Standard for Exchange of Nonclinical Data Implementation Guide: Nonclinical Studies

Version 3.1.1 (Final)

Prepared by the
CDISC Standard for Exchange of Nonclinical Data Team

Notes to Readers

This implementation guide for nonclinical studies is based upon Version 1.5 of the CDISC Study Data Tabulation Model (SDTM).

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See Appendix F for Representations and Warranties, Limitations of Liability, and Disclaimers

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1 Introduction

1.1 Purpose

This document is the Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data Implementation Guide (SENDIG) for nonclinical studies, which has been prepared by the CDISC SEND Team. The SENDIG is intended to guide the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as sponsors and contract research organizations (CROs), and for submission to regulatory authorities such as the US Food and Drug Administration (FDA).

The SENDIG is based upon and should be used in close concert with Version 1.5 of the CDISC Study Data Tabulation Model (SDTM), available at https://www.cdisc.org/standards/foundational/sdtm. The SDTM describes the conceptual model for representing study data for electronic data interchange and should be read prior to reading the SENDIG. The SENDIG provides specific domain models, assumptions, business rules, and examples for preparing standard nonclinical tabulation datasets that are based on the SDTM. This version of the SENDIG is designed to support data typically found in single-dose general toxicology, repeat-dose general toxicology, and carcinogenicity studies, as well as respiratory and cardiovascular testing done during safety pharmacology studies. The SENDIG can be used to represent data for other study types. Note that SEND is an exchange standard, rather than a presentation format; it is assumed that tabulation data will be transformed by software tools to better support viewing and analysis.

Conformance with the guidelines in this document does not guarantee that data can support all types of analysis. Science and regulation should determine what data should be collected and how. The analyses that the data need to support should be accounted for before mapping the data into the exchange format.

Because the FDA has been the leading regulator in encouraging the development of SEND, this document references some specific implementation requirements for that agency. The CDISC SEND Team welcomes input from other regulatory agencies so that future versions of the SENDIG can be maximally useful in all regions. SEND is expected to be referenced by the FDA in guidance documents, and audiences are advised to refer to these guidance documents for the most current agency recommendations for the submission of nonclinical data. Standardized datasets are expected to support (1) the FDA's efforts to develop a repository for all submitted study data, and (2) a suite of standard review tools to access, query, and view the tabulations.

1.2 Organization of this Document

This document is organized into the following sections:

- Section 1, Introduction, provides an overall introduction to the SENDIG.
- Section 2, Fundamentals of the SDTM, recaps the basic concepts of the SDTM and describes how this implementation guide should be used in concert with the SDTM.
- Section 3, Using SEND in the Context of a Data Exchange Package, explains how to describe metadata and how to assess conformance with the standards.
- Section 4, Assumptions for Domain Models, describes basic concepts, business rules, and assumptions that should be taken into consideration before applying the domain models.
- Section 5, Models for Special-purpose Domains, describes special-purpose domains.
- Section 6, Domain Models Based on the General Observation Classes, provides specific metadata models based on the 3 general observation classes, along with assumptions and example data.
- Section 7, Trial Design Model Datasets, describes implementation recommendations related to the use of the Trial Design Model described in the SDTM.
- Section 8, Representing Relationships and Data, describes how to represent relationships between separate domains, datasets, and/or records and information to help sponsors determine where data belong in the SDTM. Section 8.5 describes how to represent data from samples or subjects that have been pooled.

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- Appendices provide additional background material and describe other supplemental material relevant to implementation.

1.3 Relationship to Prior CDISC Documents

The changes to the SENDIG since the prior version (v3.1) are limited to the Pharmacokinetics Concentrations (PC) and Pharmacokinetics Parameters (PP) domains, assumptions, and examples. These changes are intended to instruct the reader on the approach to populating PC and PP variables to create the time/concentration curve and to present well-formed examples of PC, PP, and cross-domain examples.

A detailed list of all changes between SENDIG versions is provided in Appendix D, Revision History.

A list of approved SDTM variables that should not be used in SEND datasets is provided in Appendix E, SDTM Variables to Never Use in SEND.

1.4 How to Read this Implementation Guide

The SENDIG is best read online so the reader can more easily navigate the many hyperlinks to internal and external references. Note that for the purposes of modeling nonclinical data using the SENDIG, the term "subject" is equivalent to an animal; the term "trial" is equivalent to a study, and "interventions" generally refers to exposure to drug.

The following guidelines may be helpful in reading this document.

1. First, read the SDTM to gain a general understanding of SDTM concepts.
2. Next, read Sections 1-3 (Introduction, Fundamentals of the SDTM, and Using SEND in the Context of a Data Exchange Package) of this document to review the key concepts for preparing domains and submitting data to regulatory authorities. Refer to Appendix B, Glossary and Abbreviations, as necessary.
3. Read Section 4, Assumptions for Domain Models.
4. Review Sections 5 and 6 (Models for Special-purpose Domains and Domain Models Based on the General Observation Classes) in detail, referring back to Section 4 as directed (hyperlinks are provided).

   Note: The implementation examples for each domain help to provide an understanding regarding how to apply the domain models for specific types of data.

5. Read Section 7, Trial Design Model Datasets, to understand the fundamentals of the Trial Design Model datasets and consider how to apply the concepts for typical protocols.
6. Review Section 8, Representing Relationships and Data, to learn advanced concepts regarding how to express relationships between datasets and records, adding variables not specifically defined in the models, and representing single findings captured for multiple subjects.
7. Review SEND Controlled Terminology (CT) available on the CDISC website at: http://www.cdisc.org/terminology.
8. Finally, review the Appendices as appropriate.

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2 Fundamentals of the SDTM

2.1 The General Observation Classes

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. The lists of variables allowed to be used in each of these can be found in the SDTM.

- The Interventions class captures investigational, therapeutic, and other treatments that are administered to the subject (with some actual or expected physiological effect) as specified by the study protocol (e.g., exposure to study drug).
- The Events class captures subject disposition.
- The Findings class captures the observations resulting from tests or evaluations (e.g., laboratory tests, body weights, food and water consumption, clinical observations). Most data consist of measurements or responses to tests conducted at specified intervals and will fit the Findings general observation class.

SENDIG domains are based upon the SDTM and include variables relevant to model common endpoints in nonclinical studies. Use of SDTM variables must be consistent with the description of the variables in the SDTM. In most cases, the choice of general observation class appropriate to a specific collection of data can be determined according to the preceding descriptions.
All datasets based on any of the general observation classes share a common set of identifier variables and timing variables. Three general rules apply when determining which variables to include in a domain:

- The same set of identifier variables apply to all general observation classes.
- Any timing variables are permissible for use in any submission dataset based on a general observation class, except for those variables not intended for use with SEND (see Appendix E, SDTM Variables to Never Use in SEND).
- Any additional qualifier variables from the same general observation class may be added to a domain model, except for those variables not intended for use with SEND (see Appendix E, SDTM Variables to Never Use in SEND).

General assumptions for use with all domain models based on the general observation classes are described in Section 4, Assumptions for Domain Models; specific assumptions for individual domains are included with the domain model.

2.2 Special-purpose Datasets

In addition to the general observation classes, a submission will generally include a set of other special-purpose datasets of specific standardized structures to represent additional information. The SDTM includes 3 types of special-purpose datasets, each of which has a fixed structure:

- Demographics (DM), Comments (CO), and Subject Elements (SE) include study data that do not conform to 1 of the 3 general observation classes. These are described in Section 5, Models for Special-purpose Domains.
- Trial Design Model datasets, consisting of Trial Elements (TE), Trial Arms (TA), Trial Sets (TX), and Trial Summary (TS), contain information about the study design but do not contain subject data. These are described in Section 7, Trial Design Model Datasets.
- RELREC, SUPP--, and POOLDEF are relationship datasets. These are described in Section 8, Representing Relationships and Data.

2.3 The SENDIG Standard Domain Models

The following standard domains with their respective domain codes are included in this document.

Special-Purpose Domains (Section 5)

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- Demographics – DM
- Comments – CO
- Subject Elements – SE

Interventions General Observation Class (Section 6.1)

- Exposure – EX

Events General Observation Class (Section 6.2)

- Disposition – DS

Findings General Observation Class (Section 6.3)

- Body Weight – BW
- Body Weight Gain – BG
- Clinical Observations – CL
- Death Diagnosis and Details – DD
- Food and Water Consumption – FW
- Laboratory Test Results – LB
- Macroscopic Findings – MA
- Microscopic Findings – MI
- Organ Measurements – OM
- Palpable Masses – PM
- Pharmacokinetics Concentrations – PC
- Pharmacokinetics Parameters – PP
- Subject Characteristics – SC
- Tumor Findings – TF
- Vital Signs – VS
- ECG Test Results – EG
- Cardiovascular Test Results – CV
- Respiratory Test Results – RE

Trial Design Domains (Section 7)

- Trial Elements – TE
- Trial Arms – TA
- Trial Sets – TX
- Trial Summary – TS

Relationship Datasets (Section 8)

- Related Records – RELREC
- Supplemental Qualifiers – SUPP-- datasets
- Pool Definition – POOLDEF

A sponsor should submit only domain datasets for which data were actually collected (or directly derived from the collected data) for a given study. Decisions on what data to collect should be based on the scientific objectives of the study, rather than domains or examples presented in this guide. Although most studies will include DM, TX, TS, and

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a set of domains based on the 3 general observation classes, the actual domains used to represent study data will depend upon the needs of the recipient.

When preparing datasets based on SENDIG domain models, sponsors must not add any variables other than specified identifier variables (See SDTM v1.5 Table 2.2.4), timing variables (SDTM v1.5 Table 2.2.5), or qualifier variables from the same general observation class (described in SDTM v1.5 Tables 2.2.1-2.2.3). The addition of non-standard variables will compromise the ability to use the datasets (e.g., to populate a data repository and/or use standard tools). See Appendix E, SDTM Variables to Never Use in SEND, for a list of SDTM variables that should never be used in SEND.

As long as there are no data that can be mapped to a permissible variable, a sponsor may exclude the variable from a domain dataset, and the corresponding descriptions from the data definition file. New variables (other than those from the same general observation class) must not be added, and existing variables must not be renamed or modified for novel usage.

The SDTM allows for the inclusion of the sponsor's non-SDTM variables using the Supplemental Qualifiers dataset structure, described in Section 8.3, Supplemental Qualifiers - SUPP-- Datasets. As the SDTM continues to evolve, certain additional standard variables may be added to the general observation classes. Sponsors wishing to nominate such variables for future consideration should provide a rationale and description of the proposed variable(s), along with representative examples, to the CDISC SEND Team via the CDISC website (https://www.cdisc.org/contact).

2.4 Observations and Variables

The SDTM is built around the concept of observations collected about subjects included in a study. The SENDIG is based on the SDTM general framework for organizing nonclinical study information that is to be transferred between parties or submitted to regulatory authorities.

Each observation is described by a series of variables corresponding to a row in a dataset or table. Each variable can be classified according to its role. A role determines the type of information conveyed by the variable about each distinct observation and how it can be used. Variables can be classified into 5 major roles:

- **Identifier** variables identify the study, subject, domain, pool identifier, and sequence number of the record.
- **Topic** variables specify the focus of the observation (e.g., the name of a lab test).
- **Qualifier** variables include additional illustrative text or numeric values that describe the results or additional traits of the observation (e.g., units, descriptive adjectives).
- **Rule** variables express an algorithm or executable method to define start, end, and branching or looping conditions in the Trial Design Model datasets.
- **Timing** variables describe the timing of the observation (e.g., start date and end date).

The set of qualifier variables can be further categorized into 5 subclasses:

- **Grouping qualifiers** are used to group together a collection of observations within the same domain. Examples include --CAT and --SCAT.
- **Result qualifiers** describe the specific results associated with the topic variable in a Findings dataset. They answer the question raised by the topic variable. Result qualifiers include --ORRES, --STRESC, and --STRESN.
- **Synonym qualifiers** specify an alternative name for a particular variable in an observation. Examples include --MODIFY and --DECOD, which are equivalent terms for a --TRT or --TERM topic variable, and --TEST, which is an equivalent term for a --TESTCD.
- **Record qualifiers** define additional attributes of the observation record as a whole (rather than describing a particular variable within a record). Examples include AGE, SEX, SPECIES, and STRAIN in the Demographics (DM) domain and --REASND, --BLFL, --LOC, --SPEC, and --NAM in a Findings domain.
- **Variable qualifiers** 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. Examples include --ORRESU, --ORNRHI, and --ORNRLO, all of which are variable qualifiers of --ORRES, and --DOSU, which is a variable qualifier of --DOSE.

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2.5 Creating a New Domain

The creation of new domains is an ongoing activity of both the CDISC Submission Data Standards (SDS) and SEND teams. Before creating a new domain or attempting to represent data in a sponsor-defined domain, check with these teams to see if implementation guidance for this type of data exists or is being developed. Even though domains not described in this SENDIG may not be able to be evaluated for conformance with this standard, all domains must conform to the principles in the SDTM.

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3 Using SEND in the Context of a Data Exchange Package

3.1 Datasets and Domains

Test results, examinations, and observations for subjects in a nonclinical study are represented in a series of SEND domains. A *domain* is defined as a collection of logically related observations with a common topic. The logic of the relationship may pertain to the scientific subject matter of the data or to its role in the study. Typically, each domain is represented by a single dataset.

When determining which general-observation class domain model is appropriate for reporting specific observations, refer to the domain definition included in the Assumptions section for each domain model (see Section 6, Domain Models Based on the General Observation Classes). For Findings domains that have a controlled terminology codelist associated with the --TESTCD and --TEST variables, a review of that codelist also provides guidance. Although the domain name is carefully selected, it is the structures and specifications within the domain that drive placement of data. It is important to note that the domain structure is only used for organizational purposes. The --TEST and --METHOD variable entries in the domain contribute to the identification of the test performed and the conditions under which the test was performed; the domain name or organization is not intended to imply any of this information.

Each domain dataset is distinguished by a unique 2-character code that should be used consistently throughout the submission. This code, which is represented in the SDTM variable named DOMAIN, is used in 4 ways: as the dataset name, as the value of the DOMAIN variable in that dataset, as a prefix for most variable names in that dataset, and as a value in the RDOMAIN variable in relationship tables (see Section 8, Representing Relationships and Data).

All datasets are structured as flat files with rows representing observations and columns representing variables.

3.1.1 Domain Model Variable-level Metadata

The specification of each domain in this guide begins with a table describing the domain's variables (a row for each) and their associated attributes (the columns across).

The following are the attributes (columns) used in this guide to describe each domain's variables:

- The Variable Name column specifies the name of the variable; in other words, the name of the column of the dataset (e.g., "STUDYID").
- The Variable Label column specifies a descriptive label for the variable (e.g., "Study Identifier").
- The Type column specifies the data type of the variable. This must be "Num" for numeric data and "Char" for character (or alphanumeric) data.
- The Controlled Terms, Codelist, or Format column specifies any controlled terminology or formats that apply to the variable. Controlled lists are surrounded with parentheses (e.g., "(BWTESTCD)" for the BWTESTCD Controlled Terminology Codelist). When a fixed value (e.g., the value for the DOMAIN variable) applies, the available value will be displayed (e.g., "BW"). When a format applies, the name of the format will be displayed (e.g., "ISO 8601" for the ISO 8601 date format).
- The Role column specifies the role of the variable (see Section 2.4, Observations and Variables).
- The CDISC Notes column specifies details about the proper use of the variable (e.g., description of the variable's purpose, intended use, rules governing its population, example values).
- The Core column specifies whether the variable is "Req" (required), "Exp" (expected), or "Perm" (permissible); (see Section 4.1.3, Core Variables).

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3.2 Define-XML Metadata

A data definition file (see the Define-XML specification, available at https://www.cdisc.org/standards/data-exchange/define-xml) is expected to accompany any transfer of SEND datasets, so that the contents of the datasets are understood. In addition, a data definition file should accompany each study in a submission, according to the FDA Study Data Technical Conformance Guide (https://www.fda.gov/media/143550/download).

3.2.1 Dataset-level Metadata

The data definition file that accompanies any data exchange package should describe each dataset included in the submission and describe each dataset's natural key structure. Dataset definition metadata should include dataset filenames, descriptions, class, structure, purpose, keys, and location, as shown in Table 3.2.1.

In the event that no records are present in a dataset, the empty dataset should not be submitted and should not be described in the data definition file.

The Define-XML specification includes 7 distinct attributes to describe dataset-level metadata:

- Dataset — the file name of the dataset or data domain name (e.g., "dm.xpt," "DM")
- Description — a short description of the type of information contained within the dataset (e.g., "Demographics," "Laboratory Test Results")
- Class — Intervention, Events, Findings, or Relationship domain
- 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")
- Purpose — purpose for the dataset (e.g., "Tabulation," "Analysis")
- Keys (see also Section 3.2.1.1, Keys) — used to uniquely identify and index each record in a dataset; could function as foreign keys to facilitate linking to other datasets. Most datasets will have 2-5 key variables. Table 3.2.1 shows examples of the variables a sponsor might submit as natural keys for the datasets.
- Location — folder and filename where the dataset can be found

See the Define-XML specification for terms and exact case to be used.

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Table 3.2.1 Dataset Definition Metadata Example

Dataset	Description	Class	Structure	Purpose	Keys	Location
DM	Demographics	Special-Purpose Domain	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt
CO	Comments	Special-Purpose Domain	One record per comment	Tabulation	STUDYID, COSEQ	co.xpt
SE	Subject Elements	Special-Purpose Domain	One record per element experienced per subject	Tabulation	STUDYID, USUBJID, ETCD, SESTDTC	se.xpt
EX	Exposure	Interventions	One record per constant dosing interval per treatment per subject or pool	Tabulation	STUDYID, USUBJID or POOLID, EXTRT, EXSTDTC	ex.xpt
DS	Disposition	Events	One record per subject	Tabulation	STUDYID, USUBJID	ds.xpt
BW	Body Weights	Findings	One record per test per observation time per subject	Tabulation	STUDYID, USUBJID, BWTESTCD, BWDTC	bw.xpt
BG	Body Weight Gains	Findings	One record per test per interval per subject	Tabulation	STUDYID, USUBJID, BGTESTCD, BGDTC, BGENDTC	bg.xpt
CL	Clinical Observations	Findings	One record per finding per observation time per subject or pool	Tabulation	STUDYID, USUBJID or POOLID, CLTESTCD, CLCAT, CLORRES, CLLOC, CLDTC	cl.xpt
CV	Cardiovascular	Findings	One record per test per observation time or evaluation interval per subject	Tabulation	STUDYID, USUBJID, CVTESTCD, CVTPTREF, CVTPTNUM	cv.xpt
DD	Death Diagnosis and Details	Findings	One record per diagnosis per subject (for unscheduled deaths only)	Tabulation	STUDYID, USUBJID, DDORRES	dd.xpt
EG	ECG	Findings	One record per test per observation time per subject	Tabulation	STUDYID, USUBJID, EGTESTCD, EGTPTREF, EGTPTNUM	eg.xpt
FW	Food and Water Consumption	Findings	One record per test per interval per subject or pool	Tabulation	STUDYID, USUBJID or POOLID, FWTESTCD, FWDTC, FWENDTC	fw.xpt
LB	Laboratory	Findings	One record per test per specimen per observation time per subject or pool	Tabulation	STUDYID, USUBJID or POOLID, LBTESTCD, LBSPEC, LBDTC, LBTPTNUM	lb.xpt
MA	Macroscopic Findings	Findings	One record per finding per specimen per subject	Tabulation	STUDYID, USUBJID, MATESTCD, MAORRES, MASPEC, MAANTREG, MALAT, MADIR	ma.xpt
MI	Microscopic Findings	Findings	One record per finding per specimen per subject	Tabulation	STUDYID, USUBJID, MITESTCD, MISTRESC, MISPEC, MIANTREG, MILAT, MIDIR	mi.xpt
OM	Organ Measurements	Findings	One record per test per specimen per subject	Tabulation	STUDYID, USUBJID, OMTESTCD, OMSPEC, OMANTREG, OMLAT, OMDIR	om.xpt
PM	Palpable Masses	Findings	One record per test per palpable mass per observation time per subject	Tabulation	STUDYID, USUBJID, PMTESTCD, PMSPID, PMDTC	pm.xpt
PC	Pharmacokinetics Concentrations	Findings	One record per test per specimen per observation time per subject or pool	Tabulation	STUDYID, USUBJID or POOLID, PCTESTCD, PCSPEC, PCNOMDY, PCELTM, PCTPTREF	pc.xpt
PP	Pharmacokinetics Parameters	Findings	One record per Pharmacokinetic Parameter per time-concentration profile per specimen per subject or pool	Tabulation	STUDYID, USUBJID or POOLID, PPTESTCD, PPCAT, PPSPEC, PPNOMDY, PPTPTREF	pp.xpt
RE	Respiratory Test Results	Findings	One record per test per observation time or evaluation interval per subject	Tabulation	STUDYID, USUBJID, RETESTCD, REDTC, RETPT	re.xpt
SC	Subject Characteristics	Findings	One record per characteristic per subject	Tabulation	STUDYID, USUBJID, SCTESTCD	sc.xpt
TF	Tumor Findings	Findings	One record per tumor per specimen per subject	Tabulation	STUDYID, USUBJID, TFTESTCD, TFORRES, TFSPEC, TFANTREG, TFLAT, TFDIR	tf.xpt
VS	Vital Signs	Findings	One record per measurement per observation time per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VSDTC, VSTPT	vs.xpt
TE	Trial Elements	Trial Design	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt
TA	Trial Arms	Trial Design	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt
TX	Trial Sets	Trial Design	One record per Trial Set parameter per Trial Set	Tabulation	STUDYID, SETCD, TXPARMCD	tx.xpt

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Dataset	Description	Class	Structure	Purpose	Keys	Location
TS	Trial Summary	Trial Design	One record per Trial Summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt
POOLDEF	Pool Definition	Relationship Datasets	One record per subject per pool	Tabulation	STUDYID, USUBJID, POOLID	pooldef.xpt
RELREC	Related Records	Relationship Datasets	One record per related record, related group of records (e.g.,--GRPID), or related dataset	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, RELID	relrec.xpt
SUPP--	Supplemental Qualifiers for (domain name)	Relationship Datasets	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	supp--.xpt

Because the purpose of the Keys column is to aid reviewers in understanding the structure of a dataset, sponsors should list all of the variables that comprise the natural key for each dataset. This key should define uniqueness for records within the corresponding dataset, and may define a record sort order. The naming of these keys should be consistent with the description of the structure in the Structure column.

3.2.1.1 Keys

3.2.1.1.1 Primary Keys

A *primary key* is a set of 1 or more columns of a domain that uniquely defines each record and distinguishes it from any other record in the dataset. For all the general-observation class domains (and for some special-purpose domains), the --SEQ variable was created so that a unique record could be identified consistently across all of these domains using STUDYID, USUBJID or POOLID, DOMAIN, and --SEQ. In most domains, --SEQ will be a surrogate key for a set of variables that comprise the natural key.

Primary keys can be surrogate keys or natural keys.

3.2.1.1.2 Surrogate Keys

A *surrogate key* is a single-part, artificially established identifier for a record. Surrogate key assignment is a special case of derived data, one where a portion of the primary key is derived. A surrogate key is immune to changes in business needs. A common way of deriving surrogate key values is to assign integer values sequentially. The --SEQ in the SDTM datasets is an example of a surrogate key.

3.2.1.1.3 Natural Keys

Natural keys are variables that exist in the data. The advantage of natural keys is that they exist already, precluding the introduction of a new, unnatural value to the data schema. One of the difficulties in choosing a natural key is that just about any natural key has the potential to change. Because they have business meaning, natural keys are effectively coupled to the business, and they may need to be reworked when business requirements change.[1] An example of such a change in nonclinical study data would be the addition of a position or location that becomes a key in a new study, but was not collected in previous studies.

The following examples illustrate how to specify natural keys and include a case where a supplemental qualifier variable is referenced because it forms part of the natural key.

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This is an example of a Clinical Observations (CL) domain for physical examinations.

Sponsor A chooses the following natural key for the CL domain:

STUDYID, USUBJID, CLTESTCD, CLDY, CLTPT

Sponsor B collects data in such a way that the location (CLLOC) variable needs to be included in the natural key to identify a unique row, and the observation date (CLDTC) confers uniqueness. Sponsor B then defines the following natural key for the CL domain.

STUDYID, USUBJID, CLTESTCD, CLLOC, CLDTC

In certain instances, a supplemental qualifier (SUPP--) variable might also contribute to the natural key of a record for a particular domain, and therefore need to be referenced as part of the natural key for a domain. Note that a domain is not limited by physical structure. A domain may consist of more than 1 physical dataset (e.g., the main domain dataset and its associated supplemental qualifiers dataset; see Section 8.3, Supplemental Qualifiers - SUPP--Datasets). Supplemental qualifiers variables should be referenced in the natural key by using a 2-part name. The term QNAM must be used as the first part of the name to indicate that the contributing variable exists in a domain-specific SUPP-- dataset. The second part is the value of QNAM that ultimately becomes a column reference when the SUPP-- records are added to the main domain dataset (e.g., QNAM.XVAR, when the SUPP-- record has a QNAM of "XVAR").

Continuing with the CL domain example:

Sponsor B might have used ultrasound as a method of measurement and might have collected additional information such as the makes and models of ultrasound equipment employed. The sponsor considers the make and model information to be essential data that contributes to the uniqueness of the test result, and so creates supplemental qualifier variables for make (QNAM = CLMAKE) and model (QNAM = CLMODEL). The natural key is then defined as follows:

STUDYID, USUBJID, CLTESTCD, CLLOC, CLDTC, QNAM.CLMAKE, QNAM.CLMODEL

This approach becomes very useful in a Findings domain when a sponsor might choose to employ generic --TESTCD values rather than compound --TESTCD values. The use of generic test codes helps to create distinct lists of manageable controlled terminology for --TESTCD.

In studies where multiple repetitive tests or measurements are being made (e.g., in an arthritis study where repetitive measurements of bone erosion in the leg might be made using both x-ray and MRI equipment) one approach to recording this data might be to create an individual --TESTCD value for each measurement.

Taking just the phalanges, a sponsor might need to express the following in a test code in order to make it unique:

- Left or right leg
- Phalange position (proximal/distal/middle)
- Rotation of the leg
- Method of measurement (x-ray/MRI)
- Machine make
- Machine model

Trying to encapsulate all of this information within a unique value of a --TESTCD is not a recommended approach for the following reasons:

- It results in the creation of a potentially large number of test codes.
- The 8-character values of --TESTCD become less intuitively meaningful.
- Multiple test codes essentially represent the same test or measurement simply to accommodate attributes of a test within the --TESTCD value itself (e.g., to represent a body location at which a measurement was taken).

