20T09:49:39
9	ABC-123	PC	ABC-123-1001	9	XYZ123	XYZ-123	ANALYTE	PARENT	<LLOQ	ng/mL	BLQ		ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-21T09:53:00	2	1	24 hours postdose	24	PT24H	Day 1 Dose	2017-06-20T09:49:39
10	ABC-123	PC	ABC-123-1001	10	XYZ123	XYZ-123	ANALYTE	PARENT	<LLOQ	ng/mL	BLQ		ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T09:07:00	7	7	Predose	0	PT0H	Day 7 Dose	2017-06-26T09:08:40
11	ABC-123	PC	ABC-123-1001	11	XYZ123	XYZ-123	ANALYTE	PARENT	7.69	ng/mL	7.69	7.69	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T09:23:00	7	7	0.25 hour postdose	0.25	PT0.25H	Day 7 Dose	2017-06-26T09:08:40
12	ABC-123	PC	ABC-123-1001	12	XYZ123	XYZ-123	ANALYTE	PARENT	39.8	ng/mL	39.8	39.8	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T09:37:00	7	7	0.5 hour postdose	0.5	PT0.5H	Day 7 Dose	2017-06-26T09:08:40
13	ABC-123	PC	ABC-123-1001	13	XYZ123	XYZ-123	ANALYTE	PARENT	140	ng/mL	140	140	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T10:06:00	7	7	1 hour postdose	1	PT1H	Day 7 Dose	2017-06-26T09:08:40
14	ABC-123	PC	ABC-123-1001	14	XYZ123	XYZ-123	ANALYTE	PARENT	116	ng/mL	116	116	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T10:56:00	7	7	2 hours postdose	2	PT2H	Day 7 Dose	2017-06-26T09:08:40
15	ABC-123	PC	ABC-123-1001	15	XYZ123	XYZ-123	ANALYTE	PARENT	52.2	ng/mL	52.2	52.2	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T13:08:00	7	7	4 hours postdose	4	PT4H	Day 7 Dose	2017-06-26T09:08:40
16	ABC-123	PC	ABC-123-1001	16	XYZ123	XYZ-123	ANALYTE	PARENT	18.3	ng/mL	18.3	18.3	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T17:07:00	7	7	8 hours postdose	8	PT8H	Day 7 Dose	2017-06-26T09:08:40
17	ABC-123	PC	ABC-123-1001	17	XYZ123	XYZ-123	ANALYTE	PARENT	14.4	ng/mL	14.4	14.4	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T21:26:00	7	7	12 hours postdose	12	PT12H	Day 7 Dose	2017-06-26T09:08:40
18	ABC-123	PC	ABC-123-1001	18	XYZ123	XYZ-123	ANALYTE	PARENT	2.01	ng/mL	2.01	2.01	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-27T08:13:00	8	7	24 hours postdose	24	PT24H	Day 7 Dose	2017-06-26T09:08:40
19	ABC-123	PC	ABC-123-1001	19	XYZ345	XYZ-345	ANALYTE	METABOLITE	<LLOQ	ng/mL	BLQ		ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T09:49:00	1	1	Predose	0	PT0H	Day 1 Dose	2017-06-20T09:49:39
20	ABC-123	PC	ABC-123-1001	20	XYZ345	XYZ-345	ANALYTE	METABOLITE	<LLOQ	ng/mL	BLQ		ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T10:04:00	1	1	0.25 hour postdose	0.25	PT0.25H	Day 1 Dose	2017-06-20T09:49:39
21	ABC-123	PC	ABC-123-1001	21	XYZ345	XYZ-345	ANALYTE	METABOLITE	11.6	ng/mL	11.6	11.6	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T10:19:00	1	1	0.5 hour postdose	0.5	PT0.5H	Day 1 Dose	2017-06-20T09:49:39
22	ABC-123	PC	ABC-123-1001	22	XYZ345	XYZ-345	ANALYTE	METABOLITE	78.7	ng/mL	78.7	78.7	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T10:44:00	1	1	1 hour postdose	1	PT1H	Day 1 Dose	2017-06-20T09:49:39
23	ABC-123	PC	ABC-123-1001	23	XYZ345	XYZ-345	ANALYTE	METABOLITE	699	ng/mL	699	699	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T11:52:00	1	1	2 hours postdose	2	PT2H	Day 1 Dose	2017-06-20T09:49:39
24	ABC-123	PC	ABC-123-1001	24	XYZ345	XYZ-345	ANALYTE	METABOLITE	205	ng/mL	205	205	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T13:56:00	1	1	4 hours postdose	4	PT4H	Day 1 Dose	2017-06-20T09:49:39
25	ABC-123	PC	ABC-123-1001	25	XYZ345	XYZ-345	ANALYTE	METABOLITE	21.8	ng/mL	21.8	21.8	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T17:53:00	1	1	8 hours postdose	8	PT8H	Day 1 Dose	2017-06-20T09:49:39
26	ABC-123	PC	ABC-123-1001	26	XYZ345	XYZ-345	ANALYTE	METABOLITE	6.20	ng/mL	6.20	6.2	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-20T21:27:00	1	1	12 hours postdose	12	PT12H	Day 1 Dose	2017-06-20T09:49:39
27	ABC-123	PC	ABC-123-1001	27	XYZ345	XYZ-345	ANALYTE	METABOLITE	1.66	ng/mL	1.66	1.66	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-21T09:53:00	2	1	24 hours postdose	24	PT24H	Day 1 Dose	2017-06-20T09:49:39
28	ABC-123	PC	ABC-123-1001	28	XYZ345	XYZ-345	ANALYTE	METABOLITE	2.05	ng/mL	2.05	2.05	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T09:07:00	7	7	Predose	0	PT0H	Day 7 Dose	2017-06-26T09:08:40
29	ABC-123	PC	ABC-123-1001	29	XYZ345	XYZ-345	ANALYTE	METABOLITE	9.29	ng/mL	9.29	9.29	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T09:23:00	7	7	0.25 hour postdose	0.25	PT0.25H	Day 7 Dose	2017-06-26T09:08:40
30	ABC-123	PC	ABC-123-1001	30	XYZ345	XYZ-345	ANALYTE	METABOLITE	39.8	ng/mL	39.8	39.8	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T09:37:00	7	7	0.5 hour postdose	0.5	PT0.5H	Day 7 Dose	2017-06-26T09:08:40
31	ABC-123	PC	ABC-123-1001	31	XYZ345	XYZ-345	ANALYTE	METABOLITE	89.6	ng/mL	89.6	89.6	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T10:06:00	7	7	1 hour postdose	1	PT1H	Day 7 Dose	2017-06-26T09:49:39
32	ABC-123	PC	ABC-123-1001	32	XYZ345	XYZ-345	ANALYTE	METABOLITE	92.8	ng/mL	92.8	92.8	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T10:56:00	7	7	2 hours postdose	2	PT2H	Day 7 Dose	2017-06-26T09:49:39
33	ABC-123	PC	ABC-123-1001	33	XYZ345	XYZ-345	ANALYTE	METABOLITE	56.8	ng/mL	56.8	56.8	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T13:08:00	7	7	4 hours postdose	4	PT4H	Day 7 Dose	2017-06-26T09:49:39
34	ABC-123	PC	ABC-123-1001	34	XYZ345	XYZ-345	ANALYTE	METABOLITE	15.2	ng/mL	15.2	15.2	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T17:07:00	7	7	8 hours postdose	8	PT8H	Day 7 Dose	2017-06-26T09:49:39

Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCTESTCD	PCTEST	PCCAT	PCSCAT	PCORRES	PCORRESU	PCSTREC	PCSTRESN	PCSTRESU	PCNAM	PCSPEC	PCMETHOD	PCLLOQ	PCDTC	PCDY	PCNOMDY	PCTPT	PCTPTNUM	PCELT	PCTPTREF	PCRFTDTC
35	ABC-123	PC	ABC-123-1001	35	XYZ345	XYZ-345	ANALYTE	METABOLITE	10.8	ng/mL	10.8	10.8	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-26T21:26:00	7	7	12 hours postdose	12	PT12H	Day 7 Dose	2017-06-26T09:08:40
36	ABC-123	PC	ABC-123-1001	36	XYZ345	XYZ-345	ANALYTE	METABOLITE	3.66	ng/mL	3.66	3.66	ng/mL	BIOANALYSIS LAB X	PLASMA	LC/MS/MS	0.6	2017-06-27T08:13:00	8	7	24 hours postdose	24	PT24H	Day 7 Dose	2017-06-26T09:08:40

PC PP Cross-domain Example 1: PP

In this example, PPTPREF has been populated with values giving the day of dose. In this case there is only 1 daily dose; therefore, PPTPTREF populated with “Day 1 Dose” is sufficient to explain the reference and matches PCTPTREF.

pp.xpt

Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPTESTCD	PPTEST	PPCAT	PPSCAT	PPORRES	PPORRESU	PPSTREC	PPSTRESN	PPSTRESU	PPSTAT	PPREASND	PPSPEC	PPNOMDY	PPTPTREF	PPRFTDTC	PPSTINT	PPENINT
1	ABC-123	PP	ABC-123-1001	1	TMAX	Time of CMAX	XYZ-123	NON-COMPARTMENTAL	2	h	2	2	h			PLASMA	1	Day 1 Dose	2017-06-20T09:49:39		
2	ABC-123	PP	ABC-123-1001	2	CMAX	Max Conc	XYZ-123	NON-COMPARTMENTAL	108	ng/mL	108	108	ng/mL			PLASMA	1	Day 1 Dose	2017-06-20T09:49:39		
3	ABC-123	PP	ABC-123-1001	3	AUCLST	AUC to Last Nonzero Conc	XYZ-123	NON-COMPARTMENTAL	318	h*ng/mL	318	318	h*ng/mL			PLASMA	1	Day 1 Dose	2017-06-20T09:49:39		
4	ABC-123	PP	ABC-123-1001	4	TLST	Time of Last Nonzero Conc	XYZ-123	NON-COMPARTMENTAL	12	h	12	12	h			PLASMA	1	Day 1 Dose	2017-06-20T09:49:39		
5	ABC-123	PP	ABC-123-1001	5	AUCINT	AUC from T1 to T2	XYZ-123	NON-COMPARTMENTAL	330	h*ng/mL	330	330	h*ng/mL			PLASMA	1	Day 1 Dose	2017-06-20T09:49:39	PT0H	PT24H
6	ABC-123	PP	ABC-123-1001	6	TMAX	Time of CMAX	XYZ-123	NON-COMPARTMENTAL	1	h	1	1	h			PLASMA	7	Day 7 Dose	2017-06-26T09:08:40		
7	ABC-123	PP	ABC-123-1001	7	CMAX	Max Conc	XYZ-123	NON-COMPARTMENTAL	140	ng/mL	140	140	ng/mL			PLASMA	7	Day 7 Dose	2017-06-26T09:08:40		
8	ABC-123	PP	ABC-123-1001	8	AUCLST	AUC to Last Nonzero Conc	XYZ-123	NON-COMPARTMENTAL	653	h*ng/mL	653	653	h*ng/mL			PLASMA	7	Day 7 Dose	2017-06-26T09:08:40		
9	ABC-123	PP	ABC-123-1001	9	TLST	Time of Last Nonzero Conc	XYZ-123	NON-COMPARTMENTAL	24	h	24	24	h			PLASMA	7	Day 7 Dose	2017-06-26T09:08:40		
10	ABC-123	PP	ABC-123-1001	10	AUCINT	AUC from T1 to T2	XYZ-123	NON-COMPARTMENTAL	653	h*ng/mL	653	653	h*ng/mL			PLASMA	7	Day 7 Dose	2017-06-26T09:08:40	PT0H	PT24H
11	ABC-123	PP	ABC-123-1001	11	ARCMAX	Accumulation Ratio Cmax	XYZ-123	NON-COMPARTMENTAL	1.30	RATIO	1.30	1.30	RATIO			PLASMA	7	Day 7 Dose	2017-06-26T09:08:40		
12	ABC-123	PP	ABC-123-1001	12	AUCLST	AUC to Last Nonzero Conc	XYZ-345	NON-COMPARTMENTAL	1874	h*ng/mL	1874	1874	h*ng/mL			PLASMA	1	Day 1 Dose	2017-06-20T09:49:39		
13	ABC-123	PP	ABC-123-1001	13	TLST	Time of Last Nonzero Conc	XYZ-345	NON-COMPARTMENTAL	24	h	24	24	h			PLASMA	1	Day 1 Dose	2017-06-20T09:49:39		
14	ABC-123	PP	ABC-123-1001	14	AUCLST	AUC to Last Nonzero Conc	XYZ-345	NON-COMPARTMENTAL	563	h*ng/mL	563	563	h*ng/mL			PLASMA	7	Day 7 Dose	2017-06-26T09:08:40		
15	ABC-123	PP	ABC-123-1001	15	TLST	Time of Last Nonzero Conc	XYZ-345	NON-COMPARTMENTAL	24	h	24	24	h			PLASMA	7	Day 7 Dose	2017-06-26T09:08:40		

PC PP Cross-domain Example 1: SUPPC

This example shows a SUPPC domain to specify the PCCALCN value used for the PC records where the result fell below the limit of quantitation.

suppc.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	ABC-123	PC	ABC-123-1001	PCSTREC	BLQ	PCCALCN	Numeric Interpretation for Calculations	0	DERIVED

3.2.2.20.2 PC PP Multi-domain Example 2

This example shows data for 1 animal subject, where only the minimal amount of timing information was readily available electronically. The subject was dosed daily and sampled for 2 profiles, starting day 1 and day 14. A full profile was obtained from the subject on both occasions and analyzed for parent compound and 2 metabolites.

PC PP Cross-domain Example 2: PC

At a minimum, the nominal timing variables required for the analysis are PCNOMDY, PCTPTREF, and PCELT; these timing variables have been populated, but PCDTC is null. PCRFTDTC is populated with only the date of dose as the time was not recorded in a manner readily available electronically. Although not crucial for the analysis, PCTPT was recorded and therefore populated in this example.

In this example, the applicant chose to populate PCTPTNUM with a simple sequential sorting order; therefore, no timing information can be assumed from the data represented in this variable.

In the case of duration dosing (e.g., continuous infusion), all records can only have 1 reference time point; this must be consistent (i.e., always work from the start of the dose, or always work from the end of dose). If the end of dosing is used as the reference time point, then start time point = -PT1H for 1 hour infusion and immediate postdose would be PT0H.

The example shows the best practice of using PCCAT to differentiate in the dataset between the parent and metabolite. It also shows the best practice of populating PCNAM.

Rows 1-4, 6-10, 12-19, 21-26: Show example concentration data and are provided for context.

Rows 13, 20: Show that when a result is BLQ in PCSTRESP, then both PCSTRESU and PCLLOQ should be populated; and as described in the assumptions. PCELTM for predose values is represented as "PT0H" because scientific data usage takes priority over study plan; therefore, predose values are typically set to zero for statistics and graphing.

Rows 5, 11: Show that when PCORRES is null and PCSTAT=NOT DONE, then PCSTRESU and PCLLOQ can be populated.

pc.xpt

Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCTESTCD	PCTEST	PCCAT	PCORRES	PCORRESU	PCSTRESP	PCSTRESN	PCSTRESU	PCSTAT	PCREASND
1	5311016	PC	5311016-101	1	A9876543	ABC9876543	PARENT	3000	ng/mL	3000	3000	ng/mL		
2	5311016	PC	5311016-101	3	A9876543	ABC9876543	PARENT	6240	ng/mL	6240	6240	ng/mL		
3	5311016	PC	5311016-101	5	A9876543	ABC9876543	PARENT	6950	ng/mL	6950	6950	ng/mL		
4	5311016	PC	5311016-101	7	A9876543	ABC9876543	PARENT	3630	ng/mL	3630	3630	ng/mL		
5	5311016	PC	5311016-101	9	A9876543	ABC9876543	PARENT		ng/mL			ng/mL	NOT DONE	MISSING SAMPLE
6	5311016	PC	5311016-101	11	A9876543	ABC9876543	PARENT	27	ng/mL	27	27	ng/mL		
7	5311016	PC	5311016-101	2	A9871234	ABC9871234	METABOLITE	6680	ng/mL	6680	6680	ng/mL		
8	5311016	PC	5311016-101	4	A9871234	ABC9871234	METABOLITE	11700	ng/mL	11700	11700	ng/mL		
9	5311016	PC	5311016-101	6	A9871234	ABC9871234	METABOLITE	14200	ng/mL	14200	14200	ng/mL		
10	5311016	PC	5311016-101	8	A9871234	ABC9871234	METABOLITE	13900	ng/mL	13900	13900	ng/mL		
11	5311016	PC	5311016-101	10	A9871234	ABC9871234	METABOLITE		ng/mL			ng/mL	NOT DONE	MISSING SAMPLE
12	5311016	PC	5311016-101	12	A9871234	ABC9871234	METABOLITE	90.1	ng/mL	90.1	90.1	ng/mL		
13	5311016	PC	5311016-101	13	A9876543	ABC9876543	PARENT	<1	ng/mL	BLQ		ng/mL		
14	5311016	PC	5311016-101	15	A9876543	ABC9876543	PARENT	2970	ng/mL	2970	2970	ng/mL		
15	5311016	PC	5311016-101	17	A9876543	ABC9876543	PARENT	6270	ng/mL	6270	6270	ng/mL		
16	5311016	PC	5311016-101	19	A9876543	ABC9876543	PARENT	6290	ng/mL	6290	6290	ng/mL		
17	5311016	PC	5311016-101	21	A9876543	ABC9876543	PARENT	3170	ng/mL	3170	3170	ng/mL		
18	5311016	PC	5311016-101	23	A9876543	ABC9876543	PARENT	1550	ng/mL	1550	1550	ng/mL		
19	5311016	PC	5311016-101	25	A9876543	ABC9876543	PARENT	49.5	ng/mL	49.5	49.5	ng/mL		
20	5311016	PC	5311016-101	14	A9871234	ABC9871234	METABOLITE	<1	ng/mL	BLQ		ng/mL		
21	5311016	PC	5311016-101	16	A9871234	ABC9871234	METABOLITE	3350	ng/mL	3350	3350	ng/mL		
22	5311016	PC	5311016-101	18	A9871234	ABC9871234	METABOLITE	8370	ng/mL	8370	8370	ng/mL		
23	5311016	PC	5311016-101	20	A9871234	ABC9871234	METABOLITE	14800	ng/mL	14800	14800	ng/mL		
24	5311016	PC	5311016-101	22	A9871234	ABC9871234	METABOLITE	11900	ng/mL	11900	11900	ng/mL		
25	5311016	PC	5311016-101	24	A9871234	ABC9871234	METABOLITE	8610	ng/mL	8610	8610	ng/mL		
26	5311016	PC	5311016-101	26	A9871234	ABC9871234	METABOLITE	124	ng/mL	124	124	ng/mL		

Row	PCNAM	PCSPEC	PCBLFL	PCLLOQ	PCEXCLFL	PCREASEX	PCNOMDY	PCDTC	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
1	ACME INC	PLASMA		1			1		0H30MIN	1	PT30M	Day 1 dose	2018-01-01
2	ACME INC	PLASMA		1			1		1H	2	PT1H	Day 1 dose	2018-01-01
3	ACME INC	PLASMA		1			1		2H	3	PT2H	Day 1 dose	2018-01-01
4	ACME INC	PLASMA		1			1		4H	4	PT4H	Day 1 dose	2018-01-01
5	ACME INC	PLASMA		1			1		8H	5	PT8H	Day 1 dose	2018-01-01
6	ACME INC	PLASMA		1			1		24H	6	PT24H	Day 1 dose	2018-01-01
7	ACME INC	PLASMA		1			1		0H30MIN	1	PT30M	Day 1 dose	2018-01-01
8	ACME INC	PLASMA		1			1		1H	2	PT1H	Day 1 dose	2018-01-01
9	ACME INC	PLASMA		1			1		2H	3	PT2H	Day 1 dose	2018-01-01
10	ACME INC	PLASMA		1			1		4H	4	PT4H	Day 1 dose	2018-01-01
11	ACME INC	PLASMA		1			1		8H	5	PT8H	Day 1 dose	2018-01-01
12	ACME INC	PLASMA		1			1		24H	6	PT24H	Day 1 dose	2018-01-01
13	ACME INC	PLASMA		1			14		PREDOSE	1	PT0H	Day 14 dose	2018-01-14
14	ACME INC	PLASMA		1			14		0H30MIN	2	PT30M	Day 14 dose	2018-01-14
15	ACME INC	PLASMA		1			14		1H	3	PT1H	Day 14 dose	2018-01-14
16	ACME INC	PLASMA		1			14		2H	4	PT2H	Day 14 dose	2018-01-14
17	ACME INC	PLASMA		1			14		4H	5	PT4H	Day 14 dose	2018-01-14
18	ACME INC	PLASMA		1			14		8H	6	PT8H	Day 14 dose	2018-01-14
19	ACME INC	PLASMA		1			14		24H	7	PT24H	Day 14 dose	2018-01-14
20	ACME INC	PLASMA		1			14		PREDOSE	1	PT0H	Day 14 dose	2018-01-14
21	ACME INC	PLASMA		1			14		0H30MIN	2	PT30M	Day 14 dose	2018-01-14

Row	PCNAM	PCSPEC	PCBLFL	PCLLOQ	PCEXCLFL	PCREASEX	PCNOMDY	PCDTC	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
22	ACME INC	PLASMA		1			14		1H	3	PT1H	Day 14 dose	2018-01-14
23	ACME INC	PLASMA		1			14		2H	4	PT2H	Day 14 dose	2018-01-14
24	ACME INC	PLASMA		1			14		4H	5	PT4H	Day 14 dose	2018-01-14
25	ACME INC	PLASMA		1			14		8H	6	PT8H	Day 14 dose	2018-01-14
26	ACME INC	PLASMA		1	Y	Concentration result excluded due to hemolysis	14		24H	7	PT24H	Day 14 dose	2018-01-14

PC PP Cross-domain Example 2: PP

This example shows how PPTPTREF relates back to the PCTPTREF in the PC domain.

For the dose date/time, the date is known, but not the exact time; therefore, PPRFTDTC is populated with the data portion only.

pp.xpt

Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPTESTCD	PPTEST	PPCAT	PPSCAT	PPORRES	PPORRESU
1	5311016	PP	5311016-101	1	AUCINT	AUC from T1 to T2	ABC9876543	PARENT	56805	h*ng/mL
2	5311016	PP	5311016-101	2	CMAX	Max Conc	ABC9876543	PARENT	6950	ng/mL
3	5311016	PP	5311016-101	3	TMAX	Max Conc	ABC9876543	PARENT	2	h
4	5311016	PP	5311016-101	4	AUCINTD	AUC from T1 to T2 Norm by Dose	ABC9876543	PARENT	5681	h*ng/mL/(mg/kg)
5	5311016	PP	5311016-101	5	CMAXD	Max Conc Norm by Dose	ABC9876543	PARENT	695	ng/mL/(mg/kg)
6	5311016	PP	5311016-101	6	AUCINT	AUC from T1 to T2	ABC9876543	PARENT	41029	h*ng/mL
7	5311016	PP	5311016-101	7	CMAX	Max Conc	ABC9876543	PARENT	6290	ng/mL
8	5311016	PP	5311016-101	8	TMAX	Time of CMAX	ABC9876543	PARENT	2	h
9	5311016	PP	5311016-101	9	AUCINTD	AUC from T1 to T2 Norm by Dose	ABC9876543	PARENT	4103	h*ng/mL/(mg/kg)
10	5311016	PP	5311016-101	10	CMAXD	Max Conc Norm by Dose	ABC9876543	PARENT	629	ng/mL/(mg/kg)
11	5311016	PP	5311016-101	11	AUCINT	AUC from T1 to T2	ABC9871234	METABOLITE	187216	h*ng/mL
12	5311016	PP	5311016-101	12	CMAX	Max Conc	ABC9871234	METABOLITE	14200	ng/mL
13	5311016	PP	5311016-101	13	TMAX	Time of CMAX	ABC9871234	METABOLITE	2	h
14	5311016	PP	5311016-101	14	AUCINTD	AUC from T1 to T2 Norm by Dose	ABC9871234	METABOLITE	18722	h*ng/mL/(mg/kg)
15	5311016	PP	5311016-101	15	CMAXD	Max Conc Norm by Dose	ABC9871234	METABOLITE	1420	ng/mL/(mg/kg)
16	5311016	PP	5311016-101	16	AUCINT	AUC from T1 to T2	ABC9871234	METABOLITE	152945	h*ng/mL
17	5311016	PP	5311016-101	17	CMAX	Max Conc	ABC9871234	METABOLITE	14800	ng/mL
18	5311016	PP	5311016-101	18	TMAX	Time of CMAX	ABC9871234	METABOLITE	2	h
19	5311016	PP	5311016-101	19	AUCINTD	AUC from T1 to T2 Norm by Dose	ABC9871234	METABOLITE	15295	h*ng/mL/(mg/kg)
20	5311016	PP	5311016-101	20	CMAXD	Max Conc Norm by Dose	ABC9871234	METABOLITE	1480	ng/mL/(mg/kg)

Row	PPSTRESC	PPSTRESN	PPSTRESU	PPSPEC	PPNOMDY	PPTPTREF	PPRFTDTC	PPSTINT	PPENINT
1	56805	56805	h*ng/mL	PLASMA	1	Day 1 dose	2018-01-01	PT0H	PT24H
2	6950	6950	ng/mL	PLASMA	1	Day 1 dose	2018-01-01		
3	2	2	h	PLASMA	1	Day 1 dose	2018-01-01		
4	5681	5681	h*ng/mL/(mg/kg)	PLASMA	1	Day 1 dose	2018-01-01	PT0H	PT24H
5	695	695	ng/mL/(mg/kg)	PLASMA	1	Day 1 dose	2018-01-01		
6	41029	41029	h*ng/mL	PLASMA	14	Day 14 dose	2018-01-01	PT0H	PT24H
7	6290	6290	ng/mL	PLASMA	14	Day 14 dose	2018-01-01		
8	2	2	h	PLASMA	14	Day 14 dose	2018-01-01		
9	4103	4103	h*ng/mL/(mg/kg)	PLASMA	14	Day 14 dose	2018-01-01	PT0H	PT24H
10	629	629	ng/mL/(mg/kg)	PLASMA	14	Day 14 dose	2018-01-01		
11	187216	187216	h*ng/mL	PLASMA	1	Day 1 dose	2018-01-01	PT0H	PT24H
12	14200	14200	ng/mL	PLASMA	1	Day 1 dose	2018-01-01		
13	2	2	h	PLASMA	1	Day 1 dose	2018-01-14		
14	18722	18722	h*ng/mL/(mg/kg)	PLASMA	1	Day 1 dose	2018-01-14	PT0H	PT24H
15	1420	1420	ng/mL/(mg/kg)	PLASMA	1	Day 1 dose	2018-01-14		
16	152945	152945	h*ng/mL	PLASMA	14	Day 14 dose	2018-01-14	PT0H	PT24H
17	14800	14800	ng/mL	PLASMA	14	Day 14 dose	2018-01-14		
18	2	2	h	PLASMA	14	Day 14 dose	2018-01-14		
19	15295	15295	h*ng/mL/(mg/kg)	PLASMA	14	Day 14 dose	2018-01-14	PT0H	PT24H
20	1480	1480	ng/mL/(mg/kg)	PLASMA	14	Day 14 dose	2018-01-14		

PC PP Cross-domain Example 2: SUPPPC

This example shows a SUPPPC domain to specify the PCCALCN value used for the PC records where the result fell below the limit of quantitation.

supppc.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	5311016	PC	5311016-101	PCSTRESC	BLQ	PCCALCN	Numeric Interpretation for Calculations	0	DERIVED

3.2.2.20.3 PC PP Multi-domain Example 3

This multi-domain example shows a PC domain for a rodent sparse sampling study of 9 animal subjects, where all timing information was readily available electronically. The subjects were dosed daily and sampled to construct 2 time-concentration profiles, with one referencing the day 1 dose and the other referencing the day 42 dose. The concentration data were then combined by reference dose (day 1 or day 42) to create composite rat exposures in the PP domain.

PC PP Cross-domain Example 3: PC

PCCAT and PCSCAT are not populated because there is only 1 value within PCTEST/PCTESTCD.

PCTPTNUM is intended to aid in sorting. In this example, it is populated with the chronological value of time in minutes between the PCTPT and PCTPTREF, even though PCELTM represents the equivalent time in hours.

This example shows a well constructed, informative PCTPT and PCTPTREF.

pc.xpt

Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCTESTCD	PCTEST	PCCAT	PCSCAT	PCRES	PCRESU	PCSTRESC	PCSTRESN	PCSTRESU
1	ABC-123	PC	ABC-123-2001	1	LMN123	LMN-123			0.856	ug/mL	0.856	0.856	ug/mL
2	ABC-123	PC	ABC-123-2001	2	LMN123	LMN-123			28.9	ug/mL	28.9	28.9	ug/mL
3	ABC-123	PC	ABC-123-2001	3	LMN123	LMN-123			0.559	ug/mL	0.559	0.559	ug/mL
4	ABC-123	PC	ABC-123-2002	1	LMN123	LMN-123			1.76	ug/mL	1.76	1.76	ug/mL
5	ABC-123	PC	ABC-123-2002	2	LMN123	LMN-123			39	ug/mL	39	39	ug/mL
6	ABC-123	PC	ABC-123-2002	3	LMN123	LMN-123			2.89	ug/mL	2.89	2.89	ug/mL
7	ABC-123	PC	ABC-123-2003	1	LMN123	LMN-123			0.646	ug/mL	0.646	0.646	ug/mL
8	ABC-123	PC	ABC-123-2003	2	LMN123	LMN-123			33.9	ug/mL	33.9	33.9	ug/mL
9	ABC-123	PC	ABC-123-2003	3	LMN123	LMN-123			0.39	ug/mL	0.39	0.39	ug/mL
10	ABC-123	PC	ABC-123-2004	1	LMN123	LMN-123			18.9	ug/mL	18.9	18.9	ug/mL
11	ABC-123	PC	ABC-123-2004	2	LMN123	LMN-123			16.1	ug/mL	16.1	16.1	ug/mL
12	ABC-123	PC	ABC-123-2004	3	LMN123	LMN-123			1.28	ug/mL	1.28	1.28	ug/mL
13	ABC-123	PC	ABC-123-2005	1	LMN123	LMN-123			20.8	ug/mL	20.8	20.8	ug/mL
14	ABC-123	PC	ABC-123-2005	2	LMN123	LMN-123			18	ug/mL	18	18	ug/mL
15	ABC-123	PC	ABC-123-2005	3	LMN123	LMN-123			17.8	ug/mL	17.8	17.8	ug/mL
16	ABC-123	PC	ABC-123-2006	1	LMN123	LMN-123			23.9	ug/mL	23.9	23.9	ug/mL
17	ABC-123	PC	ABC-123-2006	2	LMN123	LMN-123			22.4	ug/mL	22.4	22.4	ug/mL
18	ABC-123	PC	ABC-123-2006	3	LMN123	LMN-123			0.520	ug/mL	0.520	0.520	ug/mL
19	ABC-123	PC	ABC-123-2007	1	LMN123	LMN-123			46.9	ug/mL	46.9	46.9	ug/mL
20	ABC-123	PC	ABC-123-2007	2	LMN123	LMN-123			3.45	ug/mL	3.45	3.45	ug/mL
21	ABC-123	PC	ABC-123-2007	3	LMN123	LMN-123			BLQ (<0.200)	ug/mL	BLQ	ug/mL	
22	ABC-123	PC	ABC-123-2008	1	LMN123	LMN-123			39.4	ug/mL	39.4	39.4	ug/mL
23	ABC-123	PC	ABC-123-2008	2	LMN123	LMN-123			4.44	ug/mL	4.44	4.44	ug/mL
24	ABC-123	PC	ABC-123-2008	3	LMN123	LMN-123			BLQ (<0.200)	ug/mL	BLQ	ug/mL	
25	ABC-123	PC	ABC-123-2009	1	LMN123	LMN-123			45.1	ug/mL	45.1	45.1	ug/mL
26	ABC-123	PC	ABC-123-2009	2	LMN123	LMN-123			3.16	ug/mL	3.16	3.16	ug/mL
27	ABC-123	PC	ABC-123-2009	3	LMN123	LMN-123			BLQ (<0.200)	ug/mL	BLQ	ug/mL	

Row	PCNAM	PCSPEC	PCMETHOD	PCBLFL	PCLLOQ	PCNOMDY	PCDTC	PCDY	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
1	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T09:10:45	42	Predose	0	PT0H	Day 42 Dose	2015-05-10T09:55:16

Row	PCNAM	PCSPEC	PCMETHOD	PCBLFL	PCLLOQ	PCNOMDY	PCDTC	PCDY	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
2	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T11:56:02	42	2 hour postdose	120	PT2H	Day 42 Dose	2015-05-10T09:55:16
3	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-11T09:55:28	43	24 hour postdose	1440	PT24H	Day 42 Dose	2015-05-10T09:55:16
4	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T09:11:49	42	Predose	0	PT0H	Day 42 Dose	2015-05-10T09:56:06
5	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T11:57:02	42	2 hour postdose	120	PT2H	Day 42 Dose	2015-05-10T09:56:06
6	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-11T09:56:26	43	24 hour postdose	1440	PT24H	Day 42 Dose	2015-05-10T09:56:06
7	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T09:12:53	42	Predose	0	PT0H	Day 42 Dose	2015-05-10T09:57:07
8	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T11:58:04	42	2 hour postdose	120	PT2H	Day 42 Dose	2015-05-10T09:57:07
9	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-11T09:57:50	43	24 hour postdose	1440	PT24H	Day 42 Dose	2015-05-10T09:57:07
10	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T09:45:21	42	0.25 hour postdose	15	PT0.25H	Day 42 Dose	2015-05-10T09:30:08
11	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T13:30:50	42	4 hour postdose	240	PT4H	Day 42 Dose	2015-05-10T09:30:08
12	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-12T09:30:17	44	48 hour postdose	2880	PT48H	Day 42 Dose	2015-05-10T09:30:08
13	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T09:46:10	42	0.25 hour postdose	15	PT0.25H	Day 42 Dose	2015-05-10T09:31:07
14	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T13:32:04	42	4 hour postdose	240	PT4H	Day 42 Dose	2015-05-10T09:31:07
15	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-12T09:31:42	44	48 hour postdose	2880	PT48H	Day 42 Dose	2015-05-10T09:31:07
16	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T09:47:10	42	0.25 hour postdose	15	PT0.25H	Day 42 Dose	2015-05-10T09:32:07
17	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T13:33:22	42	4 hour postdose	240	PT4H	Day 42 Dose	2015-05-10T09:32:07
18	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-12T09:32:56	44	48 hour postdose	2880	PT48H	Day 42 Dose	2015-05-10T09:32:07
19	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T10:30:02	42	1 hour postdose	60	PT1H	Day 42 Dose	2015-05-10T09:30:23
20	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T17:25:17	42	8 hour postdose	480	PT8H	Day 42 Dose	2015-05-10T09:30:23
21	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-14T09:32:45	46	96 hour postdose	5760	PT96H	Day 42 Dose	2015-05-10T09:30:23
22	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T10:31:05	42	1 hour postdose	60	PT1H	Day 42 Dose	2015-05-10T09:31:26
23	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T17:26:16	42	8 hour postdose	480	PT8H	Day 42 Dose	2015-05-10T09:31:26
24	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-14T09:33:54	46	96 hour postdose	5760	PT96H	Day 42 Dose	2015-05-10T09:31:26
25	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T10:32:22	42	1 hour postdose	60	PT1H	Day 42 Dose	2015-05-10T09:32:26
26	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-10T17:27:41	42	8 hour postdose	480	PT8H	Day 42 Dose	2015-05-10T09:32:26
27	LAB X	PLASMA	HPLC/MS/MS		0.2	42	2015-05-14T09:35:07	46	96 hour postdose	5760	PT96H	Day 42 Dose	2015-05-10T09:32:26

PC PP Cross-domain Example 3: PP

PPRFTDTC can be null due to sparse sampling. Data can be grouped by PPNOMDY and PPTPTREF.

In sparse sampling scenarios where multiple subjects contribute to a toxicokinetic result, PC and PP records cannot be directly linked by the unique timestamp for the dosing event (i.e., where EXDTC = PCRFTDTC = PPRFTDTC). In such cases, PPRFTDTC can be left null. In the event that all subjects in a pool have the same reference time point date, it would also be acceptable to populate PPRFTDTC with the date (no time) that corresponds to the description in PPTPTREF.

In this example, even though all subjects in the pool shared the same date as the reference time point for the profile, the applicant chose to leave PPRFTDTC as null.

pp.xpt

Row	STUDYID	DOMAIN	USUBJID	POOLID	PPSEQ	PPTESTCD	PPTEST	PPCAT	PPORRES	PPORRESU	PPSTRESC	PPSTRESN	PPSTRESU	PPSTAT	PPREASND	PPSPEC	PPNOMDY	PPTPTREF	PPRFTDTC
1	ABC-123	PP		PP-Group 2	1	CMAX	Max Conc	LMN-123	43.8	ug/mL	43.8	43.8	ug/mL			PLASMA	42	Day 42 Dose	
2	ABC-123	PP		PP-Group 2	2	CMAXD	Max Conc Norm by Dose	LMN-123	0.438	ug/mL/(mg/kg)	0.438	0.438	ug/mL/(mg/kg)			PLASMA	42	Day 42 Dose	
3	ABC-123	PP		PP-Group 2	3	TMAX	Time of CMAX	LMN-123	1	h	1	1	h			PLASMA	42	Day 42 Dose	
4	ABC-123	PP		PP-Group 2	4	TLST	Time of Last Nonzero Conc	LMN-123	48	h	48	48	h			PLASMA	42	Day 42 Dose	
5	ABC-123	PP		PP-Group 2	5	AUCLST	AUC to Last Nonzero Conc	LMN-123	297	h*ug/mL	297	297	h*ug/mL			PLASMA	42	Day 42 Dose	
6	ABC-123	PP		PP-Group 2	6	AUCLSTD	AUC to Last Nonzero Conc Norm by Dose	LMN-123	2.97	h*ug/mL/(mg/kg)	2.97	2.97	h*ug/mL/(mg/kg)			PLASMA	42	Day 42 Dose	
7	ABC-123	PP		PP-Group 2	7	LAMZHL	Half-Life Lambda z	LMN-123						NOT DONE	Not reported due to insufficient plasma concentration data	PLASMA	42	Day 42 Dose	

PC PP Cross-domain Example 3: SUPPPC

This example shows a SUPPC domain to specify the PCCALCN value used for the PC records where the result fell below the limit of quantitation.

supppc.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	ABC-123	PC	ABC-123-2007	PCSTRESC	BLQ	PCCALCN	Numeric Interpretation for Calculations	0	DERIVED
2	ABC-123	PC	ABC-123-2008	PCSTRESC	BLQ	PCCALCN	Numeric Interpretation for Calculations	0	DERIVED
3	ABC-123	PC	ABC-123-2009	PCSTRESC	BLQ	PCCALCN	Numeric Interpretation for Calculations	0	DERIVED

PC PP Cross-domain Example 3: POOLDEF

This example shows how the subjects were pooled.

pooldef.xpt

Row	STUDYID	POOLID	USUBJID
1	ABC-123	PP-Group 2	ABC-123-2001
2	ABC-123	PP-Group 2	ABC-123-2002
3	ABC-123	PP-Group 2	ABC-123-2003
4	ABC-123	PP-Group 2	ABC-123-2004
5	ABC-123	PP-Group 2	ABC-123-2005
6	ABC-123	PP-Group 2	ABC-123-2006
7	ABC-123	PP-Group 2	ABC-123-2007
8	ABC-123	PP-Group 2	ABC-123-2008
9	ABC-123	PP-Group 2	ABC-123-2009

3.2.2.20.4 Examples for ECG Test Results (EG) Domain Model

The Cardiovascular Test Results (CV), EG, and Respiratory Test Results (RE) domains are very similar in structure. Note that the examples provided in this section represent uses of timing variables, which could apply to any of these domains, regardless of study type or design.

Example 1

This example contains ECG measurements during a repeat dose study. Results are for a discrete observation period with a target time point (e.g., 1 hour post-dose). The duration of the ECG recording could be based on a defined period of time (e.g., a cardiologist examining a 2-hour recording and selecting a segment of waveforms for analysis) or number of complexes (e.g., after 200 good complexes are recorded). As a result, EGSTINT and EGENINT are not populated, because the specific assessment interval is not planned.

Rows 1-18: ECGs are performed once, 14 days prior to the day 1 dose; and twice on day 23, once immediately prior to dose and once 2 hours post-dose. Measurements that were collected originally in seconds are converted to units of milliseconds for the study.

eg.xpt

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGTESTCD	EGTEST	EGPOS	EGORRES	EGORRESU	EGSTRESP	EGSTRESN	EGSTRESU	EGLEAD	EGMETHOD	EGCSTATE	EGBLFL	EGDTC	EGDY	EGNOMDY	EGTPT	EGTPTRNUM	EGELTM	EGTPTRREF	EGRFTDTC
1	TSA1397	EG	1	1	EGHRMN	ECG Mean Heart Rate	SLING	89	beats/min	89	89	beats/min	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-10-28T07:46	-14	-14	Pretest	1	-P14D	Day 1 Dose	2008-11-11T08:54
2	TSA1397	EG	1	2	EGHRMN	ECG Mean Heart Rate	SLING	91	beats/min	91	91	beats/min	LEAD II	6 LEAD STANDARD	CONSCIOUS	Y	2008-12-03T09:05	23	23	Predose	2	-PT5M	Day 23 Dose	2008-12-03T09:10
3	TSA1397	EG	1	3	EGHRMN	ECG Mean Heart Rate	SLING	116	beats/min	116	116	beats/min	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-12-03T11:03	23	23	2 Hour Postdose	3	PT120M	Day 23 Dose	2008-12-03T09:10
4	TSA1397	EG	1	4	QRSAG	QRS Duration, Aggregate	SLING	0.050	sec	50	50	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-10-28T07:46	-14	-14	Pretest	1	-P14D	Day 1 Dose	2008-11-11T08:54
5	TSA1397	EG	1	5	QRSAG	QRS Duration, Aggregate	SLING	0.038	sec	38	38	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS	Y	2008-12-03T09:05	23	23	Predose	2	-PT5M	Day 23 Dose	2008-12-03T09:10
6	TSA1397	EG	1	6	QRSAG	QRS Duration, Aggregate	SLING	0.039	sec	39	39	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-12-03T11:03	23	23	2 Hour Postdose	3	PT120M	Day 23 Dose	2008-12-03T09:10
7	TSA1397	EG	1	7	PPAG	PP Interval, Aggregate	SLING	0.073	sec	73	73	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-10-28T07:46	-14	-14	Pretest	1	-P14D	Day 1 Dose	2008-11-11T08:54
8	TSA1397	EG	1	8	PPAG	PP Interval, Aggregate	SLING	0.083	sec	83	83	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS	Y	2008-12-03T09:05	23	23	Predose	2	-PT5M	Day 23 Dose	2008-12-03T09:10
9	TSA1397	EG	1	9	PPAG	PP Interval, Aggregate	SLING	0.076	sec	76	76	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-12-03T11:03	23	23	2 Hour Postdose	3	PT120M	Day 23 Dose	2008-12-03T09:10
10	TSA1397	EG	1	10	QTAG	QT Interval, Aggregate	SLING	0.209	sec	209	209	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-10-28T07:46	-14	-14	Pretest	1	-P14D	Day 1 Dose	2008-11-11T08:54
11	TSA1397	EG	1	11	QTAG	QT Interval, Aggregate	SLING	0.222	sec	222	222	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS	Y	2008-12-03T09:05	23	23	Predose	2	-PT5M	Day 23 Dose	2008-12-03T09:10
12	TSA1397	EG	1	12	QTAG	QT Interval, Aggregate	SLING	0.192	sec	192	192	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-12-03T11:03	23	23	2 Hour Postdose	3	PT120M	Day 23 Dose	2008-12-03T09:10
13	TSA1397	EG	1	13	QTCFAG	QTcF Interval, Aggregate	SLING	0.238	sec	238	238	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-10-28T07:46	-14	-14	Pretest	1	-P14D	Day 1 Dose	2008-11-11T08:54
14	TSA1397	EG	1	14	QTAG	QT Interval, Aggregate	SLING	0.255	sec	255	255	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS	Y	2008-12-03T09:05	23	23	Predose	2	-PT5M	Day 23 Dose	2008-12-03T09:10
15	TSA1397	EG	1	15	QTAG	QT Interval, Aggregate	SLING	0.240	sec	240	240	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-12-03T11:03	23	23	2 Hour Postdose	3	PT120M	Day 23 Dose	2008-12-03T09:10
16	TSA1397	EG	1	16	QTCVAG	QTcv Interval, Aggregate	SLING	0.237	sec	237	237	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-10-28T07:46	-14	-14	Pretest	1	-P14D	Day 1 Dose	2008-11-11T08:54
17	TSA1397	EG	1	17	QTCVAG	QTcv Interval, Aggregate	SLING	0.252	sec	252	252	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS	Y	2008-12-03T09:05	23	23	Predose	2	-PT5M	Day 23 Dose	2008-12-03T09:10
18	TSA1397	EG	1	18	QTCVAG	QTcv Interval, Aggregate	SLING	0.234	sec	234	234	msec	LEAD II	6 LEAD STANDARD	CONSCIOUS		2008-12-03T11:03	23	23	2 Hour Postdose	3	PT120M	Day 23 Dose	2008-12-03T09:10

Example 2

This example is for a cardiovascular assessment in telemetered animals where the results are averages derived by the equipment/device from multiple 1-hour intervals during a continuous 48-hour collection period. Means have been calculated from waveform data for 6 specific intervals within the entire collection period. A single planned dose, described in EGTPTRREF, was given on day 1 at 06:15 (EGRFTDTC="2009-04-15T06:15"). The planned 1-hour intervals are represented by the start (EGSTINT) and end (EGENDINT) of the evaluation relative to the referenced dose (EGTPTRREF). Each of the 6 intervals has a text label (e.g., "Predose", "1 hr Postdose") indicated in the EGTPT variable. The applicant has defined the labels to be the end of the interval relative to the referenced dose. The entry in ISO 8601 format in the EGELTM variable. The actual start and end date/time variables (EGDTC and EGENDTC) are the start and end of the evaluation interval, not the date and time of the entire continuous collection period.

Rows 1-4: Results calculated using data from the 1-hour interval ending at the dose on study day 1.

Rows 5-8: Results calculated using data from the 1-hour interval ending 1-hour post-dose administered on study day 1.

Rows 9-12: Results calculated using data from the 1-hour interval ending 2-hours post-dose administered on study day 1.

Rows 13-16: Results calculated using data from the 1-hour interval ending 3-hours post-dose administered on study day 1.

Rows 17-20: Results calculated using data from the 1-hour interval ending 24-hours post-dose administered on study day 1.

Rows 21-24: Results calculated using data from the 1-hour interval ending 48-hours post-dose administered on study day 1.

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Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGTESTCD	EGTEST	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU	EGLLEAD	EGMETHOD
1	XYZ	EG	XYZ-001-001	1	RRAG	RR Interval, Aggregate	UNCONSTRAINED	248.11	msec	248.11	248.11	msec	LEAD I	12 LEAD STANDARD
2	XYZ	EG	XYZ-001-001	2	EGHR	ECG Mean Heart Rate	UNCONSTRAINED	241.8	beats/min	241.8	241.8	beats/min	LEAD I	12 LEAD STANDARD
3	XYZ	EG	XYZ-001-001	3	QTAG	QT Interval, Aggregate	UNCONSTRAINED	132.17	msec	132.17	132.17	msec	LEAD I	12 LEAD STANDARD
4	XYZ	EG	XYZ-001-001	4	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	211.91	msec	211.91	211.91	msec	LEAD I	12 LEAD STANDARD
5	XYZ	EG	XYZ-001-001	5	RRAG	RR Interval, Aggregate	UNCONSTRAINED	354.13	msec	354.13	354.13	msec	LEAD I	12 LEAD STANDARD
6	XYZ	EG	XYZ-001-001	6	EGHR	ECG Mean Heart Rate	UNCONSTRAINED	169.4	beats/min	169.4	169.4	beats/min	LEAD I	12 LEAD STANDARD
7	XYZ	EG	XYZ-001-001	7	QTAG	QT Interval, Aggregate	UNCONSTRAINED	150.19	msec	150.19	150.19	msec	LEAD I	12 LEAD STANDARD
8	XYZ	EG	XYZ-001-001	8	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	213.34	msec	213.34	213.34	msec	LEAD I	12 LEAD STANDARD
9	XYZ	EG	XYZ-001-001	9	RRAG	RR Interval, Aggregate	UNCONSTRAINED	363.43	msec	363.43	363.43	msec	LEAD I	12 LEAD STANDARD
10	XYZ	EG	XYZ-001-001	10	EGHR	ECG Mean Heart Rate	UNCONSTRAINED	165.1	beats/min	165.1	165.1	beats/min	LEAD I	12 LEAD STANDARD
11	XYZ	EG	XYZ-001-001	11	QTAG	QT Interval, Aggregate	UNCONSTRAINED	150.82	msec	150.82	150.82	msec	LEAD I	12 LEAD STANDARD
12	XYZ	EG	XYZ-001-001	12	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	212.35	msec	212.35	212.35	msec	LEAD I	12 LEAD STANDARD
13	XYZ	EG	XYZ-001-001	13	RRAG	RR Interval, Aggregate	UNCONSTRAINED	361.04	msec	361.04	361.04	msec	LEAD I	12 LEAD STANDARD
14	XYZ	EG	XYZ-001-001	14	EGHR	ECG Mean Heart Rate	UNCONSTRAINED	166.2	beats/min	166.2	166.2	beats/min	LEAD I	12 LEAD STANDARD
15	XYZ	EG	XYZ-001-001	15	QTAG	QT Interval, Aggregate	UNCONSTRAINED	149.01	msec	149.01	149.01	msec	LEAD I	12 LEAD STANDARD
16	XYZ	EG	XYZ-001-001	16	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	210.76	msec	210.76	210.76	msec	LEAD I	12 LEAD STANDARD
17	XYZ	EG	XYZ-001-001	17	RRAG	RR Interval, Aggregate	UNCONSTRAINED	360.23	msec	360.23	360.23	msec	LEAD I	12 LEAD STANDARD
18	XYZ	EG	XYZ-001-001	18	EGHR	ECG Mean Heart Rate	UNCONSTRAINED	166.6	beats/min	166.6	166.6	beats/min	LEAD I	12 LEAD STANDARD
19	XYZ	EG	XYZ-001-001	19	QTAG	QT Interval, Aggregate	UNCONSTRAINED	147.98	msec	147.98	147.98	msec	LEAD I	12 LEAD STANDARD
20	XYZ	EG	XYZ-001-001	20	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	209.40	msec	209.40	209.40	msec	LEAD I	12 LEAD STANDARD
21	XYZ	EG	XYZ-001-001	21	RRAG	RR Interval, Aggregate	UNCONSTRAINED	259.89	msec	259.89	259.89	msec	LEAD I	12 LEAD STANDARD
22	XYZ	EG	XYZ-001-001	22	EGHR	ECG Mean Heart Rate	UNCONSTRAINED	230.9	beats/min	230.9	230.9	beats/min	LEAD I	12 LEAD STANDARD
23	XYZ	EG	XYZ-001-001	23	QTAG	QT Interval, Aggregate	UNCONSTRAINED	133.67	msec	133.67	133.67	msec	LEAD I	12 LEAD STANDARD

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGTESTCD	EGTEST	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU	EGLEAD	EGMETHOD
24	XYZ	EG	XYZ-001-001	24	QTCFAG	QTcf Interval, Aggregate	UNCONSTRAINED	210.99	msec	210.99	210.99	msec	LEAD I	12 LEAD STANDARD

Row	EGCSTATE	EGBLFL	EGDTC	EGDY	EGENDTc	EGENDY	EGNOMDY	EGTPT	EGTPNUM	EGLTM	EGTPREF	EGRFTDTC	EGSTINT	EGENINT
1	CONSCIOUS	Y	2009-04-15T05:12:15	1	2009-04-15T06:12:15	1	1	Predose	0	PT0H	DAY 1 DOSING	2009-04-15T06:15	-PT1H	PT0H
2	CONSCIOUS	Y	2009-04-15T05:12:15	1	2009-04-15T06:12:15	1	1	Predose	0	PT0H	DAY 1 DOSING	2009-04-15T06:15	-PT1H	PT0H
3	CONSCIOUS	Y	2009-04-15T05:12:15	1	2009-04-15T06:12:15	1	1	Predose	0	PT0H	DAY 1 DOSING	2009-04-15T06:15	-PT1H	PT0H
4	CONSCIOUS	Y	2009-04-15T05:12:15	1	2009-04-15T06:12:15	1	1	Predose	0	PT0H	DAY 1 DOSING	2009-04-15T06:15	-PT1H	PT0H
5	CONSCIOUS		2009-04-15T06:12:15	1	2009-04-15T07:12:15	1	1	1h Postdose	1	PT1H	DAY 1 DOSING	2009-04-15T06:15	PT0H	PT1H
6	CONSCIOUS		2009-04-15T06:12:15	1	2009-04-15T07:12:15	1	1	1h Postdose	1	PT1H	DAY 1 DOSING	2009-04-15T06:15	PT0H	PT1H
7	CONSCIOUS		2009-04-15T06:12:15	1	2009-04-15T07:12:15	1	1	1h Postdose	1	PT1H	DAY 1 DOSING	2009-04-15T06:15	PT0H	PT1H
8	CONSCIOUS		2009-04-15T06:12:15	1	2009-04-15T07:12:15	1	1	1h Postdose	1	PT1H	DAY 1 DOSING	2009-04-15T06:15	PT0H	PT1H
9	CONSCIOUS		2009-04-15T07:12:15	1	2009-04-15T08:12:15	1	1	2h Postdose	2	PT2H	DAY 1 DOSING	2009-04-15T06:15	PT1H	PT2H
10	CONSCIOUS		2009-04-15T07:12:15	1	2009-04-15T08:12:15	1	1	2h Postdose	2	PT2H	DAY 1 DOSING	2009-04-15T06:15	PT1H	PT2H
11	CONSCIOUS		2009-04-15T07:12:15	1	2009-04-15T08:12:15	1	1	2h Postdose	2	PT2H	DAY 1 DOSING	2009-04-15T06:15	PT1H	PT2H
12	CONSCIOUS		2009-04-15T07:12:15	1	2009-04-15T08:12:15	1	1	2h Postdose	2	PT2H	DAY 1 DOSING	2009-04-15T06:15	PT1H	PT2H
13	CONSCIOUS		2009-04-15T08:12:15	1	2009-04-15T09:12:15	1	1	3h Postdose	3	PT3H	DAY 1 DOSING	2009-04-15T06:15	PT2H	PT3H
14	CONSCIOUS		2009-04-15T08:12:15	1	2009-04-15T09:12:15	1	1	3h Postdose	3	PT3H	DAY 1 DOSING	2009-04-15T06:15	PT2H	PT3H
15	CONSCIOUS		2009-04-15T08:12:15	1	2009-04-15T09:12:15	1	1	3h Postdose	3	PT3H	DAY 1 DOSING	2009-04-15T06:15	PT2H	PT3H
16	CONSCIOUS		2009-04-15T08:12:15	1	2009-04-15T09:12:15	1	1	3h Postdose	3	PT3H	DAY 1 DOSING	2009-04-15T06:15	PT2H	PT3H
17	CONSCIOUS		2009-04-16T05:12:15	2	2009-04-16T06:12:15	2	1	24h Postdose	4	PT24H	DAY 1 DOSING	2009-04-15T06:15	PT23H	PT24H
18	CONSCIOUS		2009-04-16T05:12:15	2	2009-04-16T06:12:15	2	1	24h Postdose	4	PT24H	DAY 1 DOSING	2009-04-15T06:15	PT23H	PT24H
19	CONSCIOUS		2009-04-16T05:12:15	2	2009-04-16T06:12:15	2	1	24h Postdose	4	PT24H	DAY 1 DOSING	2009-04-15T06:15	PT23H	PT24H
20	CONSCIOUS		2009-04-16T05:12:15	2	2009-04-16T06:12:15	2	1	24h Postdose	4	PT24H	DAY 1 DOSING	2009-04-15T06:15	PT23H	PT24H
21	CONSCIOUS		2009-04-17T05:12:15	3	2009-04-17T06:12:15	3	1	48h Postdose	5	PT48H	DAY 1 DOSING	2009-04-15T06:15	PT47H	PT48H
22	CONSCIOUS		2009-04-17T05:12:15	3	2009-04-17T06:12:15	3	1	48h Postdose	5	PT48H	DAY 1 DOSING	2009-04-15T06:15	PT47H	PT48H
23	CONSCIOUS		2009-04-17T05:12:15	3	2009-04-17T06:12:15	3	1	48h Postdose	5	PT48H	DAY 1 DOSING	2009-04-15T06:15	PT47H	PT48H
24	CONSCIOUS		2009-04-17T05:12:15	3	2009-04-17T06:12:15	3	1	48h Postdose	5	PT48H	DAY 1 DOSING	2009-04-15T06:15	PT47H	PT48H

As previously noted, in the above example, the applicant has defined the interval labels to be the end of the interval relative to the referenced dose. However, applicants may label time points differently, such as from the beginning or midpoint of the interval, or use another form of labeling. In these cases, the period of evaluation (defined by EGSTINT and EGENINT) does not change, just the label (EGTPT) and its standard representation (EGLTM).

The following is a sampling of rows from the above example, with only the timing variables. Regardless of the method of labeling for the time points, the same periods of evaluation apply:

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Row	EGDTC	EGDY	EGENDTc	EGENDY	EGNOMDY	EGTPT	EGTPNUM	EGLTM	EGTPREF	EGRFTDTC	EGSTINT	EGENINT
1	2009-04-15T05:12:15	1	2009-04-15T06:12:15	1	1	(see below)	0	(see below)	DAY 1 DOSING	2009-04-15T06:15	-PT1H	PT0H
5	2009-04-15T06:12:15	1	2009-04-15T07:12:15	1	1	(see below)	1	(see below)	DAY 1 DOSING	2009-04-15T06:15	PT0H	PT1H
9	2009-04-15T07:12:15	1	2009-04-15T08:12:15	1	1	(see below)	2	(see below)	DAY 1 DOSING	2009-04-15T06:15	PT1H	PT2H
13	2009-04-15T08:12:15	1	2009-04-15T09:12:15	1	1	(see below)	3	(see below)	DAY 1 DOSING	2009-04-15T06:15	PT2H	PT3H

The following are variations on the time point labeling (EGTPT) and duration to the time point (EGELTM) for the same periods of evaluation.

End-based

Row	EGTPT	EGELTM
1	Predose	PT0H
5	1h Postdose	PT1H
9	2h Postdose	PT2H
13	3hPostdose	PT3H

In this case, intervals are labeled based on the end of the interval (e.g., the 1- to 2-hour post-dose interval is labeled as "2h Postdose"). This example is the same as that used in the full example above.

Start-based

Row	EGTPT	EGELTM
1	-1 hour predose	-PT1H
5	0 hour postdose	PT0H
9	1 hour postdose	PT1H
13	2 hour postdose	PT2H

In this case, intervals are labeled based on the start of the interval (e.g., the 1- to 2-hour post-dose interval is labeled as "1 hour postdose").

Midpoint-based

Row	EGTPT	EGELTM
1	Predose	-PT30M
5	30 min	PT30M
9	1 hr 30 min	PT1H30M
13	2 hr 30 min	PT2H30M

In this case, intervals are labeled based on the midpoint of the interval (e.g., the 1- to 2-hour post-dose interval is labeled as "1 hr 30 min").

Range Description

Row	EGTPT	EGELTM
1	-1 to 0 hour post	
5	0 to 1 hour post	
9	1 to 2 hour post	
13	2 to 3 hour post	

In this case, intervals are labeled based on the time range (e.g., the 1- to 2-hour post-dose interval is labeled as "1 to 2 hour post"). The time point does not have a determinate time from the reference point, so EGELTM is blank

Example 3

This example shows how ECG measurements, interpretations, and diagnoses may be shown within the EG domain.

- Rows 1-3:** Subject XYZ-001-001 had a QT measurement (row 1). The technician performed an interpretation, noting that the QT appeared abnormal (row 2). The cardiologist subsequently provided a diagnosis for the animal (row 3).
- Rows 4-7:** Subject XYZ-001-002 had a T wave measurement (row 4). The ECG analyst performed an interpretation, noting a T wave inversion (row 5). The cardiologist subsequently provided 2 diagnoses for the animal, 1 a targeted assessment (row 6) and 1 a general assessment (row 7).

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Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGGRPID	EGTESTCD	EGTEST	EGCAT	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN
1	XYZ	EG	XYZ-001-001	1	1	QTAG	QT Interval, Aggregate	MEASUREMENT	UNCONSTRAINED	132.172	msec	132.172	132.172
2	XYZ	EG	XYZ-001-001	2	1	INTP	Interpretation	INTERPRETATION	UNCONSTRAINED	QT MEAN POSSIBLY ABNORMAL		QT MEAN POSSIBLY ABNORMAL	
3	XYZ	EG	XYZ-001-001	3	1	INTP	Interpretation	DIAGNOSIS	UNCONSTRAINED	PROLONGED QT		PROLONGED QT	
4	XYZ	EG	XYZ-001-002	1	2	TWARAG	T Wave Area, Aggregate	MEASUREMENT	UNCONSTRAINED	-211.905	msec	-211.905	-211.905
5	XYZ	EG	XYZ-001-002	2	2	INTP	Interpretation	INTERPRETATION	UNCONSTRAINED	T WAVE INVERSION		T WAVE ABNORMALITY	
6	XYZ	EG	XYZ-001-002	3	2	INTP	Interpretation	DIAGNOSIS	UNCONSTRAINED	LEFT VENTRICULAR HYPERTROPHY		LEFT VENTRICULAR HYPERTROPHY	
7	XYZ	EG	XYZ-001-002	4	2	INTP	Interpretation	DIAGNOSIS	UNCONSTRAINED	JUNCTIONAL TACHYCARDIA		JUNCTIONAL TACHYCARDIA	

Row	EGSTRESU	EGLEAD	EGMETHOD	EGCSTATE	EGBLFL	EGEVAL	EGDTC	EGDY	EGNOMDY	EGTPT	EGTPNUM	EGTPTRF	EGRFTDTC
1	msec	LEAD I	12 LEAD STANDARD	CONSCIOUS			2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
2						TECHNICIAN	2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
3						CARDIOLOGIST	2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
4	msec	LEAD I	12 LEAD STANDARD	CONSCIOUS			2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
5						ECG ANALYST	2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
6						CARDIOLOGIST	2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
7						CARDIOLOGIST	2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00

Example 4

The study design for this example is to determine a suspected toxicity of the heart. The same test parameters were collected from different leads identifiers, using different methods, and summarized at different timepoints. The data is summarized for an hour-long interval after the day 1 dose, as indicated by EGSTINT and EGENINT.

Rows 1-4: Demonstrate an animal in an unconstrained position (EGPOS) during data collection. The lead from which data were collected is lead CV5RL (EGLEAD), and the method of collection (EGMETHOD) was the 6-lead standard.

Rows 5-8: Demonstrate an animal in a standing position (EGPOS) during data collection. The lead from which data were collected is lead II (EGLEAD), and the method of collection (EGMETHOD) was the 12-lead standard.

Rows 9-12: Demonstrate an animal in an unconstrained position (EGPOS) during data collection. The lead from which data were collected is lead I (EGLEAD), and the method of collection (EGMETHOD) was the 12-lead standard.

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Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGTESTCD	EGTEST	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU	EGLEAD
1	XYZ	EG	XYZ-101-101	1	RRAG	RR Interval, Aggregate	UNCONSTRAINED	248.105	msec	248.105	248.105	msec	LEAD CV5RL
2	XYZ	EG	XYZ-101-101	2	EGHRMN	ECG Mean Heart Rate	UNCONSTRAINED	241.833	beats/min	241.833	241.833	beats/min	LEAD CV5RL
3	XYZ	EG	XYZ-101-101	3	QTAG	QT Interval, Aggregate	UNCONSTRAINED	132.172	msec	132.172	132.172	msec	LEAD CV5RL
4	XYZ	EG	XYZ-101-101	4	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	211.905	msec	211.905	211.905	msec	LEAD CV5RL
5	XYZ	EG	XYZ-201-201	5	RRAG	RR Interval, Aggregate	STANDING	354.13	msec	354.13	354.13	msec	LEAD II
6	XYZ	EG	XYZ-201-201	6	EGHRMN	ECG Mean Heart Rate	STANDING	169.429	beats/min	169.429	169.429	beats/min	LEAD II
7	XYZ	EG	XYZ-201-201	7	QTAG	QT Interval, Aggregate	STANDING	150.19	msec	150.19	150.19	msec	LEAD II
8	XYZ	EG	XYZ-201-201	8	QTCFAG	QTcF Interval, Aggregate	STANDING	213.335	msec	213.335	213.335	msec	LEAD II
9	XYZ	EG	XYZ-301-301	9	RRAG	RR Interval, Aggregate	UNCONSTRAINED	363.428	msec	363.428	363.428	msec	LEAD I
10	XYZ	EG	XYZ-301-301	10	EGHRMN	ECG Mean Heart Rate	UNCONSTRAINED	165.1	beats/min	165.1	165.1	beats/min	LEAD I
11	XYZ	EG	XYZ-301-301	11	QTAG	QT Interval, Aggregate	UNCONSTRAINED	150.819	msec	150.819	150.819	msec	LEAD I
12	XYZ	EG	XYZ-301-301	12	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	212.351	msec	212.351	212.351	msec	LEAD I

Row	EGMETHOD	EGCSTATE	EGBLFL	EGDTIC	EGDY	EGNOMDY	EGPT	EGTPNUM	EGELTM	EGTPTRF	EGRFTDTC	EGSTINT	EGENINT
1	6 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
2	6 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
3	6 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
4	6 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
5	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
6	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
7	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
8	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
9	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
10	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
11	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
12	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H

3.2.2.20.5 Examples for Cardiovascular (CV) Domain Model

The CV, ECG Test Results (EG), and Respiratory Test Results (RE) domains are very similar in structure. Note that the examples provided in this section represent uses of timing variables which could apply to any of these domains, regardless of study type or design.

Example 1

This example shows different cardiovascular endpoints collected for 1 subject, including examples of both collected and derived baseline measurements. These endpoints were measured at a single point in time at 8 hours post-dose (CVELTM = "PT8H"), per the study protocol. Since the time point is not an interval with a planned start and end, CVSTINT and CVENINT are null.

Rows 1-2, 4-5: Show measurements performed at a specific time. Note that the same test was performed multiple times on the same day for a subject. In this example, CVDTC is part of the natural key of the dataset (CVDTC contains both date and time), distinguishing one record from the next.

Rows 3, 6: Represent the mean of the 2 previous rows, which make them derived records (CVDRVFL="Y"), and at the same time serve as baseline values (CVBLFL="Y"). CVDTC now contains information about the date (not time).