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As a result, the preferred approach is to use a generic (or simple) test code that requires associated qualifier variables to fully express the test detail. Using this approach in the preceding example:

> A generic --TESTCD value might be "EROSION" and the additional components of the compound test codes would be represented in a number of distinct qualifier variables. These may include domain variables (--LOC, etc.) and supplemental qualifier variables (QNAM.MAKE, QNAM.MODEL, etc.). Expressing the natural key becomes very important in this situation in order to communicate the variables that contribute to the uniqueness of a test.
>
> If a generic --TESTCD were used the following variables would be used to fully describe the test conducted: the test is "EROSION", the location is "LEFT MCP I", the method of measurement is "ULTRASOUND", the make of the ultrasound machine is "ACME", and the model of the ultrasound machine is "U 2.1." This domain includes both domain variables and supplemental qualifier variables that contribute to the natural key of each row and describe the uniqueness of the test.

--TESTCD	--TEST	--LOC	--METHOD	QNAM.MAKE	QNAM.MODEL
EROSION	Erosion	LEFT MCP I	ULTRASOUND	ACME	U 2.1

References

1. Choose your wow! Agile Requirements Change Management. Updated 2005-2021. Accessed March 23, 2021. http://www.agilemodeling.com/essays/changeManagement.htm

3.2.2 Variable-level Metadata

Each dataset is described by metadata definitions that provide information about the variables used in the dataset. The Define-XML specification includes 7 distinct attributes to describe variable-level metadata:

- The variable name (limited to 8 characters for compatibility with the SAS v5 transport file format)
- A descriptive variable label, using up to 40 characters, which should be unique for each variable in the dataset
- The data type (e.g. whether the variable value is a character or numeric)
- The set of controlled terminology for the value or the presentation format of the variable (controlled term, codelist, or format); see Section 4.3, Coding and Controlled Terminology Assumptions
- The origin of each variable 9e.g., whether it was collected or derived)
- The role of the variable, which determines how the variable is used in the dataset. For SEND domain models, roles are used to represent the categories of variables (e.g., identifier, topic, timing; the 5 types of qualifiers).
- Comments or other relevant information included by the sponsor as necessary to communicate information about the variable or its value content. Comments are not to be used just to copy the CDISC Notes.

The domain models in Section 6, Domain Models Based on the General Observation Classes, illustrate how to apply the SDTM to create SEND-conforming datasets. In particular, each model illustrates the selection of a subset of the variables offered in one of the general-observation classes, along with the applicable identifier and timing variables. The models also show how a standard variable from a general observation class should be adjusted to meet the specific content needs of a particular domain, including specifying controlled terminology and creating domain-specific notes and examples. Thus, the domain models demonstrate not only how to apply the model for the most common domains, but also give insight on how to apply general model concepts to other domains not yet defined by CDISC.

3.2.2.1 Origin Metadata

The Origin column of the data definition file is used to indicate where the data originated. Its purpose is to unambiguously communicate to the reviewer whether the data were collected, derived (and thus traceable to some derivation algorithm), or assigned by some subjective process (and thus traceable to some external evaluator).

The Define-XML specification lists allowable values for describing the origin metadata.

The SENDIG defines the following controlled terms for specifying origin:

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COLLECTED	A designation of "COLLECTED" means that the data were collected via manual or electronic means in a nonclinical study setting. This term should be used for data that were actually observed or recorded by a person or received from an instrument; it should not be used for data that have been calculated, interpreted, or derived from other information.
DERIVED	"DERIVED" is assigned to values that were not directly collected, but were calculated by an algorithm or reproducible rule, which was dependent upon other data values. The derivation is assumed to be performed by the producer of the dataset. This does not apply to derived lab test results performed directly by laboratories (or by devices).
OTHER	An origin of "OTHER" is used for values whose origin is known but which were neither collected nor derived. Examples include values sourced from the protocol or which are defined as part of the Trial Design preparation (see Section 7, Trial Design Model Datasets) or values created as a part of the preparation of the datasets (e.g., STUDYID, USUBJID, DOMAIN, --SEQ, --TESTCD).
NOT AVAILABLE	"NOT AVAILABLE" means that the origin of the data is not available, such as data received from another laboratory, without the associated annotations or sufficient information provided to determine the actual Origin assignment for the data. Sponsors may specify additional details about the origin that may be helpful to the reviewer in the Comments section of the data definition file.

To further illustrate the distinctions between these values:

- A collected value, or value mapped directly from a collected value (e.g., --STRESC), has an origin of "COLLECTED".
- A value derived from other collected values or populated fields (e.g., via calculations) has an origin of "DERIVED".
- Values received from a vendor (e.g., a central laboratory) with undefined origin are considered "NOT AVAILABLE" rather than "COLLECTED" or "DERIVED".

3.2.3 Value-level Metadata

When a metadata attribute is specified at the variable level, that attribute's value applies to all values for that variable.

For some variables, a metadata attribute may require multiple values to describe all of the variable's values.

For example, the Organ Measurements (OM) domain could contain subject records related to both organ weights and organ ratios. In this case, some of the values (collected organ weights) would have an origin metadata attribute of "COLLECTED"; some of the values (derived organ ratios) would have an origin metadata attribute of "DERIVED". For variables with multiple attribute values, value-level metadata should be provided in the data definition file according to the Define.XML specification.

The following table illustrates how to define value-level metadata for this OM domain example.

Value Level Metadata - OM [OMTESTCD]

Source Dataset	Source Variable	Value	Label	Origin
OM	OMTESTCD	OW	Organ Weight	COLLECTED
OM	OMTESTCD	OWBW	Organ to Body Weight Ratio	DERIVED
OM	OMTESTCD	OMBR	Organ to Brain Weight Ratio	DERIVED

3.3 Conformance

Conformance with the SENDIG domain models is minimally indicated by:

- Following the complete metadata structure for data domains
- Following SENDIG domain models wherever applicable
- Using SENDIG-specified standard domain names and prefixes per controlled terminology
- Using SENDIG-specified standard variable names
- Using SENDIG-defined variable labels for all standard domains

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- Using SDTM-specified data types for all variables
- Following SDTM/SEND-specified controlled terminology and format guidelines for variables when provided
- Including all collected and relevant derived data in one of the standard domains, special-purpose datasets, or general-observation class structures
- Including all required and expected variables as columns in standard domains, and ensuring that all required variables are populated
- Ensuring that each record in a dataset includes the appropriate identifier and timing variables as well as a topic variable
- Conforming to all business rules described in the CDISC Notes column and general and domain-specific assumptions
- Ensuring that the datasets are in SAS v5 transport file format or other transport file format required by a regulatory agency

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4 Assumptions for Domain Models

4.1 General Domain Assumptions

The examples in this are not meant to show full domain structure and may omit variables for clarity when illustrating a particular scenario.

4.1.1 Additional Timing Variables

Additional timing variables (see SDTM v1.5 Table 2.2.5; https://www.cdisc.org/standards/foundational/sdtm/) can be added as needed to a standard domain model based on the 3 general observation classes. Timing variables can be added to special-purpose domains only where specified in the SENDIG domain model assumptions. Timing variables cannot be added to SUPP-- datasets or to RELREC (see Section 8, Representing Relationships and Data). Timing variables cannot be added to the Trial Design Model datasets (see Section 7, Trial Design Model Datasets).

4.1.2 Order of the Variables

The order of variables in the SDTM domain models has been chosen to facilitate the review and application of the models. Variables in the domains should be ordered with identifiers first, followed by the topic, qualifier, and timing variables. Within each role, variables are ordered as shown in SDTM v1.5 Tables 2.2.1-2.2.5 (http://www.cdisc.org/sdtm). The order of variables in the data definition file should reflect the order of variables in the dataset.

4.1.3 Core Variables

The concept of core variable is used both as a measure of conformance and to provide general guidance to sponsors. Three categories of variables are specified in the Core column in the domain models:

- A **required** variable is any variable that is basic to the identification of a data record (i.e., essential key variables, topic variable) or which is necessary to make the record meaningful. Required variables must always be included in the dataset and cannot be null for any record.
- An **expected** variable is any variable necessary to make a record useful in the context of a specific domain. Columns for expected variables must be present in each submitted dataset, even if all values are null. Expected variables may contain some null values, but in most cases will not contain null values for every record. When no data exist for an expected variable in the whole dataset, a null column should still be included in the dataset, and a comment should be included in the data definition file to explain the absence of data in the entire column.
- A **permissible** variable should be used in a domain as appropriate when collected or derived. Except where restricted by specific domain assumptions, any SDTM timing and identifier variables and any qualifier variables from the same general observation class are permissible for use in a domain based on that general observation class. Sponsors may decide whether a permissible variable should be included as a column when all values for that variable are null.

4.1.4 Additional Guidance on Dataset File Naming

SEND datasets are named to be consistent with the domain code (see the Study Data Technical Conformance Guide for more details on naming datasets for submission to the FDA; https://www.fda.gov/media/88173/download). For example, the Demographics (DM) dataset is named dm.xpt. See SEND controlled terminology (available at http://www.cdisc.org/terminology) for a list of standard and reserved domain codes. Exceptions to this rule are described in the following subsections for general-observation class datasets. See Section 8.2, Relating Records - RELREC, for RELREC; Section 8.3, Supplemental Qualifiers - SUPP-- Datasets, for SUPP; and Section 8.5, Relating Findings To Multiple Subjects - Subject Pooling, for POOLDEF.

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4.2 General Variable Assumptions

4.2.1 Variable-naming Conventions

SDTM variables are named according to a set of conventions, using fragment names (see SDTMIG v3.2, Appendix D; available at http://www.cdisc.org/sdtm), and must be represented in uppercase. These conventions should also be followed when defining --TESTCD in Findings domains and supplemental qualifier QNAM values. Variables with names ending in --CD are "short" versions of associated variables that do not include the --CD suffix (e.g., --TESTCD is the short version of --TEST).

Values of --TESTCD and QNAM values must be limited to 8 characters, and cannot start with a number, nor can they contain characters other than letters, numbers, or underscores. This is to avoid possible incompatibility with SAS v5 transport files. This limitation will be in effect until the use of other formats (e.g., XML) becomes acceptable to regulatory authorities.

Because QNAM serves the same purpose as --TESTCD within supplemental qualifier datasets, values of QNAM are subject to the same restrictions as values of --TESTCD. Values of other --CD variables are not subject to the same restrictions as --TESTCD.

- ETCD (the companion to ELEMENT), SETCD (the short name of a specific trial set), and TSPARMCD (the companion to TSPARM) are limited to 8 characters, but do not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that they will need to serve as variable names.
- ARMCD is limited to 20 characters, but 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 studies. For example, if ARMCD values for a 7-period crossover were constructed using 2-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20.

Variable descriptive names (labels), up to 40 characters, should be provided as data variable labels. Variable names should be represented in uppercase.

Use of variable names (other than domain prefixes), formats, decodes, terminology, and data types for the same type of data (even for custom domains and supplemental qualifiers) should be consistent within and across studies within a submission. Sponsors must use the defined SENDIG-standard labels in all standard domains.

4.2.2 Two-character Domain Identifier

In order to minimize the risk of difficulty when merging or joining domains for reporting purposes, the 2-character domain identifier is used as a prefix in most variable names.

The 2-character domain code is limited to a to Z for the first character and A-Z or 0-9 for the second character, and it is always represented in uppercase. No special characters are allowed for compatibility with SAS v5 transport file format and file naming for the Electronic Common Technical Document (eCTD).

4.2.3 Identification of Subjects and Pools of Subjects

"Subject" should be used where applicable to generically refer to "animal." The term "subject" should be used consistently in all labels and comments. To identify a subject (animal) uniquely across all studies for all applications or submissions involving the product, a unique identifier (USUBJID) should be assigned to each subject on the study.

The unique subject identifier (USUBJID) or pool identifier (POOLID) is required in all datasets containing subject-level or pool-level data, respectively.

- No more than 1 subject (animal) may have the same USUBJID within a submission. Additionally, the same animal that participates in multiple studies (when this is known) must be assigned the same USUBJID value in all studies.

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- POOLID must be unique for each unique grouping (pool) of subjects within a study. A subject can be in multiple pools, but each pool needs to be defined separately.

In this example, a monkey participated in both a pharmacokinetics study and a toxicology study; USUBJID has the same value across the studies, but there are different SUBJID values.

Pharmacokinetic study

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID
1	CT1234	DM	CT1234-007	007

Toxicology study

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID
1	CT1234LTS	DM	CT1234-007	004

For information on pools of subjects, see Section 8.5, Relating Findings To Multiple Subjects - Subject Pooling.

4.2.4 Text Case in Submitted Data

Variables with controlled terminology should match the case in the controlled terminology list (see Section 4.3.2, Controlled Terminology Text Case). When extending a controlled terminology list, follow the case convention of that list.

4.2.5 Convention for Missing Values

Missing values for individual data items should be represented by nulls. Conventions for representing observations not done, using the SDTM --STAT and --REASND variables, are addressed in Section 4.5.1.3, Tests Not Done, and in the individual domain models.

4.2.6 Grouping Variables and Categorization

Grouping variables are identifiers and qualifiers that group records in the SDTM domains/datasets, such as the --CAT (category) and --SCAT (subcategory) variables assigned by sponsors to categorize data. For example, a lab record with LBTEST = "SODIUM" might have LBCAT = "CHEMISTRY" and LBSCAT = "ELECTROLYTES". Values for --CAT and --SCAT should not be redundant with the domain or dictionary classification provided by --DECOD and --BODSYS.

Hierarchy of Grouping Variables

- STUDYID
  - DOMAIN
    - --CAT
      - --SCAT
        - USUBJID
          - --GRPID
            - --REFID

How Grouping Variables Group Data

1. For the subject
   a. All records with the same USUBJID value are a group of records that describe that subject.
2. Across subjects (records with different USUBJID values)
   a. All records with the same STUDYID value are a group of records that describe that study.
   b. All records with the same DOMAIN value are a group of records that describe that domain.

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3. --CAT and --SCAT values further subset groups of tests within a domain. Generally, --CAT/--SCAT values have meaning within a particular domain, and apply to all subjects within that domain.
   a. --GRPID values further group (subset) records within USUBJID. Unlike --CAT and --SCAT, --GRPID values are not intended to have any meaning across subjects and they are usually assigned during or after data collection.
   b. Although --SPID and --REFID are identifier variables, these are usually not considered to be grouping variables, although they may have meaning across domains.

Differences Between Grouping Variables

1. The primary distinctions between -CAT/ SCAT and --GRPID are:
   a. --CAT/ SCAT are known (identified) about the data before it is collected. --CAT/ SCAT values group data across subjects. --CAT/-SCAT may have some controlled terminology.
   b. --GRPID is usually assigned during or after data collection at the discretion of the sponsor. --GRPID groups data only within a subject. --GRPID values are sponsor-defined and are not be subject to controlled terminology.
2. The primary distinction between -CAT/ SCAT and --REFID is that --CAT/-SCAT are usually textual descriptions of the data designed into the collection vehicle/process, and --REFID is usually a tracking number/value of some type assigned to an object being tracked (e.g., a blood sample).

In domains based on the Findings general observation class, the --RESCAT variable can be used to categorize results after the fact. --CAT and --SCAT by contrast, are generally predefined or used at the point of collection, not after assessing the value of findings results. See Section 6.3.3.2, Examples for Clinical Observations (CL) Domain Model, Example 3.

4.2.7 Use of FOCID for Study-specific Points of Interest

Often, 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) and is commonly referenced in data collections and tabulations.

The FOCID variable enables representation of this concept, and is available within all general observation classes. 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. When populated, it is usually part of the natural key for the domain, providing a level of granularity that would otherwise not be available through the other variables. This is especially true when the foci are all within the same area on the subject.

The following examples demonstrate records from various domains that tie to study-specific foci (i.e., injection site 1 and injection site 2) as identified in the protocol. In each case, the FOCID variable is populated identically across domains for the same focus. Note that, in this example, many variables have been omitted due to space considerations.

At each of the 2 injection sites, subject 12345001 received a different treatment (Exposure domain).

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	FOCID	EXTRT	EXDOSE	EXDOSU	EXSTDY
1	12345	EX	12345001	Injection Site 1	RP187	0	mg/kg	1
2	12345	EX	12345001	Injection Site 2	RP187	10	mg/kg	1

Clinical signs (CL domain) are recorded at each of the 2 injection sites. Rows such as these would exist for each day on which observations of the sites were made.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	FOCID	CLTESTCD	CLTEST	CLORRES	CLDY
1	12345	CL	12345001	Injection Site 1	SKINEX	Skin Examination	Fur, Thin Cover; Left Scapula	1
2	12345	CL	12345001	Injection Site 2	SKINEX	Skin Examination	No Abnormal Findings, Right Scapula	1

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Macroscopic findings (MA domain) are recorded for the skin around the 2 injection sites.

ma.xpt

Row	STUDYID	DOMAIN	USUBJID	FOCID	MAORRES	MASPEC
1	12345	MA	12345001	Injection Site 1	Fur thin cover	SKIN
2	12345	MA	12345001	Injection Site 2	Unremarkable	SKIN

Microscopic findings (MI domain) are recorded for 2 skin specimens, 1 from each injection site.

mi.xpt

Row	STUDYID	DOMAIN	USUBJID	FOCID	MIORRES	MISPEC
1	12345	MI	12345001	Injection Site 1	Inflammation, acute	SKIN
2	12345	MI	12345001	Injection Site 2	Injection channel visible, nothing remarkable	SKIN

4.2.8 Use of the Invariant Record Identifier (--RECID)

The invariant record identifier (--RECID) is available for use in any domain based on 1 of the 3 general observation classes. This variable is an identifier for a record that is unique within a domain for a study. It remains invariant through subsequent versions of the dataset, even if the content of the record is modified. When a record is deleted, this value must not be reused to identify another record in either the current or future versions of the domain for the study.

It can facilitate the determination of which records have changed between versions of a dataset for a study. If the originating data collection process can distinguish whether a record is modified, this variable enables such a distinction to be passed on to subsequent systems.

Note that the concept for --RECID is distinct from --SEQ in several ways:

- --SEQ is not required to be invariant through dataset versions.
- --SEQ is numeric, whereas --RECID may be character based.
- --SEQ is unique within a subject and a domain, whereas --RECID is unique across all records in a domain for the study.

See Section 8.2.2, RELREC Examples for Record-To-Record Relationships, for an example showing the use of --RECID.

4.2.9 Use of the Unscheduled Flag (--USCHFL)

Nonclinical studies are conducted in the context of a planned study schedule. The identification of unscheduled observations is important information for interpretation of the data. The unscheduled flag (--USCHFL) variable is populated when the timing of a performed test or observation was not driven by the study schedule.

Nonclinical studies typically have a plan for handling unscheduled events (e.g., taking a final blood draw when an animal is found to be moribund). In this case, the protocol describes what to do for the unexpected event, but the collection is considered unscheduled because it is triggered by an unscheduled event (the animal's moribund condition); the value of --USCHFL would be set to "Y".

This example shows the disposition of 2 animals. The death of 1 of the animals was unscheduled.

Row	USUBJID	DSTERM	DSDECOD	DSSTDY	DSUSCHFL
1	123-01	Accidental Death	ACCIDENTAL DEATH	28	Y
2	123-02	Final Necropsy	TERMINAL SACRIFICE	28	

This example shows the laboratory records for 1 animal. The first 2 laboratory test results were performed as part of a scheduled blood draw, whereas the last 2 were performed on an unscheduled blood draw.

Row	USUBJID	LBTEST	LBORRES	LBORRESU	LBSTAT	LBREASND	LBDTC	LBDY	LBUSCHFL
1	123-01	Albumin	30	g/L			2012-09-04T08:00	7	
2	123-01	Creatinine	0.9	mg/dL			2012-09-04T08:00	7	
3	123-01	Albumin	25	g/L			2012-09-11T06:45	14	Y
4	123-01	Creatinine			NOT DONE	No reportable result	2012-09-11T06:45	14	Y

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4.3 Coding and Controlled Terminology Assumptions

4.3.1 Types of Controlled Terminology

Controlled terminology (CT) has been developed for SEND, and is available at http://www.cdisc.org/terminology. If a controlled terminology codelist exists for a variable in a SEND domain, the name of the codelist will be populated in the Controlled Terms, Codelist, or Format column of the domain model to indicate that a distinct set of controlled values exists and is expected to be used. The SEND CT indicates whether a particular codelist is extensible. The domain dataset models included in Sections 5, Models for Special-purpose Domains, and 6, Domain Models Based on the General Observation Classes, of this document provide additional information about the Controlled Terms, Codelist, or Format column; notes on proper use; and examples.

4.3.2 Controlled Terminology Text Case

Controlled terminology should be submitted in the same text case used in the controlled terminology list. When extending a controlled terminology list, the case-sensitivity convention of that list should be followed.

Deviations from these rules should be described in the data definition file.

4.3.3 Controlled Terminology Values

The controlled terminology or a link to the controlled terminology should be included in the data definition file wherever applicable. See the Define-XML specification (available at https://www.cdisc.org/standards/data-exchange/) for details on including or referencing controlled terminology lists. Note that a null value should not be included in the permissible value set. A null value is implied for any list of controlled terms unless the variable is required (see Section 4.1.3, Core Variables).

4.3.4 Use of Controlled Terminology and Arbitrary Codes

Controlled terminology or decoded text should be used instead of arbitrary number or text codes in order to reduce ambiguity for submission reviewers. If such codes are necessary for analysis and a sponsor wishes to submit them, they may be submitted as supplemental qualifiers.

4.3.5 Use of “Yes” and “No” Values

In the case of variables for which the response is "Yes" or "No" ("Y" or "N") and the controlled terminology list is YN, the CDISC Notes column will provide guidance for proper use within a domain. Where appropriate and to eliminate confusion regarding whether a blank response indicates "N" or is a missing value, it is suggested that both "Y" and "N" be used, except where the CDISC Notes instruct otherwise.

Note: Permissible values for variables with controlled terms of "Y" or "N" may also be populated with "U" or "NA" if it is the sponsor's practice to explicitly collect or derive values indicating "Unknown" or "Not Applicable" for that variable.

4.3.6 Use of Combined Terms for Qualifier Variables

In some cases, a single variable value may be a combination of items representing a single concept (e.g., --SPEC). In others, there may be multiple values represented. The differences between the 2 cases are described in the following sections.

4.3.6.1 A Single Concept Represented by Multiple Values

A single value may represent a combination of multiple contributing items, delimited by slashes ("/"). In these cases, the combination is the collected value, the value analyzed, and so on—not the individual contributing items composing the value.A noteworthy example of this scenario is combined specimens, where a single specimen may consist of material from various tissues, and the combination is examined and analyzed together during an

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examination. For example, a specimen consisting of testis and epididymis tissues would be included as "TESTIS/EPIDIDYMIS". Another example is the DEGENERATION/REGENERATION microscopic finding: a single concept represented by multiple values (which is different from having 2 separately collected findings of degeneration and regeneration, respectively).In these scenarios, when controlled terminology applies to the corresponding variable, the combination may already exist as a controlled terminology term; in the specimen list, this is the case for several commonly combined tissues. However, there do exist combinations that do not have a dedicated controlled term and whose rarity does not warrant creating an individual controlled term for the specific combination. In these cases, when constructing the combination term, each of the contributing items should abide by controlled terminology where possible, in order to keep the combination term consistent and easily interpretable. For example, in the TESTIS/EPIDIDYMIS case, TESTIS (the preferred term for this tissue) should be used instead of TESTES, Testis, testes, and so on, and EPIDIDYMIS should be used instead of EPIDIDYMIDES or other variations. As always, the SEND Controlled Terminology Team will evaluate feedback regarding potential new terms.

4.3.6.2 Multiple Concepts Represented by Multiple Values

In some cases, a variable value may comprise multiple individual values. In these cases, each contributing value is a separately collected or analyzed item. This case is notably present in the directionality (--DIR), where often, multiple distinct values might be collected for a given record. In these scenarios, when controlled terminology applies to the corresponding variable, each contributing value must be included as its controlled terminology submission value, and delimited from other terms by a semicolon. For example, a finding with 2 directionality values of ventral and surface would be included as "VENTRAL;SURFACE."

4.3.7 Mapping Controlled Terminology

Many terms are synonyms of other terms. When there are multiple terms that express the same base concept, SEND controlled terminology provides the preferred term to include in a submission, and thus the term to which the synonymous term(s) should be mapped. The NCI Thesaurus (https://ncit.nci.nih.gov) provides the synonyms. For instance, the unit of degrees Celsius could be expressed as "°C", "degC", "C", "Degrees Celsius", and so on. The SEND preferred term for degrees Celsius is "C." Temperature can also be expressed in terms of degrees Fahrenheit, but this is a different concept from degrees Celsius. The key to mapping is determining which terms are synonymous, not which terms can be converted into one another via a conversion factor (for conversion, see Section 4.5.1.4, Example of Original and Standardized Results and Test Not Done).

Finding the submission value for a source value can be done in 2 ways. First, searching the controlled terminology list can determine whether the source value is in the list. If it is not, the easiest way to search for synonyms is the NCI Thesaurus. The NCI Thesaurus's search functionality searches terms and synonyms and provides the SEND submission value (preferred term).

This example illustrates mapping source units into their controlled terminology preferred term for --ORRESU. Note that in each case, there is only a label change (no conversion calculation).

Row 1: The source unit was "Celsius". This unit maps to the submission value of "C".

Row 2: The source unit was "microgram per liter". This unit maps to the submission value of "ug/L".

Row 3: The source unit was "ng/mL". This unit is a scientifically equivalent unit (i.e., no conversion calculation necessary) to the SEND submission value of "ug/L".

Row	Source Unit	Submission Value (--ORRESU)
1	Celsius	C
2	microgram per liter	ug/L
3	ng/mL	ug/L

4.4 Timing Assumptions

Timing variables (see SDTM v1.5, Table 2.2.5, available at https://www.cdisc.org/standards/foundational/sdtm/) are an essential component of all SDTM subject-level domain datasets. In general, all domains based on the 3 general observation classes should have at least one timing variable. In the Events or Interventions general observation class,

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this could be the start date of the event or intervention. In the Findings observation class, where data are usually collected on multiple study days, either --DTC or --DY must be used. The SENDIG requires dates and times of day to be represented according to the international standard ISO 8601 (https://www.iso.org). ISO 8601 provides a text-based representation of dates and/or times, intervals of time, and durations of time.

4.4.1 Formats for Date/Time Variables

A date/time character string (--DTC variable) may include data that is represented in ISO 8601 format as a complete date/time, a partial date/time, or an incomplete date/time.

The SENDIG template uses ISO 8601 for calendar dates and times of day, which are expressed as follows:

YYYY-MM-DDThh:mm:ss

In this format:

- [YYYY] = 4-digit year
- [MM] = 2-digit representation of the month (01-12; e.g., 01 = January)
- [DD] = 2-digit day of the month (01-31)
- [T] = time designator; indicates time information follows
- [hh] = 2 digits of hour (00-23; am/pm is NOT allowed)
- [mm] = 2 digits of minute (00-59)
- [ss] = 2 digits of second (00-59)

Other characters defined for use within the ISO 8601 standard are:

- [-] (hyphen): to separate the time elements "year" from "month" and "month" from "day"
- [:] (colon): to separate the time elements "hour" from "minute" and "minute" from "second"
- [/] (solidus or slash): to separate components in the representation of time intervals (see Section 4.4.3, Intervals of Time and Use of Duration for --DUR Variables)
- [P] (duration designator): precedes the components that represent the duration (see Section 4.4.3, Intervals of Time and Use of Duration for --DUR Variables)

Spaces are not allowed in any ISO 8601 representations.

Key aspects of the ISO 8601 standard:

- ISO 8601 represents dates as a text string using the notation YYYY-MM-DD.
- ISO 8601 represents times as a text string using the notation hh:mm:ss.
- The ISO 8601 basic format, which does not require delimiters, should not be used.
- When a date is collected with a time in the same variable (as a date/time), the date is written in front of the time and the time is preceded with "T" using the notation YYYY-MM-DDThh:mm:ss (e.g., 2001-12-26T00:00:01).

Implementation of the ISO 8601 standard means that date/time variables are character/text data types. The SEND fragment employed for date/time character variable names is DTC.

4.4.2 Date/Time Precision

The concept of representing date/time precision is handled through use of the ISO 8601 standard. According to ISO 8601, precision (also referred to by ISO 8601 as completeness or representations with reduced accuracy) can be inferred from the presence or absence of components in the date and/or time values. Missing components are represented by right truncation or a hyphen (for intermediate components that are missing). If the date and time values are completely missing, the SDTM date field should be null. Every component is represented as 2 digits except years, which are represented as 4 digits. One-digit numbers are always padded with a leading zero.

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The following table provides examples of ISO 8601 representation complete date and truncated date/time values using ISO 8601-appropriate right truncations of incomplete date/time representations. Note that if no time component is represented, the [T] time designator (in addition to the missing time) must be omitted in ISO 8601 representation.

	Date and Time as Originally Recorded	Precision	ISO 8601 Date/Time
1	December 15, 2003 13:14:17	Complete date/time	2003-12-15T13:14:17
2	December 15, 2003 13:14	Unknown seconds	2003-12-15T13:14
3	December 15, 2003 13	Unknown minutes and seconds	2003-12-15T13
4	December 15, 2003	Unknown time	2003-12-15
5	December, 2003	Unknown day and time	2003-12
6	2003	Unknown month, day, and time	2003

This date and date/time model also provides for the representation of intervals with uncertainty or date/time ranges. To represent these intervals while applying the ISO 8601 standard, it is recommended that sponsors concatenate the date/time values that describe the beginning and the end of the interval of uncertainty (using the most complete representation of the dates/times known) and separate them with a solidus or slash, as shown in the following table.

	Interval of Uncertainty	ISO 8601 Date/Time
1	Between 10:00 and 10:30 on the morning of December 15, 2003	2003-12-15T10:00/2003-12-15T10:30
2	Between the first and the tenth of December, 2003	2003-12-01/2003-12-10
3	Sometime in the first half of 2003	2003-01-01/2003-06-30

Other uncertainty intervals may be represented by the omission of components of the date when these components are unknown or missing. As previously mentioned, ISO 8601 represents missing intermediate components through the use of a hyphen where the missing component would normally be represented. This may be used in addition to "appropriate right truncations" for incomplete date/time representations. When components are omitted, the expected delimiters must still be kept in place and only a single hyphen is to be used to indicate an omitted component. Examples of this method of representing omitted components are shown in the following table.

	Date and Time as Originally Recorded	Level of Uncertainty	ISO 8601 Date/Time
1	December 15, 2003 13:15:17	Complete date and time	2003-12-15T13:15:17
2	December 15, 2003 ??:15	Unknown hour with known date and minutes	2003-12-15T-:15
3	December 15, 2003 13:??:17	Unknown minutes with known date, hours, and seconds	2003-12-15T13:-:17
4	The 15th of some month in 2003, time not collected	Unknown month and time with known year and day	2003---15
5	December 15, but year not documented, time not collected	Unknown year and time with known month and day	--12-15
6	7:15 of some unknown date	Unknown date with known hour and minute	-----T07:15

Using a character-based data type to implement the ISO 8601 date/time standard will ensure that the date/time information will be machine- and human-readable without the need for further manipulation and will be platform- and software-independent.

4.4.3 Intervals of Time and Use of Duration for --DUR Variables

As defined by ISO 8601, an *interval of time* is the part of a time axis, limited by 2 time "instants," such as the times represented in SDTM by the variables --DTC and --ENDTC. These variables represent the 2 instants that bound an interval of time, whereas the duration is the quantity of time that is equal to the difference between these time points.

Duration is frequently used during a review; however, the duration timing variable (--DUR) should generally be used in a domain if it was collected in lieu of a start date/time (DTC) and end date/time (--ENDTC). If both --DTC and --ENDTC are collected, durations can be calculated by the difference in these 2 values and need not be in the submission dataset.

Durations and associated units can be provided in a single variable, in accordance with the ISO 8601 standard as follows:

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PnYnMnDTnHnMnS
- or -
PnW

In this format:

- [P] (duration designator) precedes the alphanumeric text string that represents the duration. Note: the use of the character *P* is based on the historical use of the term "period" for duration.
- [n] represents a positive real number. It can be zero only in the case where a duration [P] is zero.
- [W] is used as week designator, preceding a data element that represents the number of calendar weeks within the calendar year (e.g., P6W represents 6 weeks of calendar time).

The letter *P* must precede other values in the ISO 8601 representation of duration. The *n* preceding each letter represents the number of years, months, days, hours, minutes, or seconds, or the number of weeks if the duration is expressed in calendar weeks. As with the date/time format, *T* is used to separate the date components from time components.

Note: In duration expressions, weeks cannot be mixed with any other date/time components such as days or months.

As is the case with the date/time representation in --DTC or –ENDTC, only the components of duration that are known or collected need to be represented. Also, as is the case with the date/time representation, if no time component is represented, the [T] time designator (in addition to the missing time) must be omitted in ISO 8601 representation.

ISO 8601 allows an interval to be represented in multiple ways. One representation, shown below, uses 2 dates in the format:

YYYY-MM-DDThh:mm:ss/YYYY-MM-DDThh:mm:ss

For the purposes of data submission, an additional format is allowed to represent "negative" intervals of time (intervals of time preceding a reference point). This format should be expressed as:

-PnYnMnDTnHnMnS
- or -
-PnW

This may be used whenever the ISO 8601 interval format is specified in this implementation guide.

ISO 8601 also allows that the "lowest order components" of duration/intervals may be represented in decimal format. This may be useful if data are collected in formats such as "one and one-half years," "two and one-half weeks," "one-half week," or "one quarter of an hour," and the sponsor wishes to represent this level of precision (or lack of precision) in ISO 8601 representation. Using decimals to express an additional level of precision is ONLY allowed in the lowest-order (right-most) component of any duration representation.

The following table provides some examples of ISO 8601 representations of durations.

Duration as Originally Recorded	ISO 8601 Duration
2 years	P2Y
10 weeks	P10W
3 months 14 days	P3M14D
3 days	P3D
6 months 17 days 3 hours	P6M17DT3H
14 days 7 hours 57 minutes	P14DT7H57M
42 minutes 18 seconds	PT42M18S

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Duration as Originally Recorded	ISO 8601 Duration
One-half hour	PT0.5H
5 days 12¼ hours	P5DT12.25H
4 ½ weeks	P4.5W
5 minutes pre-dose	-PT5M

Date and time elements, including their designator, should be omitted if their value is zero. For example, duration of 1 hour and 30 seconds (no minutes) should be represented as PT1H30S. Note that a leading zero is required with decimal values less than 1. An exception to the use of zeros in ISO 8601would be a representation of zero time (e.g., PT0H or PT0M).

4.4.4 Populating Study Day Variables

The study day variables (--DY, --STDY, and --ENDY) describe the relative day of the observation, starting with the reference date as day 1. They are determined by comparing the date portion of the respective date/time variables (--DTC, --STDTC, and --ENDTC) to the date portion of the subject reference start date (RFSTDTC from the Demographics domain).

The subject reference start date (RFSTDTC) is designated as study day 1. The study day value is incremented by 1 for each day following RFSTDTC. Dates prior to RFSTDTC are decremented by 1, with the date preceding RFSTDTC designated as study day -1 (there is no study day 0). This algorithm for determining study day is consistent with how sequential days relative to a fixed reference point are typically described, but creates problems if used for mathematical calculations because this does not allow for a day 0. Therefore, study day is not suited for use in subsequent numerical computations (e.g., calculating duration). In such calculations, the raw date values should be used rather than study day.

All study day values are integers. Thus, to calculate study day:

- --DY = (date portion of --DTC) - (date portion of RFSTDTC) + 1 if --DTC is on or after RFSTDTC
- --DY = (date portion of --DTC) - (date portion of RFSTDTC) if --DTC precedes RFSTDTC

This algorithm should be used across all domains.

4.4.4.1 Use of VISITDY

VISITDY was described in SENDIG v3.0 in several different ways, including:

- "Used to group records into a single planned study day as a label for reporting. This allows data that was collected based upon grace days to be reported in a single column on a report. The usage of VISITDY should be defined in the define file." (See Section 4.4.4, Populating Study Day Variables)
- "This is the planned study day of collection." (See Section 6.3.1, Body Weight – BW)

These concepts cannot be represented through the use of a single variable. Further, because VISITDY is associated with the clinical encounter (VISIT), it is not the appropriate variable to represent these concepts. As a result, VISITDY will be phased out of the SENDIG and initially replaced with reporting variables (--NOMDY and --NOMLBL). Adding variables to represent planned information may be considered for a future version of the SENDIG. Implementation of VISITDY is not recommended at this time. Existing implementations of SEND may discontinue or continue use of VISITDY as feasible. Conformance with SENDIG v3.1.1 is not dependent on the use of VISITDY.

4.4.4.2 Use of --NOMDY and --NOMLBL

Observations recorded on multiple days frequently get reported under a single day; therefore, the variables --NOMDY and --NOMLBL have been created. --NOMDY is used to group records collected over multiple days under a single nominal study day for reporting purposes. --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. These timing variables have been included in domains where they may be commonly used, but may be added to any general observation class domain as needed. It is not recommended that --NOMLBL be used without --NOMDY.

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The following example shows the basic timing variables populated for animal dispositions based upon a planned sacrifice that occurred over 3 days at the end of a 4-week study. All the planned sacrifices were reported under 1 study day, shown in DSNOMDY.

ds.xpt

Row	USUBJID	DSSTDTC	DSSTDY	DSNOMDY	DSNOMLBL
1	123-1	2012-09-04	28	28	Week 4 Terminal Sacrifice
2	123-2	2012-09-04	28	28	Week 4 Terminal Sacrifice
3	123-3	2012-09-05	29	28	Week 4 Terminal Sacrifice
4	123-4	2012-09-06	30	28	Week 4 Terminal Sacrifice

4.4.5 Representing Additional Study Days

The SDTM allows for --DTC values to be represented as study days (--DY) relative to RFSTDTC in the Demographics DM dataset (as described in Section 4.4.4, Populating Study Day Variables). The calculation of additional study days within subdivisions of time in a study may be based on 1 or more defined reference dates not represented by RFSTDTC. In such cases, sponsors may define supplemental qualifier variables to store these study days; the data definition file should reflect the reference dates used to calculate such study days. If a sponsor wishes to define "day" within ELEMENT or "day" within EPOCH, the reference date/time will be an element start date/time in the Subject Elements dataset (see Section 5.3.1, Subject Elements – SE).

4.4.6 Representing Timing in a Findings Domain

4.4.6.1 Date and Time in a Findings Domain

When the date/time of collection is presented in any domain, the date/time should go into the --DTC field (e.g., EGDTC for date/time of ECG). For any domain based on the Findings general observation class (e.g., lab tests based on a specimen), the collection date usually needs to be tied to when the specimen or source of the finding was captured, not necessarily when the data was recorded. In order to ensure that the critical timing information is always represented in the same variable, the --DTC variable is used to represent the time of specimen collection. For example, in the Laboratory Test Results (LB) domain, the LBDTC variable would be used for all single-point blood collections or spot urine collections. For timed lab collections (e.g., 24-hour urine collections), the LBDTC variable would be used for the start date/time of the collection and LBENDTC for the end date/time of the collection. This approach allows single-point and interval collections to use the same date/time variables consistently across all datasets for the Findings general observation class. The following table illustrates the proper use of these variables. Note that --STDTC should not be used in a Findings domain (the table is not meant to show domain structure, but to show which variables could be used, designated by the "X").

Collection Type	--DTC	--STDTC	--ENDTC
Single-point collection	X		
Interval collection	X		X

Body weights are single-point collections.

BWDTC	BWDY
2012-09-04	7
2012-09-11	14
2012-09-19	22
2012-09-25	28

Food consumption is interval collection.

FWDTC	FWENDTC	FWDY	FWENDY
2012-09-04	2012-09-11	7	14
2012-09-11	2012-09-19	14	22
2012-09-19	2012-09-25	22	28

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4.4.7 Representing Timing

4.4.7.1 Actual Timing

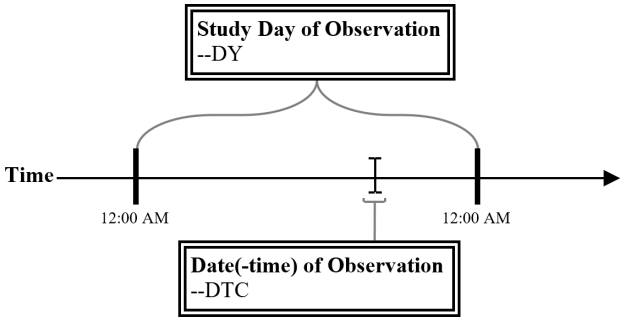
Most domains, especially Findings domains, have basic timing variables expressing the actual timing of the observation. The variables used to describe time can vary between point-in-time observations (e.g., body weights) and duration-based observations (e.g., food consumption).

Actual timing for point-in-time observations is expressed through the following variables:

- --DTC is the date when the observation occurred. Depending on the precision of the date, this can represent just the date (e.g., 2010-12-31) or a date and time (e.g., 2010-12-31T08:00). The --DTC variable is expected for many Findings domains.
- --DY is the study day when the observation actually occurred, relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.

These variables are shown in Figure 4471A.

Figure 4471A

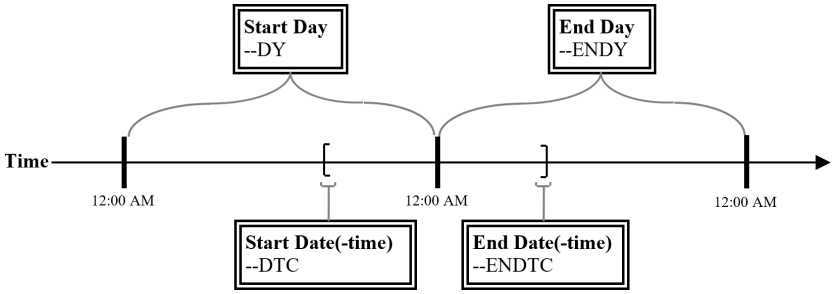


Some observations may be associated with an interval of time (e.g., a finding evaluated over 2 hours). The following variables enable the definition of these ranges:

- --ENDTC is the end date of the range of time when the observation occurred. Depending on the precision of the time, this can represent just the date (e.g., 2010-12-31) or a date and time (e.g., 2010-12-31T08:00).
- --ENDY is the end day of the range of time when the observation occurred, relative to the sponsor-defined RFSTDTC variable in the DM domain.

In these cases, the --DTC/--DY variables are used to define the start of the interval. These variables are shown in Figure 4471B, in a case where an observation spanned 2 days.

Figure 4471B



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4.4.7.2 Planned Timing

4.4.7.2.1 Planned Instances of an Activity Within a Study Day

If there are multiple planned instances of the same activity during a study day, and those instances are not scheduled at planned time intervals relative to a fixed reference point (e.g., administration of dose), the time point variables --TPT and --TPTNUM can be used to differentiate the instances. These 2 variables are used as follows:

- --TPT: the label for the time point during the study day (e.g., "AM", "PM")
- --TPTNUM: typically indicates the order of the time points (TPT) during the study day for the category and/or subcategory (CAT/--SCAT) of data within a domain. The sequence number of the time point during the day (e.g., 1 for --TPT = "AM", 2 for --TPT= "PM")

For each unique planned time point (--TPT), there must be a one-to-one relationship between the values of --TPT and --TPTNUM. Uniqueness for these time points is determined by a combination of the domain; study day; and, if present, category and/or subcategory (CAT/--SCAT).

Other variables (e.g., --TESTCD, --METHOD) may also be needed in some cases to define uniqueness. When this occurs, clarification should be provided as a comment to --TPTNUM in the define file.

Example 1: Basic Timing for Single and Multiple Observations

The following example illustrates the basic timing for single observations as well as multiple observations over the course of the day. The --TPT variable provides a label for each of the sessions; the --TPTNUM allows the sessions to be sorted to correctly reflect the planned order during the day.

Rows 1 and 2 demonstrate one time point per study day being populated for --TPT and --TPTNUM. For observations that only occur once per day, the use of --TPT and --TPTNUM is acceptable, but not required.

cl.xpt

Row	CLCAT	CLSCAT	CLDTC	CLDY	CLTPT	CLTPTNUM
1	PHYSICAL EXAM	Physical Examination	2012-09-04T08:00	7	Vet Check	1
2	OPHTHALMOLOGY	Ophthalmic Signs	2012-09-04T14:30	7	Slit Lamp	1
3	CLINICAL SIGNS	Clin Signs	2012-09-11T06:45	14	AM	1
4	CLINICAL SIGNS	Clin Signs	2012-09-11T13:45	14	PM	2
5	CLINICAL SIGNS	Clin Signs	2012-09-11T14:45	14	Detailed Obs	3
6	CLINICAL SIGNS	Cage-side observations	2012-09-04T08:30	7	AM	1
7	CLINICAL SIGNS	Cage-side observations	2012-09-04T15:30	7	PM	2
8	CLINICAL SIGNS	Cage-side observations	2012-09-11T08:10	14	AM	1
9	CLINICAL SIGNS	Cage-side observations	2012-09-11T15:45	14	PM	2
10	CLINICAL SIGNS	Cage-side observations	2012-09-11T16:10	14	Visual Check	4

Example 2: Point-in-time Time Points, Usage Across Days

The following example shows some of the time point variables for clinical observations measurements taken pre-dose and at 1 and 4 hours post-dose relative to a once-daily dose on days 1 and 2 of the study. Note that the --TPT and --TPTNUM variables have the same values across days for the same time point.

CLDY	CLTPT	CLTPTNUM
1	PREDOSE	1
	1H	2
	4H	3
2	PREDOSE	1
	1H	2
	4H	3

Example 3: Representing Timing for Observational Durations with EVLINT

The following example shows electrocardiographic examinations conducted for 1 hour in the morning and 1 hour in the afternoon on day 1. The timing of the start of each examination is not relative to any time-point reference (TPTREF). EGEVLINT conveys that each examination was 1 hour in duration, when the relative start/end from a fixed reference point is not available.

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eg.xpt

Row	EGTEST	EGDTC	EGDY	EGTPT	EGTPTNUM	EGEVLINT
1	Summary (Mean) Heart Rate	2012-09-04T08:00	1	AM	1	PT1H
2	Summary (Mean) Heart Rate	2012-09-04T14:30	1	PM	2	PT1H
3	Summary (Mean) PR Duration	2012-09-04T08:00	1	AM	1	PT1H
4	Summary (Mean) PR Duration	2012-09-04T14:30	1	PM	2	PT1H
5	Summary (Mean) QRS Duration	2012-09-04T08:00	1	AM	1	PT1H
6	Summary (Mean) QRS Duration	2012-09-04T14:30	1	PM	2	PT1H
7	Summary (Mean) QT Duration	2012-09-04T08:00	1	AM	1	PT1H
8	Summary (Mean) QT Duration	2012-09-04T14:30	1	PM	2	PT1H
9	QTcF - Fridericia's Correction Formula	2012-09-04T08:00	1	AM	1	PT1H
10	QTcF - Fridericia's Correction Formula	2012-09-04T14:30	1	PM	2	PT1H

4.4.7.2.2 Planned Time Points Relative to a Fixed Reference Point

If instances of an activity are scheduled at planned time intervals relative to a fixed reference point (e.g., administration of a dose), the following timing variables should be used:

- --TPTREF: the description of the fixed reference point event or "anchor" from which the planned observation will be made, usually the dose (e.g., "Day 1 Dose"; "Day 1, Dose 1").
- --ELTM: the planned elapsed time from the fixed reference point event (e.g., a dose) to the planned observation, in ISO 8601 format, which is usually also reflected in the --TPT label. For example, if an observation is planned for 30 minutes after the day 1 dose (e.g., --TPT = "30 minute postdose"), --TPTREF would be "Day 1 Dose" with an --ELTM of PT30M.
- --TPT: the label for the time point relative to –TPTREF planned observation, typically reflecting --ELTM. For example, if --TPT is "30 minute postdose," then --ELTM would be PT30M; a "1 hour" --TPT would have an --ELTM of PT1H .
- --TPTNUM: indicates the order of the time points (TPT) relative to the fixed reference point (TPTREF) for the category and/or subcategory (CAT/--SCAT) of data within a domain. The ordering/sequence number of the time point (e.g., 1, 2, 3) is sponsor-defined, but is usually at least unique within the given interval. For example, for a given day with 3 time points (pre-dose, 30 minutes post-dose, 1 hour post-dose), --TPTNUM could be 1 for pre-dose, 2 for 30 minutes post-dose, and 3 for 1 hour post-dose, to establish their relative order.

For each unique planned time point (--TPT), there must be a one-to-one relationship between the values of --TPT and --TPTNUM. Uniqueness for these time points is determined by a combination of the domain, fixed reference point (TPTREF), and (if present) category and/or subcategory (CAT/--SCAT).

Other variables (e.g., --TESTCD, --METHOD) may also be needed in some cases to define uniqueness. When this occurs, clarification should be provided as a comment to --TPTNUM in the define file.

--RFTDTC is used to represent the actual date/time of the fixed reference point (--TPTREF).

Example 1: Point-in-Time Time Points, Clinical Observations Prior to Dose Through 90 Minutes Postdose

The following example shows time point variables populated for clinical observation measurements taken 1 hour before dosing and at 30, 60, and 90 minutes after dosing. The actual times, as represented by CLDTC, did not adhere exactly to the planned times.

Note: If the pre-dose time point had no specific planned elapsed time, CLELTM would be null.

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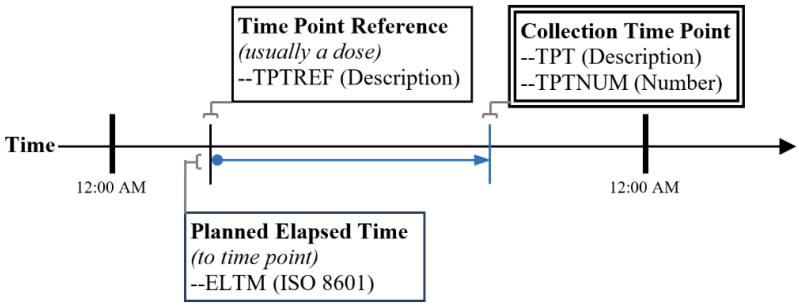
Figure. PT4



cl.xpt

Row	CLDTC	CLDY	CLTPT	CLTPTNUM	CLELTM	CLTPTREF	CLRFTDTC
1	2006-08-01T07:25	1	Predose	1	-PT1H	Day 1 Dose	2006-08-01T08:00
2	2006-08-01T08:30	1	30 MIN	2	PT30M	Day 1 Dose	2006-08-01T08:00
3	2006-08-01T09:01	1	60 MIN	3	PT1H	Day 1 Dose	2006-08-01T08:00
4	2006-08-01T09:32	1	90 MIN	4	PT1H30M	Day 1 Dose	2006-08-01T08:00

Not all time points will require all of these variables; however, it is anticipated that at least --TPTNUM will be included, and generally --TPT, to give the time point a label.

Because --RFTDTC represents the actual date/time of the fixed reference point (--TPTREF), --TPTREF should be provided whenever --RFTDTC is populated. It is also highly recommended that --TPTREF be as specific as possible when --RFTDTC is not used or is null. For example, a --TPTREF of "DOSE ADMINISTRATION" without a corresponding --RFTDTC is not very meaningful if there are multiple dose administrations within a study.

Example 2: Point-in-Time Time Points, Clinical Observations with 24-hour Time Points

The following example shows time point variables populated for clinical observation measurements taken pre-dose and 1, 4, and 24 hours relative to dosing performed on the morning and afternoon of days 7 and 14 of the study. The variables --TPTREF and --RFTDTC describe the reference time point. The example also shows that the assessments performed 24 hours after dosing on study days 8 and 15 (CLDY) are grouped for reporting with the assessments performed on the study day of dosing using nominal day values (CLNOMDY) of 7 and 14, and the reporting labels (CLNOMLBL) of week 1 and week 2.

cl.xpt

Row	CLDY	CLNOMDY	CLNOMLBL	CLTPT	CLTPTNUM	CLELTM	CLTPTREF	CLRFTDTC
1	7	7	Week 1	PREDOSE	1	PT0H	DAY 7 DOSE	2006-08-01T08:00
2	7	7	Week 1	1H	2	PT1H	DAY 7 DOSE	2006-08-01T08:00
3	7	7	Week 1	4H	3	PT4H	DAY 7 DOSE	2006-08-01T08:00
4	8	7	Week 1	24H	4	PT24H	DAY 7 DOSE	2006-08-01T08:00
5	14	14	Week 2	PREDOSE	1	PT0H	DAY 14 DOSE	2006-08-08T08:00
6	14	14	Week 2	1H	2	PT1H	DAY 14 DOSE	2006-08-08T08:00
7	14	14	Week 2	4H	3	PT4H	DAY 14 DOSE	2006-08-08T08:00
8	15	14	Week 2	24H	4	PT24H	DAY 14 DOSE	2006-08-08T08:00

4.4.7.2.3 Planned Time Points Within a Duration

Time points with collections over a duration also typically include the --STINT and --ENINT variables, which specify the start and end of the period over which the assessment was evaluated, based on the --TPTREF anchor.