Row 7: Shows an example of a measured baseline value. It is not derived (CVDRVFL is null).

cv.xpt

Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVRRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVMETHOD
1	ABC	CV	ABC-001-001	1	SYSBP	Systolic Blood Pressure	SITTING	154	mmHg	154	154	mmHg	External Cuff
2	ABC	CV	ABC-001-001	2	SYSBP	Systolic Blood Pressure	SITTING	152	mmHg	152	152	mmHg	External Cuff
3	ABC	CV	ABC-001-001	3	SYSBP	Systolic Blood Pressure	SITTING	153	mmHg	153	153	mmHg	External Cuff
4	ABC	CV	ABC-001-001	4	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg	External Cuff
5	ABC	CV	ABC-001-001	5	DIABP	Diastolic Blood Pressure	SITTING	48	mmHg	48	48	mmHg	External Cuff
6	ABC	CV	ABC-001-001	6	DIABP	Diastolic Blood Pressure	SITTING	46	mmHg	46	46	mmHg	External Cuff
7	ABC	CV	ABC-001-001	7	PULSEPR	Pulse Pressure	SITTING	107	mmHg	72	72	mmHg	External Cuff

Row	CVCSTATE	CVBLFL	CVDRVFL	CVDTC	CVDY	CVNOMDY	CVTPT	CVTPTRNUM	CVELTM	CVTPTRREF	CVSTINT	CVENINT	
1	CONSCIOUS			1999-06-19T08:45	1	1	8 hours postdose	1	PT8H	Day 1 Dose			
2	CONSCIOUS			1999-06-19T09:00	1	1	8 hours postdose	1	PT8H	Day 1 Dose			
3	CONSCIOUS	Y	Y	1999-06-19	1	1	8 hours postdose	1	PT8H	Day 1 Dose			
4	CONSCIOUS			1999-06-19T08:45	1	1	8 hours postdose	1	PT8H	Day 1 Dose			
5	CONSCIOUS			1999-06-19T09:00	1	1	8 hours postdose	1	PT8H	Day 1 Dose			
6	CONSCIOUS	Y	Y	1999-06-19	1	1	8 hours postdose	1	PT8H	Day 1 Dose			
7	CONSCIOUS	Y		1999-06-19	1	1	8 hours postdose	1	PT8H	Day 1 Dose			

Example 2

This example shows measurements on 2 animals at 3 timepoints (baseline, 120 minutes, 240 minutes) relative to the administration of the third dose level of a Latin square design (with CVTPTRREF as "Dose 3"). At each timepoint, several measurements were assessed (arterial diastolic pressure, arterial heart rate, arterial mean blood pressure). Each measurement summarizes data collected for a planned evaluation interval of 60 minutes that ended at time 0 min, 120 min, and 240 min after the dose. Subject 1003 received the third dose level on day 15 of the study and subject 1008 received this dose level on day 1. The method "Intravascular" is used for measurements taken directly from the vasculature.

cv.xpt

Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVRRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVMETHOD
1	AA222	CV	1003	1	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	50.94	mmHg	50.94	50.94	mmHg	Intravascular
2	AA222	CV	1003	2	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	50.68	mmHg	50.68	50.68	mmHg	Intravascular
3	AA222	CV	1003	3	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	49.37	mmHg	49.37	49.37	mmHg	Intravascular
4	AA222	CV	1003	4	HR	Heart Rate	UNCONSTRAINED	139.2	beats/min	139.2	139.2	beats/min	Intravascular
5	AA222	CV	1003	5	HR	Heart Rate	UNCONSTRAINED	128.3	beats/min	128.3	128.3	beats/min	Intravascular
6	AA222	CV	1003	6	HR	Heart Rate	UNCONSTRAINED	118.4	beats/min	118.4	118.4	beats/min	Intravascular
7	AA222	CV	1003	7	MAP	Mean Arterial Pressure	UNCONSTRAINED	66.96	mmHg	66.96	66.96	mmHg	Intravascular
8	AA222	CV	1003	8	MAP	Mean Arterial Pressure	UNCONSTRAINED	66.66	mmHg	66.66	66.66	mmHg	Intravascular
9	AA222	CV	1003	9	MAP	Mean Arterial Pressure	UNCONSTRAINED	65.99	mmHg	65.99	65.99	mmHg	Intravascular
10	AA1111	CV	1008	10	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	34.11	mmHg	34.11	34.11	mmHg	Intravascular

Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVRRES	CVRRESU	CVSTREC	CVSTRES	CVSTRESU	CVMETHOD
11	AA1111	CV	1008	11	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	28.63	mmHg	28.63	28.63	mmHg	Intravascular
12	AA1111	CV	1008	12	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	28.96	mmHg	28.96	28.96	mmHg	Intravascular
13	AA1111	CV	1008	13	HR	Heart Rate	UNCONSTRAINED	186.1	beats/min	186.1	186.1	beats/min	Intravascular
14	AA1111	CV	1008	14	HR	Heart Rate	UNCONSTRAINED	168.3	beats/min	168.3	168.3	beats/min	Intravascular
15	AA1111	CV	1008	15	HR	Heart Rate	UNCONSTRAINED	150.8	beats/min	150.8	150.8	beats/min	Intravascular
16	AA1111	CV	1008	16	MAP	Mean Arterial Pressure	UNCONSTRAINED	53.48	mmHg	53.48	53.48	mmHg	Intravascular
17	AA1111	CV	1008	17	MAP	Mean Arterial Pressure	UNCONSTRAINED	47.67	mmHg	47.67	47.67	mmHg	Intravascular
18	AA1111	CV	1008	18	MAP	Mean Arterial Pressure	UNCONSTRAINED	46.48	mmHg	46.48	46.48	mmHg	Intravascular

Row	CVCSTATE	CVBLFL	CVDTG	CVDY	CVNOMDY	CVTPT	CVTPTRNUM	CVELTM	CVTPTRREF	CVRFTDTC	CVSTINT	CVENINT
1	CONSCIOUS	Y	2006-09-15	15	15	0 min	0	PT0M	Dose 3	2006-09-15T10:30	-PT60M	PT0M
2	CONSCIOUS		2006-09-15	15	15	120 min	120	PT120M	Dose 3	2006-09-15T10:30	PT60M	PT120M
3	CONSCIOUS		2006-09-15	15	15	240 min	240	PT240M	Dose 3	2006-09-15T10:30	PT180M	PT240M
4	CONSCIOUS	Y	2006-09-15	15	15	0 min	0	PT0M	Dose 3	2006-09-15T10:30	-PT60M	PT0M
5	CONSCIOUS		2006-09-15	15	15	120 min	120	PT120M	Dose 3	2006-09-15T10:30	PT60M	PT120M
6	CONSCIOUS		2006-09-15	15	15	240 min	240	PT240M	Dose 3	2006-09-15T10:30	PT180M	PT240M
7	CONSCIOUS	Y	2006-09-15	15	15	0 min	0	PT0M	Dose 3	2006-09-15T10:30	-PT60M	PT0M
8	CONSCIOUS		2006-09-15	15	15	120 min	120	PT120M	Dose 3	2006-09-15T10:30	PT60M	PT120M
9	CONSCIOUS		2006-09-15	15	15	240 min	240	PT240M	Dose 3	2006-09-15T10:30	PT180M	PT240M
10	CONSCIOUS	Y	2006-09-01	1	1	0 min	0	PT0M	Dose 3	2006-09-01T10:30	-PT60M	PT0M
11	CONSCIOUS		2006-09-01	1	1	120 min	120	PT120M	Dose 3	2006-09-01T10:30	PT60M	PT120M
12	CONSCIOUS		2006-09-01	1	1	240 min	240	PT240M	Dose 3	2006-09-01T10:30	PT180M	PT240M
13	CONSCIOUS	Y	2006-09-01	1	1	0 min	0	PT0M	Dose 3	2006-09-01T10:30	-PT60M	PT0M
14	CONSCIOUS		2006-09-01	1	1	120 min	120	PT120M	Dose 3	2006-09-01T10:30	PT60M	PT120M
15	CONSCIOUS		2006-09-01	1	1	240 min	240	PT240M	Dose 3	2006-09-01T10:30	PT180M	PT240M
16	CONSCIOUS	Y	2006-09-01	1	1	0 min	0	PT0M	Dose 3	2006-09-01T10:30	-PT60M	PT0M
17	CONSCIOUS		2006-09-01	1	1	120 min	120	PT120M	Dose 3	2006-09-01T10:30	PT60M	PT120M
18	CONSCIOUS		2006-09-01	1	1	240 min	240	PT240M	Dose 3	2006-09-01T10:30	PT180M	PT240M

Example 3

This example shows heart rates for a single animal where the evaluation intervals changed across the study. The applicant chose to label its timepoints (CVTPT) based on the hours, minutes, and seconds of the planned time away from dose, based on the end of the evaluation interval.

Row 1: The pre-dose was monitored for a period of 1 hour, summarized into a 1-hour increment.

Rows 2-9: From the dose to 2 hours post-dose, the data were summarized in 15-minute increments.

Rows 10-13: From 2 hours post-dose up to 6 hours post-dose, the data were summarized into 1-hour increments.

Rows 14-16: From 6 hours post-dose up to 12 hours post-dose, the data were summarized into 2-hour increments.

cv.xpt

Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVRRES	CVRRESU	CVSTREC	CVSTRES	CVSTRESU	CVMETHOD
1	ABC-123	CV	101	1	HR	Heart Rate	UNCONSTRAINED	162	beats/min	162	162	beats/min	Intravascular
2	ABC-123	CV	101	2	HR	Heart Rate	UNCONSTRAINED	158	beats/min	158	158	beats/min	Intravascular
3	ABC-123	CV	101	3	HR	Heart Rate	UNCONSTRAINED	152	beats/min	152	152	beats/min	Intravascular
4	ABC-123	CV	101	4	HR	Heart Rate	UNCONSTRAINED	141	beats/min	141	141	beats/min	Intravascular
5	ABC-123	CV	101	5	HR	Heart Rate	UNCONSTRAINED	120	beats/min	120	120	beats/min	Intravascular
6	ABC-123	CV	101	6	HR	Heart Rate	UNCONSTRAINED	113	beats/min	113	113	beats/min	Intravascular
7	ABC-123	CV	101	7	HR	Heart Rate	UNCONSTRAINED	123	beats/min	123	123	beats/min	Intravascular
8	ABC-123	CV	101	8	HR	Heart Rate	UNCONSTRAINED	143	beats/min	143	143	beats/min	Intravascular
9	ABC-123	CV	101	9	HR	Heart Rate	UNCONSTRAINED	146	beats/min	146	146	beats/min	Intravascular
10	ABC-123	CV	101	10	HR	Heart Rate	UNCONSTRAINED	166	beats/min	166	166	beats/min	Intravascular
11	ABC-123	CV	101	11	HR	Heart Rate	UNCONSTRAINED	146	beats/min	146	146	beats/min	Intravascular
12	ABC-123	CV	101	12	HR	Heart Rate	UNCONSTRAINED	149	beats/min	149	149	beats/min	Intravascular

Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVRRES	CVRRESU	CVSTREC	CVSTRESN	CVSTRESU	CVMETHOD
13	ABC-123	CV	101	13	HR	Heart Rate	UNCONSTRAINED	123	beats/min	123	123	beats/min	Intravascular
14	ABC-123	CV	101	14	HR	Heart Rate	UNCONSTRAINED	105	beats/min	105	105	beats/min	Intravascular
15	ABC-123	CV	101	15	HR	Heart Rate	UNCONSTRAINED	100	beats/min	100	100	beats/min	Intravascular
16	ABC-123	CV	101	16	HR	Heart Rate	UNCONSTRAINED	113	beats/min	113	113	beats/min	Intravascular
Row	CVCSTATE	CVBLFL	CVDTG	CVDY	CVNOMDY	CVTPT	CVTPTNM	CVELTM	CVTPTRF	CVRFTDTC	CVSTINT	CVENINT	
1	CONSCIOUS	Y	2012-03-22	1	1	00:00:00	1	PT0M	Day 1 Dose	2012-03-22T09:52	-PT1H	PT0M	
2	CONSCIOUS		2012-03-22	1	1	00:15:00	2	PT15M	Day 1 Dose	2012-03-22T09:52	PT0M	PT15M	
3	CONSCIOUS		2012-03-22	1	1	00:30:00	3	PT30M	Day 1 Dose	2012-03-22T09:52	PT15M	PT30M	
4	CONSCIOUS		2012-03-22	1	1	00:45:00	4	PT45M	Day 1 Dose	2012-03-22T09:52	PT30M	PT45M	
5	CONSCIOUS		2012-03-22	1	1	01:00:00	5	PT1H	Day 1 Dose	2012-03-22T09:52	PT45M	PT1H	
6	CONSCIOUS		2012-03-22	1	1	01:15:00	6	PT1H15M	Day 1 Dose	2012-03-22T09:52	PT1H	PT1H15M	
7	CONSCIOUS		2012-03-22	1	1	01:30:00	7	PT1H30M	Day 1 Dose	2012-03-22T09:52	PT1H15M	PT1H30M	
8	CONSCIOUS		2012-03-22	1	1	01:45:00	8	PT1H45M	Day 1 Dose	2012-03-22T09:52	PT1H30M	PT1H45M	
9	CONSCIOUS		2012-03-22	1	1	02:00:00	9	PT2H	Day 1 Dose	2012-03-22T09:52	PT1H45M	PT2H	
10	CONSCIOUS		2012-03-22	1	1	03:00:00	10	PT3H	Day 1 Dose	2012-03-22T09:52	PT2H	PT3H	
11	CONSCIOUS		2012-03-22	1	1	04:00:00	11	PT4H	Day 1 Dose	2012-03-22T09:52	PT3H	PT4H	
12	CONSCIOUS		2012-03-22	1	1	05:00:00	12	PT5H	Day 1 Dose	2012-03-22T09:52	PT4H	PT5H	
13	CONSCIOUS		2012-03-22	1	1	06:00:00	13	PT6H	Day 1 Dose	2012-03-22T09:52	PT5H	PT6H	
14	CONSCIOUS		2012-03-22	1	1	08:00:00	14	PT8H	Day 1 Dose	2012-03-22T09:52	PT6H	PT8H	
15	CONSCIOUS		2012-03-22	1	1	10:00:00	15	PT10H	Day 1 Dose	2012-03-22T09:52	PT8H	PT10H	
16	CONSCIOUS		2012-03-22	1	1	12:00:00	16	PT12H	Day 1 Dose	2012-03-22T09:52	PT10H	PT12H	

3.2.2.21 RELREC Examples for Record-To-Record Relationships

Example 1

This example shows how to use the RELREC dataset to relate records stored in separate domains for subject 123456 who had a clinical sign (rows 1 and 4) that was related to 2 palpable masses (rows 2 and 3) and two microscopic findings (rows 5 and 6).

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELIID
1	EFC1234	CL	123456	CLSEQ	5		1
2	EFC1234	PM	123456	PMSEQ	11		1
3	EFC1234	PM	123456	PMSEQ	12		1
4	EFC1234	CL	123456	CLSEQ	5		2
5	EFC1234	MI	123456	MISEQ	47		2
6	EFC1234	MI	123456	MISEQ	48		2

Example 2

This example shows the relationship between a grouped clinical observation and 2 laboratory results.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELIID
1	EFC1234	CL	123456	CLGRPID	FECES1		1
2	EFC1234	LB	123456	LBSEQ	47		1
3	EFC1234	LB	123456	LBSEQ	48		1

Example 3

This example shows the relationship between a clinical observation for a cage (pool) and 2 laboratory results on individual subjects.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	POOLID	IDVAR	IDVARVAL	RELTYPE	RELID
1	EFC1234	CL		CAGE1	CLGRP1D	FESES1		1
2	EFC1234	LB	B00001		LBSEQ	47		1
3	EFC1234	LB	B00002		LBSEQ	48		1

Example 4

This example shows how data collection applications should use --RECID to enable downstream applications to create RELREC records that must persist between an initial creation of SEND datasets and subsequent SEND datasets. The variable --RECID is defined in the SDTM, which indicates that it may be added to SEND domains unless the SENDIG restricts it. So, --RECID may be used in most SEND domains, for example in situations where Clinical Observations (CL), Microscopic Findings (MI), Macroscopic Findings (MA), and Palpable Masses (PM) domain records need to be correlated and the following situations exist:

- A facility uses one vendor to supply software for their in-life data collection and another vendor to supply software for necropsy and histopathology data collection.
- A part of a study (e.g., histopathology) is conducted by a different organization than conducted the in-life and necropsy portions.

In both situations, the correlation between the findings in the different domains must be collected; --RELREC is not supposed to describe correlations made later in the report.

In these situations, software that periodically receives SEND transmissions (e.g., following interim necropsies) cannot rely on the --SEQ variable values on the related records to remain consistent because the standard does not require this. With this use of --RECID, the receiving system is enabled to identify changes between the current transmission and previous ones (if any) and to determine if and how previously established record relationships need to be adjusted.

In this example a gross brain finding of focus/foci, red, is correlated to the microscopic finding of thrombus.

MA Example*ma.xpt*

Row	STUDYID	DOMAIN	USUBJID	MASEQ	MARECID	MATESTCD	MATEST	MAORRES	MASTRESC	MASPEC	MASEV	MADTC
1	EFC5678	MA	ABC-101	16	046GV2APClu2	GROSPATH	Gross Pathological Examination	FOCUS/FOCI, RED, CEREBRUM, MILD, LEFT HEMISPHERE.	FOCUS/FOCI, RED	BRAIN	MILD	2000-01-31T14:33:21

MI Example*mi.xpt*

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MIRECID	MITESTCD	MITEST	MIORRES	MISTRESC	MISPEC	MISEV	MIDTC
1	EFC5678	MI	ABC-101	1	2069gT4UnyRR	MIEXAM	Microscopic Examination	BRAIN: Thrombus: subacute, focal, grade 3	THROMBUS	BRAIN	MODERATE	2000-01-31

RELREC Example Using --RECID*relrec.xpt*

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELID
1	EFC5678	MA	ABC-101	MARECID	046GV2APClu2	A
2	EFC5678	MI	ABC-101	MIRECID	2069gT4UnyRR	A

3.2.2.22 Examples of Domain-To-Domain Relationships for Masses (--SPID)**RELREC Domain-to-Domain Example 1**

This example shows how to use the RELREC dataset to represent related information that is submitted as multiple datasets that have an identifying variable in common.

In this example, all the records with the same --SPID across the domains with the same USUBJID are being related to each other. Because this relationship exists for all values of USUBJID and all values of --SPID (specified in IDVARVAL), both USUBJID and IDVARVAL are null.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	999123	CL		CLSPID		MANY	A
2	999123	MI		MISPID		MANY	A
3	999123	MA		MASPID		MANY	A

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYP	RELID
4	999123	PM		PMSPID		MANY	A
5	999123	TF		TFSPID		MANY	A

Because IDVAR identifies the keys that can be used to merge/join records between the datasets, the root values (e.g., --SPID in this example) for IDVAR are the same for all records with the same RELID. --SEQ cannot be used because --SEQ only has meaning within a subject within a domain, not across domains.

RELREC --SPID Examples

The following --SPID examples are based on the preceding RELREC dataset. These examples show only the variables from the CL, PM, MA, MI, and Tumor Findings (TF) domains that are relevant to the RELREC discussion. In a submission, additional variables would be included.

RELREC --SPID Example 1

Shows the unique mass number across the 5 domains.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLSPID
1	999123	CL	999123-102	56	MASS A

pm.xpt

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMSPID
1	999123	PM	999123-102	64	MASS A

ma.xpt

Row	STUDYID	DOMAIN	USUBJID	MASEQ	MASPID
1	999123	MA	999123-102	128	MASS A

mi.xpt

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MISPID
1	999123	MI	999123-102	84	MASS A

tf.xpt

Row	STUDYID	DOMAIN	USUBJID	TFSEQ	TFSPID
1	999123	TF	999123-102	55	MASS A

RELREC --SPID Example 2

During the course of the study a mass split into 2 masses; therefore, a new identifier was given to the second mass.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLSPID
1	999123	CL	999123-102	56	MASS A

pm.xpt

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMSPID
1	999123	PM	999123-102	64	MASS A
2	999123	PM	999123-102	228	MASS B

ma.xpt

Row	STUDYID	DOMAIN	USUBJID	MASEQ	MASPID
1	999123	MA	999123-102	128	MASS A
2	999123	MA	999123-102	345	MASS B

mi.xpt

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MISPID
1	999123	MI	999123-102	84	MASS A
2	999123	MI	999123-102	84	MASS B

tf.xpt

Row	STUDYID	DOMAIN	USUBJID	TFSEQ	TFSPID
1	999123	TF	999123-102	55	MASS A
2	999123	TF	999123-102	76	MASS B

RELREC --SPID Example 3

During the course of the study 2 masses (mass A and mass B) merge to make a single mass; a new identifier ("MASS C") was given to merged mass.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLSPID	CLDTC
1	999123	CL	999123-102	56	MASS A	2013-10-01

pm.xpt

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMSPID	PMDTC
1	999123	PM	999123-102	64	MASS A	2013-10-08
2	999123	PM	999123-102	228	MASS B	2013-10-08

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMSPID	PMDTC
3	999123	PM	999123-102	228	MASS C	2013-10-15

ma.xpt

Row	STUDYID	DOMAIN	USUBJID	MASEQ	MASPID	MADTC
1	999123	MA	999123-102	128	MASS C	2013-10-22

mi.xpt

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MISPID	MIDTC
1	999123	MI	999123-102	84	MASS C	2013-10-22

tf.xpt

Row	STUDYID	DOMAIN	USUBJID	TFSEQ	TFSPID	TFDTC
1	999123	TF	b999123-102	55	MASS C	2013-10-22

3.2.2.23 Supplemental Qualifier Dataset Examples

The following examples demonstrate how a set of SUPP-- datasets could be used to relate nonstandard information to a parent domain.

Example 1

In this dataset, parameters of mass size are defined as supplemental information to a subject's necropsy data.

suppma.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	1996001	MA	199601-101	MASPID	MASS A	MASSWDTH	Mass Width	6 mm	COLLECTED	PATHOLOGIST
2	1996001	MA	199601-101	MASPID	MASS A	MASSLGTH	Mass Length	approximately 8 mm	COLLECTED	PATHOLOGIST

Example 2

In this dataset, the principal investigator has assessed biological significance for 2 samples drawn from a pool of subjects.

supplb.xpt

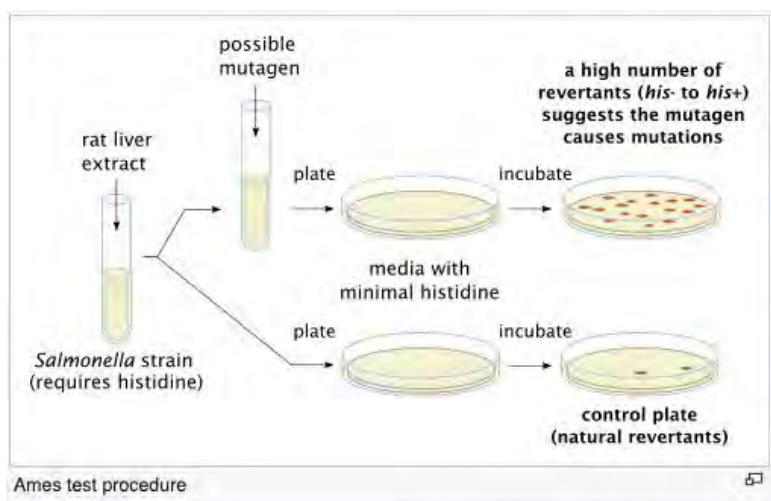
Row	STUDYID	RDOMAIN	USUBJID	POOLID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	LB		POOLS-01	LBSEQ	1	BIOSIG	Biological Significance	N	DERIVED	PRINCIPAL INVESTIGATOR
2	ABC	LB		POOLS-02	LBSEQ	6	BIOSIG	Biological Significance	N	DERIVED	PRINCIPAL INVESTIGATOR

3.2.3 In vitro Studies

In vitro studies are conducted in tobacco product research to screen for toxic and mutagenic compounds to identify potential risks. Examples in this section show in vitro test results data collected by the lab executing the study or received from a provider along with trial design datasets to describe the study design and test conditions.

3.2.3.1 Bacterial Reverse Mutation Test (Ames) Multi-Domain Example (GT, TS, TX, RELREF)

The bacterial reverse mutation test, commonly known as the Ames assay, uses amino acid-requiring strains of *Salmonella typhimurium* (*S. typhimurium*) and *Escherichia coli* (*E. coli*) to detect point mutations, which involve substitution, addition, or deletion of 1 or a few DNA base pairs. The principle of this bacterial reverse-mutation test is that it detects chemicals that induce mutations which revert mutations present in the tester strains and restore the functional capability of the bacteria to synthesize an essential amino acid. The revertant bacteria are detected by their ability to grow in the absence of the amino acid required by the parent tester strain.

**Example 1**

This is an example showing the report table, trial design, and results from a study's in vitro bacterial reverse mutation test using 4 different amino acid-requiring strains of *S. typhimurium* and 1 strain of *E. coli* to detect point mutations.

This table shows the assay results for study 8325064, test article TA1, and 3 strains of salmonella (TA98, TA100, and TA1535) at varying concentrations. For brevity, the remaining tables (e.g., additional strains, samples prepared without metabolic activation) are not included. For ease of reference in the table below, each row has been labeled in the right-hand margin with the applicant-defined trial set label (e.g., SetA). For brevity, only the four bolded sets are represented in the following example datasets.

Study Number: 8325064
 Experiment Number: 1
 Assay Conditions: Plate-incorporation Date Plated: 29-Jul-2015
 Date Counted: 03-Aug-2015

Without metabolic activation

Strain	Compound	Conc. Level ($\mu\text{g}/\text{plate}$)	Mean	Standard Deviation	Fold Increase	Revertant Numbers Per Plate	
TA98	DMSO	-	33.0	5.0	-	26, 35, 39, 35, 30	SetA
	TA1	5	29.7	5.0	0.9	25, 29, 35	SetB
		16	36.7	3.2	1.1	33, 39, 38	SetC
		50	37.0	6.6	1.1	31, 36, 44	SetD
		160	25.0	0.0	0.8	25 S, 25 S, 25 S	SetE
		500	10.0	2.0	0.3	8 M V, 10 M V, 12 M V	SetF
		1600	-	-	-	- T, - T, - T	SetG
		5000	-	-	-	- T, - T, - T	SetH
	2NF	5	1037.3	66.5	31.4	1104, 1037, 971	SetI
TA100	DMSO	-	133.8	14.1	-	109, 142, 138, 137, 143	SetJ
	TA1	5	136.3	13.7	1.0	130, 127, 152	
		16	132.3	8.3	1.0	135, 123, 139	
		50	120.3	14.6	0.9	132, 104, 125	
		160	46.0	1.7	0.3	48 V, 45 V, 45 V	
		500	-	-	-	- T, - T, - T	
		1600	-	-	-	- T, - T, - T	
		5000	-	-	-	- T, - T, - T	
	NaN ₃	2	854.3	51.7	6.4	812, 912, 839	SetR
TA1535	DMSO	-	28.8	5.9	-	31, 35, 29, 30, 19	
	TA1	5	29.0	6.1	1.0	36, 25, 26	

Positive controls**+Postfixes**

NaN ₃	Sodium azide	M	Plate counted manually
AAC	9-Aminoacridine	S	Slight thinning of background bacterial lawn
2NF	2-nitrofluorene	T	Toxic, no revertant colonies
NQO	4-nitroquinoline 1-oxide	V	Very thin background bacterial lawn

This example Trial Summary (TS) dataset shows many informational fields that provide context at the study level.

- Rows 1-2:** Show 2 records for TSPARMCD = "GLPTYP", using TSSEQ to indicate multiple records, since both GLP types apply for this study.
- Row 3:** Shows that this study was conducted as a GLP study.
- Rows 4-5:** Show the study start date and study title.
- Rows 6-7:** Show the version of SEND Implementation Guide and version of Controlled Terminology used in this study.
- Row 8:** Shows the applicant's organization.
- Row 9:** Shows that the applicant's study reference ID is not applicable.
- Rows 10-13:** Show that TSGRPID has been used to link records (name, location, country) related to the test facility (TSGRPID=1). The study director is associated with the test facility.
- Rows 14-16:** Show that TSGRPID (TSGRPID=4) has been used to link the information on the testing guideline followed on this study (TSTGDNAM, TSTGDORG, TSTGDVER).
- Row 17:** Shows the study type for this study.
- Row 18:** Shows that this study includes a Bacterial Reverse Mutation Assay.
- Rows 19-27:** Show that TSGRPID (TSGRPID = 2) has been used to link the information for 1 species (salmonella) with the 4 different strains and cell lines that are tested in this study.
- Rows 28-30:** Show that TSGRPID (TSGRPID = 3) has been used to link the information for 1 species (*E. coli*) with the strain and cell line that is tested in this study.

ts.xpt

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF
1	8325064	TS	1		GLPTYP	Good Laboratory Practice Type	FDA	
2	8325064	TS	2		GLPTYP	Good Laboratory Practice Type	OECD	
3	8325064	TS	1		GLPFL	GLP Flag	N	
4	8325064	TS	1		STSTDTC	Study Start Date	2015-07-29	
5	8325064	TS	1		STITLE	Study Title	The Bacterial Reverse Mutation Test, Study 8325064-1	
6	8325064	TS	1		SNDIGVER	SEND Implementation Guide Version	TOBACCO IMPLEMENTATION GUIDE VERSION 1.0	
7	8325064	TS	1		SNDCTVER	SEND Controlled Terminology Version	SEND Terminology 2021-09-30	
8	8325064	TS	1		APPLCNT	Applicant	Example Applicant Inc.	
9	8325064	TS	1		APREFID	Applicant's Study Reference ID		NOT APPLICABLE
10	8325064	TS	1	1	TSTFNAM	Test Facility Name	Example Tox Lab Name	
11	8325064	TS	1	1	TSTFLOC	Test Facility Location	10 Somewhere Street, Montgomery, AL 10000	
12	8325064	TS	1	1	TFCNTRY	Test Facility Country	USA	
13	8325064	TS	1	1	STDIR	Study Director	Dr. R. Smith	
14	8325064	TS	1	4	TSTGDNAM	Testing Guideline Name	Test NO. 471	
15	8325064	TS	1	4	TSTGDORG	Testing Guideline Organization	OECD	
16	8325064	TS	1	4	TSTGDVER	Testing Guideline Version	2020-06-29	
17	8325064	TS	1		SSTYP	Study Type	GENOTOXICITY IN VITRO	
18	8325064	TS	1		GNTXAID	Genetic Toxicology Assay Identifier	AMES	
19	8325064	TS	1	2	SPECIES	Species	Salmonella Typhimurium	
20	8325064	TS	1	2	STRAIN	Strain/Substrain	TA98	
21	8325064	TS	2	2	STRAIN	Strain/Substrain	TA100	
22	8325064	TS	3	2	STRAIN	Strain/Substrain	TA1535	
23	8325064	TS	4	2	STRAIN	Strain/Substrain	TA1537	
24	8325064	TS	1	2	CELLLN	Cell Line	TA 98 hisD3052; rfa-; uvrB-	
25	8325064	TS	2	2	CELLLN	Cell Line	TA 100 hisG46; rfa-; uvrB-	
26	8325064	TS	3	2	CELLLN	Cell Line	TA 1535 hisG46; rfa-; uvrB-	
27	8325064	TS	4	2	CELLLN	Cell Line	TA 1537 hisC3076; rfa-; uvrB-	
28	8325064	TS	2	3	SPECIES	Species	Escherichia Coli	
29	8325064	TS	5	3	STRAIN	Strain/Substrain	WP2 uvrA pKM101	
30	8325064	TS	5	3	CELLLN	Cell Line	trpE uvrA	

This example Trial Set (TX) dataset shows information about the test conditions for SetA and SetR in this study. For brevity, the dataset does not show information for SetF, SetG, or any other sets. A fully formed TX dataset for this example study would include information about the test conditions for all sets.

Note that there are 3 trial set parameters that link to other important datasets: SPTOBID, APDEVID, and SMKRGM.

- SPTOBID (Applicant-Defined Tobacco Product ID) is used to uniquely identify the tobacco product. The value of SPTOBID (e.g., CIG01a) matches the value for SPTOBID in all the TOPARMCD-TOVAL pairs in the Tobacco Product Identifiers and Descriptors (TO) dataset example in Section 3.1.2, [Product Design Parameters and Conformance Testing](#), Example 1. The TOPARMCD-TOVAL pairs identify this unique product, CIG01a. The TO domain is described in Section 2.8.8.1, [SDTM Tobacco Product Identifiers and Descriptors \(TO\)](#).
- The value of APDEVID (e.g., PUFFMASTER3K) matches the value of SPDEVID in all the DIPARMCD-DIVAL pairs that identify this unique device in the DI dataset. SPDEVID is the applicant-defined device identifier that is used to uniquely identify the device in the Unique Device Identification (DI) dataset (see also Section 2.8.9.7, [SEND Device Identifiers \(DI\)](#)). This is shown in the DI dataset in Section 3.1.3.2, [PHHCs, Other Constituents, and Smoking/Vaping Regimens](#), Example 1.
- SMKRGM serves as a link to the Device-In Use Properties (DU) domain (see also Section 2.8.9.8, [SEND Device-In-Use \(DU\)](#)), where a matching value of SMKRGM indicates parameters of the smoking regimen performed by the smoking machine, as in the DU dataset in Section 3.1.3.2, HPHCs, Other Constituents, and Smoking/Vaping Regimens, [Example 2](#).

Rows 1-22: Show trial set parameters and trial set values that are the test conditions specific to set SetA which is the vehicle control (i.e., Strain of TA98, vehicle control with concentration value of 0). SetA is associated with the first row, labeled "SetA", in the report table for example study 8325064.

Rows 23-44: Show trial set parameters and trial set values that comprise the test conditions for the set SetF which is the strain of TA98 with a concentration value of 500 µg/plate. SetF is associated with the sixth row, labeled "SetF", in the report table for example study 8325064.

Rows 45-66: Show trial set parameters and trial set values that comprise the test conditions for the set SetG which is the strain of TA98 with a concentration value of 1600 µg/plate. SetG is associated with the seventh row, labeled "SetG", in the report table for example study 8325064.

Rows 67-88: Show trial set parameters and trial set values that comprise the test conditions for the set SetR which is the strain of TA100, positive control with a concentration value of 2 µg/plate. SetR is associated with the eighteenth row, labeled "SetR", in the report table for example study 8325064.

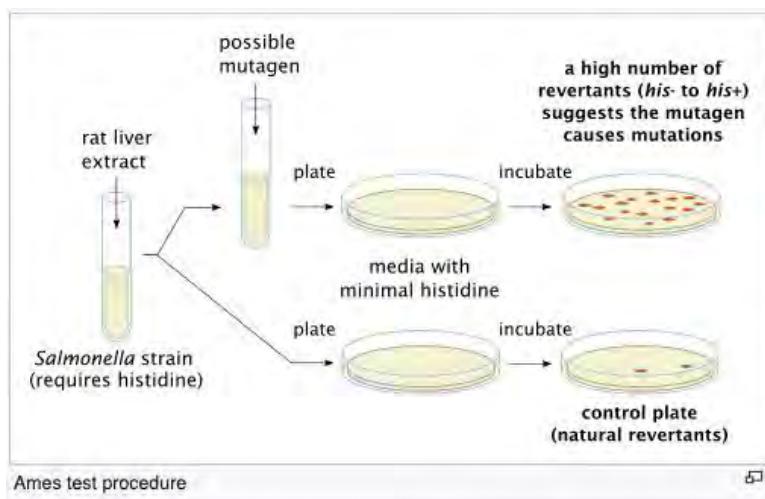
tx.xpt

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
1	8325064	TX	SetA	A-TA98-C0	1	SPECIES	Species	SALMONELLA TYPHIMURIUM
2	8325064	TX	SetA	A-TA98-C0	2	IVTDMIN	In vitro Treatment Duration Minimum	71.5
3	8325064	TX	SetA	A-TA98-C0	3	IVTDTRG	In vitro Treatment Duration Target	72
4	8325064	TX	SetA	A-TA98-C0	4	IVTDMAX	In vitro Treatment Duration Maximum	72.5
5	8325064	TX	SetA	A-TA98-C0	5	IVTDU	In vitro Treatment Duration Unit	HOURS
6	8325064	TX	SetA	A-TA98-C0	6	INCBTMRP	Incubation Temperature	37
7	8325064	TX	SetA	A-TA98-C0	7	INCBTMRPU	Incubation Temperature Unit	C
8	8325064	TX	SetA	A-TA98-C0	8	ATMRHP	Atmospheric Relative Humidity Percent	50
9	8325064	TX	SetA	A-TA98-C0	9	ATMCO2P	Atmospheric CO2 Percent	5
10	8325064	TX	SetA	A-TA98-C0	10	SPTOBID	Applicant-defined tobacco identifier	CIG01a
11	8325064	TX	SetA	A-TA98-C0	11	EXPTYP	Exposure Type	Submerged
12	8325064	TX	SetA	A-TA98-C0	12	SAMTYP	Sample Type	Total Particulate Matter in PBS
13	8325064	TX	SetA	A-TA98-C0	13	APDEVID	Applicant-defined device identifier	PUFFMASTER3K
14	8325064	TX	SetA	A-TA98-C0	14	SMKRGM	Smoking Regimen	NON-INTENSE REGIMEN
15	8325064	TX	SetA	A-TA98-C0	15	STRAIN	Strain/Substrain	TA98
16	8325064	TX	SetA	A-TA98-C0	16	MTACTIND	Metabolic Activating Agent Name	NOT APPLICABLE
17	8325064	TX	SetA	A-TA98-C0	17	METACTFL	Presence of Metabolic Activation Flag	N
18	8325064	TX	SetA	A-TA98-C0	18	ITVNAM	Intervention Article Name	DMSO
19	8325064	TX	SetA	A-TA98-C0	19	ITVTYPE	Intervention Article Type	VEHICLE
20	8325064	TX	SetA	A-TA98-C0	20	ITVCONC	Intervention Article Concentration	100
21	8325064	TX	SetA	A-TA98-C0	21	ITVCONCU	Intervention Article Concentration Unit	%
22	8325064	TX	SetA	A-TA98-C0	22	TRTV	Treatment Vehicle	DMSO
23	8325064	TX	SetF	F-TA98-C500	23	SPECIES	Species	SALMONELLA TYPHIMURIUM
24	8325064	TX	SetF	F-TA98-C500	24	IVTDMIN	In vitro Treatment Duration Minimum	71.5
25	8325064	TX	SetF	F-TA98-C500	25	IVTDTRG	In vitro Treatment Duration Target	72
26	8325064	TX	SetF	F-TA98-C500	26	IVTDMAX	In vitro Treatment Duration Maximum	72.5

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
27	8325064	TX	SetF	F-TA98-C500	27	IVTDU	In vitro Treatment Duration Unit	HOURS
28	8325064	TX	SetF	F-TA98-C500	28	INCBTMRP	Incubation Temperature	37
29	8325064	TX	SetF	F-TA98-C500	29	INCBTMRPU	Incubation Temperature Unit	C
30	8325064	TX	SetF	F-TA98-C500	30	ATMRHP	Atmospheric Relative Humidity Percent	50
31	8325064	TX	SetF	F-TA98-C500	31	ATMCO2P	Atmospheric CO2 Percent	5
32	8325064	TX	SetF	F-TA98-C500	32	SPTOBID	Applicant-defined tobacco identifier	CIG01a
33	8325064	TX	SetF	F-TA98-C500	33	EXPTYP	Exposure Type	Submerged
34	8325064	TX	SetF	F-TA98-C500	34	SAMTYP	Sample Type	Total Particulate Matter in PBS
35	8325064	TX	SetF	F-TA98-C500	35	APDEVID	Applicant-defined device identifier	PUFFMASTER3K
36	8325064	TX	SetF	F-TA98-C500	36	SMKRGM	Smoking Regimen	NON-INTENSE REGIMEN
37	8325064	TX	SetF	F-TA98-C500	37	STRAIN	Strain/Substrain	TA98
38	8325064	TX	SetF	F-TA98-C500	38	MTACTIND	Metabolic Activating Agent Name	NOT APPLICABLE
39	8325064	TX	SetF	F-TA98-C500	39	METACTFL	Presence of Metabolic Activation Flag	N
40	8325064	TX	SetF	F-TA98-C500	40	ITVNAM	Intervention Article Name	TA1
41	8325064	TX	SetF	F-TA98-C500	41	ITVTYPE	Intervention Article Type	PRODUCT
42	8325064	TX	SetF	F-TA98-C500	42	ITVCONC	Intervention Article Concentration	500
43	8325064	TX	SetF	F-TA98-C500	43	ITVCONCU	Intervention Article Concentration Unit	ug/plate
44	8325064	TX	SetF	F-TA98-C500	44	TRTV	Treatment Vehicle	DMSO
45	8325064	TX	SetG	G-TA98-C1600	45	SPECIES	Species	SALMONELLA TYPHIMURIUM
46	8325064	TX	SetG	G-TA98-C1600	46	IVTDMIN	In vitro Treatment Duration Minimum	71.5
47	8325064	TX	SetG	G-TA98-C1600	47	IVTDTRG	In vitro Treatment Duration Target	72
48	8325064	TX	SetG	G-TA98-C1600	48	IVTDMAX	In vitro Treatment Duration Maximum	72.5
49	8325064	TX	SetG	G-TA98-C1600	49	IVTDU	In vitro Treatment Duration Unit	HOURS
50	8325064	TX	SetG	G-TA98-C1600	50	INCBTMRP	Incubation Temperature	37
51	8325064	TX	SetG	G-TA98-C1600	51	INCBTMRPU	Incubation Temperature Unit	C
52	8325064	TX	SetG	G-TA98-C1600	52	ATMRHP	Atmospheric Relative Humidity Percent	50
53	8325064	TX	SetG	G-TA98-C1600	53	ATMCO2P	Atmospheric CO2 Percent	5
54	8325064	TX	SetG	G-TA98-C1600	54	SPTOBID	Applicant-defined tobacco identifier	CIG01a
55	8325064	TX	SetG	G-TA98-C1600	55	EXPTYP	Exposure Type	Submerged
56	8325064	TX	SetG	G-TA98-C1600	56	SAMTYP	Sample Type	Total Particulate Matter in PBS
57	8325064	TX	SetG	G-TA98-C1600	57	APDEVID	Applicant-defined device identifier	PUFFMASTER3K
58	8325064	TX	SetG	G-TA98-C1600	58	SMKRGM	Smoking Regimen	NON-INTENSE REGIMEN
59	8325064	TX	SetG	G-TA98-C1600	59	STRAIN	Strain/Substrain	TA98
60	8325064	TX	SetG	G-TA98-C1600	60	MTACTIND	Metabolic Activating Agent Name	NOT APPLICABLE
61	8325064	TX	SetG	G-TA98-C1600	61	METACTFL	Presence of Metabolic Activation Flag	N
62	8325064	TX	SetG	G-TA98-C1600	62	ITVNAM	Intervention Article Name	TA1
63	8325064	TX	SetG	G-TA98-C1600	63	ITVTYPE	Intervention Article Type	Product
64	8325064	TX	SetG	G-TA98-C1600	64	ITVCONC	Intervention Article Concentration	1600
65	8325064	TX	SetG	G-TA98-C1600	65	ITVCONCU	Intervention Article Concentration Unit	ug/plate
66	8325064	TX	SetG	G-TA98-C1600	66	TRTV	Treatment Vehicle	DMSO
67	8325064	TX	SetR	R-TA100-C2	67	SPECIES	Species	SALMONELLA TYPHIMURIUM
68	8325064	TX	SetR	R-TA100-C2	68	IVTDMIN	In vitro Treatment Duration Minimum	71.5
69	8325064	TX	SetR	R-TA100-C2	69	IVTDTRG	In vitro Treatment Duration Target	72
70	8325064	TX	SetR	R-TA100-C2	70	IVTDMAX	In vitro Treatment Duration Maximum	72.5
71	8325064	TX	SetR	R-TA100-C2	71	IVTDU	In vitro Treatment Duration Unit	HOURS
72	8325064	TX	SetR	R-TA100-C2	72	INCBTMRP	Incubation Temperature	37
73	8325064	TX	SetR	R-TA100-C2	73	INCBTMRPU	Incubation Temperature Unit	C
74	8325064	TX	SetR	R-TA100-C2	74	ATMRHP	Atmospheric Relative Humidity Percent	50
75	8325064	TX	SetR	R-TA100-C2	75	ATMCO2P	Atmospheric CO2 Percent	5
76	8325064	TX	SetR	R-TA100-C2	76	SPTOBID	Applicant-defined tobacco identifier	CIG01a
77	8325064	TX	SetR	R-TA100-C2	77	EXPTYP	Exposure Type	Submerged
78	8325064	TX	SetR	R-TA100-C2	78	SAMTYP	Sample Type	Total Particulate Matter in PBS
79	8325064	TX	SetR	R-TA100-C2	79	APDEVID	Applicant-defined device identifier	PUFFMASTER3K
80	8325064	TX	SetR	R-TA100-C2	80	SMKRGM	Smoking Regimen	NON-INTENSE REGIMEN
81	8325064	TX	SetR	R-TA100-C2	81	STRAIN	Strain/Substrain	TA100
82	8325064	TX	SetR	R-TA100-C2	82	MTACTIND	Metabolic Activating Agent Name	NOT APPLICABLE
83	8325064	TX	SetR	R-TA100-C2	83	METACTFL	Presence of Metabolic Activation Flag	N
84	8325064	TX	SetR	R-TA100-C2	84	ITVNAM	Intervention Article Name	NaN3
85	8325064	TX	SetR	R-TA100-C2	85	ITVTYPE	Intervention Article Type	Positive Control
86	8325064	TX	SetR	R-TA100-C2	86	ITVCONC	Intervention Article Concentration	2
87	8325064	TX	SetR	R-TA100-C2	87	ITVCONCU	Intervention Article Concentration Unit	ug/plate
88	8325064	TX	SetR	R-TA100-C2	88	TRTV	Treatment Vehicle	DMSO

REFID values are defined by the applicant to uniquely identify the observational unit within an experimental unit. In the simplified diagram of an assay procedure (below), the test tube that contains the possible mutagen is an example of an entity that would have a REFID indicating information at the level of trial set. The petri plate created from that test tube and used to count revertant numbers is an example of an entity that would be at an observational level.

This picture does not depict the more complicated procedures, trial sets, or observational units for the example study. For study 8325064, the applicant chose to define the REFIDs at the trial set level with a single character (e.g., A, F, G, R) and chose to define REFIDs at the observational level based on the location of each tube in 1 of multiple exposure/incubation plates (e.g., 6_1 for plate 6, position 1).



- Row 1:** Shows the value of REFID=A. This REFID refers to the trial set with a SETCD of "SetA", as defined in the TX dataset. LEVEL=1 and LVLDESC="EXPERIMENTAL UNIT/TRIAL SET". TRIAL SET indicates this identifier relates to the entire trial set. EXPERIMENTAL UNIT indicates this identifier received the intervention article, DMSO.
- Rows 2-6:** Show the values of 5 observational units (1_1 through 1_5) that are within the parent experimental unit, REFID=A.
- Row 7:** Shows the value of REFID=F. This REFID refers to the trial set with a SETCD of "SetF", as defined in the TX dataset. LEVEL=1 and LVLDESC="EXPERIMENTAL UNIT/TRIAL SET". TRIAL SET indicates this identifier relates to the entire trial set. EXPERIMENTAL UNIT indicates this identifier received the intervention article, TA1.
- Rows 8-10:** Show the values of 3 observational units (6_1 through 6_3) that are within the parent experimental unit, REFID=F.
- Row 11:** Shows the value of REFID=G. This REFID refers to the trial set with a SETCD of "SetG", as defined in the TX dataset. LEVEL=1 and LVLDESC="EXPERIMENTAL UNIT/TRIAL SET". TRIAL SET indicates this identifier relates to the entire trial set. EXPERIMENTAL UNIT indicates this identifier received the intervention article, TA1.
- Rows 12-14:** Show the values of 3 observational units (7_1 through 7_3) that are within the parent experimental unit, REFID=G.
- Row 15:** Shows the value of REFID=R. This REFID refers to the trial set with a SETCD of "SetG", as defined in the TX dataset. LEVEL=1 and LVLDESC="EXPERIMENTAL UNIT/TRIAL SET". TRIAL SET indicates this identifier relates to the entire trial set. EXPERIMENTAL UNIT indicates this identifier received the intervention article, NaN3.
- Rows 16-18:** Show the values of 3 observational units (18_1 through 18_3) that are within the parent experimental unit, REFID=R.

relref.xpt

Row	STUDYID	SETCD	REFID	PARENT	LEVEL	LVLDESC
1	8325064	SetA	A		1	EXPERIMENTAL UNIT/TRIAL SET
2	8325064	SetA	1_1	A	2	OBSERVATIONAL UNIT
3	8325064	SetA	1_2	A	2	OBSERVATIONAL UNIT
4	8325064	SetA	1_3	A	2	OBSERVATIONAL UNIT
5	8325064	SetA	1_4	A	2	OBSERVATIONAL UNIT
6	8325064	SetA	1_5	A	2	OBSERVATIONAL UNIT
7	8325064	SetF	F		1	EXPERIMENTAL UNIT/TRIAL SET
8	8325064	SetF	6_1	F	2	OBSERVATIONAL UNIT
9	8325064	SetF	6_2	F	2	OBSERVATIONAL UNIT
10	8325064	SetF	6_3	F	2	OBSERVATIONAL UNIT
11	8325064	SetG	G		1	EXPERIMENTAL UNIT/TRIAL SET
12	8325064	SetG	7_1	G	2	OBSERVATIONAL UNIT
13	8325064	SetG	7_2	G	2	OBSERVATIONAL UNIT
14	8325064	SetG	7_3	G	2	OBSERVATIONAL UNIT
15	8325064	SetR	R		1	EXPERIMENTAL UNIT/TRIAL SET
16	8325064	SetR	18_1	R	2	OBSERVATIONAL UNIT
17	8325064	SetR	18_2	R	2	OBSERVATIONAL UNIT
18	8325064	SetR	18_3	R	2	OBSERVATIONAL UNIT

Rows 1-5: Show the number of revertant colonies per plate collected for each of 5 observational units, GTREFID=1_1 through 1_5 (see description in the RELREF dataset).

Rows 6, 7: Show summary values collected (mean, standard deviation) for GTREFID=A that apply to the entire trial set, SetA, as indicated by LEVEL=1 and LVLDESC=TRIAL SET for this REFID as shown in the RELREF dataset.

Rows 8-13: Revertent colonies were counted for each of 3 plates/observational units (GTREFID=6_1 through 6_3) and each value is associated with a record to show a postfix code of "V" (Very thin background bacterial lawn).

Rows 14-16: Show summary values collected (mean, standard deviation, fold increase) for GTREFID=F that apply to the entire trial set, SetF, as indicated by LEVEL=1 and LVLDESC=TRIAL SET for this REFID in the RELREF dataset.

Rows 17-19: Show 3 plates/observational units (GTREFID=7_1 through 7_3) where no revertant colonies were counted due to too much cytotoxicity and a postfix code of "T".

Rows 20-22: Show the number of revertant colonies per plate collected for each of 3 observational units (GTREFID=18_1 through 18_3).

Rows 23-25: Show summary values collected (mean, standard deviation, fold increase) for GTREFID=R that apply to the entire trial set, SetR, as indicated by LEVEL=1 and LVLDESC=TRIAL SET for this REFID in the RELREF dataset.

gt.xpt

Row	STUDYID	DOMAIN	GTSEQ	GTREFID	GTTESTCD	GTTEST	GTORRES	GTORRESU	GTCOLSRT	GTSTRESC	GTSTRESN	GTSTRESU	GTSTAT	GTREASND	GTMETHOD	GTDTC
1	8325064	GT	1	1_1	RPP	Revertant Colony Numbers Per Plate	26			26	26				INSTRUMENT COUNTED	2015-08-03
2	8325064	GT	2	1_2	RPP	Revertant Colony Numbers Per Plate	35			35	35				INSTRUMENT COUNTED	2015-08-03
3	8325064	GT	3	1_3	RPP	Revertant Colony	39			39	39				INSTRUMENT COUNTED	2015-08-03

Row	STUDYID	DOMAIN	GTSEQ	GTREFID	GTTESTCD	GTTEST	GTORRES	GTORRESU	GTCOLSRT	GTSTRESC	GTSTRESN	GTSTRESU	GTSTAT	GTREASND	GTMETHOD	GTDTC
						Numbers Per Plate										
4	8325064	GT	4	1_4	RPP	Revertant Colony Numbers Per Plate	35			35	35				INSTRUMENT COUNTED	2015-08-03
5	8325064	GT	5	1_5	RPP	Revertant Colony Numbers Per Plate	30			30	30				INSTRUMENT COUNTED	2015-08-03
6	8325064	GT	6	A	RPP	Revertant Colony Numbers Per Plate	33.0		MEAN	33.0	33.0					2015-08-03
7	8325064	GT	7	A	RPP	Revertant Colony Numbers Per Plate	5.0		STANDARD DEVIATION	5.0	5.0					2015-08-03
8	8325064	GT	8	6_1	RPP	Revertant Colony Numbers Per Plate	8			8	8				MANUALLY COUNTED	2015-08-03
9	8325064	GT	9	6_1	CYTOTOX	Cytotoxicity	Very thin background bacterial lawn			V						2015-08-03
10	8325064	GT	10	6_2	RPP	Revertant Colony Numbers Per Plate	10			10	10				MANUALLY COUNTED	2015-08-03
11	8325064	GT	11	6_2	CYTOTOX	Cytotoxicity	Very thin background bacterial lawn			V						2015-08-03
12	8325064	GT	12	6_3	RPP	Revertant Colony Numbers Per Plate	12			12	12				MANUALLY COUNTED	2015-08-03
13	8325064	GT	13	6_3	CYTOTOX	Cytotoxicity	Very thin background bacterial lawn			V						2015-08-03
14	8325064	GT	14	F	RPPMEAN	Mean Rev Colony Num Per Plate	10.0		MEAN	10.0	10.0					2015-08-03
15	8325064	GT	15	F	RPPSTDDEV	Std Dev Rev Colony Num Per Plate	2.0		STANDARD DEVIATION	2.0	2.0					2015-08-03
16	8325064	GT	16	F	RPPFLDIC	Fold Increase Rev Colony Num Per Plate	0.3		FOLD INCREASE	0.3	0.3					2015-08-03
17	8325064	GT	17	7_1	CYTOTOX	Cytotoxicity	Toxic No Revertant Colonies			T			NOT DONE	TOO MUCH CYTOTOXICITY		2015-08-03

Row	STUDYID	DOMAIN	GTSEQ	GTREFID	GTTESTCD	GTTEST	GTORRES	GTORRESU	GTCOLSRT	GTSTRESC	GTSTRESN	GTSTRESU	GTSTAT	GTREASND	GTMETHOD	GTDTC
18	8325064	GT	18	7_2	CYTOTOX	Cytotoxicity	Toxic No Revertant Colonies			T			NOT DONE	TOO MUCH CYTOTOXICITY		2015-08-03
19	8325064	GT	19	7_3	CYTOTOX	Cytotoxicity	Toxic No Revertant Colonies			T			NOT DONE	TOO MUCH CYTOTOXICITY		2015-08-03
20	8325064	GT	20	18_1	RPP	Revertant Colony Numbers Per Plate	812			812	812				INSTRUMENT COUNTED	2015-08-03
21	8325064	GT	21	18_2	RPP	Revertant Colony Numbers Per Plate	912			912	912				INSTRUMENT COUNTED	2015-08-03
22	8325064	GT	22	18_3	RPP	Revertant Colony Numbers Per Plate	839			839	839				INSTRUMENT COUNTED	2015-08-03
23	8325064	GT	23	R	RPPMEAN	Mean Rev Colony Num Per Plate	854.3		MEAN	854.3	854.3					2015-08-03
24	8325064	GT	24	R	RPPSTDV	Std Dev Rev Colony Num Per Plate	51.7		STANDARD DEVIATION	51.7	51.7					2015-08-03
25	8325064	GT	25	R	RPPFLDIC	Fold Increase Rev Colony Num Per Plate	6.4		FOLD INCREASE	6.4	6.4					2015-08-03

3.2.3.2 In Vitro Mammalian Cell Gene Mutation (MLA) Multi-domain Example (GT, TS,TX, RELREF)

This is an example showing trial design, results data, and related datasets (e.g, tobacco description, device identification, smoking regimen) for study #123, test article TA321: *In Vitro* Mammalian Cell Gene Mutation Test (L5178Y/TK^{±/-} Mouse Lymphoma Assay).

In this example, the tobacco product is dissolved in a solvent (vehicle is PBS). Some experimental units are treated with a metabolic activation system (S9, using rat liver). There were 6 concentrations of test article used, treating duplicate cultures (A, B). The test article is added to the cell suspension, where the percent suspension growth is measured. Treatment exposure is for 4 hours; then there is a wash process, followed by a 2-day phenotypic expression period. The suspension is then plated onto 3 plates with trifluorothymidine (TFT) and three plates with cloning medium without TFT or cloning efficiency (CE) colonies. After incubation for an additional 10-day mutant selection duration, the total mutant frequency and induced mutant frequency are calculated from the TFT colony plates and the percent relative total growth is calculated from the TFT and CE colony plates based upon percent suspension growth.

3.2.3.2.1 Table 1. Initial Definitive Mutagenicity Assay (4-Hour Exposure -S9)

DOSE LEVEL ($\mu\text{g/mL}$)	PRECIP.	% SUSP. GROWTH	CE COLONIES				TFT COLONIES				TOTAL MUTANT FREQUENCY (PER 10^6 CELLS)	INDUCED MUTANT FREQUENCY (PER 10^6 CELLS)	% RELATIVE TOTAL GROWTH			
			PLATE COUNTS				PLATE COUNTS									
			1	2	3	MEAN	1	2	3	MEAN						
SOLVENT A		100	188	175	196	186	59	79	76	71	77	N/A	100			
SOLVENT B			181	*	180	181	52	77	56	62	68					
15.6 A		103	****	****	****		****	****	****							
15.6 B		110	****	****	****		****	****	****							
31.3 A		103	180	192	193	188	50	44	41	45	48	-25	105			
31.3 B		94	148	140	143	144	46	59	69	58	81	8	74			
62.5 A		102	162	157	194	171	51	44	52	49	57	-15	95			
62.5 B		98	185	186	181	184	50	49	76	58	63	-9	98			
125 A		96	183	165	147	165	85	60	30	58	71	-2	86			
125 B		100	176	160	168	168	77	59	62	66	79	6	91			
250 A		92	154	154	150	153	56	60	83	66	87	14	77			
250 B		99	166	173	137	159	69	66	72	69	87	15	86			
500 A		98	183	176	189	183	45	67	83	65	71	-1	98			
500 B		103	187	150	*	169	66	56	51	58	68	-4	95			
POSITIVE CONTROL: Methyl methanesulfonate (MMS) ($\mu\text{g/mL}$)																
20		41	80	52	67	66	185	152	160	166	499	427	15			
15		51	82	65	59	69	220	196	189	202	587	515	19			
MEAN SOLVENT TOTAL SUSPENSION GROWTH: 26.3																
MEAN SOLVENT CLONING EFFICIENCY: 92%																
MEAN SOLVENT MUTANT FREQUENCY: 72 (PER 10^6 CELLS)																

Solvent = PBS

A and B are duplicate cultures

****= Cultures treated at other concentrations were not cloned as higher concentrations were available for evaluation

*= Plate contaminated

**= Precipitation

- Rows 1-2:** Show 2 records for TSPARMCD = "GLPTYP", using TSSEQ to indicate multiple records, since both GLP types apply for this example study.
- Row 3:** Shows that this study was conducted as a GLP study.
- Rows 4-5:** Shows the study start date and study title.
- Rows 6-7:** Show the version of SEND Implementation Guide and version of Controlled Terminology used in this study.
- Row 8:** Shows the applicant's organization.
- Rows 9-12:** Show that TSGRPID has been used to link records (name, location, country) related to the test facility (TSGRPID = 1). The study director is associated with the test facility.
- Rows 13-15:** Show that TSGRPID (TSGRPID=2) has been used to link the information on the testing guideline followed on this study (TSTGDNAM, TSTGDORG, TSTGDVER).
- Row 16:** Shows the study type for this study.
- Row 17:** Shows that this study includes a mammalian cell gene mutation assay.
- Rows 18-19:** Show that TSGRPID (TSGRPID = 3) has been used to link the information for 1 species (mouse) with the cell line that is tested in this study.

ts.xpt

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL
1	123	TS	1		GLPTYP	Good Laboratory Practice Type	FDA
2	123	TS	2		GLPTYP	Good Laboratory Practice Type	OECD
3	123	TS	1		GLPFL	GLP Flag	Y
4	123	TS	1		STSTDTC	Study Start Date	2020-01-01
5	123	TS	1		STITLE	Study Title	Study #123, Test Article TA321: In Vitro Mammalian Cell Gene Mutation Test (L5178Y/TK+/- Mouse Lymphoma Assay)
6	123	TS	1		SNDIGVER	SEND Implementation Guide Version	TOBACCO IMPLEMENTATION GUIDE VERSION 1.0
7	123	TS	1		SNDCTVER	SEND Controlled Terminology Version	SEND Terminology 2021-09-30

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL
8	123	TS	1		APPLCNT	Applicant	Example Applicant Inc.
9	123	TS	1	1	TSTFNAM	Test Facility Name	Example Tox Lab Name
10	123	TS	1	1	TSTFLOC	Test Facility Location	10 Somewhere Street, Montgomery, AL 10000
11	123	TS	1	1	TFCNTRY	Test Facility Country	USA
12	123	TS	1	1	STDIR	Study Director	Dr. R. Smith
13	123	TS	1	2	TSTGDNAM	Testing Guideline Name	TEST NO. 490
14	123	TS	1	2	TSTGDORG	Testing Guideline Organization	OECD
15	123	TS	1	2	TSTGDVER	Testing Guideline Version	2016-07-29
16	123	TS	1		SSTYP	Study Type	GENOTOXICITY IN VITRO
17	123	TS	1		GNTXAID	Genetic Toxicology Assay Identifier	MLA
18	123	TS	1	3	SPECIES	Species	Mouse
19	123	TS	1	3	CELLLN	Cell Line	TK+/- -3.7.2C subline of L5178Y cells

This example Trial Set (TX) dataset shows information about the test conditions for all the trial sets (A1, A1CE, A1TFT, A2, A2CE, A2TFT) in this study.

Note that there are 3 trial set parameters that link to other important datasets: SPTOBID, APDEVID, and SMKRGM.

- SPTOBID (Applicant-Defined Tobacco Product ID) is used to uniquely identify the tobacco product. The value of SPTOBID (e.g., CIG01a) matches the value for SPTOBID in all the TOPARMCD-TOVAL pairs in the Tobacco Product Identifiers and Descriptors (TO) dataset example in Section 3.1.2, [Product Design Parameters and Conformance Testing](#), Example 1. The TOPARMCD-TOVAL pairs identify this unique product, CIG01a. The TO domain is described in Section 2.8.8.1, [SDTM Tobacco Product Identifiers and Descriptors \(TO\)](#).
- The value of APDEVID (e.g., PUFFMASTER3K) matches the value of SPDEVID in all the DIPARMCD-DIVAL pairs that identify this unique device in the DI dataset. SPDEVID is the applicant-defined device identifier that is used to uniquely identify the device in the Unique Device Identification (DI) dataset (see also Section 2.8.9.7, [SEND Device Identifiers \(DI\)](#)). This is shown in the DI dataset in Section 3.1.3.2, [HPHCs, Other Constituents, and Smoking/Vaping Regimens](#), Example 1.
- SMKRGM serves as a link to the Device-In Use Properties (DU) domain (see also Section 2.8.9.8, [SEND Device-In-Use \(DU\)](#)), where a matching value of SMKRGM indicates parameters of the smoking regimen performed by the smoking machine, as in the DU dataset in Section 3.1.3.2, HPHCs, Other Constituents, and Smoking/Vaping Regimens, [Example 2](#).

Rows 1-23: Show trial set parameters and trial set values that comprise the test conditions for the set A1, both cultures A and B. Set A1 is the data for the product at a concentration of 31.3 ug/mL, with 4-hour exposure, without S9 metabolic activation.
Set A1 is associated with rows 5 and 6 of the report table for example study 123.

Rows 24-47: Show trial set parameters and trial set values that comprise the test conditions for the set A1CE, both cultures A and B. Set A1CE is the data for the product at a concentration of 31.3 ug/mL, with 4-hour exposure, without S9 metabolic activation in cloning efficiency (CE) colonies, in other words in plates with cloning medium without trifluorothymidine (TFT).

Rows 48-74: Show trial set parameters and trial set values that comprise the test conditions for the set A1TFT, both cultures A and B. Set A1TFT is the data for the product at a concentration of 31.3 ug/mL, with 4-hour exposure, without S9 metabolic activation in plates with cloning medium with trifluorothymidine (TFT).

Rows 75-93: Show trial set parameters and trial set values that comprise the test conditions for the set A2, both cultures A and B. Set A2 is the data for the product at a concentration of 500 ug/mL, with 4-hour exposure, without S9 metabolic activation.
Set A2 is associated with rows 13 and 14 of the report table for example study 123.

Rows 94-113: Show trial set parameters and trial set values that comprise the test conditions for the set A2CE, both cultures A and B. Set A2CE is the data for the product at a concentration of 500 ug/mL, with 4-hour exposure, without S9 metabolic activation in cloning efficiency (CE) colonies, in other words in plates with cloning medium without trifluorothymidine (TFT).

Rows 114-136: Show trial set parameters and trial set values that comprise the test conditions for the set A2TFT, both cultures A and B. Set A2 is the data for the product at a concentration of 500 ug/mL, with 4-

hour exposure, without S9 metabolic activation in plates with cloning medium with trifluorothymidine (TFT).

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
1	123	TX	A1	4_-S9_C31.3	1	MTACTIND	Metabolic Activating Agent Name	NOT APPLICABLE
2	123	TX	A1	4_-S9_C31.3	2	METACTFL	Presence of Metabolic Activation Flag	N
3	123	TX	A1	4_-S9_C31.3	3	IVTDMIN	In vitro Treatment Duration Minimum	3
4	123	TX	A1	4_-S9_C31.3	4	IVTDTRG	In vitro Treatment Duration Target	3.5
5	123	TX	A1	4_-S9_C31.3	5	IVTDMAX	In vitro Treatment Duration Maximum	4
6	123	TX	A1	4_-S9_C31.3	6	IVTDU	In vitro Treatment Duration Unit	HOURS
7	123	TX	A1	4_-S9_C31.3	7	PHNXPDUR	In vitro Phenotypic Expression Duration	2
8	123	TX	A1	4_-S9_C31.3	8	PHNXPDU	In vitro Phenotypic Expression Duration Unit	DAYS
9	123	TX	A1	4_-S9_C31.3	9	MUTNDUR	In vitro Mutant Selection Duration	10
10	123	TX	A1	4_-S9_C31.3	10	MUTNDU	In vitro Mutant Selection Duration Unit	DAYS
11	123	TX	A1	4_-S9_C31.3	11	INCBTMR	Incubation Temperature	37
12	123	TX	A1	4_-S9_C31.3	12	INCBTMRU	Incubation Temperature Unit	C
13	123	TX	A1	4_-S9_C31.3	13	ATMRPH	Atmospheric Relative Humidity Percent	50
14	123	TX	A1	4_-S9_C31.3	14	ATMCO2P	Atmospheric CO2 Percent	5
15	123	TX	A1	4_-S9_C31.3	15	SPTOBID	Applicant defined tobacco identifier	CIG01a
16	123	TX	A1	4_-S9_C31.3	16	EXPTYP	Exposure Type	SUBMERGED
17	123	TX	A1	4_-S9_C31.3	17	SAMTYP	Sample Type	TOTAL PARTICULATE MATTER IN PBS
18	123	TX	A1	4_-S9_C31.3	18	ITVNAME	Intervention Article Name	Tobacco ProdA
19	123	TX	A1	4_-S9_C31.3	19	ITVTYPE	Intervention Article Type	PRODUCT
20	123	TX	A1	4_-S9_C31.3	20	ITVCONC	Intervention Article Concentration	31.3
21	123	TX	A1	4_-S9_C31.3	21	ITVCONCU	Intervention Article Concentration Unit	ug/mL
22	123	TX	A1	4_-S9_C31.3	22	SPDEVID	Applicant defined device identifier	PUFFMASTER3K
23	123	TX	A1	4_-S9_C31.3	23	SMKRGM	Smoking Regimen	NON-INTENSE REGIMEN
24	123	TX	A1CE	4_-S9_C31.3_CE	24	MTACTIND	Metabolic Activating Agent Name	NOT APPLICABLE
25	123	TX	A1CE	4_-S9_C31.3_CE	25	METACTFL	Presence of Metabolic Activation Flag	N
26	123	TX	A1CE	4_-S9_C31.3_CE	26	IVTDMIN	In vitro Treatment Duration Minimum	3
27	123	TX	A1CE	4_-S9_C31.3_CE	27	IVTDTRG	In vitro Treatment Duration Target	3.5
28	123	TX	A1CE	4_-S9_C31.3_CE	28	IVTDMAX	In vitro Treatment Duration Maximum	4
29	123	TX	A1CE	4_-S9_C31.3_CE	29	IVTDU	In vitro Treatment Duration Unit	HOURS
30	123	TX	A1CE	4_-S9_C31.3_CE	30	PHNXPDUR	In vitro Phenotypic Expression Duration	2
31	123	TX	A1CE	4_-S9_C31.3_CE	31	PHNXPDU	In vitro Phenotypic Expression Duration Unit	DAYS
32	123	TX	A1CE	4_-S9_C31.3_CE	32	MUTNDUR	In vitro Mutant Selection Duration	10
33	123	TX	A1CE	4_-S9_C31.3_CE	33	MUTNDU	In vitro Mutant Selection Duration Unit	DAYS
34	123	TX	A1CE	4_-S9_C31.3_CE	34	INCBTMR	Incubation Temperature	37
35	123	TX	A1CE	4_-S9_C31.3_CE	35	INCBTMRU	Incubation Temperature Unit	C
36	123	TX	A1CE	4_-S9_C31.3_CE	36	ATMRPH	Atmospheric Relative Humidity Percent	50
37	123	TX	A1CE	4_-S9_C31.3_CE	37	ATMCO2P	Atmospheric CO2 Percent	5
38	123	TX	A1CE	4_-S9_C31.3_CE	38	SPTOBID	Applicant defined tobacco identifier	CIG01a
39	123	TX	A1CE	4_-S9_C31.3_CE	39	EXPTYP	Exposure Type	SUBMERGED
40	123	TX	A1CE	4_-S9_C31.3_CE	40	SAMTYP	Sample Type	TOTAL PARTICULATE MATTER IN PBS
41	123	TX	A1CE	4_-S9_C31.3_CE	41	ITVNAME	Intervention Article Name	Tobacco ProdA
42	123	TX	A1CE	4_-S9_C31.3_CE	42	ITVTYPE	Intervention Article Type	PRODUCT
43	123	TX	A1CE	4_-S9_C31.3_CE	43	ITVCONC	Intervention Article Concentration	31.3
44	123	TX	A1CE	4_-S9_C31.3_CE	44	ITVCONCU	Intervention Article Concentration Unit	ug/mL
45	123	TX	A1CE	4_-S9_C31.3_CE	45	SPDEVID	Applicant defined device identifier	PUFFMASTER3K
46	123	TX	A1CE	4_-S9_C31.3_CE	46	SMKRGM	Smoking Regimen	NON-INTENSE REGIMEN
47	123	TX	A1CE	4_-S9_C31.3_CE	47	SELAPIND	Selective Agent Present Indicator	N
48	123	TX	A1TFT	4_-S9_C31.3_TFT	48	MTACTIND	Metabolic Activating Agent Name	NOT APPLICABLE
49	123	TX	A1TFT	4_-S9_C31.3_TFT	49	METACTFL	Presence of Metabolic Activation Flag	N
50	123	TX	A1TFT	4_-S9_C31.3_TFT	50	IVTDMIN	In vitro Treatment Duration Minimum	3
51	123	TX	A1TFT	4_-S9_C31.3_TFT	51	IVTDTRG	In vitro Treatment Duration Target	3.5
52	123	TX	A1TFT	4_-S9_C31.3_TFT	52	IVTDMAX	In vitro Treatment Duration Maximum	4
53	123	TX	A1TFT	4_-S9_C31.3_TFT	53	IVTDU	In vitro Treatment Duration Unit	HOURS
54	123	TX	A1TFT	4_-S9_C31.3_TFT	54	PHNXPDUR	In vitro Phenotypic Expression Duration	2
55	123	TX	A1TFT	4_-S9_C31.3_TFT	55	PHNXPDU	In vitro Phenotypic Expression Duration Unit	DAYS
56	123	TX	A1TFT	4_-S9_C31.3_TFT	56	MUTNDUR	In vitro Mutant Selection Duration	10
57	123	TX	A1TFT	4_-S9_C31.3_TFT	57	MUTNDU	In vitro Mutant Selection Duration Unit	DAYS
58	123	TX	A1TFT	4_-S9_C31.3_TFT	58	INCBTMR	Incubation Temperature	37

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
59	123	TX	A1TFT	4_-S9_C31.3_TFT	59	INCBTMPU	Incubation Temperature Unit	C
60	123	TX	A1TFT	4_-S9_C31.3_TFT	60	ATMRPH	Atmospheric Relative Humidity Percent	50
61	123	TX	A1TFT	4_-S9_C31.3_TFT	61	ATMCO2P	Atmospheric CO2 Percent	5
62	123	TX	A1TFT	4_-S9_C31.3_TFT	62	SPTOBID	Applicant defined tobacco identifier	CIG01a
63	123	TX	A1TFT	4_-S9_C31.3_TFT	63	EXPTYP	Exposure Type	SUBMERGED
64	123	TX	A1TFT	4_-S9_C31.3_TFT	64	SAMTYP	Sample Type	TOTAL PARTICULATE MATTER IN PBS
65	123	TX	A1TFT	4_-S9_C31.3_TFT	65	ITVNAM	Intervention Article Name	Tobacco ProdA
66	123	TX	A1TFT	4_-S9_C31.3_TFT	66	ITVTYPE	Intervention Article Type	PRODUCT
67	123	TX	A1TFT	4_-S9_C31.3_TFT	67	ITVCONC	Intervention Article Concentration	31.3
68	123	TX	A1TFT	4_-S9_C31.3_TFT	68	ITVCONCU	Intervention Article Concentration Unit	ug/mL
69	123	TX	A1TFT	4_-S9_C31.3_TFT	69	SPDEVID	Applicant defined device identifier	PUFFMASTER3K
70	123	TX	A1TFT	4_-S9_C31.3_TFT	70	SMKRGM	Smoking Regimen	NON-INTENSE REGIMEN
71	123	TX	A1TFT	4_-S9_C31.3_TFT	71	SELAPIND	Selective Agent Present Indicator	Y
72	123	TX	A1TFT	4_-S9_C31.3_TFT	72	SELANAM	Selective Agent Name	Trifluorothymidine
73	123	TX	A1TFT	4_-S9_C31.3_TFT	73	SELCONC	Selective Agent Concentration	5
74	123	TX	A1TFT	4_-S9_C31.3_TFT	74	SELCONCU	Selective Agent Concentration Unit	ug/mL
75	123	TX	A2	4_-S9_C500	75	MTACTIND	Metabolic Activating Agent Name	NOT APPLICABLE
76	123	TX	A2	4_-S9_C500	76	METACTFL	Presence of Metabolic Activation Flag	N
77	123	TX	A2	4_-S9_C500	77	IVTDMIN	In vitro Treatment Duration Minimum	3
78	123	TX	A2	4_-S9_C500	78	IVTDTRG	In vitro Treatment Duration Target	3.5
79	123	TX	A2	4_-S9_C500	79	IVTDMAX	In vitro Treatment Duration Maximum	4
80	123	TX	A2	4_-S9_C500	80	IVTDU	In vitro Treatment Duration Unit	HOURS
81	123	TX	A2	4_-S9_C500	81	INCBTMP	Incubation Temperature	37
82	123	TX	A2	4_-S9_C500	82	INCBTMPU	Incubation Temperature Unit	C
83	123	TX	A2	4_-S9_C500	83	ATMHRP	Atmospheric Relative Humidity Percent	50
84	123	TX	A2	4_-S9_C500	84	ATMCO2P	Atmospheric CO2 Percent	5
85	123	TX	A2	4_-S9_C500	85	SPTOBID	Applicant-defined tobacco identifier	CIG01a
86	123	TX	A2	4_-S9_C500	86	EXPTYP	Exposure Type	SUBMERGED
87	123	TX	A2	4_-S9_C500	87	SAMTYP	Sample Type	TOTAL PARTICULATE MATTER IN PBS
88	123	TX	A2	4_-S9_C500	88	ITVNAM	Intervention Article Name	Tobacco ProdA
89	123	TX	A2	4_-S9_C500	89	ITVTYPE	Intervention Article Type	PRODUCT
90	123	TX	A2	4_-S9_C500	90	ITVCONC	Intervention Article Concentration	500
91	123	TX	A2	4_-S9_C500	91	ITVCONCU	Intervention Article Concentration Unit	ug/mL
92	123	TX	A2	4_-S9_C500	92	SPDEVID	Applicant-defined device identifier	PUFFMASTER3K
93	123	TX	A2	4_-S9_C500	93	SMKRGM	Smoking Regimen	NON-INTENSE REGIMEN
94	123	TX	A2CE	4_-S9_C500_CE	94	MTACTIND	Metabolic Activating Agent Name	NOT APPLICABLE
95	123	TX	A2CE	4_-S9_C500_CE	95	METACTFL	Presence of Metabolic Activation Flag	N
96	123	TX	A2CE	4_-S9_C500_CE	96	IVTDMIN	In vitro Treatment Duration Minimum	3
97	123	TX	A2CE	4_-S9_C500_CE	97	IVTDTRG	In vitro Treatment Duration Target	3.5
98	123	TX	A2CE	4_-S9_C500_CE	98	IVTDMAX	In vitro Treatment Duration Maximum	4
99	123	TX	A2CE	4_-S9_C500_CE	99	IVTDU	In vitro Treatment Duration Unit	HOURS
100	123	TX	A2CE	4_-S9_C500_CE	100	INCBTMP	Incubation Temperature	37
101	123	TX	A2CE	4_-S9_C500_CE	101	INCBTMPU	Incubation Temperature Unit	C
102	123	TX	A2CE	4_-S9_C500_CE	102	ATMHRP	Atmospheric Relative Humidity Percent	50
103	123	TX	A2CE	4_-S9_C500_CE	103	ATMCO2P	Atmospheric CO2 Percent	5
104	123	TX	A2CE	4_-S9_C500_CE	104	SPTOBID	Applicant-defined tobacco identifier	CIG01a
105	123	TX	A2CE	4_-S9_C500_CE	105	EXPTYP	Exposure Type	SUBMERGED
106	123	TX	A2CE	4_-S9_C500_CE	106	SAMTYP	Sample Type	TOTAL PARTICULATE MATTER IN PBS
107	123	TX	A2CE	4_-S9_C500_CE	107	ITVNAM	Intervention Article Name	Tobacco ProdA
108	123	TX	A2CE	4_-S9_C500_CE	108	ITVTYPE	Intervention Article Type	PRODUCT
109	123	TX	A2CE	4_-S9_C500_CE	109	ITVCONC	Intervention Article Concentration	500
110	123	TX	A2CE	4_-S9_C500_CE	110	ITVCONCU	Intervention Article Concentration Unit	ug/mL
111	123	TX	A2CE	4_-S9_C500_CE	111	SPDEVID	Applicant-defined device identifier	PUFFMASTER3K
112	123	TX	A2CE	4_-S9_C500_CE	112	SMKRGM	Smoking Regimen	NON-INTENSE REGIMEN
113	123	TX	A2CE	4_-S9_C500_CE	113	SELAPIND	Selective Agent Present Indicator	N
114	123	TX	A2TFT	4_-S9_C500_TFT	114	MTACTIND	Metabolic Activating Agent Name	NOT APPLICABLE
115	123	TX	A2TFT	4_-S9_C500_TFT	115	METACTFL	Presence of Metabolic Activation Flag	N
116	123	TX	A2TFT	4_-S9_C500_TFT	116	IVTDMIN	In vitro Treatment Duration Minimum	3

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
117	123	TX	A2TFT	4_-S9_C500_TFT	117	IVTDTRG	In vitro Treatment Duration Target	3.5
118	123	TX	A2TFT	4_-S9_C500_TFT	118	IVTDMAX	In vitro Treatment Duration Maximum	4
119	123	TX	A2TFT	4_-S9_C500_TFT	119	IVTDU	In vitro Treatment Duration Unit	HOURS
120	123	TX	A2TFT	4_-S9_C500_TFT	120	INCBTMRP	Incubation Temperature	37
121	123	TX	A2TFT	4_-S9_C500_TFT	121	INCBTMRPU	Incubation Temperature Unit	C
122	123	TX	A2TFT	4_-S9_C500_TFT	122	ATMHRRP	Atmospheric Relative Humidity Percent	50
123	123	TX	A2TFT	4_-S9_C500_TFT	123	ATMCO2P	Atmospheric CO2 Percent	5
124	123	TX	A2TFT	4_-S9_C500_TFT	124	SPTOBID	Applicant-defined tobacco identifier	CIG01a
125	123	TX	A2TFT	4_-S9_C500_TFT	125	EXPTYP	Exposure Type	SUBMERGED
126	123	TX	A2TFT	4_-S9_C500_TFT	126	SAMTYP	Sample Type	TOTAL PARTICULATE MATTER IN PBS
127	123	TX	A2TFT	4_-S9_C500_TFT	127	ITVNAME	Intervention Article Name	Tobacco ProdA
128	123	TX	A2TFT	4_-S9_C500_TFT	128	ITVTYPE	Intervention Article Type	PRODUCT
129	123	TX	A2TFT	4_-S9_C500_TFT	129	ITVCONC	Intervention Article Concentration	500
130	123	TX	A2TFT	4_-S9_C500_TFT	130	ITVCONCU	Intervention Article Concentration Unit	ug/mL
131	123	TX	A2TFT	4_-S9_C500_TFT	131	SPDEVID	Applicant-defined device identifier	PUFFMASTER3K
132	123	TX	A2TFT	4_-S9_C500_TFT	132	SMKRGM	Smoking Regimen	NON-INTENSE REGIMEN
133	123	TX	A2TFT	4_-S9_C500_TFT	133	SELAPIND	Selective Agent Present Indicator	Y
134	123	TX	A2TFT	4_-S9_C500_TFT	134	SELANAM	Selective Agent Name	Trifluorothymidine
135	123	TX	A2TFT	4_-S9_C500_TFT	135	SELCONC	Selective Agent Concentration	5
136	123	TX	A2TFT	4_-S9_C500_TFT	136	SELCONCU	Selective Agent Concentration Unit	ug/mL

The applicant chose to define the REFID values to indicate the duration of exposure, the existence of S9 metabolic activation, the concentration of intervention article, and the presence of selective agent, such that a duration of 4 hours without S9 activation at a concentration of 31.3 ug/mL in the presence of TFT as the selective agent would be indicated as a REFID of 4_-S9_C31.3_TFT.