For these duration-based time points, the sponsor can choose the --TPT (and corresponding --ELTM) to be based on the end, start, or somewhere in the middle of the assessment interval; however, the --STINT and --ENINT variables will remain the same for the same assessment interval. In this respect, --TPT and --ELTM act as the "label" for where the time point should be considered. The --STINT and --ENINT variables definitively state the bounds of the evaluation and would represent the assessment interval consistently across sponsors, regardless of labeling style.

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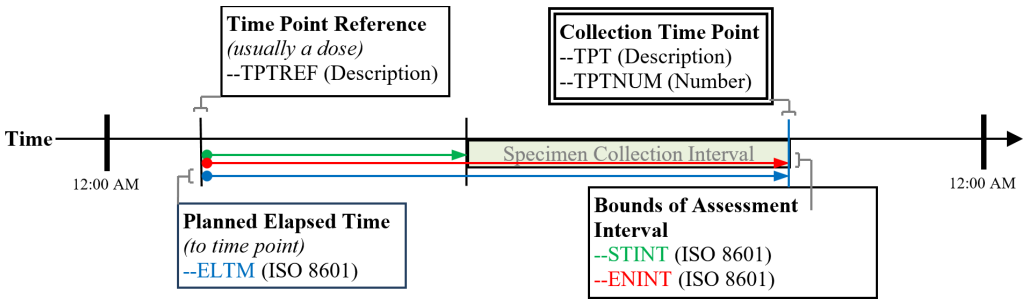
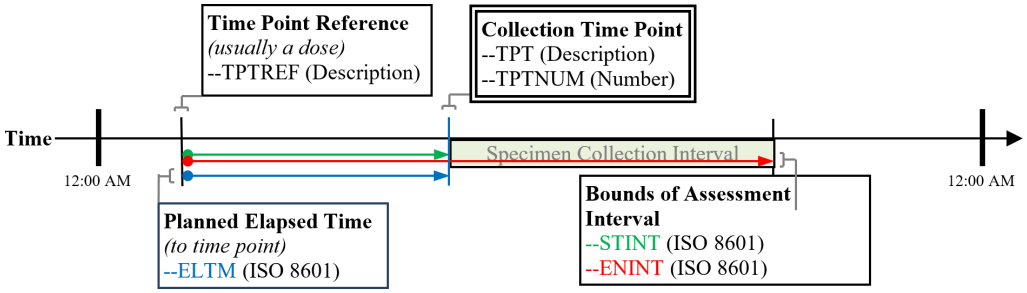
Figure 44723A shows a duration-based time point where --TPT is based at the end of the assessment interval, such as if there were a time point labeled "1 hour," representing an evaluation of the last hour of data. This is the most typical way that duration-based time points are represented.

Figure 44723A



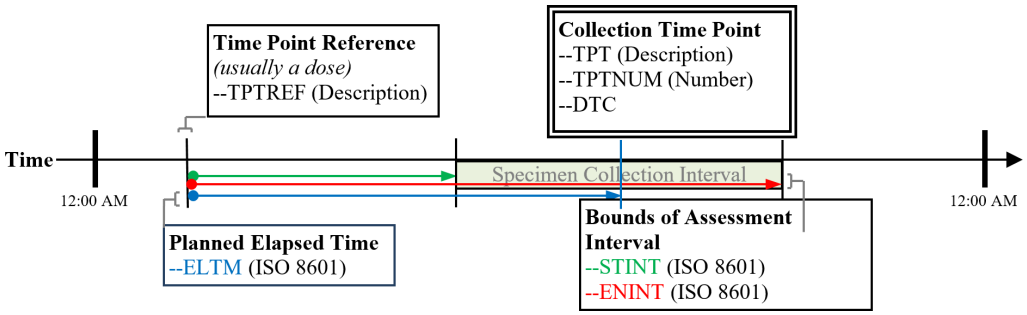
Another way to express a duration-based time point is based on the beginning of the assessment interval, such as a time point labeled "0 hour", representing an evaluation of the next hour of data. This scenario is shown in Figure 44723B. Note that --STINT and --ENINT are identical to that in Figure 44723A; only --TPT and its associated --ELTM change.

Figure 44723B



Another less common way to express a duration-based time point is based on a window around the time point, such as a time point labeled "30 minute", representing an assessment interval of 30 minutes before and after the 30-minute mark. This scenario is shown in Figure 44723C. Note that --STINT and --ENINT are identical compared to Figures 44723A and 44723B; only --TPT and its associated --ELTM change.

Figure 44723C



Example 1: Duration-based Time Points Based on the End of the Assessment

In this example, at each hour, the previous hour's data are summarized into the result. Thus, --TPT and --ELTM are defined around the end of the assessment (e.g., the zero- to 1-hour period assigned to RETPT of "1 Hour" and REELTM of "PT1H"), with the assessment period bounded by the RESTINT and REENINT (e.g., the zero- to 1-hour period assigned to RESTINT of PT0H and REENINT of PT1H).

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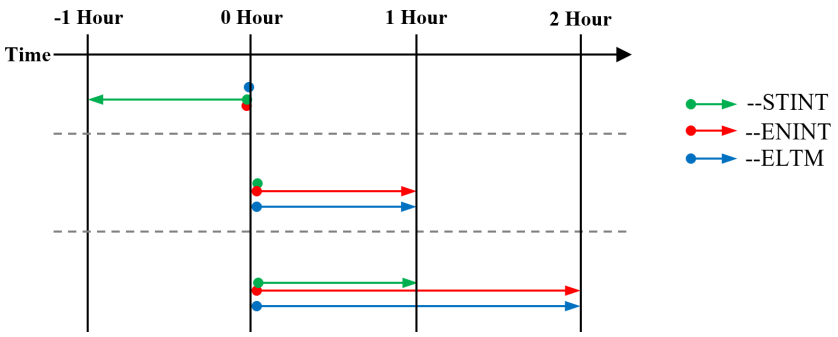
Figure. PT6



re.xpt

Row	RETPT	RETPTNUM	REELTM	RETPTREF	RESTINT	REENINT
1	Baseline	0	PT0H	Day 1 Dose	-PT1H	PT0H
2	1 Hour	1	PT1H	Day 1 Dose	PT0H	PT1H
3	2 Hour	2	PT2H	Day 1 Dose	PT1H	PT2H

Example 2: Duration-based Time Points Based on the Start of the Assessment

The following table presents the same scenario as the previous example, except with the time point based on the start of the assessment. At each hour, the following hour's data are summarized into the result. Thus, --TPT and --ELTM are defined around the start of the assessment (e.g., the zero- to 1-hour period assigned to RETPT of "0 Hour" and REELTM of "PT0H"), yet RESTINT and REENINT are populated identically to the previous example (it remains the same period of time regardless of the label used).

re.xpt

Row	RETPT	RETPTNUM	REELTM	RETPTREF	RESTINT	REENINT
1	Baseline	0	-PT1H	Day 1 Dose	-PT1H	PT0H
2	0 Hour	1	PT0H	Day 1 Dose	PT0H	PT1H
3	1 Hour	2	PT1H	Day 1 Dose	PT1H	PT2H

Example 3: Duration-based Time Points Based in the Middle of the Assessment

The following table presents the same scenario as in Example 2, except with the time point based in the middle of the assessment; 30 minutes of data on either side of each time point (time points at 30 minutes pre-dose and 30 and 90 minutes post-dose) count toward the time point's assessment period. To represent this case, --TPT and --ELTM are defined at the desired time, with the RESTINT and REENINT set to the start and end of the window.

Row	RETPT	RETPTNUM	REELTM	RETPTREF	RESTINT	REENINT
1	Baseline	0	-PT30M	Day 1 Dose	-PT1H	PT0H
2	0.5 Hour	1	PT30M	Day 1 Dose	PT0H	PT1H
3	1.5 Hour	2	PT90M	Day 1 Dose	PT1H	PT2H

4.5 Other Assumptions

4.5.1 Original and Standardized Results of Findings and Tests Not Done

4.5.1.1 Original and Standardized Results

The --ORRES variable contains the result of the measurement or finding as originally received or collected. ORRES is an expected variable and should always be populated, except when --STAT = "NOT DONE".

When --ORRES is populated, --STRESC must also be populated, regardless of whether the data values are character or numeric. The --STRESC variable is either derived by the conversion of values in --ORRES to values with standard units, or by the assignment of the value of --ORRES (as in the Clinical Observations domain, where --STRESC could contain a dictionary-derived term). In the Macroscopic and Microscopic Findings (MA/MI)

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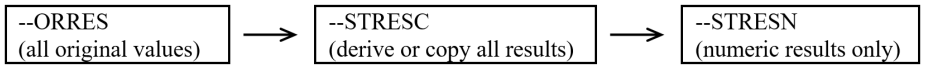
domains, --ORRES may contain a finding with multiple concatenated modifiers. In this case, --STRESC would contain only the finding without the modifiers. A further step is necessary when --STRESC contains numeric values. These are converted to numeric type and written to --STRESN. Because --STRESC may contain a mixture of numeric and character values, --STRESN may contain null values, as shown in the following flowchart.

Figure. Original to Standardized Results



When the original measurement or finding is a selection from a defined codelist, in general, the --ORRES and --STRESC variables contain results in decoded format (i.e., the textual interpretation of whichever code was selected from the codelist). In some cases, the code values in the codelist are statistically meaningful, standardized values or scores, which are defined by sponsors or by valid methodologies. The --ORRES variables will contain the decoded format, whereas the --STRESC variables, as well as the --STRESN variables, will contain the standardized values or scores.

Occasionally data that are intended to be numeric are collected with characters attached that cause the character-to-numeric conversion to fail. For example, numeric cell counts in the source data may be specified with a greater than (>) or less than (<) sign attached (e.g., >10,000, <1). These values should have a null result in the --STRESN column, because only numeric values can be represented in the --STRESN field. If it is necessary to provide a numeric equivalent to these results for the purposes of calculation (analysis), this data should be supplied in a SUPP-- dataset. The supplemental qualifier record should be linked to the record that contains the non-numeric --ORRES value, with a QNAM value of --CALCN, a QLABEL of "Numeric Interpretation for Calculations", and QVAL equal to the value used by the sponsor for calculations. The units of this value should be the same as the standardized units in --STRESU. If the value was not considered numeric for calculation purposes, this type of SUPP-- record should not be provided. Examples of this can be found in Sections 4.5.1.4, Example of Original and Standardized Results and Test Not Done, and 6.3.13, PC PP Cross-Domain Examples.

4.5.1.2 Result Significance

For numeric non-derived data, --ORRES should be presented at the meaningful precision to which the result was collected. The precision should not be artificially changed due to computer storage considerations.

For numeric derived data, --ORRES and --STRESC should contain the correct number of significant figures based upon the calculation used to derive the value. For example, trailing zeroes should be retained when significant.

4.5.1.3 Tests Not Done

When an entire examination (e.g., Laboratory Test Results (LB), Clinical Observations (CL)), a group of tests (e.g., hematology or urinalysis), or an individual test (e.g., glucose) is not done for a subject or pool, and this information is explicitly captured with the reason for not collecting the information, record(s) could be created in the dataset to represent this information. A sponsor has 2 options: (1) to submit individual records for each test not done for each subject or pool, or (2) to submit 1 record for each subject or pool for a group of tests that were not done.

For example, if urinalysis is not done, then:

- LBTESTCD = "LBALL"
- LBTEST = "Laboratory Data"
- LBCAT = "URINALYSIS"
- LBORRES should be null
- LBSTAT should be "NOT DONE"
- LBREASND, if collected, might be "no urine sample present"

4.5.1.4 Example of Original and Standardized Results and Test Not Done

The following examples are meant to illustrate the use of Findings results variables and are not meant as comprehensive domain examples.

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Lab Data Example

Row 1: Numeric values that have been converted.

Row 2: A character result that has been copied.

Row 3: Numeric values that have been copied.

Row 4: A result of "TRACE" shows "TRACE" in LBSTRESC, and LBSTRESN is null.

Row 5: Value of "1+" in LBORRES, "1+" in LBSTRESC and LBSTRESN is null. The sponsor decided not to assign a numeric value to this result, so no additional SUPPLB information is provided.

Row 6: A result of "BLQ" was collected. That value was copied to LBSTRESC and LBSTRESN is null. Note that the standard units are populated by sponsor decision, but could be left null.

Row 7: Result variables are not populated because the observation was "NOT DONE" as reflected in the --STAT variable; neither LBORRES nor LBSTRESC is populated.

Row 8: A result is derived from multiple records such as an average of baseline measurements for a baseline value, so LBDRVFL = Y. Note that records from which this result was derived are not shown in this example.

Row 9: A category of tests was not completed as planned.

Row 10: When a value has a greater than (>) or less than (<) sign attached in --ORRES (e.g., <4000), the entire value with the greater than (>) or less than (<) sign is shown in --STRESC and --STRESN is null. The sponsor has decided to assign a numeric value of 4000 to this result for the purpose of calculations; row 1 of the SUPPLB example reflects this information by using the LBCALCN supplemental qualifier.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSTAT	LBREASND	LBSPEC	LBMETHOD	LBBLFL	LBDRVFL	LBDTC	LBDY
1	LBEX1	LB	LBEX1-001	1	GLUC	Glucose	CHEMISTRY	6.0	g/mL	60	60	g/dL			PLASMA				2010-01-20T15:00	8
2	LBEX1	LB	LBEX1-001	2	BACT	Bacteria	URINALYSIS	MODERATE		MODERATE					URINE				2010-01-20T18:00	8
3	LBEX1	LB	LBEX1-001	3	ALT	Alanine Aminotransferase	CHEMISTRY	12.1	U/L	12.1	12.1	U/L			PLASMA				2010-01-20T15:00	8
4	LBEX1	LB	LBEX1-001	4	RBC	Erythrocytes	URINALYSIS	TRACE		TRACE					URINE				2010-01-20T18:00	8
5	LBEX1	LB	LBEX1-001	5	WBC	Leukocytes	URINALYSIS	1+		1+					URINE				2010-01-20T18:00	8
6	LBEX1	LB	LBEX1-001	6	KETONES	Ketones	URINALYSIS	BLQ	mmol/L	BLQ		mmol/L			URINE				2010-01-20T15:00	8
7	LBEX1	LB	LBEX1-002	1	HCT	Hematocrit	HEMATOLOGY						NOT DONE	Insufficient Sample	WHOLE BLOOD				2010-01-20T15:00	8
8	LBEX1	LB	LBEX1-002	2	MCHC	Ery. Mean Corpuscular HGB Concentration	HEMATOLOGY	33.8	g/dL	33.8	33.8	g/dL			WHOLE BLOOD			Y	2010-01-20T15:00	8
9	LBEX1	LB	LBEX1-003	1	LBALL	Laboratory Data	HEMATOLOGY						NOT DONE	Sample Exhausted					2010-01-20T15:00	8
10	LBEX1	LB	LBEX1-004	1	WBC	Leukocytes	HEMATOLOGY	<4000	/uL	<4000		/uL			WHOLE BLOOD				2010-01-20T15:00	8

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Lab Data Example: SUPPLB

supplb.xpt

Row	STUDYID	RDOMAIN	USUBJID	POOLID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	LBEX1	LB	LBEX1-004		LBSEQ	1	LBCALCN	Numeric Interpretation for Calculations	4000	DERIVED

4.5.1.5 Standardizing Units Within a Study

Sponsors may choose to standardize units within a study for a given test (e.g., data are collected from multiple sites, units change across intervals). In this case, a conversion calculation may be required from LBORRESU to LBSTRESU.

The following example shows a case of the Laboratory Test Results (LB) domain where the laboratory test work for a study was performed at different sites, and the unit reported by the sites differed (the original units for serum creatinine include mg/dL, milligrams per deciliter, and umol/L). The sponsor has chosen to standardize the unit for creatinine for the study to mg/dL. So, the LBORRESU field contains the controlled terminology submission values for these units (e.g., "mg/dL," "mg/dL," and "umol/L," respectively), and the LBSTRESU field contains the harmonized unit's controlled terminology submission value (e.g., "mg/dL"). Note that some required and expected LB domain variables have been omitted for example purposes.

Row 1: Represents a test done at the LAB A site (LBNAM = "LAB A"), where the test was collected with a reported unit of "mg/dL." The original unit of collection is already the submission value (so no mapping is necessary for LBORRESU) as well as the chosen harmonized unit (so no conversion calculation is necessary from LBORRESU to LBSTRESU).

Row 2: Represents a test done at the LAB B site (LBNAM = "LAB B"), where the test was collected with a reported unit of "milligrams per deciliter". in this case, the unit originally collected is a synonym of "mg/dL," so LBORRESU is "mg/dL." This is the chosen harmonized unit, so no conversion calculation is necessary from LBORRESU to LBSTRESU.

Row 3: Represents a test done at the LAB C site (LBNAM = "LAB C"), where the test was collected with a reported unit of "umol/L." The source unit is already the submission value for the micromoles per liter unit, so no mapping is necessary for LBORRESU. However, this unit is different from the chosen standardized unit for the study, so a conversion calculation is done from LBORRESU to LBSTRESU to "mg/dL."

lb.xpt

Row	Source Unit	USUBJID	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBNAM
1	mg/dL	MOCK_134	CREAT	Creatinine	1.0	mg/dL	1.0	1	mg/dL	LAB A
2	milligrams per deciliter	MOCK_1212	CREAT	Creatinine	1.1	mg/dL	1.1	1.1	mg/dL	LAB B
3	umol/L	MOCK_311	CREAT	Creatinine	80	umol/L	0.9	0.9	mg/dL	LAB C

4.5.2 Text Strings That Exceed the Maximum Length for General Observation Class Domain Variables

Because of limitations of SAS v5 transport files, the lengths of data values cannot exceed 200 characters. Because --TEST values may become column labels upon transformation, the SDTM additionally restricts them to 40 characters. Section 4.5.2.1, Test Name (--TEST) Greater Than 40 Characters, provides instructions for handling values of --TEST longer than 40 characters; Section 4.5.2.2, Text Strings Greater than 200 Characters in Other Variables, addresses values of other general-observation class variables longer than 200 characters.

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4.5.2.1 Test Name (--TEST) Greater Than 40 Characters

Sponsors may have test descriptions (--TEST) longer than 40 characters in their operational databases. Because the --TEST variable is meant to serve as a label for --TESTCD when a Findings dataset is transposed to a horizontal format, the length of --TEST is normally limited to 40 characters to conform to the limitations of the SAS v5 transport file format currently used for submission datasets. Therefore, sponsors have the choice to either insert the first 40 characters or a text string abbreviated to 40 characters in --TEST. To address this issue, sponsors may include the full description for these variables:

- in the data definition file Origin column for --TEST, provide a link to the source containing the full test description; or
- in a PDF document storing full-text descriptions. In such cases, in the data definition file Comments column for --TEST, insert a link to the full-text description in the PDF.

4.5.2.2 Text Strings Greater than 200 Characters in Other Variables

Some sponsors may have data values longer than 200 characters for some variables. Because of the current requirement for SAS v5 transport file format, it will not be possible to store those long text strings using only 1 variable. Therefore, the SENDIG has defined a convention for storing a long text string by using a combination of the standard domain dataset and the supplemental qualifiers (SUPP--) datasets, which applies to all domains based on a general observation class. Note that the Comments (CO) and Trial Summary (TS) domains are not based on general observation classes and have different rules. See Section 5.2, Comments, and Section 7.6, Trial Summary, for information on handling comment or trial summary text more than 200 characters long.

The first 200 characters of text should be submitted in the standard domain variable, and each additional 200 characters of text should be represented as a record in the SUPP-- dataset (see Section 8, Representing Relationships and Data). In this dataset, the value for QNAM should contain a sequential variable name, which is formed by appending a 1-digit integer, beginning with 1, to the original standard domain variable name. When splitting a text string into several records, the text should be split between words to improve readability.

The following example shows how to use supplemental qualifiers when original result (TFORRES) exceeds 200 characters, which is the SAS limitation for any data field.

In this example, the original result or finding as collected was slightly over 600 characters in length, so the sponsor put the first 200 characters of text in the standard domain variable and dataset (TFORRES in Tumor Findings), the next 200 characters of text as a first supplemental record in the SUPPTF dataset, the next set of 200 characters as a second record in SUPPTF, and the final few characters of text as a third record in the SUPPTF dataset. The QNAM variable has the values TFORRES1, TFORRES2, and TFORRES3 for these 3 records in SUPPTF, respectively, for this particular text string. Sponsors should place the text itself into variable QVAL and the label of the original standard domain variable into variable QLABEL. In this case, IDVAR and IDVARVAL should be used in SUPPTF to relate the associated supplemental text records to the parent record containing the first 200 characters of text in the standard domain.

Row 1: The first 200 characters of text should be submitted in the standard domain variable.

tf.xpt

Row	STUDYID	DOMAIN	USUBJID	TFSEQ	TFSPID	TFTESTCD	TFTEST	TFORRES	TFSTRESC	TFRESCAT	TFSPEC	TFDTHREL	TFDETECT
1	ABC	TF	ABC-560	88530	MASS 2	TUMEX	Tumor Examination	Progressive nephropathy shown by a thickening of the basement membrane, some tubules have multiple layers of regenerative epithelium, others have flattened, atrophic epithelium. There is prominent	CARCINOMA, BASAL CELL, MALIGNANT	MALIGNANT	KIDNEY	Y	650

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Rows 1-3: Each additional 200 characters of text should be represented as a record in the SUPPTF dataset. In this dataset, the values for QNAM and QLABEL should contain a sequential variable name, which is formed by appending a one-digit integer, beginning with 1, to the original standard domain variable name. When splitting a text string into several records, the text should be split between words to improve readability.

supptf.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	ABC	TF	ABC-560	TFSEQ	88530	TFORRES1	Original Result or Finding as Collected1	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	COLLECTED
2	ABC	TF	ABC-560	TFSEQ	88530	TFORRES2	Original Result or Finding as Collected2	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	COLLECTED
3	ABC	TF	ABC-560	TFSEQ	88530	TFORRES3	Original Result or Finding as Collected3	in Bowman's capsule.	COLLECTED

4.5.3 Biological Significance for Findings Observation Class Data

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. 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.

It should be noted that biological significance is different from the concepts of normal and abnormal, which are generally submitted in --ORRES.

4.5.4 Supplemental Reason Variables

The SDTM general observation classes include the --REASND variable to submit the reason an observation was not collected. However, sponsors sometimes collect the reason that something *was* done. For the Interventions general observation class, --INDC and --ADJ are available to indicate the reason for the intervention or for the dose adjustment. For the Findings general observation class, if the sponsor collects the reason for performing a test or examination, it should be placed in the SUPP-- dataset as described in Section 8.3, Supplemental Qualifiers - SUPP-- Datasets. The standard SUPP-- QNAM value of --REAS should be used as described in Section 8, Representing Relationships and Data.

For example, if the sponsor collects the reason that extra lab tests were done, the SUPP-- record might be populated as follows.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	12345	LB	99-123	LBSEQ	3	LBREAS	Reason Test or Examination was Performed	ORIGINAL SAMPLE LOST

4.5.5 Derived Records

For a result variable (e.g., --ORRES) whose origin is defined as COLLECTED in the define file, there may be the occasional need to derive other records (e.g., mean or ratio). In such a case, --DRVFL would have a value of "Y".

The following table shows an abbreviated example of some blood pressure readings (Cardiovascular Test Results domain), highlighting the use of --DRVFL to indicate that a record in the CV domain was derived from other records also in the domain.

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cv.xpt

Row	CVTEST	CVORRES	CVDRVFL	CVDTC
1	Systolic Blood Pressure	154		2010-01-19T09:52
2	Systolic Blood Pressure	149		2010-01-19T09:54
3	Systolic Blood Pressure	153		2010-01-19T09:55
4	Systolic Blood Pressure	152	Y	2010-01-19

The following table shows collected protein and creatinine chemistry lab tests.

Row 3: Shows a protein/creatinine test that was not generated directly by the instrument, but rather derived from rows 1 and 2; therefore, --DRVFL has a value of "Y".

Row 4: Shows a protein/creatinine ratio generated directly by the instrument.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSPEC	LBDRVFL	LBDTC	LBDY
1	ABC	LB	ABC-1001	303	PROT	Protein	Chemistry		6.3	mg/dL	6.3	6.3	mg/dL	SERUM		2011-01-09T12:51:00	9
2	ABC	LB	ABC-1001	307	CREAT	Creatinine	Chemistry		0.5	mg/dL	0.5	0.5	mg/dL	SERUM		2011-01-09T12:51:00	9
3	ABC	LB	ABC-1001	5550	PROTCRT	Protein/Creatinine	Chemistry		12.6	RATIO	12.6	12.6	RATIO	SERUM	Y	2011-01-09	9
4	ABC	LB	ABC-1001	5550	PROTCRT	Protein/Creatinine	Chemistry		12.6	RATIO	12.6	12.6	RATIO	SERUM		2011-01-09T12:51:00	9

Note that a sponsor may also set --GRPID to more explicitly define the relationship between each derived record and the records from which it was sourced. 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).

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5 Models for Special-purpose Domains

5.1 Demographics

5.1.1 Demographics – DM

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

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	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 treatment. Study day calculation (the --DY variable) in all domains will be based on this date. The sponsor must define what collected date is used to populate RFSTDTC in the data definition file.	Req
RFENDTC	Subject Reference End Date/Time	Char	ISO 8601	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 sponsor must define what collected date is used to populate RFENDTC in the data definition file.	Exp
RFXSTDTC	Date/Time of First Study Treatment	Char	ISO 8601	Record Qualifier	First date/time of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC. Note: Absolute first.	Perm
RFXENDTC	Date/Time of Last Study Treatment	Char	ISO 8601	Record Qualifier	Last date/time of exposure to any protocol-specified treatment or therapy, 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
BRTHDTC	Date/Time of Birth	Char	ISO 8601	Record Qualifier	Date/Time of birth of the subject, in ISO 8601 format.	Perm
AGE	Age	Num		Record Qualifier	May be derived (RFSTDTC – BRTHDTC), but BRTHDTC 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 BRTHDTC 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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
SEX	Sex	Char	(SEX)	Record Qualifier	The sex of the subject.	Req
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 sponsor to enter further details qualifiying 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 (e.g., Low Dose, Mid Dose, 10 mg/kg/day dose, Third 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 sponsor. Maximum of 8 characters. This represents the Trial Set for which parameters are being submitted.	Req

5.1.1.1 Assumptions for (DM) Demographics Domain Model

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/treatment identification: When a sponsor is 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, sponsors should place this information 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. BRTHDTC, 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.

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b. If information is available about the time of birth for the subject, it should be presented in the variable BRTHDTC in ISO 8601 format, even if this is only partial information (not a complete date of birth). Section 4.4.2, Date/Time Precision, discusses how to represent date/time precision in ISO 8601.

c. Data in BRTHDTC 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. Sponsors may choose to derive AGE and AGEU using an algorithm involving BRTHDTC and RFSTDTC. Sponsors should indicate how AGE was populated in the define file comments.

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 by the sponsor 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, treatment strategies, inherent characteristics (e.g., strain) parameters, and/or sponsor-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. For further explanation of SETCD, see Section 7.4, Trial Sets.

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 a "treatment group," although it is not necessarily a treatment 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. See Section 7.4, Trial Sets, for further details.

5.1.1.2 Examples for Demographics (DM) Domain Model

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.

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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	UN	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

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5.2 Comments

5.2.1 Comments – CO

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

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	Sponsor-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. See Assumption 4 in Section 5.2.1.1.	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	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 sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

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5.2.1.1 Assumptions for Comments (CO) Domain Model

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). Assumptions for populating IDVAR and IDVARVAL are further described in Section 8.2, Relating Records - RELREC.
   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. (See Example 1, rows 8-9.)
   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. (See Example 1, row 10.)
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. (See Example 1, row 7). **Note:** When using COVAL1-COVALn, the variable label should match the corresponding variable name (e.g., Comment1, Comment2).
5. See Section 8.2, Relating Records - RELREC, 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.

5.2.1.2 Examples for Comments (CO) Domain Model

Example 1

Rows 1-6: Show comments related to parent records in the BW, LB, CL, and 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; therefore, IDVAR and IDVARVAL are null and COREF is populated.

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Row 10: Shows how to add a comment related to a specific domain, but unrelated to a specific subject or record. Therefore 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	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

5.3 Subject Elements

An *element* is a basic building block in the trial design. It involves administering a planned intervention, which may be treatment or no treatment, during a period of time. The Subject Elements (SE) domain contains the design elements that each subject actually experienced. As a reference, the Trial Elements (TE), Trial Arms (TA), and Trial Sets (TX) datasets in the Trial Design Model describe and use the various planned design elements (see Section 7, Trial Design Model Datasets) that subjects may experience. The subject's assignment to an arm is reported in the ARM and ARMCD variables in the Demographics (DM) domain.

5.3.1 Subject Elements – SE

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

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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	Timing	Start date/time for an Element for each subject, in ISO 8601 format.	Req
SEENDTC	End Date/Time of Element	Char	ISO 8601	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

5.3.1.1 Assumptions for Subject Elements (SE) Domain Model

1. The Subject Elements domain allows the submission of data on the individual experience: the actual timing and sequence of elements a subject experienced. See Section 7.2, Trial Elements, and Section 7.3, Trial Arms; the TE and TA datasets define a study's planned elements and describe the planned sequences of elements for the arms of the study. 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 sponsor 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.

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5.3.1.2 Examples for Subject Elements (SE) Domain Model

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	Vehicle 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 Drug 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 Drug 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	Vehicle Control		Treatment
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 Drug A		Treatment
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 Drug A		Treatment

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 Treatment 1").

Example 2: Parallel Design

In this example, all of the subjects experienced their planned sequence of elements. The SE dataset documents their start and end date/times for each element.

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	Vehicle 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

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Row	STUDYID	DOMAIN	USUBJID	SESEQ	ETCD	ELEMENT	SESTDTC	SEENDTC
5	CDF2	SE	CDF2-010	2	TREATB	100 mg/kg Drug 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 Drug 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 Drug A	2008-01-14T07:00	2008-01-27T10:30
12	CDF2	SE	CDF2-030	3	RECOVERY	Rest	2008-01-27T10:30	2008-02-02T07:00

Note: The exact time for the start of the screen element was not recorded. Therefore, the value of SESTDTC for the screen element only reflects the date (without the exact time) the element commenced.

ta.xpt

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	EPOCH
1	CDF2	TA	1	Control	1	PRETEST	Screen	Randomized to Treatment 1	Screen
2	CDF2	TA	1	Control	2	TREATA	Vehicle Control		Treatment
3	CDF2	TA	1	Control	3	RECOVERY	Rest		Rest
4	CDF2	TA	2	Low	1	PRETEST	Screen	Randomized to Treatment 2	Screen
5	CDF2	TA	2	Low	2	TREATB	100 mg/kg Drug A		Treatment
6	CDF2	TA	2	Low	3	RECOVERY	Rest		Rest
7	CDF2	TA	3	Mid	1	PRETEST	Screen	Randomized to Treatment 3	Screen
8	CDF2	TA	3	Mid	2	TREATC	300 mg/kg Drug A		Treatment
9	CDF2	TA	3	Mid	3	RECOVERY	Rest		Rest
10	CDF2	TA	4	High	1	PRETEST	Screen	Randomized to Treatment 4	Screen
11	CDF2	TA	4	High	2	TREATD	900 mg/kg Drug A		Treatment
12	CDF2	TA	4	High	3	RECOVERY	Rest		Rest

Example 3: Mis-dosing of an Animal

In this example, subject CDF2-020 received an incorrect dose on 2008-01-20. This example should be understood in the context of the TA dataset provided in Example 2.

se.xpt

Row	STUDYID	DOMAIN	USUBJID	SESEQ	ETCD	ELEMENT	SESTDTC	SEENDTC	SEUPDES
1	CDF2	SE	CDF2-001	1	PRETEST	Screen	2008-01-08	2008-01-14T07:00	
2	CDF2	SE	CDF2-001	2	TREATA	Vehicle 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	

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Row	STUDYID	DOMAIN	USUBJID	SESEQ	ETCD	ELEMENT	SESTDTC	SEENDTC	SEUPDES
5	CDF2	SE	CDF2-010	2	TREATB	100 mg/kg Drug A	2008-01-14T07:00	2008-01-27T9:30	
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 Drug A	2008-01-14T07:00	2008-01-20T10:30	
9	CDF2	SE	CDF2-020	3	UNPLAN		2008-01-20T10:30	2008-01-21T07:00	Misdosed with 900 mg/kg A
10	CDF2	SE	CDF2-020	4	TREATC	300 mg/kg Drug A	2008-01-21T07:00	2008-01-27T10:30	
11	CDF2	SE	CDF2-020	5	RECOVERY	Rest	2008-01-27T10:30	2008-02-02T07:00	
12	CDF2	SE	CDF2-030	1	PRETEST	Screen	2008-01-08	2008-01-14T07:00	
13	CDF2	SE	CDF2-030	2	TREATD	900 mg/kg Drug A	2008-01-14T07:00	2008-01-27T10:30	
14	CDF2	SE	CDF2-030	3	RECOVERY	Rest	2008-01-27T10:30	2008-02-02T07:00	
15	CDF2	SE	CDF2-040	1	PRETEST	Screen	2008-01-08	2008-01-14T07:00	
16	CDF2	SE	CDF2-040	2	TREATE	Positive Control Drug XY	2008-01-14T07:00	2008-01-27T10:30	

Example 4: 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	Vehicle 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 Drug 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 Drug 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 Drug A	2008-01-14T07:00	2008-01-21T07:00
12	CDF2	SE	CDF2-030	3	TREATD2	700 mg/kg Drug 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 Drug XY	2008-01-14T07:00	2008-01-27T10:30

Example 5: Animal Skipping an Element

The ARMCD variable in the Demographics (DM) domain can be used with the TA table to determine the planned elements for USUBJID CDF2-020. The SE domain is intended to reflect the actual experiences of the subject, not variations from plan. What is important to note in this example is that a missed planned

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element does not result in an unplanned entry ("UNPLAN" in ETCD). Because subject CDF2-020 went directly from one planned element to a subsequent planned element (skipping a planned element in between), there is no entry to reflect the missed element. Specifically, subject CDF2-020 did not experience any unplanned elements.

1. PLANNED Animal Treatment Elements: Screen → Treatment (300 mg/kg Drug A) → Treatment (500 mg/kg Drug B) → Recovery
2. ACTUAL Animal Treatment Elements: Screen → Treatment (300 mg/kg Drug A) → Treatment (500 mg/kg Drug B) SKIPPED → Recovery

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	Vehicle 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 Drug A	2008-01-14T07:00	2008-01-22T09:30
6	CDF2	SE	CDF2-010	3	TREATC	100 mg/kg Drug B	2008-01-22T09:30	2008-01-28T09:30
7	CDF2	SE	CDF2-010	4	RECOVERY	Rest	2008-01-28T09:30	2008-02-02T07:00
8	CDF2	SE	CDF2-020	1	PRETEST	Screen	2008-01-08	2008-01-13T07:00
9	CDF2	SE	CDF2-020	2	TREATD	300 mg/kg Drug A	2008-01-13T07:00	2008-01-21T10:30
10	CDF2	SE	CDF2-020	3	RECOVERY	Rest	2008-01-21T10:30	2008-02-02T07:00

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6 Domain Models Based on the General Observation Classes

6.1 Interventions

6.1.1 Exposure – EX

ex.xpt, Exposure - Interventions. One record per constant dosing interval per treatment per subject or pool, Tabulation.

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
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, such as a drug application site, e.g., "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 Treatment	Char		Topic	Name of the treatment, as defined by the protocol.	Req
EXDOSE	Dose per Administration	Num		Record Qualifier	Amount of treatment administered.	Exp
EXDOSTXT	Dose Description	Char		Record Qualifier	If the amount of treatment administered cannot be represented as a number and populated in EXDOSE, this field is used to describe the amount of treatment 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 treatment (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 one solution,	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					suspension, or dietary food concentration. If no test article was administered, EXLOT should be null.	
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
EXTRTV	Treatment Vehicle	Char		Record Qualifier	Describes vehicle used for treatment. Example: SALINE.	Exp
EXVAMT	Amount Administered	Num		Record Qualifier	The amount (volume or weight) of the treatment compound 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 Treatment	Char	ISO 8601	Timing	Date/Time when administration of the treatment indicated by EXTRT and EXDOSE began, in ISO 8601 format.	Exp
EXENDTC	End Date/Time of Treatment	Char	ISO 8601	Timing	Date/Time when administration of the treatment indicated by EXTRT and EXDOSE ended, in ISO 8601 format.	Perm
EXSTDY	Study Day of Start of Treatment	Num		Timing	Study day when administration of the treatment began, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
EXENDY	Study Day of End of Treatment	Num		Timing	Study day when administration of the treatment ended, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
EXDUR	Duration of Treatment	Char	ISO 8601	Timing	Duration and unit of time for a continuous treatment. 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 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	Timing	Planned elapsed time (in ISO 8601 format) relative to the planned fixed reference (EXTPTREF). 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 EXTPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by EXTPTREF.	Perm
EXTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by EXELTM, if used for EXTPTNUM, and EXTPT. It is recommended that EXTPTREF be as descriptive as possible so the reference time point can be inferred without looking at other variables. Examples: Previous dose, previous feed.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
EXRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/Time of the reference time point, EXTPTREF.	Perm

6.1.1.1 Assumptions for Exposure (EX) Domain Model

1. Definition:
   a. The Exposure (EX) domain model records the details of a subject's administered dose of protocol-specified study treatment. "Study treatment" 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 treatments 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 sponsor-defined and represents a specific period of time during which a subject was treated 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 treatment phase. Alternatively, a separate entry can be made for each treatment administration and for any deviations in treatment that occur. For this example, there could be up to 6 records (one for each weekly administration).
   c. Either USUBJID or POOLID must be populated.
2. Treatment description:
   a. EXTRT captures the name of the administered treatment. Because EXTRT is the topic variable, it is required and must have a value. EXTRT should include only the treatment name and should not include dosage, formulation, or other qualifying information. For example, "ASPIRIN 100 mg TABLET" is not a valid value for EXTRT. This example should be expressed as EXTRT= "ASPIRIN," EXDOSE= "100," EXDOSU= "mg," and EXDOSFRM= "TABLET".
   b. A single control for multiple compounds should contain values separated with a pipe/vertical bar (|).
3. If a subject is treated sequentially with different lots, then a new record must be created for each lot number given.
4. EXDOSE: The sponsor'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 treatment is captured by the start/end date and start/end time of each constant-dosing interval. The sponsor defines the dosing interval.
6. Other additional qualifiers from the SDTM Interventions class may be added to this domain.

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6.1.1.2 Examples for Exposure (EX) Domain Model

Example 1: Intravenous Dosing

This is an example of an EX dataset for selected animals from a typical nonclinical study. Subjects were randomized to 1 of 4 treatment groups with 1 test article at 3 different treatment levels (20 mg/kg, 40 mg/kg, 120 mg/kg) with once-daily administration and 1 control. The test article was infused intravenously for a duration of 10 minutes.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXLOC	EXMETHOD	EXTRTV	EXVAMT	EXVAMTU	EXSTDTC	EXENDTC	EXSTDY	EXENDY	EXDUR
1	12345	EX	12345001	1	CX2345	0	mg/kg	SOLUTION	QD	INTRAVENOUS		Left forelimb	INFUSION	Saline	5	mL	2008-04-08T09:00	2008-04-08T09:10	1	1	PT10M
2	12345	EX	12345002	2	CX2345	20	mg/kg	SOLUTION	QD	INTRAVENOUS	AB789.1	Left forelimb	INFUSION	Saline	5	mL	2008-04-09T09:00	2008-04-09T09:10	2	2	PT10M
3	12345	EX	12345003	3	CX2345	40	mg/kg	SOLUTION	QD	INTRAVENOUS	AB789.1	Left forelimb	INFUSION	Saline	5	mL	2008-04-10T09:00	2008-04-10T09:10	3	3	PT10M
4	12345	EX	12345004	4	CX2345	120	mg/kg	SOLUTION	QD	INTRAVENOUS	AB789.1	Left forelimb	INFUSION	Saline	5	mL	2008-04-11T09:00	2008-04-11T09:10	4	4	PT10M

Example 2: Capsule Dosing Represented as 1 Record per Dose

This is an example of an EX dataset for a dose-ranging study where a pair of animals (non-rodent) is administered the test article at ascending doses until the maximum-tolerated dose is reached. There was a minimum 2-day washout period between doses. Before each dose administration, the animals were food deprived for 12 hours and were fed for 1 hour after dose administration on the days of treatment.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXTRTV	EXSTDTC	EXENDTC	EXSTDY	EXENDY	EXTPT	EXTPTREF
1	12345	EX	12345001	1	FDA23456	20	mg/kg	CAPSULE	QD	ORAL	FDA.099		2002-10-01	2002-10-01	1	1	12 hours	PREVIOUS FEED
2	12345	EX	12345001	2	FDA23456	60	mg/kg	CAPSULE	QD	ORAL	FDA.099		2002-10-04	2002-10-04	4	4	12 hours	PREVIOUS FEED
3	12345	EX	12345001	3	FDA23456	100	mg/kg	CAPSULE	QD	ORAL	FDA.099		2002-10-08	2002-10-08	8	8	12 hours	PREVIOUS FEED
4	12345	EX	12345001	4	FDA23456	75	mg/kg	CAPSULE	QD	ORAL	FDA.099		2002-10-11	2002-10-11	11	11	12 hours	PREVIOUS FEED
5	12345	EX	12345002	5	FDA23456	20	mg/kg	CAPSULE	QD	ORAL	FDA.099		2002-10-01	2002-10-01	1	1	12 hours	PREVIOUS FEED
6	12345	EX	12345002	6	FDA23456	60	mg/kg	CAPSULE	QD	ORAL	FDA.099		2002-10-04	2002-10-04	4	4	12 hours	PREVIOUS FEED
7	12345	EX	12345002	7	FDA23456	100	mg/kg	CAPSULE	QD	ORAL	FDA.099		2002-10-08	2002-10-08	8	8	12 hours	PREVIOUS FEED
8	12345	EX	12345002	8	FDA23456	75	mg/Kg	CAPSULE	QD	ORAL	FDA.099		2002-10-11	2002-10-11	11	11	12 hours	PREVIOUS FEED

Example 3: 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 treatment 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 treatment. 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 treatment throughout the study. With respect to timing of doses, the sponsor only collected the start and stop dates of uninterrupted periods of treatment.

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

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Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXTRTV	EXADJ	EXSTDTC	EXENDTC	EXSTDY	EXENDY
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 4: Dermal Dosing with 1 Record for Multiple Days of Dosing

This is an example of an EX dataset for selected animals from a typical nonclinical study. The test article was administered twice a day by dermal application for 91 days, after which the animals were euthanized. The test article was applied to 10% of the body surface. The formulation was administered as supplied at 0.01%. The exposure was calculated using the weekly body weights. In the example below, results are shown for 1 subject during the first five weeks of the study.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXLOC	EXTRTV	EXVAMT	EXVAMTU	EXSTDTC	EXENDTC	EXSTDY	EXENDY
1	12345	EX	12345001	1	E453	0.28	mg/kg	LOTION	BID	TOPICAL	RTE567	DORSAL	Diethyl Sebacate, JPE (5.0%), Benzyl Alcohol, NF (1.0%), White Petrolatum, USP (10.0%)	0.05	mL	2007-01-07	2007-01-13	1	7
2	12345	EX	12345001	2	E453	0.29	mg/kg	LOTION	BID	TOPICAL	RTE567	DORSAL	Diethyl Sebacate, JPE (5.0%), Benzyl Alcohol, NF (1.0%), White Petrolatum, USP (10.0%)	0.06	mL	2007-01-14	2007-01-20	8	14
3	12345	EX	12345001	3	E453	0.28	mg/kg	LOTION	BID	TOPICAL	RTE567	DORSAL	Diethyl Sebacate, JPE (5.0%), Benzyl Alcohol, NF (1.0%), White Petrolatum, USP (10.0%)	0.06	mL	2007-01-21	2007-01-27	15	21
4	12345	EX	12345001	4	E453	0.26	mg/kg	LOTION	BID	TOPICAL	RTE567	DORSAL	Diethyl Sebacate, JPE (5.0%), Benzyl Alcohol, NF (1.0%), White Petrolatum, USP (10.0%)	0.05	mL	2007-01-28	2007-02-05	22	30
5	12345	EX	12345001	5	E453	0.27	mg/kg	LOTION	BID	TOPICAL	RTE567	DORSAL	Diethyl Sebacate, JPE (5.0%), Benzyl Alcohol, NF (1.0%), White Petrolatum, USP (10.0%)	0.05	mL	2007-02-06	2007-02-12	31	37

Example 5: Diet Dosing

This is an example of an EX dataset for selected animals; subjects were randomized to 1 of 4 treatment groups. The animals were group housed, so exposure has been derived for each animal. The test article was administered in the diet for 13 weeks at concentrations of 0 ppm, 300 ppm, 750 ppm, and 1500 ppm. The administered dose was calculated based on food consumption and body weight, using the following formula:

Exposure = [Dietary concentration (mg/kg) × Food consumption (g/rat/day)] / Body weight (g)

Rows 1-3: Subject 12345001 received test article PHJU during weeks 1, 2, and 3.

Row 1: EXLOT shows the dietary concentration for week 1 dosing using only lot ABC1.

Row 2: EXLOT shows that 2 lots of PHJU were mixed into 1 dietary concentration for week 2 dosing; therefore, EXLOT is concatenated as ABC1;ABC2.

Row 3: EXLOT shows the dietary concentration for week 3 dosing, using only lot ABC2.

Rows 4-6: EXLOT shows lot DEF1 was used for each dietary concentration of PHJU given to subject 12345025 during weeks 1-3.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXTRTV	EXSTDTC	EXENDTC	EXSTDY	EXENDY
1	12345	EX	12345001	1	PHJU	26.91	mg/kg/day	POWDER	AD LIBITUM	DIETARY	ABC1	FEED	2007-06-07T07:30	2007-06-13T07:30	1	7
2	12345	EX	12345001	2	PHJU	23.43	mg/kg/day	POWDER	AD LIBITUM	DIETARY	ABC1;ABC2	FEED	2007-06-13T7:30	2007-06-20 T7:30	7	14
3	12345	EX	12345001	3	PHJU	20.63	mg/kg/day	POWDER	AD LIBITUM	DIETARY	ABC2	FEED	2007-06-20T7:30	2007-06-27T7:30	14	21

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Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXTRTV	EXSTDTC	EXENDTC	EXSTDY	EXENDY
4	12345	EX	12345025	4	PHJU	53.52	mg/kg/day	POWDER	AD LIBITUM	DIETARY	DEF1	FEED	2007-06-07T7:30	2007-06-13T7:30	1	7
5	12345	EX	12345025	5	PHJU	46.87	mg/kg/day	POWDER	AD LIBITUM	DIETARY	DEF1	FEED	2007-06-13T7:30	2007-06-20T7:30	7	14
6	12345	EX	12345025	6	PHJU	43.53	mg/kg/day	POWDER	AD LIBITUM	DIETARY	DEF1	FEED	2007-06-20T7:30	2007-06-27T7:30	17	21

Example 6: Continuous Intravenous Dosing with Periods of Test Article and Periods of Saline

This is an example of an EX dataset for 1 animal from a continuous infusion study. The infusion pump was set in a 24-hour cycle to deliver the test article over a duration of 6 hours and saline for 18 hours. In the 6-hour dosing period, the animals received 10 ug/kg/hour; in the remaining period they received only saline in a constant infusion rate of 1 mL/kg/hour. In this example, results are shown for subject 12345 during the first 3 24-hour cycles. The animal did not receive the whole dose on day 3 due to a pump failure.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXMETHOD	EXTRTV	EXVAMT	EXVAMTU	EXADJ	EXSTDTC	EXENDTC	EXSTDY	EXENDY
1	12345	EX	12345001	1	GF2145	10	ug/kg/hour	SOLUTION	CONTINUOUS	INTRAVENOUS	2013.34	CONTINUOUS INFUSION	Saline	1	mL/kg/hour		2013-01-08T08:00	2013-01-08T14:00	1	1
2	12345	EX	12345001	2	GF2145	0	ug/kg/hour	SOLUTION	CONTINUOUS	INTRAVENOUS		CONTINUOUS INFUSION	Saline	1	mL/kg/hour		2013-01-08T14:00	2013-01-09T08:00	1	2
3	12345	EX	12345001	3	GF2145	10	ug/kg/hour	SOLUTION	CONTINUOUS	INTRAVENOUS	2013.34	CONTINUOUS INFUSION	Saline	1	mL/kg/hour		2013-01-09T08:00:00	2013-01-09T14:00	2	2
4	12345	EX	12345001	4	GF2145	0	ug/kg/hour	SOLUTION	CONTINUOUS	INTRAVENOUS		CONTINUOUS INFUSION	Saline	1	mL/kg/hour		2013-01-09T14:00	2013-01-10T08:00	2	3
5	12345	EX	12345001	5	GF2145	8	ug/kg/hour	SOLUTION	CONTINUOUS	INTRAVENOUS	2013.34	CONTINUOUS INFUSION	Saline	1	mL/kg/hour	Pump failure	2013-01-10T08:00:00	2013-01-10T14:00	3	3
6	12345	EX	12345001	6	GF2145	0	ug/kg/hour	SOLUTION	CONTINUOUS	INTRAVENOUS		CONTINUOUS INFUSION	Saline	1	mL/kg/hour		2013-01-10T14:00	2013-01-11T08:00	3	4

Example 7: Intraperitoneal Exposure with 1 Record for Multiple Dosing Days

This is an example of an EX dataset for selected animals from a toxicology study using a vehicle and positive control groups with once-daily intraperitoneal administration for 5 days. Subjects were randomized to 1 of 5 groups with 1 test article at 3 different treatment levels (10 mg/kg, 25 mg/kg, and 100 mg/kg), 1 vehicle control and a positive control group receiving 40 mg/kg cyclophosphamide. In this example, results are shown for five subjects, 1 in each group with 1 record per constant dosing interval of five days.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXTRTV	EXVAMT	EXVAMTU	EXSTDTC	EXENDTC	EXSTDY	EXENDY	EXDUR	
1	12345	EX	12345001	1	RP187	Cyclophosphamide	0	mg/kg	SOLUTION	QD	INTRAPERITONEAL		Saline	5	mL	2013-08-20	2013-08-24	1	5	PT5D
2	12345	EX	12345002	2	RP187	10	mg/kg	SOLUTION	QD	INTRAPERITONEAL	Ta.1308	Saline	5	mL	2013-08-20	2013-08-24	1	5	PT5D	
3	12345	EX	12345003	3	RP187	25	mg/kg	SOLUTION	QD	INTRAPERITONEAL	Ta.1308	Saline	5	mL	2013-08-20	2013-08-24	1	5	PT5D	
4	12345	EX	12345004	4	RP187	100	mg/kg	SOLUTION	QD	INTRAPERITONEAL	Ta.1308	Saline	5	mL	2013-08-20	2013-08-24	1	5	PT5D	
5	12345	EX	12345005	5	Cyclophosphamide	40	mg/kg	SOLUTION	QD	INTRAPERITONEAL	Pc.1308	Saline	5	mL	2013-08-20	2013-08-24	1	5	PT5D	

Example 8: 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 treatments 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 treatment is listed as the 2 treatment 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

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Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXTRTV	EXVAMT	EXVAMTU	EXSTDTC	EXSTDY
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

Example 9: Subcutaneous Dosing with Multiple Sites

This is an example of an EX dataset for selected animals from a local toxicity study including where local tolerance assessment is the most important endpoint. The identification of injection sites is carried throughout the study for all measurements performed across domains.