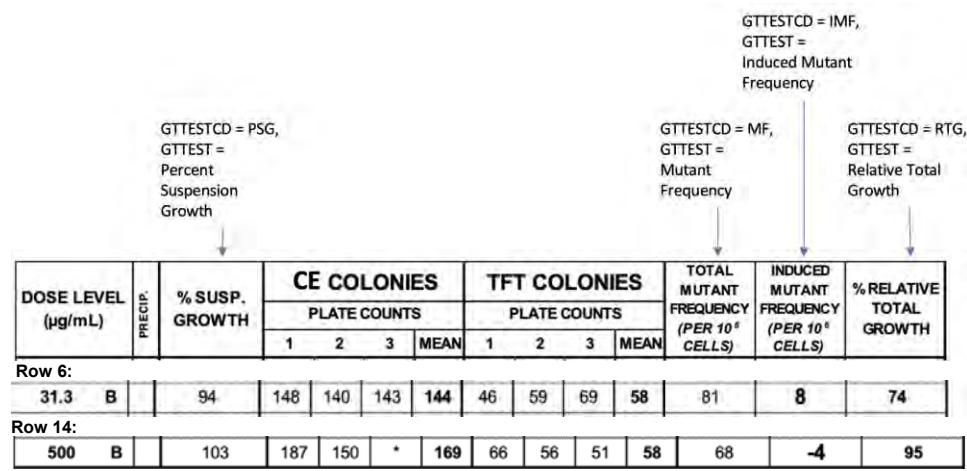
- Row 1:** Shows the REFID for 4_-S9_C31.3_B_OS which has a LVLDESC of observational summary, where the study has recorded data for summary statistics based upon all CE and TFT plates as well as percent suspension growth at the concentration of 31.3 ug/mL (based upon the descendants of 4_-S9_C31.3_B_OS).
- Row 2:** Shows the REFID for the experimental unit 4_-S9_C31.3_B (i.e., the suspension where the test article was added under test conditions described in set A1, at a concentration of 31.3 ug/mL) and that the percent suspension growth was measured for the 4-hour exposure without S9 metabolic activation.
- Row 3:** Shows the REFID for the trial set that represents the suspension without TFT. This REFID is the identifier for results attributed to all 3 CE colony plates (e.g., mean).
- Rows 4-6:** Show the REFIDs for the observational units (i.e., the identifiers for the plates where the suspension without TFT was added; thus, the CE colonies).
- Row 7:** Shows the REFID for the trial set that represents the suspension with TFT. This REFID is the identifier for results attributed to all 3 TFT colony plates.
- Rows 8-10:** Show the REFIDs for the observational units (i.e., the identifiers for the plates where the suspension with TFT was added; thus, the TFT colonies).
- Row 11:** Shows the REFID for 4_-S9_C500_B_OS which has a LVLDESC of observational summary, where the study has recorded data for summary statistics based upon all CE and TFT plates as well as percent suspension growth at the concentration of 500 ug/mL (based upon the descendants of 4_-S9_C500_B_OS).

- Row 12:** Shows the REFID for the experimental unit (i.e., the suspension where the test article was added under test conditions described in set A2, at a concentration of 500 ug/mL) and that the percent suspension growth was measured for the 4-hour exposure without S9 metabolic activation.
- Row 13:** Shows the REFID for the trial set that represents the suspension without TFT. This REFID is the identifier for results attributed to all 3 CE colony plates.
- Rows 14-16:** Show the REFIDs for the observational units (i.e., the identifiers for the plates where the suspension was added without TFT; thus, the CE colonies).
- Row 17:** Shows the REFID for the trial set that represents the suspension with TFT. This REFID is the identifier for results attributed to all 3 TFT colony plates.
- Rows 18-20:** Show the REFIDs for the observational units (i.e., the identifiers for the plates where the suspension was added with TFT; thus, the TFT colonies).

relref.xpt

Row	STUDYID	SETCD	REFID	PARENT	LEVEL	LVLDESC
1	123	A1	4_-S9_C31.3_B_OS		1	OBSERVATIONAL SUMMARY
2	123	A1	4_-S9_C31.3_B	4_-S9_C31.3_B_OS	2	EXPERIMENTAL UNIT/OBSERVATIONAL UNIT
3	123	A1CE	4_-S9_C31.3_B_CE	4_-S9_C31.3_B	3	TRIAL SET/OBSERVATIONAL SUMMARY
4	123	A1CE	4_-S9_C31.3_B_CE_1	4_-S9_C31.3_B_CE	4	OBSERVATIONAL UNIT
5	123	A1CE	4_-S9_C31.3_B_CE_2	4_-S9_C31.3_B_CE	4	OBSERVATIONAL UNIT
6	123	A1CE	4_-S9_C31.3_B_CE_3	4_-S9_C31.3_B_CE	4	OBSERVATIONAL UNIT
7	123	A1TFT	4_-S9_C31.3_B_TFT	4_-S9_C31.3_B	3	TRIAL SET/OBSERVATIONAL SUMMARY
8	123	A1TFT	4_-S9_C31.3_B_TFT_1	4_-S9_C31.3_B_TFT	4	OBSERVATIONAL UNIT
9	123	A1TFT	4_-S9_C31.3_B_TFT_2	4_-S9_C31.3_B_TFT	4	OBSERVATIONAL UNIT
10	123	A1TFT	4_-S9_C31.3_B_TFT_3	4_-S9_C31.3_B_TFT	4	OBSERVATIONAL UNIT
11	123	A2	4_-S9_C500_B_OS		1	OBSERVATIONAL SUMMARY
12	123	A2	4_-S9_C500_B	4_-S9_C500_B_OS	2	EXPERIMENTAL UNIT/OBSERVATIONAL UNIT
13	123	A2CE	4_-S9_C500_B_CE	4_-S9_C500_B	3	TRIAL SET/OBSERVATIONAL UNIT
14	123	A2CE	4_-S9_C500_B_CE_1	4_-S9_C500_B_CE	4	OBSERVATIONAL UNIT
15	123	A2CE	4_-S9_C500_B_CE_2	4_-S9_C500_B_CE	4	OBSERVATIONAL UNIT
16	123	A2CE	4_-S9_C500_B_CE_3	4_-S9_C500_B_CE	4	OBSERVATIONAL UNIT
17	123	A2TFT	4_-S9_C500_B_TFT	4_-S9_C500_B	3	TRIAL SET/OBSERVATIONAL UNIT
18	123	A2TFT	4_-S9_C500_B_TFT_1	4_-S9_C500_B_TFT	4	OBSERVATIONAL UNIT
19	123	A2TFT	4_-S9_C500_B_TFT_2	4_-S9_C500_B_TFT	4	OBSERVATIONAL UNIT
20	123	A2TFT	4_-S9_C500_B_TFT_3	4_-S9_C500_B_TFT	4	OBSERVATIONAL UNIT

For ease of reviewing the results in the Genetic Toxicology In Vitro Test Results (GT) dataset, 2 rows of the sample report for study 123 (the sixth row and the fourteenth row) are repeated in the following graphic, with labels corresponding to their test codes and tests in the GT domain.



*= Plate contaminated

- Row 1:** Shows results for the experimental unit A1 as shown in row 6 of Table 1, concentration 31.3, in the sample report for study 123 . The GTREFID aligns with the REFID for SETCD=A1 in the RELREF dataset, matching the test conditions of A1 in the TX dataset.
- Rows 2-4:** Show results for each of 3 observational units within the trial set A1CE as shown in the 3 plates numbered 1, 2, and 3 under "CE Colonies, Plate Counts" on row 6 of Table 1 in the sample report for study 123. The GTREFIDs align with the REFID for SETCD=A1CE in the RELREF dataset,

matching the test conditions of trial set A1CE in the TX dataset. The A1CE entries in the TX dataset indicate that there is no selective agent present on these plates.

- Row 5:** Shows the result for 4_-S9_C31.3_B_CE. Looking at the RELREF dataset, this REFID aligns with the SETCD A1CE in the TX dataset where the parameter codes indicate a suspension without TFT. This result (i.e., mean) is an observational summary attributed to all 3 CE colony plates because they are children of 4_-S9_C31.3_B_CE.
- Rows 6-8:** Show results for each of 3 observational units within the trial set A1TFT as shown in the 3 plates numbered 1, 2, and 3 under "TFT Colonies, Plate Counts" on row 6 of Table 1 in the sample report for study 123. The GTREFIDs align with the REFID for SETCD=A1TFT in the RELREF dataset, matching the test conditions of trial set A1TFT in the TX dataset. The A1TFT entries in the TX dataset indicate that the selective agent trifluorothymidine is present on these plates in a concentration of 5 ug/mL.
- Rows 9-11:** Show results for the trial set A1TFT that represents the suspension with a 31.3 ug/mL of intervention article and with TFT. These results (i.e., mean, mutant frequency) are attributed to all 3 TFT colony plates. GTCOLSRT is populated with MEAN to distinguish this test from the Colony Numbers Per Plate of the individual plates.
- Row 12:** Shows results for 4_-S9_C31.3_B_OS. Looking at the RELREF dataset, this REFID aligns with the SETCD A1 in the TX dataset where the parameter codes indicate a dose concentration of 31.3 ug/mL. This result (i.e., relative total growth) is an observational summary attributed to all plates in row 6 of the sample report table (the descendants of 4_-S9_C31.3_B_OS).
- Row 13:** Shows results for experimental unit A2 as shown in row 14 of Table 1, concentration 500, in the sample report for study 123. The GTREFID aligns with the REFID for SETCD=A2 in the RELREF dataset, matching the test conditions of trial set A2 in the TX dataset.
- Rows 14-16:** Show results for each of 3 observational units within the trial set A2CE as shown in the 3 plates numbered 1, 2, and 3 under "CE Colonies, Plate Counts" on row 14 of Table 1 in the sample report for study 123. The GTREFID aligns with the REFID for SETCD=A2CE in the RELREF dataset, matching the test conditions of trial set A2CE in the TX dataset. The A2CE entries in the TX dataset indicate that there is no selective agent present on these plates.
- Row 17:** Shows the result for 4_-S9_C500_B_CE. Looking at the RELREF dataset, this REFID aligns with the SETCD A2CE in the TX dataset where the parameter codes indicate a suspension with 500 ug/mL of intervention article but without TFT. This result (i.e., mean) is an observational summary attributed to all 3 CE colony plates because they are children of 4_-S9_C500_B_CE.
- Rows 18-20:** Show results for each of 3 observational units within the trial set A2TFT as shown in the 3 plates numbered 1, 2, and 3 under "TFT Colonies, Plate Counts" on row 14 of Table 1 in the sample report for study 123. The GTREFID aligns with the REFID for SETCD=A2TFT in the RELREF dataset, matching the test conditions of trial set A2TFT in the TX dataset. The A2TFT entries in the TX dataset indicate that the selective agent trifluorothymidine is present on these plates in a concentration of 5 ug/mL.
- Rows 21-23:** Show results for the trial set A2TFT that represents the suspension with a 500 ug/mL of intervention article and with TFT. These results (i.e., mean, mutant frequency) are attributed to all 3 TFT colony plates. GTCOLSRT is populated with MEAN to distinguish this test from the Colony Numbers Per Plate of the individual plates.
- Row 24:** Shows results for 4_-S9_C500_B_CE_OS. Looking at the RELREF dataset, this REFID aligns with the SETCD A2 in the TX dataset where the parameter codes indicate a dose concentration of 500 ug/mL. This result (i.e., relative total growth) is an observational summary attributed to all plates in row 14 of the sample report table (the descendants of 4_-S9_C500_B_CE_OS).

gt.xpt

Row	STUDYID	DOMAIN	GTSEQ	GTREFID	GTTESTCD	GTTEST	GTORRES	GTORRESU	GTCOLSRT	GTSTRESC	GTSTRESN	GTSTRESU	GTSPCCND	GTRUNID	GTDTC
1	123	GT	1	4_-S9_C31.3_B	PSG	Percent Suspension Growth	94	%		94	94	%	PRECIPITATED	1	2020-01-01
2	123	GT	2	4_-S9_C31.3_B_CE_1	CPP	Colony Numbers Per Plate	148			148	148			1	2020-01-01
3	123	GT	3	4_-S9_C31.3_B_CE_2	CPP	Colony Numbers Per Plate	140			140	140			1	2020-01-01
4	123	GT	4	4_-S9_C31.3_B_CE_3	CPP	Colony Numbers Per Plate	143			143	143			1	2020-01-01
5	123	GT	5	4_-S9_C31.3_B_CE	CPP	Colony Numbers Per Plate	144		MEAN	144	144			1	2020-01-01
6	123	GT	6	4_-S9_C31.3_B_TFT_1	CPP	Colony Numbers Per Plate	46							1	2020-01-01
7	123	GT	7	4_-S9_C31.3_B_TFT_2	CPP	Colony Numbers Per Plate	59							1	2020-01-01
8	123	GT	8	4_-S9_C31.3_B_TFT_3	CPP	Colony Numbers Per Plate	69							1	2020-01-01
9	123	GT	9	4_-S9_C31.3_B_TFT	CPP	Colony Numbers Per Plate	58		MEAN					1	2020-01-01
10	123	GT	10	4_-S9_C31.3_B_TFT	MF	Mutant Frequency	81	/10^6		81	81	/10^6		1	2020-01-01
11	123	GT	11	4_-S9_C31.3_B_TFT	IMF	Induced Mutant Frequency	8	/10^6		8	8	/10^6		1	2020-01-01
12	123	GT	12	4_-S9_C31.3_B_OS	RTG	Relative Total Growth	74	%		74	74	%		1	2020-01-01
13	123	GT	1	4_-S9_C500_B	PSG	Percent Suspension Growth	103	%		103	103	%		1	2020-01-01
14	123	GT	2	4_-S9_C500_B_CE_1	CPP	Colony Numbers Per Plate	187			187	187			1	2020-01-01
15	123	GT	3	4_-S9_C500_B_CE_2	CPP	Colony Numbers Per Plate	150			150	150			1	2020-01-01
16	123	GT	4	4_-S9_C500_B_CE_3	CPP	Colony Numbers Per Plate							CONTAMINATED	1	2020-01-01
17	123	GT	5	4_-S9_C500_B_CE	CPP	Colony Numbers Per Plate	169		MEAN	169	169			1	2020-01-01
18	123	GT	6	4_-S9_C500_B_TFT_1	CPP	Colony Numbers Per Plate	56			56	56			1	2020-01-01
19	123	GT	7	4_-S9_C500_B_TFT_2	CPP	Colony Numbers Per Plate	66			66	66			1	2020-01-01
20	123	GT	8	4_-S9_C500_B_TFT_3	CPP	Colony Numbers Per Plate	51			51	51			1	2020-01-01

Row	STUDYID	DOMAIN	GTSEQ	GTREFID	GTTESTCD	GTTEST	GTORRES	GTORRESU	GTCOLSRT	GTSTRESC	GTSTRESN	GTSTRESU	GTSPCCND	GTRUNID	GTDTC
21	123	GT	9	4_-S9_C500_B_TFT	CPP	Colony Numbers Per Plate	58		MEAN	58	58			1	2020-01-01
22	123	GT	10	4_-S9_C500_B_TFT	MF	Mutant Frequency	68	/10^6		68	68	/10^6		1	2020-01-01
23	123	GT	11	4_-S9_C500_B_TFT	IMF	Induced Mutant Frequency	-4	/10^6		-4	-4	/10^6		1	2020-01-01
24	123	GT	12	4_-S9_C500_B_CE_OS	RTG	Relative Total Growth	95	%		95	95	%		1	2020-01-01

3.2.3.3 In Vitro Mammalian Cell Micronucleus Test Multi-Domain Example (GT, TS, TX, RELREF)

The in vitro micronucleus test is a genotoxicity test for the detection of micronuclei in the cytoplasm of interphase cells. Micronuclei may originate from acentric chromosome fragments (i.e., lacking a centromere), or whole chromosomes that are unable to migrate to the poles during the anaphase stage of cell division. The assay detects the activity of clastogenic and aneugenic test substances in cells that have undergone cell division during or after exposure to the test substance.

Example 1

This example shows a sample report table, trial design, and results dataset for study 123 for the determination of the in vitro genotoxicity potential of tobacco products using the in vitro micronucleus assay.

Table 1: Raw data after ST exposure to increasing concentrations of test article in the presence of S9 mix

Test date	Treatment	Conc. [µg/ml]	Cells [x10 ³]	Cytotoxicity [%]										Average relative MN frequency	
				RICC	RCC	RPD	sum of cells ev.	cells with MN	sum of cells ev.	cells with MN	sum of cells ev.	cells with MN	sum of cells ev.	cells with MN	
25.05.2022	ST+S9 [5µg/ml]	0	15.4	0.0	0.0	0.0	2205	15	2474	13	2758	17	2669	12	0.57
		1250	13.4	15.7	13.0	7.9	3266	20	2190	17	2758	13	2714	21	0.66
		2500	12.9	19.6	16.2	10.1	2441	11	1313	2	3105	18	2701	13	0.42
		3750	13.7	13.3	11.0	6.6	2059	8	3515	19	1351	7	2385	7	0.44
		5000	12.5	22.7	18.8	11.9	2914	16	3251	24	2876	17	2547	12	0.59
		CPA	10.1	41.6	34.4	24.0	1560	32	1751	19	2477	29	2362	37	1.47

Statistically significant increases (p<0.05) as compared to medium control are highlighted in bold;

Table 2: Raw data after ST exposure to increasing concentrations of test article in the absence of S9 mix

Test date	Treatment	Conc. [µg/ml]	Cells [x10 ³]	Cytotoxicity [%]										Average relative MN frequency	
				RICC	RCC	RPD	sum of cells ev.	cells with MN	sum of cells ev.	cells with MN	sum of cells ev.	cells with MN	sum of cells ev.	cells with MN	
25.05.2022	ST-S9 [0,2µg/ml]	0	15.4	0.0	0.0	0.0	3584	15	3144	11	4219	22	3032	10	0.40
		1250	13.6	15.5	11.7	8.8	2418	10	2168	7	2867	16	2678	12	0.44
		2500	14.5	7.7	5.8	4.3	1522	2	1102	3	3194	14	3637	20	0.35
		3750	12.7	23.2	17.5	13.7	1823	3	1765	2	2362	4	1721	3	0.16
		5000	14.0	12.0	9.1	6.8	2767	7	2061	6	3188	14	2784	7	0.31
		BLEO	9.5	50.7	38.3	34.3	2691	32	2803	22	2395	30	2181	24	1.08

Statistically significant increases (p<0.05) as compared to medium control are highlighted in bold;

Table 3: Raw data after LT exposure to increasing concentrations of test article in the absence of S9 mix

Test date	Treatment	Conc. [µg/ml]	Cells [x10 ³]	Cytotoxicity [%]										Average relative MN frequency	
				RICC	RCC	RPD	sum of cells ev.	cells with MN	sum of cells ev.	cells with MN	sum of cells ev.	cells with MN	sum of cells ev.	cells with MN	
25.05.2022	LT-S9 [0,5µg/ml]	0	17.1	0.0	0.0	0.0	1871	6	2816	10	1147	3	1096	2	0.28
		1250	16.6	5.3	2.9	3.7	1246	2	1881	8	1148	8	1060	5	0.44
		2500	16.4	7.5	4.1	5.3	2437	6	1327	6	2036	10	1973	7	0.39
		3750	14.6	26.6	14.6	19.9	1746	7	NA**	NA**	1067	2	1865	6	0.30
		5000	15.1	21.3	11.7	15.6	1405	6	1817	7	1873	6	1364	6	0.39
		BLEO	12.7	46.9	25.7	37.4	2745	31	1887	13	1822	26	1512	18	1.11

Statistically significant increases (p<0.05) as compared to medium control are highlighted in bold; **: One replicate is missing due to technical problems. The number of cells evaluated is

- Rows 1-2:** Show 2 records for TSPARMCD = "GLPTYP", using TSSEQ to indicate multiple records, since both GLP types apply for this example study.
- Row 3:** Shows that this study was conducted as a GLP study.
- Rows 4-5:** Show the study start date and study title.
- Rows 6-7:** Show the version of SEND Implementation Guide and version of Controlled Terminology used in this study.
- Row 8:** Shows the applicant's organization.
- Row 9:** Shows that the applicant's study reference ID is not applicable.
- Rows 10-13:** Show that TSGRPID has been used to link records (name, location, country) related to the test facility (TSGRPID = 1). The study director is associated with the test facility.
- Rows 14-16:** Show that TSGRPID (TSGRPID=2) has been used to link the information on the testing guideline followed on this study (TSTGDNAM, TSTGDORG, TSTGDVER).
- Row 17:** Shows the study type for this study.
- Row 18:** Shows that this study includes a Mammalian Cell Micronucleus Assay.
- Rows 19-20:** Show that the species is human and the cell line is TK6 lymphoblastoid in this study.

ts.xpt

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF
1	123	TS	1		GLPTYP	Good Laboratory Practice Type	FDA	
2	123	TS	2		GLPTYP	Good Laboratory Practice Type	OECD	
3	123	TS	1		GLPFL	GLP Flag	Y	
4	123	TS	1		STSTDTC	Study Start Date	2022-05-25	
5	123	TS	1		STITLE	Study Title	Determination of the in vitro genotoxicity potential using the in vitro Neutral Red Uptake assay	
6	123	TS	1		SNDIGVER	SEND Implementation Guide Version	TOBACCO IMPLEMENTATION GUIDE VERSION 1.0	
7	123	TS	1		SNDCTVER	SEND Controlled Terminology Version	SEND Terminology 2021-09-30	
8	123	TS	1		APPLCNT	Applicant	Example Applicant, Inc.	
9	123	TS	1		APREFID	Study Reference ID		NOT APPLICABLE
10	123	TS	1	1	TSTFNAM	Test Facility Name	Example Test Lab Name	
11	123	TS	1	1	TSTFLOC	Test Facility Location	10 Somewhere Street, Montgomery, AL 10000	
12	123	TS	1	1	TFCNTRY	Test Facility Country	USA	
13	123	TS	1	1	STDIR	Study Director	Dr. R. Smith	
14	123	TS	1	2	TSTGDNAM	Testing Guideline Name	GUIDELINE FOR THE TESTING OF CHEMICALS No. 487	
15	123	TS	1	2	TSTGDORG	Testing Guideline Organization	OECD	
16	123	TS	1	2	TSTGDVER	Testing Guideline Version	29-July-2016	
17	123	TS	1		SSTYP	Study Type	GENOTOXICITY IN VITRO	
18	123	TS	1		GNTXAID	Genetic Toxicology Assay Identifier	MNvit	
19	123	TS	1		SPECIES	Species	HUMAN	
20	123	TS	1		CELLLN	Cell Line	TK6 LYMPHOBLASTOID	

This example Trial Sets dataset shows information about the test conditions for set A1 and A2 in this example study. Sets A1 and A2 can be seen in the first and second rows respectively of the sample report Table 1 (above). For brevity, the TX dataset and the findings (GT) dataset do not show information for any other sets. Fully formed datasets for this example study would include information about the test conditions and findings for all sets.

- Rows 1-23:** Show trial set parameters and values that comprise the test conditions for trial set A1. Set A1 is the data for the negative control (concentration 0) with short-term exposure and metabolic activation S9. The applicant has chosen to give a long name (SET) equal to "ST+S9_C0".

Set A1 is associated with the first row in the sample report table for study 123.

Rows 24-46: Show trial set parameters and values that comprise the test conditions for trial set A2. Set A2 is the data for the short-term exposure with metabolic activation S9 at a concentration of 1250 ug/ml. The applicant has chosen to give the set a long name (SET) equal to "ST+S9_C1250".

Set A2 is associated with the second row in the sample report table for study 123.

tx.xpt

Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
1	123	TX	A1	ST+S9_C0	1	MTACTIND	Metabolic Activating Agent Name	+S9
2	123	TX	A1	ST+S9_C0	2	METACTFL	Presence of Metabolic Activation Flag	Y
3	123	TX	A1	ST+S9_C0	3	IVTDMIN	In vitro Treatment Duration Minimum	3
4	123	TX	A1	ST+S9_C0	4	IVTDTRG	In vitro Treatment Duration Target	3.5
5	123	TX	A1	ST+S9_C0	5	IVTDMAX	In vitro Treatment Duration Maximum	4
6	123	TX	A1	ST+S9_C0	6	IVTDU	In vitro Treatment Duration Unit	HOURS
7	123	TX	A1	ST+S9_C0	7	RCVDMIN	Recovery Duration Minimum	23.5
8	123	TX	A1	ST+S9_C0	8	RCVDTRG	Recovery Duration Target	24
9	123	TX	A1	ST+S9_C0	9	RCVDMAX	Recovery Duration Maximum	24.5
10	123	TX	A1	ST+S9_C0	10	RCVDU	Recovery Duration Unit	HOURS
11	123	TX	A1	ST+S9_C0	11	INCBTMRP	Incubation Temperature	37
12	123	TX	A1	ST+S9_C0	12	INCBTMRPU	Incubation Temperature Unit	C
13	123	TX	A1	ST+S9_C0	13	ATMRHP	Atmospheric Relative Humidity Percent	50
14	123	TX	A1	ST+S9_C0	14	ATMCO2P	Atmospheric CO2 Percent	5
15	123	TX	A1	ST+S9_C0	15	SPTOBID	Applicant-defined tobacco identifier	CIG01a
16	123	TX	A1	ST+S9_C0	16	EXPTYP	Exposure Type	Submerged
17	123	TX	A1	ST+S9_C0	17	SAMTYP	Sample Type	Total Particulate Matter in DMSO
18	123	TX	A1	ST+S9_C0	18	ITVNAM	Intervention Article Name	Tobacco ProdA
19	123	TX	A1	ST+S9_C0	19	ITVTYPE	Intervention Article Type	Negative Control
20	123	TX	A1	ST+S9_C0	20	ITVCONC	Intervention Article Concentration	0
21	123	TX	A1	ST+S9_C0	21	ITVCONCU	Intervention Article Concentration Unit	ug/ml
22	123	TX	A1	ST+S9_C0	22	SPDEVID	Applicant-defined device identifier	PUFFMASTER3K
23	123	TX	A1	ST+S9_C0	23	SMKRGM	Smoking Regimen	MEDIUM INTENSITY REGIMEN
24	123	TX	A2	ST+S9_C1250	24	MTACTIND	Metabolic Activating Agent Name	+S9
25	123	TX	A2	ST+S9_C1250	25	METACTFL	Presence of Metabolic Activation Flag	Y
26	123	TX	A2	ST+S9_C1250	26	IVTDMIN	In vitro Treatment Duration Minimum	3
27	123	TX	A2	ST+S9_C1250	27	IVTDTRG	In vitro Treatment Duration Target	3.5
28	123	TX	A2	ST+S9_C1250	28	IVTDMAX	In vitro Treatment Duration Maximum	4
29	123	TX	A2	ST+S9_C1250	29	IVTDU	In vitro Treatment Duration Unit	HOURS
30	123	TX	A2	ST+S9_C1250	30	RCVDMIN	Recovery Duration Minimum	23.5
31	123	TX	A2	ST+S9_C1250	31	RCVDTRG	Recovery Duration Target	24
32	123	TX	A2	ST+S9_C1250	32	RCVDMAX	Recovery Duration Maximum	24.5
33	123	TX	A2	ST+S9_C1250	33	RCVDU	Recovery Duration Unit	HOURS
34	123	TX	A2	ST+S9_C1250	34	INCBTMRP	Incubation Temperature	37
35	123	TX	A2	ST+S9_C1250	35	INCBTMRPU	Incubation Temperature Unit	C
36	123	TX	A2	ST+S9_C1250	36	ATMRHP	Atmospheric Relative Humidity Percent	50
37	123	TX	A2	ST+S9_C1250	37	ATMCO2P	Atmospheric CO2 Percent	5
38	123	TX	A2	ST+S9_C1250	38	SPTOBID	Applicant-defined tobacco identifier	CIG01a
39	123	TX	A2	ST+S9_C1250	39	EXPTYP	Exposure Type	Submerged
40	123	TX	A2	ST+S9_C1250	40	SAMTYP	Sample Type	Total Particulate Matter in DMSO
41	123	TX	A2	ST+S9_C1250	41	ITVNAM	Intervention Article Name	Tobacco ProdA
42	123	TX	A2	ST+S9_C1250	42	ITVTYPE	Intervention Article Type	Product
43	123	TX	A2	ST+S9_C1250	43	ITVCONC	Intervention Article Concentration	1250
44	123	TX	A2	ST+S9_C1250	44	ITVCONCU	Intervention Article Concentration Unit	ug/ml
45	123	TX	A2	ST+S9_C1250	45	SPDEVID	Applicant-defined Device Identifier	PUFFMASTER2023
46	123	TX	A2	ST+S9_C1250	46	SMKRGM	Smoking Regimen	HIGH INTENSITY REGIMEN

- Row 1:** Shows the value of REFID=C0. This REFID refers to the trial set with a SETCD of "A1", as defined in the TX dataset. LEVEL=1 and LVLDESC="EXPERIMENTAL UNIT/TRIAL SET" indicates this identifier is referring to both the experimental unit and the unit to which the treatment is applied, and to the entire trial set.
- Rows 2-5:** Show the values of 4 observational units (C0_Count1 through C0_Count4) that are within the parent experimental unit, REFID=C0. In this example assay, these observational units are also all within the same trial set, as defined in the TX dataset.
- Row 6:** Shows the value of REFID=C1250. This REFID refers to the trial set with a SETCD of "A2", as defined in the TX dataset. LEVEL=1 and LVLDESC="EXPERIMENTAL UNIT/TRIAL SET" indicates this identifier is referring to both the experimental unit and the unit to which the treatment is applied, and to the entire trial set.
- Rows 7-10:** Show the values of 4 observational units (C1250_Count1 through C1250_Count4) that are within the parent experimental unit, REFID=C1250. In this example assay, these observational units are also all within the same trial set, as defined in the TX dataset.

relref.xpt

Row	STUDYID	SETCD	REFID	PARENT	LEVEL	LVLDESC
1	123	A1	C0		1	EXPERIMENTAL UNIT/TRIAL SET
2	123	A1	C0-Count1	C0	2	OBSERVATIONAL UNIT
3	123	A1	C0-Count2	C0	2	OBSERVATIONAL UNIT
4	123	A1	C0-Count3	C0	2	OBSERVATIONAL UNIT
5	123	A1	C0-Count4	C0	2	OBSERVATIONAL UNIT
6	123	A2	C1250		1	EXPERIMENTAL UNIT/TRIAL SET
7	123	A2	C1250-Count1	C1250	2	OBSERVATIONAL UNIT
8	123	A2	C1250-Count2	C1250	2	OBSERVATIONAL UNIT
9	123	A2	C1250-Count3	C1250	2	OBSERVATIONAL UNIT
10	123	A2	C1250-Count4	C1250	2	OBSERVATIONAL UNIT

- Rows 1-3, 8:** Show percentage result values that apply to GTREFID=C0. REFID=C0, as shown in the RELREF dataset, relates this data to the trial set in the first row of table 1 in the sample report table for study 123.
- Rows 4-7:** Show the 4 micronucleated cell counts for the observational units with GTREFID from C0-Count1 through C0-Count4, for which their relationship to test conditions (in tx.xpt) and experimental units (in relref.xpt) are shown in the RELREF dataset.
- Rows 9-11, 16:** Show percentage result values that apply to GTREFID=C1250. REFID=C1250, as shown in the RELREF dataset, relates this data to the trial set in the second row of table 1 in the sample report table for study 123.
- Rows 12-15:** Show the 4 micronucleated cell counts for the observational units with GTREFID from C1250-Count1 through C1250-Count4, for which their relationship to test conditions (in tx.xpt) and experimental units (in relref.xpt) are shown in the RELREF dataset.

gt.xpt

Row	STUDYID	DOMAIN	GTSEQ	GTREFID	GTTESTCD	GTTEST	GTCELLEV	GTORRES	GTORRESU	GTCOLSRT	GTSTRESC	GTSTRESN	GTSTRESU	GTDTG
1	123	GT	1	C0	RICC	Relative Increase in Cell Count	154	0	%		0	0	%	2022-05-25
2	123	GT	2	C0	RCC	Relative Cell Count	154	0	%		0	0	%	2022-05-25
3	123	GT	3	C0	RPD	Relative Population Doubling	154	0	%		0	0	%	2022-05-25
4	123	GT	4	C0-Count1	MNCE	Micronucleated Cells	2205	15			15	15		2022-05-25
5	123	GT	5	C0-Count2	MNCE	Micronucleated Cells	2474	13			13	13		2022-05-25
6	123	GT	6	C0-Count3	MNCE	Micronucleated Cells	2758	17			17	17		2022-05-25
7	123	GT	7	C0-Count4	MNCE	Micronucleated Cells	2669	12			12	12		2022-05-25
8	123	GT	8	C0	MNCECE	Micronucleated Cells/Total Cells		0.57	%		0.57	0.57	%	2022-05-25
9	123	GT	1	C1250	RICC	Relative Increase in Cell Count	134	15.7	%		15.7	15.7	%	2022-05-25
10	123	GT	2	C1250	RCC	Relative Cell Count	134	13.0	%		13.0	13.0	%	2022-05-25

Row	STUDYID	DOMAIN	GTSEQ	GTREFID	GTTESTCD	GTTEST	GTCELLEV	GTORRES	GTORRESU	GTCOLSRT	GTSTRESC	GTSTRESN	GTSTRESU	GTDTG
11	123	GT	3	C1250	RPD	Relative Population Doubling	134	7.9	%		7.9	7.9	%	2022-05-25
12	123	GT	4	C1250-Count1	MNCE	Micronucleated Cells	3266	20			20	20		2022-05-25
13	123	GT	5	C1250-Count2	MNCE	Micronucleated Cells	2190	17			17	17		2022-05-25
14	123	GT	6	C1250-Count3	MNCE	Micronucleated Cells	2758	13			13	13		2022-05-25
15	123	GT	7	C1250-Count4	MNCE	Micronucleated Cells	2714	21			21	21		2022-05-25
16	123	GT	8	C1250	MNCECE	Micronucleated Cells/Total Cells		0.66	%		0.66	0.66	%	2022-05-25

3.2.3.4 Neutral Red Uptake Assay Multi-Domain Example (GT, TS, TX, RELREF)

The neutral red uptake assay for mainstream tobacco smoke provides a quantitative estimation of the number of viable cells in a culture. It is one of the most used cytotoxicity tests with many biomedical and environmental applications. It is based on the ability of viable cells to incorporate and bind the supravital dye neutral red in the lysosomes.

Example 1

This example shows a report table, trial design, and results data for the in vitro neutral red uptake (NRU) cytotoxicity assay in example study 123.

Sample from Report Table



The following shows example data for study 123 in a report table. This report includes summary statistics (i.e., average, standard deviation, coefficient variation) for each plate and an EC50 value for the entire assay. In the table below, the light grey shading for plate 1 are values from wells that do not contain the NHK cells. The dark grey shading represents the column and row location within the 96-well plate, and in this example the applicant chose to use these column and row locations to assign their REFID values in the RELREF dataset and GT dataset.

For brevity, the datasets in this example are not comprehensive but are intended to demonstrate a range of proper use.

Neutral Red Cytotoxicity Assay Results (Relative Absorbance Data)																
Sample ID	Smoke Regime	Replicate Number	Plate Number	Relative Assay Plate Absorbance Readings											EC50 (µg/ml)	
				Cigarette Smoke Condensate (µg/mL)												
				Well Column:	1	2	3	4	5	6	7	8	9	10		
				Well Row:	0	10	50	75	100	120	140	160	200	110	200	0
030001	Medium	1	1	A	0.046*	0.046*	0.039*	0.012*	0.030*	0.003*	0.057*	0.032*	0.003*	0.050*	0.044*	0.040*
030001	Medium	1	1	B	0.048*	107	77.7	65.7	30.2	15.6	9.79	5.41	2.49	8.09	0.791	0.014*

030001	Medium	1	1	C	0.005*	98.6	77.4	57.7	35.8	8.09	7.36	3.22	0.791	6.38	0.061	0.050*
030001	Medium	1	1	D	0.049*	94.9	81.5	38.2	31.2	7.60	5.17	3.22	0.791	5.17	0.304	0.017*
030001	Medium	1	1	E	0.047*	111	78.1	64.5	32.9	8.82	5.90	2.74	1.28	10.3	0.547	0.011*
030001	Medium	1	1	F	0.032*	96.6	76.2	48.0	26.8	7.84	4.20	2.74	1.52	8.09	4.93	0.022*
030001	Medium	1	1	G	0.044*	105	77.9	58.2	28.3	8.09	4.68	1.76	0.547	8.57	1.76	0.056*
030001	Medium	1	1	H	0.056*	0.013*	0.040*	0.008*	0.013*	0.002*	0.029*	0.018*	0.006*	0.016*	0.024*	0.046*
Average					101	78.2	54.5	29.9	9.70	6.17	3.37	1.19	8.94	1.22		
Std. Dev.					6	2.9	9.4	3.6	2.95	2.19	1.12	0.72	2.72	1.58		
Coeff. Var.					5.8	3.6	17.2	11.9	30.4	35.5	33.1	61.0	30.5	129.9		
*media without cells																
030001	Medium	1	2	A	93.4	74.0	56.0	35.1	11.8	8.70	5.10	1.98	5.34	1.02		
030001	Medium	1	2	B	102	75.2	53.3	35.1	11.8	7.74	5.58	3.66	5.34	1.02		
030001	Medium	1	2	C	107	79.0	55.0	26.5	10.1	6.06	3.66	1.74	7.02	0.780		
030001	Medium	1	2	D	104	80.2	55.3	29.8	8.94	3.90	3.66	1.50	6.30	0.780		
030001	Medium	1	2	E	101	75.7	54.1	26.7	4.86	4.38	1.26	1.02	6.30	1.02		
030001	Medium	1	2	F	110	85.7	67.7	26.0	5.34	4.62	3.42	1.50	6.30	0.540		
030001	Medium	1	2	G	104	77.8	64.9	27.7	8.22	3.18	2.46	1.02	6.30	0.780		
030001	Medium	1	2	H	103	71.6	58.9	25.5	9.42	4.14	3.90	1.26	4.38	0.780		
Average					103	77.4	58.1	29.0	8.82	5.34	3.63	1.71	5.91	0.840		
Std. Dev.					5	4.4	5.3	4.0	2.63	1.97	1.37	0.86	0.83	0.170		
Coeff. Var.					4.6	5.6	9.2	13.6	29.8	36.9	37.6	50.0	14.1	20.2		
EC50 (µg/ml). Effective concentration at 50% cytotoxicity. (using a specific sigmoidal equation = model).																123

Rows 1-2: Show 2 records for TSPARMCD = "GLPTYP", using TSSEQ to indicate multiple records, since both GLP types apply for this example study.

Row 3: Shows that this study was conducted as a GLP study.

Rows 4-5: Show the study start date and study title.

Rows 6-7: Show the version of SEND Implementation Guide and version of Controlled Terminology used in this study.

Row 8: Shows the applicant's organization.

Row 9: Shows that the applicant's study reference ID is not applicable.

Rows 10-13: Show that TSGRPID has been used to link records (name, location, country) related to the test facility (TSGRPID = 1). The study director is associated with the test facility.

Rows 14-16: Show that TSGRPID (TSGRPID=4) has been used to link the information on the testing guideline followed on this study (TSTGDNAM, TSTGDORG, TSTGDVER).

Row 17: Shows the study type for this study.

Row 18: Shows that this study includes a Neutral Red Uptake Assay.

Rows 19-20: Show that the species is human and the cell line is NHK in this study.

ts.xpt

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF
1	123	TS	1		GLPTYP	Good Laboratory Practice Type	FDA	
2	123	TS	2		GLPTYP	Good Laboratory Practice Type	OECD	
3	123	TS	1		GLPFL	GLP Flag	Y	
4	123	TS	1		STSTDTC	Study Start Date	2022-05-25	
5	123	TS	1		STITLE	Study Title	Determination of the in vitro genotoxicity potential using the in vitro Neutral Red Uptake assay	

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF
6	123	TS	1		SNDIGVER	SEND Implementation Guide Version	TOBACCO IMPLEMENTATION GUIDE VERSION 1.0	
7	123	TS	1		SNDCTVER	SEND Controlled Terminology Version	SEND Terminology 2021-09-30	
8	123	TS	1		APPLCNT	Applicant	Example Applicant Inc.	
9	123	TS	1		APREFID	Applicant Study Reference ID		NOT APPLICABLE
10	123	TS	1	1	TSTFNAM	Test Facility Name	Example Test Lab Name	
11	123	TS	1	1	TSTFLOC	Test Facility Location	10 Somewhere Street, Montgomery, AL 10000	
12	123	TS	1	1	TFCNTRY	Test Facility Country	USA	
13	123	TS	1	1	STDIR	Study Director	Dr. R. Smith	
14	123	TS	1	4	TSTGDNAME	Testing Guideline Name	Publication No. 07-4519	
15	123	TS	1	4	TSTGDORG	Testing Guideline Organization	NIH	
16	123	TS	1	4	TSTGDVER	Testing Guideline Version	2006-11	
17	123	TS	1		SSTYP	Study Type	GENOTOXICITY IN VITRO	
18	123	TS	1		GNTXAID	Genetic Toxicology Assay Identifier	NRU	
19	123	TS	1		SPECIES	Species	HUMAN	
20	123	TS	1		CELLLN	Cell Line	NHK	

Rows 1-12: Show the test conditions for the set with a short name or SETCD value of NRU. The applicant chose this value to represent test conditions for the entire assay.

Rows 13-31: Show the test conditions for the set with a short name or SETCD value of CSC-50b. The applicant chose this value to represent plate number 1, well row A, well column 3, with a concentration of 50 µg/mL of cigarette smoke condensate as shown in the report table for study 123. The value for Cell Line (CELLLN) is not applicable because the well is a media-only well, having no NHK cells.

Rows 32-50: Show the test conditions for the set with a short name or SETCD value of CSC-50. The applicant chose this value to represent plate number 1, well rows B-G, well column 3 and plate number 2, well rows A-H, well column 3. These all have the concentration of 50 µg/mL of cigarette smoke condensate as shown in the report table for study 123.

Rows 51-69: Show the test conditions for the set with a short name or SETCD value of SLS-110. The applicant chose this value to represent plate number 1, well rows B-G, well column 10, and plate number 2, well rows A-H, well column 10. These all have the concentration of 110 µg/mL of sodium laurel sulfate as shown in the report table for study 123.

tx.xpt

ROW	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
1	123	TX	NRU	NRU_ASSAY	1	IVTDMIN	In vitro Treatment Duration Minimum	47.5
2	123	TX	NRU	NRU_ASSAY	2	IVTDTRG	In vitro Treatment Duration Target	48
3	123	TX	NRU	NRU_ASSAY	3	IVTDMAX	In vitro Treatment Duration Maximum	48.5
4	123	TX	NRU	NRU_ASSAY	4	IVTDU	In vitro Treatment Duration Unit	HOURS
5	123	TX	NRU	NRU_ASSAY	5	INCBTMRP	Incubation Temperature	37
6	123	TX	NRU	NRU_ASSAY	6	INCBTMRPU	Incubation Temperature Unit	C
7	123	TX	NRU	NRU_ASSAY	7	SWAVENM	Spectrophotometer Wavelength	540
8	123	TX	NRU	NRU_ASSAY	8	ATMRHP	Atmospheric Relative Humidity Percent	90
9	123	TX	NRU	NRU_ASSAY	9	ATMCO2P	Atmospheric CO2 Percent	5
10	123	TX	NRU	NRU_ASSAY	10	SPDEVID	applicant defined device identifier	PUFFMASTER3k
11	123	TX	NRU	NRU_ASSAY	11	SMKRGM	Smoking Regimen	MEDIUM INTENSITY REGIMEN
12	123	TX	NRU	NRU_ASSAY	12	SPTOBID	Applicant-defined tobacco identifier	CIG01a
13	123	TX	CSC-50b	CSC-50-blank	13	IVTDMIN	In vitro Treatment Duration Minimum	47.5
14	123	TX	CSC-50b	CSC-50-blank	14	IVTDTRG	In vitro Treatment Duration Target	48
15	123	TX	CSC-50b	CSC-50-blank	15	IVTDMAX	In vitro Treatment Duration Maximum	48.5
16	123	TX	CSC-50b	CSC-50-blank	16	IVTDU	In vitro Treatment Duration Unit	HOURS
17	123	TX	CSC-50b	CSC-50-blank	17	INCBTMRP	Incubation Temperature	37
18	123	TX	CSC-50b	CSC-50-blank	18	INCBTMRPU	Incubation Temperature Unit	C
19	123	TX	CSC-50b	CSC-50-blank	19	SWAVENM	Spectrophotometer Wavelength	540

ROW	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
20	123	TX	CSC-50b	CSC-50-blank	20	ATMRHP	Atmospheric Relative Humidity Percent	90
21	123	TX	CSC-50b	CSC-50-blank	21	ATMCO2P	Atmospheric CO2 Percent	5
22	123	TX	CSC-50b	CSC-50-blank	22	SPDEVID	applicant defined device identifier	PUFFMASTER3k
23	123	TX	CSC-50b	CSC-50-blank	23	SMKRGM	Smoking Regimen	MEDIUM INTENSITY REGIMEN
24	123	TX	CSC-50b	CSC-50-blank	24	SPTOBID	Applicant-defined tobacco identifier	CIG01a
25	123	TX	CSC-50b	CSC-50-blank	25	EXPTYP	Exposure Type	Air Liquid Interface
26	123	TX	CSC-50b	CSC-50-blank	26	SAMTYP	Sample Type	Whole Smoke Conditioned Media
27	123	TX	CSC-50b	CSC-50-blank	27	ITVNAM	Name of the Intervention Article	Tobacco ProdA
28	123	TX	CSC-50b	CSC-50-blank	28	ITVTYPE	Intervention Article Type	PRODUCT
29	123	TX	CSC-50b	CSC-50-blank	29	ITVCONC	Intervention Article Concentration	50
30	123	TX	CSC-50b	CSC-50-blank	30	ITVCONCU	Intervention Article Concentration Unit	ug/ml
31	123	TX	CSC-50b	CSC-50-blank	31	CELLLN	Cell Line	NOT APPLICABLE
32	123	TX	CSC-50	CSC-50	32	IVTDMIN	In vitro Treatment Duration Minimum	47.5
33	123	TX	CSC-50	CSC-50	33	IVTDTRG	In vitro Treatment Duration Target	48
34	123	TX	CSC-50	CSC-50	34	IVTDMAX	In vitro Treatment Duration Maximum	48.5
35	123	TX	CSC-50	CSC-50	35	IVTDU	In vitro Treatment Duration Unit	HOURS
36	123	TX	CSC-50	CSC-50	36	INCBTMRP	Incubation Temperature	37
37	123	TX	CSC-50	CSC-50	37	INCBTMRPU	Incubation Temperature Unit	C
38	123	TX	CSC-50	CSC-50	38	SWAVENM	Spectrophotometer Wavelength	540
39	123	TX	CSC-50	CSC-50	39	ATMRHP	Atmospheric Relative Humidity Percent	90
40	123	TX	CSC-50	CSC-50	40	ATMCO2P	Atmospheric CO2 Percent	5
41	123	TX	CSC-50	CSC-50	41	SPDEVID	applicant defined device identifier	PUFFMASTER3k
42	123	TX	CSC-50	CSC-50	42	SMKRGM	Smoking Regimen	MEDIUM INTENSITY REGIMEN
43	123	TX	CSC-50	CSC-50	43	SPTOBID	Applicant-defined tobacco identifier	CIG01a
44	123	TX	CSC-50	CSC-50	44	EXPTYP	Exposure Type	Air Liquid Interface
45	123	TX	CSC-50	CSC-50	45	SAMTYP	Sample Type	Whole Smoke Conditioned Media
46	123	TX	CSC-50	CSC-50	46	ITVNAM	Intervention Article Name	Tobacco ProdA
47	123	TX	CSC-50	CSC-50	47	ITVTYPE	Intervention Article Type	PRODUCT
48	123	TX	CSC-50	CSC-50	48	ITVCONC	Intervention Article Concentration	50
49	123	TX	CSC-50	CSC-50	49	ITVCONCU	Intervention Article Concentration Unit	ug/ml
50	123	TX	CSC-50	CSC-50	50	CELLLN	Cell Line	NHK
51	123	TX	SLS-110	SLS-110	51	IVTDMIN	In vitro Treatment Duration Minimum	47.5
52	123	TX	SLS-110	SLS-110	52	IVTDTRG	In vitro Treatment Duration Target	48
53	123	TX	SLS-110	SLS-110	53	IVTDMAX	In vitro Treatment Duration Maximum	48.5
54	123	TX	SLS-110	SLS-110	54	IVTDU	In vitro Treatment Duration Unit	HOURS
55	123	TX	SLS-110	SLS-110	55	INCBTMRP	Incubation Temperature	37
56	123	TX	SLS-110	SLS-110	56	INCBTMRPU	Incubation Temperature Unit	C
57	123	TX	SLS-110	SLS-110	57	SWAVENM	Spectrophotometer Wavelength	540
58	123	TX	SLS-110	SLS-110	58	ATMRHP	Atmospheric Relative Humidity Percent	90
59	123	TX	SLS-110	SLS-110	59	ATMCO2P	Atmospheric CO2 Percent	5
60	123	TX	SLS-110	SLS-110	60	SPDEVID	applicant defined device identifier	PUFFMASTER3k
61	123	TX	SLS-110	SLS-110	61	SMKRGM	Smoking Regimen	MEDIUM INTENSITY REGIMEN
62	123	TX	SLS-110	SLS-110	62	SPTOBID	Applicant-defined tobacco identifier	CIG01a
63	123	TX	SLS-110	SLS-110	63	EXPTYP	Exposure Type	Air Liquid Interface
64	123	TX	SLS-110	SLS-110	64	SAMTYP	Sample Type	Liquid
65	123	TX	SLS-110	SLS-110	65	ITVNAM	Intervention Article Name	Sodium Laurel Sulfate
66	123	TX	SLS-110	SLS-110	66	ITVTYPE	Intervention Article Type	POSITIVE CONTROL
67	123	TX	SLS-110	SLS-110	67	ITVCONC	Intervention Article Concentration	110
68	123	TX	SLS-110	SLS-110	68	ITVCONCU	Intervention Article Concentration Unit	ug/ml
69	123	TX	SLS-110	SLS-110	69	CELLLN	Cell Line	NHK

The applicant chose to define the REFID values to indicate the Plate, the Column, and the Row of the wells of the 96-well plate in use, such that the well on plate 2, column 10, row G would assigned a REFID of 2-10-G.

Row 1: Shows the REFID of 123NRU that indicates the entire assay.

- Rows 2-4:** Show the REFIDs at the second level, all within the parent assay of 123NRU (REFID values of 1-3, 1-10, 2-10) which have LVLDESC of OBSERVATIONAL SUMMARY. If this study had recorded summary statistics for an entire trial set (e.g., across both plates for the same dose level), there would be an additional REFID for the trial set (with a LVLDESC of TRIAL SET).
- Rows 5-6:** Show the REFIDs 1-3-A and 1-3-H that indicate two experimental units that are also observational units within the SETCD of CSC-50b that have the parent REFID of 123NRU.
- Rows 7-8:** Show the REFIDs 1-3-B and 1-3-C that indicate two experimental units that are also observational units within the SETCD of CSC-50 that have the parent REFID of 1-3.
- Row 9:** Shows the REFID of 1-10-G that indicates the experimental unit that is also an observational unit within the SETCD of SLS-110 that has the parent REFID of 1-10.
- Row 10:** Shows the REFID of 2-10-G that indicates the experimental unit that is also an observational unit within the SETCD of SLS-110 that has the parent REFID of 2-10.

relref.xpt

Row	STUDYID	SETCD	REFID	PARENT	LEVEL	LVLDESC
1	123	NRU	123NRU		1	ASSAY
2	123	CSC-50	1-3	123NRU	2	OBSERVATIONAL SUMMARY
3	123	SLS-110	1-10	123NRU	2	OBSERVATIONAL SUMMARY
4	123	SLS-110	2-10	123NRU	2	OBSERVATIONAL SUMMARY
5	123	CSC-50b	1-3-A	123NRU	2	EXPERIMENTAL UNIT/OBSERVATIONAL UNIT
6	123	CSC-50b	1-3-H	123NRU	2	EXPERIMENTAL UNIT/OBSERVATIONAL UNIT
7	123	CSC-50	1-3-B	1-3	3	EXPERIMENTAL UNIT/OBSERVATIONAL UNIT
8	123	CSC-50	1-3-C	1-3	3	EXPERIMENTAL UNIT/OBSERVATIONAL UNIT
9	123	SLS-110	1-10-G	1-10	3	EXPERIMENTAL UNIT/OBSERVATIONAL UNIT
10	123	SLS-110	2-10-G	2-10	3	EXPERIMENTAL UNIT/OBSERVATIONAL UNIT

Certain data (Absorbance Reading and Background Corrected Absorbance Reading) are not shown in the sample report table above but are included here for completeness of the NRU assay.

- Rows 1-3:** Show the experimental unit data for GTREFID 1-3-B.
- Rows 4-6:** Show the experimental unit data for GTREFID 1-3-C.
- Rows 7-9:** Show the data for the entire trial set, GTREFID=1-3.
- Rows 10-12:** Show the experimental unit data for GTREFID 1-10-G
- Rows 13-15:** Show the data for the entire trial set, GTREFID=1-10
- Rows 16-18:** Show the experimental unit data for GTREFID 2-10-G.
- Rows 19-21:** Show the data for the entire trial set, GTREFID=2-10
- Row 22:** Shows the data for the entire assay, GTREFID=123NRU.

gt.xpt

Row	STUDYID	DOMAIN	GTSEQ	GTREFID	GTTESTCD	GTTEST	GTORRES	GTORRESU	GTCOLSR	GTSTRESC	GTSTRESN	GTSTRESU
1	123	GT	1	1-3-B	ABSORB	Absorbance Reading	1.7			1.7	1.7	
2	123	GT	2	1-3-B	BKCABS	Background Corrected Absorbance Reading	1.6			1.6	1.6	
3	123	GT	3	1-3-B	RELABS	Relative Absorbance Reading	77.7			77.7	77.7	

Row	STUDYID	DOMAIN	GTSEQ	GTREFID	GTTESTCD	GTTEST	GTORRES	GTORRESU	GTCOLSR	GTSTRESC	GTSTRESN	GTSTRESU
4	123	GT	4	1-3-C	ABSORB	Absorbance Reading	1.8			1.8	1.8	
5	123	GT	5	1-3-C	BKCABS	Background Corrected Absorbance Reading	1.7			1.7	1.7	
6	123	GT	6	1-3-C	RELABS	Relative Absorbance Reading	77.4			77.4	77.4	
7	123	GT	7	1-3	RELABS	Relative Absorbance Reading	78.2	%	MEAN	78.2	78.2	%
8	123	GT	8	1-3	RELABS	Relative Absorbance Reading	2.9	%	STANDARD DEVIATION	2.9	2.9	%
9	123	GT	9	1-3	RELABS	Relative Absorbance Reading	3.6		COEFFICIENT OF VARIANCE	3.6	3.6	
10	123	GT	10	1-10-G	ABSORB	Absorbance Reading	0.7			0.7	0.7	
11	123	GT	11	1-10-G	BKCABS	Background Corrected Absorbance Reading	0.6			0.6	0.6	
12	123	GT	12	1-10-G	RELABS	Relative Absorbance Reading	8.57			8.57	8.57	
13	123	GT	13	1-10	RELABS	Relative Absorbance Reading	8.94	%	MEAN	8.94	8.94	
14	123	GT	14	1-10	RELABS	Relative Absorbance Reading	2.72	%	STANDARD DEVIATION	2.72	2.72	
15	123	GT	15	1-10	RELABS	Relative Absorbance Reading	30.5		COEFFICIENT OF VARIANCE	30.5	30.5	
16	123	GT	16	2-10-G	ABSORB	Absorbance Reading	0.9					
17	123	GT	17	2-10-G	BKCABS	Background Corrected Absorbance Reading	0.8					
18	123	GT	18	2-10-G	RELABS	Relative Absorbance Reading	6.30			6.30	6.30	
19	123	GT	19	2-10	RELABS	Relative Absorbance Reading	5.91	%	MEAN	5.91	5.91	
20	123	GT	20	2-10	RELABS	Relative Absorbance Reading	0.83	%	STANDARD DEVIATION	0.83	0.83	
21	123	GT	21	2-10	RELABS	Relative Absorbance Reading	14.1		COEFFICIENT OF VARIANCE	14.1	14.1	
22	123	GT	22	123NRU	EC50CYTX	Effective Concentration of 50 Percent Cytotoxicity	123	ug/ml		123	123	ug/ml

3.3 Product Impact on Individual Health

Studies involving a tobacco product may include assessments of pattern of product use, extent of exposure to toxicants and biological effects, abuse potential, and consumer perception of the product, as well as other physiological and subjective effects. This may include nicotine pharmacokinetics, questionnaires, and daily diaries to assess tobacco and nicotine use status, biomarkers of exposure as well as medical history, physical examination, and other routine data. These study types include abuse liability studies, in-laboratory studies (subject uses the product once or a few times, but only in a laboratory setting), short-term studies (<2 weeks of duration on a particular product), intermediate-term studies (> 2 weeks and ≤ 12 months), or long-term studies (>12 months).

Most subject-level observations collected during the study should be represented according to 1 of the 3 SDTM general observation classes, and the special-purpose domains which represent data that do not fit any of the general observation classes. Given this, referring to both the CDASH Model when applicable and the SDTM is highly recommended when using domains to support understanding of intended scope and to inform extensions and creation of custom domains when needed. See also Section 2.1, [How To Determine Where Data Belong](#), Section 2.7, [Standards for Collection](#), and Section 2.8, [Standards for Tabulation](#).

The examples in this section illustrate how to represent various aspects of studies involving a tobacco product using the CDASH Model and the SDTM, including

- guidance on the use of domains and variables;
- sample aCRFs;
- examples of SDTM datasets, with text describing the context and example records of note.

The domain specification tables include rows for all required and expected variables for a domain and for a set of permissible variables are most likely relevant. The permissible variables do not include all the variables that are allowed for the domain; they are a set of variables that are considered likely to be included.

It is important to note that ***the inclusion of concepts in this implementation guide should not be construed as a requirement to collect data on these concepts in any particular study.*** The examples included are intended to show how data of particular kinds can be represented using CDISC standards. ***The examples given are for guidance only and should not be over-interpreted .***

3.3.1 Trial Design

This section includes example studies, which illustrate the intended implementation of Trial Design datasets.

3.3.1.1 Experimental Design (TV, TA, TE)

The Trial Visits (TV) domain contains the planned order and number of visits in the study within each arm. The Trial Design datasets—Trial Arms (TA) and Trial Elements (TE)—describe the planned design of the study, and provide the representation of the study product in its most granular components, as well as the representation of all sequences of these components as described in the protocol. The TA and TE datasets are interrelated, and they provide the building blocks for the development of actual subject-level information included in the Demographics (DM) and Subject Elements (SE) domains.

This section includes example studies which illustrate TV and the development of the TA and TE datasets.

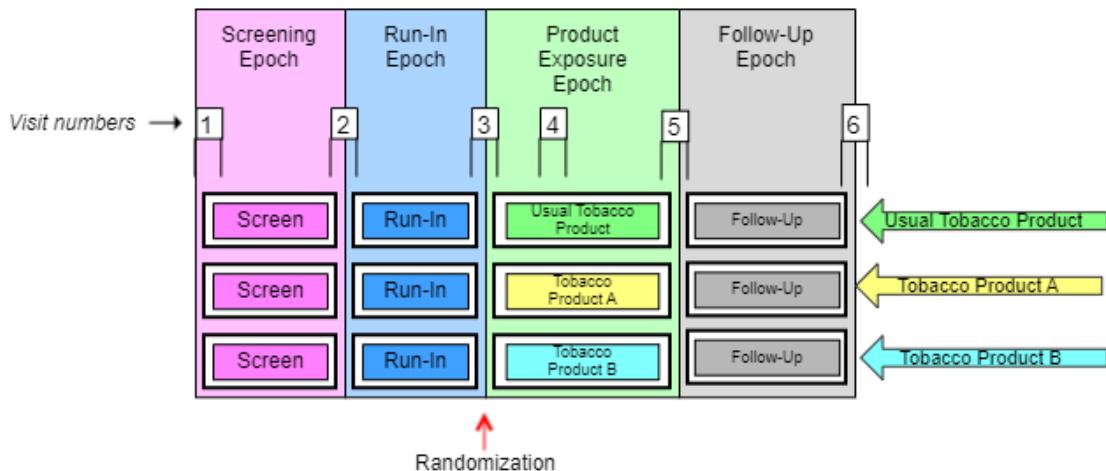
3.3.1.1.1 Schedule for Assessments (TV)

The Trial Visits (TV) domain, based on the Trial Design Model, contains the planned order and number of visits in the study within each arm. Visits are defined as "clinical encounters" and are described using the timing variables VISIT, VISITNUM, and VISITDY. Protocols define visits in order to describe assessments and procedures that are to be performed at the visits.

Example 1

The following diagram represents visits as numbered "flags" with visit numbers. Each flag has 2 supports, one at the beginning of the visit and the other at the end of the visit. Note that visits 2 and 3 span epoch transitions. In other words, the transition event that marks the beginning of the run-in epoch (confirmation of eligibility) occurs during visit 2, and the transition event that marks the beginning of the study product administration epoch (the first study product administration of the study tobacco product) occurs during visit 3.

Example Study 1, Parallel Design Planned Visits



Two TV datasets are shown for this trial. The first shows a somewhat idealized situation, where the protocol has provided specific timings for the visits. The second shows a more common situation, where the timings have been described only loosely. TVSTRL shows the rule that defines the start of the visit, and TVENRL shows the rule that defines the end of the visit.

tv.xpt

Row	STUDYID	DOMAIN	VISITNUM	VISIT	TVSTRL	TVENRL
1	EX1	TV	1	SCREENING	Start of Screen Epoch	1 hour after start of Visit
2	EX1	TV	2	BASELINE	30 minutes before end of Screen Epoch	30 minutes after start of Run-in Epoch
3	EX1	TV	3	WEEK 2	30 minutes before end of Run-in Epoch	1 hour after start of Product Exposure Epoch
4	EX1	TV	4	WEEK 4	1 week after start of Product Exposure Epoch	1 hour after start of Visit
5	EX1	TV	5	WEEK 6	2 weeks after start of Product Exposure Epoch	1 hour after start of Visit
6	EX1	TV	6	FOLLOW-UP	After last Product Exposure Epoch	1 hour after start of Visit

tv.xpt

Row	STUDYID	DOMAIN	VISITNUM	VISIT	TVSTRL	TVENRL
1	EX1	TV	1	SCREENING	Start of Screen Epoch	
2	EX1	TV	2	BASELINE	On the same day as, but before, the end of the Screen Epoch	On the same day as, but after, the start of the Run-in Epoch
3	EX1	TV	3	WEEK 2	On the same day as, but before, the end of the Run-in Epoch	On the same day as, but after, the start of the Study Product Exposure Epoch
4	EX1	TV	4	WEEK 4	1 week after start of Product Exposure Epoch	
5	EX1	TV	5	WEEK 6	2 weeks after start of Product Exposure Epoch	
6	EX1	TV	6	FOLLOW-UP	After last Product Exposure Epoch	At Trial Exit

Although the start and end rules in this example reference the starts and ends of epochs, the start and end rules of some visits for trials with epochs that span multiple elements will need to reference elements rather than epochs. When an arm includes repetitions of the same element, it may be necessary to use TAETORD as well as an element name to specify when a visit is to occur.

3.3.1.1.2 Trial Arms (TA)

The core of the Trial Design Model is the TA dataset. For each arm of the trial, the TA dataset contains 1 record for each occurrence of an element in the path of the arm.

Although the TA dataset has 1 record for each trial element traversed by subjects assigned to the arm, it is generally more useful to work out the overall design of the trial at the study cell level first, then to work out the elements within each study cell, and finally to develop the definitions of the elements that are contained in the Trial Elements (TE) table.

When working out the design of a trial, it is generally useful to draw diagrams such as those mentioned in ICH E3. The protocol may include a diagram that can serve as a starting point. Such a diagram can then be converted into a trial design matrix that displays the study cells and which in turn can be converted into the TA dataset.

This section uses example trials of increasing complexity to illustrate the concepts of trial design. For each example trial, the process of working out the TA table is illustrated by means of a series of diagrams and tables, including:

- A diagram showing the branching structure of the trial in a “study schema” format such as might appear in a protocol
- A diagram that shows the “prospective” view of the trial (i.e., the view of those participating in the trial). This is similar to the study schema view in that it usually shows a single pool of subjects at the beginning of the trial, with the pool of subjects being split into separate product groups at randomizations and other branches. Such diagrams include the epochs of the trial, and, for each group of subjects and each epoch, the sequence of elements within each epoch for that product group. The arms are also indicated on these diagrams.
- A diagram that shows the “retrospective” view of the trial (i.e., the view of the analyst reporting on the trial). This style of diagram looks more like a matrix; it is also more like the structure of the TA dataset. The retrospective view is arm-centered and shows, for each study cell (epoch/arm combination) the sequence of elements within that study cell. It can be thought of as showing, for each arm, the elements traversed by a subject who completed that arm as intended.
- If the trial is blinded, a diagram that shows the trial as it appears to a blinded participant
- A trial design matrix, an alternative format for representing most of the information in the diagram that shows arms and epochs, and which emphasizes the study cells
- The TA dataset

The TE dataset contains the definitions of the elements that appear in the TA dataset. An element may appear multiple times in the TA table because it appears either (1) in multiple arms, (2) multiple times within an arm, or (3) both. However, an element will appear only once in the TE table.

Each row in the TE dataset may be thought of as representing a "unique element" in the same sense of "unique" as a CRF template page for a collecting certain type of data is referred to as "unique page." For instance, a CRF might be described as containing 87 pages, but only 23 unique pages. By analogy, the trial design matrix in Example Trial 1 below has 12 study cells, each of which contains 1 element, but the same trial design matrix contains only 5 unique elements, so the TE dataset for that trial has only 6 records.

An element is a building block for creating study cells, and an arm is composed of study cells. Or, from another point of view, an arm is composed of elements; that is, the trial design assigns subjects to arms, which comprise a sequence of steps (elements).

Trial elements represent an interval of time that serves a purpose in the trial and are associated with certain activities affecting the subject. "Week 2 to week 4" is not a valid element. A valid element has a name that describes the purpose of the element and includes a description of the activity or event that marks the subject's transition into the element as well as the conditions for leaving the element.

Example 1 should be reviewed before reading other examples, as it explains the conventions used for all diagrams and tables in the examples.

Example 1

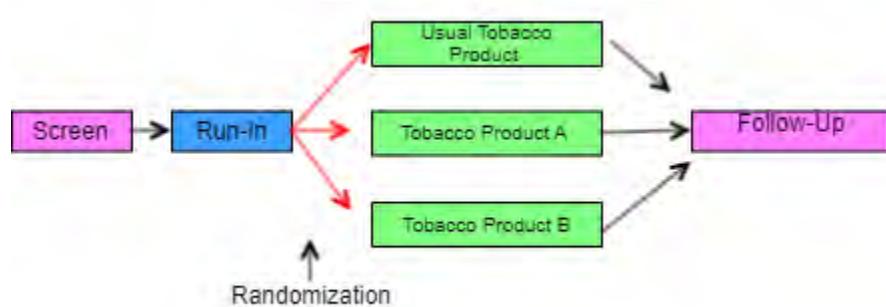
Diagrams that represent study schemas generally conceive of time as moving from left to right, using horizontal lines to represent periods of time and slanting lines to represent branches into separate arms, convergence into a common follow-up, or crossover to a different product.

In this type of document, diagrams are drawn using "blocks" corresponding to trial elements rather than horizontal lines. Trial elements are the various time periods of the trial and might otherwise be "hidden" in a single horizontal line. See Section 3.3.1.1.3, [Trial Elements \(TE\)](#), for more information about defining trial elements. In general, the elements of a trial will be fairly clear. However, in the process of working out a trial design, alternative definitions of trial elements may be considered, in which case diagrams for each alternative may be constructed.

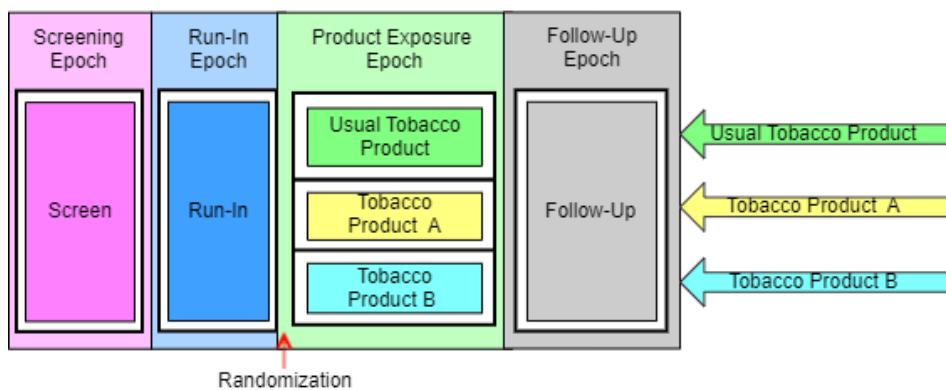
In the study schema diagrams in this example, the only slanting lines used are those that represent branches (i.e., decision points where subjects are divided into separate groups). One advantage of this style of diagram, which does not show convergence of separate paths into a single block, is that the number of arms in the trial can be determined by counting the number of parallel paths at the right end of the diagram.

As illustrated in the study schema diagram for Example Trial 1, this simple parallel trial has 3 arms, corresponding to the 3 possible left-to-right "paths" through the trial. Each path corresponds to 1 of the 3 elements at the right end of the diagram. Randomization is represented by the 3 red arrows leading from the Run-in block.

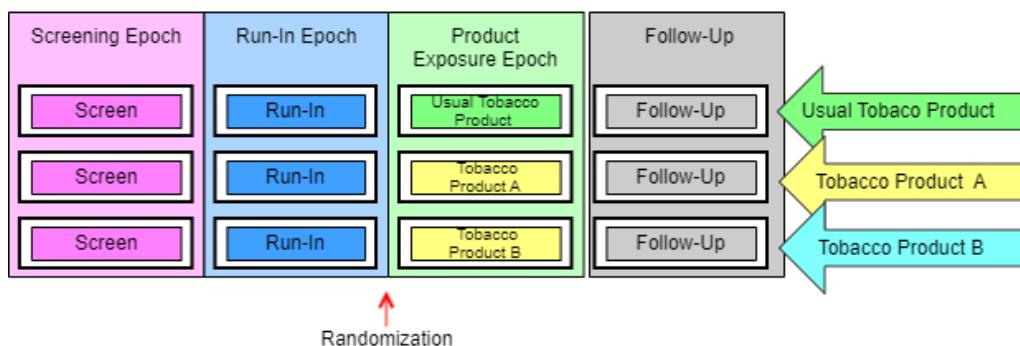
Example Study 1, Parallel Design Study Schema



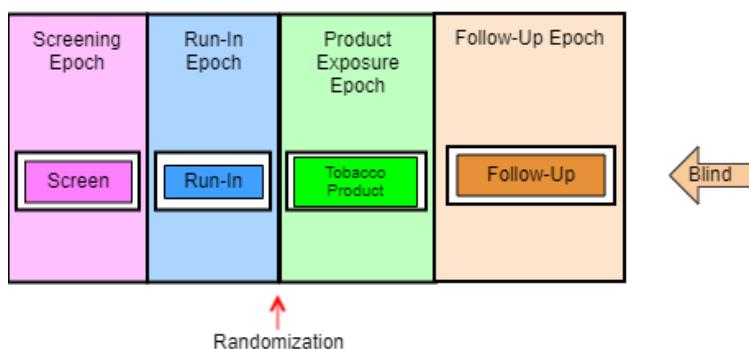
The next diagram for this trial shows the 4 epochs of the trial, indicates the 3 arms, and shows the sequence of elements for each group of subjects in each epoch. The arrows are at the right side of the diagram because it is at the end of the trial that all the separate paths through the trial can be seen. Note that, in this diagram, randomization—which was shown using 3 red arrows connecting the Run-in block with the 3 product exposure blocks in the first diagram—is indicated by a note with an arrow pointing to the line between 2 epochs.

Example Study 1, Parallel Design Prospective View

The next diagram can be thought of as the retrospective view of a trial, the view back from a point in time when a subject's assignment to an arm is known. In this view, the trial appears as a grid, with an arm represented by a series of study cells, one for each epoch, and a sequence of elements within each study cell. In this example (as in many trials), there is exactly 1 element in each study cell. In more complicated designs this is not always the case.

Example Study 1, Parallel Design Retrospective View

The next diagram shows the trial from the viewpoint of blinded participants. To blinded participants in this trial, all arms look alike. They know when a subject is in the screen element or the run-in element, but when a subject is in the product exposure epoch, participants know only that the subject is receiving a study product, not which study product, and therefore not which element.

Example Study 1, Blinded View

A *trial design matrix* is a table with a row for each arm in the trial and a column for each epoch in the trial. It is closely related to the retrospective view of the trial, and many users may find it easier to construct a table than to draw a diagram. The cells in the matrix represent the study cells, which are populated with trial elements. In this trial, each study cell contains exactly 1 element.

As illustrated in the following table, the columns of a trial design matrix are the epochs of the trial, the rows are the arms of the trial, and the cells of the matrix (the study cells) contain elements. Note that randomization is not represented in the trial design matrix. All of the preceding diagrams and the trial design matrix are alternative representations of the trial design. None of them contains all the information that will be in the finished TA dataset; users may find it useful to draw some or all of these diagrams when working out the dataset.

Trial Design Matrix

	Screen	Run-in	Study Product Exposure	Follow-Up
Usual Brand	Screen	Run-in	Usual Tobacco Product	Follow-Up
A	Screen	Run-in	Tobacco Product A	Follow-Up
B	Screen	Run-in	Tobacco Product B	Follow-Up

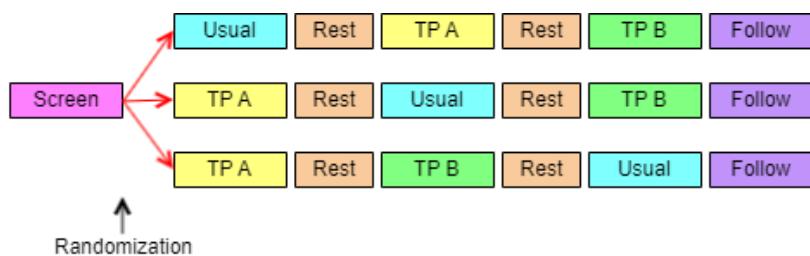
For Example Trial 1, the conversion of the trial design matrix into the TA dataset is straightforward. For each cell of the matrix, there is a record in the TA dataset. ARM, EPOCH, and ELEMENT can be populated directly from the matrix. TAETORD acts as a sequence number for the elements within an arm, so it can be populated by counting across the cells in the matrix. The randomization information, which is not represented in the trial design matrix, is held in TABRANCH in the TA dataset. TABRANCH is populated only if there is a branch at the end of an element for the arm. When TABRANCH is populated, it describes how the decision at the branch point would result in a subject being in this arm. TATRANS is not used for this design but as it is an expected variable it is included in the dataset.

ta.xpt

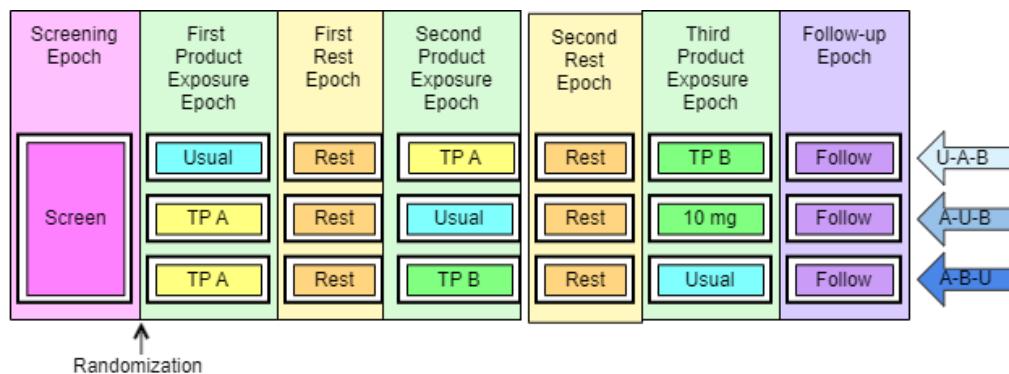
Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
1	TOB1	TA	UB	Usual Brand of Tobacco	1	SCRN	Screen			SCREENING
2	TOB1	TA	UB	Usual Brand of Tobacco	2	RI	Run-In	Randomized to Usual Brand of Tobacco		RUN-IN
3	TOB1	TA	UB	Usual Brand of Tobacco	3	UB	Usual Brand of Tobacco			STUDY PRODUCT EXPOSURE
4	TOB1	TA	UB	Usual Brand of Tobacco	4	FU	Follow-Up			FOLLOW-UP
5	TOB1	TA	TOBP A	Tobacco Product A	1	SCRN	Screen			SCREENING
6	TOB1	TA	TOBP A	Tobacco Product A	2	RI	Run-In	Randomized to Tobacco Product A		RUN-IN
7	TOB1	TA	TOBP A	Tobacco Product A	3	TOBP A	Tobacco Product A			STUDY PRODUCT EXPOSURE
8	TOB1	TA	TOBP A	Tobacco Product A	4	FU	Follow-Up			FOLLOW-UP
9	TOB1	TA	TOBP B	Tobacco Product B	1	SCRN	Screen			SCREENING
10	TOB1	TA	TOBP B	Tobacco Product B	2	RI	Run-In	Randomized to Tobacco Product B		RUN-IN
11	TOB1	TA	TOBP B	Tobacco Product B	3	TOBP B	Tobacco Product B			STUDY PRODUCT EXPOSURE
	TOB1	TA	TOBP B	Tobacco Product B	4	FU	Follow-Up			FOLLOW-UP

Example 2

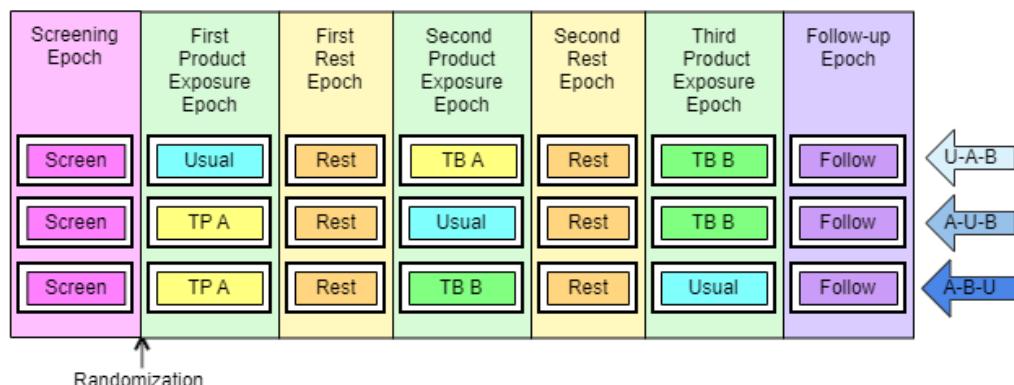
The following diagram for a crossover study does not use the crossing slanted lines sometimes used to represent crossover studies, because the order of the blocks is sufficient to represent the design of the study. Slanted lines are used only to represent the branch point at randomization, when a subject is assigned to a sequence of study product exposures. As in most crossover studies, the arms are distinguished by the order of study product exposures, with the same study product exposure present in each arm. Note that even though all 3 arms of this study end with the same block (i.e., the block for the follow-up element), the diagram does not show the arms converging into one block. Also note that the same block (the "rest" element) occurs twice within each arm. Elements are conceived of as "reusable" and can appear in more than 1 arm, in more than 1 epoch, and more than once in an arm.

Example Study 2, Crossover Trial Study Schema

The next diagram for this crossover study shows the prospective view of the study; it identifies the epoch and arms of the study, and gives each a name. As for most crossover studies, the objectives of the study will be addressed by comparisons between the arms and by within-subject comparisons between study product exposures. Because the design depends on differentiating the periods during which the subject receives the 3 different study product exposures, there are 3 different study product exposure epochs. The fact that the rest periods are identified as separate epochs suggests that these also play an important part in the design of the study; they are probably designed to allow subjects to return to “baseline,” with data collected to show that this occurred. Note that epochs are not considered reusable; each epoch has a different name, even though all the study product exposure epochs are similar and both the rest epochs are similar. As with the first example study, there is a one-to-one relationship between the epochs of the study and the elements in each arm.

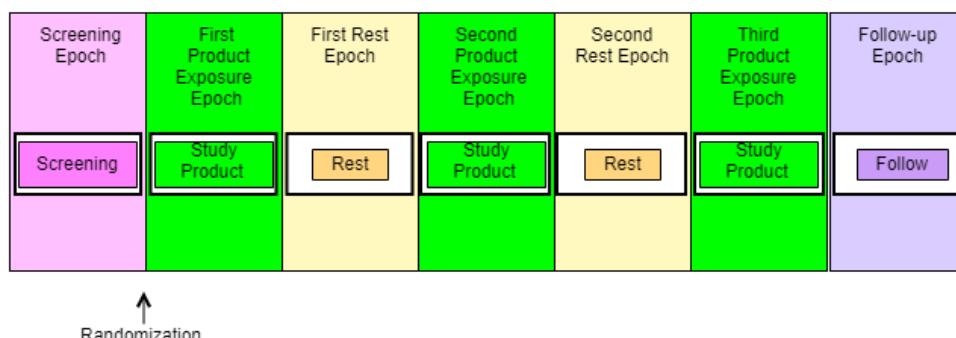
Example Study 2, Crossover Study Prospective View

The next diagram shows the retrospective view of the study.

Example Study 2, Crossover Trial Retrospective View

The last diagram for this study shows the study from the viewpoint of blinded participants. As in the simple parallel study in Example Study 1, blinded participants see only 1 sequence of elements; during the product exposure epochs they do not know which of the product exposure elements a subject is in.

Example Study 2, Crossover Study Blinded View



The following table illustrates the study design matrix for this crossover example study. It corresponds closely to the preceding retrospective diagram.

Trial Design Matrix

	Screen	First Study Product Exposure	First Rest	Second Study Product Exposure	Second Rest	Third Study Product Exposure	Follow-up
U-A-B	Screen	Usual Tobacco Product	Rest	Tobacco Product A	Rest	Tobacco Product B	Follow-up
A-U-B	Screen	Tobacco Product A	Rest	Usual Tobacco Product	Rest	Tobacco Product B	Follow-up
B-A-U	Screen	Tobacco Product B	Rest	Tobacco Product A	Rest	Usual Tobacco Product	Follow-up

It is straightforward to produce the TA dataset for this crossover study from the diagram showing arms and epochs, or from the design matrix.

ta.xpt

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
1	EX2	TA	U-A-B	UTP-TPA-TPB	1	SCRN	Screen	Randomized to UTP -TPA-TPB		SCREENING
2	EX2	TA	U-A-B	UTP-TPA-TPB	2	UTP	Usual			STUDY PRODUCT EXPOSURE 1
3	EX2	TA	U-A-B	UTP-TPA-TPB	3	REST	Rest			WASHOUT 1
4	EX2	TA	U-A-B	UTP-TPA-TPB	4	TPA	Prod A			STUDY PRODUCT EXPOSURE 2
5	EX2	TA	U-A-B	UTP-TPA-TPB	5	REST	Rest			WASHOUT 2
6	EX2	TA	U-A-B	UTP-TPA-TPB	6	TPB	Prod B			STUDY PRODUCT EXPOSURE 3
7	EX2	TA	U-A-B	UTP-TPA-TPB	7	FU	Follow-up			FOLLOW-UP
8	EX2	TA	A-U-B	TPA-UTP-TPB	1	SCRN	Screen	Randomized to TPA- UTP-TPB		SCREENING
9	EX2	TA	A-U-B	TPA-UTP-TPB	2	TBA	Prod A			STUDY PRODUCT EXPOSURE 1
10	EX2	TA	A-U-B	TPA-UTP-TPB	3	REST	Rest			WASHOUT 1
1	EX2	TA	A-U-B	TPA-UTP-TPB	4	UTP	Usual			STUDY PRODUCT EXPOSURE 2
12	EX2	TA	A-U-B	TPA-UTP-TPB	5	REST	Rest			WASHOUT 2
13	EX2	TA	A-B-U	TPA-UTP-TPB	6	TPB	Prod B			STUDY PRODUCT EXPOSURE 3
14	EX2	TA	A-B-U	TPA-UTP-TPB	7	FU	Follow-up			FOLLOW-UP
15	EX2	TA	A-B-U	TPA-TPB-Usual	1	SCRN	Screen	Randomized to TBA - TPB - Usual		SCREENING
16	EX2	TA	A-B-U	TPA-TPB-Usual	2	TPA	Prod A			STUDY PRODUCT EXPOSURE 1
17	EX2	TA	A-B-U	TPA-TPB-Usual	3	REST	Rest			WASHOUT 1
18	EX2	TA	A-B-U	TPA-TPB-Usual	4	TPB	Prod B			STUDY PRODUCT EXPOSURE 2

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
19	EX2	TA	A-B-U	TPA-TPB-Usual	5	REST	Rest			WASHOUT 2
20	EX2	TA	A-B-U	TPA-TPB-Usual	6	UTP	Usual			STUDY PRODUCT EXPOSURE 3
21	EX2	TA	A-B-U	TPA-TPB-Usual	7	FU	Follow-up			FOLLOW-UP

3.3.1.1.3 Trial Elements (TE)

The Trial Elements domain contains the element code that is unique for each element, the element description, and the rules for starting and ending an element.

The TE dataset contains the definitions of the elements that appear in the Trial Arms (TA) dataset. An element may appear multiple times in the TA table because it appears either (1) in multiple arms, (2) multiple times within an arm, or (3) both. However, an element will appear only once in the TE table.

Each row in the TE dataset may be thought of as representing a "unique element" in the same sense of "unique" as a CRF template page for a collecting certain type of data is referred to as "unique page." For instance, a CRF might be described as containing 87 pages, but only 23 unique pages. By analogy, the trial design matrix in [TA Example Trial 1](#) has 12 study cells, each of which contains 1 element, but the same trial design matrix contains only 6 unique elements, so the TE dataset for that trial has only 6 records.

An *element* is a building block for creating study cells, and an *arm* is composed of study cells. Or, from another point of view, an arm is composed of elements; that is, the trial design assigns subjects to arms, which comprise a sequence of steps (elements). The element typically indicates the study product being administered (e.g., Study Product A) or, if no study product is being administered, the other activities that are the purpose of this period of time (e.g., "Screening", "Follow-up", "Washout"). In some cases, this time period may be quite passive (e.g., "Rest"; "Wait, for protocol defined event").

Trial elements represent an interval of time that serves a purpose in the trial and are associated with certain activities affecting the subject. "Week 2 to week 4" is not a valid element. A valid element has a name that describes the purpose of the element and includes a description of the activity or event that marks the subject's transition into the element as well as the conditions for leaving the element.

The trial in Section 3.3.1.1.2, [Trial Arms \(TA\)](#) (Example 1) is assumed to have fixed-duration elements. The wording in TESTRL is intended to separate the description of the event that starts the element into the part that would be visible to a blinded participant in the trial (e.g., "First dose of a product epoch") from the part that is revealed when the study is unblinded (e.g., "where dose is 5 mg"). Care must be taken in choosing such descriptions to ensure that they are arm- and epoch-neutral. For instance, in a crossover trial such as [Trial Arms Example 2](#), where an element may appear in 1 of multiple epochs, the wording must be appropriate for all possible epochs (e.g., "OPEN LABEL PRODUCT"). The CDISC Submission Data Standards Team is considering adding a separate variable to the TE dataset that would hold information on the product that is associated with an element. This would make it clearer which elements are "product elements" and, therefore, which epochs contain product elements and thus are "product epochs."

Example 1

This example shows the TE dataset for TA Example Trial 1.

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	EX1	TE	SCRN	Screen	Informed consent	1 week after start of Element	P7D
2	EX1	TE	RI	Run-In	Eligibility confirmed	2 weeks after start of Element	P14D
3	EX1	TE	U	Usual	First dose of study product administration, where study product is Usual Tobacco Product	2 weeks after start of Element	P14D
4	EX1	TE	A	Tobacco Product A	First dose of study product administration, where study product is Tobacco Product A	2 weeks after start of Element	P14D
5	EX1	TE	B	Tobacco Product B	First dose of study product administration, where study product is Tobacco Product B	2 weeks after start of Element	P14D
6	EX1	TE	FU	Follow-Up	First day of after end of tobacco product administration	1 week after start of Element	PD7

Example 2

This example shows the TE dataset for TA Example Trial 2.

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	EX2	TE	SCRN	Screen	Informed consent	2 weeks after start of Element	P14D
2	EX2	TE	USL	Usual	First dose of product administration in Product Exposure Epoch, where product is the usual tobacco product	2 weeks after start of Element	P14D
3	EX2	TE	TPA	TP A	First dose of product administration in Product Exposure Epoch, where dose is tobacco product A	2 weeks after start of Element	P14D
4	EX2	TE	TPB	TP B	First dose of product administration in Product Exposure Epoch, where dose is tobacco product B	2 weeks after start of Element	P14D
5	EX2	TE	REST	Rest	After last dose of preceding Product Exposure Epoch	1 week after start of Element	P7D
6	EX2	TE	FU	Follow-up	After last dose of last preceding Product Exposure Epoch	3 weeks after start of Element	P21D

3.3.1.2 Trial Eligibility and Summary (TI, TS)

This section describes the trial eligibility (inclusion/exclusion criteria) and summary domains that are based on the Trial Design Model. They describe subject eligibility criteria for trial participation and characteristics of the trial. The TI and TS datasets are tabular synopses of parts of the study protocol.

3.3.1.2.1 Trial Inclusion/Exclusion Criteria (TI)

TI – Proposed Removal of Variable TIRL

The variable TIRL was included in the Trial Inclusion/Exclusion Criteria (TI) domain in anticipation of developing a way to represent eligibility criteria in a computer-executable manner. However, such a method has not been developed, and it is not clear that an SDTM dataset would be the best place to represent such a computer-executable representation.

TI – Description/Overview

A trial design domain that contains 1 record for each of the inclusion and exclusion criteria for the trial. This domain is not subject oriented.

TI contains all the inclusion and exclusion criteria for the trial, and thus provides information that may not be present in the subject-level data on inclusion and exclusion criteria. The IE domain contains records only for inclusion and exclusion criteria that subjects did not meet.

Example 1

This example shows records for a trial that had 2 versions of inclusion/exclusion criteria.

Rows 1-3: Show the 2 inclusion criteria and 1 exclusion criterion for version 1 of the protocol.

Rows 4-6: Show the inclusion/exclusion criteria for version 2.2 of the protocol, which changed the minimum age for entry from 21 to 18.

ti.xpt

Row	STUDYID	DOMAIN	IETESTCD	IETEST	IECAT	TIVERS
1	XYZ	TI	INCL01	Typically smoking menthol cigarettes	INCLUSION	1
2	XYZ	TI	INCL02	Age 21 or greater	INCLUSION	1
3	XYZ	TI	EXCL01	Pregnant or lactating	EXCLUSION	1
4	XYZ	TI	INCL01	Typically smoking menthol cigarette	INCLUSION	2.2
5	XYZ	TI	INCL02A	Age 18 or greater	INCLUSION	2.2
6	XYZ	TI	EXCL01	Pregnant or lactating	EXCLUSION	2.2

3.3.1.2.2 Trial Summary (TS)

Trial Summary (TS) is a trial design domain that contains 1 record for each trial summary characteristic. This domain is not subject oriented.

The TS dataset allows the applicant to submit a summary of the trial in a structured format. Each record in the TS dataset contains the value of a parameter, a characteristic of the trial. For example, TS is used to record basic information about the study such as trial phase, protocol title, and trial objectives. The TS dataset contains information about the planned and actual trial characteristics.

Example 1

This example shows a subset of published controlled terminology parameters and the relationship of values across response variables TSVAL, TSVALNF, TSVALCD, TSVCDREF, and TSVCDVER. Text over 200 characters can be added to additional columns TSVAL1-TSVALn. This example does not include any text over 200 characters. Applicants should consult with regulators regarding which parameters are expected/required to be submitted. When required items are not applicable, TSVALNF may be used.

TSVALNF contains a “null flavor,” a value that provides additional coded information when TSVAL is null. For example, for TSPARM = "AGEMAX" (Planned Maximum Age of Subjects), there is no value if a study does not specify a maximum age. In this case, the appropriate null flavor is "PINF", which stands for "positive infinity." TSVALNF can also be used in a case where the value of a particular parameter is unknown. However, in a tobacco study conducted in healthy volunteers where the study/trial phase classification is not established, the value (TSVAL) for TSPARM = "TPHASE" would be "NOT APPLICABLE". TSVAL should not be left null in this case.

Sequence number is given to ensure uniqueness within a parameter. In this example, TSPARMCD (FCNTRY) is repeated twice to indicate that the study was conducted in the US and Canada. TSSEQ is assigned "1" for the US and "2" for Canada.

TSGRID is used to tie together a group of related records. For example, DCUTDTC, and DCUTDESC below are tied together using TSGRID.

ts.xpt

Row	STUDYID	DOMAIN	TSSEQ	TSGRID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
1	XYZ	TS	1		ACTSUB	Actual Number of Subjects	304				
2	XYZ	TS	1		ADAPT	Adaptive Design	N				
3	XYZ	TS	1		ADDON	Added on to Existing Treatments	Y		C49487	CDISC CT	2023-03-31
4	XYZ	TS	1		AGEMAX	Planned Maximum Age of Subjects	PINF				
5	XYZ	TS	1		AGEMIN	Planned Minimum Age of Subjects	P18Y			ISO 8601	
6	XYZ	TS	1	PA	DCUTDTC	Data Cutoff Date	2010-04-10			ISO 8601	
7	XYZ	TS	1	PA	DCUTDESC	Data Cutoff Description	PRIMARY ANALYSIS				
8	XYZ	TS	1		FCNTRY	Planned Country of Investigational Sites	USA			ISO 3166-1 Alpha-3	
9	XYZ	TS	2		FCNTRY	Planned Country of Investigational Sites	CAN			ISO 3166-1 Alpha-3	
10	XYZ	TS	1		INDIC	Trial Disease/Condition Indication	Tobacco smoking consumption		266918002	SNOMED	2011-03
11	XYZ	TS	1		LENGTH	Trial Length	P3M			ISO 8601	
12	XYZ	TS	1		NARMS	Planned Number of Arms	3				
13	XYZ	TS	1		OBJPRIM	Trial Primary Objective	Change in concentration of Nicotine in urine from baseline				
14	XYZ	TS	1		OBJSEC	Trial Secondary Objective	Change in concentration of Cotinine in urine from baseline				
15	XYZ	TS	1		PLANSUB	Planned Number of Subjects	300				
16	XYZ	TS	1		RANDOM	Trial is Randomized	Y		C49488	CDISC CT	2023-03-31
17	XYZ	TS	1		REGID	Registry Identifier	NCT123456789		NCT123456789	ClinicalTrials.gov	
18	XYZ	TS	2		REGID	Registry Identifier	XXYYZZ456		XXYYZZ456	EudraCT	
19	XYZ	TS	1		SENDC	Study End Date	2011-04-01			ISO 8601	
20	XYZ	TS	1		SEXPOL	Sex of Participants	BOTH		C49636	CDISC CT	2023-03-31
21	XYZ	TS	1		APPLCNT	Applicant	TobaccoCo		123456789	D-U-N-S NUMBER	
22	XYZ	TS	1		STOPRULE	Study Stop Rules	NONE				
23	XYZ	TS	1		TBLIND	Trial Blinding Schema	DOUBLE BLIND		C15228	CDISC CT	2023-03-31
24	XYZ	TS	1		TCNTRL	Control Type	ACTIVE		C49649	CDISC CT	2023-03-31
25	XYZ	TS	1		TITLE	Trial Title	A 3 month study of tobacco biomarkers in subjects using ENDS devices				

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
26	XYZ	TS	1		TDIGRP	Diagnosis Group		NA			
27	XYZ	TS	1		TINDEP	Trial Intent Type		NA	C49656	CDISC CT	2023-03-31
28	XYZ	TS	1		TPHASE	Trial Phase Classification	NOT APPLICABLE				
29	XYZ	TS	1		TTYPE	Trial Type	PHARMACOKINETIC		C49663	CDISC CT	2023-03-31
30	XYZ	TS	1		STYPE	Study Type	INTERVENTIONAL		C98388	CDISC CT	2023-03-31
31	XYZ	TS	1		SDTIGVER	SDTM IG Version	3.4				
32	XYZ	TS	1		STDMDVER	SDTM Version	1.4				
33	XYZ	TS	1		TIGVER	Tobacco IG Version	1.0				

3.3.2 Routinely Collected Data in Tobacco Product Studies

All studies, including studies on tobacco products, collect general information about a subject/participant. This section shows information typically collected in all studies, such as study disposition, demographic and subject characteristic information (e.g., sex, age), information about prior tobacco product use, safety laboratory tests, and medical history. Most subject-level observations collected during the study should be represented according to 1 of the 3 SDTM general observation classes: Interventions, Events, or Findings.

3.3.2.1 Subject Inclusion/Exclusion Criteria (IE)

The Inclusion/Exclusion Criteria (IE) domain is a Findings domain that contains criteria that cause the subject to be in violation of the protocol inclusion/exclusion criteria. The trial design domain TI (not shown here; see Section 3.3.1, [Trial Design](#)) is used to describe the criteria. One record for each of the inclusion and exclusion criteria for the trial are included in TI. The TI domain is not subject oriented.

Example 1

This is an example CRF used to collect subject inclusion/exclusion criteria.

Tobacco Implementation Guide-Inclusion/Exclusion	
<p>All procedures must be performed and the subject's eligibility determined within <protocol-specified time period prior to study medication administration></p> <p>(If applicable, include the following instructions) Complete the Inclusion/Exclusion Worksheet as source document by recording a "Yes" or "No" response to each criterion.</p> <p>Record the criterion identification that was an exception.</p>	
Any Inc/Exc	
Were all eligibility criteria met? Record Yes if all eligibility criteria were met at the time the subject was enrolled. Record No if the subject did not meet all criteria at the time the subject was enrolled.	NOT SUBMITTED IEYN
Inc/Exc Criteria	
What was the category of the criterion? Record whether the criterion exception was Inclusion or Exclusion.	IECAT IECAT
What was the identifier of the inclusion criterion the subject did not meet or the exclusion criterion the subject met? If the subject was not eligible, record the identifying code for each criterion that was an exception	IETESTCD IETESTCD
<p>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</p>	

CDASH IE Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
Section 1										
1	Were all eligibility criteria met?	Met Criteria	Record Yes if all eligibility criteria were met at the time the subject was enrolled. Record No if the subject did not meet all criteria at the time the subject was enrolled.	Text	IEYN		Not Submitted			
Section 2										
2	What was the category of the criterion?	Criterion Type	Record whether the criterion exception was Inclusion or Exclusion.	Text	IECAT	IECAT				
3	What was the identifier of the inclusion criterion the subject did not meet or the exclusion criterion the subject met?	Exception Criterion Identifier	If the subject was not eligible, record the identifying code for each criterion that was an exception.	Text	IETESTCD	IETESTCD				

This is an example SDTM dataset that represents data collected on a protocol inclusion/exclusion CRF. The IECAT column uses the controlled terminology (EXCLUSION or INCLUSION). IETEST and IETESTCD are defined in the TI domain. The applicant assigned a number to each criteria from the study protocol using the permissible variable IESPID (Applicant-defined Identifier).

Rows 1-2: Show data for a subject with 2 inclusion/exclusion exceptions.

Rows 3-4: Show data for 2 other subjects, both of whom failed the same inclusion criterion.

ie.xpt

Row	STUDYID	DOMAIN	USUBJID	IESEQ	IESPID	IETESTCD	IETEST	IECAT	IEORRES	IESTRESC	VISITNUM	VISIT	VISITDY	IEDTC	IEDY
1	XYZ	IE	XYZ-0007	1	17	EXCL17	Ventricular Rate	EXCLUSION	Y	Y	1	WEEK -8	-56	1999-01-10	-58
2	XYZ	IE	XYZ-0007	2	3	INCL03	Laboratory Test results within normal range	INCLUSION	N	N	1	WEEK -8	-56	1999-01-10	-58
3	XYZ	IE	XYZ-0047	1	3	INCL03	Laboratory Test results within normal range	INCLUSION	N	N	1	WEEK -8	-56	1999-01-12	-56
4	XYZ	IE	XYZ-0096	1	3	INCL03	Laboratory Test results within normal range	INCLUSION	N	N	1	WEEK -8	-56	1999-01-13	-55

3.3.2.2 Disposition Events (DS)

The Disposition Events (DS) domain contains information encompassing and representing data related to subject disposition. It provides an accounting for all subjects who enter a study. It includes disposition events and protocol milestones (e.g., informed consent obtained, randomized). Applicants may choose which disposition events and milestones/other events to submit for a study. See ICH E3, Section 10.1 (available at <https://www.ema.europa.eu/en/documents/>), for information about disposition events.

In the DS domain, DSCAT is used to distinguish between disposition events, protocol milestones, and other events. The controlled terminology for DSCAT consists of "DISPOSITION EVENT", "PROTOCOL MILESTONE", and "OTHER EVENT". The data collection scenario is similar for disposition events that are considered protocol milestones or other events, whereas the data collection scenario for subject disposition events is different.

Disposition events describe a subject's completion status or reason for discontinuation of the entire study or a phase or segment of the study, including screening and post-study product exposure follow-up. The codelist (NCOMPLT) is used for DSDECOD. The codelist (NCOMPLT) is only used when DSCAT = "DISPOSITION EVENT".

Example 1

This is an example CRF used to collect informed consent.

Tobacco Implementation Guide - Protocol Milestones		
Informed Consent		
What was the category of the disposition?	PROTOCOL MILESTONE	DSCAT="PROTOCOL MILESTONE" where DSDECOD and DSTERM="INFORMED CONSENT OBTAINED" DSCAT
What was the informed consent date? (DD-MMM-YYYY) <i>Record the date of informed consent as defined in the protocol and/or CRF completion instructions using this format.</i>		DSSTDTC DSSTDAT
<i>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</i>		

CDASH IC Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
1	What was the category of the disposition?	Disposition Category	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	Text	DSCAT	DSCAT	DSCAT="PROTOCOL MILESTONE" where DSDECOD and DSTERM="INFORMED CONSENT OBTAINED"	(DSCAT)		PROTOCOL MILESTONE
2	What was the informed consent date?	Informed Consent Date	Record the date of informed consent as defined in the protocol and/or CRF completion instructions using this format.	Date	DSSTDAT	DSSTDTC				

Example 2

This is an example CRF used to collect disposition at the end of each epoch of a study. Additionally, the CRF is used to collect information on the next epoch entered for administrative reasons; this data is not submitted.

Tobacco Implementation Guide -Disposition		
Disposition		
What was the category of the disposition? <i>If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.</i>	Protocol Milestone	DACAT DSDCAT
What is the study epoch for this disposition event? <i>Select the study epoch for which disposition is being recorded</i>	<input type="radio"/> Screening <input type="radio"/> Product Exposure <input type="radio"/> Follow-up	EPOCH EPOCH
What was the subject's status? <i>Document the subject's status for the study or study period. If the subject discontinued prematurely, record the primary reason for discontinuation.</i>	<input type="radio"/> Completed <input type="radio"/> Adverse Experience <input type="radio"/> Death <input type="radio"/> Lost To Follow-up <input type="radio"/> Protocol Deviation <input type="radio"/> Screen Failure <input type="radio"/> Site Terminated by Applicant <input type="radio"/> Withdrawal by Subject <input type="radio"/> Study Terminated by Applicant <input type="radio"/> Other	DSDECOD DSDECOD
What was the verbatim reason for the subject status? <i>If Adverse Experiences, Death, Protocol Deviation or Other is selected from the Status list, provide the verbatim reason.</i>		DSTERM DSTERM
What was the completion/discontinuation date? <i>(DD-MMM-YYYY)</i> <i>Record the date that the subject completed the study or study period using this format. If the subject did not complete the study or study period, record the date that the subject discontinued.</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	DSSTOTC DSSTDAT
Will the subject continue into the next epoch? <i>Record if the subject will be continuing to the next study period of this study.</i>	<input type="checkbox"/>	NOT SUBMITTED DSCONT
What is the next epoch the subject will continue to enter? <i>Record the planned subsequent study epoch in which the subject intends to participate.</i>		NOT SUBMITTED DSNEXT
<i>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</i>		

CDASH DS Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
1	What was the category of the disposition?	Disposition Category	If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.	Text	DSCAT	DSCAT		(DSCAT)		DISPOSITION EVENT
2	What is the trial epoch for this disposition event?	Epoch	Select the study epoch for which disposition is being recorded.	Text	EPOCH	EPOCH		(EPOCH)	SCREENING; PRODUCT EXPOSURE; FOLLOW-UP;	
3	What was the completion/discontinuation date?	Completion/Discontinuation Date	Record the date that the subject completed the study or study period using this format. If the subject did not complete the study or study period, record the date that the subject discontinued.	Date	DSSTDAT	DSSTDTC				
4	What was the subject's status?	Status	Document the subject's status for the study or study period. If the subject discontinued prematurely, record the primary reason for discontinuation.	Text	DSDECOD	DSDECOD		(TNCOMPLT)	COMPLETED; ADVERSE EXPERIENCE; DEATH; LOST TO FOLLOW-UP; PROTOCOL DEVIATION; SCREEN FAILURE; SITE TERMINATED BY APPLICANT; STUDY TERMINATED BY APPLICANT; WITHDRAWAL BY SUBJECT; OTHER.	
5	What was the verbatim reason for the subject status?	Specify	If Adverse Experiences, Death, Protocol Deviation or Other is selected from the Status list, provide the verbatim reason.	Text	DSTERM	DSTERM				
6	Will the subject continue into the next epoch?	Continue	Record if the subject will be continuing to the next study period of this study.	Text			NOT SUBMITTED	(NY)	No; Yes	
7	What is the next epoch the subject will continue to enter?	Next Epoch	Record the planned subsequent study epoch in which the subject intends to participate.	Text			NOT SUBMITTED	(EPOCH)	PRODUCT EXPOSURE; FOLLOW-UP.	

This is an example SDTM dataset used to represent the data collected on the above example CRFs and information on randomization.

Rows 1, 2, 6, 8, 9, 12, 13, 17, 18: Show records for protocol milestones. DSTERM and DSDECOD are populated with the same value, the name of the milestone. Note that for randomization events, EPOCH = "SCREENING", because randomization occurred before the start of product exposure, during the screening epoch.

Rows 3-5: Show 3 records for a subject who completed 3 stages of the study ("SCREENING", "PRODUCT EXPOSURE", "FOLLOW-UP").

Row 7: Shows disposition of a subject who was a screen failure. The Disposition CRF showed that the subject discontinued for a "PROTOCOL DEVIATION". The specify reason the subject was a screen failure was then collected using DSTERM. Because the subject did not complete the screening epoch, DSDECOD is not "COMPLETED" but another appropriate

controlled term, "PROTOCOL DEVIATION ". The date of discontinuation is in DSSTDTC. The protocol deviation event itself would be represented in the DV dataset.

Rows 10-11:

Show disposition of a subject who completed the screening stage but did not complete the protocol exposure epoch. For completed epochs, both DSTERM and DSDECOD are "COMPLETED". For epochs that were not completed, the verbatim reason for non-completion of the product exposure epoch is in DSTERM, while the value from controlled terminology is in DSDECOD.

Rows 14-16:

Show disposition of a subject who completed product exposure epoch, but did not complete follow-up. Note that for final disposition event, the date of collection of the event information, DSDTC, was different from the date of the disposition event (the subject's death), DSSTDTC.

Rows 19-21:

Show disposition of a subject who discontinued the product exposure epoch due to an adverse experience, but who went on to complete the follow-up epoch of the trial.

ds.xpt

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	DSSCAT	EPOCH	DSDTC	DSSTDTC
1	ABC123	DS	123101	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		SCREENING	2003-09-21	2003-09-21
2	ABC123	DS	123101	2	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		SCREENING	2003-09-30	2003-09-30
3	ABC123	DS	123101	3	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	SCREENING	2003-09-30	2003-09-29
4	ABC123	DS	123101	4	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	PRODUCT EXPOSURE	2003-10-31	2003-10-31
5	ABC123	DS	123101	5	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	FOLLOW-UP	2003-11-15	2003-11-15
6	ABC123	DS	123102	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		SCREENING	2003-11-21	2003-11-21
7	ABC123	DS	123102	2	SUBJECT DENIED MRI PROCEDURE	PROTOCOL VIOLATION	DISPOSITION EVENT	STUDY PARTICIPATION	SCREENING	2003-11-22	2003-11-20
8	ABC123	DS	123103	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		SCREENING	2003-09-15	2003-09-15
9	ABC123	DS	123103	2	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		SCREENING	2003-09-30	2003-09-30
10	ABC123	DS	123103	3	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	SCREENING	2003-09-30	2003-09-22
11	ABC123	DS	123103	4	SUBJECT MOVED	LOST TO FOLLOW-UP	DISPOSITION EVENT	STUDY PARTICIPATION	PRODUCT EXPOSURE	2003-10-31	2003-10-31
12	ABC123	DS	123104	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		SCREENING	2003-09-15	2003-09-15
13	ABC123	DS	123104	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		SCREENING	2003-09-30	2003-09-30
14	ABC123	DS	123104	2	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	SCREENING	2003-09-30	2003-09-22
15	ABC123	DS	123104	4	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	PRODUCT EXPOSURE	2003-10-15	2003-10-15
16	ABC123	DS	123104	5	AUTOMOBILE ACCIDENT	DEATH	DISPOSITION EVENT	STUDY PARTICIPATION	FOLLOW-UP	2003-10-31	2003-10-29
17	ABC123	DS	123105	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		SCREENING	2003-09-28	2003-09-28
18	ABC123	DS	123105	2	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		SCREENING	2003-10-02	2003-10-02
19	ABC123	DS	123105	3	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	SCREENING	2003-10-02	2003-10-02
20	ABC123	DS	123105	4	ANEMIA	ADVERSE EXPERIENCE	DISPOSITION EVENT	STUDY PARTICIPATION	PRODUCT EXPOSURE	2003-10-17	2003-10-17
21	ABC123	DS	123105	5	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	FOLLOW-UP	2003-11-02	2003-11-02

3.3.2.3 Subject Protocol Deviations (DV)

Protocol Deviations (DV) is an Events domain that contains protocol violations and deviations during the course of the study.

Example 1

This example DV CRF has 2 sections: Section 1 collects whether the subject had any protocol deviations, and the second section creates a row/record for every deviation each subject experienced.

Tobacco Implementation Guide-Protocol Deviations	
Any Protocol Deviations	
Were there any protocol deviations? <i>Enter Yes if a protocol deviation occurred and No if none occurred. Ensure that any adverse event which triggers a protocol deviation (e.g., concomitant medication use, newly discovered medical history) is noted on the respective CRF.</i>	<input type="radio"/> No Not Submitted <input checked="" type="radio"/> Yes DVYN
Protocol Deviations	
What is the protocol deviation identifier? <i>(DD-MMM-YYYY) If collected on the CRF, applicant may insert instructions to ensure each record has a unique identifier.</i>	<input type="text"/> DVSPID DVSPID
What was the protocol deviation? <i>Record protocol deviations identified and/or select the appropriate code from the list of protocol deviation terms.</i>	<input checked="" type="radio"/> Prohibited Medications DVDECOD <input type="radio"/> Informed Consent Issues DVDECOD <input type="radio"/> Inclusion Exclusion Criteria Violations <input type="radio"/> Adverse Event Not Reported in Timeline <input type="radio"/> Procedure not performed per protocol <input type="radio"/> Visit out of window <input type="radio"/> Other
What was the protocol deviation term? <i>Record the protocol deviation</i>	<input type="text"/> DVTERM DVTERM
What was the protocol deviation start date? <i>(DD-MMM-YYYY) Record the start date for the protocol deviation using this format. This should be the start or occurrence of the protocol deviation, not the date it was discovered or reported.</i>	<input type="text"/> DVSTDTC DVSTDAT
What was the protocol deviation end date? <i>(DD-MMM-YYYY) Record the end date for the protocol deviation using this format. This should be the date the protocol deviation stopped, not the date it was discovered or reported.</i>	<input type="text"/> DVSTDTC DVSTDAT
<i>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</i>	

CDASH DV Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
Section 1										
1	Were there any protocol deviations?	Any Deviations	Enter Yes if a protocol deviation occurred and No if none occurred. Ensure that any adverse event which triggers a protocol deviation (e.g., concomitant	Text	DVYN		Not Submitted	(NY)	No;Yes;	

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
			medication use, newly discovered medical history) is noted on the respective CRF.							
Section 2										
2	What is the protocol deviation identifier?	DV Number	If collected on the CRF, applicant may insert instructions to ensure each record has a unique identifier.	Text	DVSPID	DVSPID				
3	What was the protocol deviation?	Protocol Deviation	Record protocol deviations identified and/or select the appropriate code from the list of protocol deviation terms.	Text	DVDECOD	DVDECOD			INFORMED CONSENT NOT OBTAINED; INCLUSION CRITERIA NOT MET; STUDY PRODUCT ASSIGNMENT DEVIATION; STUDY PRODUCT ADMINISTRATION DEVIATION; EXCLUDED CONCOMITANT MEDICATION; OTHER	
4	What was the protocol deviation term?	Specify Protocol Deviation	Record the protocol deviation	Text	DVTERM	DVTERM				
5	What was the protocol deviation start date?	Start Date	Record the start date for the protocol deviation using this format (DD-MON-YYYY). This should be the start or occurrence of the protocol deviation, not the date it was discovered or reported.	Date	DVSTDTC	DVSTDTC				
6	What was the protocol deviation end date?	End Date	Record the end date of the protocol deviation using this format (DD-MON-YYYY). This should be the date the protocol deviation stopped, not the date it was discovered or reported.	Date	DVENDTC	DVENDTC				

This is the SDTM data that was collected on a DV CRF. The DVDECOD column is for controlled terminology; the DVTERM captures free text.

Rows 1, 3: Show examples of a study product assignment and study product administration protocol deviations.

Row 2: Shows an example of a deviation due to the subject taking a prohibited concomitant medication.

Row 4: Shows an example of a medication that should not be taken during the study.

dv.xpt

Row	STUDYID	DOMAIN	USUBJID	DVSEQ	DVTERM	DVDECOD	EPOCH	DVSTDTC
1	ABC123	DV	123101	1	IVRS PROCESS DEVIATION - NO DOSE CALL PERFORMED.	STUDY PRODUCT ASSIGNMENT DEVIATION	STUDY PRODUCT EXPOSURE	2003-09-21
2	ABC123	DV	123103	1	BUPROPION ADMINISTERED DURING STUDY PRODUCT EXPSCOURSE	EXCLUDED CONCOMITANT MEDICATION	STUDY PRODUCT EXPOSURE	2003-10-30
3	ABC123	DV	123103	2	VISIT 3 DOSE <15 MG	STUDY PRODUCT ADMINISTRATION DEVIATION	STUDY PRODUCT EXPOSURE	2003-10-30
4	ABC123	DV	123104	1	TOOK ASPIRIN	EXCLUDED CONCOMITANT MEDICATION	STUDY PRODUCT EXPOSURE	2003-11-30

3.3.2.4 Demography (DM)

The Demography domain (DM) is a special-purpose domain that includes a set of essential standard variables that describe each subject in a study. Companies use different methods to distinguish sites and investigators. CDISC assumes that SITEID will always be present, with INVID and INVNAME used as necessary. Every subject in a study must have a subject identifier (SUBJID). In some cases a subject may participate in more than 1 study. To identify a subject uniquely across all studies for all applications or submissions involving the product, a unique identifier (USUBJID) must be included in all datasets.

The DM domain includes required variables that are often not directly collected on the Demography CRF. This data is populated using other applicant sources of information.

Demographic information is collected about subjects in all studies. The amount of demographic information collected will be determined by the analysis needs of the study and regulatory requirements, and may be affected by local restrictions related to data privacy.

Example 1

This is an example Demographics CRF where the applicant collected information about a subject's race and ethnicity. The applicant collected the race and ethnicity values listed in the FDA guidance. Additionally, this applicant collected more details for subjects who reported ASIAN or BLACK OR AFRICAN AMERICAN for Race. When multiple races were self-reported, the applicant recorded "MULTIPLE" as the Race and used Supplemental Qualifiers to record the self-reported race. In order to save space, some of the example permissible values are only shown in the metadata specifications.

Applicants may append a suffix to denote multiple collected races and ethnicities (e.g. RACE1, RACE2, CRACE1, CRACE2, CETHNIC1, CETHNIC2). The appended suffixes shown for the CDASH variables QNAM and QLABEL in this aCRF are only examples and are not indicative of any prescribed values that must be followed.

Tobacco Implementation Guide-Demography	
General Demography	
What is the subject's date of birth? (DD-MMM-YYYY)	<input style="width: 100px; height: 20px; border: 1px solid #ccc;" type="text"/> BRTHDT BRTHDAT
What is the sex of the subject?	<input type="radio"/> Female SEX <input type="radio"/> Male SEX <input type="radio"/> Unknown <input type="radio"/> Undifferentiated
Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	<input type="radio"/> Hispanic or Latino ETHNIC <input type="radio"/> Not Hispanic or Latino ETHNIC <input type="radio"/> Not Reported <input type="radio"/> Unknown
Which of the following five racial designations best describes you? (More than one choice is acceptable.)	<input type="radio"/> American Indian or Alaska Native RACE or RACE="MULTIPLE" and each race is represented as a SUPPDM_QVAL where SUPPDM_QNAM = "CRACE(n)" and SUPPDM_QLABEL = "Race(n)" <input type="radio"/> Asian <input type="radio"/> Black or African American RACE <input type="radio"/> Native Hawaiian or Other Pacific Islander <input type="radio"/> White <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> Other
If Race: Asian	
Which of the following Asian racial designations best describes you? (More than 1 choice is acceptable.)* Select each value that applies:	For each value that applies, SUPPDM_QVAL where SUPPDM_QNAM = "CRACE(n)" and SUPPDM_QLABEL = "Collected Race n" where n is the choice value. CRACE05-CRACE10
If Race: Black or African American	
Which of the following black or african american racial designations best describes you? (More than 1 choice is acceptable.)* Select each value that applies:	For each value that applies, SUPPDM_QVAL where SUPPDM_QNAM = "CRACE(n)" and SUPPDM_QLABEL = "Collected Race n" where n is the choice value. CRACE11-CRACE17

CDASH DM Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions		Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
Section 1											
1	What is the subject's year of birth?	Birth Date	Record the subject's year of birth (e.g., YYYY, a 4-digit year).	Date	BRTHDTC	BRTHDAT					
2	What is the sex of the subject?	Sex	Record the appropriate sex (e.g., Female, Male).	Text	SEX	SEX		(SEX)	Female; Male; Unknown; Undifferentiated		
3	Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	Ethnicity	Record the participants self-report ethnicity.	Text	ETHNIC	ETHNIC		(ETHNIC)	Hispanic or Latino; Not Hispanic or Latino; Not Reported; Unknown		
4	Which of the following racial designations best describes you? (More than 1 choice is acceptable.)	Race	Record the participant self-report race,	Text	RACE1-RACE6	RACE SUPPDM.QVAL	RACE or RACE="MULTIPLE" and each Race is represented as a SUPPDM.QVAL where SUPPDM.QNAM = RACE(n) and SUPPDM.QLABEL = Race (n)	(RACE)	AMERICAN INDIAN OR ALASKA NATIVE; ASIAN; BLACK OR AFRICAN AMERICAN; NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER; WHITE; NOT REPORTED; UNKNOWN; OTHER		
Section 2: If the study participant answered: ASIAN or "BLACK OR AFRICAN AMERICAN"											
5	Which of the following racial designations best describes you? (More than 1 choice is acceptable.)	Race	If the subject answered "ASIAN" Select each value that applies.	Text	CRACE05-CRACE10	SUPPDM.QVAL	For each value that applies, SUPPDM.QVAL where SUPPDM.QNAM = "CRACE(n" and SUPPDM.QLABEL = "Collected Race n" where n is the choice value.		ASIAN AMERICAN; ASIAN INDIAN; BANGLADESHI; CHINESE; JAPANESE; KOREAN;		
6	Which of the following racial designations best describes you? (More than 1 choice is acceptable.)	Race	If the subject answered "BLACK OR AFRICAN AMERICAN".Select each value that applies.	Text	CRACE11-CRACE17	SUPPDM.QVAL	For each value that applies, SUPPDM.QVAL where SUPPDM.QNAM = "CBACE(n" and SUPPDM.QLABEL = "Collected Race n" where n is the choice value.		AFRICAN; AFRICAN AMERICAN; AFRICAN CARIBBEAN; BAHAMIAN; BARBadian; BLACK; BLACK CENTRAL AMERICAN;		

This is an example SDTM dataset. This dataset includes information that is expected to be provided, but not usually collected directly on the Demography CRF. This includes RFSTDTC, RFENDTC, RFXSTDTC, RFXENDTC, RFCSTDTC, RFCENDTC, RFICDTC. DTHDTC and DTHFL are also expected to be included. For a subject who has not died, the value of variable DTHF is null. The death date may be blank if unknown. When multiple races were self reported, the applicant recorded "MULTIPLE" as the Race and used Supplemental Qualifiers to record the self-reported race.

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC	DTHDTC	DTHFL	SITEID	INVNAM	BRTHDTC	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS	ACTARMUD	COUNTRY
1	ABC123	DM	ABC123-0001	0001	2006-10-11	2007-01-10	2006-10-11	2007-01-10	2006-10-03	2007-02-01			01	JOHNSON, M	1948-12-13	M	WHITE	NOT HISPANIC OR LATINO	A	Product A	A	Product A			USA
2	ABC123	DM	ABC123-0002	0002	2006-01-15	2006-02-28	2006-01-15	2006-02-28	2006-01-04	2006-03-26			01	JOHNSON, M	1955-03-22	M	WHITE	NOT HISPANIC OR LATINO	B	Product B	B	Product B			USA
3	ABC123	DM	ABC123-0003	0003	2006-01-16	2006-03-19	2006-01-16	2006-03-19	2006-01-02	2006-03-19			01	JOHNSON, M	1938-01-19	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	B	Product B	B	Product B			USA
4	ABC123	DM	ABC123-0004	0004					2006-01-07	2006-01-08			01	JOHNSON, M	1941-07-02	M	ASIAN	NOT HISPANIC OR LATINO					SCREEN FAILURE		USA
5	ABC123	DM	ABC123-2001	2001	2006-02-02	2006-03-31	2006-02-02	2006-03-31	2006-01-15	2006-04-12			02	GONZALEZ, E	1950-06-23	F	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	B	Product B	B	Product B			USA
6	ABC123	DM	ABC123-2002	2002	2006-02-03	2006-04-05	2006-02-03	2006-04-05	2006-01-10	2006-04-25			02	GONZALEZ, E	1956-05-05	F	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDERS	NOT HISPANIC OR LATINO	A	Product A	A	Product A			USA
7	ABC123	DM	ABC123-2003	2003					2006-02-07	2006-02-08			03	GONZALEZ, E	1945-04-06	F	MULTIPLE	NOT HISPANIC OR LATINO					SCREEN FAILURE		USA

- Row 1:** Shows USUBJID ABC123-0004 selected "JAPANESE" as the specific ASIAN race collected.
- Row 2:** Shows USUBJID ABC123-0003 selected "AFRICAN AMERICAN" as the specific BLACK OR AFRICAN AMERICAN race collected.
- Rows 3-4:** Show USUBJID ABC123-2003 specified "AMERICAN INDIAN OR ALASKA NATIVE" and "WHITE" as the race.

suppdm.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC123	DM	ABC123-0004			CRACE9	Collected Race 9	JAPANESE	CRF	
2	ABC123	DM	ABC123-0003			CRACE12	Collected Race 12	AFRICAN AMERICAN	CRF	
3	ABC123	DM	ABC123-2003			RACE5	Race 5	WHITE	CRF	
4	ABC123	DM	ABC123-2003			RACE1	Race 1	AMERICAN INDIAN OR ALASKA NATIVE	CRF	

3.3.2.5 Subject Characteristics (SC)

Subject Characteristics (SC) is a Findings domain and is an extension of demographics data, including socioeconomic or other broad characteristics. Subject characteristics may be collected periodically over time. Some examples of subject characteristics include education level, marital status, and national origin.

Associations between some subject characteristic tests and response codelists are described in the SC Codetable (available at <https://www.cdisc.org/standards/terminology/controlled-terminology>).

Example 1

This is an example CRF used to collect some basic subject characteristics data. There are 2 sections in this example. The questions in the first section focus on whether subject characteristics were collected and the questions in the second section are each subject characteristic collected. For an eCRF, if "No" is selected as the answer to the question in the first section, the second section would not be displayed.

Tobacco Implementation Guide-Subject Characteristics		
Any Subject Characteristics		
Were subject characteristics collected? <i>Indicate if subject characteristics information was collected. If Yes, record the appropriate details.</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<small>// SCPERF = "Y", NOT SUBMITTED. IF SCPERF = "N", SCSTAT where SCTESTCD = "SCALL".</small> <small>SCPERF</small>
Subject Characteristics		
What is the subject's education level?	<input type="radio"/> Did not complete Secondary School or Less than High School <input type="radio"/> Some Secondary School or High School Education <input type="radio"/> High School or Secondary School Degree Complete <input type="radio"/> Associate's or Technical Degree Complete; College or Baccalaureate Degree Complete <input type="radio"/> Doctoral or Postgraduate Education	
What is the subject's employment status?	<input type="radio"/> Full-time <input type="radio"/> Part-time <input type="radio"/> Not Employed	
What is the subject's income?	<input type="radio"/> <100% poverty guideline <input type="radio"/> 100-200% poverty guidelines <input type="radio"/> >200% poverty guidelines;	
What is the subject's marital status?	<input type="radio"/> Never Married <input type="radio"/> Married <input type="radio"/> Divorced <input type="radio"/> Legally Separated <input type="radio"/> Widowed	
What is the subject's national origin status?	<small>SCORRES WHERE SCTESTCD = "NATORIG".</small> <small>NATORIG_SCORRES</small>	
What is the subject's military status?	<input type="radio"/> No Military Service <input type="radio"/> Active Service <input type="radio"/> Veteran	

Tobacco Implementation Guide-Subject Characteristics		
Subject Characteristics		
Was the subject exposed to second hand smoke ?	<input type="radio"/> No Exposure to Second Hand Smoke <input type="radio"/> Exposure at Home Only <input type="radio"/> Exposure at work only <input type="radio"/> Exposure at Work and Home	<small>SCORRES WHERE SCTESTCD = "SHSMEXST"</small> <small>SHSMEXST_SCORES</small>
What was the age of the subject when they started smoking?	<input type="radio"/> 16-24 years <input type="radio"/> 25-34 years <input type="radio"/> 45-64 years <input type="radio"/> 65 years and older	<small>SCORRES WHERE SCTESTCD = "AGESTSMK"</small> <small>AGESTSMK_SCORES</small>
Did the subject have any tobacco cessation counseling?	<input type="radio"/> No <input type="radio"/> Yes	<small>SCORRES WHERE SCTESTCD = "TBCESSCO"</small> <small>TBCESSCO_SCORES</small>
What is the longest duration of previous abstinence from tobacco use?	<input type="radio"/> ≤7 days <input type="radio"/> 8-28 Days <input type="radio"/> 1-6 months <input type="radio"/> >6 Months	<small>SCORRES WHERE SCTESTCD = "LDURABS"</small> <small>LDURABS_SCORES</small>
<small>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</small>		

CDASH SC Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
Section 1										
1	Were subject characteristics collected?	Subject Characteristics Collected	Indicate if subject characteristics information was collected. If Yes, record the appropriate details.	Text	SCPERF	SCSTAT	If SCPERF = "Y", NOT SUBMITTED. If SCPERF = "N", SCSTAT where SCTESTCD = "SCALL".	(NY)	Yes; No	
Section 2										
2	What is the subject's education level?	Education Level	Indicate the subject's education level.	Text	EDLEVEL_SCORES	SCORRES;	SCORRES WHERE SCTESTCD = "EDLEVEL"		Did not complete Secondary School or Less than High School; Some Secondary School or High School Education; High School or Secondary School Degree Complete; Associate's or Technical Degree Complete; College or Baccalaureate Degree Complete; Doctoral or Postgraduate Education	LAST ATTEMPTED USE WITH THIS MEDICATION
3	What is the subject's employment status?	Employment Status	Indicate the subject's employment status.	Text	JOBCLAS_SCORES	SCORRES	SCORRES WHERE SCTESTCD = "JOBCLAS"	(EMPSTAT)	Full-time; Part-time; Not employed	

CDISC Tobacco Implementation Guide (Version 1.0 Final)

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
4	What is the subject's income?	Income	Indicate the subject's income.	Text	INCOME_SCORRES	SCORRES	SCORRES WHERE SCTESTCD = "INCOME"		<100% poverty guideline.;100-200% poverty guidelines; >200% poverty guidelines;	
5	What is the subject's marital status?	Marital Status	Indicate the subject's marital status.	Text	MARISTAT_SCORRES	SCORRES	SCORRES WHERE SCTESTCD = "MARISTAT"	(MARISTAT)	Never Married; Married; Legally Separated; Divorced; Widowed	
6	NATORIG_SCORRES	What is the subject's national origin status?	National Origin	Indicate the subject's national origin	NATORIG_SCORRES	SCORRES	SCORRES WHERE SCTESTCD = "NATORIG"			
7	MILTSTAT_SCORRES	What is the subject's military status?	Military Status	Indicate the subject's military status.	MILTSTAT_SCORRES	SCORRES	SCORRES WHERE SCTESTCD = "MILTSTAT"		NO MILITARY SEVICE; ACTIVE SERVICE; VETERAN;	
8	SHSMEXST_SCORRES	Was the subject exposed to second hand smoke?	Second Hand Smoke Exposure Status	Indicate the subject's exposure to second hand smoke	SHSMEXST_SCORRES	SCORRES	SCORRES WHERE SCTESTCD = "SHSMEXST"		No Exposure to Second Hand smoke; Exposure at Home only; Exposure at work only; Exposure at Work and Home;	
9	AGESTSMK_SCORRES	What was the age of the subject when they started smoking?	Age Started Smoking	Record the Age Category when the subject started smoking	AGESTSMK_SCORRES	SCORRES	SCORRES WHERE SCTESTCD = "AGESTSMK"		16-24 years; 25-34 years; 45-64 years; 65 years and older	
10	TBCESSCO_SCORRES	Did the subject have any tobacco cessation counseling?	Tobacco Cessation Counseling	Indicate whether the subject had previous tobacco cessation counseling.	TBCESSCO_SCORRES	SCORRES	SCORRES WHERE SCTESTCD = "TBCESSCO"	(NY)	Yes; No	
11	LDURABS_SCORRES	What is the longest duration of previous abstinence from tobacco use?	Longest Duration of Abstinence	Record the longest duration of tobacco abstinence	LDURABS_SCORRES	SCORRES	SCORRES WHERE SCTESTCD = "LDURABS"		≤7 days; 8-28 days; 1-6 months; >6 months	
2	What is the subject's education level?	Education Level	Indicate the subject's education level.	Text	EDLEVEL_SCORRES	SCORRES	SCORRES WHERE SCTESTCD = "EDLEVEL"		Did not complete Secondary School or Less than High School; Some Secondary School or High School Education; High School or Secondary School Degree Complete; Associate's or Technical Degree Complete; College or Baccalaureate Degree Complete; Doctoral or Postgraduate Education	LAST ATTEMPTED USE WITH THIS MEDICATION

This is an example of the SDTM dataset based on the data collected on the above CRF.

sc.xpt

Row	STUDYID	DOMAIN	USUBJID	SCSEQ	SCTESTCD	SCTEST	SCRES	SCSTRESC	SCSTAT	SCDTC
1	ABC	SC	ABC-001-001	1	NATORIG	National Origin	UNITED STATES	USA		1999-06-19
2	ABC	SC	ABC-001-001	2	MARISTAT	Marital Status	DIVORCED	DIVORCED		1999-06-19
3	ABC	SC	ABC-001-001	3	EDLEVEL	Educational Level	COLLEGE OR BACCALAUREATE DEGREE COMPLETE	COLLEGE OR BACCALAUREATE DEGREE COMPLETE		1999-06-19
4	ABC	SC	ABC-001-001	4	MILSTAT	Military Status	VETERAN	VETERAN		1999-06-19
5	ABC	SC	ABC-001-001	5	JOBCLAS	Employment Status	NOT EMPLOYED	NOT EMPLOYED		1999-06-19
6	ABC	SC	ABC-001-001	6	SHSMEXST	Second Hand Smoke Exposure Status	EXPOSURE AT WORK AND HOME	EXPOSURE AT WORK AND HOME		1999-06-19
7	ABC	SC	ABC-001-001	7	INCOME	Income	<100% POVERTY GUIDELINES	<100% POVERTY GUIDELINES		1999-06-19
8	ABC	SC	ABC-001-001	8	AGESTSMK	Age Started Smoking	16-24 years	16-24 years		1999-06-19
9	ABC	SC	ABC-001-001	9	TBCESSCO	Tobacco Cessation Counseling	N	N		1999-06-19
10	ABC	SC	ABC-001-001	10	LDURABS	Longest Duration of Abstinence	1-6 months	1-6 months		1999-06-19
11	ABC	SC	ABC-001-002	1	SCALL	Subject Characteristics			NOT DONE	2000-08-19

3.3.2.6 Medical History (MH)

Medical History (MH) is an Events domain used to represent information collected about medical conditions that started prior to the start of the study. The study timepoint at which events stop being pre-study events (medical history) is determined by the applicant according to the requirements of the study. However, the "stop" timepoint may be no earlier than the date of informed consent (which is recorded for each subject in the RFICDTC variable in the Demographics (DM) domain) and no later than the start date of the study reference period (which is recorded for each subject in the RFSTDTC variable in the DM dataset). The timepoint is usually identifiable as the point at which medical history information is collected; medical conditions starting after the collection of medical history information are often considered to be on-study events. Note: The relative timing variables used to represent medical history events as being "prior" or "ongoing" will depend on whether the collection of medical history information coincides with the start of the study reference period.