The 4 injection sites per subject received a different treatment each. Injection site 1 serves as control, receiving only saline. Note that the FOCID variable completes the natural key, providing a level of granularity that would otherwise be missing with existing variables.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	FOCID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXTRTV	EXVAMT	EXVAMTU	EXSTDTC	EXSTDY
1	12345	EX	12345001	Injection site 1	1	RP187	0	mg/kg	SOLUTION	QD	SUBCUTANEOUS		Saline	0.2	mL	2013-08-20	1
2	12345	EX	12345001	Injection site 2	2	RP187	10	mg/kg	SOLUTION	QD	SUBCUTANEOUS	Ta.1308	Saline	0.2	mL	2013-08-20	1
3	12345	EX	12345001	Injection site 3	3	RP187	25	mg/kg	SOLUTION	QD	SUBCUTANEOUS	Ta.1308	Saline	0.2	mL	2013-08-20	1
4	12345	EX	12345001	Injection site 4	4	RP187	100	mg/kg	SOLUTION	QD	SUBCUTANEOUS	Ta.1308	Saline	0.2	mL	2013-08-20	1
5	12345	EX	12345002	Injection site 1	1	RP187	0	mg/kg	SOLUTION	QD	SUBCUTANEOUS		Saline	0.2	mL	2013-08-20	1
6	12345	EX	12345002	Injection site 2	2	RP187	10	mg/kg	SOLUTION	QD	SUBCUTANEOUS	Ta.1308	Saline	0.2	mL	2013-08-20	1
7	12345	EX	12345002	Injection site 3	3	RP187	25	mg/kg	SOLUTION	QD	SUBCUTANEOUS	Ta.1308	Saline	0.2	mL	2013-08-20	1
8	12345	EX	12345002	Injection site 4	4	RP187	100	mg/kg	SOLUTION	QD	SUBCUTANEOUS	Ta.1308	Saline	0.2	mL	2013-08-20	1

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Example 10: Oral Dosing Reported with 2 Records for Each Day of Dosing; 2 Test Articles Administered per Treatment Group; Treatments Administered Consecutively

In this example, each treatment group received daily administration of 2 test articles in separate doses, one after the other. Each test article utilized a different vehicle, and a control group received both vehicles.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXLOT	EXTRTV	EXSTDTC	EXSTDY
1	12345	EX	12345001	1	TA1	0	mg/kg	SUSPENSION	QD	ORAL		Vehicle 1	2007-01-01T08:52	1
2	12345	EX	12345001	2	TA2	0	mg/kg	SUSPENSION	QD	ORAL		Vehicle 2	2007-01-01T08:53	1
3	12345	EX	12345001	3	TA1	0	mg/kg	SUSPENSION	QD	ORAL		Vehicle 1	2007-01-02 T08:54	2
4	12345	EX	12345001	4	TA2	0	mg/kg	SUSPENSION	QD	ORAL		Vehicle 2	2007-01-02 T08:55	2
5	12345	EX	12345001	5	TA1	0	mg/kg	SUSPENSION	QD	ORAL		Vehicle 1	2007-01-03 T08:56	3
6	12345	EX	12345001	6	TA2	0	mg/kg	SUSPENSION	QD	ORAL		Vehicle 2	2007-01-03 T08:57	3
7	12345	EX	12345002	7	TA1	20	mg/kg	SUSPENSION	QD	ORAL	ABC123	Vehicle 1	2007-01-01 T08:58	1
8	12345	EX	12345002	8	TA2	40	mg/kg	SUSPENSION	QD	ORAL	CDE456	Vehicle 2	2007-01-01 T08:59	1
9	12345	EX	12345002	9	TA1	20	mg/kg	SUSPENSION	QD	ORAL	ABC123	Vehicle 1	2007-01-02 T08:40	2
10	12345	EX	12345002	10	TA2	40	mg/kg	SUSPENSION	QD	ORAL	CDE456	Vehicle 2	2007-01-02 T08:41	2
11	12345	EX	12345002	11	TA1	20	mg/kg	SUSPENSION	QD	ORAL	ABC123	Vehicle 1	2007-01-03 T08:42	3
12	12345	EX	12345002	12	TA2	40	mg/kg	SUSPENSION	QD	ORAL	CDE456	Vehicle 2	2007-01-03 T08:43	3
13	12345	EX	12345003	13	TA1	40	mg/kg	SUSPENSION	QD	ORAL	ABC123	Vehicle 1	2007-01-01 T08:44	1
14	12345	EX	12345003	14	TA2	60	mg/kg	SUSPENSION	QD	ORAL	CDE456	Vehicle 2	2007-01-01 T08:45	1
15	12345	EX	12345003	15	TA1	40	mg/kg	SUSPENSION	QD	ORAL	ABC123	Vehicle 1	2007-01-02 T08:46	2
16	12345	EX	12345003	16	TA2	60	mg/kg	SUSPENSION	QD	ORAL	CDE456	Vehicle 2	2007-01-02 T08:47	2
17	12345	EX	12345003	17	TA1	40	mg/kg	SUSPENSION	QD	ORAL	ABC123	Vehicle 1	2007-01-03 T08:48	3
18	12345	EX	12345003	18	TA2	60	mg/kg	SUSPENSION	QD	ORAL	CDE456	Vehicle 2	2007-01-03 T08:49	3

6.2 Events

6.2.1 Disposition – DS

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

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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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	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 sponsor-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

6.2.1.1 Assumptions for Disposition (DS) Domain Model

1. Definition:
   a. 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.
   b. Disposition records are required for carcinogenicity studies to support the creation of the tumor.xpt file.
   c. The DSDECOD values of MISSING, REMOVED FROM STUDY ALIVE, RECOVERY SACRIFICE, and NON-MORIBUND SACRIFICE do not map to the DTHSACST variable of the tumor.xpt (see Appendix C2, Mapping DSDECOD to DTHSACST).
2. DS Description and coding: DSTERM is not under controlled terminology, but should be mapped to controlled terminology for DSDECOD.
3. Timing variables:
   a. 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). The use of an interval of uncertainty, as described in Section 4.4.2, Date/Time Precision, cannot be used for DSSTDTC.

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6.2.1.2 Examples for Disposition (DS) Domain Model

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.ds.

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 sponsor 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

Example 3

This is another example of a complex DS dataset. It shows 2 different types of disposition events for subjects in this study: 1 for subjects that were sacrificed and another for a subject that was removed from the study alive.

Rows 1-3: In this example, DSSEQ has been given sequential numbers, to demonstrate that for the DS domain the DSSEQ makes no difference since there is 1 and only 1 record per subject. Note that although the time of disposition is not recorded in this example, the values still uphold the ISO 8601 format.

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Rows 1-2: 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.

Row 3: The original value of "Removed for washout" was recorded in the DSTERM column and mapped to the controlled term "REMOVED FROM STUDY ALIVE" in the DSDECOD column.

ds.xpt

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSSTDTC	DSSTDY	DSNOMDY
1	840522	DS	xx-xx90	1	Final Phase sacrifice	TERMINAL SACRIFICE	1996-02-06	28	28
2	840522	DS	xx-xx91	2	Final Phase sacrifice	TERMINAL SACRIFICE	1996-02-06	28	28
3	840522	DS	xx-xx92	3	Removed for washout	REMOVED FROM STUDY ALIVE	1996-02-06	28	28

6.3 Findings

6.3.1 Body Weight – BW

bw.xpt, Body Weight - Findings. One record per test per observation time per subject, Tabulation.

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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 sponsor defined.	Exp
BWFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status. The value should by Y or null.	Perm
BWEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Y if the result should be excluded from all calculations, otherwise null.	Perm
BWREASEX	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	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 sponsor-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
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

6.3.1.1 Assumptions for Body Weight (BW) Domain Model

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. Body weight gains are submitted in the Body Weight Gain (BG) domain.

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6.3.1.2 Examples for Body Weight (BW) Domain Model

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	BWTESTCD	BWTEST	BWORRES	BWORRESU	BWSTRESC	BWSTRESN	BWSTRESU	BWSTAT	BWREASND	BWBLFL	BWFAST	BWEXCLFL	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
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

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6.3.2 Body Weight Gain – BG

bg.xpt, Body Weight Gains - Findings. One record per test per interval per subject, Tabulation.

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	BG	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
BGSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
BGTESTCD	Test Short Name	Char	(BGTESTCD)	Topic	Short name of the measurement, test, or examination described in BGTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in BGTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). BGTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
BGTEST	Test Name	Char	(BGTEST)	Synonym Qualifier	Long name for BGTESTCD. The value in BGTEST cannot be longer than 40 characters.	Req
BGORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
BGORRESU	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
BGSTRESC	Standardized Result in Character Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from BGORRES in a standard format or standard units. BGSTRESC should store all results or findings in character format; if results are numeric, they should also be submitted in numeric format in BGSTRESN.	Exp
BGSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of BGSTRESC. BGSTRESN should store all numeric test results or findings.	Exp
BGSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for BGSTRESC and BGSTRESN.	Exp
BGSTAT	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 BGORRES.	Perm
BGREASND	Reason Not Done	Char		Record Qualifier	Describes why BGSTAT is NOT DONE, such as MISSING BODY WEIGHT.	Perm
BGEXCLFL	Exclusion Flag	Char	(NY)	Record Qualifier	Y if the result should be excluded from all calculations, otherwise null.	Perm
BGREASEX	Reason for Exclusion	Char		Record Qualifier	The reason the result should be excluded from all calculations. Used only when BGEXCLFL is Y.	Perm
BGDTC	Date/Time Animal Weighed	Char	ISO 8601	Timing	Date/Time of the start of the weight interval, in ISO 8601 format.	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
BGENDTC	End Date/Time Animal Weighed	Char	ISO 8601	Timing	Date/Time of the end of the weight interval, in ISO 8601 format.	Exp
BGDY	Study Day of Start of Interval	Num		Timing	Study day of the start of the weight interval, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
BGENDY	Study Day of End of Weight Interval	Num		Timing	Study day of the end of the weight interval, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

6.3.2.1 Assumptions for Body Weight Gain (BG) Domain Model

1. Definition: Body weight gain is the actual difference between 2 body weight measurements for any given interval for a subject. This is most commonly shown as the difference between 2 consecutive body weight measurements.
2. Additional BGTEST/BGTESTCD values may be used for alternative representations of body weight gain measurements (e.g., percentage gain, average gain).
3. BGORRESU may change over the course of the study (e.g., g to kg), but BGSTRESU should remain consistent throughout the course of the study.
4. If 1 of the 2 body weights needed for the calculation is missing, BGSTAT should be "NOT DONE," and BGREASND could be "MISSING BODY WEIGHT."
5. If 1 of the 2 body weights needed for the calculation has an exclusion flag, then the corresponding BG values should also have BGEXCL = "Y". The BGREASEX value should be "EXCLUDED BODY WEIGHT".
6. Note that the BGDTC and BGENDTC variables are used for the start and end of the period as described in Section 4.4.6, Representing Timing in a Findings Domain.

6.3.2.2 Examples for Body Weight Gain (BG) Domain Model

Example 1

Row 1: Shows body weight gain value recorded in standard units.

Rows 2-11: Show 10 records for body weight gain at weekly intervals for a single animal.

Rows 4-5: Show excluded body weight gains due to excluded body weight.

Row 7: Shows a decrease in body weight.

Rows 8-9: Show the proper use of the BGSTAT variable to indicate "NOT DONE" when one of the the body weights for the interval was missing.

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Row	STUDYID	DOMAIN	USUBJID	BGSEQ	BGTESTCD	BGTEST	BGORRES	BGORRESU	BGSTRESC	BGSTRESN	BGSTRESU	BGSTAT	BGREASND	BGEXCLFL	BGREASEX	BGDTC	BGENDTC	BGDY	BGENDY
1	ABC	BG	ABC-001-001	1	BWGAIN	Body Weight Gain	58.3	g	58.3	58.3	g					2008-04-27	2008-05-04	1	8
2	ABC	BG	ABC-001-001	2	BWGAIN	Body Weight Gain	43.0	g	43.0	43.0	g					2008-05-04	2008-05-11	8	15
3	ABC	BG	ABC-001-001	3	BWGAIN	Body Weight Gain	62.2	g	62.2	62.2	g					2008-05-11	2008-05-18	15	22
4	ABC	BG	ABC-001-001	4	BWGAIN	Body Weight Gain	15.1	g	15.1	15.1	g			Y	EXCLUDED BODY WEIGHT	2008-05-18	2008-05-25	22	29
5	ABC	BG	ABC-001-001	5	BWGAIN	Body Weight Gain	48.8	g	48.8	48.8	g			Y	EXCLUDED BODY WEIGHT	2008-05-25	2008-06-01	29	36
6	ABC	BG	ABC-001-001	6	BWGAIN	Body Weight Gain	44.4	g	44.4	44.4	g					2008-06-01	2008-06-08	36	43
7	ABC	BG	ABC-001-001	7	BWGAIN	Body Weight Gain	-5.1	g	-5.1	-5.1	g					2008-06-08	2008-06-15	43	50
8	ABC	BG	ABC-001-001	8	BWGAIN	Body Weight Gain						NOT DONE	MISSING BODY WEIGHT			2008-06-15		50	
9	ABC	BG	ABC-001-001	9	BWGAIN	Body Weight Gain						NOT DONE	MISSING BODY WEIGHT				2008-06-29		64
10	ABC	BG	ABC-001-001	10	BWGAIN	Body Weight Gain	25.1	g	25.1	25.1	g					2008-06-29	2008-07-06	64	71
11	ABC	BG	ABC-001-001	11	BWGAIN	Body Weight Gain	27.8	g	27.8	27.8	g					2008-07-06	2008-07-13	71	78

Example 2

Row 1: Shows body weight gain value recorded as an absolute gain for the interval.

Row 2: Shows body weight gain value recorded as the average body weight gain per day.

Row 3: Shows body weight gain value recorded as the percentage body weight gain for the interval.

bg.xpt

Row	STUDYID	DOMAIN	USUBJID	BGSEQ	BGTESTCD	BGTEST	BGORRES	BGORRESU	BGSTRESC	BGSTRESN	BGSTRESU	BGDTC	BGENDTC	BGDY	BGENDY
1	ABC	BG	ABC-001-001	1	BWGAIN	Body Weight Gain	58.3	g	58.3	58.3	g	2008-04-27	2008-05-04	1	8
2	ABC	BG	ABC-001-001	2	BWGAINA	Average Body Weight Gain	8.3	g/day	8.3	8.3	g/day	2008-04-27	2008-05-04	1	8
3	ABC	BG	ABC-001-001	3	BWGAINP	Percentage Body Weight Gain	16.7	%	16.7	16.7	%	2008-04-27	2008-05-04	1	8

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6.3.3 Clinical Observations – CL

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

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. An example could be a drug application site, e.g. "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 treatment group number.	Perm
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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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
CLREASEX	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	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	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 sponsor-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 sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm
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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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	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	Timing	Date/Time of the reference time point, CLTPTREF.	Perm

6.3.3.1 Assumptions for Clinical Observations (CL) Domain Model

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 sponsor 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, Microscopic Findings, and Tumor 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).

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6.3.3.2 Examples for Clinical Observations (CL) Domain Model

Example 1

This example shows clinical signs captured in the collection system using categorization by CLSCAT 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	Pale		2003-01-20T15:45:39	7	7
3	13456	CL	13456-01	3	EY	Eyes	CLINICAL SIGNS	Squinting	Squinting		2003-01-20T15:45:55	7	7
4	13456	CL	13456-02	1	GO	General Observations	CLINICAL SIGNS	Salivation	Salivation		2003-01-28T15:44:42	15	15
5	13456	CL	13456-02	2	GO	General Observations	CLINICAL SIGNS	Tremors; >10 mins	Tremors		2003-01-28T15:44:42	15	15
6	13456	CL	13456-03	1	GO	General Observations	CLINICAL SIGNS	Normal	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 CLSCAT 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 CLSTRESC.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	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

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Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	CLLOC	CLDTC	CLDY	CLNOMDY
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	CLSTRESC	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	CLSTRESC	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

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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.

Rows 1-5: 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 8.5.1, 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

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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.

Rows 1-6: CLTPT is used to specify the observation session in which the observations were collected. CLELTM 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.

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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 physical examinations 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 1-5: CLTESTCD and CLTEST are used to describe the tests whose results were recorded during the examination. CLRESCAT was used to further categorize data during analysis

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	CLRESCAT	CLLOC	CLSEV	CLDTC	CLDY	CLNOMDY
1	13456	CL	13456-01	1	OE	Oral Examination	PHYSICAL EXAM	Teeth broken	Teeth broken	Facial			2005-12-15T09:15:16	1	1
2	13456	CL	13456-01	2	EA	External Appearance	PHYSICAL EXAM	Hordeolum, Mild, Right Eye	Hordeolum	Facial	Right Eye	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	Facial	Left Eye		2005-12-15T09:22:51	1	1
4	13456	CL	13456-02	1	PS	Pelage/Skin	PHYSICAL EXAM	Skin discolored	Skin discolored	Skin			2005-12-16T07:02:58	2	2
5	13456	CL	13456-02	2	RE	Respiration	PHYSICAL EXAM	Breathing difficult, Severe	Breathing difficult	Other		Severe	2005-12-16T07:02:58	2	2

Example 10

This example shows physical examinations captured in the collection system using categorization by CLSCAT. CLTESTCD and CLTEST are used to capture the collection system's breakdown of observations.

Rows 1-5: CLTESTCD and CLTEST are used to describe the tests whose results were recorded during the examination. CLSCAT is used to break tests into multiple categories as recorded during the examination.

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Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLSCAT	CLORRES	CLSTRESC	CLLOC	CLSEV	CLDTC	CLDY	CLNOMDY
1	13456	CL	13456-01	1	OE	Oral Examination	PHYSICAL EXAM	Whole Body Appearance	Teeth broken	Teeth broken			2005-12-15T09:15:16	1	1
2	13456	CL	13456-01	2	EA	Eye Examination	PHYSICAL EXAM	Whole Body Appearance	Hordeolum, Mild, Right Eye	Hordeolum	Right Eye	Mild	2005-12-15T09:20:42	1	1
3	13456	CL	13456-01	3	EA	Eye Examination	PHYSICAL EXAM	Eye Appearance	Material around eyes, Red, Left Eye	Material around eyes, Red	Left Eye		2005-12-15T09:22:51	1	1
4	13456	CL	13456-02	1	FE	Fur Examination	PHYSICAL EXAM	Whole Body Appearance	Fur discolored	Fur discolored			2005-12-16T07:02:58	2	2
5	13456	CL	13456-02	2	RE	Respiratory Examination	PHYSICAL EXAM	Respiration	Breathing difficult, Severe	Breathing difficult		Severe	2005-12-16T07:02:58	2	2

Example 11

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	CLORRES	CLSTRESC	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 12

This example shows ophthalmoscopic examinations captured in the collection system using result categorization applied after collection for reporting purposes. CLTESTCD and CLTEST are used to capture the collection system's breakdown of observations.

Rows 1-5: CLRESCAT was used to categorize data during analysis for further categorization of data.

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Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	CLRESCAT	CLLOC	CLSEV	CLDTC	CLDY	CLNOMDY
1	13456	CL	13456-01	1	OP	Ophthalmoscopic Examination	OPHTHALMOLOGY	Nictitating membrane protruding, Left Eye	Nictitating membrane protruding	Facial	Left Eye		2005-12-15T09:15:16	1	1
2	13456	CL	13456-01	2	OP	Ophthalmoscopic Examination	OPHTHALMOLOGY	Chorioretinal hypoplasia, Moderate, Both Eyes	Chorioretinal hypoplasia	Facial	Both Eyes	Moderate	2005-12-15T09:20:42	1	1
3	13456	CL	13456-01	3	OP	Ophthalmoscopic Examination	OPHTHALMOLOGY	Conjunctivitis, Mild, Right Eye	Conjunctivitis	Facial	Right Eye	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	Facial	Left Eye	Severe	2005-12-16T07:02:58	2	2
5	13456	CL	13456-02	2	OP	Ophthalmoscopic Examination	OPHTHALMOLOGY	Iritis, Mild, Both Eyes	Iritis	Facial	Both Eyes	Mild	2005-12-16T07:02:58	2	2

Example 13

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	CLORRES	CLSTRESC	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 14

Clinical sign related to a finding in anther 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 MA record.

Row 1: CLSPID is used to identify the mass on the animal's jaw.

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Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLSPID	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	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	RELID
1	PY001002	CL	AA-12012		CLSEQ	1065		62
2	PY001002	MA	AA-12012		MASEQ	233		62

Example 15

This is an example for selected animals from a local toxicity study including where local tolerance assessment is the most important endpoint.

The identification of injection sites is carried throughout the study for all measurements performed across all domains. The values in FOCID would be expected to be used in Exposure (EX) to designate the dose administered at each injection site.

Note that the concept of "MASS 1" (in CLSPID) is different from "Injection site 1" (in FOCID); information in the FOCID variable is known prior to the start of the study, but the mass ID/sponsor identifier is assigned as part of the examination. FOCID thereby relates to the test, whereas CLSPID is related to 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	NORMAL	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	NORMAL	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	NORMAL	Left Scapula		2004-07-19	42	42
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	Abrasion	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

Example 16: Qualitative Food Consumption

This example shows multiple possibilities for presenting food consumption within the Clinical Observations domain when it is collected as text and reported as a qualitative measure.

Example 16a

Often when food consumption is collected qualitatively, it is done by exception: A record exists only when the value is not normal. "None" indicates that no feed was consumed, and "Low" indicates that the consumption was less than normal.

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cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	CLLOC	CLDTC	CLDY	CLNOMDY	CLTPT	CLTPTNUM
1	123456	CL	12345-01	1	QUALFC	Qualitative Food Consumption	CLINICAL SIGNS	Low	Low		2003-01-20T15:44:42	3	3	p.m. obs	3
2	123456	CL	12345-01	2	QUALFC	Qualitative Food Consumption	CLINICAL SIGNS	Low	Low		2003-01-21T15:45:39	4	4	p.m. obs	3
3	123456	CL	12345-01	3	QUALFC	Qualitative Food Consumption	CLINICAL SIGNS	None	None		2003-01-22T08:26:32	5	5	a.m. obs	1

Example 16b

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	CLORRES	CLSTRESC	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

Example 16c

This row shows a qualitative food consumption record collected as part of the protocol-specified afternoon check for signs of ill health or reaction to treatment. The CLSCAT shows the clinical sign subcategory, and the CLTPT indicates the specified collection timepoint.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLSCAT	CLORRES	CLSTRESC	CLLOC	CLDTC	CLDY	CLNOMDY	CLTPT	CLTPTNUM
1	321654	CL	321654-01	1	CS	Clinical Signs	CLINICAL SIGNS	SIRT/Cage Observations	Reduced Appetite	Reduced Appetite		2013-02-13T15:00:56	35	35	PM SIRT	3

Example 16d

In this example, food consumption activity is collected as part of the standard clinical signs and presented as qualitative assessment of the food consumption.

cl.xpt

Row	STUDYID	DOMAIN	USUBJID	CLSEQ	CLTESTCD	CLTEST	CLCAT	CLORRES	CLSTRESC	CLLOC	CLDTC	CLDY	CLNOMDY
1	345612	CL	345612-1000	1	EFC	Estimated Food Consumed	CLINICAL SIGNS	Food Qualitative 0%	Food Qualitative 0%		2013-02-13T15:00:00	35	35
2	345612	CL	345612-1001	2	EFC	Estimated Food Consumed	CLINICAL SIGNS	Food Qualitative 50%	Food Qualitative 50%		2013-02-13T15:01:00	35	35
3	345612	CL	345612-1002	3	EFC	Estimated Food Consumed	CLINICAL SIGNS	Food Qualitative 100%	Food Qualitative 100%		2013-02-13T15:02:00	35	35
4	345612	CL	345612-1003	4	EFC	Estimated Food Consumed	CLINICAL SIGNS	Other (see comment)	Other (see comment)		2013-02-13T15:03:00	35	35

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6.3.4 Death Diagnosis and Details – DD

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

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: TREATMENT RELATED, NONTREATMENT RELATED, UNDETERMINED, ACCIDENTAL, etc.	Perm
DDEVAL	Evaluator	Char		Record Qualifier	Role of the person who provided the evaluation. Examples: TOX PATHOLOGIST, PEER REVIEW, SPONSOR, VETERINARIAN.	Perm
DDDTC	Date/Time	Char	ISO 8601	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 sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

6.3.4.1 Assumptions for Death Diagnosis and Details (DD) Domain Model

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.

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6.3.4.2 Examples for Death Diagnosis And Details (DD) Domain Model

Example 1

This example shows sample death diagnosis findings.

Rows 1-3: The original result contains all text collected for the death diagnosis, whereas the DDSTRESC values have the standardized cause of death, DDDTC shows the date of subject disposition, and DDDY shows the study day.

dd.xpt

Row	STUDYID	DOMAIN	USUBJID	DDSEQ	DDTESTCD	DDTEST	DDORRES	DDSTRESC	DDDTC	DDDY
1	123456	DD	123456-1001	1	DEATHD	Death Diagnosis	SYSTEMIC: Gastric reflux	Gastric reflux	1996-03-06	360
2	123456	DD	123456-1002	1	DEATHD	Death Diagnosis	MUSCULOSKELETAL MISCELLANEOUS: Inflammation, SEVERE	Inflammation	1996-03-02	356
3	123456	DD	123456-1003	1	DEATHD	Death Diagnosis	SYSTEMIC: Amyloidosis	Amyloidosis	1996-03-05	359

Example 2

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

6.3.5 Food and Water Consumption – FW

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

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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 treatment 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
FWREASEX	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	Timing	Date/Time of the start of the observation in IS0 8601 format.	Exp
FWENDTC	End Date/Time of Observation	Char	ISO 8601	Timing	Date/Time of the end of the observation in IS0 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 sponsor-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 sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

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6.3.5.1 Assumptions for Food and Water Consumption (FW) Domain Model

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 as described in Section 4.4.6, Representing Timing in a Findings Domain.

6.3.5.2 Examples for Food And Water Consumption (FW) Domain Model

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

Rows 1-4: Show examples of food consumption records where the animals were housed together; therefore, USUBJID is null and the POOLID is populated.

Rows 1-4: Show FWORRES is populated with the total consumption per cage, and the FWSTRESC and FWSTRESN are populated with the calculation of the g/animal/week.

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Row 3: Shows Animals 301 and 302 housed together, and POOLDEF Rows 5-6 show Animals 301 and 302 as a pool C1-301-302. Note that the collection period was only 3 days, and a conversion was made to g/animal/week.

Row 4: Animal 301 died. Therefore, the USUBJID is not populated and a new POOLID is generated as demonstrated in POOLDEF Row 7. Note that the collection period was only 4 days, and a conversion was made to g/animal/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	1	FC	Food Consumption	400	g	200	200	g/animal/week	2003-01-20T15:44:42	2003-01-27T15:43:47	1	8
2	13456	FW		C1-201-202	2	FC	Food Consumption	420	g	210	210	g/animal/week	2003-01-20T15:44:42	2003-01-27T15:43:47	1	8
3	13456	FW		C1-301-302	3	FC	Food Consumption	176	g	205	205	g/animal/week	2003-01-20T15:44:42	2003-01-23T13:40:42	1	4
4	13456	FW		C1-302	4	FC	Food Consumption	69	g	120	120	g/animal/week	2003-01-23T13:40:42	2003-01-27T15:43:47	4	8

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
5	13456	C1-301-302	ABC1-301
6	13456	C1-301-302	ABC1-302
7	13456	C1-302	ABC1-302

Example 3

This example shows when the data collection system stores the FWORRES as the total cage consumption. Note that this is a variation on the data in Example 2.

Rows 1-3: Show FWORRES is populated with the total consumption per cage, with FWSTRESC and FWSTRESN copied from that; this lab reports consumption only at the cage level.

Rows 1-2: Show examples of food consumption records where the animals were housed together; therefore, USUBJID is null and POOLID is populated.

Row 3: Shows that subject 302 was in a cage alone; it was previously housed with a subject (301) that died. USUBJID is still null and the pool now consists of 1 animal.

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	400	400	g	2003-01-20T15:44:42	2003-01-27T15:43:47	1	7
2	13456	FW		C1-201-202	2	FC	Food Consumption	420	g	420	420	g	2003-01-20T15:44:42	2003-01-27T15:43:47	1	7
3	13456	FW		C1-302	3	FC	Food Consumption	120	g	120	120	g	2003-01-20T15:44:42	2003-01-27T15:43:47	1	7

pooldef.xpt

Row	STUDYID	POOLID	USUBJID
1	13456	C1-101-102	ABC1-101
2	13456	C1-101-102	ABC1-102

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Row	STUDYID	POOLID	USUBJID
3	13456	C1-201-202	ABC1-201
4	13456	C1-201-202	ABC1-202
5	13456	C1-302	ABC1-302

Example 4

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 5

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.

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fw.xpt

Row	STUDYID	DOMAIN	USUBJID	FWSEQ	FWTESTCD	FWTEST	FWORRES	FWORRESU	FWSTRESC	FWSTRESN	FWSTRESU	FWEXCLFL	FWEXREASEX	FWDTC	FWENDTC	FWDY	FWENDY
1	123456	FW	12345-101	1	FC	Food Consumption	220	g	220	220	g			2006-07-19T12:17:26	2006-07-19T16:05:47	1	1
2	123456	FW	12345-101	2	FCRELBW	Food Consumption Relative to Body Wt	20.2	g/kg	20.2	20.2	g/kg			2006-12-29	2006-12-29	160	160
3	123456	FW	12345-102	3	FC	Food Consumption	260	g	260	260	g	Y	FOOD WET	2006-07-19T12:17:26	2006-07-19T16:05:47	1	1
4	123456	FW	12345-101	4	WC	Water Consumption	220	mL	220	220	mL			2006-07-19T13:17:26	2006-07-19T17:05:47	1	1
5	123456	FW	12345-101	5	WCRELBW	Water Consumption Relative to Body Wt	20.2	mL/kg	20.2	20.2	mL/kg			2006-12-29	2006-12-29	160	160

6.3.6 Laboratory Test Results – LB

lb.xpt, Laboratory - Findings. One record per test per specimen per observation time per subject or pool, Tabulation.

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 treatment group number.	Perm
LBREFID	Specimen Identifier	Char		Identifier	Internal or external specimen identifier. Example: 1009570101.	Perm
LBSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
LBORNRLO	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
LBSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of LBSTRESC. LBSTRESN should store all numeric test results or findings.	Exp
LBSTRESU	Unit of the Standardized Result	Char	(UNIT)	Variable Qualifier	Standardized unit used for LBSTRESC 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 LBORNRLO and LBORNRHI, LBSTRNRLO and LBSTNRHI, or by LBSTNRC. Examples: NORMAL, ABNORMAL, HIGH, LOW. Sponsors 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 LBORRES.	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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 sponsor defined.	Exp
LBFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status. The value should be Y or null	Perm
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 sponsor 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 sponsor 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	Timing	Date/Time of specimen collection, in IS0 8601 format.	Exp
LBENDTC	End Date/Time of Specimen Collection	Char	ISO 8601	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 sponsor-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 sponsor-defined RFSTDTC variable in the Demographics (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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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	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	Timing	Date/Time of the reference time point, LBTPTREF	Perm

6.3.6.1 Assumptions for Laboratory Test Results (LB) Domain Model

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 definition:
   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. LBORNRLO and LBORNRHI 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"; LBORRES, 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.

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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 (see Section 8.5.1, Pool Definition - POOLDEF).
   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 (LBORNRLO and LBORNRHI), but not both. LBNRIND is used as a reference range indicator for the range being used.

6.3.6.2 Examples for Laboratory Test Results (LB) Domain Model

Example 1

Row 1: Shows a value collected in one unit, but converted to selected standard unit.

Rows 2-4: Show two 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 (LBBLFL = "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 LBORNRHI or LBSTNRHI; however, a sponsor may decide, e.g., to enter "0" into LBORNRLO and "199" in LBORNRHI. The sponsor 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	LBSTNRHI	LBNRIND	LBSTAT	LBREASND	LBSPEC	LBMETHOD	LBBLFL	LBFAST	LBDRVFL	LBUSCHFL	LBDTC	LBDY	LBNOMDY	LBNOMLBL
1	ABC	LB	ABC-001-001	1	ALB	Albumin	CLINICAL CHEMISTRY	LIVER FUNCTION	30	kg/m3	3.0	3	g/dL	3.5	5	LOW			SERUM		Y	Y			2006-07-19T08:30	1	1	Chemistry Day 1
2	ABC	LB	ABC-001-001	2	ALP	Alkaline Phosphatase	CLINICAL CHEMISTRY	GENERAL	398	U/L	398	398	U/L	40	160				SERUM			Y			2006-07-19T08:30	1	1	Chemistry Day 1
3	ABC	LB	ABC-001-001	3	ALP	Alkaline Phosphatase	CLINICAL CHEMISTRY	GENERAL	350	U/L	350	350	U/L	40	160				SERUM			Y			2006-07-20T12:30	2	1	Chemistry Day 1
4	ABC	LB	ABC-001-001	4	ALP	Alkaline Phosphatase	CLINICAL CHEMISTRY	GENERAL	374	U/L	374	374	U/L	40	160				SERUM		Y	Y	Y		2006-07-19T08:30	1	1	Chemistry Day 1
5	ABC	LB	ABC-001-001	5	WBC	Leukocytes	HEMATOLOGY		5.9	10^9/L	5.9	5.9	10^9/L	4	11				WHOLE BLOOD		Y	Y			2006-07-19T08:30	1	1	Hematology Day 1
6	ABC	LB	ABC-001-001	6	LYMLE	Lymphocytes/ Leukocytes	HEMATOLOGY	DIFFERENTIAL	6.7	%	6.7	6.7	%	25	40	LOW			WHOLE BLOOD		Y	Y			2006-07-19T08:30	1	1	Hematology Day 1
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				WHOLE BLOOD		Y	Y			2006-07-19T08:30	1	1	Hematology Day 1
8	ABC	LB	ABC-001-001	8	PH	pH	URINALYSIS		7.5		7.5	7.5		5.00	9.00				URINE		Y	Y			2006-07-19T08:30	1	1	Urinalysis Day 1
9	ABC	LB	ABC-001-001	9	ALB	Albumin	CLINICAL CHEMISTRY	LIVER FUNCTION									NOT DONE	Insufficient sample	SERUM						2006-07-24T09:00	6	6	Chemistry Day 6

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Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRLO	LBSTNRHI	LBNRIND	LBSTAT	LBREASND	LBSPEC	LBMETHOD	LBBLFL	LBFAST	LBDRVFL	LBUSCHFL	LBDTC	LBDY	LBNOMDY	LBNOMLBL
10	ABC	LB	ABC-001-001	10	CREAT	Creatinine	CLINICAL CHEMISTRY		0.9	mg/Dl	80	80	umol/L	44.201	114.9226				SERUM						2006-07-24T09:00	6	6	Chemistry Day 6
11	ABC	LB	ABC-001-001	11	WBC	Leukocytes	HEMATOLOGY		5.9	10^9/L	5.9	5.9	10^9/L	4	11				WHOLE BLOOD			Y			2006-07-24T09:00	6	6	Hematology Day 6
12	ABC	LB	ABC-001-001	12	CHOL	Cholesterol	CLINICAL CHEMISTRY		229	mg/dL	229	229	mg/dL	0	199	HIGH			SERUM						2006-07-24T09:00	6	6	Chemistry Day 6
13	ABC	LB	ABC-001-001	13	WBC	Leukocytes	HEMATOLOGY		9.8	10^9/L	9.8	9.8	10^9/L	4	11				WHOLE BLOOD					Y	2006-07-27T06:42	9	9	Unscheduled Hematology Day 9

supplb.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	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	LBORNRLO	LBORNRHI	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRLO	LBSTNRHI	LBSPEC	LBMETHOD	LBBLFL	LBDTC	LBENDTC	LBDY	LBENDY	LBNOMDY	LBTPT	LBTPTNUM	LBELTM	LBTPTREF	LBRFTDTC
1	ABC	LB	ABC-001-001	1	GLUCOSE	Glucose	URINALYSIS	7	mg/dL	1	15	0.39	0.39	mmol/L	0.06	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	ABC	LB	ABC-001-001	2	GLUCOSE	Glucose	URINALYSIS	11	mg/dL	1	15	0.61	0.61	mmol/L	0.06	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	ABC	LB	ABC-001-001	3	GLUCOSE	Glucose	URINALYSIS	9	mg/dL	1	15	0.50	0.50	mmol/L	0.06	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	ABC	LB	ABC-001-001	4	COLOR	Color	URINALYSIS	YELLOW				YELLOW					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.

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Row 2: Shows an example of a serum glucose test that was not performed because the sample was exhausted, and the sponsor felt it was necessary to report a record documenting the reason why the test was not performed.

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Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSTAT	LBREASND	LBSPEC	LBMETHOD	LBBLFL	LBDTC	LBDY	LBNOMDY
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	LBNOMDY
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 one point and not over a given interval.

Rows 1-2: Show an example of urine ketones tests performed for two animals. The test's values are categorical, using a list of NEGATIVE, TRACE, SMALL, MODERATE, and 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 two animals. The test's values are categorical, using a list of NEGATIVE, 1+, 2+, or 3+ which represent 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 two animals. The test's values are categorical, using a list of NEGATIVE, TRACE, 30, and 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.

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Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRC	LBSPEC	LBMETHOD	LBBLFL	LBDTC	LBDY	LBNOMDY
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
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

6.3.7 Macroscopic Findings – MA

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

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. An example could be a drug application site, e.g., "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
MAGRPID	Group Identifier	Char		Identifier	Used to tie together a block of related records in a single domain for a subject. This is not the treatment group number.	Perm
MAREFID	Specimen Reference Identifier	Char		Identifier	Internal or external specimen identifier. Example: 1009570101.	Perm
MASPID	Mass Identifier	Char		Identifier	Mass identifier such as MASS 1 or 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, such as severity, origin, classification, size, color, etc.	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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 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
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, SPONSOR 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	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 sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

6.3.7.1 Assumptions for Macroscopic Findings (MA) Domain Model

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.

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   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 (see Section 8.2, Relating Records - RELREC).

6.3.7.2 Examples for Macroscopic Findings (MA) Domain Model

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.

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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

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suppma.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	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	CODTC	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 CL, PM, MA, MI, and 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

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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/sponsor identifier is assigned as part of the examination. FOCID thereby qualifies the test, whereas CLSPID qualifies the result.

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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
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	Abrasion	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

6.3.8 Microscopic Findings – MI

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

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. An example could be a drug application site, e.g., "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 treatment group number.	Perm
MIREFID	Specimen Reference Identifier	Char		Identifier	Internal or external specimen identifier. Example: Specimen barcode number.	Perm
MISPID	Mass Identifier	Char		Identifier	Mass identifier such as MASS 1 or 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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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, elctron, confocal, etc).	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	(CHRNCTY)	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, orgain, 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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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
MIEVAL	Evaluator	Char		Record Qualifier	Role of the person who provided the evaluation. Examples: TOX PATHOLOGIST, PEER REVIEW, SPONSOR PATHOLOGIST.	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	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 sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

6.3.8.1 Assumptions for Microscopic Findings (MI) Domain Model

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.

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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; Example 2 shows 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.

QNAM (Variable Name)	QLABEL (Variable Label)	QVAL (Controlled Terms, Codelist, or Format)	Variable Definition
MIRESMOD	Result Modifiers	See Assumption 4.c	Key adjective(s) that further describe(s) or qualify a particular base pathologic process contained in MISTRESC.Key adjectives include a specific region affected by the base pathological process (e.g., Stomach – forestomach, cardia, fundus, pylorus), the specific cell type or tissue affected (e.g., neutrophilic, granulomatous, hepatocellular), tinctorial changes, types of pigments (e.g., hemosiderin), cell locations (e.g., extracellular, intracellular), inclusions (e.g., macrovesicular, microvesicular) and infectious agents (e.g., bacterial, fungal). Modifiers captured in other variables (e.g.

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QNAM (Variable Name)	QLABEL (Variable Label)	QVAL (Controlled Terms, Codelist, or Format)	Variable Definition
			SEV, DISTR, CHRON) should not be repeated in this variable.

f. The use of MIRESMOD does not preclude sponsors 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 sponsor-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, since they are not needed to create the tumor.xpt file (see Appendix C, Mapping To tumor.xpt File).

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". NOTE: Failure to adhere to this assumption will preclude generation of the tumor.xpt dataset.

   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.

6.3.8.2 Examples for Microscopic Findings (MI) Domain Model

Example 1

This example shows different types of histopathological findings for 3 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.

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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 MIGRPID 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 sponsor decided to include row 13 ("SITE, UNCERTAIN PRIMARY") to represent the source tumor. This record is related to rows 12 and 13 via the MIGRPID 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 MIGRPID 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 MIGRPID 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 sponsor decided to include a row to represent the base tumor (TFSPEC="SITE, UNCERTAIN PRIMARY") related to the metastasis row via the MIGRPID of 2, and defining it as the cause of death (MIDTHREL="Y"). Note: The use of "SITE, UNCERTAIN PRIMARY" is sponsor-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 demonstrates 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.

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Row	STUDYID	DOMAIN	USUBJID	MISEQ	MIGRPID	MISPID	MISTESTCD	MITEST	MIORRES	MISTRESC	MICHRON	MIDISTR	MIRESCAT	MISTAT	MIREASND	MISPEC	MIANTREG	MISPCCND	MISPCUFL	MILAT	MIDIR	MISEV	MIDTHREL	MIDTC	MIDY
1	123	MI	123-01	1			MIEXAM	Microscopic Examination	Amyloidosis, grade 2	AMYLOID			NON-NEOPLASTIC			TESTIS/EPIDIDYMIS						MILD		2015-10-27	365
2	123	MI	123-01	2			MIEXAM	Microscopic Examination	Inflammation, acute, grade 2	INFLAMMATION	ACUTE		NON-NEOPLASTIC			TESTIS/EPIDIDYMIS						MILD		2015-10-27	365
3	123	MI	123-01	3			MIEXAM	Microscopic Examination	Degeneration/regeneration, myofiber, grade 4	DEGENERATION/ REGENERATION			NON-NEOPLASTIC			MUSCLE, SKELETAL						MARKED		2015-10-27	365
4	123	MI	123-01	4			MIEXAM	Microscopic Examination						NOT DONE	Tissue not present for histologic examination no glandular tissue in section	GLAND, MAMMARY								2015-10-27	365
5	123	MI	123-01	5			MIEXAM	Microscopic Examination	Normal	UNREMARKABLE						GLAND, PARATHYROID								2015-10-27	365
6	123	MI	123-02	6			MIEXAM	Microscopic Examination	Inflammation, meninges, grade 5	INFLAMMATION			NON-NEOPLASTIC			BRAIN						SEVERE	Y	2015-05-15	200
7	123	MI	123-03	7			MIEXAM	Microscopic Examination	Hyperplasia, endometrial cystic, grade 3	HYPERPLASIA			NON-NEOPLASTIC			UTERUS						MODERATE		2015-10-27	365
8	123	MI	123-03	8		MASS 1	MIEXAM	Microscopic Examination	Adenoma: tubulostromal (benign neoplasm), left	ADENOMA, TUBULOSTROMAL, BENIGN			BENIGN			OVARY				LEFT			N	2015-10-27	365
9	123	MI	123-03	9	1	MASS 2	MIEXAM	Microscopic Examination	Sarcoma: endometrial stromal (malignant neoplasm), Primary	STROMAL SARCOMA, ENDOMETRIAL, MALIGNANT			MALIGNANT			UTERUS							N	2015-10-27	365
10	123	MI	123-03	10	2		MIEXAM	Microscopic Examination	Lymphoma: metastasis	LYMPHOMA, MALIGNANT			METASTATIC			UTERUS							U	2015-10-27	365
11	123	MI	123-03	11	1	MASS 3	MIEXAM	Microscopic Examination	Sarcoma: metastasis; Uterus was the primary site	SARCOMA, MALIGNANT			METASTATIC			VAGINA							N	2015-10-27	365
12	123	MI	123-03	12	2		MIEXAM	Microscopic Examination	Lymphoma: metastasis	LYMPHOMA, MALIGNANT			METASTATIC			VAGINA							U	2015-10-27	365
13	123	MI	123-03	13	2		MIEXAM	Microscopic Examination	Lymphoma: multicentric	LYMPHOMA, MALIGNANT			MALIGNANT			SITE, UNCERTAIN PRIMARY							Y	2015-10-27	365
14	123	MI	123-04	14			MIEXAM	Microscopic Examination	Infiltrate, mononuclear cell, grade 1	INFILTRATE			NON-NEOPLASTIC			MENINGES						MINIMAL		2015-10-27	365
15	123	MI	123-04	15			MIEXAM	Microscopic Examination	Atrophy, multifocal, grade 2	ATROPHY		MULTIFOCAL	NON-NEOPLASTIC			TESTIS						MILD		2015-10-27	365
16	123	MI	123-04	16			MIEXAM	Microscopic Examination	Intra-alveolar hemorrhage, right, grade 2	HEMORRHAGE			NON-NEOPLASTIC			LUNG	CRANIAL LOBE			RIGHT		MILD		2015-10-27	365
17	123	MI	123-04	17			MIEXAM	Microscopic Examination	Cyst, right, anterior	CYST			NON-NEOPLASTIC			KIDNEY				RIGHT	ANTERIOR			2015-10-27	365
18	123	MI	123-05	18			MIEXAM	Microscopic Examination	Inflammation, moderate, chronic, multifocal, mucosal, forestomach, grade 3	INFLAMMATION	CHRONIC	MULTIFOCAL	NON-NEOPLASTIC			STOMACH						MODERATE		2015-10-27	365
19	123	MI	123-06	19			MIEXAM	Microscopic Examination	Hepatocellular carcinoma (malignant neoplasm without metastasis), incidental	CARCINOMA, HEPATOCELLULAR, MALIGNANT			MALIGNANT			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.

co.xpt

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 one 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.

mi.xpt

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	MIEXAM	Microscopic Examination	Necrosis-hepatocytes in centrilobular area surrounded by slight acute inflammation with moderate hemorrhage	NECROSIS			LIVER				1991-05-17	91
2	ABC	MI	ABC-101	2	1	101-A1	MIEXAM	Microscopic Examination	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	MIEXAM	Microscopic Examination	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

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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	MIEXAM	Microscopic Examination	Subcutaneous Inflammation, Minimal	INFLAMMATION			SITE, INJECTION			MINIMAL	2015-10-27	42
2	ABC	MI	ABC-101	Injection Site 1	2	MIEXAM	Microscopic Examination	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	MIEXAM	Microscopic Examination	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	MITESTCD	MITEST	MIORRES	MISTRESC	MICHRON	MIDISTR	MISPEC	MISPCCND	MISPCUFL	MILAT	MISEV	MIDTC	MIDY
1	ABC	MI	ABC-101	1	MIEXAM	Microscopic Examination	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

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6.3.9 Organ Measurements – OM

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

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 (http://www.cdisc.org/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	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					FASICULATA, ZONA RETICULARIS, CRANIAL, MEDIAN, ACCESSORY, SPINAL, LUMBAR, FRONTAL.	
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
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	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 sponsor-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

6.3.9.1 Assumptions for Organ Measurements (OM) Domain Model

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 sponsor 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.

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6.3.9.2 Examples for Organ Measurements (OM) Domain Model

Example 1

The following example shows how a sponsor 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
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

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Example 2: Using Anatomical Regions

om.xpt

Row	STUDYID	DOMAIN	USUBJID	OMSEQ	OMTESTCD	OMTEST	OMORRES	OMORRESU	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

6.3.10 Palpable Masses – PM

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

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 treatment group number.	Perm
PMSPID	Mass Identifier	Char		Identifier	Mass identifier such as MASS 1 or 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
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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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
PMDTC	Date/Time of Observation	Char	ISO 8601	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 sponsor-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

6.3.10.1 Assumptions for Palpable Masses (PM) Domain Model

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.

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6.3.10.2 Examples for Palpable Masses (PM) Domain Model

Example 1

This example shows palpable masses captured in the collection system with length, width, and ulceration captured.

Rows 1-6: Reflect the findings for the first mass of subject 13456-01, observed on the left hind limb. Rows 1-3 list the findings collected on day 14, and rows 4-6 list the findings for a re-evaluation on day 21 for the same mass.

Rows 7-9: Reflect the findings for a second mass of subject 13456-01, observed on the right shoulder. The mass disappeared between the time of original finding and the re-evaluation, so there are no new findings recorded.

Rows 10-15: Reflect the findings for the first mass of subject 13456-02, observed on the left axillary region.

Rows 16-21: Reflect the findings for the first mass of subject 13456-03, observed on the lower abdomen. At the time of the re-evaluation, the mass could not be measured.

pm.xpt

Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMSPID	PMTESTCD	PMTEST	PMORRES	PMORRESU	PMSTRESC	PMSTRESN	PMSTRESU	PMSTAT	PMREASND	PMLOC	PMDTC	PMDY	PMNOMDY
1	13456	PM	13456-01	23	MASS 1	LENGTH	Length	2.0	mm	2.0	2	mm			LEFT HIND LIMB	2006-10-07T15:44:42	14	14
2	13456	PM	13456-01	24	MASS 1	WIDTH	Width	1.8	mm	1.8	1.8	mm			LEFT HIND LIMB	2006-10-07T15:44:42	14	14
3	13456	PM	13456-01	25	MASS 1	ULCER	Ulceration	NON-ULCERATED		NON-ULCERATED					LEFT HIND LIMB	2006-10-07T15:44:42	14	14
4	13456	PM	13456-01	110	MASS 1	LENGTH	Length	2.4	mm	2.4	2.4	mm			LEFT HIND LIMB	2006-10-14T11:53:01	21	21
5	13456	PM	13456-01	111	MASS 1	WIDTH	Width	2.2	mm	2.2	2.2	mm			LEFT HIND LIMB	2006-10-14T11:53:01	21	21
6	13456	PM	13456-01	112	MASS 1	ULCER	Ulceration	ULCERATED		ULCERATED					LEFT HIND LIMB	2006-10-14T11:53:01	21	21
7	13456	PM	13456-01	26	MASS 2	LENGTH	Length	1.7	mm	1.7	1.7	mm			RIGHT SHOULDER	2006-10-07T15:51:08	14	14
8	13456	PM	13456-01	27	MASS 2	WIDTH	Width	1.6	mm	1.6	1.6	mm			RIGHT SHOULDER	2006-10-07T15:51:08	14	14
9	13456	PM	13456-01	28	MASS 2	ULCER	Ulceration	NON-ULCERATED		NON-ULCERATED					RIGHT SHOULDER	2006-10-07T15:51:08	14	14
10	13456	PM	13456-02	29	MASS 1	LENGTH	Length	4.7	mm	4.7	4.7	mm			LEFT AXILLARY REGION	2006-10-07T16:02:37	14	14
11	13456	PM	13456-02	30	MASS 1	WIDTH	Width	4.3	mm	4.3	4.3	mm			LEFT AXILLARY REGION	2006-10-07T16:02:37	14	14
12	13456	PM	13456-02	31	MASS 1	ULCER	Ulceration	ULCERATED		ULCERATED					LEFT AXILLARY REGION	2006-10-07T16:02:37	14	14
13	13456	PM	13456-02	113	MASS 1	LENGTH	Length	4.4	mm	4.4	4.4	mm			LEFT AXILLARY REGION	2006-10-15T08:12:20	22	22
14	13456	PM	13456-02	114	MASS 1	WIDTH	Width	4.1	mm	4.1	4.1	mm			LEFT AXILLARY REGION	2006-10-15T08:12:20	22	22

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Row	STUDYID	DOMAIN	USUBJID	PMSEQ	PMSPID	PMTESTCD	PMTEST	PMORRES	PMORRESU	PMSTRESC	PMSTRESN	PMSTRESU	PMSTAT	PMREASND	PMLOC	PMDTC	PMDY	PMNOMDY
15	13456	PM	13456-02	115	MASS 1	ULCER	Ulceration	NON-ULCERATED		NON-ULCERATED					LEFT AXILLARY REGION	2006-10-15T08:12:20	22	22
16	13456	PM	13456-03	48	MASS 1	LENGTH	Length	5.5	mm	5.5	5.5	mm			LOWER ABDOMEN	2006-10-07T10:51:00	14	14
17	13456	PM	13456-03	49	MASS 1	WIDTH	Width	1.9	mm	1.9	1.9	mm			LOWER ABDOMEN	2006-10-07T10:51:00	14	14
18	13456	PM	13456-03	50	MASS 1	ULCER	Ulceration	ULCERATED		ULCERATED					LOWER ABDOMEN	2006-10-07T10:51:00	14	14
19	13456	PM	13456-03	132	MASS 1	LENGTH	Length						NOT DONE	Measurement impossible due to excessive ulceration of mass	LOWER ABDOMEN	2006-10-14T07:43:59	21	21
20	13456	PM	13456-03	133	MASS 1	WIDTH	Width						NOT DONE	Measurement impossible due to excessive ulceration of mass	LOWER ABDOMEN	2006-10-14T07:43:59	21	21
21	13456	PM	13456-03	134	MASS 1	ULCER	Ulceration	ULCERATED		ULCERATED					LOWER ABDOMEN	2006-10-14T07:43:59	21	21

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.