Example 1

This is an example Medical History CRF. This CRF collects verbatim descriptions of any medical conditions or events experienced by the subject. This CRF was designed to allow the applicant to use either MHENRF or MHENRTPT to represent an event was ongoing.

Tobacco Implementation Guide-Medical History		
Any Medical History Events		
Were any medical conditions or events reported? <i>Indicate if the subject experienced any medical conditions or events. If Yes, include the appropriate details where indicated on the CRF.</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes	NOT SUBMITTED MHYN
What is the category?	GENERAL MEDICAL HISTORY	MHCAT MHCAT
Medical History Events		
What is the medical condition or event identifier? <i>Applicant Defined CRF Completion Instructions</i>	MHSPID MHSPID	
What is the medical condition or event term? <i>Record all relevant medical conditions or events, as defined in the protocol. Record only one medical condition or event per line. Ensure that the medical conditions or events listed on the Medical History page do not meet any of the exclusion criteria.</i>	MHTERM MHTERM	
What was the medical event or condition start date? (DD-MMM-YYYY) <i>Record the start date of the medical event or condition</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	MHSTDTC MHSTDAT
Is the medical condition or event ongoing? <i>Record the medical condition or event as ongoing (Yes) if it has not ended at the time of data collection; the end date should be left blank.</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes	MHENRF or MHENRPT. MHONGO
What was the medical condition or event end date? (DD-MMM-YYYY) <i>Record the end date of the medical event or condition using this format</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	MHENDTA MHENDAT
<i>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</i>		

CDASH MH Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
Section 1										
1	Has the subject had any medical conditions or events?	Any Medical History	Indicate if the subject experienced any medical conditions or events. If Yes, include the appropriate details where indicated on the CRF.	Text	MHYN	N/A	Not Submitted	(NY)	No;Yes	
Section 2										
2	What is the category?	Medical History Category		Text	MHCAT	MHCAT			GENERAL MEDICAL HISTORY	
3	What is the medical condition or event identifier?	MH Number	Applicant-Defined CRF Completion Instructions	Text	MHSPID	MHSPID				
4	What is the medical condition or event term?	Medical History Term	Record all relevant medical conditions or events, as defined in the protocol. Record only one medical condition or event per line. Ensure that the medical conditions or events listed on the Medical History page do not meet any of the exclusion criteria.	Text	MHTERM	MHTERM				
5	What was the medical condition or event start date?	Start Date	Record the start date of the medical event or condition using this format (DD-MON-YYYY).	Date	MHSTDAT	MHSTDTC				
6	Is the medical condition or event ongoing?	Ongoing	Record the medical condition or event as ongoing (Yes) if it has not ended at the time of data collection; the end date should be left blank.	Text	MHONGO	MHENRF/ MHENRTPT	MHENRF or MHENRTPT	(NY)	No;Yes	
7	What was the medical condition or event end date?	End Date	Record the end date of the medical event or condition using this format (DD-MON-YYYY).	Date	MHENDTC	MHENDAT				
2	What is the category?	Medical History Category		Text	MHCAT	MHCAT			GENERAL MEDICAL HISTORY	

This is an example SDTM dataset used to represent the medical history collected on the above CRF. This CRF was designed to allow the applicant to use either MHENRF or MHENRTPT to represent an event that was ongoing. This SDTM dataset uses MHENRTPT. (For more information, see Section 2.8.7.6, [Representing References and Relative Timing](#).)

Rows 1-2: The reported events were coded using a standard dictionary. MHDECOD and MHBODSYS display the preferred term and body system assigned through the coding process. MHENRTPT was populated based on the response to the "Ongoing" question on the Medical History CRF. MHENTPT displays the reference date for MHENRTPT (i.e., the date the information was collected). If "Yes" was specified for Ongoing, MHENRTPT = "ONGOING"; if "No" was checked, MHENRTPT = "BEFORE".

Row 3: Displays the start and end date of the reported event.

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHSPID	MHTERM	MHDECOD	MHCAT	MHBODSYS	MHSTDTC	MHENDTC	MHENRTPT	MHENTPT
1	ABC123	MH	123101	1	01	ASTHMA	Asthma	GENERAL MEDICAL HISTORY	Respiratory system disorders	2003		ONGOING	2004-09-18
2	ABC123	MH	123101	2	02	FREQUENT HEADACHES	Headache	GENERAL MEDICAL HISTORY	Central and peripheral nervous system disorders	2004-07		ONGOING	2004-09-18
3	ABC123	MH	123101	3	03	BROKEN LEG	Bone fracture	GENERAL MEDICAL HISTORY	Musculoskeletal system disorders	2005-07-15	2005-08-31		

3.3.2.7 Prior Usage of Recreational Products (Including Tobacco Products) (SU, FASU, CM, FACM)

The Interventions general-observation class domains are used to represent investigational, therapeutic, and other products administered to a subject (with some actual or expected physiological effect) either as specified by the study protocol—for example, exposure to study product coincident with the study assessment period (e.g., concomitant medications)—or self-administered by the subject (e.g., use of alcohol, tobacco, caffeine).

Recreational drugs are chemical substances taken for enjoyment or leisure purposes, rather than for medical reasons. They are often drugs that are misused or abused or drugs self-administered by the subject. To support standardization, CDISC defined a Substance Use (SU) domain. This domain is used to represent interventions that involve substances used for non-medical purposes and which often may be harmful to the individual or others (e.g., alcohol, marijuana, tobacco).

Other domains have been established to record other types of interventions. Interventions administered to the subject coincident with the study assessment period are referred to as "concomitant medications" and represented in the Concomitant/Prior Medications (CM) domain; interventions administered as protocol-specified study products are represented in the Exposure (EX) and Exposure as Collected (EC) domains.

In trials studying tobacco products, tobacco products being used for non-medical purposes will be represented in the SU domain. However, products used to reduce the usage of these self-administered tobacco products will be considered either concomitant medications or the product under study.

The examples provided here illustrate the different ways a subject's history of recreational product usage may be collected in studies.

Note:

- The Findings About Events or Interventions structure ("FA structure") is used to represent collected data that are findings about an event or intervention that cannot be represented within an event or intervention record or as a supplemental qualifier to such a record. Not all findings associated with an event or intervention should be represented in the FA structure.
- The Findings About Events or Interventions (FA-) is a specialization of the Findings general observation class. It shares all qualities and conventions of findings observations but is specialized by the addition of the --OBJ variable.

Example 1

This example CRF collects data on all types of recreational products previously used by the subject. The applicant only collected the general type of product used; the actual dates of usage were not collected. The subject provided the duration of use. Usage of these recreational products is represented in the SU domain.

There are 2 sections of this example CRF: The questions in the first section focus on the whether any recreational products were used, and the questions in the second section are for each recreational product used. The applicant did not include subjects that did not use recreational products in the SDTM dataset. In order to save space, some of the permissible values are only shown in the metadata specifications.

The metadata/specification in the first section focus on the whether any recreational products were used. The metadata/specification in the second section focus on each recreational product used.

Tobacco Implementation Guide -Recreational Product Usage		
Any Recreational Products Used		
Substance Use Category	RECREATIONAL PRODUCT	SUCAT SUCAT
Were any recreational products used? <i>Indicate if the subject had ever used any recreational products.</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Not Done	SUSTAT = "NOT DONE" and SUTRT = "RECREATIONAL PRODUCT" SUYN
What was the reason the recreational product usage was not done? <i>Record the reason recreational product usage was not done.</i>		SUREASND SUREASND
Recreational Products Used		
What was the recreational product used? <i>Record each recreational product used on a new line.</i>		SUTRT SUTRT
Does the subject currently use or formerly use recreational product?	<input type="radio"/> Formerly <input checked="" type="radio"/> Current	SUSTPT, SUSRPT, SUENPT; SUENRPT; SUPRESP SUNCF
What was the amount of the recreational product used? <i>Indicate the amount of recreational product the subject consumes on a regular basis.</i>		SUDOSE or SUDOSTXT SUDSTXT
What was the dose unit? <i>Record the unit. See the protocol for a list of units to use.</i>		SUDOSU SUDOSU
What was the frequency of recreational product use? <i>Record how often the recreational product was taken (e.g., BID, PRN).</i>	<input type="radio"/> Occasional <input checked="" type="radio"/> Intermittent <input type="radio"/> Daily <input type="radio"/> PRN <input type="radio"/> Unknown	SUDOSFRQ SUDOSFRQ
CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).		

CDASH SU Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
Section 1										
1	What is the category of the substance used?	Substance Use Category	Record the recreational product category, if not pre-printed on the CRF.	Text	SUCAT				RECREATIONAL PRODUCT	
2	Were any recreational products used?	Any Recreational Product Used	Indicate if the subject had used any recreational products.	Text	SUYN		SUSTAT = "NOT DONE" and SUTRT = "RECREATIONAL PRODUCT" where SUYN = "Not Done"	(NY)	Yes; No; Not Done	

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
3	What was the reason the recreational product use was not done?	Reason Not Done	Record the reason recreational product use was not done.	Text	SUREASND	SUREASND				
Section 2										
4	What was the recreational product used?	Type of Recreational Product Used	Record each recreational product used on a new line.	Text	SUTRT				Alcohol; Tobacco; Marijuana; Hallucinogen Drugs; Non-medical prescription drugs use; Stimulants; Other	
5	Does the subject currently use or formerly used recreational products?	Usage	Check the appropriate box to indicate if the subject currently or formerly used recreational products.	Text	SUNCF	SUSTTPT; SUSTRPT; SUENTPT; SUENRPT; SUPRESP			(NCF)	FORMERLY:CURRENT;
6	What was the amount of the recreational product used?	Amount	Indicate the amount of recreational drug the subject consumes on a regular basis.	Text	SUDOSE; SUDOSTXT					
7	SUDOSU	What was the unit?	Record the unit. See the protocol for a list of units.	Text	SUDOSU	SUDOSU	(UNIT)			
8	SUDOSFRQ	What was the frequency of recreational product use?	Record how often the subject regularly uses the recreational product.	Text	SUDOSFRQ		(FREQ)		Occasionally; Intermittent; Daily; PRN; Unknown	

This is the SDTM dataset used to represent the above collected data. The applicant populated SUPRESP="Y" for all substances specified in the drop-down list on the CRF. Other substances were not considered prespecified.

- Row 1:** Shows that the subject was using cigarettes before the baseline visit and was expected to continue to use cigarettes after the baseline visit. The baseline visit occurred on 2006-01-01. This is represented using SUSTTPT, SUSTRPT, SUENTPT and SUENRPT. SUPRESP is used to indicate that the use of cigarettes was solicited on the CRF.
- Row 2:** Shows the subject uses marijuana starting in 2002 and stopped using it on the day of the baseline visit. SUPRESP is used to indicate that the use of marijuana was solicited on the CRF.
- Row 3:** Subject 1234006 is a former smoker. The date this subject began smoking is unknown, but it was sometime before the assessment date; this is shown by the values of SUSTTPT and SUSTRPT. The end date of smoking was collected, so SUENTPT and SUENRPT are not populated. Instead, the end date is in SUENDTC.
- Row 4:** Shows the subjects had missing data for the usage of recreational products; this is indicated by SUSTAT = "NOT DONE". The reason is in SUREASND.

SU.xpt

Row	STUDYID	DOMAIN	USUBJID	SUSEQ	SUTRT	SUCAT	SUPRESP	SUSTAT	SUREASND
1	1234	SU	1234005	1	CIGARETTES	RECREATIONAL PRODUCT	Y		
2	1234	SU	1234005	2	MARIJUNA	RECREATIONAL PRODUCT	Y		
3	1234	SU	1234006	1	CIGARETTES	RECREATIONAL PRODUCT	Y		
4	1234	SU	1234007	1	RECREATIONAL PRODUCT	RECREATIONAL PRODUCT		NOT DONE	Subject left office before CRF was completed
Row	SUDOSE	SUDOSU	SUDOSFRQ	SUSTDTC	SUENDTC	SUSRTRPT	SUSTTPT	SUENRPT	SUENTPT
1	2	PACK	QD			BEFORE	2006-01-01	ONGOING	2006-01-01
2				2002	2006-01-01				
3	1	PACK	QD		2003	BEFORE	2006-03-15		
4									

Example 2

This example CRF illustrates how tobacco use history data could be collected—including cigarettes, cigars, pipes, chewing tobacco, snus or tobacco pouches, or tobacco dips; this example does not include tobacco products used as a medically acceptable therapy for smoking cessation. The specific brand name of the product was collected. The applicant collected whether the product was still being used, and if not, the end date of usage. Usage of these products is represented in the SU domain.

Tobacco Implementation Guide_Tobacco Usage History		
Tobacco Usage History		
What is the object?	TOBACCO <small>FAOBJ FAOBJ</small>	
What was the age of the subject when they started smoking? <i>Record the Age Category when the subject started smoking</i>	<input type="radio"/> 16-24 years <input type="radio"/> 25-34 years <input type="radio"/> 45-64 years <input type="radio"/> 65 years and older <small>FAORRES WHERE FATESTCD = "AGESTSMK" and FAOBJ = "TOBACCO" AGESTSMK_FAORRES</small>	
Did the subject have any tobacco cessation counseling? <i>Indicate whether the subject had previous tobacco cessation counseling</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes <small>FAORRES WHERE FATESTCD = "TBCESSCO" and FAOBJ = "TOBACCO" TBCESSCO_FAORRES</small>	
What is the longest duration of previous abstinence from tobacco use? <i>Record the longest duration of tobacco abstinence</i>	<input type="radio"/> ≤7 days <input type="radio"/> 8-28 days <input type="radio"/> 1-6 months <input type="radio"/> >6 months <small>FAORRES WHERE FATESTCD = "TBCESSCO" and FAOBJ = "TOBACCO" LDURABS_FAORRES</small>	
Tobacco Product Used		
What is the type of tobacco product used by the subject? <i>Record the type of tobacco product used</i>	<input type="radio"/> Smoked Tobacco Product <input checked="" type="radio"/> Smokeless Tobacco Product <small>SUCAT SUCAT</small>	
What was the brand name of the tobacco product? <i>Record the brand name of the tobacco product used</i>	<small>SUTRT SUTRT</small>	
Is this the subject's usual brand of tobacco product? <i>Indicate if this is the subject's usual brand of tobacco product used</i>	<input type="radio"/> Usual Brand <input checked="" type="radio"/> Not Usual Brand <small>SUSCAT</small>	
What was the duration of use of the tobacco product ? <i>Provide the duration for the product used</i>	<small>SUDUR SUCDUR</small>	
What is the unit? <i>Select the appropriate duration unit for the product used</i>	<small>SUDUR SUCDURU</small>	
Is the tobacco use ongoing? <i>Record the product used as ongoing if the subject has not stopped taking the product used at the time of data collection. The end date should be left blank.</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes <small>SUENP or SUENRPT SUONGO</small>	
What is the end date? (DD-MMM-YYYY) <i>Record the date the product used was stopped. If the subject has not stopped taking the product used leave this field blank</i>	<input type="text"/> <small>SUENDAT SUENDAT</small>	
CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).		

CDASH FA/SU Metadata Specifications

Order	Question Text	Prompt	CRF Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology Code List Name	Permissible Values	Pre-Populated Value
Section 1										
1	What is the object?			Text	FAOBJ	FAOBJ				TOBACCO
2	What was the age of the subject when they started smoking?	Age Started Smoking	Record the Age Category when the subject started smoking	Text	AGESTSMK_FAORRES	FAORRES	FAORRES WHERE FATESTCD = "AGESTSMK" and FAOBJ = "TOBACCO"		16-24 years; 25-34 years; 45-64 years; 65 years and older	
3	Did the subject have any tobacco cessation counseling?	Tobacco Cessation Counseling	Indicate whether the subject had previous tobacco cessation counseling	Text	TBCESSCO_FAORRES	FAORRES	FAORRES WHERE FATESTCD = "TBCESSCO" and FAOBJ = "TOBACCO"	(NY)	No;Yes	
4	What is the longest duration of previous abstinence from tobacco use?	Longest Duration of Abstinence	Record the longest duration of tobacco abstinence	Text	LDURABS_FAORRES	FAORRES	FAORRES WHERE FATESTCD = "LDURABS" and FAOBJ = "TOBACCO"		≤7 days; 8-28 days; 1-6 months; >6 months	
Section 2										
5	What is the type of tobacco product used by the subject?	Substance Use Category	Record the type of tobacco product used.	Text	SUCAT	SUCAT			SMOKED TOBACCO PRODUCT; SMOKELESS TOBACCO PRODUCT (e.g., CHEWING TOBACCO, SNUFF, DIP, SNUS, or DISSOLVABLE TOBACCO PRODUCT)	
6	What was the brand name of the tobacco product?	Product Name	Record the brand name of the tobacco product used.	Text	SUTRT	SUTRT				
7	Is this the subject's usual brand of tobacco product?	Substance Use Subcategory	Indicate if this is the subject's usual brand of tobacco product used	Text	SUSCAT	SUSCAT			USUAL BRAND; NOT USUAL BRAND	
9	What was the duration of use of the tobacco product?	Duration	Provide the duration for the product used	Text	SUCDUR	SUDUR				
9	What was the unit of duration of use of the tobacco product?	Unit	Select the appropriate duration unit for the product used	Text	SUCDURU	SUDUR			DAYS; MONTHS; YEARS;	
10	Is the tobacco use ongoing?	Ongoing	Record the product used as ongoing if the subject has not stopped taking the product used at the time of data collection. The end date should be left blank.	Text	SUONGO	SUENRF; SUENRPT	SUENRF or SUENRPT	(NY)	No;Yes	
11	What was the end date?	End Date	Record the date the product used was	Date	SUENDAT	SUENDTC				

Order	Question Text	Prompt	CRF Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology Code List Name	Permissible Values	Pre-Populated Value
			stopped using this format (DD-MON-YYYY). If the subject has not stopped taking the product used leave this field blank.							

The example SDTM datasets used to represent the collected data are shown below.

SUTRT represents the brand name of the tobacco product. The applicant added the UPC code of the product to the dataset. Some applicants may collect the UPC code on the CRF. The duration was represented using ISO 8601 duration format. The applicant used the first visit date to populate SUSTPT and SUENTPT.

Row 1: Shows that the subject used the tobacco product shown in SUTRT. SUCAT and SUSCAT categorize the product used. The dates of use were not known, but SUSTPT, SUSTRPT, SUENTPT and SUENRPT indicate that the use started before the visit and was still ongoing,

Row 2: Shows that the subject used smokeless tobacco product shown in SUTRT. This was not the subject's usual brand of smokeless tobacco product.

su.xpt

Row	STUDYID	DOMAIN	USUBJID	SUSEQ	SUTRT	SUCAT	SUSCAT	SUDUR	SUENDTC	SUSTRPT	SUSTPT	SUENRPT	SUENTPT
1	TB901	SU	TB901005	1	XYZ Menthol King Size	SMOKED TOBACCO PRODUCT	USUAL BRAND	P20Y		BEFORE	2006-01-01	ONGOING	2006-01-01
2	TB901	SU	TB901006	2	AAA Chewing Tobacco	SMOKELESS TOBACCO PRODUCT	NOT USUAL BRAND	P3M	2006-01-01	BEFORE	2006-01-01		

The additional information was represented as findings about events (FASU). For the general questions about tobacco usage, the applicant assigned FAOBJ to "TOBACCO". Otherwise, the name of the tobacco product (SUTRT) associated with the data in the row was represented in FAOBJ. The UPC code was used by the applicant to identify the product. FADTC is the date of collection, in this situation the applicant used the visit date.

fasu.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU	VISITNUM	FADTC
1	TB901	FA	TB901005	1	AGESTSMK	Age Started Smoking	TOBACCO	16-24	Years	16-24		Years	1	2006-01-01
2	TB901	FA	TB901005	2	TBCESSCO	Tobacco Cessation Counseling	TOBACCO	N		N			1	2006-01-01
3	TB901	FA	TB901005	3	LDURABS	Longest Duration of Abstinence	TOBACCO	>6 months		>6 months			1	2006-01-01
4	TB901	FA	TB901005	4	UPCCODE	UPC Code	XYZ Menthol King Size	974411001532		974411001532	974411001532		1	2006-01-01
5	TB901	FA	TB901005	5	UPCCODE	UPC Code	AAA Chewing Tobacco	974411001532		974411001532	974411001532		1	2006-01-01

3.3.2.8 Concomitant Medication (Including Products Related to Nicotine Dependency) (CM, FACM)

Concomitant Medication (CM) is an Interventions domain is used to represent information relating to concomitant and prior medications used by the subject, such as those given on an as-needed basis or condition-appropriate medications. The same basic data collection variables should be collected for all medications, treatments, and therapies (prior, general concomitant medications, and medications of interest). Recreational substances are not represented in this domain (see Section 3.3.2.7, [Prior Usage of Recreational Products \(Including Tobacco Products\) \(SU, FASU, CM, FACM\)](#)), but rather medical products recognized to reduce nicotine dependence (e.g., nicotine replacement patches).

Example 1

This is an example CRF used to collect general concomitant medications/products in a study. This CRF was designed to allow the applicant to use either CMENRF or CMENRTPT to represent an intervention was ongoing. In order to save space, some of the example permissible values are only shown in the metadata specifications.

Tobacco Implementation Guide-Concomitant Medications		
Any Concomitant Medications		
Were any concomitant medications/products taken? <i>Indicate if the subject took any concomitant medications/products. If Yes, include the appropriate details where indicated on the CRF.</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes	NOT SUBMITTED CMYN
Medications		
What is the category for the concomitant medication/product? <i>Record the medication category, if not pre-printed on the CRF.</i>	CMCAT CMCAT	
What is the line number? <i>If collected on the CRF, sponsor may insert instructions to ensure each record has a unique identifier.</i>	CMSPID CMSPID	
What was the medication/product? <i>Record only one medication/product per line. Provide the full trade or proprietary name of the medication/product; otherwise, record the generic name</i>	CMIRT CMIRT	
For what indication was the medication/product taken? <i>Record the reason the medication/product was taken based on clinical investigator's evaluation. If taken to treat a condition, and a diagnosis was made, the indication should be the diagnosis. If taken to treat a condition, and no diagnosis was made, the indication should be the signs and symptoms. If taken as prophylaxis, report as "Prophylaxis for" and include a description of the condition(s).</i>	CMINDC CMINDC	
What was the individual dose of the medication/product? <i>Record the dose of medication/product.</i>	CMDSTXT or CMDOSE CMDSTXT	

What is the unit? Record the dose unit of the dose of medication/product [e.g., mg.]	CMDOSU CMDOSU
What was the dose form of the medication/product? Record the pharmaceutical dosage form (e.g., TABLET CAPSULE, SYRUP) of delivery for the medication/product taken	CMDOSFRM CMDOSFRM
What was the route of administration of the medication/product? Provide the route of administration for the medication/product.	CMRROUTE CMROUTE
What was the frequency of the medication/product? Record how often the medication/product was taken (e.g., BID, PRN).	CMDOSFREQ CMDOSFREQ
What was the medication/product dose start date? (DD-MMM-YYYY) <i>Record the date the medication/product was first taken. If the subject has been taking the medication/product for a considerable amount of time prior to the start of the study, it is acceptable to have an incomplete date. Medication/product taken during the study are expected to have a complete start date. Prior medication/product that are exclusionary should have both a start and end date.</i>	<input type="text"/> / <input type="text"/> CMSSTDTC CMSSTDAT
Is the medication/product ongoing? <i>Record the medication/product as ongoing if the subject has not stopped taking the medication/product at [the timepoint defined by the study]. If the medication/product is ongoing, the end date should be left blank</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes CMEONRF or CMEONRTPT CMONGO
What was the end date? (DD-MMM-YYYY) <i>Record the date the medication/product was stopped. If the subject has not stopped taking the medication/product leave this field blank.</i>	<input type="text"/> / <input type="text"/> CMEENDTC CMEENDAT
<i>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</i>	

CDASH CM Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
Section 1										
1	Were any concomitant medications/products taken?	Any Concomitant Medications/Products	Indicate if the subject took any concomitant medications/products. If Yes, include the appropriate details where indicated on the CRF.	Text			Not Submitted	(NY)		
Section 2										
2	What is the category for the concomitant medication/product?	Concomitant Medication/Product Category	Record the medication/product category, if not pre-printed on the CRF.	Text	CMCAT	CMCAT			GENERAL	
3	What is the medication/product line number?	CM Line Number	If collected on the CRF, applicant may insert instructions to ensure each record has a unique identifier.	Text	CMSPID	CMSPID				
4	What was the medication/product?	Medication/Product	Record only one medication/product per line. Provide the full trade or proprietary name of the medication/product; otherwise, record the generic name.	Text	CMTRT	CMTRT				
5	For what indication was the medication/product taken?	Indication	Record the reason the medication/product was taken based on clinical investigator's evaluation. If taken to treat a condition, and a diagnosis was made, the indication should be the diagnosis. If taken to treat a condition, and no diagnosis was made, the indication should be the signs and symptoms. If taken as prophylaxis, report as "Prophylaxis for" and include a description of the condition(s).	Text	CMINDC	CMINDC				
6	What was the individual dose of the medication/product?	Dose	Record the dose of medication/treatment per administration (e.g., 200).	Text	CMDOSTXT OR CMDOSE	CMDOSTXT/ CMDOSE				
7	What is the unit?	Unit	Record the dose unit of the dose of medication/product taken (e.g., mg).	Text	CMDOSU	CMDOSU	(UNIT)	CAPSULE; g; IU; mg; mL; PUFF; TABLET; ug		
8	What was the dose form of the medication/product?	Dose Form	Record the pharmaceutical dosage form (e.g., TABLET CAPSULE, SYRUP) of delivery for the medication/product taken.	Text	CMDOSFRM	CMDOSFRM	(FRM)	AEROSOL; CAPSULE; CREAM; GAS; GEL; OINTMENT; PATCH; POWDER; SPRAY; SUPPOSITORY; SUSPENSION; TABLET		
9	What was the frequency of the medication/product?	Frequency	Record how often the medication/product was taken (e.g., BID, PRN).	Text	CMDOSFRQ	CMDOSFRQ	(FREQ)	BID; PRN; QD; QID; QM; QOD; TID		
10	What was the route of administration of the medication/product?	Route	Provide the route of administration for the medication/product.	Text	CMROUTE	CMROUTE	(ROUTE)	INTRAESIONAL; INTRAMUSCULAR; INTRAOULAR; INTRAPERITONEAL; NASAL; ORAL; RECTAL; RESPIRATORY (INHALATION); SUBCUTANEOUS; TOPICAL; TRANSDERMAL; VAGINAL		
11	What was the start date?	Start Date	Record the date the medication/treatment was first	Date	CMSTDTC	CMSTDAT				

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
			taken using this format. If the subject has been taking the medication/product for a considerable amount of time prior to the start of the study, it is acceptable to have an incomplete date. Medications/Products taken during the study are expected to have a complete start date. Prior medications/products that are exclusionary should have both a start date and an end date.							
12	Is the medication ongoing?	Ongoing	Record the medication/product as ongoing if the subject has not stopped taking the medication/product at the time of data collection and the end date should be left blank.	Text	CMENRF OR CMENRTPT	CMENRF or CMENRTPT	(NY)	No; Yes		
13	What was the end date?	End Date	Record the date the medication/product was stopped using this format. If the subject has not stopped taking the medication/product leave this field blank.	Date	CMENDTC	CMENDAT				

This is the SDTM dataset associated with the preceding example CRF. This SDTM dataset used CMENRF to represent ongoing interventions. More information can be found in Section 2.8.7.6, [Representing References and Relative Timing](#).

The applicant included CMDECOD. The applicant is required to provide the dictionary name and version in the Define-XML document.

Rows 1-4: The subject reported each instance of aspirin use. The frequency of each instance is represented in CMDOSFRQ and is ONCE.

Rows 6-8: The subject reports the use of 3 medications. Diovan and Zoloft were still being taken by the subject, Astelin was a nasal spray where 2 sprays were taken twice a day in each nostril. Note that only partial start dates are provided for Diovan and Zoloft.

Row 9: The subject took aspirin with a frequency of "PRN". This approach assumes that knowing exactly when aspirin was used is not important for evaluating the product in this study.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMDECOD	CMINDC	CMCLAS	CMDOSE
1	ABC123	CM	ABC123-0001	1	ASPIRIN	acetylsalicylic acid	MIGRAINE	ANALGESICS	100
2	ABC123	CM	ABC123-0001	2	ASPIRIN	acetylsalicylic acid	MIGRAINE	ANALGESICS	100
3	ABC123	CM	ABC123-0001	3	ASPIRIN	acetylsalicylic acid	MIGRAINE	ANALGESICS	100
4	ABC123	CM	ABC123-0001	4	ASPIRIN	acetylsalicylic acid	MIGRAINE	ANALGESICS	100
5	ABC123	CM	ABC123-0001	5	ASPIRIN	acetylsalicylic acid	MIGRAINE	ANALGESICS	100
6	ABC123	CM	ABC123-0002	1	DIOVAN	valsartan	HYPERTENSION	ANTIHYPERTENSIVES	20
7	ABC123	CM	ABC123-0002	2	ZOLOFT	sertraline	PANIC ATTACKS	PSYCHOANALEPTICS	50
8	ABC123	CM	ABC123-0002	3	ASTELIN	azelastine	INFLUENZA	NASAL PREPARATIONS	
9	ABC123	CM	ABC123-0002	4	ASPIRIN	acetylsalicylic acid	PAIN	ANALGESICS	100

Row	CMDOSTXT	CMDOSU	CMDOSFRM	CMDOSFRQ	CMROUTE	CMSTDTC	CMENDTC	CMENRF
1		mg	TABLET	ONCE	ORAL	2006-10-14	2006-10-14	
2		mg	TABLET	ONCE	ORAL	2006-10-15	2006-10-15	
3		mg	TABLET	ONCE	ORAL	2006-10-16	2006-10-16	
4		mg	TABLET	ONCE	ORAL	2006-10-17	2006-10-17	
5		mg	TABLET	ONCE	ORAL	2006-01-18	2006-01-18	
6		mg	TABLET	BID	ORAL	2004		AFTER
7		mg	TABLET	OD	ORAL	2004-01		AFTER

Row	CMDOSTXT	CMDOSU	CMDOSFRM	CMDOSFRQ	CMROUTE	CMSTDTC	CMENDTC	CMENRF
8	2 sprays in each nostril-137 mcg	mcg	SPRAY	BID	NASAL	2006-02-26		AFTER
9		mg	TABLET	PRN	ORAL	2004-01-01		AFTER

Example 2

In this example, the applicant collected information on previous medically recognized products used to reduce nicotine dependency at the baseline visit. The applicant only collected details on the last attempt to reduce nicotine dependency for each type of product used. These products are represented in the Concomitant Medication (CM) domain.

Tobacco Implementation Guide-Medications Used for Nicotine Dependency		
Medications		
What was the medically recognized product name?	DRUG USED IN NICOTINE DEPENDENCE	CMTRT CMTRTC
Pre-Specified Intervention	Y	CMPRESP CMPRESP
Did the subject previously use medically recognized products to reduce nicotine dependency? <i>Indicate if the subject had used any medically acceptable products to attempt to reduce nicotine dependency</i>	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Done	CMOCCUR CMOCCUR
How many times did the subject attempt to use medically recognized products to attempt to reduce nicotine dependency? <i>Record the number of times a subject attempted to use medically recognized products to reduce nicotine dependency</i>	1	FAORRES where FAOBJ = "MEDICATION USED IN NICOTINE DEPENDENCE" and FATEST = Total Number FAORRES
Category Applicant Defined	ATTEMPTS TO REDUCE NICOTINE DEPENDENCE	FACAT FACAT
LAST ATTEMPT FOR EACH MEDICATION TYPE		
What is the category of the medication/product the subject used to attempt to reduce nicotine dependency?	<input checked="" type="radio"/> Nicotine Replacement Therapy (NRT) <input type="radio"/> Not a NRT	CMCAT CMCAT

What is the medication/product subcategory, if not pre-printed on the CRF. <i>Applicant Defined</i>	LAST ATTEMPTED USE WITH THIS MEDICATION CMSCAT CMSCAT
What was the name of the medication/product the subject used to reduce nicotine dependency? <i>Record only one medication/product per line. Provide the full trade or proprietary name of the medication/product; otherwise, record the generic name.</i>	CMTRT CMTRT
What was the duration of the medication/product used to reduce nicotine dependency for the last attempt? <i>Provide the duration of the medication/product used.</i>	1 1 1 1 1 . 1 CMDUR CMCDUR
What was the duration unit of the medication/product used to reduce nicotine dependency for the last attempt? <i>Select the appropriate duration unit of the medication/product used.</i>	<input checked="" type="radio"/> Days <input type="radio"/> Month <input type="radio"/> Years CMDUR CMDURU
<i>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</i>	

CDASH CM Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
1	What was the medically recognized product name?	Medication		Text	CMTRTC	CMTRT				DRUG USED IN NICOTINE DEPENDENCE
2		Pre-Specified Intervention		Text	CMPRESP	CMPRESP				Y
3	Did the subject previously use medically recognized products to reduce nicotine dependency?	Any Medically Recognized Products Taken For Nicotine Dependency	Indicate if the subject had used any medically recognized products to attempt to reduce nicotine dependency	Text	CMOCCUR	CMOCCUR		(NY)	No;Yes;Not Done	
4	How many times did the subject attempt to use use medically recognized products to reduce nicotine dependency	Times the Subject Attempted to Reduce Nicotine Dependency	Record the number of times a subject attempted to use medically recognized products to reduce nicotine dependency	Text	FAORRES	FAORRES	FAORRES where FAOBJ ="MEDICATION USED IN NICOTINE DEPENDENCE" and FATEST= Total Number "			
5		Category		Text	FACAT	FACAT				ATTEMPTS TO REDUCE NICOTINE DEPENDENCE
6	What is the category of the medication/product the subject used to attempt to reduce nicotine dependency?	Medication		Text	CMTRT	CMCAT			NICOTINE REPLACEMENT THERAPY: NOT A NRT	

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
7	What is the medication/product subcategory, if not pre-printed on the CRF.	Subcategory	Applicant Defined	Text	CMSCAT	CMSCAT			LAST ATTEMPTED USE WITH THIS MEDICATION	
8	What was the name of the medication/product the subject used to reduce nicotine dependency?	Medication	Record only one medication/product per line. Provide the full trade or proprietary name of the medication/product; otherwise, record the generic name.	Text	CMTRT	CMTRT				
9	What was the duration of the medication/product used to reduce nicotine dependency for the last attempt?	Collected Duration	Provide the duration of the medication/product used.	Text	CMDUR	CMDUR				

These example SDTM datasets represent the data collected on the above CRF.

Rows 1, 3, 7, 9: Show whether the subject has used any medications to help with nicotine dependence. This was prespecified on the CRF, hence CMPRESP="Y". The applicant assigned CMTRT to "DRUG USED IN NICOTINE DEPENDENCE" which was the category name in an external dictionary.

Rows 2, 4, 5, 6, 8: Show the various medications that were used by subjects. CMSCAT is used to indicate that these data are associated with the last attempted use. CMDUR is the collected duration of the product use. This is used only if collected on the CRF and not derived from start and end date/times. CMDUR is provided using ISO 8601 duration notation. CMPRESP is null since the specific medication used is not prespecified.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMCAT	CMSCAT	CMPRESP	CMOCCUR	CMDTC	CMDUR
1	1234	CM	1234005	1	DRUG USED IN NICOTINE DEPENDENCE			Y	Y	2008-08-08	
2	1234	CM	1234005	2	NICOTINE PATCH XYZ	NICOTINE REPLACEMENT THERAPY	LAST ATTEMPTED USE WITH THIS MEDICATION				P2M
3	1234	CM	1234006	1	DRUG USED IN NICOTINE DEPENDENCE			Y	Y	2008-11-12	
4	1234	CM	1234006	2	NICOTINE GUM ABC	NICOTINE REPLACEMENT THERAPY	LAST ATTEMPTED USE WITH THIS MEDICATION				P3M
5	1234	CM	1234006	3	NICOTINE LOZENGES ABC	NICOTINE REPLACEMENT THERAPY	LAST ATTEMPTED USE WITH THIS MEDICATION				P2W
6	1234	CM	1234006	1	BUPROPION	DRUG USED IN REDUCING NICOTINE DEPENDENCE OTHER THAN NRTS	LAST ATTEMPTED USE WITH THIS MEDICATION				P1M
7	1234	CM	1234007	2	DRUG USED IN NICOTINE DEPENDENCE			Y	Y	2008-06-12	
8	1234	CM	1234007	3	VARENICLINE	DRUG USED IN REDUCING NICOTINE DEPENDENCE OTHER THAN NRTS	LAST ATTEMPTED USE WITH THIS MEDICATION				P40D
9	1234	CM	1234012	1	DRUG USED IN NICOTINE DEPENDENCE			Y	N	2008-03-05	

FACM was used to represent the total number of times the subject attempted to reduce nicotine dependency using a medically acceptable product. Only subjects who had attempted to reduce nicotine dependence are included in the FACM dataset.

facm.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTC	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC	FADTC
1	1234	FA	1234005	1	TOTNUM	Total Number	DRUG USED IN NICOTINE DEPENDENCE	ATTEMPTS TO REDUCE NICOTINE DEPENDENCE	4	4	2008-08-08
2	1234	FA	1234006	1	TOTNUM	Total Number	DRUG USED IN NICOTINE DEPENDENCE	ATTEMPTS TO REDUCE NICOTINE DEPENDENCE	5	5	2008-11-12

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC	FADTC
3	1234	FA	1234007	1	TOTNUM	Total Number	DRUG USED IN NICOTINE DEPENDENCE	ATTEMPTS TO REDUCE NICOTINE DEPENDENCE	3	3	2008-06-12

Example 3

In this example, data were collected on the previous use of smoking cessation products at the baseline visit. This example illustrates the use of CMOCCUR and CMPRESP. The reason why a product was discontinued and any use in the last 14 days was of interest.

This example CRF has 2 sections: Questions in the first section focus on whether any smoking cessation product has been used, and the questions in the second section collect each individual product used. In order to save space, some of the permissible values are only shown in the metadata specifications.

Tobacco Implementation Guide-Products Used For Smoking Cessation		
Any Products Used for Smoking Cessation		
What is the category for the medication?	SMOKING CESSION PRODUCT	CMCAT CMCAT
Were any smoking cessation products taken? <i>Indicate if the subject took any smoking cessation products. If Yes, complete the next section of the form.</i>	<input type="radio"/> Yes <input type="radio"/> No	CMOCCUR ANY_CMOCCUR
Smoking Cessation Product		
For each smoking cessation product listed, complete the requested information. If multiple other products are used, create a row for each other product.		
Smoking Cessation Product* <i>Select the smoking cessation product.</i>	CMTRT; CMPRESP; // CMTRT="OTHER" Then CMTRT and CMPRESP are NULL CMTRT	
Did the subject previously use the selected product for smoking cessation? <i>Indicate if the subject had used the selected smoking cessation product</i>	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Done	CMOCCUR CMOCCUR
What was the name of the other smoking cessation product used? <i>Indicate the Other type of product previously used.</i>	CMTRT CMTRTO	
Was the smoking cessation product discontinued due to an adverse experience? <i>Indicate if the product was discontinued due to a adverse experience.</i>	<input type="radio"/> No <input type="radio"/> Yes	If Yes then CMRSDIS = "ADVERSE EXPERIENCE" CMRSDIS
CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).		

CDASH CM Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
Section 1										
1	What is the category for the medication?	Concomitant Medication Category		Text	CMCAT					SMOKING CESSATION PRODUCT
2	Were any smoking cessation products taken?	Any Smoking Cessation Products Taken	Indicate if the subject took any smoking cessation products If yes, include the appropriate details where indicated on the CRF.	Text	CMOCCUR	CMOCCUR;	(NY)	No;Yes		
Section 2										
3	What was the smoking cessation product used?	Smoking Cessation Product	Select the smoking cessation product.	Text	CMTRT	CMTRT	CMTRT; CMPRESP; If CMTRT="OTHER" Then CMTRT and CMPRESP are NULL.		NICOTINE PATCH; NICOTINE GUM; NICOTINE LOZENGE; NICOTINE INHALER; VARENICLINE; BUPROPION; OTHER	
4	Did the subject previously use the selected medication/product for smoking cessation?	Smoking Cessation Product Used	Indicate if the subject had used the selected smoking cessation product	Text	CMOCCUR	CMOCCUR	(NY)	No; Yes		
5	What was the name of the other smoking cessation product used?	Smoking Cessation Product Other	Indicate the Other type of product previously used.	Text	CMTRTO	CMTRT				
6	Was the smoking cessation product discontinued due to an adverse experience?	Reason Smoking Cessation Product Discontinued	Indicate if the product was discontinued due to an Adverse Experience	Text	CMRSDISC	CMRSDISC	If Yes then CMRSDISC = "ADVERSE EXPERIENCE"	(NY)	No;Yes:	
7	What was the last date the product was used?	Last Date Smoking Cessation Product Used	Indicate the last date the product was used. If the product was used with the last 14 days, a complete date must be recorded. Otherwise, partial dates can be recorded.	Date	CMENDAT	CMENDTC				

This is the SDTM date for the data collected above. In this example, the applicant only represented whether the product was used in the last 14 days. CMPRESP was populated by the applicant for all prespecified products. Medication specified as "OTHER" were not considered prespecified.

- Row 1:** Shows the subject reported they had not previously used any smoking cessation product (CMOCCUR ="N"). CMPRESP was included to indicate that the use of smoking cessation product was specifically asked on the CRF.
- Rows 2, 5, 8, 11, 14, 17:** Show the subject reported they had used a smoking cessation product (CMOCCUR ="Y") . CMPRESP was included to indicate that the use of a smoking cessation product was specifically asked on the CRF.
- Rows 3, 6, 9, 12, 15, 18:** Show the subject reported they had not used nicotine patches (CMOCCUR is "N"). Note that all other rows for the products not used are not shown for simplicity; CMPRESP is used to represent that this product was prespecified.
- Rows 4, 7, 10, 13, 16:** Show the subject reported using the product specified in CMTRT. CMENDTC indicates the last day the product was used. CMPRESP is used to represent that this product was prespecified. CMOCCUR is Y. Subject ABC-0006 discontinued BUPROPION for an adverse event.

Row 19: Shows the subject used natural supplement ABC for smoking cessation. Since this product was not specified on the CRF, CMPRESP is null.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMCAT	CMPRESP	CMOCCUR	CMRSDISC	CMDTC	CMENDTC
1	ABC	CM	ABC-0001	1	SMOKING CESSATION PRODUCT		Y	N		2020-01-05	
2	ABC	CM	ABC-0002	1	SMOKING CESSATION PRODUCT		Y	Y		2020-02-15	
3	ABC	CM	ABC-0002	2	NICOTINE PATCH	SMOKING CESSATION PRODUCT	Y	N		2020-02-15	
4	ABC	CM	ABC-0002	3	NICOTINE GUM	SMOKING CESSATION PRODUCT	Y	Y		2020-02-15	2020-02-02
5	ABC	CM	ABC-0003	1	SMOKING CESSATION PRODUCT		Y	Y		2020-04-15	
6	ABC	CM	ABC-0003	2	NICOTINE PATCH	SMOKING CESSATION PRODUCT	Y	N		2020-04-15	
7	ABC	CM	ABC-0003	3	NICOTINE LOZENGE	SMOKING CESSATION PRODUCT	Y	Y		2020-04-15	2012
8	ABC	CM	ABC-0004	1	SMOKING CESSATION PRODUCT		Y	Y		2021-04-16	
9	ABC	CM	ABC-0004	2	NICOTINE PATCH	SMOKING CESSATION PRODUCT	Y	N		2020-04-16	
10	ABC	CM	ABC-0004	3	NICOTINE INHALER	SMOKING CESSATION PRODUCT	Y	Y		2021-04-16	2021-01
11	ABC	CM	ABC-0005	1	SMOKING CESSATION PRODUCT		Y	Y		2020-09-24	
12	ABC	CM	ABC-0005	2	NICOTINE PATCH	SMOKING CESSATION PRODUCT	Y	N		2020-09-24	
13	ABC	CM	ABC-0005	3	VARENICLINE	SMOKING CESSATION PRODUCT	Y	Y		2020-09-24	2020-08-07
14	ABC	CM	ABC-0006	1	SMOKING CESSATION PRODUCT		Y	Y		2021-04-16	
15	ABC	CM	ABC-0002	2	NICOTINE PATCH	SMOKING CESSATION PRODUCT	Y	N		2021-04-16	
16	ABC	CM	ABC-0006	3	BUPROPION	SMOKING CESSATION PRODUCT	Y	Y	ADVERSE EVENT	2021-04-16	2020-01-09
17	ABC	CM	ABC-0007	1	SMOKING CESSATION PRODUCT		Y	Y		2020-07-10	
18	ABC	CM	ABC-0002	2	NICOTINE PATCH	SMOKING CESSATION PRODUCT	Y	N		2020-07-10	
19	ABC	CM	ABC-0007	2	NATURAL SUPPLEMENT ABC	SMOKING CESSATION PRODUCT		Y		2020-07-10	2020-04-10

3.3.2.9 Electrocardiogram (EG)

The Electrocardiogram (EG) domain is a Findings domain used to represent ECG data, including the position of the subject; method of evaluation; all cycle measurements; and all findings from the ECG, including an overall interpretation, if collected. This data may be collected at the local site or at a central lab. Routine ECG data collected in studies is often collected at the study site.

Example 1

This example shows a CRF that collects electrocardiogram data utilizing a local reader.

Tobacco Implementation Guide-ECG- Local Reading		
ECG - Local Reading		
Was the ECG performed? <i>Indicate whether or not an ECG or specific ECG test was done.</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<i>Not Submitted</i> EGPERF
What was the method used for the ECG? <i>Record the method used for the ECG.</i>	<input type="radio"/> 12 LEAD STANDARD <input type="radio"/> HOLTER CONTINUOUS ECG RECORDING	<i>EGMETHOD</i> EGMETHOD
What was the position of the subject during the ECG measurement? <i>Record the position of the subject during the ECG</i>	<input type="radio"/> Sitting <input type="radio"/> Standing <input type="radio"/> Supine <input type="radio"/> Semi-Recumbent <input type="radio"/> Semi-Fowler's	<i>EGPOS</i> EGPOS
What was the date of the ECG? (DD-MMM-YYYY) <i>Record the date ECG was done using this format</i>	<input type="text"/> []	<i>EGOTC</i> EGDAT
ECG Mean Heart Rate Result	<input type="text"/> []	<i>EGORRES</i> EGHRMN_EGORRES
Unit	beats/min	<i>EGORRES where EGTESTCD="HRMN"</i> HRMN_EGORRESU
QRS Duration, Aggregate Result	<input type="text"/> []	<i>ERORESS WHERE EGTESTCD="QRSAG"</i> QRSAG_ERORES
Unit	msecs	<i>EGORRES where EGTESTCD="QRSAG"</i> QRSAG_EGORRESI
PR Interval, Single Beat Result	<input type="text"/> []	<i>EGORRES WHERE EGTESTCD="PRSB"</i> PRSB_EGORRES
Unit	msecs	<i>EGORRES where EGTESTCD="PPRA"</i> PPRA_EGORRESU
QT Interval, Aggregate Result	<input type="text"/> []	<i>EGORRES WHERE</i> QTAG_EGORRES
Unit	msecs	<i>EGORRES where EGTESTCD="QTAC"</i> HRMN_EGORRESU
QTca Interval, Aggregate Result	<input type="text"/> []	<i>EGORRES WHERE</i> QTCAAG_EGORRES
Unit	Millisecond	<i>EGORRES where EGTESTCD="QTCAAG"</i> QTCAAG_EGORRESI
Interpretation	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal	<i>EGORRES WHERE EGTESTCD="INTP"</i> INTP_EGORRES
	Was the ECG clinically significant?	
	<input type="radio"/> No <input checked="" type="radio"/> Yes	<i>EGCLSIG</i> EGCLSIG
<i>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</i>		

CDASH EG Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
1	Was the ECG performed?	ECG Performed	Indicate whether or not an ECG or specific ECG test was done.	Text	EGSTAT	EGSTAT		(NY)	N;Y	
2	What was the method used for the ECG?	Method	Record the method used for the ECG.	Text	EGMETHOD	EGMETHOD		(EGMETHOD)	12 LEAD STANDARD;HOLTER CONTINUOUS ECG RECORDING	
3	What was the position of the subject during the ECG measurement?	Position	Record the position of the subject during the ECG.	Text	EGPOS	EGPOS		(POSITION)	SITTING;STANDING;SUPINE;SEMI-RECUMBENT;SEMI-FOWLERS	
4	What was date of the ECG?	ECG Date	Record the date ECG was done using this format.	Date	EGDTC	EGDTC				
5	What was the Mean Heart Rate?	ECG Mean Heart Rate	Record the test result.	Integer	EGHRMN_EGORRES	EGORRES	EGORRES where EGTESTCD = "EGHRMN"			
6	What was the unit of the Mean Heart Rate?	Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	EGHRMN_EGORRESU	EGORRESU	EGORRESU where EGTESTCD = "EGHRMN"	(Unit)	beats/min	
7	What was the Aggregate PR Interval?	PR Interval, Aggregate	Record the test result.	Integer	PRAG_EGORRES	EGORRES	EGORRES where EGTESTCD = "PRAG"			
8	What was the unit of the Aggregate PR Interval?	Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	PRAG_EGORRESU	EGORRESU	EGORRESU where EGTESTCD = "PRAG"	(Unit)	msecs	
9	What was the Aggregate QRS Duration?	QRS Duration, Aggregate	Record the test result.	Integer	QRSAG_EGORRES	EGORRES	EGORRES where EGTESTCD = "QRSAG"			
10	What was the unit of the Aggregate QRS Duration?	Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	QRSAG_EGORRESU	EGORRESU	EGORRESU where EGTESTCD = "QRSAG"	(Unit)	msecs	
11	What was the Aggregate QT Interval?	QT Interval, Aggregate	Record the test result.	Integer	QTAG_EGORRES	EGORRES	EGORRES where EGTESTCD = "QTAG"			
12	What was the unit of the Aggregate QT Interval result?	Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	QTAG_EGORRESU	EGORRESU	EGORRESU where EGTESTCD = "QTAG"	(Unit)	msecs	
13	What was the Aggregate QTca Interval?	QTca Interval, Aggregate	Record the test result.	Integer	QTCAAG_EGORRES	EGORRES	EGORRES where EGTESTCD = "QTCA"			
14	What was the unit of the Aggregate QTca Interval?	Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	QTCAAG_EGORRESU	EGORRESU	EGORRESU where EGTESTCD = "QTCA"	(Unit)	msecs	
15	What was the overall interpretation of the ECG?	Interpretation	Record the the test result.	Text	INTP_EGORRES	EGORRES	EGORRES where EGTESTCD = "INTP"	(NORMABNM)	NORMAL; ABNORMAL	
16	Was the ECG clinically significant?	Clinically Significant	Record whether ECG results were clinically significant.	Text	EGCLSIG	EGCLSIG		(NY)	N;Y	

This is the SDTM data associated with the CRF above.

Row 1: Shows a measurement of ventricular rate.

Row 2: Shows a measurement of PR interval.

Rows 3-4: These interval measurements were collected in seconds. However, in this submission, the standard unit for these tests was milliseconds, so the results have been converted in EGSTRESC and EGSTRESN.

Row 5: Shows "QTcB Interval, Aggregate". This result was derived by the applicant, as indicated by the "Y" in the EGDRVFL column. Note that EGORRES is null for these derived records.

Row 6: Shows the result of the TEST "Interpretation" (i.e., the interpretation of the ECG strip as a whole), which for this ECG was "ABNORMAL". This result was assessed as clinically significant (EGCLSIG = "Y").

eg.xpt

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGREFID	EGTESTCD	EGTEST	EGCAT	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU	EGNAM	EGMETHOD	EGDRVFL	EGCLSIG	VISITNUM	VISIT	EGDTC	EGDY	
1	XYZ	EG	XYZ-US-701-002	1	334PT89	EGHRMN	ECG Mean Heart Rate	MEASUREMENT	SUPINE	62	beats/min	62	62	beats/min	Test Lab	12 LEAD STANDARD			1	SCREENING	2003-04-15T11:58	-36	
2	XYZ	EG	XYZ-US-701-002	2	334PT89	PRAG	PR Interval, Aggregate	INTERVAL	SUPINE	0.15	sec	150	150	msec	Test Lab	12 LEAD STANDARD			1	SCREENING	2003-04-15T11:58	-36	
3	XYZ	EG	XYZ-US-701-002	3	334PT89	QRSAG	QRS Duration, Aggregate	INTERVAL	SUPINE	0.103	sec	103	103	msec	Test Lab	12 LEAD STANDARD			1	SCREENING	2003-04-15T11:58	-36	
4	XYZ	EG	XYZ-US-701-002	4	334PT89	QTAG	QT Interval, Aggregate	INTERVAL	SUPINE	0.406	sec	406	406	msec	Test Lab	12 LEAD STANDARD			1	SCREENING	2003-04-15T11:58	-36	
5	XYZ	EG	XYZ-US-701-002	5	334PT89	QTCA	QTcA Interval, Aggregate	INTERVAL	SUPINE			469	469	msec	Test Lab	12 LEAD STANDARD	Y		1	SCREENING	2003-04-15T11:58	-36	
6	XYZ	EG	XYZ-US-701-002	12	334PT89	INTP	Interpretation		SUPINE	ABNORMAL		ABNORMAL							Y	1	SCREENING	2003-04-15T11:58	-36

Example 2

This example shows a SDTM dataset that represents basic electrocardiogram data.

Row 1: Shows the result of the TEST "Interpretation" (i.e., the interpretation of the ECG strip as a whole), which for this ECG was "ABNORMAL".

Row 2: Shows an ECG that was not performed and the reason it was not performed.

eg.xpt

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGTESTCD	EGTEST	EGORRES	EGSTRESC	EGSTAT	EGREASND	EGCLSIG	VISITNUM	VISIT	EGDTC	EGDY
1	TBEG1	EG	S-701-002	1	INTP	Interpretation	ABNORMAL	ABNORMAL		Y	1	SCREENING	2003-04-15	-36	
2	TBEG1	EG	S-701-003	1	EGALL	ECG Test Results			NOT DONE	SUBJECT REFUSED	1	SCREENING			

3.3.2.10 Vital Signs (VS)

Vital Signs (VS) is a Findings domain used to represent vital signs measurements, including (but not limited) to blood pressure, temperature, respiration, body surface area, BMI, height, and weight.

Example 1

This is an example of a CRF used to collect vital signs.

Tobacco Implementation Guide-Vital Signs		
Vital Signs		
What was the date of the measurements? (DD-MMM-YYYY) <i>Record date of measurements.</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	VSDTC VSDAT
What was the time of the measurements? (24 hour clock) <i>Record time of measurement.</i>	<input type="text"/> <input type="text"/> <input type="text"/>	VSDTC VSTM
What was the result of the height measurement? <i>Record the height result.</i>	<input type="text"/> <input type="text"/> <input type="text"/>	VSORRES where VSTESTCD = "HEIGHTSBP" HEIGHT
What was the unit of the height measurement? <i>Record or select the original unit in which these data were collected, if not pre-printed on CRF.</i>	<input checked="" type="radio"/> Centimeter <input type="radio"/> Inch	VSORRESU where VSTESTCD = "HEIGHT" HEIGHTU
What was the result of the weight measurement? <i>Record the weight result.</i>	<input type="text"/> <input type="text"/> <input type="text"/>	VSORRES where VSTESTCD = "WEIGHT" WEIGHT
What was the unit of the weight measurement? <i>Record or select the original unit in which these data were collected, if not pre-printed on CRF.</i>	<input checked="" type="radio"/> Kilogram <input type="radio"/> Pound	VSORRESU where VSTESTCD = "WEIGHT" WEIGHTU
What was the result of the temperature measurement? <i>Record the temperature result.</i>	<input type="text"/> <input type="text"/> <input type="text"/>	VSORRES where VSTESTCD = "TEMP" TEMP
What was the unit of the temperature measurement?	<input checked="" type="radio"/> Celsius <input type="radio"/> Fahrenheit	VSORRESU where VSTESTCD = "TEMP" TEMPU
What was the result of the respiratory rate measurement? <i>Record the respiratory rate result.</i>	<input type="text"/> <input type="text"/> <input type="text"/>	VSORRES where VSTESTCD = "RESP" RESP
What was the unit of the respiratory rate measurement? <i>Record or select the original unit in which these data were collected, if not pre-printed on CRF.</i>	breaths/min	VSORRESU where VSTESTCD = "RESP" RESPU
What was the systolic blood pressure measurement? <i>Record the systolic blood pressure result.</i>	<input type="text"/> <input type="text"/>	VSORRES where VSTESTCD = "SYSBP" SYSBP
What was the unit of the systolic blood pressure measurement? <i>Record or select the original unit in which these data were collected, if not pre-printed on CRF.</i>	mmHg	VSORRESU where VSTESTCD = "SYSBP" SYSBPU
What was the diastolic blood pressure measurement? <i>Record the diastolic blood pressure result.</i>	<input type="text"/> <input type="text"/>	VSORRES where VSTESTCD = "DIABP" DIABP
What was the unit of the diastolic blood pressure unit?	mmHg	VSORRESU where VSTESTCD = "DIABP" DIABPU
What was the pulse measurement? <i>Record the pulse rate result.</i>	<input type="text"/> <input type="text"/>	VSORRES where VSTESTCD = "PULSE" Pulse
What was the unit of the pulse measurement? <i>Record or select the original unit in which these data were collected, if not pre-printed on CRF.</i>	beats/min	VSORRESU where VSTESTCD = "PULSE" PULSE
<i>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</i>		

CDASH VS Metadata Specifications

Order	Question Text	Prompt	CRF Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology Code List Name	Permissible Values	Pre-Populated Value
1	What was the date of the measurements?	Date	Record date of measurements.	Date	VSDAT	VSDTC				
2	What was the time of the measurements?	Time	Record time of measurement.	Time	VSTIM	VSDTC				
3	What was the result of the height measurement?	Height	Record the height result.	Float	HEIGHT	VSORRES	VSORRES where VTESTCD = "HEIGHT"			
4	What was the unit of the height measurement?	Height Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	HEIGHTU	VSORRESU	VSORRESU where VTESTCD = "HEIGHT"	(VSRESU)	centimeter; iinch	
5	What was the result of the weight measurement?	Weight	Record the weight result.	Float	WEIGHT	VSORRESS				
6	What was the unit of the weight measurement?	Weight Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	WEIGHTU	VSORRESU	VSORRESU where VTESTCD = "WEIGHT"	(VSRESU)	kilogram; Pound	
7	What was the result of the temperature measurement?	Temperature	Record the temperature result.	Float	TEMP	VSORRES	VSORRES where VTESTCD = "TEMP"			
8	What was the unit of the temperature measurement?	Temperature Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	TEMPU	VSORRESU	VSORRESU where VTESTCD = "TEMP"	(VSRESU)	Celsius; Fahrenheit	
9	What was the result of the respiratory rate measurement?	Respiratory Rate	Record the respiratory rate result.	Float	RESP	VSORRES	VSORRES where VTESTCD = "RESP"			
10	What was the unit of the respiratory rate measurement?	Respiratory Rate Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	RESPU	VSORRESU	VSORRESU where VTESTCD = "RESP"	(VSRESU)		breaths/min
11	What was the result of the systolic blood pressure measurement?	Systolic Blood Pressure	Record the systolic blood pressure result.	Integer	SYSBP	VSORRES	VSORRES where VTESTCD = "SYSBP"			
12	What was the unit of the systolic blood pressure measurement?	Systolic Blood Pressure Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	SYSBPU	VSORRESU	VSORRESU where VTESTCD = "SYSBP"	(VSRESU)		mmHg
13	What was the result of the diastolic blood pressure measurement?	Diastolic Blood Pressure	Record the diastolic blood pressure result.	Integer	DIABP	VSORRES	VSORRES where VTESTCD = "DIABP"			
14	What was the unit of the diastolic blood pressure measurement?	Diastolic Blood Pressure Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	DIABPU	VSORRESU	VSORRESU where VTESTCD = "DIABP"	(VSRESU)		mmHg
15	What was the result of the pulse measurement?	Pulse Rate	Record the pulse rate result.	Integer	PULSE	VSORRES	VSORRES where VTESTCD = "PULSE"			
16	What was the unit of the pulse rate measurement?	Pulse Rate Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	PULSEU	VSORRESU	VSORRESU where VTESTCD = "PULSE"	(VSRESU)		beats/min

This is an example of the SDTM VS domain.

Rows 1-4, 6-7: VSTPT and VSTPTNUM are populated because more than 1 measurement was taken at this visit.

Rows 2, 4-5, 7-9: VSLOBXFL="Y" indicates that the observation was used as the last observation before exposure measurement.

Rows 10-11: Show blood pressure observations obtained at visit 2.

Row 12: Shows a value collected in one unit, but converted to selected standard unit.

Row 13: Shows the proper use of the --STAT variable to indicate "NOT DONE" where a reason was collected when a test was not done.

VS.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VTESTCD	VTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSSTAT	VSREASND	VSLOC	VSLAT	VSLOBXFL	VISITNUM	VISIT	VISITDY	VSDTC	VSDY	VSTPT	VSTPTNUM
1	ABCVS	VS	ABCVS-001-001	1	SYSBP	Systolic Blood Pressure	SITTING	154	mmHg	154	154	mmHg			ARM	LEFT		1	Baseline	1	1999-06-19T08:45	1	BASELINE 1	1
2	ABCVS	VS	ABCVS-001-001	2	SYSBP	Systolic Blood Pressure	SITTING	152	mmHg	152	152	mmHg			ARM	LEFT	Y	1	Baseline	1	1999-06-19T09:00	1	BASELINE 2	2
3	ABCVS	VS	ABCVS-001-001	3	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg			ARM	LEFT		1	Baseline	1	1999-06-19T08:45	1	BASELINE 1	1
4	ABCVS	VS	ABCVS-001-001	4	DIABP	Diastolic Blood Pressure	SITTING	48	mmHg	48	48	mmHg			ARM	LEFT	Y	1	Baseline	1	1999-06-19T09:00	1	BASELINE 2	2
5	ABCVS	VS	ABCVS-001-001	5	PULSE	Pulse Rate	SITTING	72	beats/min	72	72	beats/min			ARM	LEFT	Y	1	Baseline	1	1999-06-19	1		

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VTESTCD	VTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTAT	VSREASND	VSLOC	VSLAT	VSLOBXFL	VISITNUM	VISIT	VISITDY	VSDTC	VSDY	VSTPT	VSTPTNUM	
6	ABCVS	VS	ABCVS-001-001	6	TEMP	Temperature		34.7	C	34.7	34.7	C		SUBLINGUAL REGION			1	Baseline	1	1999-06-19T08:45	1	BASELINE 1	1	
7	ABCVS	VS	ABCVS-001-001	7	TEMP	Temperature		36.2	C	36.2	36.2	C		SUBLINGUAL REGION		Y	1	Baseline	1	1999-06-19T09:00	1	BASELINE 2	2	
8	ABCVS	VS	ABCVS-001-001	8	WEIGHT	Weight		90.5	kg	90.5	90.5	kg					Y	1	Baseline	1	1999-06-19	1		
9	ABCVS	VS	ABCVS-001-001	9	HEIGHT	Height		157	cm	157	157	cm					Y	1	Baseline	1	1999-06-19	1		
10	ABCVS	VS	ABCVS-001-001	10	SYSBP	Systolic Blood Pressure	SITTING	95	mmHg	95	95	mmHg		ARM	LEFT		2	Visit 2	35	1999-07-21	33			
11	ABCVS	VS	ABCVS-001-001	11	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg		ARM	LEFT		2	Visit 2	35	1999-07-21	33			
12	ABCVS	VS	ABCVS-001-001	12	TEMP	Temperature		97.16	F	36.2	36.2	C		SUBLINGUAL REGION			2	Visit 2	35	1999-07-21	33			
13	ABCVS	VS	ABCVS-001-001	13	WEIGHT	Weight							NOT DONE	SUBJECT REFUSED				2	Visit 2	35	1999-07-21	33		

3.3.2.11 Adverse Experiences (AE)

The PMTA rule defines *adverse experiences* in tobacco product studies, whereas clinical trials use the term "adverse events." Some of the procedures in the collection of adverse experiences in tobacco product studies follow the conventions used for collecting adverse events (e.g., coding dictionaries, definition of severity). Thus, the term "adverse event" may be used as a synonym for "adverse experiences" in this document.

In tobacco product studies, the Adverse Events (AE) domain is used for representing adverse experiences. The FDA's PMTA rule defines adverse experience as any unfavorable physical or psychological effect in a person that is temporally associated with the use of or exposure to a tobacco product, whether or not the person uses the tobacco product, and whether or not the effect is considered to be related to the use of or exposure to the tobacco product. In consultation with regulatory authorities, applicants may extend or limit the scope of collection (e.g., collecting pre-exposure experiences related to trial conduct, not collecting events that are assessed as study endpoints). It is the applicant's responsibility to define an event and the appropriate collection period for events. This definition may vary based on product characterization and reporting of product safety. In consultation with regulatory authorities, applicants may extend or limit the scope of event collection. Adverse events may be captured either as free text or via a prespecified list of terms.

Example 1

This is an example of a CRF used to collect all adverse experiences that occurred after informed consent was obtained. Adverse experiences were collected using free text. The CRF was designed to allow the applicant to use either AEENRF or AEENRTPT to represent an event that was ongoing.

This example CRF has 2 sections: Section 1 collects whether a subject experienced any adverse experiences, while section 2 collects a record/row for each adverse experience.

Tobacco Implementation Guide-Adverse Experiences		
<p>Record all adverse experiences (AEs) except [list of protocol-defined exceptions] on the AE CRF</p> <p>All serious adverse experiences (SAEs), regardless of relationship to study product, must be reported via telephone or fax within 24 hours of discovery.</p> <p>Safety information (e.g., AE, SAE) identified for all subjects must be recorded on source documents from the time informed consent is obtained.</p>		
Any Adverse Experiences		
Were there any adverse experiences? <i>Indicate if the subject experienced any adverse experiences. If Yes, include the appropriate details where indicated on the CRF.</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes	NOT SUBMITTED AEYN
Adverse Experiences		
What is the category of the adverse experience? <i>Record the adverse experience category, if not pre-printed on the CRF.</i>	Applicant Defined AECAT AECAT	
What is the subcategory of the adverse experience? <i>Record the adverse experience subcategory, if not pre-printed on the CRF.</i>	Applicant Defined AESCAT AESCAT	
What is the adverse experience identifier? <i>If collected on the CRF, the applicant may insert instructions to ensure each record has a unique identifier.</i>	 AESPID AESPID	
What is the adverse experience term? <i>Record only 1 diagnosis, sign, or symptom per line (e.g., nausea and vomiting should not be recorded in the same entry, but as 2 separate entries). Using accepted medical terminology, enter the diagnosis (if known); otherwise, enter a sign or symptom.</i>	 AETERM AETERM	
What is the adverse experience start date? (DD-MMM-YYYY) <i>Record the start date of the Adverse Experience</i>	 AESTDT AESTDT	
Ongoing <i>Indicate if the adverse experience has not resolved at the time of data collection; leave the End Date blank.</i>	AEENRNF or AEENRPT AEONGO	
What was the adverse experience end date? (DD-MMM-YYYY) <i>Record the date that the AE resolved</i>	 AEENDTC AEENDAT	
What is the severity of the adverse experience? <i>The reporting physician/healthcare professional will assess the severity of the adverse experience using applicant-defined categories. This assessment is subjective and the reporting physician/healthcare professional should use medical judgment to compare the reported AE to similar type experiences observed in clinical practice. Severity is not equivalent to seriousness.</i>	<input type="radio"/> Mild <input type="radio"/> Moderate <input checked="" type="radio"/> Severe	AESEV AESEV
Was the experience serious?	<input type="radio"/> No <input checked="" type="radio"/> Yes	AESER AESER
Did the adverse experience result in death?	<input type="radio"/> No <input checked="" type="radio"/> Yes	AESDTH AESDTH

Was the adverse experience life threatening?	<input type="radio"/> Yes AESLIFE <input type="radio"/> No AESLIFE
Did the adverse experience result in initial or prolonged hospitalization for the subject?	<input type="radio"/> No AESHOSP <input type="radio"/> Yes AESHOSP
Did the adverse experience result in disability or permanent damage?	<input type="radio"/> No AESDISAB <input type="radio"/> Yes AESDISAB
Was the adverse experience associated with a congenital anomaly or birth defect?	<input type="radio"/> No AESCONG <input type="radio"/> Yes AESCONG
Was the adverse experience a medically important event not covered by other "serious" criteria?	<input type="radio"/> No AESMIE <input type="radio"/> Yes AESMIE
Was this adverse experience related to study product? <i>Indicate if the cause of the adverse experience was related to the study product and cannot be reasonably explained by other factors (e.g., subject's clinical state, concomitant therapy, other interventions).</i>	<input type="radio"/> Not-Related AEREL <input type="radio"/> Unlikely Related AEREL <input type="radio"/> Possibly Related AEREL <input type="radio"/> Related AEREL
What action was taken with study product? <i>Record changes made to the study product resulting from the adverse experience.</i>	<input type="radio"/> Product Increased AEACN <input type="radio"/> Product Not Changed AEACN <input type="radio"/> Product Reduced AEACN <input type="radio"/> Product Interrupted AEACN <input type="radio"/> Product Stopped AEACN <input type="radio"/> Not Applicable AEACN
What other action was taken? <i>Record all other action(s) taken resulting from the adverse experience that are unrelated to study product given because of this adverse experience.</i>	AEACNOTH AEACNOTH
What was the action taken with a device? <i>Record any action taken with a tobacco device as the result of the adverse experience. The device may or may not be a device under study..</i>	<input type="radio"/> Device Replaced AEACDEV <input type="radio"/> Battery Replaced AEACDEV <input type="radio"/> Calibration AEACDEV <input type="radio"/> Reprogramming AEACDEV
What was the outcome of this adverse experience?	<input type="radio"/> Fatal AEOUT <input type="radio"/> Not Recovered or Not Resolved AEOUT <input type="radio"/> Recovered or Resolved AEOUT <input type="radio"/> Recovered or Resolved with Sequelae AEOUT <input type="radio"/> Recovering or Resolving AEOUT <input type="radio"/> Unknown AEOUT
Was this adverse experience related to a device?	<input type="radio"/> Not-Related AERLDEV <input type="radio"/> Unlikely Related AERLDEV <input type="radio"/> Possibly Related AERLDEV <input type="radio"/> Related AERLDEV
<i>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</i>	

CDASH AE Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
Section 1										
1	Were there any adverse experiences?	Any Adverse Experiences	Indicate if the subject experienced any adverse experiences. If Yes, include the appropriate details where indicated on the CRF.	Text	AEYN	N/A		(NY)	Yes; No	
Section 2										
2	What is the category of the adverse experience?	Adverse Experiences Category	Record the adverse experience category, if not pre-printed on the CRF.	Text	AECAT	AECAT				Applicant Defined
3	What is the subcategory of the adverse experience?	Adverse Experience Subcategory	Record the adverse experience subcategory, if not pre-printed on the CRF.	Text	AESCAT	AESCAT				Applicant Defined
4	What is the adverse experience identifier?	AE Number	If collected on the CRF, the applicant may insert instructions to ensure each record has a unique identifier.	Integer	AESPID	AESPID				
5	What is the adverse experience term?	Adverse Experiences	Record only 1 diagnosis, sign, or symptom per line (e.g., nausea and vomiting should not be recorded in the same entry, but as 2 separate entries). Using accepted medical terminology, enter the diagnosis (if known); otherwise, enter a sign or symptom.	Text	AETERM	AETERM				
6	What is the adverse experience start date?	Start Date	Record the start date of the Adverse Experience using this format (DD-MON-YYYY).	Date	AESTDAT	AESTDTC				
7	Is the adverse experience ongoing?	Ongoing	Indicate if the adverse experience has not resolved at the time of data collection; leave the End Date blank.	Text	AEONGO	AEENRPT; AEENRF	AEENRPT/ AEENRF	(NY)	Yes	
8	What was the adverse experience end date?	End Date	Record the date that the AE resolved using this format (DD-MON-YYYY). If the AE is ongoing, leave the field blank.	Date	AEENDAT	AEENDTC				
9	What is the severity of the adverse experience?	Severity	The reporting physician/healthcare professional will assess the severity of the experience using applicant-defined categories. This assessment is subjective, and the reporting physician/healthcare professional should use medical judgment to compare the reported AE to similar type experiences observed in clinical practice. Severity is not equivalent to seriousness.	Text	AESEV	AESEV		(AESEV)	MILD; MODERATE; SEVERE	

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Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
10	Was the adverse experience serious?	Serious	Assess if an adverse experience should be classified as serious based on the criteria defined in the protocol.	Text	AESER	AESER		(NY)	Yes; No	
11	Did the adverse experience result in death?	Death	Record whether the serious adverse experience resulted in death.	Text	AESDTH	AESDTH		(NY)	Yes; No	
12	Was the adverse experience life-threatening?	Life Threatening	Record whether the serious adverse experience is life-threatening.	Text	AESLIFE	AESLIFE		(NY)	Yes; No	
13	Did the adverse experience result in initial or prolonged hospitalization for the subject?	Hospitalization (initial or prolonged)	Record whether the serious adverse experience resulted in an initial or prolonged hospitalization.	Text	AESHOSP	AESHOSP		(NY)	Yes; No	
14	Did the adverse experience result in disability or permanent damage?	Disability or Permanent Damage	Record whether the serious adverse experience resulted in a persistent or significant disability or incapacity.	Text	AESDISAB	AESDISAB		(NY)	Yes; No	
15	Was the adverse experience associated with a congenital anomaly or birth defect?	Congenital Anomaly or Birth Defect	Record whether the serious adverse experience was associated with congenital anomaly or birth defect.	Text	AESCONG	AESCONG		(NY)	Yes; No	
16	Did the adverse experience require intervention to prevent permanent impairment or damage resulting from the use of a medical product?	Needs Intervention to Prevent Impairment	Record whether the serious adverse experience required intervention to prevent permanent impairment or damage due to the use of a medical product.	Text	AESINTV	SUPPAE.QVAL		(NY)	Yes; No	
17	Was the adverse experience a medically important event not covered by other "serious" criteria?	Other Serious (Important Medical Events)	Record whether the serious adverse experience is an important medical event, which may be defined in the protocol or in the investigator brochure.	Text	AESMIE	AESMIE		(NY)	Yes; No	
18	Was this adverse experience related to study product?	Relationship to Study Product	Indicate if the cause of the adverse experience was related to the study product and cannot be reasonably explained by other factors (e.g., subject's clinical state, concomitant therapy, other interventions).	Text	AEREL	AEREL			NOT RELATED; UNLIKELY RELATED; POSSIBLY RELATED; RELATED	
19	What action was taken with the study product?	Action Taken with Study Product	Record changes made to the study product resulting from the adverse experience.	Text	AEACN	AEACN		(TPACN)	DRUG WITHDRAWN; DOSE REDUCED; DOSE INCREASED; DOSE NOT CHANGED; UNKNOWN; NOT APPLICABLE	
20	What other action was taken?	Other Action Taken	Record all other action(s) taken resulting from the adverse	Text	AEACNOTH	AEACNOTH				

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
			experience that are unrelated to study product given because of this adverse experience.							
21	What is the action taken with a device?	Action Taken with Device	Record any action taken with a device as the result of the adverse experience. The device may or may not be a device under study.	Text	AEACNDEV	AEACNDEV		(DEACNDEV)	DEVICE REPLACED: BATTERY REPLACED:CALIBRATION; REPROGRAMMING	
22	What is the outcome of this adverse experience?	Outcome	Record the appropriate outcome of the experience in relation to the subject's status.	Text	AEOUT	AEOUT		(OUT)	FATAL;NOT RECOVERED/ NOT RESOLVED;RECOVERED/RESOLVED; RECOVERED/RESOLVED WITH SEQUELAE; RECOVERING/RESOLVING; UNKNOWN	
23	Was this adverse experience related to a device?	Relationship of Experience to Device	Record the relationship of the adverse experience to device	Text	AERLDEV	AERLDEV			NOT RELATED; UNLIKELY RELATED; POSSIBLY RELATED; RELATED	

This SDTM dataset illustrates data collected on the example AE CRF. This SDTM dataset used AENRTPT. For more information, see Section 2.8.7.6, [Representing References and Relative Timing](#).

AEs were coded using MedDRA, and the applicant's procedures include the possibility of modifying the reported term to aid in coding. The CRF was structured so that seriousness category variables (e.g., AESDTH, AESHOSP) were checked only when AESER is answered "Y." In this study, the study reference period started at the start of product exposure. Three AEs were reported for this subject. This SDTM dataset used AEENRF to represent ongoing events. Expected variables (e.g., AELLT, AELLTCD, AEPT, AEPTCD, AEHLT, AEHLTC, AEHLGT, AEHLCTCD, AEBDSYCD, AESOC, AESOCCD) are not included to save space.

The applicant also collected information about whether the event was associated with a device. These subjects did not have any device-related issues. See Section 3.3.3.4, [Tobacco Product Events and Malfunctions](#), for an example of device-related events.

Rows 1-2: Show examples of modifying the reported term for coding purposes, with the modified term in AEMODIFY. These adverse events were not serious, so the seriousness criteria variables are null. Note that for the event in row 2, AESTDY = "1". Day 1 was the day product was started; the AE start and end times, as well as dates, were collected to allow comparison of the AE timing to the start of product.

Row 3: Shows an example of the overall seriousness question AESER answered with "Y" and the relevant corresponding seriousness category variables (AESHOSP and AESLIFE) answered "Y". The other seriousness category variables are left blank. This row also shows AEENRF being populated because the AE was marked as "Continuing" as of the end of the study reference period for the subject.

ae.xpt

Row	STUDYID	DOMAIN	SPDEVID	USUBJID	AESEQ	AETERM	AEMODIFY	AEDECOD	AEBODSYS	AESEV	AESER	AEACN	AEACNDEV	AEREL	AERLDEV
1	ABC123	AE		ABC123-0001	1	POUNDING HEADACHE	HEADACHE	Headache	Nervous system disorders	SEVERE	N	NOT APPLICABLE		DEFINITELY NOT RELATED	
2	ABC123	AE		ABC123-0001	2	BACK PAIN FOR 6 HOURS	BACK PAIN	Back pain	Musculoskeletal and connective tissue disorders	MODERATE	N	DOSE REDUCED		PROBABLY RELATED	
3	ABC123	AE		ABC123-0002	1	INFLUENZA	Influenza	Influenza	Infections and infestations	SEVERE	Y	PRODUCT WITHDRAWN		PROBABLY NOT RELATED	
Row	AEOOUT	AESCONG	AESDISAB	AESDTH	AESHOSP	AESLIFE	AESMIE	AECONTRT	EPOCH	AESTDT	AEENDTC	AESTDY	AEENDY	AEENRF	
1	RECOVERED/RESOLVED								Y	PRODUCT EXPOSURE	2006-10-14	2006-10-18	2	5	

Row	AEOOUT	AESCONG	AESDISAB	AESDTH	AESHOSP	AESLIFE	AESMIE	AECONTRT	EPOCH	AESTDTC	AEENDTC	AESTDY	AEENDY	AEENRF
2	RECOVERED/RESOLVED							N	PRODUCT EXPOSURE	2006-10-13T13:05	2006-10-13T19:00	1	1	
3	RECOVERING/RESOLVING				Y	Y		Y	PRODUCT EXPOSURE	2006-02-26		12		AFTER

3.3.2.12 Laboratory - Routine Safety (LB)

Laboratory Test Results (LB) is a Findings domain used to represent laboratory test data such as hematology, clinical chemistry, and urinalysis. This domain does not include microbiology or pharmacokinetic concentration data, which are stored in separate domains. The laboratory data collected for studies is typically handled by 2 types of labs (i.e., central labs, local labs). Whereas data from local labs are usually captured directly on aCRF, central lab data is usually provided electronically.

Three different data collection scenarios (see also Section 2.7.6.8, [CDASH Laboratory Test Results \(LB\)](#)) may be used for for laboratory test results. It is up to the applicant to determine which data collection scenario best meets the study needs.

Scenario 1: Central processing. In this scenario, subject specimens are taken at the site and sent out for processing. Results are provided in an electronic file; the applicant has chosen to collect reconciliation data (e.g., LBDAT, LBTIM, VISITNUM, LBREFID) on the CRF. This scenario may also apply if the central lab results are imported into a applicant's EDC system. The fields for test results are not defined here, as these data are not part of the CRF.

Scenario 2: Central processing with investigator assessment of clinical significance for abnormal values. In this scenario, subject specimens are taken at the site and sent to a central lab for processing. The results are provided in an electronic file to the applicant. In addition, the results are provided to the investigator for assessment of clinical significance for any abnormal values, and that information is provided to the applicant on the CRF.

Scenario 3: Local processing. In this scenario, subject specimens are taken and analyzed, and then the results are recorded directly on the CRF.

This section only discusses routine safety laboratory tests. For more information on biomarkers typically tested in tobacco studies, see Section 3.3.3.1, [Biomarkers of Exposure or Potential Harm \(LB, SUPPLB\)](#).

Logical Observation Identifiers Names and Codes (LOINC) is clinical terminology that is important for laboratory test orders and results, and is 1 of a suite of designated standards for use in US federal government systems for the electronic exchange of clinical health information. It is recommended that if the laboratory used for testing is able to provide the appropriate LOINC, that these be included in the SDTM dataset. If using LBLOINC, the applicant is expected to provide the dictionary name and version used to map the terms, utilizing Define-XML external codelist attributes.

Example 1

This is an example CRF used to collect routine safety laboratory tests from local laboratories in tobacco studies. The lab names may be collected only when multiple labs are used by a site. The lab test name are often preprinted on the CRF. The names are not included as they are study specific. In order to save space, some of the permissible values are only shown in the metadata specifications.

Tobacco Implementation Guide -Routine Laboratory- Local Processing		
Laboratory		
What was the name of the laboratory used? <i>Record the laboratory name.</i>	<input type="text"/> LBNAM LBNAM	
Was the lab performed? <i>Indicate whether or not lab specimen was collected or measurement performed.</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes	LBSTAT = "NOT DONE" where LBPERF = "N" and LBSTAT = null where LBPERF = "Y" LBPERF
What was the date of the lab specimen collection? (DD-MMM-YYYY) <i>Indicate whether or not lab specimen was collected or measurement performed.</i>	<input type="text"/> LBOTC	LBDAT
What was the (start) time of the lab specimen collection? (24 hour clock) <i>Record time of collection (as complete as possible).</i>	<input type="text"/> LBOTC	LBTIM
Was the subject fasting? <i>Record whether the subject was fasting prior to the test being performed.</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes	LBFAST LBFAST
Laboratory Tests		
Lab Test Name <i>Record the name of the Lab measurement or finding, if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.</i>	<input type="text"/> LBTEST LBTEST	
What was the result? <i>Record laboratory test result.</i>	<input type="text"/> LBORRES LBORRES	
What was the lab test unit? <i>Record the unit of the Lab measurement or finding, if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.</i>	<input type="text"/> LBUNIT LBORRESU	
What was the upper limit of the reference range for this lab test? <i>Record the upper limit of the reference range of the lab test.</i>	<input type="text"/> LBORNRHI LBORNRHI	
What was the lower limit of the reference range for this lab test? <i>Record the lower limit of the reference range of the lab test.</i>	<input type="text"/> LBORNRLD LBORNRLD	
Was this result clinically significant? <i>Record whether lab results were clinically significant.</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes	LBCLSIG LBCLSIG
CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).		

CDASH LB Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
Section 1										
1	What was the name of the laboratory used?	Laboratory Name	Record the laboratory name	Text	LBNAM	LBNAM				
2	Was the lab performed?	Lab Performed	Indicate whether or not lab specimen was collected, or measurement performed.	Text	LBPERF	LBSTAT	LBSTAT = "NOT DONE" where LBPERF = "N" and LBSTAT = null where LBPERF = "Y"	(NY)	Yes; No	
3	What was the date of the lab specimen collection?	Specimen Collection Date	Record the date of specimen collection .	Date	LBDAT	LBDTC				
4	What was the time of the lab specimen collection?	Specimen Collection Time	Record time of collection (as complete as possible).	Time	LBTIM	LBDTC				
5	Was the subject fasting?	Fasting	Record whether the subject was fasting prior to the test being performed	Text	LBFAST	LBFAST				
Section 2										
6	What is the lab test name?	Lab Test Name	Record the name of the lab measurement or finding, if not pre-printed on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.	Text	LBTEST	LBTEST; LBTESTCD	LBTEST and LBTESTCD	(LBTEST)	WBC; RBC, cells, Protein, Urinalysis; Cholesterol, Albumin, Creatinine	
7	What was the result of the lab test?	Result	Record laboratory test result.	Text	LBORRES	LBORRES				
8	What was the unit of the lab result?	Unit	Record or select the original unit in which these data were collected, if not pre-printed on CRF.	Text	LBORRESU	LBORRESU		(UNIT)	g/L; mg/dL; mg/L; U/mL; ug/L; sec; RATIO	
9	What was the lower limit of the reference range for this lab test?	Normal Range Lower Limit	Record the lower limit of the reference range of the lab test.	Text	LBORNRLLO	LBORNRLLO				
10	What was the high limit of the reference range for this lab test?	Normal Range Upper Limit	Record the upper limit of the reference range of the lab test.	Text	LBORNRHI	LBORNRHI				
11	Was this result clinically significant?	Clinically Significant	Record whether lab results were clinically significant.	Text	LBCLSIG	LBCLSIG		(NY)	Yes; No	

This is an example of the SDTM LB dataset used to represent routine safety laboratory tests.

The LB dataset used the UNIT codelist for LBORRESU and LBORRESU. The LBLOINC variable contains a code from the LOINC database that identifies a specific laboratory test. The LOINC to LB Mapping Codetable (available at <https://www.cdisc.org/standards/terminology/controlled-terminology>) may be used to identify appropriate CDISC CT values for a test with a particular LOINC code.

LBNRIND was added to indicate where a result falls with respect to reference range defined by LBORNRL and LBORNRI. LBSTNRC was used to populated a normal range values that are character values for an ordinal scale (e.g., "NEGATIVE"). LBORNRL, LBORNRI, LBSTNRL, and LBSTNRHI are null for these types of tests.

Rows 1-4: Show records for common tests to evaluate hematology. The applicant used LBCAT (HEMATOLOGY) to group these tests.

Rows 5, 7, 8: Show records for common tests. LBCAT indicates the category assigned for these laboratory tests.

Row 6: Shows a value collected in 1 unit but converted to selected standard unit.

Row 9: Shows use of LBSTNRC for cannabinoids that is not reported as a continuous numeric result. The result was evaluated by the investigator and determined to be clinically significant.

lb.xpt

ROW	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRL	LBORNRI	LBSTRESC
1	TBLB001	LB	001-001	1	WBC	Leukocytes	HEMATOLOGY	11.0	10^9/L	4.5	11.0	11.0
2	TBLB001	LB	001-001	2	RBC	RBC	HEMATOLOGY	5.4	10^12/L	4.7	6.1	5.4
3	TBLB001	LB	001-001	3	PLAT	Platelets	HEMATOLOGY	158	10^9/L	150	400	158
4	TBLB001	LB	001-001	4	HGB	Hemoglobin	HEMATOLOGY	14.5	g/dL	14	18	14.5
5	TBLB001	LB	001-001	5	CHOL	Cholesterol	CLINICAL CHEMISTRY	229	mg/dL	200		229
6	TBLB001	LB	001-001	6	ALB	Albumin	CLINICAL CHEMISTRY	40.0	g/L	34	54	4.0
7	TBLB001	LB	001-001	7	CREAT	Creatinine	CLINICAL CHEMISTRY	0.8	mg/dL	0.7	1.3	0.8
8	TBLB001	LB	001-001	8	SPGRAV	Specific Gravity	URINALYSIS	1.002		1.005	1.030	
9	TBLB001	LB	001-001	9	CANNAB	Cannabinoids	DRUG TOXICITY	POSITIVE				POSITIVE

ROW	LBSTRESN	LBSTRESU	LBSTNRC	LBSTNRL	LBSTNRHI	LBNRIND	LBLOINC	LBSPEC	LBLOBXFL	LBCLSIG	VISITNUM	LBDTC
1	11.0	10^9/L		4.5	11.0		26464-8	BLOOD	Y		1	2020-12-01
2	5.4	10^12/L		4.7	6.1		33051-4	BLOOD	Y		1	2020-12-01
3	158	10^9/L		150	400		49497-1	BLOOD	Y		1	2020-12-01
4	14.5	g/dL		14	18		718-7	BLOOD	Y		1	2020-12-01
5	229	mg/dL		200			2093-3	BLOOD	Y		1	2020-12-01
6	4.0	g/dL		3.4	5.4		2862-1	BLOOD	Y		1	2020-12-01
7	0.8	mg/dl		0.7	1.3		2160-0	BLOOD	Y		1	2020-12-01
8				1.005	1.030		2965-2	URINE	Y		1	2020-12-01
9		POSITIVE				ABNORMAL	18282-4	URINE	Y	Y	1	2020-12-01

3.3.2.13 Subject Elements/EPOCHS (SE)

The Subject Elements dataset consolidates information about the timing of each subject's progress through the epochs and elements of the study or trial. For elements that involve study product exposure, the identification of which element the subject passed through (e.g., tobacco product X vs. placebo) is likely to derive from data in the Exposure domain or another Interventions domain. The dates of a subject's transition from one element to the next will be taken from the Interventions domain(s) and from other relevant domains, according to the definitions (TESTRL values) in the Trial Elements (TE) dataset (see Section 3.3.1, [Trial Design](#)).

The SE dataset is particularly useful for studies with multiple product periods (e.g., crossover studies). The SE dataset contains the date/times at which a subject moved from one element to another, so when this dataset, the Trial Arms (TA), and the Trial Elements (TE) dataset are included in a submission, reviewers can relate all observations made about a subject to that subject's progression through the trial.

- Comparison of the --DTC of a finding observation to the element transition dates (values of SESTDTC and SEENDTC) identifies which element the subject was in at the time of the finding. Similarly, one can determine the element during which an event or intervention started or ended.

- “Day within Element” or “Day within Epoch” can be derived. Such variables relate an observation to the start of an element or epoch in the same way that study day (--DY) variables relate it to the reference start date (RFSTDTC) for the study as a whole.
- Having knowledge of SE start and end dates can be helpful in the determination of baseline values.

This example shows data for 2 subjects for a crossover study with 4 epochs.

- Row 1:** The record for the SCREEN element for subject 789. Note that only the date of the start of the SCREEN element was collected, whereas for the end of the element (which corresponds to the start of PRODUCT X) both date and time were collected.
- Row 2:** The record for the FIRST PRODUCT EXPOSURE element for subject 789. The FIRST PRODUCT EXPOSURE element started with the start of PRODUCT X dosing and ended with the start of PRODUCT Y dosing, and full date/times were collected for both.
- Row 3:** The record for the SECOND PRODUCT EXPOSURE element for subject 789. Only the date, and not the time, of the start of follow-up was collected.
- Row 4:** The FOLLOWUP element for subject 789 started and ended on the same day. Presumably, the element had a positive duration, but no times were collected.
- Rows 5-8:** Subject 790 was exposed to products in the wrong order. This subject entered the PRODUCT X element before the PRODUCT Y element, although the planned order of elements for this subject was PRODUCT Y, then PRODUCT X. The applicant has assigned EPOCH values for this subject according to the actual order of elements, rather than the planned order. Per Assumption 6, TAETORD is missing for the elements that were out of order. The correct order of elements is the subject's ARMCD, shown in the DM dataset.

se.xpt

Row	STUDYID	USUBJID	SESEQ	ETCD	SESTDTC	SEENDTC	SEUPDES	TAETORD	EPOCH
1	SEABC	789	1	SCREEN	2006-06-01	2006-06-03T10:32		1	SCREENING
2	SEABC	789	2	PRODUCT X EXPOSURE	2006-06-03T10:32	2006-06-10T09:47		2	PRODUCT EXPOSURE 1
3	SEABC	789	3	PRODUCT Y EXPOSURE	2006-06-10T09:47	2006-06-17		3	PRODUCT EXPOSURE 2
4	SEABC	789	4	FOLLOWUP	2006-06-17	2006-06-17		4	FOLLOW-UP
5	SEABC	790	1	SCREEN	2006-06-01	2006-06-03T10:14		1	SCREENING
6	SEABC	790	2	PRODUCT X EXPOSURE	2006-06-03T10:14	2006-06-10T10:32			PRODUCT EXPOSURE 1
7	SEABC	790	3	PRODUCT Y EXPOSURE	2006-06-10T10:32	2006-06-17			PRODUCT EXPOSURE 1
8	SEABC	790	4	FOLLOWUP	2006-06-17	2006-06-17		4	FOLLOW-UP

Row 1: Subject 789 was assigned to the Prod X-Prod Y arm and was exposed accordingly.

Row 2: Subject 790 was assigned to the Prod Y-Prod X arm, but their actual product exposure order was product X, then product Y .

dm.xpt

Row	STUDYID	USUBJID	SUBJID	RFSTDTC	RFENDTC	SITEID	INVNAM	BIRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS	ACTARMUD	COUNTRY
1	SEABC	789	001	2006-06-03	2006-06-17	01	SMITH, J	1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO	XY	Prod X-Prod Y	XY	Prod X-Prod Y			USA
2	SEABC	790	002	2006-06-03	2006-06-17	01	SMITH, J	1955-03-22	51	YEARS	M	WHITE	NOT HISPANIC OR LATINO	YX	Prod Y-Prod X	XY	Prod X-Prod Y			USA

3.3.2.14 Subject Visits (SV)

Subject Visits (SV) is a special-purpose domain that contains information for each subject's actual and planned visits.

The SV domain consolidates information about the timing of subject visits that is otherwise spread over domains that include the visit variables (VISITNUM and possibly VISIT and/or VISITDY). Unless the beginning and end of each visit is collected, populating the SV dataset will involve derivations. In a simple case where for each subject visit exactly 1 date appears in every such domain, the SV dataset can be created easily by populating both SVSTDTC and SVENDTC with the single date for a visit. When there are multiple dates and/or date/times for a visit for a particular subject, the derivation of values for SVSTDTC and SVENDTC may be more complex. The method for deriving these values should be consistent with the visit definitions in the Trial Visits (TV) dataset (see Section 3.3.1.1.1, [Schedule for Assessments \(TV\)](#)).

For some studies, a "visit" may be defined to correspond with a single encounter that occurs within 1 day, whereas for other studies a visit may reflect data collection over a multiday period.

The SV dataset provides reviewers with a summary of a subject's visits over the course of their participation in a study. Comparison of an individual subject's SV dataset with the TV dataset, which describes the planned visits for the study, supports the identification of planned but not expected visits due to a subject not completing the study. Comparison of the values of SVSTDY and SVENDY to VISIT and/or VISITDY can often highlight departures from the planned timing of visits.

The data below represent the visits for a single subject.

- Row 1:** Data for the screening visit was gathered over the course of 6 days.
- Row 2:** The visit called "DAY 1" started and ended as planned, on day 1.
- Row 3:** The visit scheduled for day 8 occurred one day early, on day 7.
- Row 4:** The visit called "WEEK 2" started and ended as planned, on day 15.
- Row 5:** Shows an unscheduled visit. SVUPDES provides the information that this visit dealt with evaluation of an adverse event. Since this visit was not planned, VISITDY was not populated. The applicant chose not to populate VISIT. VISITNUM was populated, probably because the data collected at this encounter is in a Findings domain such as EG, LB, or VS, in which VISIT is treated as an important timing variable.
- Row 6:** This subject had their last visit, a follow-up visit on study day 26, 8 days after the unscheduled visit, but well before the scheduled visit day of 71.

sv.xpt

Row	STUDYID	DOMAIN	USUBJID	VISITNUM	VISIT	VISITDY	SVSTDTC	SVENDTC	SVSTDY	SVENDY	SVUPDES
1	123456V	SV	101	1	SCREEN	-7	2006-01-15	2006-01-20	-6	-1	
2	123456V	SV	101	2	DAY 1	1	2006-01-21	2006-01-21	1	1	
3	123456V	SV	101	3	WEEK 1	8	2006-01-27	2006-01-27	7	7	
4	123456V	SV	101	4	WEEK 2	15	2006-02-04	2006-02-04	15	15	
5	123456V	SV	101	4.1			2006-02-07	2006-02-07	18	18	Evaluation of AE
6	123456V	SV	101	8	FOLLOW-UP	71	2006-02-15	2006-02-15	26	26	

3.3.3 Assessments of Interest in Tobacco Product Studies

Tobacco studies also collect general information about the effect of tobacco on the subject/participant. This section provides examples of data on the effects of tobacco on the subject, including biomarkers, tobacco product exposure, and health outcomes associated with tobacco use in studies.

3.3.3.1 Biomarkers of Exposure or Potential Harm (LB, SUPPLB)

In tobacco studies, biomarkers to assess exposure or potential harm are both of interest. Biomarkers of exposure are tobacco constituents or their metabolites in a biological fluid, tissue, hair, nails, or exhaled breath. Biomarkers of tobacco exposure are typically measured in blood (serum or plasma) and urine. Urine testing is usually recommended to detect chronic use because analytes are detectable for a longer period of time in urine than in serum or plasma. Biomarkers of harm or potential harm are measurements of an effect from exposure. These biomarkers could be indicative of exposure to tobacco products or could be related to environmental exposure.

The FDA has established a list of HPHCs in tobacco products and tobacco smoke (see <https://www.fda.gov/tobacco-products/>). Additionally, there is a list of 20 HPHCs, selected from the full list of HPHCs, for which testing methods are well established and widely available. The HPHC list focuses on chemicals that are linked to the 5 most serious health effects of tobacco use (i.e., cancer, cardiovascular disease, respiratory effects, reproductive problems, addiction).

The use of tobacco products result in the uptake of nicotine and a wide range of other chemicals. Biomarkers of exposure to tobacco and nicotine delivery products are limited to the chemicals taken up during product use or during exposure to product emissions. Total nicotine equivalents (TNE), defined as the molar sum of the urinary concentrations of nicotine and all of its known metabolites (e.g., nicotine, total cotinine, total 3-hydroxycotinine, nicotine N-oxide), is a biomarker of nicotine consumption. Cotinine is a metabolite of nicotine and is a widely used biomarker of nicotine exposure. Nicotine replacement therapy and tobacco use can be distinguished by the detection of a tobacco-specific alkaloid such as anabasine. Cotinine has 6 notable metabolites (i.e., 3-hydroxycotinine, cotinine glucuronide, 5-hydroxycotinine, cotinine N-oxide, cotinine methonium ion, norcotinine).

Biomarkers of exposure may be used to evaluate the pharmacokinetics of tobacco products. After the specific tobacco product is used, these biomarkers are measured serially to determine well-defined pharmacokinetic parameters (e.g., AUC, TMX, T 1/2); the concentration levels at prespecified timepoints would be represented in the PC/PK SDTM domains (Section 3.3.3.2, [Pharmacokinetics Concentration and Parameters \(PC, PP\)](#)). Otherwise, these biomarkers would be represented in the Laboratory Testing Results (LB) domain.

Example 1

This is an example of a study where biomarkers were collected. All subjects participated in a baseline biomarker assessment and smokers were then switched to exclusive use of their assigned product. Subjects were directed to use their assigned product exclusively for 6 months with collection of samples for biomarker assessment at day 1 (visit 1, baseline), day 90 (visit 2), and day 180 (visit 3). Blood and 24-hour urine samples were collected at each visit.

Many biomarkers were measured; only a few representative biomarkers are shown in this example. Note that a value derived by a central lab according to the lab's procedures is considered collected rather than derived. Sometimes these biomarkers are normalized by dividing the concentration of the biomarker of interest by the urine creatinine concentration obtained in the same urine sample. The results then may be reported as the concentration of biomarker of interest per creatinine. This normalization process is usually represented in an ADaM dataset (see below). Normalization may also be done using the total urine volume in the collected sample.

Controlled terminology was developed for the test names of the majority of biomarkers used in tobacco studies, including biomarkers of exposure or potential harm.

The variables LBORNRL0, LBORNRI0, LBSTNRLO, LBSTNRHI, LBNRIND and LBLOBXFL are expected variables. but are typically not used in these types of studies. Hence these variables are included in the dataset but the values are null. These variables are not included below to save space.

For lab tests where the specimen is collected over time (e.g., 24-hour urine collection), the start date/time of the collection is represented in LBDTC and the end date/time of collection is represented in LBENDTC. LBDTC and LBENDTC dates are based on the specimen collection date. If the date of the assay is needed, it can be added as an NSV.

Selected rows are included for illustration purposes only, in order to save space. The LOINC code, if included, should be provided by the testing laboratory. The applicant may also include the method used for testing if it is of interest.

The biomarkers were categorized using LBCAT and LBSCAT. These categories were based on the scientific classification of the type of biomarker and the associated constituent being evaluated by the biomarker test. Other categorization may be done by the applicant, based on the study design. These may include using biomarkers of tobacco exposure, of harm or potential harm, of compliance, and so on. LBSCAT can be used to provide the type of markers (e.g., tobacco alkaloid, polynuclear aromatic hydrocarbons, tobacco-specific nitrosamines) or the health impact of the biomarker (e.g., cancer, cardiovascular disease, respiratory effects, reproductive problems, addiction).

TNE (TNE-7) were calculated by the applicant based on the data below and represented in an ADaM dataset. TNE are the sum of nicotine, cotinine, 3-hydroxycotinine and their glucuronide conjugates. Other estimates of TNE can be used and are typically denoted using terms like TE-2, TE-3. For example, TE-2 is the sum of cotinine + 3'-hydroxycotinine.

- Rows 1-2:** Show the nicotine and cotinine measurements from a serum blood sample. These tests were performed at every visit but only the nicotine results at visit 1 and the cotinine results at visit 3 are shown.
- Rows 3-4:** Urine creatinine and 24-hour urine volume are shown.
- Rows 5-16:** Show various biomarkers which were categorized as TOBACCO ALKALOID in LBCAT. These were obtained from a planned 24-hour urine sample. The start and end time of the urine collection are provided in LBDTC and LBENDTC. Only the results from day 180 are shown.
- Rows 17-22:** Show various biomarkers which were categorized as shown in LBCAT. Results from day 60 are shown. The specimen types are shown in LBSPEC.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU
1	TOB777	LB	001	1	NICOTINE	Nicotine	TOBACCO ALKALOID	NICOTINE	30	ng/mL	30	30	ng/mL
2	TOB777	LB	001	2	COTININE	Cotinine	TOBACCO ALKALOID	NICOTINE	400	ng/mL	400	400	ng/mL
3	TOB777	LB	002	1	CREAT	Creatinine	24-HOUR URINE TEST		0.8	ng/mL	0.8	0.8	ng/mL
4	TOB777	LB	002	2	VOLUME	Volume	24-HOUR URINE TEST		1875	mL	1875	1875	mL
5	TOB777	LB	002	3	NICOTINE	Nicotine	TOBACCO ALKALOID	NICOTINE	45	ng/mL	45	45	ng/mL
6	TOB777	LB	002	4	NICGLUC	Nicotine-glucuronide	TOBACCO ALKALOID	NICOTINE	40	ng/mL	40	40	ng/mL
7	TOB777	LB	002	5	NOXT	Nicotine-1 N-oxide	TOBACCO ALKALOID	NICOTINE	113.5	ng/mL	113.5	113.5	ng/mL
8	TOB777	LB	002	6	COTININE	Cotinine	TOBACCO ALKALOID	NICOTINE	300	ng/mL	300	300	ng/mL
9	TOB777	LB	002	7	COTGLUC	Cotinine-glucuronide	TOBACCO ALKALOID	NICOTINE	275	ng/mL	275	275	ng/mL
10	TOB777	LB	002	8	COXT	Cotinine-n-oxide	TOBACCO ALKALOID	NICOTINE	117.5	ng/mL	117.5	117.5	ng/mL
11	TOB777	LB	002	9	T3HCT	Trans-3-Hydroxycotinine	TOBACCO ALKALOID	NICOTINE	2000	ng/mL	2000	2000	ng/mL
12	TOB777	LB	002	10	T3OHCOTG	Trans-3-Hydroxycotinine Glucuronide	TOBACCO ALKALOID	NICOTINE	3529	ng/mL	3529	3529	ng/mL
13	TOB777	LB	002	11	NORNCTN	Nornicotine	TOBACCO ALKALOID	NICOTINE	6	ng/mL	6	6	ng/mL
14	TOB777	LB	002	12	ANABASN	Anabasine	TOBACCO ALKALOID	NICOTINE	5	ng/mL	5	5	ng/mL
15	TOB777	LB	002	13	NORCOTN	Norcotinine	TOBACCO ALKALOID	NICOTINE	2	ng/mL	2	2	ng/mL
16	TOB777	LB	002	14	ANATABN	Anatabine	TOBACCO ALKALOID	NICOTINE	9.1	ng/mL	9.1	9.1	ng/mL
17	TOB777	LB	2001	1	OHFLRN2	2-Hydroxyfluorene	POLYNUCLEAR AROMATIC HYDROCARBON		30	ng/mL	30	30	ng/mL
18	TOB777	LB	2001	2	OHNPHTH1	1-Hydroxynaphthalene	POLYNUCLEAR AROMATIC HYDROCARBON		400	ng/mL	400	400	ng/mL
19	TOB777	LB	2001	3	OHPHNTR1	1-Hydroxyphenanthrene	POLYNUCLEAR AROMATIC HYDROCARBON		45	ng/mL	45	45	ng/mL
21	TOB777	LB	2001	4	OHBZAPY3	3-Hydroxybenzo[a]pyrene	POLYNUCLEAR AROMATIC HYDROCARBON		300	ng/mL	300	300	ng/mL
22	TOB777	LB	2001	5	CMONOX	Carbon Monoxide	VARIOUS GASES		10	%	10	10	%

Row	LBNAME	LBLOINC	LBSPEC	LBMETHOD	LBLOBXFL	LBLLOQ	VISITNUM	VISIT	LBDTC	LBENDTC
1	Tobacco Marker Testing Laboratory, Inc.	3853-9	SERUM	LC/MS/MS	Y	2	1	BASELINE	2021-01-17	
2	Tobacco Marker Testing Laboratory, Inc.	10365-5	SERUM	LC/MS/MS		2	3	Day 180	2021-07-20	
3	Tobacco Marker Testing Laboratory, Inc.		URINE	LC-MS-MS	Y		1	BASELINE	2021-06-21T08:00	2021-06-22T08:00
4	Tobacco Marker Testing Laboratory, Inc.		URINE		Y		1	BASELINE	2021-06-21T08:00	2021-06-22T08:00
5	Tobacco Marker Testing Laboratory, Inc.	3854-7	URINE	LC-MS/MS		0.2	3	Day 180	2021-12-15T08:00	2021-12-16T08:00
6	Tobacco Marker Testing Laboratory, Inc.		URINE			0.2	3	Day 180	2021-12-15T08:00	2021-12-16T08:00
7	Tobacco Marker Testing Laboratory, Inc.		URINE	HPLC-ESI-MS/MS		2.50	3	Day 180	2021-12-15T08:00	2021-12-16T08:00
8	Tobacco Marker Testing Laboratory, Inc.	10366-3	URINE	LC/MS/MS		0.05	3	Day 180	2021-12-15T08:00	2021-12-16T08:00
9	Tobacco Marker Testing Laboratory, Inc.		URINE			0.2	3	Day 180	2021-12-15T08:00	2021-12-16T08:00
10	Tobacco Marker Testing Laboratory, Inc.		URINE	HPLC-ESI-MS/MS		2.02	3	Day 180	2021-12-15T08:00	2021-12-16T08:00
11	Tobacco Marker Testing Laboratory, Inc.		URINE			0.1	3	Day 180	2021-12-15T08:00	2021-12-16T08:00
12	Tobacco Marker Testing Laboratory, Inc.		URINE			0.03	3	Day 180	2021-12-15T08:00	2021-12-16T08:00
13	Tobacco Marker Testing Laboratory, Inc.	33917-6	URINE	LC/MS/MS		2.50	3	Day 180	2021-12-15T08:00	2021-12-16T08:00
14	Tobacco Marker Testing Laboratory, Inc.	33915-0	URINE	LC/MS/MS		0.51	3	Day 180	2021-12-15T08:00	2021-12-16T08:00
15	Tobacco Marker Testing Laboratory, Inc.	77740-9	URINE			1.11	3	Day 180	2021-12-15T08:00	2021-12-16T08:00

Row	LBNAM	LBLOINC	LBSPEC	LBMETHOD	LBLOBXFL	LBLLOQ	VISITNUM	VISIT	LBDTC	LBENDTC
16	Tobacco Marker Testing Laboratory, Inc.		URINE	HPLC-ESI-MS/MS			3	Day 180	2021-12-15T08:00	2021-12-16T08:00
17	Tobacco Marker Testing Laboratory, Inc.		URINE	LC-MS/MS			2	Day 60	2021-09-15T010:00	2021-09-16T009:20
18	Tobacco Marker Testing Laboratory, Inc.		URINE	LC-MS/MS			2	Day 60	2021-09-15T010:00	2021-09-16T009:20
19	Tobacco Marker Testing Laboratory, Inc.		URINE	LC-MS/MS			2	Day 60	2021-09-15T010:00	2021-09-16T009:20
21	Tobacco Marker Testing Laboratory, Inc.		URINE	LC-MS/MS			2	Day 60	2021-09-15T010:00	2021-09-16T009:20
22	Tobacco Marker Testing Laboratory, Inc.		EXPIRED AIR	Multiple Wavelength Spectrophotometer			2	Day 60	2021-09-15	

The 2 rows of the SUPPLB dataset add qualifying information to the laboratory data collected (RDOMAIN = "LB"). IDVAR defines the key variable used to link this information to the LB data (LBSEQ). IDVARVAL specifies the value of the key variable within the parent LB record to which the SUPPLB record applies. The remaining columns specify the supplemental variable names LBNVOID and LBNMVIOD, labels, values, origin.

Row 1: Shows the subject had 4 voids during the 24-hour urine collection.

Row 2: Shows subject had 2 voids missed during the 24-hour urine collection.

supplb.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	TOB777	LB	002	LBSEQ	2	LBNVOID	Number of Voids During Collection	4	CRF	
2	TOB777	LB	002	LBSEQ	2	LBMISVOD	Number of Missed Voids During Collection	2	CRF	

3.3.3.2 Pharmacokinetics Concentration and Parameters (PC, PP)

Pharmacokinetics Concentrations (PC) is a Findings domain used to represent concentrations of drugs or metabolites in fluids or tissues as a function of time. Pharmacokinetics Parameters (PP) is a Findings domain used to represent pharmacokinetic parameters derived from pharmacokinetic concentration-time (PC) data. PP is a derived dataset.

Measuring nicotine blood concentration profile after a subject is exposed to a tobacco product is a widely used method to quantify exposure.

Example 1

This is an example of a study designed to evaluate plasma nicotine pharmacokinetic (PK) parameters following the use of nicotine. Two different nicotine products were used in the study. Each product was evaluated in a 180-minute test session with 1-3 days in between each product use. Plasma samples were taken at 45, 30, and 15 minutes prior to the start of product use and 2, 4, 7, 10, 15, 20, 30, 40, 50, 60, and 120 minutes after the start of product use. (More time points are often used; these timepoints presented were used only for illustration to save space.)

The PCLLOQ for the analytes measured were reported; PCULOQs were not reported.

Rows 1-3: Show the day 1 pre-dose concentrations of nicotine in plasma at 45, 30 and 15 min before start of delivery of the nicotine. PCDTC is populated to indicate when these specimens were collected.

Rows 4-8: Show the day 1 concentrations of nicotine in plasma after the start of delivery of the nicotine.

Rows 9-16: Show the day 4 pre- and post-dose concentrations of nicotine in plasma.

Rows 17-18: Show the day 1 pre-dose plasma concentrations of cotinine and N'-Nitrosonornicotine in plasma.

pc.xpt

Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCGRPID	PCREFID	PCTESTCD	PCTEST	PCCAT	PCSPEC	PCORRES	PCORRESU	PCSTRESC
1	A123	PC	A2008	1	Day 1	A10	NICOTINE	Nicotine	ANALYTE	PLASMA	<0.1	ng/mL	<0.1
2	A123	PC	A2008	2	Day 1	A11	NICOTINE	Nicotine	ANALYTE	PLASMA	<1.0	ng/mL	<1.0
3	A123	PC	A2008	3	Day 1	A12	NICOTINE	Nicotine	ANALYTE	PLASMA	<1.0	ng/mL	<0.1

Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCGRPID	PCREFID	PCTESTCD	PCTEST	PCCAT	PCSPEC	PCORRES	PCORRESU	PCSTRESC	
4	A123	PC	A2008	4		Day 1	A13	NICOTINE	Nicotine	ANALYTE	PLASMA	1.5	ng/mL	1.5
5	A123	PC	A2008	5		Day 1	A14	NICOTINE	Nicotine	ANALYTE	PLASMA	3.0	ng/mL	3.0
6	A123	PC	A2008	6		Day 1	A15	NICOTINE	Nicotine	ANALYTE	PLASMA	8.0	ng/mL	8.0
7	A123	PC	A2008	7		Day 1	A16	NICOTINE	Nicotine	ANALYTE	PLASMA	5.0	ng/mL	5.0
8	A123	PC	A2008	8		Day 1	A16	NICOTINE	Nicotine	ANALYTE	PLASMA	3.0	ng/mL	3.0
9	A123	PC	A2008	9		Day 4	A17	NICOTINE	Nicotine	ANALYTE	PLASMA	5.44	ng/mL	5.44
10	A123	PC	A2008	10		Day 4	A18	NICOTINE	Nicotine	ANALYTE	PLASMA	1.09	ng/mL	1.09
11	A123	PC	A2008	11		Day 4	A19	NICOTINE	Nicotine	ANALYTE	PLASMA	<0.1	ng/mL	<0.1
13	A123	PC	A2008	12		Day 4	A20	NICOTINE	Nicotine	ANALYTE	PLASMA	3.41	ng/mL	3.41
13	A123	PC	A2008	13		Day 4	A21	NICOTINE	Nicotine	ANALYTE	PLASMA	<0.1	ng/mL	<0.1
14	A123	PC	A2008	14		Day 4	A22	NICOTINE	Nicotine	ANALYTE	PLASMA	8.74	ng/mL	8.74
15	A123	PC	A2008	15		Day 4	A23	NICOTINE	Nicotine	ANALYTE	PLASMA	4.2	ng/mL	4.2
16	A123	PC	A2008	16		Day 4	A24	NICOTINE	Nicotine	ANALYTE	PLASMA	245	ng/mL	245
17	A123	PC	A2008	17		Day 1	A10	COTININE	Cotinine	ANALYTE	PLASMA	1	ng/mL	1
18	A123	PC	A2008	18		Day 1	A10	NNN	N'-Nitrosonornicotine	ANALYTE	PLASMA	<0.1	pg/mL	<.3

Row	PCSTRESN	PCSTRESU	PCLLQO	VISITNUM	VISIT	VISITDY	PCDTC	PCDY	PCTPT	PCTPTNUM	PCTPTREF	PCRFTDTC	PCELTM
1		ng/mL	0.10	1	DAY 1	1	2001-02-01T07:15	1	45 MIN PREDOSE	1	Day 1 Dose	2021-02-01T08:00	-PT45M
2			0.10	1	Day1	1	2001-02-01T07:30	1	30 MIN PREDOSE	2	Day 1 Dose	2021-02-01T08:00	-PT30M
3		ng/mL	0.10	1	DAY 1	1	2001-02-01T07:45	1	15 MIN PREDOSE	3	Day 1 Dose	2021-02-01T08:00	-PT15M
4	1.5	ng/mL	0.10	1	DAY 1	1	2001-02-01T08:02	1	2 MIN	4	Day 1 Dose	2021-02-01T08:00	PT2M
5	3.0	ng/mL	0.10	1	DAY 1	1	2001-02-01T08:04	1	4 MIN	5	Day 1 Dose	2021-02-01T08:00	PT4M
6	8.0	ng/mL	0.10	1	DAY 1	1	2001-02-01T08:08	1	8 MIN	6	Day 1 Dose	2021-02-01T08:00	PT8M
7	5.0	ng/mL	0.10	1	DAY 1	1	2001-02-01T09:00	1	60 MIN	7	Day 1 Dose	2021-02-01T08:00	PT60
8	3.0	ng/mL	0.10	1	DAY 1	1	2001-02-01T010:00	1	120 MIN	8	Day 1 Dose	2021-02-01T08:00	PT120
9	5.44	ng/mL	0.10	2	DAY 4	4	2001-02-04T10:15	4	45 MIN PREDOSE	1	Day 4 Dose	2021-02-04T08:00	-PT45M
10	1.09	ng/mL	0.10	2	DAY 4	4	2001-02-04T07:30	4	30 MIN PREDOSE	2	Day 4 Dose	2021-02-04T08:00	-PT30M
11		ng/mL	0.10	2	DAY 4	4	2001-02-04T07:15	4	15 MIN REDOSE	3	Day 4 Dose	2021-02-04T08:00	-PT15M
13	3.41	ng/mL	0.10	2	DAY 4	4	2001-02-04T08:02	4	2 MIN	4	Day 4 Dose	2021-02-04T08:00	PT2M
13		ng/mL	0.10	2	DAY 4	4	2001-02-04T08:04	4	4 MIN	5	Day 4 Dose	2021-02-04T08:00	PT4M
14	8.74	ng/mL	0.10	2	DAY 4	4	2001-02-04T08:08	4	8 MIN	6	Day 4 Dose	2021-02-04T08:00	PT8M
15	4.2	ng/mL	0.10	2	DAY 4	4	2001-02-04T09:00	4	60 MIN	7	Day 4 Dose	2021-04-11T08:00	PT160M
16	245	ng/mL	0.10	2	DAY 4	4	2001-02-04T010:00	4	120 MIN	8	Day 4 Dose	2021-04-11T08:00	PT120M
17	1	ng/mL	.075	1	DAY 1	1	2001-02-01T07:15	1	45 MIN PREDOSE	1	Day 1 Dose	2021-02-01T08:00	-PT45M
18		pg/mL	0.3	1	DAY 1	1	2001-02-01T07:15	1	45 MIN PREDOSE	1	Day 1 Dose	2021-02-01T08:00	-PT45M

Example 2

In this PK study, C_{\max} , time to reach C_{\max} (t_{\max}), and the baseline-corrected area under the plasma concentration–time curves (i) from start of product use (t_0) to the last quantifiable nicotine concentration time point ($AUC_{0-\text{last}}$) and (ii) from t_0 to 10 minutes after t_0 (AUC_{0-10}). The pharmacokinetic parameters were derived from plasma nicotine concentrations-versus-time data by means of noncompartmental analysis and corrected for baseline where the baseline (C_0) was defined as the average concentration of the 3 time points prior to t_0 (45, 30, and 15 minutes prior to t_0). The analysis methods for the baseline corrected values were provided in the study protocol.

This example shows the PP parameters calculated from time-concentration profiles for the nicotine for one subject at day 1. Typically, the same PP parameters would be provided for cotinine and NNN but are only shown for TMAX. Note that PPRFTDTC is populated in order to link the PP records to the respective PC records.

Other parameters may be calculated but are not shown. They may include: (1) R2, R Squared; (2) R2ADJ, R Squared Adjusted; (3) AUCIFO, AUC Infinity Obs; (4) AUCPEO, AUC %Extrapolation Obs; (5) AUCTAU, AUC Over Dosing Interval; (6) LAMZNPT, Number of Points for Lambda z; (7) LAMZUL, Lambda z Upper Limit; or (8) LAMZLL, Lambda z Lower Limit. These PP parameters are included in the controlled terminology.

Rows 1-2: Show parameters TMAX and CMAX for day 1.

Rows 3-4: Show parameters AUC for day 1. Note AUCALL was calculated as AUC from 0- to the last value and AUCINT was calculated as 0 to 10 minutes. This interval is represented in PPSTINI, and PPENINT.

Rows 5-6: Show parameter TMAX for cotinine and NNN.

pp.xpt

Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPGRPID	PPTESTCD	PPTEST	PPCAT	PPORRES	PPORRESU	PPSTRESC	PPSTRESN	PPSTRESU	PPSPEC	PPANMETH	VISITNUM	VISIT	PPDTG	PPRFTDTC	PPSTINT	PPENINT
1	A123	PP	A2008	1	DAY1	TMAX	Time of CMAX	NICOTINE	5	m	5	5	m	PLASMA	non-compartmental analysis. and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00		
2	A123	PP	A2008	2	DAY1	CMAX	Max Conc	NICOTINE	13	ng/mL	13	13	ng/mL	PLASMA	non-compartmental analysis. and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00		
3	A123	PP	A2008	3	DAY1	AUCALL	AUC All	NICOTINE	11.4	h*ng/mL	11.4	11.4	h*ng/mL	PLASMA	non-compartmental analysis. and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00		
4	A123	PP	A2008	4	DAY1	AUCINT	AUC from T1 to T2	NICOTINE	6.0	h*ng/mL	6.0	6.0	h*ng/mL	PLASMA	non-compartmental analysis. and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00	0	10
5	A123	PP	A2008	5	DAY1	TMAX	Time of CMAX	COTININE	6	m	6	6	m	PLASMA	non-compartmental analysis. and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00		
6	A123	PP	A2008	6	DAY1	TMAX	Time of CMAX	NNN	7	m	7	7	m	PLASMA	non-compartmental analysis. and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00		

3.3.3.3 Respiratory Assessments (RE)

Respiratory assessments may be measured in studies on tobacco products to evaluate impact on respiratory function. Spirometry is a test that measures how an individual inhales or exhales volumes of air as a function of time, and is a test of general respiratory health.

The Respiratory System Findings (RE) domain is a body system-based morphology/physiology domain. This Findings domain is used to represent physiological and morphological findings related to the respiratory system, including the organs that are involved in breathing such as the nose, throat, larynx, trachea, bronchi, and lungs.

Example

In this example, spirometry was used to evaluate lung function. This shows results from several spirometry tests using either a spirometer or a peak flow meter where only the best result is available. The spirometry was assessed with and without bronchodilator use (represented in RECAT). Only select variables are shown.

Rows 1-2, 6-7: Show the data in original units of measure in REORRES for the best result for spirometry tests with the predicted values in REORREF.

Rows 3-4, 8-9: Show the data in original units of measure in REORRES of percent predicted tests as output by the spirometer device. REORREF is null as there are no reference results for percent predicted tests.

Rows 5, 10: Show the data in original units of measure in REORRES for the peak flow test with the predicted values in REORREF.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	RECAT	REORRES	REORRESU	REORREF	...	VISITNUM	VISIT	REDTC
1	XYZ	RE	XYZ-001-001	ABC001	1	FEV1	Forced Expiratory Volume in 1 Second	WITH BRONCHODILATOR	2.73	L	3.37		2	VISIT 2	2013-06-30
2	XYZ	RE	XYZ-001-001	ABC001	2	FVC	Forced Vital Capacity	WITH BRONCHODILATOR	3.91	L	3.86		2	VISIT 2	2013-06-30
3	XYZ	RE	XYZ-001-001	ABC001	3	FEV1PP	Percent Predicted FEV1	WITH BRONCHODILATOR	81	%			2	VISIT 2	2013-06-30
4	XYZ	RE	XYZ-001-001	ABC001	4	FVCPP	Percent Predicted FVC	WITH BRONCHODILATOR	101.3	%			2	VISIT 2	2013-06-30
5	XYZ	RE	XYZ-001-001	DEF999	5	PEF	Peak Expiratory Flow	WITH BRONCHODILATOR	6.11	L/s	7.33		4	VISIT 2	2013-07-17
6	XYZ	RE	XYZ-001-001	ABC001	6	FEV1	Forced Expiratory Volume in 1 Second	WITHOUT BRONCHODILATOR	2.69	L	3.37		2	VISIT 2	2013-06-30
7	XYZ	RE	XYZ-001-001	ABC001	7	FVC	Forced Vital Capacity	WITHOUT BRONCHODILATOR	3.81	L	3.86		2	VISIT 2	2013-06-30
8	XYZ	RE	XYZ-001-001	ABC001	8	FEV1PP	Percent Predicted FEV1	WITHOUT BRONCHODILATOR	76	%			2	VISIT 2	2013-06-30
9	XYZ	RE	XYZ-001-001	ABC001	9	FVCPP	Percent Predicted FVC	WITHOUT BRONCHODILATOR	98.3	%			2	VISIT 2	2013-06-30
10	XYZ	RE	XYZ-001-001	DEF999	18	PEF	Peak Expiratory Flow	WITHOUT BRONCHODILATOR	5.54	L/s			4	VISIT 2	2013-07-17

3.3.3.4 Tobacco Product Device Events and Malfunctions (EM)

In tobacco studies, subjects may report events (problems) or malfunctions with the device used to deliver the tobacco product. Often the true cause of the issue cannot be determined until a cause analysis is performed. The applicant decides when tobacco product device events and malfunctions are collected. If malfunction or product event results in an adverse event, then that information should be recorded in the AE domain using the appropriate device-related variables (e.g., AEACNDEV, AERLDEV).

The Tobacco Product Events and Malfunctions (EM) domain is based on the Events general observation class and is used to represent device issues and/or events.

There is more than 1 approach to identifying tobacco product devices involved with these events/incidents. The method chosen will depend upon the granularity at which the applicant needs to track the tobacco product devices and will affect how the data are modeled. A tobacco product device can be identified as a single unit or its components can be separately identified. The level of granularity an applicant chooses will be influenced by whether the components will be replaced and/or tracked, and how tobacco product device/adverse event relationships and actions taken will be assessed.

Example 1

This is an example of a study where the applicant collected issues and events associated with the operation of the electronic cigarette product and any adverse events that a subject experienced as a result of the product issue or event.

This form collects events and malfunctions associated with the operation of the tobacco product device.

Tobacco Implementation Guide -Tobacco Device Product Events or Malfunctions		
Any Product Device Events or Malfunctions		
Were any tobacco product events or malfunctions experienced? <i>Indicate if the subject experienced any tobacco product device events or malfunctions. If Yes, include the appropriate details where indicated on the CRF</i>	<input type="radio"/> No <input checked="" type="radio"/> Yes	NOT SUBMITTED EMYN
What was the tobacco product identifier? <i>Indicate the tobacco product device that was associated with the event.</i>	SPTOBID SPTOBID	
Product Device Events or Malfunctions		
What was the event associated with this device? <i>Record a description of the tobacco product device event that occurred. Record only 1 event or malfunction per line.</i>	EMTERM EMTERM	
Start Date (DD-MMM-YYYY) <i>Record the date that the event or malfunction first occurred or was noted</i>	<input type="text"/> / <input type="text"/>	EMSTDT EMSTDAT
What was the pattern of the event? <i>Indicate the pattern of the event over time.</i>	<input type="radio"/> Single Event <input type="radio"/> Intermittent <input type="radio"/> Continuous	EMPATT EMPATT
What action was taken with the device? <i>Record what action was taken with the device as a result of the event.</i>	<input type="radio"/> Device Replaced <input type="radio"/> Battery Replaced <input type="radio"/> Calibration <input type="radio"/> Reprogramming	EMACNDEV EMACNDEV

What was the identifier for the primary adverse experience(s) associated with or related to this device event? Record the ID of the primary AE associated with event, if any.	ASSOCIATE WITH RELATED RECORD VIA RELREC EMAENO1
What was the identifier for the primary adverse experience(s) associated with or related to this device event? Record the ID of the primary AE associated with event, if any.	ASSOCIATE WITH RELATED RECORD VIA RELREC EMAENO1
<i>CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).</i>	

CDASH EM Metadata Specifications

Order	Question Text	Prompt	Case Report Form Completion Instructions	Type	Collection Variable	Tabulation Target	Mapping Instructions	Controlled Terminology CodeList Name	Permissible Values	Pre-Populated Value
Section 1										
1	Any Tobacco Product Events	Any Tobacco Product Events	Indicate if the subject experienced any medical conditions or events. If Yes, include the appropriate details where indicated on the CRF.	Text	EMYN	EMYN	N/A	(NY)	No;Yes	
2	Tobacco Product Identifier	Tobacco Product Identifier	Indicate the product that was associated with the event.	Text	SPTOBID	SPTOBID				VAPE-Z01
Section 2										
3	What was the event or malfunction associated with this device?	Tobacco Product Device Event	Record a description of the tobacco product device event or malfunction that occurred.	Text	EMTERM	EMTERM				
4	What was the start date when the event or malfunction first occurred or was identified?	Start Date	Record the date that the event or malfunction first occurred or was noted using this format (DD-MON-YYYY).	Date	EMSTDAT	EMSTDTC				
5	What was the pattern of the event or malfunction?	Pattern of Tobacco Product Device Event	Record the pattern of the event or malfunction that occurred.	Text	EMPATT	EMPATT			Single Event; Intermittent; Continuous	
6	What action was taken with the device?	Action Taken With Device	Record what action was taken with the device as a result of the event.	Text	EMACNDEV	EMACNDEV		(DEACNDEV)	No Action Taken; Device Replaced; Battery Replaced	
7	What was the identifier for the primary adverse event(s) associated with or related to this device event?	Related Adverse Event ID	Record the ID of the primary AE associated with event, if any.	Text	EMAENO(n)	N/A	ASSOCIATE WITH RELATED RECORD VIA RELREC			
3	What was the event or malfunction associated with this device?	Tobacco Product Device Event	Record a description of the tobacco product device event or malfunction that occurred.	Text	EMTERM	EMTERM				
4	What was the start date when the event or malfunction first occurred or was identified?	Start Date	Record the date that the event or malfunction first occurred or was noted using this format (DD-MON-YYYY).	Date	EMSTDAT	EMSTDTC				

These SDTM datasets represent the data collected above. An abbreviated Tobacco Product Identifiers and Descriptors (TO) domain example is also provided for reference. TO provides a mechanism for uniquely identifying a tobacco product and is the source of the SPTOBID variable. For more information on this domain, see Section 3.1.1, [Tobacco Product Identifiers and Descriptors](#). Only 1 tobacco product was of interest in the study.

to.xpt

Row	STUDYID	DOMAIN	SPTOBID	TOSEQ	TOPARMCD	TOPARM	TOCAT	TOVAL
1	TB123	TO	VAPE-Z01	1	TBPRDCAT	Tobacco Product Category	PRODUCT IDENTIFIER	ENDS (VAPES)
2	TB123	TO	VAPE-Z01	2	TBPRSCAT	Tobacco Product Subcategory	PRODUCT IDENTIFIER	CLOSED E-CIGARETTE
3	TB123	TO	VAPE-Z01	3	MANUF	Manufacturer	PRODUCT IDENTIFIER	XXX VAPES USA

These product malfunctions and events are represented in EM. Events not specifically associated with the product device should not be represented in this domain.

The applicant used a standardized or dictionary-derived text for the description of an issue or events. (Note: CDISC does not prescribe what standardized or dictionary-derived text should be used.) The applicant decided to use the International Medical Device Regulators Forum (IMDRF) document terminologies for categorized adverse event reporting for the medical problem codes. The name and version of the dictionary used to map terms must be provided in a Define.XML ExternalCodeList element (see Section 2.10, [Standards for Data Exchange](#)).

EMDECOD was the Level 3 IMDRF term. NSVs were used to represent the various coding level variables defined in the dictionary.

Example SUPPEM Variable Metadata

Variable	Label	Type	Codelist
EMIMDRCD	IMDRF Code	text	IMDRFANNEXA
EMIMDRFL2	IMDRF Level 2	text	IMDRFANNEXA
EMIMDRFL1	IMDRF Level 1	text	IMDRFANNEXA

Example External Dictionaries

Codelist	External Dictionary Name	Dictionary Version	Reference
IMDRFANNEXA	IMDRF Terminologies for Categorized Adverse Event Reporting (AER): Terms, Terminology Structure and Codes: Annex A	Release Number: 2022	https://www.imdrf.org/consultations/imdrf-terminologies-categorized-adverse-event-reporting-aer-terms-terminology-structure-and-codes

The SDTM EM dataset is shown below.

em.xpt

Row	STUDYID	DOMAIN	USUBJID	SPTOBID	EMSEQ	EMLNKID	EMTERM	EMDECOD	EMMODIFY	EMACNDEV	EMPATT	EMSTDTC
1	TB123	EM	2029	VAPE-Z01	1		Broken Heater	Mechanical Problem	Mechanical Problem	DEVICE REPLACED	SINGLE	2009-12-28
2	TB123	EM	1059	VAPE-Z01	1		Won't charge	Charging Problem	Charging Problem	BATTERY REPLACED	SINGLE	2009-01-05
3	TB123	EM	3067	VAPE-Z01	1	1	Battery Malfunction	Battery Problem	Battery Problem	BATTERY REPLACED	INTERMITTENT	2009-01-05

The SUPPEM dataset is used to represent the NSVs used for coding the malfunction or event. The parent domain (RDOMAIN) is EM, and IDVAR is EMSEQ. QNAM holds the name of the supplemental qualifier variable being defined. This only shows the data for subject 2029. The data recorded in QVAL applies to the subject's records, where IDVAR (EMSEQ) equals the value specified in IDVARVAL.

suppem.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	TB123	EM	2029	EMSEQ	1	EMIMDRCD	IMDR Code	A05	ASSIGNED	
2	TB123	EM	2029	EMSEQ	1	EMIMDRL2	IMDR Level 2	Mechanical Problem	ASSIGNED	
3	TB123	EM	2029	EMSEQ	1	EMIMDRL1	IMDR Level 1	Mechanical Problem	ASSIGNED	

In this study, subject 3067 had an AE associated with the battery problem. This was reported in the AE dataset. Not all variables are shown below for brevity.

ae.xpt

Row	STUDYID	DOMAIN	USUBJID	SPTOBID	AESEQ	AELNKID	AETERM	AERLDEV	EPOCH	AESTDTC	AEENDTC	AESTDY	AEENDY
1	TB123	AE	3067	VAPE-Z01	1	1	SKIN REDNESS	RELATED	PRODUCT EXPOSURE	2009-01-05	2009-01-07	14	17

The RELREC dataset was used to record the relationship between the EM dataset and any reported AE represented in the AE dataset.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	TB005	EM		EMLNKID		ONE	AEEM1
2	TB005	AE		AELNKID		ONE	AEEM1

3.3.4 Exposure Assessments During Tobacco Product Studies

Self-reporting of nicotine exposure often may be biased and lead to inaccurate measures of exposure. Hence, biomarkers are often used to provide objective measures of nicotine exposure. Studies on tobacco products typically collect the quantities of the tobacco product used through self-reporting, while the actual nicotine exposure is measured by biomarkers.

Studies evaluate the protocol-specified study product exposure. These study products are typically supplied by the applicant. However, applicants often collect exposure to other nicotine sources.

The subject's normal nicotine product usage (e.g., brand of cigarettes, nicotine replacement patches) may be allowed or discouraged in a study. These products are not supplied by the applicant, and are not considered a study product. The use of these products would be represented in the Substance Use (SU; for cigarettes) and Concomitant Medications (CM; for nicotine replacement patches) domains.

Studies may be performed under controlled circumstances in clinics, to ensure that the only nicotine exposure is the study product itself.

Exposure data on the study product of interest are reported in the Exposure as Collected (EC) and/or the Exposure (EX) domains as well as the Product Accountability (DA) domain.

- The DA domain is a Findings domain for representing the accountability of study products (e.g., information on receipt, dispensing, return, packaging).
- The EC domain is an Interventions domain for representing information about protocol-specified study product administrations, as collected.
- The EX domain is an Interventions domain for representing a subject's exposure to protocol-specified study product. *Study product* is usually an intervention that is prospectively defined as a test material within a study, and is typically but not always supplied to the subject.

The EC domain is typically used to reflect amounts at the product level (e.g., number of cigarettes, number of cartridges, number of patches), not the actual exposure to the product, which would be represented in EX. The EX data are derived from EC, DA, and the protocol-specific details on the study product.

The domains needed to represent the exposure in a tobacco product study are decided by the applicant. Some applicants use the EC domain to reflect the collected exposure data, and then derive EX. The degree of summarization of records from EC to EX is applicant defined and is used to support the study purpose and analysis. EX derivations must be described in the Define-XML document. More detail summarization may also be performed in ADaM. For

example, the estimated daily nicotine exposure may based on self-reported nicotine exposure may be provided; because these are estimates, they are typically not reported in EX.

Applicants may find it easier to report both the collected data in EC and the derived EX data to provide tracking of the summarized exposure to what was collected.

In some situations, applicants may elect to only use the EX and, if needed, the DA domain. EX would be used when little relevant information is represented in EC (i.e., when EC and EX would essentially be duplicates). For example, the derivation for EX may just be the unmasking of the product, and a applicant may decide not to show the EC because the derivations used for EX are obvious.

The EX domain is required for all studies that include protocol-specified study product exposure. Exposure records may be directly or indirectly determined; metadata should describe how the records were derived. Common methods for determining exposure (from most direct to least direct) include:

- Derived from actual observation of the administration of study product by the investigator
- Derived from an automated dispensing device that records administrations
- Derived from subject recall
- Derived from product accountability data
- Derived from the protocol. When a study is still masked and protocol-specified study product exposure cannot yet be reflected in the protocol-specified unit due to blinding requirements, then the EX domain is not expected to be populated.

3.3.4.1 Tobacco Product Exposure

The examples in this section illustrate various methods for displaying study product exposure data, as well as data that may be collected on the use of other nicotine sources. These examples are provided to illustrate specific exposure based on how it was measured (e.g., by volume, by weight, number of product consumed).

Example 1

In this study, subjects were randomized to different doses of a nicotine inhaler. The recommended usage instructions for the nicotine inhaler were provided to the subject at each visit. At visits 1-3, subjects were to use 6-10 cartridges per day, and during visits 4-6 subjects were to use 3-6 cartridges per day. Subjects were encouraged not to use any other tobacco products, nicotine replacement therapies, or alcohol during the study. Data on usage of these products were collected using an e-diary, where subjects provided information on the products used each day. Only days where a product was used were represented.

Alcohol usage and tobacco product usage were represented in the Substance Use (SU) domain. SUCAT allows the records to be grouped into tobacco-related data and alcohol-related data. In this example, the products were prespecified so SUTRT does not require a standardized SUDECOD equivalent. The applicant only includes SUSTDTC and SUENDTC as timing variables.

Row 1: Shows the cigarettes used for the day of assessment. SUDOSFRQ was represented using the controlled terminology for per day, QD.

Rows 2-3: Show 2 other records for a subject's usage of tobacco products on 2 other days.

Row 4: Shows the subject's use of alcohol. Note: The applicant collected the ounces of the product used using a prespecified amount per drink.

su.xpt

Row	STUDYID	DOMAIN	USUBJID	SUSEQ	SUTRT	SUCAT	SUDOSE	SUDOSU	SUDOSFRQ	SUSTDTC	SUENDTC
1	TIN111	SU	TIN701	1	CIGARETTE	TOBACCO	1	CIGARETTE	QD	2020-06-26	2020-06-26
2	TIN111	SU	TIN701	2	CIGAR	TOBACCO	2	CIGAR	QD	2020-07-27	2020-07-27
3	TIN111	SU	TIN801	1	CIGARETTE	TOBACCO	1	CIGARETTE	QD	2020-07-15	2020-07-15
4	TIN111	SU	TIN801	2	BEER	ALCOHOL	24	OZ	QD	2020-07-20	2020-07-20

Drugs used to treat nicotine dependency are considered drugs and were represented in the Concomitant Medication (CM) domain. This subject used a 14 mg nicotine replacement patch. The applicant included the CMCLASS, CMDECOD, and CMMODIFY. These were included to reflect standardized coding of the medication.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMMODIFY	CMDECOD	CMCLAS	CMDOSE	CMDOSU	CMDOSFRM	CMSTDTC	CMENDTC
1	TIN111	CM	TIN701	1	Nicotine Replacement Patch	Nicotine	NICOTINE	DRUGS USED IN NICOTINE DEPENDENCE	14	mg	PATCH	2020-06-26	2020-06-27

The Product Accountability (DA) domain was used to represent the amount of study product transferred to or from the study subjects. At each visit, each subject was supplied with 90 cartridges per week for weeks 1-3, and 50 cartridges per week for weeks 4-6. The number of cartridges returned were counted. DACAT was used to indicate that the product of interest was the study product. DASPID and DAREFID can be used for code numbers that appeared on the study product label; in this case, no code numbers were included on the labels. The applicant included VISITNUM and DADTC as these variables are expected in this domain. DADTC was the date the supplies were dispensed or returned, these corresponded to the dates of the visits.

Rows 1, 3: Show the number of cartridges dispensed to the subject.

Rows 2, 4: Show the number of cartridges returned by the subject.

da.xpt

Row	STUDYID	DOMAIN	USUBJID	DASEQ	DATESTCD	DATEST	DACAT	DAORRES	DAORRESU	DASTRESC	DASTRESN	DASTRESU	VISITNUM	DADTC
1	TIN111	DA	TIN701	1	DISPAMT	Dispensed Amount	STUDY PRODUCT	90	CARTRIDGE	90	90	CARTRIDGE	1	2004-06-26
2	TIN111	DA	TIN701	2	RETAMT	Returned Amount	STUDY PRODUCT	13	CARTRIDGE	13	13	CARTRIDGE	2	2020-07-06
3	TIN111	DA	TIN701	3	DISPAMT	Dispensed Amount	STUDY PRODUCT	50	CARTRIDGE	50	50	CARTRIDGE	2	2020-07-06
4	TIN111	DA	TIN701	4	RETAMT	Returned Amount	STUDY PRODUCT	10	CARTRIDGE	10	10	CARTRIDGE	3	2020-07-14

The applicant used a patient diary (not shown here) to determine how many cartridges the subject used on each day, then created the EC data to represent the collected exposure data. Usage recommendations were represented in ECDOSRGM, which is the intended dose regimen. The ECMOOD permissible variable was used to reflect the prescribed and the actual usage of the inhaled nicotine. When this variable is used, it must be populated for all records. This variable cannot be used in EX.

Row 1: Shows the scheduled usage recommendation for the inhaled nicotine. Note: The details on the scheduled records are described at a different level than the performed records. ECDOSRGM shows that for these start and end dates the subject was recommended to use 6-12 cartridges every day.

Rows 2, 3: Show the actual "performed" amount of inhaled nicotine used by the subject each day. Only a few rows of the performed records are shown.

Row 4: Shows the scheduled usage recommendation for the inhaled nicotine. ECDOSRGM shows for these start and end dates the subject was recommended to use 3-6 cartridges per day.

Row 5: Shows the actual performed amount of inhaled nicotine used by the subject each day. Only a few rows of the performed records are shown.

ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECTRT	ECMOOD	ECDOSE	ECDOSU	ECDOSFRM	ECDOSRGM	ECROUTE	EPOCH	ECSTDTC	ECENDTC
1	TIN111	EC	TIN701	1	INHALED NICOTINE	SCHEDULED		CARTRIDGE	CARTRIDGE	6 -10 cartridges per day	RESPIRATORY (INHALATION)	PRODUCT EXPOSURE	2004-06-26	2004-07-06
2	TIN111	EC	TIN701	2	INHALED NICOTINE	PERFORMED	7	CARTRIDGE	CARTRIDGE		RESPIRATORY (INHALATION)	PRODUCT EXPOSURE	2004-06-26	2004-06-26
3	TIN111	EC	TIN701	3	INHALED NICOTINE	PERFORMED	2	CARTRIDGE	CARTRIDGE		RESPIRATORY (INHALATION)	PRODUCT EXPOSURE	2004-06-27	2004-06-27
4	TIN111	EC	TIN701	4	INHALED NICOTINE	SCHEDULED		CARTRIDGE	CARTRIDGE	3-6 cartridges per day	RESPIRATORY (INHALATION)	PRODUCT EXPOSURE	2004-07-06	2004-07-14
5	TIN111	EC	TIN701	5	INHALED NICOTINE	PERFORMED	3	CARTRIDGE	CARTRIDGE		RESPIRATORY (INHALATION)	PRODUCT EXPOSURE	2004-07-07	2004-07-07

The EX dataset shows actual administrations. Scheduled records are not included, and only a few rows are shown for illustration purposes. The pharmaceutical strength was included to identify the dose of the nicotine inhaler used by the subject. Because EXENDTC is an expected variable, the applicant populated this timing variable with the start date.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXPSTRG	EXPSTRGU	EPOCH	EXSTDTC	EXENDTC
1	TIN111	EX	TIN701	1	INHALED NICOTINE	7	CARTRIDGE	CARTRIDGE	RESPIRATORY (INHALATION)	6	mg	PRODUCT EXPOSURE	2004-06-26	2004-06-26
2	TIN111	EX	TIN701	2	INHALED NICOTINE	2	CARTRIDGE	CARTRIDGE	RESPIRATORY (INHALATION)	6	mg	PRODUCT EXPOSURE	2004-06-27	2004-06-27
3	TIN111	EX	TIN701	1	INHALED NICOTINE	3	CARTRIDGE	CARTRIDGE	RESPIRATORY (INHALATION)	4	mg	PRODUCT EXPOSURE	2004-07-07	2004-07-07

In this example, the EC domain is not used by the applicant to represent collected exposure. Exposure is represented based on the volume of the e-nicotine liquid cartridges.

Example 2

In this study, subjects were randomized to 1 of 3 nicotine dosage levels. At the baseline visit (week 0), they received an ENDS device that used 0, 8, or 24 mg/ml nicotine liquid. Self-reported daily cigarette consumption was recorded for each day of the study for 4 weeks. The subjects were supplied replacement nicotine cartridges at each weekly visit. The applicant used an e-diary to track when cartridges were inserted and removed, and the daily number of cigarettes smoked. Subjects used their normal brand of cigarettes; these were not supplied by the applicant, and are not considered a study product. Each cartridge was 8 mL. No other nicotine replacement products were allowed to be used. Multiple cartridges were dispensed at a visit.

The applicant represented the cigarettes used in the SU domain. After the first visit, the number of cigarettes smoked for each day of the study were represented. If no cigarettes were smoked,(although "0" records are typically not included), 0 was recorded as the data was collected. Only a few rows are shown.

SU.xpt

Row	STUDYID	DOMAIN	USUBJID	SUSEQ	SUTRT	SUCAT	SUDOSE	SUDOSU	SUDOSFRQ	SUSTDTC	SUENDTC
1	TENDS01	SU	TEN01001	1	CIGARETTES	TOBACCO	6	CIGARETTE	QD	2020-06-27	2020-06-27
2	TENDS01	SU	TEN01001	2	CIGARETTES	TOBACCO	1	CIGARETTE	QD	2020-06-28	2020-06-28
3	TENDS01	SU	TEN01001	3	CIGARETTES	TOBACCO	0	CIGARETTE	QD	2020-06-29	2020-06-29

The DA domain was used to represent dispensed and returned amounts. The ENDS product used in the study was assigned a product identifier (VAPE-Z27), and each cartridge had a uniquely assigned number. This unique number was represented in DAREFID. Multiple cartridges were dispensed at weekly visits, and each cartridge was tracked. At each weekly visit, all previously dispensed cartridges were returned and new cartridges dispensed. Cartridges were replaced at each visit. DADTC are the visit dates when the cartridge was returned or dispensed. Cartridges not used were recorded as having the full volume returned.

da.xpt

Row	STUDYID	DOMAIN	USUBJID	DASEQ	SPTOBID	DAREFID	DATESTCD	DATEST	DACAT	DAORRES	DAORRESU	DASTRESC	DASTRESN	DASTRESU	VISITNUM	DADTC
1	TENDS01	DA	TEN01001	1	VAPE-Z27	CRT8754	DISPAMT	Dispensed Amount	STUDY PRODUCT	8	mL	8	8	mL	1	2020-06-26
2	TENDS01	DA	TEN01001	2	VAPE-Z27	CRT8768	DISPAMT	Dispensed Amount	STUDY PRODUCT	8	mL	8	8	mL	1	2020-06-26
3	TENDS01	DA	TEN01001	3	VAPE-Z27	CRT8769	DISPAMT	Dispensed Amount	STUDY PRODUCT	8	mL	8	8	mL	1	2020-06-26
4	TENDS01	DA	TEN01001	4	VAPE-Z27	CRT8754	RETAMT	Returned Amount	STUDY PRODUCT	2	mL	2	2	mL	2	2020-07-06
2	TENDS01	DA	TEN01001	5	VAPE-Z27	CRT8768	RETAMT	Returned Amount	STUDY PRODUCT	1.6	mL	1.6	1.6	mL	2	2020-07-06
3	TENDS01	DA	TEN01001	6	VAPE-Z27	CRT8769	RETAMT	Returned Amount	STUDY PRODUCT	8	mL	8	8	mL	2	2020-07-06
5	TENDS01	DA	TEN01001	7	VAPE-Z27	CRT9756	DISPAMT	Dispensed Amount	STUDY PRODUCT	8	mL	8	8	mL	2	2020-07-06
6	TENDS01	DA	TEN01001	8	VAPE-Z27	CRT9756	RETAMT	Returned Amount	STUDY PRODUCT	1	mL	1	1	mL	3	2020-07-10

Because the data in EC would be practically identical to the summarized EX domain, the applicant did not submit the EC domain. The applicant unblinded the study before creating the EX domain. The unblinded product name is provided in EXTRT; here, a dummy name is used for the tobacco product.

The applicant used an e-diary to collect the start and end date of the insertion and removal date of each cartridge in the ENDS device. For simplicity, in this example the actual times of insertion/removal were not collected, although this may often be collected.

The total amount of liquid product used from each cartridge was determined using the data in the DA domain. The associated nicotine pharmaceutical strength of each cartridge was known. The applicant used this information in the analysis. The summaries included in the analysis were the estimated number of cartridges used per week, and the estimated nicotine exposure from the cartridges per day.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	SPTOBID	EXREFID	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXPSTRG	EXPSTRGU	EXSTDTC	EXENDTC
1	TENDS01	EX	TEN01001	1	VAPE-Z27	CRT8754	Nicotine e-liquid	6	mL	CARTRIDGE	RESPIRATORY (INHALATION)	8	mg/mL	2020-06-26	2020-07-01
2	TENDS01	EX	TEN01001	2	VAPE-Z27	CRT8768	Nicotine e-liquid	6.4	mL	CARTRIDGE	RESPIRATORY (INHALATION)	8	mg/mL	2020-07-01	2020-07-06
3	TENDS01	EX	TEN01001	3	VAPE-Z27	CRT9756	Nicotine e-liquid	7	mL	CARTRIDGE	RESPIRATORY (INHALATION)	8	mg/mL	2020-07-06	2020-07-10
3	TENDS01	EX	TEN01001	4	VAPE-Z27	CRT9778	Nicotine e-liquid	8	mL	CARTRIDGE	RESPIRATORY (INHALATION)	8	mg/mL	2020-07-10	2020-07-14
4	TENDS01	EX	TEN0002	1	VAPE-Z27	CRT8000	Nicotine e-liquid	5	mL	CARTRIDGE	RESPIRATORY (INHALATION)	0	mg/mL	2020-09-01	2020-09-07
5	TENDS01	EX	TEN0002	2	VAPE-Z27	CRT9006	Nicotine e-liquid	7	mL	CARTRIDGE	RESPIRATORY (INHALATION)	0	mg/mL	2020-09-07	2020-09-14
6	TENDS01	EX	TEN0002	3	VAPE-Z27	CRT9008	Nicotine e-liquid	8	mL	CARTRIDGE	RESPIRATORY (INHALATION)	0	mg/mL	2020-09-14	2020-09-21
7	TENDS01	EX	TEN0002	4	VAPE-Z27	CRT9017	Nicotine e-liquid	6	mL	CARTRIDGE	RESPIRATORY (INHALATION)	0	mg/mL	2020-09-21	2020-09-28
8	TENDS01	EX	TEN0002	5	VAPE-Z27	CRT9089	Nicotine e-liquid	7	mL	CARTRIDGE	RESPIRATORY (INHALATION)	0	mg/mL	2020-09-28	2020-09-31
9	TENDS01	EX	TEN0002	6	VAPE-Z27	CRT9128	Nicotine e-liquid	8	mL	CARTRIDGE	RESPIRATORY (INHALATION)	0	mg/mL	2020-10-31	2020-10-08
10	TENDS01	EX	TEN0002	7	VAPE-Z27	CRT6868	Nicotine e-liquid	6.7	mL	CARTRIDGE	RESPIRATORY (INHALATION)	0	mg/mL	2020-10-08	2020-10-15
11	TENDS01	EX	TEN0002	8	VAPE-Z27	CRT7868	Nicotine e-liquid	5.5	mL	CARTRIDGE	RESPIRATORY (INHALATION)	0	mg/mL	2020-10-15	2020-10-22

In this example, both the EC and EX domains are used. Exposure is based on the weight of the e-nicotine liquid cartridges.

Example 3

In this study, subjects were randomized to either nicotine replacement patches or ENDS devices using e-nicotine liquid cartridges. In order to maintain the blind, subjects used both the nicotine replacement patches and the ENDS devices. Subjects were requested not to smoke, but the number of regular cigarettes used were collected. Subject were seen every day for 15 days. The nicotine patch was applied, at rotating sites, and the nicotine cartridge was replaced every day. The cartridge was weighed when dispensed and upon return. On days, 1, 5, and 10 subjects remained in the clinic for 4 hours for collection of biomarkers. On these

days, a new ENDS nicotine cartridge was inserted and 10 puffs were taken over 10 minutes, and not used for the remaining collection period. A new cartridge was inserted at the end of the 4-hour collection period. A nicotine replacement patch was applied prior to using the ENDS device on these days.

The SU domain was used to represent the number of cigarettes used, but is not shown.

In this study, the weight of the contents in the cartridge was tracked. The DA domain was used to represent dispensed and returned weights of each cartridge. Only a few rows are shown. The product accountability information was not provided for the nicotine replacement patches.

da.xpt

Row	STUDYID	DOMAIN	USUBJID	DASEQ	DAREFID	DATESTCD	DATEST	DACAT	DASCAT	DAORRES	DAORRESU	DASTRESC	DASTRESN	DASTRESU	VISITNUM	DADTC
1	TEDP07	DA	10001	1	CRT8754	DISPAMT	Dispensed Amount	STUDY PRODUCT	E-LIQUID	25.3	g	25	25	g	1	2004-06-06
2	TEDP07	DA	10001	2	CRT8754	RETAMT	Returned Amount	STUDY PRODUCT	E-LIQUID	23	g	23	23	g	1	2020-06-06
3	TEDP07	DA	10001	3	CRT9756	DISPAMT	Dispensed Amount	STUDY PRODUCT	E-LIQUID	25.1	g	25	25	g	1	2020-06-07
4	TEDP07	DA	10001	4	CRT9756	RETAMT	Returned Amount	STUDY PRODUCT	E-LIQUID	10	g	14	14	g	2	2020-06-08
5	TEDP07	DA	10001	5	CRT9955	DISPAMT	Dispensed Amount	STUDY PRODUCT	E-LIQUID	25.2	g	25	25	g	2	2004-06-08

EC was used to represent the collected exposure data since a double-blind design was used. The EX domain was used to represent the subject's exposure to the actual product containing nicotine. The applicant represented each cartridge and patch used. The dose was represented as "1" to indicate 1 cartridge or patch. The actual date and specific time of usage of the cartridge was recorded on days 1, 5, and 10, while only the date of usage was recorded on other days.

ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECTRT	ECDOSE	ECDOSTXT	ECDSU	ECDOSEFRM	ECROUTE	ECLOC	ECLAT	ECDIR	EPOCH	ECSTDTC	ECENDTC
1	TEDP07	EC	10001	1	ENDS	10		PUFF	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	2020-06-01T08:00	2020-06-01T08:10
2	TEDP07	EC	10001	2	PATCH	1		PATCH	PATCH	TRANSDERMAL	ARM	RIGHT	UPPER	PRODUCT EXPOSURE	2020-06-01	2020-06-02
3	TEDP07	EC	10001	3	ENDS		AD LIBITUM	PUFF	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	2020-06-01T12:10	2020-06-02
4	TEDP07	EC	10001	4	ENDS		AD LIBITUM	PUFF	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	2020-06-02	2020-06-03
5	TEDP07	EC	10001	5	PATCH	1		PATCH	PATCH	TRANSDERMAL	ARM	LEFT	UPPER	PRODUCT EXPOSURE	2020-06-02	2020-06-03
6	TEDP07	EC	10001	6	ENDS		AD LIBITUM	PUFF	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	2020-06-03	2020-06-04
7	TEDP07	EC	10001	7	PATCH	1		PATCH	PATCH	TRANSDERMAL	LEG	LEFT	UPPER	PRODUCT EXPOSURE	2020-06-03	2020-06-04
7	TEDP07	EC	10001	8	ENDS		AD LIBITUM	PUFF	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	2020-06-04	2020-06-05
8	TEDP07	EC	10001	9	PATCH	1		PATCH	PATCH	TRANSDERMAL	LEG	LEFT	LOWER	PRODUCT EXPOSURE	2020-06-04	2020-06-05
9	TEDP07	EC	10001	10	ENDS	10		PUFF	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	2020-06-10T8:30	2020-06-10T8:40
10	TEDP07	EC	10001	11	PATCH	1		PATCH	PATCH	TRANSDERMAL	LEG	RIGHT	LOWER	PRODUCT EXPOSURE	2020-06-10	2020-06-11
11	TEDP07	EC	10001	12	ENDS		AD LIBITUM	PUFF	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	2020-06-10T12:40	2020-06-11

Subject 10001 was randomized to the 5% pharmaceutical strength of the nicotine e-liquid, and subject 20001 was randomized to the nicotine patch with a pharmaceutical strength of 14mg. The applicant only represented the active product exposure for each subject in EX.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXLOC	EXLAT	EXDIR	EPOCH	EXPSTRG	EXPSTRGU	EXSTDTC	EXENDTC
1	TEDP07	EX	10001	1	e nicotine liquid	1.7	g	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	5	%	2020-06-01T08:00	2020-06-01T8:10
2	TEDP07	EX	10001	2	e nicotine liquid	15.1	g	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	5	%	2020-06-01T12:10	2020-06-02
3	TEDP07	EX	10001	3	e nicotine liquid	13	g	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	5	%	2020-06-02	2020-06-03
4	TEDP07	EX	10001	4	e nicotine liquid	12	g	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	5	%	2020-06-03	2020-06-04
5	TEDP07	EX	10001	5	e nicotine liquid	9	g	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	5	%	2020-06-04	2020-06-05
6	TEDP07	EX	10001	6	e nicotine liquid	7	g	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	5	%	2020-06-10T08:30	2020-06-10T08:40
7	TEDP07	EX	10001	7	e nicotine liquid	5	g	CARTRIDGE	RESPIRATORY (INHALATION)				PRODUCT EXPOSURE	5	%	2020-06-10T12:40	2020-06-11
8	TEDP07	EX	20001	1	nicotine replacement therapy	1	PATCH	PATCH	TRANSDERMAL	ARM	RIGHT	UPPER	PRODUCT EXPOSURE	14	mg	2020-06-01	2020-06-02
9	TEDP07	EX	20001	2	nicotine replacement therapy	1	PATCH	PATCH	TRANSDERMAL	ARM	LEFT	UPPER	PRODUCT EXPOSURE	14	mg	2020-06-02	2020-06-03
10	TEDP07	EX	20001	3	nicotine replacement therapy	1	PATCH	PATCH	TRANSDERMAL	LEG	LEFT	UPPER	PRODUCT EXPOSURE	14	mg	2020-06-03	2020-06-04
11	TEDP07	EX	20001	4	nicotine replacement therapy	1	PATCH	PATCH	TRANSDERMAL	LEG	LEFT	LOWER	PRODUCT EXPOSURE	14	mg	2020-06-04	2020-06-05
12	TEDP07	EX	20001	5	nicotine replacement therapy	1	PATCH	PATCH	TRANSDERMAL	LEG	RIGHT	LOWER	PRODUCT EXPOSURE	14	mg	2020-06-10	2020-06-11

In this example, subjects were exposed to multiple study products. The actual dates and times of use for each product are represented.

Example 4

This is an example of a crossover study testing 7 smokeless tobacco products. All products contain nicotine except for product F, which was a nicotine-/tobacco-free product. Each subject first used the product ad libitum; the next day, the product usage was evaluated in the morning, as specified in the protocol. Subjects were confined to the site. Products were supplied to the subjects as needed by site staff. Each usage was recorded. The applicant did not submit a DA domain, nor an EC domain. The name of the actual product would be used, but a dummy name is used in this example.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXCAT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXPSTRG	EXPSTRGU	VISITNUM	VISIT	VISITDY	EPOCH	EXSTDTC	EXENDTC
1	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	1	PRODUCT C	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	6	mg	10	DAY -1	-1	PRODUCT EXPOSURE	2019-06-27T13:10:33	2019-06-27T13:38:49
2	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	2	PRODUCT C	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	6	mg	10	DAY -1	-1	PRODUCT EXPOSURE	2019-06-27T14:29:13	2019-06-27T14:54:53
3	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	3	PRODUCT C	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	6	mg	11	DAY 1	1	PRODUCT EXPOSURE	2019-06-28T08:00:12	2019-06-28T08:30:21
4	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	4	PRODUCT E	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	4	mg	11	DAY 1	1	PRODUCT EXPOSURE	2019-06-28T14:01:52	2019-06-28T14:55:27
5	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	5	PRODUCT E	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	4	mg	11	DAY 1	1	PRODUCT EXPOSURE	2019-06-28T15:18:35	2019-06-28T15:57:33
6	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	6	PRODUCT E	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	4	mg	12	DAY 2	2	PRODUCT EXPOSURE	2019-06-29T08:00:08	2019-06-29T08:30:13
7	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	7	PRODUCT B	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	2	mg	12	DAY 2	2	PRODUCT EXPOSURE	2019-06-29T14:01:50	2019-06-29T14:50:11
8	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	8	PRODUCT B	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	2	mg	12	DAY 2	2	PRODUCT EXPOSURE	2019-06-29T15:24:33	2019-06-29T15:59:46
9	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	9	PRODUCT B	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	2	mg	13	DAY 3	3	PRODUCT EXPOSURE	2019-06-30T08:00:00	2019-06-30T08:30:00
10	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	10	PRODUCT D	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	6	mg	13	DAY 3	3	PRODUCT EXPOSURE	2019-06-30T14:12:32	2019-06-30T14:47:47
11	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	11	PRODUCT D	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	6	mg	13	DAY 3	3	PRODUCT EXPOSURE	2019-06-30T15:24:46	2019-06-30T16:04:57
12	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	12	PRODUCT D	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	6	mg	14	DAY 4	4	PRODUCT EXPOSURE	2019-07-01T08:00:00	2019-07-01T08:30:00
13	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	13	PRODUCT A	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	8	mg	14	DAY 4	4	PRODUCT EXPOSURE	2019-07-01T14:02:36	2019-07-01T14:47:33
14	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	14	PRODUCT A	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	8	mg	14	DAY 4	4	PRODUCT EXPOSURE	2019-07-01T15:37:45	2019-07-01T15:58:15
15	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	15	PRODUCT A	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	8	mg	15	DAY 5	5	PRODUCT EXPOSURE	2019-07-02T08:00:00	2019-07-02T08:30:01
16	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	16	PRODUCT F	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	0	mg	15	DAY 5	5	PRODUCT EXPOSURE	2019-07-02T14:11:00	2019-07-02T14:54:08

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXCAT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXPSTRG	EXPSTRGU	VISITNUM	VISIT	VISITDY	EPOCH	EXSTDTC	EXENDTC
17	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	17	PRODUCT F	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	0	mg	15	DAY 5	5	PRODUCT EXPOSURE	2019-07-02T15:38:52	2019-07-02T15:59:50
18	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	18	PRODUCT F	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	0	mg	16	DAY 6	6	PRODUCT EXPOSURE	2019-07-03T08:00:00	2019-07-03T08:30:00
19	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	19	PRODUCT G	UNCONTROLLED PRODUCT USE	3.37	g	QUID	ORAL	4	mg	16	DAY 6	6	PRODUCT EXPOSURE	2019-07-03T14:13:14	2019-07-03T14:57:40
20	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	20	PRODUCT G	UNCONTROLLED PRODUCT USE	3.2	g	QUID	ORAL	4	mg	16	DAY 6	6	PRODUCT EXPOSURE	2019-07-03T15:35:01	2019-07-03T16:07:25
21	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10001	21	PRODUCT G	CONTROLLED PRODUCT USE	2	g	QUID	ORAL	4	mg	17	DAY 7/EARLY TERMINATION	7	PRODUCT EXPOSURE	2019-07-04T08:00:04	2019-07-04T08:30:05
22	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	1	PRODUCT E	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	8	mg	10	DAY -1	-1	PRODUCT EXPOSURE	2019-07-04T14:06:09	2019-07-04T14:14:14
23	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	2	PRODUCT E	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	8	mg	11	DAY 1	1	PRODUCT EXPOSURE	2019-07-05T08:00:00	2019-07-05T08:30:00
24	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	3	PRODUCT D	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	4	mg	11	DAY 1	1	PRODUCT EXPOSURE	2019-07-05T14:02:39	2019-07-05T14:18:57
25	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	4	PRODUCT D	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	4	mg	12	DAY 2	2	PRODUCT EXPOSURE	2019-07-06T08:00:00	2019-07-06T08:30:00
26	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	5	PRODUCT C	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	6	mg	12	DAY 2	2	PRODUCT EXPOSURE	2019-07-06T14:00:00	2019-07-06T14:08:40
27	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	6	PRODUCT C	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	6	mg	12	DAY 2	2	PRODUCT EXPOSURE	2019-07-06T15:52:53	2019-07-06T15:59:21
28	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	7	PRODUCT C	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	6	mg	13	DAY 3	3	PRODUCT EXPOSURE	2019-07-07T08:00:00	2019-07-07T08:30:00
29	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	8	PRODUCT F	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	2	mg	13	DAY 3	3	PRODUCT EXPOSURE	2019-07-07T14:01:12	2019-07-07T14:12:25
30	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	9	PRODUCT F	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	0	mg	13	DAY 3	3	PRODUCT EXPOSURE	2019-07-07T14:57:49	2019-07-07T15:07:07
31	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	10	PRODUCT F	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	0	mg	14	DAY 4	4	PRODUCT EXPOSURE	2019-07-08T08:00:00	2019-07-08T08:30:00
32	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	11	PRODUCT B	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	0	mg	14	DAY 4	4	PRODUCT EXPOSURE	2019-07-08T14:00:52	2019-07-08T14:17:31
33	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	12	PRODUCT B	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	2	mg	14	DAY 4	4	PRODUCT EXPOSURE	2019-07-08T14:46:07	2019-07-08T14:53:43
34	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	13	PRODUCT B	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	2	mg	15	DAY 5	5	PRODUCT EXPOSURE	2019-07-09T08:00:01	2019-07-09T08:30:01
35	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	14	PRODUCT G	UNCONTROLLED PRODUCT USE	2.69	g	QUID	ORAL	4	mg	15	DAY 5	5	PRODUCT EXPOSURE	2019-07-09T14:06:24	2019-07-09T14:30:16
36	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	15	PRODUCT G	UNCONTROLLED PRODUCT USE	3.3	g	QUID	ORAL	4	mg	15	DAY 5	5	PRODUCT EXPOSURE	2019-07-09T14:49:39	2019-07-09T15:15:16
37	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	16	PRODUCT G	CONTROLLED PRODUCT USE	2	g	QUID	ORAL	4	mg	16	DAY 6	6	PRODUCT EXPOSURE	2019-07-10T08:00:00	2019-07-10T08:30:00
38	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	17	PRODUCT A	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	8	mg	16	DAY 6	6	PRODUCT EXPOSURE	2019-07-10T14:02:07	2019-07-10T14:35:40
39	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	18	PRODUCT A	UNCONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	8	mg	16	DAY 6	6	PRODUCT EXPOSURE	2019-07-10T15:27:37	2019-07-10T15:58:24
40	ALCS-REG-STUDY	EX	ALCS-REG-STUDY_10002	19	PRODUCT A	CONTROLLED PRODUCT USE	1	POUCH	POUCH	ORAL	8	mg	17	DAY 7/EARLY TERMINATION	7	PRODUCT EXPOSURE	2019-07-11T08:00:00	2019-07-11T08:30:00

3.3.4.2 Puff Topography

Smoking/vaping *puff topography* is how a smoker smokes or vapes a tobacco product. Measures of vaping/smoking behavior is critical to understanding exposure to biomarkers of nicotine and toxins. Topography devices are used to measure cigarette and e-cigarette puffing behavior. Puff inhalation and exhalation duration, puff volume, and inter-puff interval are often measured.

Puff topography is typically considered data about the subject's exposure to the test product. As these data represent information about study product exposure, the data is represented in the Exposure (EX) domain (see Section 3.3.4, [Exposure Assessments During Tobacco Product Studies](#)).

Puff topography is often measured using smoking machines. Information about devices—not the study subject nor the study itself—are represented using the SDTM Device domains.

Example 1

This is a study where subjects were randomized to 3 different concentrations of nicotine e-liquid, or their usual brand of cigarettes. The subjects used the product at home for 2 weeks. This 2-week period allowed subjects to become familiar with the e-cigarette. After 2 weeks, subjects were confined to the clinic for 1 day. They were required to not use any tobacco products for 12 hours prior to the visit. Subjects had to have CO levels below a prespecified level to attend the visit. If the level was too high, the visit was rescheduled. Subjects were instructed to take 10 puffs on the e-cigarette/usual brand of cigarettes in the morning and afternoon. Puff topography was measured in the morning and afternoon using the same device for all subjects. Subjects were not allowed to use any tobacco products between the morning and afternoon sessions.

Device Identifiers (DI), a Study Reference domain, was used to identify the device used to measure puff topography. This provides a consistent variable (SPDEVID) for linking data. Because device identifiers exist independently from subjects, the DI domain does not contain USUBJID. Only 1 device was used for all subjects in the study.

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	TOPT001	DI	PUFANYXYZ	1	DEVTYPE	Device Type	PUFF TOPOGRAPHY ANALYZER
2	TOPT001	DI	PUFANYXYZ	2	MODEL	Model	PUFFALYZER 900
3	TOPT001	DI	PUFANYXYZ	3	MANUF	Manufacturer	ACME

The applicant submitted the Exposure (EX) domain to represent use of the tobacco product. Usage for the 2-week period is represented for each subject, along with the specified use during the in-clinic visit. The applicant elected not to represent each puff in this EX dataset, although each puff could have been recorded.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	SPTOBID	EXSEQ	EXLNKID	EXTRT	EXDOSE	EXDOSTXT	EXDOSU	EXDOSFRM	EXROUTE	EXPSTRG	EXPSTRGU	EXSTDTC	EXENDTC
1	TOPT001	EX	3001	EC-333	1		Nicotine e-liquid		AD LIBITUM		CARTRIDGE	RESPIRATORY (INHALATION)	8	mg/mL	2020-06-26	2020-07-14
2	TOPT001	EX	3001	EC-333	2	1	Nicotine e-liquid	10		PUFF	CARTRIDGE	RESPIRATORY (INHALATION)	8	mg/mL	2020-07-15T9:45	
3	TOPT001	EX	3001	EC-333	3	2	Nicotine e-liquid	10		PUFF	CARTRIDGE	RESPIRATORY (INHALATION)	8	mg/mL	2020-07-15T3:00	2020-07-15T3:45
4	TOPT001	EX	4001	EC-333	1		Nicotine e-liquid		AD LIBITUM		CARTRIDGE	RESPIRATORY (INHALATION)	16	mg/mL	2020-09-06	2020-09-22
5	TOPT001	EX	4001	EC-333	2	1	Nicotine e-liquid	10		PUFF	CARTRIDGE	RESPIRATORY (INHALATION)	16	mg/mL	2020-09-22T9:00	2020-09-22T9:30
6	TOPT001	EX	4001	EC-333	3	2	Nicotine e-liquid	10		PUFF	CARTRIDGE	RESPIRATORY (INHALATION)	16	mg/mL	2020-09-22T3:00	2020-09-22T3:30
7	TOPT001	EX	5004		1		Cigarettes Brand XYZ		AD LIBITUM		CIGARETTE	RESPIRATORY (INHALATION)	12.1	mg/cigarette	2020-10-08	2020-10-22
8	TOPT001	EX	5004		2	1	Cigarettes Brand XYZ	10		PUFF	CIGARETTE	RESPIRATORY (INHALATION)	12.1	mg/cigarette	2020-10-22T9:00	2020-09-22T9:30
9	TOPT0011	EX	5004		3	2	Cigarettes Brand XYZ	10		PUFF	CIGARETTE	RESPIRATORY (INHALATION)	12.1	mg/cigarette	2020-10-22T3:00	2020-09-22T3:30

The FAEX domain was used to represent the puff topography associated with the in-clinic visit. The Findings About Events or Interventions structure ("FA structure") is used to represent collected data that are findings about an event or intervention that cannot be represented within an event or intervention record or as a supplemental qualifier to such a record. Not all findings associated with an event or intervention should be represented in the FA structure.

A puff-by puff analysis was performed. Only selected data for puffs 1 and 10 are shown. No data are shown for 2-9 to simplify dataset review. FATPT was used to represent the time point (in this case, AM and PM). Typically, applicants derive summary results using individual source data records; these summary results are represented in ADaM. However, if summary results are collected on a CRF or provided by an external vendor, these derived results can be represented in FAEX using the variable FACOLSRT. In this example, the applicant created an ADaM dataset to represent the summary data (not shown).

Rows 1, 6: Show the number of puffs taken in the time interval specified in FADTC and FAENDTC. This was prespecified in the design, but the applicant reported the actual number of puffs taken.

Rows 2-5: Show the various measurements recorded for subject 3001 for puff 1 during the morning administration of the tobacco product. FADTC and FAENDTC provide the timing of each puff. The individual puff data for the afternoon are not shown.

Rows 7-10: Show the various measurements recorded for subject 3001 for puff 10 during the afternoon administration of the tobacco product. FADTC and FAENDTC provide the timing of each puff. The individual puff data for the morning session are not shown. Note: Data for puffs 2-9 are not shown to simplify dataset review.

Rows 12-15: Show the various measurements recorded for subject 4001. Only a few rows are shown to simplify dataset review.

faex.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	SPTOBID	FASEQ	FALNKID	FASPID	FATESTCD	FATEST	FAOBJ	FACT	FAORRES	FAORRESU	FASTRESC	FASTRESU	VISITNUM	FADTC	FAENDTC	FATPT
1	TOPT001	FA	3001	PUFANYXYZ	EC-333	1	1		PUFF TOT	Total Number of Puffs	Nicotine e-liquid	PUFF TOPOGRAPHY	10	PUFFS	10	PUFFS	2	2020-07-15T09:00	2020-07-15TT9:45	AM
2	TOPT001	FA	3001	PUFANYXYZ	EC-333	2	1	PUFF 1	PUFFVOL	Puff Volume	Nicotine e-liquid	PUFF TOPOGRAPHY	36.7	mL/sec	37	mL/sec	2	2020-07-15T09:01:36	2020-07-15T09:01:38	AM
3	TOPT001	FA	3001	PUFANYXYZ	EC-333	3	1	PUFF 1	AVGFLOW	Average Flow rate	Nicotine e-liquid	PUFF TOPOGRAPHY	15.5	mL/sec	15.5	mL/sec	2	2020-07-15T09:01:36	2020-07-15T09:01:38	AM
4	TOPT001	FA	3001	PUFANYXYZ	EC-333	4	1	PUFF 1	PKFLOW	Peak Flow Rate	Nicotine e-liquid	PUFF TOPOGRAPHY	20.5	mL/sec	20.5	mL/sec	2	2020-07-15T09:01:36	2020-07-15T09:01:38	AM
5	TOPT001	FA	3001	PUFANYXYZ	EC-333	5	1	PUFF 1	PUFFDUR	Puff Duration	Nicotine e-liquid	PUFF TOPOGRAPHY	2.0	msec	1.6	msec	2	2020-07-15T09:01:36	2020-07-15T09:01:38	AM
6	TOPT001	FA	3001	PUFANYXYZ	EC-333	6	2		PUFF TOT	Total Number of Puffs	e-nicotin liquid	PUFF TOPOGRAPHY	9	PUFFS	9	PUFFS	2	2020-07-15T03:00	2020-07-15T03:30	PM
7	TOPT001	FA	3001	PUFANYXYZ	EC-333	7	2	PUFF 10	INTPUFIN	Puff Interval	Nicotine e-liquid	PUFF TOPOGRAPHY	910396.8	sec	910396.8	sec	2	2020-07-15T03:30:34	2020-07-15T03:30:36	PM
8	TOPT001	FA	3001	PUFANYXYZ	EC-333	8	2	PUFF 10	PUFFVOL	Puff Volume	Nicotine e-liquid	PUFF TOPOGRAPHY	43	mL/sec	43	mL/sec	2	2020-07-15T03:30:34	2020-07-15T03:30:36	PM
9	TOPT001	FA	3001	PUFANYXYZ	EC-333	9	2	PUFF 10	AVGFLOW	Average Flow rate	Nicotine e-liquid	PUFF TOPOGRAPHY	14.5	mL/sec	14.5	mL/sec	2	2020-07-15T03:30:34	2020-07-15T03:30:36	PM
10	TOPT001	FA	3001	PUFANYXYZ	EC-333	10	2	PUFF 10	PKFLOW	Peak Flow Rate	Nicotine e-liquid	PUFF TOPOGRAPHY	22.5	mL/sec	22.5	mL/sec	2	2020-07-15T03:30:34	2020-07-15T03:30:36	PM
12	TOPT001	FA	4001	PUFANYXYZ	EC-333	1	1		PUFF TOT	Total Number of Puffs	Nicotine e-liquid	PUFF TOPOGRAPHY	10	PUFFS	10	PUFFS	2	2020-08-15T9:00	2020-08-15TT9:45	AM
13	TOPT001	FA	4001	PUFANYXYZ	EC-333	2	1	PUFF 1	PUFFVOL	Puff Volume	Nicotine e-liquid	PUFF TOPOGRAPHY	34.7	mL/sec	34	mL/sec	2	2020-08-15T09:01:36	2020-08-15T09:01:38	AM
14	TOPT001	FA	4001	PUFANYXYZ	EC-333	3	1	PUFF 1	AVGFLOW	Average Flow rate	Nicotine e-liquid	PUFF TOPOGRAPHY	15.5	mL/sec	15.5	mL/sec	2	2020-08-15T09:01:36	2020-08-15T09:01:38	AM
15	TOPT001	FA	4001	PUFANYXYZ	EC-333	4	1	PUFF 1	PKFLOW	Peak Flow Rate	Nicotine e-liquid	PUFF TOPOGRAPHY	23.5	mL/sec	23.5	mL/sec	2	2020-08-15T09:01:36	2020-08-15T09:01:38	AM

The RELREC dataset was used to record the relationship between the records in EX and the records in FAEX.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	TD23	EX		EXLNKID		ONE	EXFA1
2	TD23	FAEX		FALNKID		MANY	EXFA1

Reference:

CORESTA. *Assessing Product Use Behaviour and Exposure: Definitions and Methods*. October 2022. Accessed October 17, 2023. <https://www.coresta.org/assessing-product-use-behaviour-and-exposure-definitions-and-methods-36737.html>

3.3.5 Questionnaires, Ratings, and Scales

Data from QRS instruments are represented in the Functional Tests (FT), Questionnaires (QS), and Disease Response and Clinical Classification (RS) domains (see Section 2.4, [About Questionnaires, Ratings, and Scales](#)).

There are no published CDISC QRS supplements for the evaluation of applicant-defined general single-item assessments. These instruments assess symptoms or other disease-related items (e.g., overall quality of life), and may be evaluated using applicant-defined general codelist scales, visual analog scales (VAS), or numeric rating scales (NRS). VAS and NRS use various methods for describing the anchor points and may have descriptor anchors (e.g., beginning, middle, end) for various gradations or numbers. These assessments may be in the public domain or may be copyrighted. Applicants are responsible for the appropriate use of any copyrighted assessments. There may be examples of these assessments in the literature, but they are not considered CDISC QRS instruments for standard development purposes, due to the extreme variability in the methods of capturing these types of assessments.

These general single-item assessments are represented in the Findings About Events or Interventions (FA) domain.

FA is a specialization of the Findings general observation class. As such, it shares all qualities and conventions of Findings observations but is specialized by the addition of the --OBJ variable.

Example 1

This is an example of a single-item VAS used to assess the level of craving (i.e., the question “In the past 24 hours, how strong is your craving for cigarettes?”) on a scale from “no craving” to “strong craving” by measuring the number of millimeters (0–100 mm) from the “no craving” dot to the point at which the drawn line intersected the scale.

The FA domain was used to represent the assessment of craving. Applicants may represent findings data in a single FA dataset or split the FA domain into separate datasets. In this example, a FACE dataset was used, indicating that data are findings about clinical events. The craving itself is considered a clinical event, whereas craving at specific time points is considered findings about the clinical event. A parent record in the Clinical Events (CE) domain is not required.

Row 1: Shows the craving VAS for subject 001 at baseline

Row 2: Shows the craving VAS for subject 001 at visit 12.

face.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU	FAMETHOD	FAEVAL	VISITNUM	FADTC	FAEVINT
1	TGI400	FA	001	1	SEV	SEVERITY/INTENSITY	CRAVING	SYMPTOM ASSESSMENT	98	mm	98	98	mm	VISUAL ANALOG SCALE (100 MM)	STUDY SUBJECT	1	2015-06-15	-P24H
2	TGI400	FA	001	2	SEV	SEVERITY/INTENSITY	CRAVING	SYMPTOM ASSESSMENT	43	mm	43	43	mm	VISUAL ANALOG SCALE (100 MM)	STUDY SUBJECT	12	2016-07-15	-P24H

This example illustrates how information on the scale scoring may be represented as supplemental qualifier variables. A record in a SUPPFA dataset relates back to the parent record(s) via the key identified by the STUDYID, RDOMAIN, USUBJID, and IDVAR/IDVARVAL variables. Here the parent domain (RDOMAIN) is FA, and IDVAR is FASEQ. QNAME holds the name of the supplemental qualifier variable being defined.

suppfa.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAME	QLABEL	QVAL	QORIG	QEVAL
1	TGI400	FA	001	FASEQ	1	FAANTXLO	ANCHOR TEXT LOW	NO CRAVING	ASSIGNED	
2	TGI400	FA	001	FASEQ	1	FAANVLLO	ANCHOR VALUE LOW	0	ASSIGNED	
3	TGI400	FA	001	FASEQ	1	FAANTXHI	ANCHOR TEXT HIGH	STRONG CRAVING	ASSIGNED	
3	TGI400	FA	001	FASEQ	1	FAANVLHI	ANCHOR VALUE HIGH	100	ASSIGNED	

3.3.6 Analysis Datasets

This section includes examples which illustrate the intended implementation of analysis datasets.

3.3.6.1 Subject-level Analysis Dataset (ADSL)

This is an example of an ADSL dataset and is based on input from the SDTM Demographics (DM) and Disposition (DS) datasets. This is just an example and does not mean to indicate that all of the variables described are necessarily those that would be included in a particular study.

Example 1

These are example SDTM datasets used to create the ADSL dataset. Only variables needed for illustration are shown in the examples.

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC	DTHDTC	DTHFL	SITEID	INVNAME
1	A123	DM	A2001	2001	2021-01-08	2021-01-28	2021-01-08	2021-01-28	2021-01-02	2021-02-04			01	JOHNSON, M
2	A123	DM	A2008	2008	2021-02-08	2021-03-01	2021-02-08	2021-03-01	2021-02-02	2021-03-10			02	JAMES, A
3	A123	DM	A3009	3009	2021-06-09	2021-06-21	2021-06-09	2021-06-21	2021-06-01	2021-06-30			03	ADAMS, J

Row	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS	ACTARMUD	COUNTRY
1	1948-12-13	72	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Plac	Placebo	Plac	Placebo			USA
2	1955-03-22	65	YEARS	M	WHITE	NOT HISPANIC OR LATINO	A	Product A	A	Product A			USA
3	1964-01-19	57	YEARS	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	B	Product B	B	Product B			USA

ds.xpt

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	DSSCAT	EPOCH	DSDTC	DSSTDTC
1	A123	DS	A2001	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE			2021-01-02	2021-01-02
2	A123	DS	A2001	2	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE			2021-01-08	2021-01-08
3	A123	DS	A2001	3	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	SCREENING	2021-01-08	2021-01-08
4	A123	DS	A2001	4	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	PRODUCT EXPOSURE	2021-01-28	2021-01-28
5	A123	DS	A2001	5	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	FOLLOW-UP	2021-02-04	2021-02-04
6	A123	DS	A2008	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE			2021-02-02	2021-02-02
7	A123	DS	A2008	2	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE			2021-02-08	2021-02-08
3	A123	DS	A2008	3	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	SCREENING	2021-02-08	2021-02-08
4	A123	DS	A2008	4	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	PRODUCT EXPOSURE	2021-03-01	2021-03-01
5	A123	DS	A2008	5	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	FOLLOW-UP	2021-03-10	2021-03-10
8	A123	DS	A3009	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE			2021-06-01	2021-06-01
9	A123	DS	A3009	2	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE			2021-06-09	2021-06-09
10	A123	DS	A3009	3	COMPLETED	COMPLETED	DISPOSITION EVENT	STUDY PARTICIPATION	SCREENING	2021-06-09	2003-06-09
10	A123	DS	A3009	4	FLU	ADVERSE EVENT	DISPOSITION EVENT	STUDY PARTICIPATION	PRODUCT EXPOSURE	2021-06-21	2021-06-21
11	A123	DS	A3009	5	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP	DISPOSITION EVENT	STUDY PARTICIPATION	FOLLOW-UP	2021-06-30	2021-06-30

This is an example of the ADSL dataset and associated metadata.

adsl.xpt

Row	STUDYID	USUBJID	SUBJID	SITEID	AGE	AGEU	AGEGR1	SEX	RACE	ETHNIC	SAFFL	RANDFL	ARM
1	A123	A2008	2008	01	72	YEARS	>=65 Years	M	WHITE	NOT HISPANIC OR LATINO	Y	Y	Placebo
2	A123	A2008	2008	02	65	YEARS	>=65 Years	M	WHITE	NOT HISPANIC OR LATINO	Y	Y	Product A
3	A123	A3008	3008	03	57	YEARS	<65 Years	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	Y	Y	Product B

Row	ACTARM	TRT01P	TRT01PN	TRT01A	TRT01AN	TRTSDT	TRTEDT	EOSSTT	EOSDT	DCSREAS	EOTSTT	DCTREAS	RANDTT
1	Placebo	Placebo	1	Placebo	1	2021-01-08	2021-01-28	COMPLETED	2021-02-04				2021-01-08

Row	ACTARM	TRT01P	TRT01PN	TRT01A	TRT01AN	TRTSDT	TRTEDT	EOSSTT	EOSDT	DCSREAS	EOTSTT	DCTREAS	RANDDT
2	Product A	Product A	2	Product A	2	2021-02-08	2021-03-01	COMPLETED	2021-03-10				2021-02-08
3	Product B	Product B	3	Product B	3	2021-06-09	2021-06-21	COMPLETED	2021-06-30		DISCONTINUED	ADVERSE EVENT	2021-06-09

ADSL Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADSL	Subject-Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET	One record per subject	Analysis	STUDYID, USUBJID	ADSL.xpt	ADSL.SAS/SAP

ADSL Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
STUDYID	Study Identifier	Char		Req	DM.STUDYID
USUBJID	Unique Subject Identifier	Char		Req	DM.USUBJID
SUBJID	Subject Identifier for the Study	Char		Req	DM.SUBJID
SITEID	Study Site Identifier	Char		Req	DM.SITEID
AGE	Age	Num		Req	DM.AGE
AGEU	Age Units	Char	(AGEU)	Req	DM.AGEU
AGEGR1	Pooled Age Group 1	Char		Perm	Character description of a grouping or pooling of the subject's age for analysis purposes.
SEX	Sex	Char	(SEX)	Req	DM.SEX
RACE	Race	Char	(RACE)	Req	DM.RACE
ETHNIC	Ethnicity	Char		Perm	DM.ETHNIC
SAFFL	Safety Population Flag	Char	Y; N	Cond	Y if ADSL.TRTSDT is not null, otherwise N
RANDFL	Randomized Population Flag	Char	Y; N	Cond	Y if the subject was randomized, otherwise N
ARM	Description of Planned Arm	Char		Req	DM.ARM
ACTARM	Description of Actual Arm	Char		Perm	DM.ACTARM
TRT01P	Planned Product for Period 01	Char		Req	DM.ARM
TRT01PN	Planned Product for Period 01 (N)	Num		Perm	Assigned based on the ARM value
TRT01A	Actual Product for Period 01	Char		Cond	DM.ACTARM
TRT01AN	Actual Product for Period 01 (N)	Num		Perm	Assigned based on the ACTARM value
TRTSDT	Date of First Exposure to Product	Num		Cond	Numeric version of RFXSTDTC
TRTEDT	Date of Last Exposure to Product	Num		Cond	Numeric version of RFXENDTC
EOSSTT	End of Study Status	Char	(SBJTSTAT)	Perm	The subject's status as of the end of study or data cutoff. Examples: COMPLETED, DISCONTINUED, ONGOING.
EOSDT	End of Study Date	Num		Perm	Date subject ended the study - either date of completion or date of discontinuation or data cutoff date for interim analyses.
DCSREAS	Reason for Discontinuation from Study	Char		Perm	Reason for subject's discontinuation from study. The source would most likely be the SDTM DS dataset. Null for subjects who completed the study.
EOTSTT	End of Product Status	Char	(SBJTSTAT)	Perm	The subject's status as of the end of product or data cutoff. Examples: COMPLETED, DISCONTINUED, ONGOING.
DCTREAS	Reason for Discontinuation of Product	Char		Perm	If a subject discontinued product in the study, then this variable indicates the reason for discontinuation. This is for discontinuation of product in the overall study and not to be used for discontinuation reason within individual product periods.
RANDDT	Date of Randomization	Num		Cond	DS.DSSTDTC where DSDECOD=RANDOMIZED

3.3.6.2 Medical History (ADMH)

The ADMH dataset is based primarily on input from the SDTM MH dataset. Other administrative data about the subjects are based on the ADSL dataset provided in Section 3.3.6.1, [Subject-level Analysis Dataset \(ADSL\)](#).

Example 1

This is an example of an input SDTM MH datasets used to create the example ADMH dataset. Only variables needed for illustration are shown in the examples.

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHSID	MHTERM	MHDECOD	MHCAT	MHBODSYS	MHSTDTC	MHENDT	MHENRPT	MHENPT
1	A123	MH	A2001	1	01	ASTHMA	Asthma	GENERAL MEDICAL HISTORY	Respiratory system disorders	2010		ONGOING	2021-01-02
2	A123	MH	A2001	2	02	FREQUENT HEADACHES	Headache	GENERAL MEDICAL HISTORY	Central and peripheral nervous system disorders	2010-07		ONGOING	2021-01-02
3	A123	MH	A2001	3	03	BROKEN LEG	Bone fracture	GENERAL MEDICAL HISTORY	Musculoskeletal system disorders	2014-07-15	2014-08-31		

This is an example of the ADMH dataset and associated metadata. This is just an example and does not mean to indicate that ADMH must be used as the dataset name, nor are the parameters described necessarily those that would be used in a particular study.

admh.xpt

Row	STUDYID	USUBJID	MHTERM	MHDECOD	MHBODSYS	ASTDT	AENDT	AOCCFL	AOCCPFL	AOCCSFL	TRTP
1	A123	2001	ASTHMA	Asthma	Respiratory system disorders			Y	Y	Y	Placebo
2	A123	2001	FREQUENT HEADACHES	Headache	Central and peripheral nervous system disorders				Y	Y	Placebo
3	A123	2001	BROKEN LEG	Bone fracture	Musculoskeletal system disorders	15JUL2005	31AUG2005		Y	Y	Placebo
Row	TRTA	SAFFL	RANDFL	TRTSDT	TRTEDT	MHCAT	MHSTDTC	MHENDT	MHENRPT	MHENPT	MHSEQ
1	Placebo	Y	Y			GENERAL MEDICAL HISTORY	2003		ONGOING	2021-01-02	1
2	Placebo	Y	Y			GENERAL MEDICAL HISTORY	2004-07		ONGOING	2021-01-02	2
3	Placebo	Y	Y			GENERAL MEDICAL HISTORY	2005-07-15	2005-08-31			3

ADMH Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADMH	Medical History Analysis Dataset	OCCDS	one record per subject per event	Analysis	USUBJID, MHTERM	ADMH.xpt	ADMH.SAS/SAP

ADMH Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
STUDYID	Study Identifier	text		Req	MH.STUDYID
USUBJID	Unique Subject Identifier	text		Req	MH.USUBJID
MHTERM	Reported Term for the Medical History	text		Req	MH.MHTERM
MHDECOD	Dictionary-Derived Term	text		Cond	MH.MHDECOD
MHBODSYS	Body System or Organ Class	text		Cond	MH.MHBODSYS
ASTDT	Analysis Start Date	integer		Cond	Convert MH.MHSTDTC from character ISO8601 format to numeric date format
AENDT	Analysis End Date	integer		Cond	Convert MH.MHENDT from character ISO8601 format to numeric date format
AOCCFL	1st Occurrence within Subject Flag	text	Y	Perm	Sort the data in the required order and flag the first for each subject
AOCCPFL	1st Occurrence of Preferred Term Flag	text	Y	Perm	Sort the data in the required order and flag the first record for each MHDECOD for each subject
AOCCSFL	1st Occurrence of SOC Flag	text	Y	Perm	Sort the data in the required order and flag the first record for each body system for each subject
TRTP	Planned Product	text	Product A;Product B	Cond	ADSL.TRTO1P
TRTA	Actual Product	text	Product A;Product B	Cond	ADSL.TRTO1A
SAFFL	Safety Population Flag	text	Y;N	Cond	ADSL.SAFFL
RANDFL	Randomized Population Flag	text	Y;N	Cond	ADSL.RANDFL
TRTSDT	Date of First Exposure to Product	integer		Perm	ADSL.TRTSDT
TRTEDT	Date of Last Exposure to Product	integer		Perm	ADSL.TRTEDT
MHCAT	Category for Medical History	text		Perm	MH.MHCAT
MHSTDTC	Start Date/Time of Medical History Event	text		Perm	MH.MHSTDTC
MHENDT	End Date/Time of Medical History Event	text		Perm	MH.MHENDT
MHENRPT	End Relative to Reference Time Point	text		Perm	MH.MHENRPT
MHENPT	End Reference Time Point	text		Perm	MH.MHENPT
MHSEQ	Sequence Number	integer		Perm	MH.MHSEQ

3.3.6.3 Adverse Experience (ADAE)

This is an example of an ADAE dataset and is based primarily on input from the SDTM AE dataset. Other administrative data about the subjects are based on the ADSL dataset provided in Section 3.3.6.1, [Subject-level Analysis Dataset \(ADSL\)](#). Only variables needed for illustration are shown in the examples.

Example 1

This is an example of the input SDTM AE datasets used to create the ADAE.

ae.xpt

Row	STUDYID	DOMAIN	SPDEVID	USUBJID	AESEQ	AETERM	AEMODIFY	AEDECOD	AEBODSYS	AESEV	AE SER	AEACN	AEACNDEV	AEREL		
1	A123	AE		A2001	1	POUNDING HEADACHE	HEADACHE	Headache	Nervous system disorders	SEVERE	N	DOSE NOT CHANGED		DEFINITELY NOT RELATED		
2	A123	AE	VAPE-Z01	A2008	1	SKIN REDNESS	SKIN REDNESS	Skin Redness		Moderate	N	DOSE NOT CHANGED	DEVICE REPLACED	PROBABLY RELATED		
3	A123	AE		A3009	1	INFLUENZA	INFLUENZA	Influenza	Infections and infestations	SEVERE	Y	PRODUCT DISCONTINUED		PROBABLY NOT RELATED		
Row	AERLDEV		AEOUT		AESCONG	AESDISAB	AESDTH	AESHOSP	AESLIFE	AESMIE	AECONTRT	EPOCH	AESTDTC	AEENDTC	AESTDY	AEENDY
1			RECOVERED/RESOLVED							Y		PRODUCT EXPOSURE	2021-01-21	2021-01-21	16	16
2	RELATED		RECOVERED/RESOLVED							N		PRODUCT EXPOSURE	2021-02-16	2021-02-21	8	13
3			RECOVERING/RESOLVING					Y	Y		Y	PRODUCT EXPOSURE	2021-06-21	2021-06-26	13	18

The example ADAE dataset and associated metadata serve as an example and are not intended to indicate that ADAE must be used as the dataset name, nor are the parameters described necessarily those that would be used in a particular study.

adae.xpt

Row	STUDYID	USUBJID	AETERM	AEMODIFY	AEDECOD	AEBODSYS	ASTDT	AENDT	ASTDY	AENDY	PREFL	TRTEMFL	FUPFL	AETRTEM	AOCCFL	AOCCPFL	AOCCSFL	AE SER	AEREL
1	A123	A2001	POUNDING HEADACHE	HEADACHE	Headache	Nervous system disorders	21JAN2021	21JAN2021	14	14	Y				N		DEFINITELY NOT RELATED		
2	A123	A2008	SKIN REDNESS	SKIN REDNESS	Skin Redness		16FEB2021	21FEB2021	9	14	Y		Y	Y	Y	Y	PROBABLY RELATED		
3	A123	A3009	INFLUENZA	INFLUENZA	Influenza	Infections and infestations	21JUN2021	26JUN2021	13	18	Y	Y	Y	Y	Y	Y	PROBABLY NOT RELATED		
Row	AERLDEV	RELGR1	AESEV	AEACN	AEACNDEV	AEOUT	TRTA	SAFFL	TRTSDT	TRTEDT	AESEQ	AESTDTC	AEENDTC	AESTDY	AEENDY	AEENRF			
1	NOT RELATED	SEVERE	DOSE NOT CHANGED			RECOVERED/RESOLVED	Placebo	Y	08JAN2021	28JAN2021	1	2021-01-21	2021-01-21	14	14				
2	RELATED	RELATED	Moderate	DOSE NOT CHANGED	DEVICE REPLACED	RECOVERED/RESOLVED	Placebo	Y	08FEB2021	01MAR2021	2	2021-02-16	2021-02-21	9	14				
3	NOT RELATED	SEVERE	TRIAL INTERVENTION DISCONTINUED			RECOVERING/RESOLVING	Placebo	Y	09JUN2021	21JUN2021	3	2021-06-21	2021-06-26	13	18				

ADAE Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADAE	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE	One record per subject per adverse event	Analysis	STUDYID, USUBJID, AEBODSYS, AEDECOD, AETERM	ADAE.xpt	ADAE.SAS/SAP

ADAE Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
STUDYID	Study Identifier	text		Req	AE.STUDYID
USUBJID	Unique Subject Identifier	text		Req	AE.USUBJID
AETERM	Reported Term for the Adverse Experience	text		Req	AE.AETERM
AEMODIFY	Modified Reported Term	text		Perm	AE.MODIFY
AEBODSYS	Body System or Organ Class	text		Req	AE.AEBODSYS
AEDECOD	Dictionary-Derived Term	text		Req	AE.AEDECOD
ASTDT	Analysis Start Date	integer		Cond	Created from converting AE.AESTDTC from character ISO8601 format to numeric date format
AENDT	Analysis End Date	integer		Cond	Created from converting AE.AEENDTC from character ISO8601 format to numeric date format
ASTDY	Analysis Start Relative Day	integer		Cond	ASTDT - ADSL.TRTSDT + 1 if ASTDT ≥ TRTSDT, else ASTDT - ADSL.TRTSDT if ASTDT < TRTSDT
AENDY	Analysis End Relative Day	integer		Cond	AENDT - ADSL.TRTSDT + 1 if AENDT ≥ TRTSDT, else AENDT - ADSL.TRTSDT if AENDT < TRTSDT
PREFL	Pre-product Flag	text	Y	Cond	If ASTDT < ADSL.TRTSDT then PREFL='Y'
TRTEMFL	Product Emergent Analysis Flag	text	Y	Cond	If ADSL.TRTSDT≤ASTDT then TRTEMFL='Y'
FUPFL	Follow-up Flag	text	Y	Cond	If ASTDT > ADSL.TRTEDT then FUPFL='Y'
AETRTEM	Product Emergent Flag	text	(NY)	Perm	SUPPAE.QVAL where QNAME='AETRTEM'.
AOCCFL	1st Occurrence within Subject Flag	text	Y	Perm	Sort the data in the required order and flag the first product emergent record for each subject.

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
AOCCPFL	1st Occurrence of Preferred Term Flag	text	Y	Perm	Sort the data in the required order and flag the first product emergent record for each AEDECOD for each subject.
AOCCSFL	1st Occurrence of SOC Flag	text	Y	Perm	Sort the data in the required order and flag the first product emergent record for each body system for each subject.
AESER	Serious Experience	text	(NY)	Req	AE.AESER
AEREL	Causality	text		Perm	AE.AEREL
AERLDEV	Relationship of Event to Device	text	*	Perm	AE.AERLDEV
RELGR1	Pooled Causality Group y	text		Perm	set to RELATED if AE.AEREL in (DEFINITELY,PROBABLY,POSSIBLY), set to NOT RELATED if AEREL in (PROBABLY NOT, DEFINITELY NOT)
AEACN	Action Taken with Study Product	text	(TPACN)	Perm	AE.AEACN
AEACNDEV	Action Taken with Device	text		Perm	AE.AEACNDEV
AEOUT	Outcome of Adverse Experience	text	(OUT)	Perm	AE.AEOUT
TRA	Actual Product	text		Cond	ADSL.TRT01A
SAFFL	Safety Population Flag	text		Cond	ADSL.SAFFL
TRTSDF	Date of First Exposure to Product	integer		Perm	ADSL.TRTSDF
TRTEDT	Date of Last Exposure to Product	integer		Perm	ADSL.TRTEDT
AEOUT	Outcome of Adverse experience	text		Perm	AE.AEOUT
AESEQ	Sequence Number	integer		Perm	AE.AESEQ
AESTDT	Start Date/Time of Adverse Experience	text		Perm	AE.AESTDT
AEENDTC	End Date/Time of Adverse Experience	text		Perm	AE.AEENDTC
AESTDY	Study Day of Start of Adverse Experience	text		Perm	AE.AESTDY
AEENDY	Study Day of End of Adverse Experience	text		Perm	AE.AEENDY
AEENRF	End Relative to Reference Period	text		Perm	AE.AEENRF

3.3.6.4 Concomitant Medication (ADCM)

This is an example of an ADCM dataset and is based primarily on input from the SDTM CM dataset. Other administrative data about the subjects are based on the ADSL dataset provided in Section 3.3.6.1, [Subject-level Analysis Dataset \(ADSL\)](#).

Example 1

This is an example of the input SDTM CM datasets used to create the ADCM. Only variables needed for illustration are shown in the examples.

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMDECOD	CMINDC	CMCLAS	CMDOSE	CMDOSTXT	CMDOSU	CMDOSFRM	CMDOSFRQ	CMROUTE	CMSTDTC	CMENDTC	CMENRF
1	A123	CM	A2001	1	ASPIRIN	acetylsalicylic acid	MIGRAINE	ANALGESICS	100		mg	TABLET	ONCE	ORAL	2021-01-21	2021-01-22	
2	A123	CM	A2008	1	DIOVAN	valsartan	HYPERTENSION	ANTIHYPERTENSIVES	20		mg	TABLET	BID	ORAL	2004		AFTER
3	A123	CM	A2008	2	ZOLOFT	sertraline	PANIC ATTACKS	PSYCHOANALEPTICS	50		mg	TABLET	QD	ORAL	2010-01		AFTER
4	A123	CM	A2008	3	ASTELIN	azelastine	INFLUENZA	NASAL PREPARATIONS		2 sprays in each nostril-137 mcg	mcg	SPRAY	BID	NASAL	2006-02-26		AFTER
5	A123	CM	A3009	1	ASPIRIN	acetylsalicylic acid	PAIN	ANALGESICS	100		mg	TABLET	PRN	ORAL	2004-01-01		AFTER

The following is an example ADaM dataset designed to support the summarization of concomitant medications. Included are a subset of variables that are commonly included to support a basic summary table.

adcm.xpt

Row	STUDYID	USUBJID	CMTRT	CMDECOD	CMCLAS	ASTDT	ASTDTF	AENDT	AENDTF	ASTDY	AENDY	AOC CFL	AOC CPFL	AOC C01FL	PREFL
1	ABC123	A2001	ASPIRIN	acetylsalicylic acid	ANALGESICS	21JAN2021		22JAN2021		1	2	Y	Y	Y	
2	ABC123	A2008	DIOVAN	valsartan	ANTIHYPERTENSIVES	01JAN2004	M			-6230					
3	ABC123	A2008	ZOLOFT	sertraline	PSYCHOANALEPTICS	01JAN2010	D			-4038					
4	ABC123	A2008	ASTELIN	azelastine	NASAL PREPARATIONS	26FEB2006				-5443					
5	ABC123	A3009	ASPIRIN	acetylsalicylic acid	ANALGESICS	01JAN2004				-6230					

Row	ONTRTFL	FUPFL	TRTP	SAFFL	CMDOSE	CMDOSTXT	CMDOSU	CMINDC	CMDOSFRM	CMDOSFRQ	CMROUTE	CMSTDTC	CMENDTC	CMENRF	CMSEQ
1	Y		Placebo	Y	100		mg	MIGRAINE	TABLET	ONCE	ORAL	2021-01-21	2021-01-22		1
2	Y	Y	Product A	Y	20		mg	HYPERTENSION	TABLET	BID	ORAL	2004		AFTER	2
3	Y	Y	Product A	Y	50		mg	PANIC ATTACKS	TABLET	QD	ORAL	2010-01		AFTER	3
4	Y	Y	Product A	Y	2 sprays in each nostril-137 mcg		mcg	INFLUENZA	SPRAY	BID	NASAL	2006-02-26		AFTER	4
5	Y	Y	Product B	Y	100		mg	PAIN	TABLET	PRN	ORAL	2004-01-01		AFTER	5

ADCM Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADCM	Concomitant Medications Analysis Dataset	OCCURRENCE DATA STRUCTURE	One record per subject per medication	Analysis	STUDYID, USUBJID, CMDECOD, CMTRT	ADCM.xpt	ADCM.SAS/SAP

ADA M Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	text		Req	CM.STUDYID
USUBJID	Unique Subject Identifier	text		Req	CM.USUBJID
CMTRT	Reported Name of Drug, Med, or Therapy	text		Req	CM.CMTRT
CMDECOD	Standardized Medication Name	text		Perm	CM.CMDECOD
CMCLAS	Medication Class	text		Perm	CM.CMCLAS
ASTDT	Analysis Start Date	integer		Perm	numeric SAS date variable based on CMSTDTC with no imputation for partial dates
ASTDTF	Analysis Start Date Imputation Flag			Perm	
AENDT	Analysis End Date	integer		Perm	numeric SAS date variable based on CMENDTC with no imputation for partial dates
AENDTF	Analysis End Date Imputation Flag			Perm	
ASTDY	Analysis Start Relative Day	integer		Perm	ASTDT-TRTSDT - add one if ASTDT is on or after TRTSDT
AENDY	Analysis End Relative Day	integer		Perm	AENDT-TRTSDT - add one if ASTDT is on or after TRTSDT
AOCCFL	1st Occurrence within Subject Flag	text	Y	Perm	sort by USUBJID, CMCLAS, CMDECOD, CMSTDTC and then set to Y for the first record
AOCCPFL	1st Occurrence of Preferred Term Flag	text	Y	Perm	sort by USUBJID, CMCLAS, CMDECOD, CMSTDTC and then set to Y for the first record within CMCLAS and CMDECOD
AOCC01FL	1st Occurrence of CMCLAS	text	Y	Perm	sort by USUBJID, CMCLAS, CMDECOD, CMSTDTC and then set to Y for the first record within CMCLAS
PREFL	Pre-product Flag	text	Y	Cond	
ONTRTFL	On Product Record Flag	text	Y	Cond	
FUPFL	Follow-up Flag	text	Y	Cond	
TRTP	Planned Product	text		Cond	ADSL.TRT01P
SAFFL	Safety Population Flag	text	Y:N	Cond	ADSL.SAFFL
CMDOSE	Dose per Administration	integer		Perm	CM.CMDOSE
CMDOSTXT	Dose Description	text		Perm	CM.CMDOSTXT
CMDOSU	Dose Units	text		Perm	CM.CMDOSU
CMINDC	Indication	text		Perm	CM.CMINDC
CMDOSFRM	Dose Form	text		Perm	CM.CMDOSFRM
CMDOSFRQ	Dosing Frequency per Interval	text		Perm	CM.CMDOSFRQ
CMROUTE	Route of Administration	text		Perm	CM.CMROUTE
CMSTDTC	Start Date/Time of Medication	text		Perm	CM.CMSTDTC
CMENDTC	End Date/Time of Medication	text		Perm	CM.CMENDTC
CMENRF	End Relative to Reference Period	text		Perm	CM.CMENRF
CMSEQ	Sequence Number	integer		Cond	CM.CMSEQ

3.3.6.5 Exposure (ADEX)

This is an example of an ADEX dataset and is based primarily on input from the SDTM EX dataset. Other administrative data about the subjects are based on the ADSL dataset provided in Section 3.3.6.1, [Subject-level Analysis Dataset \(ADSL\)](#).

Example 1

This is an example of the input SDTM EX dataset used to create the ADEX. Only variables needed for illustration are shown in the example.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	SPTOBID	EXREFID	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXROUTE	EXPSTRG	EXPSTRGU	EXSTDTC	EXENDTC
1	A123	EX	A2001	1	VAPE-Z27	CRT8754	e-nicotine liquid	6	mL	CARTRIDGE	RESPIRATORY (INHALATION)	0	mg/mL	2021-01-08	2021-01-14
2	A123	EX	A2001	2	VAPE-Z27	CRT8768	e-nicotine liquid	6.4	mL	CARTRIDGE	RESPIRATORY (INHALATION)	0	mg/mL	2021-01-15	2021-01-21
3	A123	EX	A2001	3	VAPE-Z27	CRT9756	e-nicotine liquid	7	mL	CARTRIDGE	RESPIRATORY (INHALATION)	0	mg/mL	2021-01-22	2021-01-28
4	A123	EX	A2008	1	VAPE-Z27	CRT8000	e-nicotine liquid	5	mL	CARTRIDGE	RESPIRATORY (INHALATION)	8	mg/mL	2021-02-08	2021-02-14
5	A123	EX	A2008	2	VAPE-Z27	CRT9006	e-nicotine liquid	7	mL	CARTRIDGE	RESPIRATORY (INHALATION)	8	mg/mL	2021-02-15	2021-02-21
6	A123	EX	A2008	3	VAPE-Z27	CRT9008	e-nicotine liquid	8	mL	CARTRIDGE	RESPIRATORY (INHALATION)	8	mg/mL	2021-02-22	2021-03-01
7	A123	EX	A3009	1	VAPE-Z27	CRT9128	e-nicotine liquid	8	mL	CARTRIDGE	RESPIRATORY (INHALATION)	4	mg/mL	2021-06-09	2021-06-15
8	A123	EX	A3009	2	VAPE-Z27	CRT6868	e-nicotine liquid	6.7	mL	CARTRIDGE	RESPIRATORY (INHALATION)	4	mg/mL	2021-06-16	2021-06-21

This is an example of the ADEX dataset and associated metadata.

adex.xpt

Row	STUDYID	USUBJID	ASTDT	ASTDY	AENDT	AENDY	EXTRT	DOSCUA	EXSTDTC	EXENDTC	TRTA	EXDOSE	EXDOSU	SAFFL
1	A123	A2001	08JAN2021	1	14JAN2021	7	e-nicotine liquid	6	021-01-08	2021-01-14	Placebo	6	mL	Y
2	A123	A2001	15JAN2021	8	21JAN2021	14	e-nicotine liquid	12.4	2021-01-15	2021-01-21	Placebo	6.4	mL	Y
3	A123	A2001	22JAN2021	15	28JAN2021	21	e-nicotine liquid	19.4	2021-01-22	2021-01-28	Placebo	7	mL	Y
4	A123	A2008	08FEB2021	1	14FEB2021	7	e-nicotine liquid	5	2021-02-08	2021-02-14	Product A	5	mL	Y
5	A123	A2008	15FEB2021	8	21FEB2021	14	e-nicotine liquid	12	2021-02-15	2021-02-21	Product A	7	mL	Y
6	A123	A2008	22FEB2021	15	01MAR2021	22	e-nicotine liquid	20	2021-02-22	2021-03-01	Product A	8	mL	Y
7	A123	A3009	09JUN2021	1	15JUN2021	7	e-nicotine liquid	8	2021-06-09	2021-06-15	Product B	8	mL	Y
8	A123	A3009	16JUN2021	8	21JUN2021	13	e-nicotine liquid	14.7	2021-06-16	2021-06-21	Product B	6.7	mL	Y

ADEX Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADEX	Exposure Analysis Dataset	OCCURRENCE DATA STRUCTURE	One record per subject per product (EXTRT) per start date	Analysis	STUDYID, USUBJID, EXTRT, ASTDT	ADEX.xpt	ADEX.SAS/SAP

ADEX Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	text		Req	EX.STUDYID
USUBJID	Unique Subject Identifier	text		Req	EX.USUBJID
ASTDT	Analysis Start Date	integer		Perm	EX.EXSTDTC captured as a numeric variable
ASTDY	Analysis Start Relative Day	integer		Perm	ASTDT-ADT.TRTSDT+1
AENDT	Analysis End Date	integer		Perm	EX.EXENDTC captured as a numeric variable
AENDY	Analysis End Relative Day	integer		Perm	AENDT-ADT.TRTSDT+1
EXTRT	Name of Product	text		Req	EX.EXTRT
DOSCUA	Cumulative Actual Product Dose	float		Perm	Cumulative dose within USUBJID
EXSTDTC	Start Date/Time of Product	text		Perm	EX.EXSTDTC
EXENDTC	End Date/Time of Product	text		Perm	EX.EXENDTC
TRTA	Actual Product	text		Cond	ADSL.TRTO1A
EXDOSE	Dose	float		Perm	EX.EXDOSE
EXDOSU	Dose Units	text		Perm	EX.EXDOSU
SAFFL	Safety Population Flag	text		Cond	ADSL.SAFFL

adexsum.xpt

Row	STUDYID	USUBJID	TRTA	PARAM	PARAMCD	PARAMN	AVAL	SAFFL
1	A123	A2001	Placebo	Number of Days Exposed	N DAYS	1	21	Y
2	A123	A2001	Placebo	Average Daily Dose	ADD	2	0.92381	Y
3	A123	A2001	Placebo	Total Dose	TOTDOSE	3	19.4	Y
4	A123	A2008	Product A	Number of Days Exposed	N DAYS	1	22	Y
5	A123	A2008	Product A	Average Daily Dose	ADD	2	0.90909	Y
6	A123	A2008	Product A	Total Dose	TOTDOSE	3	20	Y
7	A123	A3009	Product B	Number of Days Exposed	N DAYS	1	13	Y
8	A123	A3009	Product B	Average Daily Dose	ADD	2	1.13077	Y
9	A123	A3009	Product B	Total Dose	TOTDOSE	3	14.7	Y

ADEXSUM Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADEXSUM	Exposure Summary Analysis Dataset	BASIC DATA STRUCTURE	One or more records per subject per analysis parameter	Analysis	STUDYID, USUBJID, PARAM	ADEXSUM.xpt	ADEXSUM.SAS/SAP

ADEXSUM Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	Char		Req	ADEX.STUDYID
USUBJID	Unique Subject Identifier	Char		Req	ADEX.USUBJID
TRTA	Actual Product	Char		Cond	ADEX.TRT01A
PARAM	Parameter	Char		Req	Assigned
PARAMCD	Parameter Code	text		Req	Assigned
PARAMN	Parameter (N)	Num		Perm	Assigned
AVAL	Analysis Value	Num		Cond	see parameter level metadata
SAFFL	Safety Population Flag	Char	Y:N	Cond	ADSL.SAFFL

3.3.6.6 Laboratory Analysis Dataset (ADLB)

This is an example of an ADLB dataset and is based on input from the SDTM LB dataset. Other administrative data about the subjects are based on the ADSL dataset provided in Section 3.3.6.1, [Subject-level Analysis Dataset \(ADSL\)](#).

Example 1

This is an example SDTM datasets used to create the ADLB dataset. Only variables needed for illustration are shown in the examples.

lb.xpt

ROW	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRL0	LBORNRH1	LBSTRESC	LBSTRESN
1	A123	LB	A2001	1	WBC	Leukocytes	HEMATOLOGY	11.0	10^9/L	4.5	11.0	11.0	11.0
2	A123	LB	A2001	2	RBC	RBC	HEMATOLOGY	5.4	10^12/L	4.7	6.1	5.4	5.4
3	A123	LB	A2001	3	PLAT	Platelets	HEMATOLOGY	158	10^9/L	150	400	158	158
4	A123	LB	A2001	4	HGB	Hemoglobin	HEMATOLOGY	14.5	g/dL	14	18	14.5	14.5
5	A123	LB	A2001	5	CHOL	Cholesterol	CLINICAL CHEMISTRY	229	mg/dL	200		229	229
6	A123	LB	A2001	6	ALB	Albumin	CLINICAL CHEMISTRY	40.0	g/L	34	54	4.0	4.0
7	A123	LB	A2001	7	CREAT	Creatinine	CLINICAL CHEMISTRY	0.8	mg/dL	0.7	1.3	0.8	0.8
8	A123	LB	A2001	8	SPGRAV	Specific Gravity	URINALYSIS	1.002		1.005	1.030		
9	A123	LB	A2001	9	CANNAB	Cannabinoids	DRUG TOXICITY	POSITIVE				POSITIVE	

ROW	LBSTRESU	LBSTNRNC	LBSTNRLO	LBSTNRHI	LBNRIND	LBLOINC	LBSPEC	LBLOBXFL	LBCLSIG	VISITNUM	LBDTC
1	10^9/L		4.5	11.0		26464-8	BLOOD	Y		1	2021-1-02
2	10^12/L		4.7	6.1		33051-4	BLOOD	Y		1	2021-1-02
3	10^9/L		150	400		49497-1	BLOOD	Y		1	2021-1-02
4	g/dL		14	18		718-7	BLOOD	Y		1	2021-1-02
5	mg/dL		200			2093-3	BLOOD	Y		1	2021-1-02
6	g/dL		3.4	5.4		2862-1	BLOOD	Y		1	2021-1-02
7	mg/dl		0.7	1.3		2160-0	BLOOD	Y		1	2021-1-02
8			1.005	1.030		2965-2	URINE	Y		1	2021-1-02
9		NEGATIVE			ABNORMAL	18282-4	URINE	Y	Y	1	2021-1-02

This is an example of the ADLB dataset and associated metadata. This is just an example and does not mean to indicate that ADLB must be used as the dataset name, nor are the parameters described necessarily those that would be used in a particular study.

adlb.xpt

Row	STUDYID	USUBJID	TRTP	TRT01P	TRTA	TRT01A	ADT	ADY	AVISIT	AVISITN	PARAM	PARAMCD	PARAMN	PARCAT1	AVAL	AVALC	BASE	CHG
1	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	-6	SCREENING	1	Leukocytes (10^9/L)	WBC	6	HEMATOLOGY	11.0		11.0	
2	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	-6	SCREENING	1	RBC (10^12/L)	RBC	8	HEMATOLOGY	5.4		5.4	

Row	STUDYID	USUBJID	TRTP	TRT01P	TRTA	TRT01A	ADT	ADY	AVISIT	AVISITN	PARAM	PARAMCD	PARAMN	PARCAT1	AVAL	AVALC	BASE	CHG
3	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	-6	SCREENING	1	Platelets (10 ⁹ /L)	PLAT	7	HEMATOLOGY	158		158	
4	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	-6	SCREENING	1	Hemoglobin (g/dL)	HGB	5	HEMATOLOGY	14.5		14.5	
5	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	-6	SCREENING	1	Cholesterol (mg/dL)	CHOL	2	CLINICAL CHEMISTRY	229		229	
6	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	-6	SCREENING	1	Albumin (g/L)	ALB	1	CLINICAL CHEMISTRY	4.0		4.0	
7	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	-6	SCREENING	1	Creatinine (mg/dL)	CREAT	3	CLINICAL CHEMISTRY	0.8		0.8	
8	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	-6	SCREENING	1	Urine Specific Gravity	USPGRAV	9	URINALYSIS				
9	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	-6	SCREENING	1	Cannabinoids	CANNAB	4	DRUG TOXICITY		POSITIVE		

Row	PCHG	ABLFL	ANL01FL	LBSTNRC	ANRLO	ANRHI	ANRIND	LBLOINC	LBSPEC	RANDFL	SAFFL	TRTSDT	TRTEDT	LBCLSIG	LBSEQ	VISITNUM	LBDTC	
1		Y	Y		4.5	11.0		26464-8	BLOOD	Y	Y	2021-01-08	2021-01-28		1	1	2021-01-02	
2		Y	Y		4.7	6.1		33051-4	BLOOD	Y	Y	2021-01-08	2021-01-28		2	1	2021-01-02	
3		Y	Y		150	400		49497-1	BLOOD	Y	Y	2021-01-08	2021-01-28		3	1	2021-01-02	
4		Y	Y		14	18		718-7	BLOOD	Y	Y	2021-01-08	2021-01-28		4	1	2021-01-02	
5		Y	Y		200			2093-3	BLOOD	Y	Y	2021-01-08	2021-01-28		5	1	2021-01-02	
6		Y	Y		3.4	5.4		2862-1	BLOOD	Y	Y	2021-01-08	2021-01-28		6	1	2021-01-02	
7		Y	Y		0.7	1.3		2160-0	BLOOD	Y	Y	2021-01-08	2021-01-28		7	1	2021-01-02	
8		Y	Y		1.005	1.030		2965-2	URINE	Y	Y	2021-01-08	2021-01-28		8	1	2021-01-02	
9				NEGATIVE				ABNORMAL	18282-4	URINE	Y	Y	2021-01-08	2021-01-28	Y	9	1	2021-01-02

ADLB Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADLB	Laboratory Analysis Dataset	BASIC DATA STRUCTURE	One or more records per subject per analysis parameter per analysis visit per analysis timepoint	Analysis	STUDYID, USUBJID, PARAM, PARAMCD, AVISIT,	ADLB.xpt	ADLB.SAS/SAP

ADLB Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	CDISC Notes
STUDYID	Study Identifier	Char		Req	LB.STUDYID
USUBJID	Unique Subject Identifier	Char		Req	LB.USUBJID
TRTP	Planned Product	Char		Cond	ADSL.TRT01P
TRT01P	Planned Product for Period 01	Char		Cond	ADSL.TRT01P
TRTA	Actual Product	Char		Cond	ADSL.TRT01A
TRT01A	Actual Product for Period 01	Char		Cond	ADSL.TRT01A
ADT	Analysis Date	Num		Perm	LB.LBDTC captured in numeric format
ADY	Analysis Relative Day	Num		Perm	LB.LBDY
AVISIT	Analysis Visit	Char		Cond	LB.VISIT
AVISITN	Analysis Visit (N)	Num		Perm	LB.VISITNUM
PARAM	Parameter	Char		Req	LB.LBTTEST concatenated with LB.LBSTRESU - if PARCAT1=URINALYSIS then preface with Urine
PARAMCD	Parameter Code	text		Req	LB.LBTTESTCD - if PARCAT1=URINALYSIS then preface with U
PARAMN	Parameter (N)	Num		Perm	Numeric representation of PARAM. Sort by PARCAT1 and PARAMCD and increment by 1 for each new LBTESTCD
PARCAT1	Parameter Category 1	Char		Perm	LB.LBCAT
AVAL	Analysis Value	Num		Cond	LB.LBTESTSN
AVALC	Analysis Value (C)	Char		Cond	LB.LBTESTSC where LB.LBTESTSN is null
BASE	Baseline Value	Num		Cond	AVAL where ABLFL=Y
CHG	Change from Baseline	Num		Perm	AVAL-BASE - populated on ABLFL=Y records and post-baseline records
PCHG	Percent Change from Baseline	Num		Perm	derived as ((AVAL-BASE)/BASE)*100
ABLFL	Baseline Record Flag	Char	Y	Cond	set to Y for last pre-product value within each PARAM
ANL01FL	Analysis Flag 01	Char	Y	Cond	set to Y for last value within PARAM and AVISIT
RANDFL	Randomized Population Flag	Char	Y;N	Cond	ADSL.RANDFL
SAFFL	Safety Population Flag	Char	Y;N	Cond	ADSL.SAFFL
TRTSDT	Date of First Exposure to Product	Num		Perm	ADSL.TRTSDT
TRTEDT	Date of Last Exposure to Product	Num		Perm	ADSL.TRTEDT
LBSEQ	Sequence Number	Num		Perm	LB.LBSEQ
VISITNUM	Visit Number	Num		Perm	LB.VISITNUM
LBDTC	Date/Time of Specimen Collection	Char		Perm	LB.LBDTC

3.3.6.7 Vital Signs Analysis Dataset (ADVS)

This is an example of an ADVS dataset and is based on input from the SDTM VS dataset. Other administrative data about the subjects are based on the ADSL dataset provided in Section 3.3.6.1, [Subject-level Analysis Dataset \(ADSL\)](#).

Example 1

This is an example SDTM datasets used to create the ADVS dataset. Only variables needed for illustration are shown in the examples.

vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VTESTCD	VTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSSTAT	VSREASND	VSLOC	VSLAT	VSLOBXFL	VISITNUM	VISIT	VSDTG	VSTPT	VSTPTNUM
1	A123	VS	A2001	1	SYSBP	Systolic Blood Pressure	SITTING	154	mmHg	154	154	mmHg			ARM	LEFT		1	Baseline	2021-01-02T08:45	BASELINE 1	1
2	A123	VS	A2001	2	SYSBP	Systolic Blood Pressure	SITTING	152	mmHg	152	152	mmHg			ARM	LEFT	Y	1	Baseline	2021-01-02T09:00	BASELINE 2	2
3	A123	VS	A2001	3	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg			ARM	LEFT		1	Baseline	2021-01-02T08:45	BASELINE 1	1
4	A123	VS	A2001	4	DIABP	Diastolic Blood Pressure	SITTING	48	mmHg	48	48	mmHg			ARM	LEFT	Y	1	Baseline	2021-01-02T09:00	BASELINE 2	2
5	A123	VS	A2001	5	PULSE	Pulse Rate	SITTING	72	beats/min	72	72	beats/min			ARM	LEFT	Y	1	Baseline	2021-01-02T08:45		
6	A123	VS	A2001	6	TEMP	Temperature		34.7	C	34.7	34.7	C			SUBLINGUAL REGION			1	Baseline	2021-01-02T08:45	BASELINE 1	1
7	A123	VS	A2001	7	TEMP	Temperature		36.2	C	36.2	36.2	C			SUBLINGUAL REGION		Y	1	Baseline	2021-01-02T09:00	BASELINE 2	2
8	A123	VS	A2001	8	WEIGHT	Weight		90.5	kg	90.5	90.5	kg					Y	1	Baseline	2021-01-02		
9	A123	VS	A2001	9	HEIGHT	Height		157	cm	157	157	cm					Y	1	Baseline	2021-01-02		
10	A123	VS	A2001	10	SYSBP	Systolic Blood Pressure	SITTING	95	mmHg	95	95	mmHg			ARM	LEFT		2	Visit 4	2021-01-28		
11	A123	VS	A2001	11	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg			ARM	LEFT		2	Visit 4	2021-01-28		
12	A123	VS	A2001	12	TEMP	Temperature		97.16	F	36.2	36.2	C			SUBLINGUAL REGION			2	Visit 4	2021-01-28		
13	A123	VS	A2001	13	WEIGHT	Weight							NOT DONE	SUBJECT REFUSED				2	Visit 4	2021-01-28		

This is an example of the ADVS dataset and associated metadata. This is just an example and does not mean to indicate that ADVS must be used as the dataset name, nor are the parameters described necessarily those that would be used in a particular study.

advs.xpt

Row	STUDYID	USUBJID	TRTP	TRT01P	TRTA	TRT01A	ADT	ADTM	ADY	AVISIT	AVISITN	ATPT	ATPTN	APHASE	PARAM	PARAMCD	PARAMN	AVAL	BASE	CHG	PCHG	DTYPE	
1	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	01JAN2021:08:45	-6	Baseline	1	Baseline 1	1	SCREENING	Systolic Blood Pressure (mmHg)	SYSBP	4	154					
2	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	01JAN2021:09:00	-6	Baseline	1	Baseline 2	2	SCREENING	Systolic Blood Pressure (mmHg)	SYSBP	4	152					
3	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021		-6	Baseline	1			SCREENING	Systolic Blood Pressure (mmHg)	SYSBP	4	153	153	0		AVERAGE	
4	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	01JAN2021:08:45	-6	Baseline	1	Baseline 1	1	SCREENING	Diastolic Blood Pressure (mmHg)	DIABP	1	44					
5	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	01JAN2021:09:00	-6	Baseline	1	Baseline 2	2	SCREENING	Diastolic Blood Pressure (mmHg)	DIABP	1	48					
6	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021		-6	Baseline	1			SCREENING	Diastolic Blood Pressure 7(mmHg)	DIABP	1	46	46	0		AVERAGE	
7	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021		-6	Baseline	1			SCREENING	Pulse Rate (beats/min)	PULSE	3	72	72	0			
8	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	01JAN2021:08:45	-6	Baseline	1	Baseline 1	1	SCREENING	Temperature (C)	TEMP	5	34.7					
9	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021	01JAN2021:09:00	-6	Baseline	1	Baseline 2	2	SCREENING	Temperature (C)	TEMP	5	36.2					
10	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021		-6	Baseline	1			SCREENING	Temperature (C)	TEMP	5	35.45	35.45	0		AVERAGE	
11	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021		-6	Baseline	1			SCREENING	Weight (kg)	WEIGHT	6	90.5	90.5	0			
12	A123	A2001	Placebo	Placebo	Placebo	Placebo	02JAN2021		-6	Baseline	1			SCREENING	Height (cm)	HEIGHT	2	157	157	0			
13	A123	A2001	Placebo	Placebo	Placebo	Placebo	28JAN2021		21	Visit 2	2			PRODUCT	Systolic Blood Pressure (mmHg)	SYSBP	4	95	153	-58	-37.9085		
14	A123	A2001	Placebo	Placebo	Placebo	Placebo	28JAN2021		21	Visit 2	2			PRODUCT	Diastolic Blood Pressure (mmHg)	DIABP	1	44	46	-2	-4.3478		
15	A123	A2001	Placebo	Placebo	Placebo	Placebo	28JAN2021		21	Visit 2	2			PRODUCT	Temperature (C)	TEMP	5	36.2	35.45	.75	2.1157		

Row	STUDYID	USUBJID	TRTP	TRT01P	TRTA	TRT01A	ADT	ADTM	ADY	AVISIT	AVISITN	ATPT	ATPTN	APHASE	PARAM	PARAMCD	PARAMN	AVAL	BASE	CHG	PCHG	DTYPE
16	A123	A2001	Placebo	Placebo	Placebo	Placebo	28JAN2021		21	Visit 2	2			PRODUCT	Weight (kg)	WEIGHT	6					
Row	ABLFL	ANL01FL	SAFFL	RANDFL	TRTSDT	TRTEDT	VSSEQ	VTESTCD	VTEST	VSSTAT	VSREASND	VSLOC	VSLAT	VSLOBXFL	VISITNUM	VISIT	VSDTC	VSDY	VSTPT	VSTPTNUM		
1		Y	Y	Y	2021-01-08	2021-01-28	1	SYSBP	Systolic Blood Pressure			ARM	LEFT		1	Baseline	2021-01-02T08:45	-6	BASELINE 1	1		
2		Y	Y	Y	2021-01-08	2021-01-28	2	SYSBP	Systolic Blood Pressure			ARM	LEFT	Y	1	Baseline	2021-01-02-T09:00	-6	BASELINE 2	2		
3	Y	Y	Y	Y	2021-01-08	2021-01-28																
4		Y	Y	Y	2021-01-08	2021-01-28	3	DIABP	Diastolic Blood Pressure			ARM	LEFT		1	Baseline	2021-01-02T08:45	-6	BASELINE 1	1		
5		Y	Y	Y	2021-01-08	2021-01-28	4	DIABP	Diastolic Blood Pressure			ARM	LEFT	Y	1	Baseline	2021-01-02-T09:00	-6	BASELINE 2	2		
6	Y	Y	Y	Y	2021-01-08	2021-01-28																
7	Y	Y	Y	Y	2021-01-08	2021-01-28	5	PULSE	Pulse Rate			ARM	LEFT	Y	1	Baseline	2021-01-02T08:45	-6				
8		Y	Y	Y	2021-01-08	2021-01-28	6	TEMP	Temperature			SUBLINGUAL REGION				1	Baseline	2021-01-02T08:45	-6	BASELINE 1	1	
9		Y	Y	Y	2021-01-08	2021-01-28	7	TEMP	Temperature			SUBLINGUAL REGION		Y	1	Baseline	2021-01-02-T09:00	-6	BASELINE 2	2		
10	Y	Y	Y	Y	2021-01-08	2021-01-28																
11	Y	Y	Y	Y	2021-01-08	2021-01-28	8	WEIGHT	Weight					Y	1	Baseline	2021-01-02	-6				
12	Y	Y	Y	Y	2021-01-08	2021-01-28	9	HEIGHT	Height					Y	1	Baseline	2021-01-02	-6				
13		Y	Y	Y	2021-01-08	2021-01-28	10	SYSBP	Systolic Blood Pressure			ARM	LEFT		2	Visit 2	2021-01-28	21				
14		Y	Y	Y	2021-01-08	2021-01-28	11	DIABP	Diastolic Blood Pressure			ARM	LEFT		2	Visit 2	2021-01-28	21				
15		Y	Y	Y	2021-01-08	2021-01-28	12	TEMP	Temperature			SUBLINGUAL REGION			2	Visit 2	2021-01-28	21				
16		Y	Y		2021-01-08	2021-01-28	13	WEIGHT	Weight	NOT DONE	SUBJECT REFUSED				2	Visit 2	2021-01-28	21				

ADVS Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADVS	Vital Signs Analysis Dataset	BASIC DATA STRUCTURE	One or more records per subject per analysis parameter per analysis visit per analysis timepoint	Analysis	STUDYID, USUBJID, PARAM, PARAMCD, AVISIT, ATPT	ADVS.xpt	ADVS.SAS/SAP

ADVS Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
STUDYID	Study Identifier	text		Req	VS.STUDYID
USUBJID	Unique Subject Identifier	text		Req	VS.USUBJID
TRTP	Planned Product	Char		Cond	ADSL.TRT01P
TRT01P	Planned Product for Period 01	Char		Cond	ADSL.TRT01P
TRTA	Actual Product	Char		Cond	ADSL.TRT01A
TRT01A	Actual Product for Period 01	Char		Cond	ADSL.TRT01A
ADT	Analysis Date	Num		Perm	VS.VSDTC captured as a date in numeric format.
ADTM	Analysis Datetime	integer		Perm	VS.VSDTC captured as a datetime in numeric format.
ADY	Analysis Relative Day	Num		Perm	VS.VSDY
AVISIT	Analysis Visit	Char		Cond	VS.VISIT
AVISITN	Analysis Visit (N)	Num		Perm	VS.VISITNUM
ATPT	Analysis Timepoint	Char		Cond	VS.VSTPT
ATPTN	Analysis Timepoint (N)	Num		Cond	VS.VSTPTNUM
APHASE	Phase	Char		Perm	if ADT lt ADSL.TRTSDT then set to SCREENING, else if TRTSDT le ADT le TRTEDT then set to PRODUCT, else if ADT gt TRTEDT then set to FOLLOW-UP
PARAM	Parameter	Char		Req	set to VS.VSTEST concatenated with VS.VSTRESU
PARAMCD	Parameter Code	text		Req	set to VS.VSTESTCD
PARAMN	Parameter (N)	Num		Perm	Numeric representation of PARAM, sort by VTESTCD and increment by 1 for each unique value of VTESTCD
AVAL	Analysis Value	Num		Cond	VS.VSSTRESN for records taken from VS, Average of values taken on same datedataset.
BASE	Baseline Value	Num		Cond	AVAL where ABLFL=Y
CHG	Change from Baseline	Num		Perm	AVAL-BASE
PCHG	Percent Change from Baseline	Num		Perm	((AVAL-BASE)/BASE)*100
DTYPE	Derivation Type	Char	AVERAGE	Cond	set to AVERAGE for rows added to capture average value for parameters with multiple assessments done at a VISIT
ABLFL	Baseline Record Flag	Char	Y	Cond	set to Y on the record that captures the baseline value
ANL01FL	Analysis Flag 01	Char	Y	Cond	set to Y on record chosen to represent AVISIT for analysis
SAFFL	Safety Population Flag	Char	Y;N	Cond	ADSL.SAFFL
RANDFL	Randomized Population Flag	Char	Y;N	Cond	ADSL.RANDFL
TRTSDT	Date of First Exposure to Product	Num		Perm	ADSL.TRTSDT
TRTEDT	Date of Last Exposure to Product	Num		Perm	ADSL.TRTEDT
VSSEQ	Sequence Number	Num		Perm	VS.VSSEQ
VISIT	Visit Name	Char		Perm	VS.VISIT
VISITNUM	Visit Number	Num		Perm	VS.VISITNUM

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
VSTPT	Planned Time Point Name	Char		Perm	VS.VSTPT
VSTPTNUM	Planned Time Point Number	Char		Perm	VS.VSTPTNUM

3.3.6.8 Pharmacokinetic Parameters (ADPP)

This is an example of an ADPP dataset and is based on input from the SDTM PP dataset. Other administrative data about the subjects are based on the ADSL dataset provided in Section 3.3.6.1, Subject-level Analysis Dataset (ADSL).

Example 1

In this PK study, Cmax, time to reach Cmax (tmax), and the baseline-corrected area under the plasma concentration–time curves (i) from start of product use (t0) to the last quantifiable nicotine concentration time point (AUC0-last) and (ii) from t0 to 10 minutes after t0 (AUC0-10'). The pharmacokinetic parameters were derived from plasma nicotine concentrations-versus-time data by means of noncompartmental analysis and corrected for baseline where the baseline (C0) was defined as the average concentration of the 3 time points prior to t0 (45, 30, and 15 minutes prior to t0). The analysis methods for the baseline corrected values were provided in the study protocol.

This example shows the PP parameters calculated from time-concentration profiles for the nicotine for one subject at day 1. Typically, the same PP parameters would be provided for cotinine and NNN but are only shown for TMAX. Note that PPRFTDTC is populated in order to link the PP records to the respective PC records.

Other parameters may be calculated but are not shown. They may include: (1) R2, R Squared; (2) R2ADJ, R Squared Adjusted; (3) AUCIFO, AUC Infinity Obs; (4) AUCPEO, AUC %Extrapolation Obs; (5) AUCTAU, AUC Over Dosing Interval; (6) LAMZNPT, Number of Points for Lambda z; (7) LAMZUL, Lambda z Upper Limit; or (8) LAMZLL, Lambda z Lower Limit. These PP parameters are included in the controlled terminology.

Rows 1-2: Show parameters TMAX and CMAX for day 1.

Rows 3-4: Show parameters AUC for day 1. Note AUCALL was calculated as AUC from 0- to the last value and AUCINT was calculated as 0 to 10 minutes. This interval is represented in PPSTINI, and PPENINT.

Rows 5-6: Show parameter TMAX for cotinine and NNN.

pp.xpt

Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPGRPID	PPTESTCD	PPTEST	PPCAT	PPORRES	PPORRESU	PPSTRESC	PPSTRESN	PPSTRESU	PPSPEC	PPANMETH	VISITNUM	VISIT	PPDTG	PPRFTDTC	PPSTINT	PPENINT
1	A123	PP	A2008	1	DAY1	TMAX	Time of CMAX	NICOTINE	5	m	5	5	m	PLASMA	non-compartmental analysis, and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00		
2	A123	PP	A2008	2	DAY1	CMAX	Max Conc	NICOTINE	13	ng/mL	13	13	ng/mL	PLASMA	non-compartmental analysis, and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00		
3	A123	PP	A2008	3	DAY1	AUCALL	AUC All	NICOTINE	11.4	h*ng/mL	11.4	11.4	h*ng/mL	PLASMA	non-compartmental analysis, and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00		
4	A123	PP	A2008	4	DAY1	AUCINT	AUC from T1 to T2	NICOTINE	6.0	h*ng/mL	6.0	6.0	h*ng/mL	PLASMA	non-compartmental analysis, and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00	0	10
5	A123	PP	A2008	5	DAY1	TMAX	Time of CMAX	COTININE	6	m	6	6	m	PLASMA	non-compartmental analysis, and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00		
6	A123	PP	A2008	6	DAY1	TMAX	Time of CMAX	NNN	7	m	7	7	m	PLASMA	non-compartmental analysis, and corrected for baseline	1	DAY 1	2022-01-07	2021-02-08T08:00		

Values from ADSL and PP are combined to capture observations that can be summarized. This is just an example and does not mean to indicate that ADPP must be used as the dataset name, nor are the parameters described necessarily those that would be used in a particular study. One item to note is the use of PARQUAL, which will appear in a future version of the ADaM.

adpp.xpt

Row	STUDYID	USUBJID	TRTA	AVISIT	PARQUAL	PARAM	PARAMCD	AVAL	PPSPEC	PPSEQ	PKFL
1	A123	A2008	Product A	Day 1	NICOTINE	AUC All (h*ng/mL)	AUCALL	11.4	PLASMA	3	Y
2	A123	A2008	Product A	Day 1	NICOTINE	Max Conc (ng/mL)	CMAX	13	PLASMA	2	Y
3	A123	A2008	Product A	Day 1	NICOTINE	Time of CMAX (h)	TMAX	5	PLASMA	1	Y

Row	STUDYID	USUBJID	TRTA	AVISIT	PARQUAL	PARAM	PARAMCD	AVAL	PPSPEC	PPSEQ	PKFL
4	A123	A2008	Product A	Day 1	COTININE	Time of CMAX (h)	TMAX	6	PLASMA	5	Y
5	A123	A2008	Product A	Day 1	NNN	Time of CMAX (h)	TMAX	7	PLASMA	6	Y

ADPP Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADPP	PP Analysis Data	Basic Data Structure	One record per subject per parameter per analysis visit	Analysis	STUDYID, USUBJID, PARQUAL, PARAMCD, AVISIT,	ADPP.xpt	ADPP.SAS/SAP

ADPP Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
STUDYID	Study Identifier	text	ABC-123	Req	ADSL.STUDYID
USUBJID	Unique Subject Identifier	text		Req	PP.STUDYID
TRTA	Actual Product	text	Product A	Cond	ADSL.TRT01A
AVISIT	Analysis Visit	text	Day 1	Cond	Set to propcase of PP.VISIT
PARQUAL	Parameter Qualifier	text	NICOTINE_COTININENN	Perm	PP.PPCAT
PARAM	Parameter	text	AUC All (h*ng/mL) Max Conc (ng/mL) Time of CMAX (h)	Req	Assigned
PARAMCD	Parameter Code	text	AUCALL CMAX TMAX	Req	Assigned
AVAL	Analysis Value	float		Req	PP.PPSTRESN
PPSPEC	Specimen Material Type	text	PLASMA	Perm	PP.PPSPEC
PPSEQ	Sequence Number	text		Perm	PP.PPSEQ
PKFL	PK Population Flag	text	Y;N	Cond	ADSL.PKFL

3.4 Product Impact on Population Health

Tobacco products can lead to chronic health effects that can take decades to manifest (e.g., lung cancer can take 20+ years), which would require long-term studies to assess. Population models and simulations provide a desirable alternative for making estimates and predictions of likely impact on morbidity/mortality at the population level in the absence of empirical data. Mathematical, computational, and simulation models can also help guide regulatory activities such as new product authorizations and policy development. Such models take into consideration both users and nonusers of tobacco products and include but are not limited to cohort models, agent-based models, deterministic and stochastic systemic dynamic models, and static and dynamic social network models. Examples in this section illustrate how CDISC analysis standards represent parameters used as inputs to such modeling.

3.4.1 Population Modeling Module

The objective of population modeling is to study the impact of tobacco products on the population as whole. Input parameters include demographic information, tobacco use transition probability, and mortality and/or morbidity. Input parameters are typically derived from population-level sources (e.g., census data or other population-level surveys). However, depending on the objective, other sources of data may be used. When using these other sources, steps should be taken to ensure they are representative of the population.

Input parameters are an important component of model development, verification, and validation. In many population models in a tobacco research setting, input parameters are used to incorporate tobacco use behaviors and risks that occur under scenarios of interest—for example, models to evaluate the health impact associated with introducing a new tobacco or policy that may result in product switching, dual use, or polytobacco use. Input parameters may be obtained from a variety of data sources and, depending on the objectives of the model, may include population surveys representative of the population of interest (e.g., population distribution, birth rates, migration rates, death/other morbidity rates, tobacco product use behavior prevalence). This section provides a characterization of several classes input parameters informative in developing the TIG.

In this section, the inputs to these models and how they are represented in CDISC standards for submission to a regulatory authority are discussed. Model outputs are not currently covered in this section but may be covered in a later release. However, regulatory agencies expect full information to replicate the analysis based in the outputs.

3.4.1.1 Initial Population

In many population models, the simulation starts with an initial population that reflects the sex, age, race/ethnicity, and prevalence of tobacco product use behavior (never, current, former dual use, polytobacco use) in the population of interest at a particular period. The initial population represents the initial year in population projections. For example, the initial population could be the distribution of individuals in the US by sex, age, race and tobacco use status for year 2000. An example of data associated with the initial population includes prevalence of tobacco product use by sex, age, or time since cessation. These data are typically estimated from population survey representative of the US population, and tabulated based on sex, age, and race.

Example 1

This is an example of an ADaM dataset designed to capture reference data describing the initial population.

Rows 1-6: Show the counts of subjects in each combination of the population and therefore only STRTM1/STRTM2/STRM3 are populated in the example. These counts are independent of any tobacco usage (or non-usage) and therefore STRTM4/STRVAL4 and STRTM5/STRVAL5 columns are null. The INPRM value contains the concept captured in INPRMVAL and INPRMU captures the unit of the INPRMVAL value.

Rows 7-15: Show initial tobacco usage status for several product combinations and the prevalence of each usage status.

rfip.xpt

Row	STRTM1	STRVAL1	STRTM2	STRVAL2	STRTM3	STRVAL3	STRTM4	STRVAL4	STRTM5	STRVAL5	INPRM	INPRMVAL	INPRMU	REFSRCE
1	AGE	0	SEX	M	RACE	WHITE					POPULATION COUNT	50	COUNT	initial population 2017.xlsx
2	AGE	10	SEX	M	RACE	WHITE					POPULATION COUNT	48	COUNT	initial population 2017.xlsx
3	AGE	20	SEX	M	RACE	WHITE					POPULATION COUNT	49	COUNT	initial population 2017.xlsx
4	AGE	30	SEX	M	RACE	WHITE					POPULATION COUNT	50	COUNT	initial population 2017.xlsx
5	AGE	40	SEX	M	RACE	WHITE					POPULATION COUNT	51	COUNT	initial population 2017.xlsx
6	AGE	50	SEX	M	RACE	WHITE					POPULATION COUNT	52	COUNT	initial population 2017.xlsx
7	AGE	0	SEX	M	RACE	WHITE	TOBACCO PRODUCT CATEGORY	CIGARETTE	TOBACCO PRODUCT USE STATUS	NEVER	PREVALENCE	70	PERCENT	initial population 2017.xlsx
8	AGE	10	SEX	M	RACE	WHITE	TOBACCO PRODUCT CATEGORY	CIGARETTE	TOBACCO PRODUCT USE STATUS	NEVER	PREVALENCE	68	PERCENT	initial population 2017.xlsx
9	AGE	20	SEX	M	RACE	WHITE	TOBACCO PRODUCT CATEGORY	CIGARETTE	TOBACCO PRODUCT USE STATUS	CURRENT	PREVALENCE	10	PERCENT	initial population 2017.xlsx
10	AGE	30	SEX	M	RACE	WHITE	TOBACCO PRODUCT CATEGORY	CIGARETTE	TOBACCO PRODUCT USE STATUS	CURRENT	PREVALENCE	14	PERCENT	initial population 2017.xlsx
11	AGE	40	SEX	M	RACE	WHITE	TOBACCO PRODUCT CATEGORY	CIGARETTE	TOBACCO PRODUCT USE STATUS	FORMER	PREVALENCE	16	PERCENT	initial population 2017.xlsx
12	AGE	50	SEX	M	RACE	WHITE	TOBACCO PRODUCT CATEGORY	CIGARETTE	TOBACCO PRODUCT USE STATUS	FORMER	PREVALENCE	17	PERCENT	initial population 2017.xlsx
13	AGE	20	SEX	M	RACE	WHITE	TOBACCO PRODUCT CATEGORY	CIGARETTE/ENDS	TOBACCO PRODUCT USE STATUS	FORMER/CURRENT	PREVALENCE	20	PERCENT	initial population 2017.xlsx
14	AGE	30	SEX	M	RACE	WHITE	TOBACCO PRODUCT CATEGORY	CIGARETTE/ENDS	TOBACCO PRODUCT USE STATUS	FORMER/CURRENT	PREVALENCE	25	PERCENT	initial population 2017.xlsx
15	AGE	40	SEX	M	RACE	WHITE	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS	CURRENT/CURRENT	PREVALENCE	10	PERCENT	initial population 2017.xlsx

RFIP Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
RFIP	Reference Data for Initial Population	REFERENCE DATA STRUCTURE	one record per input value	reference	STRTM1, STRM2, STRTM3, STRTM4, STRTM5	rflip.xpt	N/A

RFIP Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
STRTM1	Stratum 1	text	AGE	Req	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the left-most column in this example
STRVAL1	Stratum 1 Value	text		Req	populate with the STRTM1 values in the source data (Age in this example)
STRTM2	Stratum 2	text	SEX	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the lower level of the fifth column in this example
STRVAL2	Stratum 2 Value	text	M;F	Cond	populate with the STRTM2 values in the source data (Sex in this example)
STRTM3	Stratum 3	text	RACE	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the upper level of the fifth column in this example
STRVAL3	Stratum 3 Value	text	WHITE	Cond	populate with the STRTM3 values in the source data (Race in this example)
STRTM4	Stratum 4	text	TOBACCO PRODUCT CATEGORY	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier)
STRVAL4	Stratum 4 Value	text	CIGARETTE;CIGARETTE/ENDS;CIGARETTE/CIGAR	Cond	populate with the STRTM4 values in the source data
STRTM5	Stratum 5	text	TOBACCO PRODUCT USE STATUS	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier)
STRVAL5	Stratum 5 Value	text	NEVER;CURRENT;FORMER;FORMER/CURRENT;CURRENT/CURRENT	Cond	populate with the STRTM5 values in the source data
INPRM	Input Parameter	text	POPULATION COUNT;PREVALENCE	Req	populate with the concept describing the value in the cell being captured in the dataset. it may come from a spreadsheet tab name, a spreadsheet name, or any desired parameter identifying value

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
INPRMVAL	Input Parameter Value	float		Req	populate with the cell value from the referenced data that is being described by the STRMVALy values
INPRMU	Input Parameter Unit	text	COUNT;PERCENT	Perm	populate with the unit describing the cell values if appropriate
REFSRCE	Reference Data Source	text	initial population 2017.xlsx	Perm	populate with the file that is the source of the reference data (the same columns and rows will change over time so identifying the source allows for traceability)

3.4.1.2 Input Probabilities and Rates

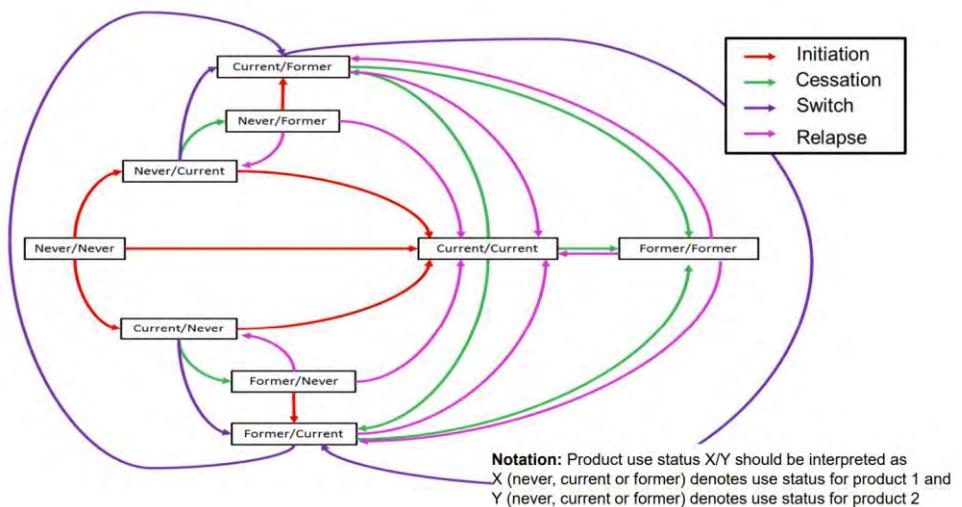
Selection of initial model input parameters is an important step during model development. Input parameters are typically chosen to represent characteristics of the entire population: transitional probabilities (e.g., initiation, cessation, quitting, switching) and health outcomes (e.g., mortality and/or morbidity rates). The initial values of these parameters are typically estimated from sources representative of the population, such as complex probability-based surveys or census data.

Transitional Probabilities

Transition probabilities are typically chosen to represent characteristics of the population of interest (e.g. initiation, cessation, quitting, switching). Transition probabilities determine the rate at which the population changes with respect to time during the period of interest. Transition probabilities are estimated from population surveys and other sources, and they are typically tabulated by sex, age and race. In some models, these are constant during the entire simulation period, but they could also change over time.

For example, one might be interested in projecting the health impact of introducing a new tobacco product to the US population for a period of 50 years starting with the year 2000; transition probabilities govern transition between tobacco use behavior as well as health outcome during the projection period (50 years, in this example).

The following figure illustrates transitional probabilities for a 2-product model.



Example 1

This is an example of an ADaM dataset designed to capture the reference data describing historical transitional probabilities. When there are 2 products in the TOBACCO PRODUCT CATEGORY there are 27 different possible transitions. In the example data, STRTM4 captures the combination of tobacco products of interest for this particular set of probabilities and STRTM5 captures the status of product(s) of interest pre-transition. STRTM6 captures the transition type of the combination of usage at the point of probability and STRTM7 captures the status of product(s) of interest post-transition.

Row 1: Shows initiation of both products going from NEVER/NEVER to CURRENT/CURRENT.

Row 2: Shows cessation of both products going from CURRENT/CURRENT to FORMER/FORMER.

Row 3: Shows relapse of both products going from FORMER/FORMER to CURRENT/CURRENT.

Rows 4-27: Show various combinations and pathways of transitional probabilities that are captured in the historical data.

rtransp.xpt

Row	STRTM1	STRVAL1	STRTM2	STRVAL2	STRTM3	STRVAL3	STRTM4	STRVAL4	STRTM5	STRVAL5	STRTM6	STRVAL6	STRTM7	STRVAL7	INPRM	INPRMVAL	INPRMU
1	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	NEVER/NEVER	TOBACCO PRODUCT USE TRANSITION TYPE	INITIATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/CURRENT	TRANSITION PROBABILITY	0.15	RATIO / 10 PER 1000
2	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	CURRENT/CURRENT	TOBACCO PRODUCT USE TRANSITION TYPE	CESSATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	FORMER/FORMER	TRANSITION PROBABILITY	0.03	RATIO / 10 PER 1000
3	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	FORMER/FORMER	TOBACCO PRODUCT USE TRANSITION TYPE	RELAPSE	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/CURRENT	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
4	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	NEVER/NEVER	TOBACCO PRODUCT USE TRANSITION TYPE	INITIATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	NEVER/CURRENT	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
5	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	NEVER/CURRENT	TOBACCO PRODUCT USE TRANSITION TYPE	SWITCHING	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/FORMER	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
6	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	NEVER/CURRENT	TOBACCO PRODUCT USE TRANSITION TYPE	CESSATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	NEVER/FORMER	TRANSITION PROBABILITY	0.06	RATIO / 10 PER 1000
7	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	CURRENT/FORMER	TOBACCO PRODUCT USE TRANSITION TYPE	SWITCHING	TOBACCO PRODUCT USE STATUS POST-TRANSITION	FORMER/CURRENT	TRANSITION PROBABILITY	0.03	RATIO / 10 PER 1000
8	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	CURRENT/FORMER	TOBACCO PRODUCT USE TRANSITION TYPE	CESSATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	FORMER/FORMER	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
9	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	FORMER/FORMER	TOBACCO PRODUCT USE TRANSITION TYPE	RELAPSE	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/FORMER	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
10	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	CURRENT/FORMER	TOBACCO PRODUCT USE TRANSITION TYPE	RELAPSE	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/CURRENT	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000

Row	STRTM1	STRVAL1	STRTM2	STRVAL2	STRTM3	STRVAL3	STRTM4	STRVAL4	STRTM5	STRVAL5	STRTM6	STRVAL6	STRTM7	STRVAL7	INPRM	INPRMVAL	INPRMU
11	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	CURRENT/CURRENT	TOBACCO PRODUCT USE TRANSITION TYPE	CESSATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/FORMER	TRANSITION PROBABILITY	0.01	RATIO / 10 PER 1000
12	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	NEVER/FORMER	TOBACCO PRODUCT USE TRANSITION TYPE	INITIATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/FORMER	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
13	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	NEVER/FORMER	TOBACCO PRODUCT USE TRANSITION TYPE	RELAPSE	TOBACCO PRODUCT USE STATUS POST-TRANSITION	NEVER/CURRENT	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
14	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	NEVER/FORMER	TOBACCO PRODUCT USE TRANSITION TYPE	RELAPSE	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/CURRENT	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
15	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	NEVER/NEVER	TOBACCO PRODUCT USE TRANSITION TYPE	INITIATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/NEVER	TRANSITION PROBABILITY	0.01	RATIO / 10 PER 1000
16	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	CURRENT/NEVER	TOBACCO PRODUCT USE TRANSITION TYPE	SWITCHING	TOBACCO PRODUCT USE STATUS POST-TRANSITION	FORMER/CURRENT	TRANSITION PROBABILITY	0.03	RATIO / 10 PER 1000
17	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	CURRENT/NEVER	TOBACCO PRODUCT USE TRANSITION TYPE	CESSATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	FORMER/NEVER	TRANSITION PROBABILITY	0.04	RATIO / 10 PER 1000
18	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	FORMER/NEVER	TOBACCO PRODUCT USE TRANSITION TYPE	RELAPSE	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/CURRENT	TRANSITION PROBABILITY	0.03	RATIO / 10 PER 1000
19	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	FORMER/NEVER	TOBACCO PRODUCT USE TRANSITION TYPE	RELAPSE	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/NEVER	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
20	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	FORMER/NEVER	TOBACCO PRODUCT USE TRANSITION TYPE	INITIATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	FORMER/CURRENT	TRANSITION PROBABILITY	0.05	RATIO / 10 PER 1000
21	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	FORMER/CURRENT	TOBACCO PRODUCT USE TRANSITION TYPE	RELAPSE	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/CURRENT	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
22	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	FORMER/CURRENT	TOBACCO PRODUCT USE TRANSITION TYPE	CESSATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	FORMER/FORMER	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
23	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	FORMER/FORMER	TOBACCO PRODUCT USE TRANSITION TYPE	RELAPSE	TOBACCO PRODUCT USE STATUS POST-TRANSITION	FORMER/CURRENT	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
24	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	CURRENT/NEVER	TOBACCO PRODUCT USE TRANSITION TYPE	INITIATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/CURRENT	TRANSITION PROBABILITY	0.01	RATIO / 10 PER 1000
25	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	CURRENT/CURRENT	TOBACCO PRODUCT USE TRANSITION TYPE	CESSATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	FORMER/CURRENT	TRANSITION PROBABILITY	0.01	RATIO / 10 PER 1000

Row	STRTM1	STRVAL1	STRTM2	STRVAL2	STRTM3	STRVAL3	STRTM4	STRVAL4	STRTM5	STRVAL5	STRTM6	STRVAL6	STRTM7	STRVAL7	INPRM	INPRMVAL	INPRMU
26	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	NEVER/CURRENT	TOBACCO PRODUCT USE TRANSITION TYPE	INITIATION	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/CURRENT	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000
27	YEAR	2000	AGE	24	SEX	F	TOBACCO PRODUCT CATEGORY	CIGARETTE/CIGAR	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	FORMER/CURRENT	TOBACCO PRODUCT USE TRANSITION TYPE	SWITCHING	TOBACCO PRODUCT USE STATUS POST-TRANSITION	CURRENT/FORMER	TRANSITION PROBABILITY	0.02	RATIO / 10 PER 1000

RFTRANSP Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
RFTRANSP	Reference Data for Transition Prob	REFERENCE DATA STRUCTURE	one record per input value	reference	STRTM1, STRM2, STRTM3, STRTM4 STRTM5 STRTM6 STRTM7	rfransp.xpt	NA

RFTRANSP Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
STRTM1	Stratum 1	text	YEAR	Req	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the left-most column in this example
STRVAL1	Stratum 1 Value	text		Req	populate with the STRTM1 values in the source data (Age in this example)
STRTM2	Stratum 2	text	AGE	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the first part of the second column concept in this example
STRVAL2	Stratum 2 Value	text		Cond	populate with the STRTM2 values in the source data (F in this example for displayed data)
STRTM3	Stratum 3	text	SEX	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the second part of the second column concept in this example
STRVAL3	Stratum 3 Value	text	F	Cond	populate with the STRTM3 values in the source data (Transition Type in this example)
STRTM4	Stratum 4	text	TOBACCO PRODUCT CATEGORY	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the third part of the second column concept in this example
STRVAL4	Stratum 4 Value	text	CIGARETTE/CIGAR	Cond	populate with the STRTM4 values in the source data (Product in this example)
STRTM5	Stratum 5	text	TOBACCO PRODUCT USE STATUS PRE-TRANSITION	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the second part of the second column concept in this example
STRVAL5	Stratum 5 Value	text	CURRENT/CURRENT;CURRENT/FORMER;CURRENT/NEVER; FORMER/CURRENT;FORMER/FORMER;FORMER/NEVER; NEVER/CURRENT; NEVER/FORMER;NEVER/NEVER	Cond	populate with the STRTM5 values in the source data (Transition Type in this example)
STRTM6	Stratum 6	text	TOBACCO PRODUCT USE TRANSITION TYPE	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the second part of the second column concept in this example
STRVAL6	Stratum 6 Value	text	INITIATION;CESSATION;SWITCHING;RELAPSE	Cond	populate with the STRTM6 values in the source data (Transition Type in this example)
STRTM7	Stratum 7	text	TOBACCO PRODUCT USE STATUS POST-TRANSITION	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the second part of the second column concept in this example
STRVAL7	Stratum 7 Value	text	CURRENT/CURRENT;CURRENT/FORMER;CURRENT/NEVER; FORMER/CURRENT;FORMER/FORMER;FORMER/NEVER; NEVER/CURRENT; NEVER/FORMER	Cond	populate with the STRTM7 values in the source data (Transition Type in this example)
INPRM	Input Parameter	text	TRANSITION PROBABILITY	Req	populate with the concept describing the value in the cell being captured in the dataset. it may come from a spreadsheet tab name, a spreadsheet name, or any desired parameter identifying value
INPRMVAL	Input Parameter Value	float		Req	populate with the cell value from the referenced data that is being described by the STRMVALy values
INPRMU	Input Parameter Unit	text	RATIO / 10 PER 1000	Perm	populate with the unit describing the cell values if appropriate

Mortality Rates and Risks

Another type of input parameters are those related to risk; this included mortality rates and risks related to comorbidities. For many models, these are projected over the entire simulation period (e.g., 50 years in the future), and they are estimated from population surveys or other data sources. These parameters are tabulated based on age, sex, race, tobacco use status, and years of tobacco use and/or former use.

Example 2

This is an example of an ADaM dataset designed to capture the reference data describing mortality rates.

rfmort.xpt

Row	STRTM1	STRVAL1	STRTM2	STRVAL2	STRTM3	STRVAL3	STRTM4	STRVAL4	STRTM5	STRVAL5	INPRM	INPRMVAL
1	AGE	0	SEX	M	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0
2	AGE	1	SEX	M	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0
3	AGE	2	SEX	M	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0
4	AGE	3	SEX	M	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0.001
5	AGE	4	SEX	M	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0.001
6	AGE	5	SEX	M	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0.001
7	AGE	0	SEX	F	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0
8	AGE	1	SEX	F	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0
9	AGE	2	SEX	F	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0
10	AGE	3	SEX	F	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0.001
11	AGE	4	SEX	F	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0.002
12	AGE	5	SEX	F	RACE	WHITE	YEAR	2000	PRODUCT COMPARATORS	DEP1	MORTALITY PROBABILITY	0.002

RFMORT Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
RFMORT	Reference Data for Mortality Rates	REFERENCE DATA STRUCTURE	one record per input value	reference	STRTM1, STRM2, STRTM3, STRTM4, STRTM5	rfmort.xpt	NA

RFMORT Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
STRTM1	Stratum 1	text	AGE	Req	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the left-most column in this example
STRVAL1	Stratum 1 Value	integer		Req	populate with the STRTM1 values in the source data (Age in this example)
STRTM2	Stratum 2	text	SEX	Req	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the second column in this example
STRVAL2	Stratum 2 Value	text	M;F	Req	populate with the STRTM2 values in the source data (Sex in this example)
STRTM3	Stratum 3	text	RACE	Req	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the third column in this example
STRVAL3	Stratum 3 Value	text	WHITE	Req	populate with the STRTM3 values in the source data (Race in this example)
STRTM4	Stratum 4	text	YEAR	Req	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the fourth column in this example
STRVAL4	Stratum 4 Value	integer		Req	populate with the STRTM4 values in the source data (Year in this example)
STRTM5	Stratum 5	text	PRODUCT COMPARATORS	Req	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the fifth column in this example
STRVAL5	Stratum 5 Value	text	DED1	Req	populate with the STRTM5 values in the source data
INPRM	Input Parameter	text	MORTALITY PROBABILITY	Req	populate with the concept describing the value in the cell being captured in the dataset. It may come from a spreadsheet tab name, a spreadsheet name, or any desired parameter identifying value
INPRMVAL	Input Parameter Value	float		Req	populate with the cell value from the referenced data that is being described by the STRMVALy values

Birth Rate

At each step of the simulation period (e.g., each year), individuals may enter the population according to birth rates that are projected across the time horizon of the model. These rates are typically obtained from government census data.

Example 3

This is an example of an ADaM dataset designed to capture the reference data describing historical birth rates.

STRTMy captures the different stratum variables describing the content of a particular cell in the dataset. Stratum may be based on any combination of factors used to describe reference values (e.g., year in the birth rate data); sometimes these factors may be defined as compound factors (e.g., sex_race as sex and race in the birth rate source data). The y index for STRTMy does not indicate any particular ordering; the y value merely indicates a unique factor. If STRTMy concepts change across source data, the same STRTMy variable is still used (e.g., in the source data if a stratum changes from SEX to ETHNIC as the second stratum, then the same STRTM2 variable would be used and the value would change from Sex to Ethnic). The general assumption is that combinations of levels of granularity will be consistent across the source reference data. If that is not the case, then some of the STRTMy/STRMVALy variables may be null.

rfbr.xpt

Row	STRTM1	STRVAL1	STRTM2	STRVAL2	STRTM3	STRVAL3	INPRM	INPRMVAL	INPRMU	REFSRCE
1	YEAR	2000	SEX	F	RACE	TOTAL	BIRTH RATE	0.048156602	RATIO / 10 PER 1000	birthrate 2015.xlsx
2	YEAR	2001	SEX	F	RACE	TOTAL	BIRTH RATE	0.050162384	RATIO / 10 PER 1000	birthrate 2015.xlsx
3	YEAR	2002	SEX	F	RACE	TOTAL	BIRTH RATE	0.049912072	RATIO / 10 PER 1000	birthrate 2015.xlsx
4	YEAR	2003	SEX	F	RACE	TOTAL	BIRTH RATE	0.049953214	RATIO / 10 PER 1000	birthrate 2015.xlsx
5	YEAR	2004	SEX	F	RACE	TOTAL	BIRTH RATE	0.050199534	RATIO / 10 PER 1000	birthrate 2015.xlsx
6	YEAR	2005	SEX	M	RACE	TOTAL	BIRTH RATE	0.050497803	RATIO / 10 PER 1000	birthrate 2015.xlsx
7	YEAR	2001	SEX	M	RACE	TOTAL	BIRTH RATE	0.052554053	RATIO / 10 PER 1000	birthrate 2015.xlsx
8	YEAR	2002	SEX	M	RACE	TOTAL	BIRTH RATE	0.052289152	RATIO / 10 PER 1000	birthrate 2015.xlsx
9	YEAR	2003	SEX	M	RACE	TOTAL	BIRTH RATE	0.052334712	RATIO / 10 PER 1000	birthrate 2015.xlsx
10	YEAR	2004	SEX	M	RACE	TOTAL	BIRTH RATE	0.052594772	RATIO / 10 PER 1000	birthrate 2015.xlsx
11	YEAR	2000	SEX	F	RACE	WHITE	BIRTH RATE	0.043829866	RATIO / 10 PER 1000	birthrate 2015.xlsx
12	YEAR	2001	SEX	F	RACE	WHITE	BIRTH RATE	0.04509937	RATIO / 10 PER 1000	birthrate 2015.xlsx
13	YEAR	2002	SEX	F	RACE	WHITE	BIRTH RATE	0.044711283	RATIO / 10 PER 1000	birthrate 2015.xlsx
14	YEAR	2003	SEX	F	RACE	WHITE	BIRTH RATE	0.044899939	RATIO / 10 PER 1000	birthrate 2015.xlsx
15	YEAR	2004	SEX	F	RACE	WHITE	BIRTH RATE	0.045284915	RATIO / 10 PER 1000	birthrate 2015.xlsx

RFBR Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
RFBR	Reference Data for Birthrate	REFERENCE DATA STRUCTURE	one record per input value	reference	STRTM1, STRM2, STRTM3	rfbr.xpt	N/A

RFBR Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
STRTM1	Stratum 1	text	YEAR	Req	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the left-most column in this example
STRVAL1	Stratum 1 Value	text		Req	populate with the STRTM1 values in the source data (years 2000-2050 in this example)
STRTM2	Stratum 2	text	SEX	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the first part of the second column concept in this example
STRVAL2	Stratum 2 Value	text	M;F	Cond	populate with the STRTM2 values in the source data (M/F in this example for displayed data)
STRTM3	Stratum 3	text	RACE	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the second part of the second column concept in this example
STRVAL3	Stratum 3 Value	text	TOTAL;WHITE	Cond	populate with the STRTM3 values in the source data (Race in this example)
INPRM	Input Parameter	text	BIRTH RATE	Req	populate with the concept describing the value in the cell being captured in the dataset. it may come from a spreadsheet tab name, a spreadsheet name, or any desired parameter identifying value
INPRMVAL	Input Parameter Value	float		Req	populate with the cell value from the referenced data that is being described by the STRMVALy values
INPRMU	Input Parameter Unit	text	RATIO / 10 PER 1000	Perm	populate with the unit describing the cell values if appropriate
REFSRCE	Reference Data Source	text		Perm	populate with the file that is the source of the reference data (the same columns and rows will change over time so identifying the source allows for traceability)

Migration

Similar to birth rates, at each step of the simulation period individuals may enter the population according to migration rates. Base migration rates are generally obtained from national census data and if necessary are projected across the simulation timeframe. Depending on specific modeling assumptions, immigration demographics define the sex, age, race/ethnicity, and prevalence of tobacco product use behavior (e.g., never, current, former dual use, polytobacco use) in the immigrating population at a particular period.

Example 4

This is an example of an ADaM dataset designed to capture the reference data describing historical migration rates.

rfmigrat.xpt

Row	STRTM1	STRVAL1	STRTM2	STRVAL2	STRTM3	STRVAL3	INPRM	INPRMVAL	INPRMU
1	YEAR	2001	SEX	F	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
2	YEAR	2002	SEX	F	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
3	YEAR	2003	SEX	F	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
4	YEAR	2004	SEX	F	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
5	YEAR	2005	SEX	F	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
6	YEAR	2001	SEX	M	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
7	YEAR	2002	SEX	M	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
8	YEAR	2003	SEX	M	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
9	YEAR	2004	SEX	M	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
10	YEAR	2005	SEX	M	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
11	YEAR	2001	SEX	TOTAL	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
12	YEAR	2002	SEX	TOTAL	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
13	YEAR	2003	SEX	TOTAL	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
14	YEAR	2004	SEX	TOTAL	RACE	TOTAL	NET MIGRATION RATE	100	COUNT
15	YEAR	2005	SEX	TOTAL	RACE	TOTAL	NET MIGRATION RATE	100	COUNT

RFMIGRAT Dataset Metadata

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
RFMIGRAT	Reference Data for Migration Rates	REFERENCE DATA STRUCTURE	one record per input value	reference	STRTM1, STRM2, STRTM3	rfmigrat.xpt	NA

RFMIGRAT Variable Metadata

Variable Name	Variable Label	Type	Codelist/Controlled Terms	Core	Notes
STRTM1	Stratum 1	text	YEAR	Req	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the left-most column in this example
STRVAL1	Stratum 1 Value	integer		Req	populate with the STRTM1 values in the source data (Age in this example)
STRTM2	Stratum 2	text	SEX	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the first part of the second column concept in this example
STRVAL2	Stratum 2 Value	text	M;F;TOTAL	Cond	populate with the STRTM2 values in the source data (F/M/Total in this example for displayed data)
STRTM3	Stratum 3	text	RACE	Cond	populate with the variable descriptor of one of the cell descriptors (either a row identifier or a column identifier) - the second part of the second column concept in this example
STRVAL3	Stratum 3 Value	text	TOTAL	Cond	populate with the STRTM3 values in the source data (Race in this example)
INPRM	Input Parameter	text	NET MIGRATION RATE	Req	populate with the concept describing the value in the cell being captured in the dataset, it may come from a spreadsheet tab name, a spreadsheet name, or any desired parameter identifying value
INPRMVAL	Input Parameter Value	integer		Req	populate with the cell value from the referenced data that is being described by the STRMVALy values
INPRMU	Input Parameter Unit	text	COUNT	Perm	populate with the unit describing the cell values if appropriate

Appendices

Appendix A: CDISC TIG Team

CDISC would like to thank the Tobacco Implementation Guide (TIG) Team and the many volunteers who contributed to the development, review, and publication of the TIG Version 1.0. This publication would not have been possible without the support of volunteers.

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Appendix B: Glossary and Abbreviations

The following table lists some of the terms and abbreviations used in this guide. Additional definitions can be found in the individual sections of this document and in the CDISC Glossary (available at <https://www.cdisc.org/standards/glossary>).

aCRF	Annotated CRF
ADaM	Analysis Data Model
ADaMIG	ADaM Implementation Guide
ADSL	(ADaM) Subject-level Analysis Dataset
API	Application programming interface
Applicant	Any party, which may include the tobacco manufacturer and its authorized representative, who is subject to FDA's jurisdiction under chapter IX of the FD&C Act and submits an application to FDA for authority to market a tobacco product.
ATC	Anatomic Therapeutic Chemical (classification system; WHO)
BDS	(ADaM) Basic Data Structure
BMI	Body mass index
BQL	Below limit of quantification
CAS	Chemical Abstracts Service (a division of the American Chemical Society)
CDASH	Clinical Data Acquisition Standards Harmonization (Model)
CDASHIG	CDASH Implementation Guide
CDISC	Clinical Data Interchange Standards Consortium
CDM	Clinical data management
CQ	Customized (MedDRA) query
Conformance	Refers to whether implementation of standards per this guide meets the requirements of the standards
CRF	Case report form (sometimes <i>case record form</i>). In this guide, CRF refers to both paper CRFs and electronic CRFs (eCRFs) unless otherwise specified.
CRO	Contract research organization
CTCAE	(NCI) Common Terminology Criteria for Adverse Events
CTP	(US FDA) Center for Tobacco Products
DAO	Data as observed
Dataset	A collection of structured data in a single file
Data collection field(s)	Data elements that are commonly on a CRF
Data collection variable(s)	Data elements stored in an EDC system
Define-XML	CDISC standard for transmitting metadata that describes any tabular dataset structure
Domain	In the context of the CDASH Model and the SDTM, a collection of logically related observations with a common, specific topic. The logic of the relationship may pertain to the scientific subject matter of the data or its role in a study or trial.
ECG	Electrocardiogram
EDC	Electronic data capture (sometimes <i>collection</i>)
eDT	Electronic data transfer

ENDS	Electronic nicotine delivery systems
EVS	(NCI) Enterprise Vocabulary Services
FDA	(US) Food and Drug Administration
GLP	Good laboratory practice
GMDN	Global Medical Device Nomenclature
H&E	Hematoxylin and eosin (staining)
HPHC	Harmful and potentially harmful constituents
HTP	Heated tobacco product
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
ISO 8601	ISO character representation of dates, date/times, intervals, and durations of time. The SDTM uses the extended format.
IUPAC	International Union of Pure and Applied Chemistry (developer of chemical nomenclature and terminology)
IVRS	Interactive voice response system
LOCF	Last observation carried forward
LOINC	Logical Observation Identifiers Names and Codes
Mechanisms for data collection	Different approaches used to control how data are collected (e.g., on a CRF) including tick boxes, checkboxes, radio buttons, and drop-down lists
MedDRA	Medical Dictionary for Regulatory Activities
MRI	Magnetic resonance imaging
Nonclinical study	A scientific experiment, typically involving animal subjects, which is intended to address certain scientific questions that are the objectives of the study
NCI	(NIH) National Cancer Institute
NHK	Normal human keratinocytes
NIH	(US) National Institutes of Health
NNN	N-nitrosonornicotine
NRS	Numeric rating scale
NSV	Non-standard variable; in the context of standards for tabulation, an NSV is a variable which is not defined in the SDTM
Null	In the context of populating a value in a variable, <i>null</i> indicates no value will be populated.
Observation	An <i>observation</i> refers to a discrete piece of information collected during a study (e.g., a vital sign measured/observed for a specific subject at a specific time as part of a study)
OCCDS	(ADaM) Structure for Occurrence Data
ODM	Operational Data Model
PBS	Phosphate-buffered saline
PK	Pharmacokinetic
PMTA	Premarket tobacco product applications (rule)
QRS	Questionnaires, ratings, and scales
SAE	Serious adverse event
SAP	Statistical analysis plan
SDTM	Study Data Tabulation Model
SDTMIG	SDTM Implementation Guide
SEND	Standard for Exchange of Nonclinical Data
SENDIG	SEND Implementation Guide: Human Clinical Trials
SI	International System of Units
SMQ	Standardized MedDRA query
SOC	System organ class
SOP	Standard operating procedure

SPF	Specific pathogen-free (facility)
STN	(FDA) Submission tracking number
TIG	Tobacco Implementation Guide
TK	Toxicokinetics
TNE	Total nicotine equivalents
UDI	(FDA) Unique Device Identifier
UNII	(FDA) Unique Ingredient Identifier
USDA	US Department of Agriculture
UUID	Universally unique identifier
VAS	Visual analog scale
WHO	World Health Organization
WHO-ART	World Health Organization Adverse Reaction Terminology
WHODrug	(WHO) Global medicinal information dictionary
WOCF	Worst observation carried forward
XML	Extensible markup language

Appendix C: CDASH Model Metadata Tables

This section provides an explanation of the metadata table columns used in the CDASH Model. Please refer to the CDASH Model for additional guidance.

Heading	Explanation
Observation Class	This column contains the SDTM class for the domain.
Domain	This column contains the 2-letter domain code.
Order Number	The values in this column are used to help sequence the variables as they appear in the metadata table. There is no implied meaning, significance, or conformance expectations. The values increase by 1 for each variable within a unique grouping of Observation Class plus domain.
CDASHIG Variable	This column provides the CDASH root variable name (e.g., --ONGO, --DAT).
CDASHIG Variable Label	This column contains a suggested root variable label that may be used for the CDASHIG variable
DRAFT CDASHIG Definition	This column provides a draft definition of the root variable. This text may or may not mirror text in the SDTM. Currently, there is a new CDASH/SDTM team creating variable definitions. Once these definitions are finalized, the CDASH definitions will be updated to harmonize with them.
Question Text	This column in the CDASH Model contains the recommended question text for the data collection field. Question Text is a complete sentence. Some text is presented inside brackets [] or parentheses (). The text inside brackets should be replaced with protocol-specified verbiage; text inside parentheses is optional. Text separated with a forward slash indicates optional wording from which the applicant may choose.
Prompt	This column in the CDASH Model contains the recommended prompt text for the data collection field. The Prompt is a short version of the question. Some text is presented inside brackets [] or parentheses (). The text inside brackets should be replaced with protocol-specific verbiage; text inside parentheses is optional. Text separated with a forward slash / indicates optional wording from which the applicant may choose
Data Type	This column contains the simple data type of the CDASH variable (i.e., Char, Num, Date, Time).
SDTMIG Target	This column provides the suggested mapping to the SDTM root variable. When no direct mapping to an SDTM root variable is available, the column contains "N/A." When the column contains "SUPP--QNAME", it means that the value represented in the CDASH variable shall be mapped to an SDTM Supplemental Qualifier. Note: CDASH variables noted as not having a direct map to SDTM variables (i.e., NSVs) may have SDTM variable equivalents in future versions.
Mapping Instructions	This column contains information on the suggested mapping of the root variable to the SDTM variable.

Heading	Explanation
Controlled Terminology Codelist Name	<p>This column contains the Controlled Terminology (CT) codelist name (e.g., "LOC") that is associated with the field. Certain variables (e.g., dates) use ISO formats as CT; however, in CDASH these variables are generally not collected using ISO CT, but rather converted to the ISO format when the SDTM-based submission datasets are created.</p> <p>Whereas the SDTM Model provides the NCI C Code for each variable, the CDASH Model includes the Controlled Terminology codelist name. However, when individual codelist names are used for each domain, the CDASH model does not include any codelist name.</p> <p>For example, the CDASH model variable --TEST includes no Controlled Terminology codelist Name. However, the CDASH metadata table for each findings domain provides the Controlled Terminology codelist name (e.g., VTEST).</p>
Implementation Notes	This column contains further information, such as rationale and implementation instructions, regarding how to implement the CRF data collection fields and how to map CDASHIG variables to SDTMIG variables.

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