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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	DIAM	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	DIAM	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

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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
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.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	F012-007	PM	001-0329	PMSPID	MASS 3		34
2	F012-007	CL	001-0329	CLSPID	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
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

6.3.11 Pharmacokinetics Concentrations – PC

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

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 treatment group number.	Perm
PCREFID	Sample Identifier	Char		Identifier	Internal or external specimen identifier. Example: 1009570101.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
PCSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-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
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
PCNAM	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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 sponsor-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	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	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 sponsor-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 sponsor-defined RFSTDTC variable in DM domain.	Perm
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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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	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: "PT0H" 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	Timing	Date/Time of the reference time point, PCTPTREF.	Exp
PCEVLINT	Evaluation Interval	Char	ISO 8601	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

6.3.11.1 Assumptions for Pharmacokinetics Concentrations (PC) Domain Model

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.

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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. See Section 4.4.7.2.2, Planned Time Points Relative To a Fixed Reference Point, for further explanation about populating ISO 8601-conformant durations.

   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 (See Section 4.5.1.1, Original and Standardized Results).

   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.

6.3.11.2 Examples for Pharmacokinetics Concentrations (PC) Domain Model

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	PCSPEC	PCMETHOD	PCLLOQ	PCUSCHFL	PCDTC	PCDY	PCNOMDY	PCNOMLBL	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
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	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

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6.3.12 Pharmacokinetics Parameters – PP

pp.xpt, Pharmacokinetics Parameters - Findings. One record per pharmacokinetic parameter per time-concentration profile per specimen per subject or pool, Tabulation.

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 treatment 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
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 (http://www.cdisc.org/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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 Section 4.3.6.2 for 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	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	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	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

6.3.12.1 Assumptions for Pharmacokinetics Parameters (PP) Domain Model

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.

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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.

6.3.12.2 Examples for Pharmacokinetics Parameters (PP) Domain Model

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	PPSTRESN	PPSTRESU	PPSTAT	PPREASND	PPSPEC	PPNOMLBL	PPTPTREF	PPRFTDTC	PPSTINT	PPENINT
1	ABC-123	PP	ABC-123-1001	1	AUCINT	AUC from T1 to T2	XYZ-123		271	h*ng/mL	271	271	h*ng/mL			PLASMA	1	Day 1 Dose	2018-01-01T09:50:36	PT0H	PT24H
2	ABC-123	PP	ABC-123-1001	2	AUCLST	AUC to Last Nonzero Conc	XYZ-123		271	h*ng/mL	271	271	h*ng/mL			PLASMA	1	Day 1 Dose	2018-01-01T09:50:36		
3	ABC-123	PP	ABC-123-1001	3	TLST	Time of Last Nonzero Conc	XYZ-123		24	h	24	24	h			PLASMA	1	Day 1 Dose	2018-01-01T09:50:36		
4	ABC-123	PP	ABC-123-1001	4	AUCINT	AUC from T1 to T2	XYZ-123		270	h*ng/mL	270	270	h*ng/mL			PLASMA	28	Day 28 Dose	2018-01-28T09:55:14	PT0H	PT24H
5	ABC-123	PP	ABC-123-1001	5	AUCINT	AUC from T1 to T2	XYZ-123		324	h*ng/mL	324	324	h*ng/mL			PLASMA	28	Day 28 Dose	2018-01-28T09:55:14	PT0H	PT72H
6	ABC-123	PP	ABC-123-1001	6	AUCLST	AUC to Last Nonzero Conc	XYZ-123		324	h*ng/mL	324	324	h*ng/mL			PLASMA	28	Day 28 Dose	2018-01-28T09:55:14		
7	ABC-123	PP	ABC-123-1001	7	TLST	Time of Last Nonzero Conc	XYZ-123		72	h	72	72	h			PLASMA	28	Day 28 Dose	2018-01-28T09:55:14		

6.3.12.3 Relating PP Records to PC Records – RELREC is Optional at this Time for SEND

This section serves as a reference for sponsors wishing to document relationships between pharmacokinetic parameter records in a PP dataset and specific time-point concentration records in a PC dataset according to the SDTM using the RELREC table.

6.3.12.3.1 Relating Datasets

If all time-point concentrations in PC are used to calculate all parameters for all subjects, then the relationship between the 2 datasets can be documented as shown in the following table. Note that incorporating the name of the analyte and the day of the collection into the value of --GRPID (or some equivalent method for assigning different values of --GRPID for all the combinations of analytes and reference time points) is necessary when there is more than one reference time point (PCRFTDTC and PPRFTDTC, which are the same for related records) and more than one analyte (PCTESTCD, copied into PPCAT to indicate the analyte with which the parameters are associated), because these variables are part of the natural key for both datasets. In this case, --GRPID is a surrogate key used for the relationship.

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relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC		PCGRPID		MANY	A
2	ABC-123	PP		PPGRPID		MANY	A

6.3.12.3.2 Relating Records

This section describes 4 possible examples of different types of relationships between PC and PP records for the same drug (drug X). All of these examples use the same PC and PP data. The only variables whose values change across the examples are the sponsor-defined PCGRPID and PPGRPID. As in the case for relating datasets, --GRPID values must take into account all combinations of analytes and reference time points, since both are part of the natural key for both datasets. To conserve space, the PC and PP domains appear only once, but with 4 --GRPID columns, 1 for each of the examples. Note that a submission dataset would contain only a single --GRPID column with a set of values such as those shown in 1 of the 4 columns in the PC and PP datasets, or values defined by the sponsor.

In Example 1, all pharmacokinetic time point-concentration values in the PC dataset are used to calculate all the pharmacokinetic parameters in the PP dataset for days 1 and 8 for 1 subject.

- Pharmacokinetic Concentrations (PC) Dataset for All Examples
- Pharmacokinetic Parameters (PP) Dataset for All Examples
- RELREC Example 1: All PC records used to calculate all pharmacokinetic parameters.
- Method A (Many to many, using PCGRPID and PPGRPID)
- Method B (One to many, using PCSEQ and PPGRPID)
- Method C (Many to one, using PCGRPID and PPSEQ)
- Method D (One to one, using PCSEQ and PPSEQ)

In Example 2, 2 PC values were excluded from the calculation of all pharmacokinetic parameters for the day 1 data. Day 8 values are related per Example 1.

- RELREC Example 2: Only some records in PC used to calculate all pharmacokinetic parameters.
- Method A (Many to many, using PCGRPID and PPGRPID)
- Method B (One to many, using PCSEQ and PPGRPID)
- Method C (Many to one, using PCGRPID and PPSEQ)
- Method D (One to one, using PCSEQ and PPSEQ)

In Example 3, 2 PC values were excluded from the calculation of 2 pharmacokinetic parameters, but used in the others for day 1. Day 8 values are related per Example 1.

- RELREC Example 3: Only some records in PC used to calculate some parameters.
- Method A (Many to many, using PCGRPID and PPGRPID)

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- Method B (One to many, using PCSEQ and PPGRPID)
- Method C (Many to one, using PCGRPID and PPSEQ)
- Method D (One to one, using PCSEQ and PPSEQ)

In Example 4, only some PC records for day 1 were used to calculate parameters: Time point 5 was excluded from Tmax, time point 6 from Cmax, and time points 11 and 12 were excluded from AUC. Day 8 values are related per Example 1.

- RELREC Example 4: Only some records in PC used to calculate parameters.
- Method A (Many to many, using PCGRPID and PPGRPID)
- Method B (One to many omitted; see note below)
- Method C (Many to one omitted; see note below)
- Method D (One to one, using PCSEQ and PPSEQ)

For each example, PCGRPID and PPGRPID were used to group related records within each respective dataset. The values for these, as well as the values for PCSEQ and PPSEQ, were then used to populate combinations of IDVAR and IDVARVAL in the RELREC table using four methods (A-D) for Examples 1-3.

Note: Only 2 methods (A and D) are shown for Example 4, due to its complexity. Because the relationship between PC records and PP records for day 8 data does not change across the examples, it is shown only for Example 1 and not repeated.

Pharmacokinetic Concentrations (PC) Dataset for All Examples

pc.xpt

Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCGRPID1	PCGRPID2	PCGRPID3	PCGRPID4	PCREFID	PCTESTCD	PCTEST	PCCAT	PCORRES	PCORRESU	PCSTRESC	PCSTRESN	PCSTRESU	PCSPEC	PCBLFL	PCLLOQ	PCDTC	PCDY	PCNOMDY	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
1	ABC-123	PC	ABC-123-0001	1	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-01	DRUG X	STUDYDRUG	ANALYTE	9	ug/mL	9	9	ug/mL	PLASMA		1.00	2001-02-01T08:35	1	1	5 min	1	PT5M	Day 1 Dose	2001-02-01T08:30
2	ABC-123	PC	ABC-123-0001	2	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-02	DRUG X	STUDYDRUG	ANALYTE	20	ug/mL	20	20	ug/mL	PLASMA		1.00	2001-02-01T08:55	1	1	25 min	2	PT25M	Day 1 Dose	2001-02-01T08:30
3	ABC-123	PC	ABC-123-0001	3	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-03	DRUG X	STUDYDRUG	ANALYTE	31	ug/mL	31	31	ug/mL	PLASMA		1.00	2001-02-01T09:20	1	1	50 min	3	PT50M	Day 1 Dose	2001-02-01T08:30
4	ABC-123	PC	ABC-123-0001	4	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-04	DRUG X	STUDYDRUG	ANALYTE	38	ug/mL	38	38	ug/mL	PLASMA		1.00	2001-02-01T09:45	1	1	75 min	4	PT1H15M	Day 1 Dose	2001-02-01T08:30
5	ABC-123	PC	ABC-123-0001	5	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_B	123-0001-05	DRUG X	STUDYDRUG	ANALYTE	45	ug/mL	45	45	ug/mL	PLASMA		1.00	2001-02-01T10:10	1	1	100 min	5	PT1H40M	Day 1 Dose	2001-02-01T08:30
6	ABC-123	PC	ABC-123-0001	6	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_C	123-0001-06	DRUG X	STUDYDRUG	ANALYTE	48	ug/mL	48	48	ug/mL	PLASMA		1.00	2001-02-01T10:35	1	1	125 min	6	PT2H5M	Day 1 Dose	2001-02-01T08:30
7	ABC-123	PC	ABC-123-0001	7	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-07	DRUG X	STUDYDRUG	ANALYTE	41	ug/mL	41	41	ug/mL	PLASMA		1.00	2001-02-01T11:00	1	1	150 min	7	PT2H30M	Day 1 Dose	2001-02-01T08:30
8	ABC-123	PC	ABC-123-0001	8	DY1_DRGX	EXCLUDE	DY1_DRGX_B	DY1_DRGX_A	123-0001-08	DRUG X	STUDYDRUG	ANALYTE	35	ug/mL	35	35	ug/mL	PLASMA		1.00	2001-02-01T11:50	1	1	200 min	8	PT3H20M	Day 1 Dose	2001-02-01T08:30
9	ABC-123	PC	ABC-123-0001	9	DY1_DRGX	EXCLUDE	DY1_DRGX_B	DY1_DRGX_A	123-0001-09	DRUG X	STUDYDRUG	ANALYTE	31	ug/mL	31	31	ug/mL	PLASMA		1.00	2001-02-01T12:40	1	1	250 min	9	PT4H10M	Day 1 Dose	2001-02-01T08:30
10	ABC-123	PC	ABC-123-0001	10	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-10	DRUG X	STUDYDRUG	ANALYTE	25	ug/mL	25	25	ug/mL	PLASMA		1.00	2001-02-01T14:45	1	1	375 min	10	PT6H15M	Day 1 Dose	2001-02-01T08:30
11	ABC-123	PC	ABC-123-0001	11	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_D	123-0001-11	DRUG X	STUDYDRUG	ANALYTE	18	ug/mL	18	18	ug/mL	PLASMA		1.00	2001-02-01T16:50	1	1	500 min	11	PT8H20M	Day 1 Dose	2001-02-01T08:30
12	ABC-123	PC	ABC-123-0001	12	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_D	123-0001-12	DRUG X	STUDYDRUG	ANALYTE	12	ug/mL	12	12	ug/mL	PLASMA		1.00	2001-02-01T18:30	1	1	600 min	12	PT10H	Day 1 Dose	2001-02-01T08:30
13	ABC-123	PC	ABC-123-0001	13	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-13	DRUG X	STUDYDRUG	ANALYTE	10	ug/mL	10	10	ug/mL	PLASMA		1.00	2001-02-08T08:35	8	8	5 min	1	PT5M	Day 8 Dose	2001-02-08T08:30

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Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCGRPID1	PCGRPID2	PCGRPID3	PCGRPID4	PCREFID	PCTESTCD	PCTEST	PCCAT	PCORRES	PCORRESU	PCSTRESC	PCSTRESN	PCSTRESU	PCSPEC	PCBLFL	PCLLOQ	PCDTC	PCDY	PCNOMDY	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
14	ABC-123	PC	ABC-123-0001	14	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-14	DRUG X	STUDYDRUG	ANALYTE	21	ug/mL	21	21	ug/mL	PLASMA		1.00	2001-02-08T08:55	8	8	25 min	2	PT25M	Day 8 Dose	2001-02-08T08:30
15	ABC-123	PC	ABC-123-0001	15	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-15	DRUG X	STUDYDRUG	ANALYTE	32	ug/mL	32	32	ug/mL	PLASMA		1.00	2001-02-08T09:20	8	8	50 min	3	PT50M	Day 8 Dose	2001-02-08T08:30
16	ABC-123	PC	ABC-123-0001	16	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-16	DRUG X	STUDYDRUG	ANALYTE	39	ug/mL	39	39	ug/mL	PLASMA		1.00	2001-02-08T09:45	8	8	75 min	4	PT1H15M	Day 8 Dose	2001-02-08T08:30
17	ABC-123	PC	ABC-123-0001	17	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-17	DRUG X	STUDYDRUG	ANALYTE	46	ug/mL	46	46	ug/mL	PLASMA		1.00	2001-02-08T10:10	8	8	100 min	5	PT1H40M	Day 8 Dose	2001-02-08T08:30
18	ABC-123	PC	ABC-123-0001	18	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-18	DRUG X	STUDYDRUG	ANALYTE	48	ug/mL	48	48	ug/mL	PLASMA		1.00	2001-02-08T10:35	8	8	125 min	6	PT2H5M	Day 8 Dose	2001-02-08T08:30
19	ABC-123	PC	ABC-123-0001	19	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-19	DRUG X	STUDYDRUG	ANALYTE	40	ug/mL	40	40	ug/mL	PLASMA		1.00	2001-02-08T11:00	8	8	150 min	7	PT2H30M	Day 8 Dose	2001-02-08T08:30
20	ABC-123	PC	ABC-123-0001	20	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-20	DRUG X	STUDYDRUG	ANALYTE	35	ug/mL	35	35	ug/mL	PLASMA		1.00	2001-02-08T11:50	8	8	200 min	8	PT3H20M	Day 8 Dose	2001-02-08T08:30
21	ABC-123	PC	ABC-123-0001	21	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-21	DRUG X	STUDYDRUG	ANALYTE	30	ug/mL	30	30	ug/mL	PLASMA		1.00	2001-02-08T12:40	8	8	250 min	9	PT4H10M	Day 8 Dose	2001-02-08T08:30
22	ABC-123	PC	ABC-123-0001	22	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-22	DRUG X	STUDYDRUG	ANALYTE	24	ug/mL	24	24	ug/mL	PLASMA		1.00	2001-02-08T14:45	8	8	375 min	10	PT6H15M	Day 8 Dose	2001-02-08T08:30
23	ABC-123	PC	ABC-123-0001	23	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-23	DRUG X	STUDYDRUG	ANALYTE	17	ug/mL	17	17	ug/mL	PLASMA		1.00	2001-02-08T16:50	8	8	500 min	11	PT8H20M	Day 8 Dose	2001-02-08T08:30
24	ABC-123	PC	ABC-123-0001	24	DY8_DRGX	DY8_DRGX	DY8_DRGX	DY8_DRGX	123-0002-24	DRUG X	STUDYDRUG	ANALYTE	11	ug/mL	11	11	ug/mL	PLASMA		1.00	2001-02-08T18:30	8	8	600 min	12	PT10H	Day 8 Dose	2001-02-08T08:30

Pharmacokinetic Parameters (PP) Dataset for All Examples

pp.xpt

Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPGRPID1	PPGRPID2	PPGRPID3	PPGRPID4	PPTESTCD	PPTEST	PPCAT	PPORRES	PPORRESU	PPSTRESC	PPSTRESN	PPSTRESU	PPSPEC	PPNOMDY	PPRFTDTC
1	ABC-123	PP	ABC-123-0001	1	DY1DRGX	DY1DRGX	DY1DRGX_A	TMAX	TMAX	Time of CMAX	DRUG X	1.87	h	1.87	1.87	h	PLASMA	1	2001-02-01T08:35
2	ABC-123	PP	ABC-123-0001	2	DY1DRGX	DY1DRGX	DY1DRGX_A	CMAX	CMAX	Max Conc	DRUG X	44.5	ng/mL	44.5	44.5	ng/mL	PLASMA	1	2001-02-01T08:35
3	ABC-123	PP	ABC-123-0001	3	DY1DRGX	DY1DRGX	DY1DRGX_A	AUC	AUCALL	AUC All	DRUG X	294.7	h*ug/mL	294.7	294.7	h*ug/mL	PLASMA	1	2001-02-01T08:35
4	ABC-123	PP	ABC-123-0001	5	DY1DRGX	DY1DRGX	DY1DRGX_HALF	OTHER	LAMZHL	Half-Life Lambda z	DRUG X	4.69	h	4.69	4.69	h	PLASMA	1	2001-02-01T08:35
5	ABC-123	PP	ABC-123-0001	6	DY1DRGX	DY1DRGX	DY1DRGX_A	OTHER	VZO	Vz Obs	DRUG X	10.9	L	10.9	10.9	L	PLASMA	1	2001-02-01T08:35
6	ABC-123	PP	ABC-123-0001	7	DY1DRGX	DY1DRGX	DY1DRGX_A	OTHER	CLO	Total CL Obs	DRUG X	1.68	L/h	1.68	1.68	L/h	PLASMA	1	2001-02-01T08:35
7	ABC-123	PP	ABC-123-0001	8	DY8DRGX	DY8DRGX	DY8DRGX	DY8DRGX	TMAX	Time of CMAX	DRUG X	1.91	h	1.91	1.91	h	PLASMA	8	2001-02-08T08:35
8	ABC-123	PP	ABC-123-0001	9	DY8DRGX	DY8DRGX	DY8DRGX	DY8DRGX	CMAX	Max Conc	DRUG X	46.0	ng/mL	46.0	46.0	ng/mL	PLASMA	8	2001-02-08T08:35
9	ABC-123	PP	ABC-123-0001	10	DY8DRGX	DY8DRGX	DY8DRGX	DY8DRGX	AUCALL	AUC All	DRUG X	289.0	h*ug/mL	289.0	289.0	h*ug/mL	PLASMA	8	2001-02-08T08:35
10	ABC-123	PP	ABC-123-0001	12	DY8DRGX	DY8DRGX	DY8DRGX	DY8DRGX	LAMZHL	Half-Life Lambda z	DRUG X	4.50	h	4.50	4.50	h	PLASMA	8	2001-02-08T08:35
11	ABC-123	PP	ABC-123-0001	13	DY8DRGX	DY8DRGX	DY8DRGX	DY8DRGX	VZO	Vz Obs	DRUG X	10.7	L	10.7	10.7	L	PLASMA	8	2001-02-08T08:35
12	ABC-123	PP	ABC-123-0001	14	DY8DRGX	DY8DRGX	DY8DRGX	DY8DRGX	CLO	Total CL Obs	DRUG X	1.75	L/h	1.75	1.75	L/h	PLASMA	8	2001-02-08T08:35

Example 1

All PC records used to calculate all pharmacokinetic parameters.

Method A (Many to many, using PCGRPID and PPGRPID)

RELID 1 indicates all PC records with GRPID = DY1_DRGX are related to all PP records with GRPID = DY1DRGX.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCGRPID	DY1_DRGX		1
2	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX		1

Method B (One to many, using PCSEQ and PPGRPID)

RELID 1 indicates records with PCSEQ values of 1-12 are related to records with PPGRPID = DY1DRGX.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCSEQ	1		1
2	ABC-123	PC	ABC-123-0001	PCSEQ	2		1
3	ABC-123	PC	ABC-123-0001	PCSEQ	3		1
4	ABC-123	PC	ABC-123-0001	PCSEQ	4		1
5	ABC-123	PC	ABC-123-0001	PCSEQ	5		1
6	ABC-123	PC	ABC-123-0001	PCSEQ	6		1
7	ABC-123	PC	ABC-123-0001	PCSEQ	7		1
8	ABC-123	PC	ABC-123-0001	PCSEQ	8		1
9	ABC-123	PC	ABC-123-0001	PCSEQ	9		1
10	ABC-123	PC	ABC-123-0001	PCSEQ	10		1
11	ABC-123	PC	ABC-123-0001	PPGRPID	DY1DRGX		1

Method C (Many to one, using PCGRPID and PPSEQ)

RELID 1 indicates records with a PCGRPID value of DY1_DRGX are related to records with PPSEQ values of 1-7.

RELID 2 indicates records with a PCGRPID value of DY8_DRGX are related to records with PPSEQ values of 8-14.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCGRPID	DY1_DRGX		1
2	ABC-123	PP	ABC-123-0001	PPSEQ	1		1
3	ABC-123	PP	ABC-123-0001	PPSEQ	2		1
4	ABC-123	PP	ABC-123-0001	PPSEQ	3		1
5	ABC-123	PP	ABC-123-0001	PPSEQ	4		1
6	ABC-123	PP	ABC-123-0001	PPSEQ	5		1
7	ABC-123	PP	ABC-123-0001	PPSEQ	6		1
8	ABC-123	PP	ABC-123-0001	PPSEQ	7		1
9	ABC-123	PC	ABC-123-0001	PCGRPID	DY8_DRGX		2
10	ABC-123	PP	ABC-123-0001	PPSEQ	8		2
11	ABC-123	PP	ABC-123-0001	PPSEQ	9		2
12	ABC-123	PP	ABC-123-0001	PPSEQ	10		2
13	ABC-123	PP	ABC-123-0001	PPSEQ	11		2
14	ABC-123	PP	ABC-123-0001	PPSEQ	12		2
15	ABC-123	PP	ABC-123-0001	PPSEQ	13		2
16	ABC-123	PP	ABC-123-0001	PPSEQ	14		2

Method D (One to one, using PCSEQ and PPSEQ)

RELID 1 indicates records with PCSEQ values of 1-12 are related to records with PPSEQ values of 1-7.

RELID 2 indicates records with PCSEQ values of 13-24 are related to records with PPSEQ values of 8-14.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCSEQ	1		1
2	ABC-123	PC	ABC-123-0001	PCSEQ	2		1
3	ABC-123	PC	ABC-123-0001	PCSEQ	3		1
4	ABC-123	PC	ABC-123-0001	PCSEQ	4		1
5	ABC-123	PC	ABC-123-0001	PCSEQ	5		1
6	ABC-123	PC	ABC-123-0001	PCSEQ	6		1
7	ABC-123	PC	ABC-123-0001	PCSEQ	7		1
8	ABC-123	PC	ABC-123-0001	PCSEQ	8		1
9	ABC-123	PC	ABC-123-0001	PCSEQ	9		1
10	ABC-123	PC	ABC-123-0001	PCSEQ	10		1
11	ABC-123	PC	ABC-123-0001	PCSEQ	11		1
12	ABC-123	PC	ABC-123-0001	PCSEQ	12		1
13	ABC-123	PP	ABC-123-0001	PPSEQ	1		1
14	ABC-123	PP	ABC-123-0001	PPSEQ	2		1
15	ABC-123	PP	ABC-123-0001	PPSEQ	3		1
16	ABC-123	PP	ABC-123-0001	PPSEQ	4		1
17	ABC-123	PP	ABC-123-0001	PPSEQ	5		1
18	ABC-123	PP	ABC-123-0001	PPSEQ	6		1
19	ABC-123	PP	ABC-123-0001	PPSEQ	7		1
20	ABC-123	PC	ABC-123-0001	PCSEQ	13		2
21	ABC-123	PC	ABC-123-0001	PCSEQ	14		2
22	ABC-123	PC	ABC-123-0001	PCSEQ	15		2
23	ABC-123	PC	ABC-123-0001	PCSEQ	16		2
24	ABC-123	PC	ABC-123-0001	PCSEQ	17		2
25	ABC-123	PC	ABC-123-0001	PCSEQ	18		2
26	ABC-123	PC	ABC-123-0001	PCSEQ	19		2
27	ABC-123	PC	ABC-123-0001	PCSEQ	20		2
28	ABC-123	PC	ABC-123-0001	PCSEQ	21		2
29	ABC-123	PC	ABC-123-0001	PCSEQ	22		2
30	ABC-123	PC	ABC-123-0001	PCSEQ	23		2
31	ABC-123	PC	ABC-123-0001	PCSEQ	24		2
32	ABC-123	PP	ABC-123-0001	PPSEQ	8		2
33	ABC-123	PP	ABC-123-0001	PPSEQ	9		2
34	ABC-123	PP	ABC-123-0001	PPSEQ	10		2
35	ABC-123	PP	ABC-123-0001	PPSEQ	11		2
36	ABC-123	PP	ABC-123-0001	PPSEQ	12		2
37	ABC-123	PP	ABC-123-0001	PPSEQ	13		2
38	ABC-123	PP	ABC-123-0001	PPSEQ	14		2

Example 2

Only some records in PC used to calculate all pharmacokinetic parameters: Time points 8 and 9 on day 1 were not used for any pharmacokinetic parameters.

Method A (Many to many, using PCGRPID and PPGRPID)

Day 8 relationships are the same as those shown in Example 1.

RELID 1 Indicates only PC records with PCGRPID = DY1_DRGX are related to all PP records with PPGRPID = DY1DRGX. PC records with PCGRPID = EXCLUDE were not used.

RELID 2 Indicates all PC records with PCGRPID = DY8_DRGX are related to all PP records with PPGRPID = DY8DRGX.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCGRPID	DY1_DRGX		1
2	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX		1

Method B (One to many, using PCSEQ and PPGRPID)

Day 8 relationships are the same as those shown in Example 1.

RELID 1 Indicates records with PCSEQ values of 1-7 and 10-12 are related to records with PPGRPID = DY1DRGX.

RELID 2 Indicates records with PCSEQ values of 13-24 are related to records with PPGRPID = DY8DRGX.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCSEQ	1		1
2	ABC-123	PC	ABC-123-0001	PCSEQ	2		1
3	ABC-123	PC	ABC-123-0001	PCSEQ	3		1
4	ABC-123	PC	ABC-123-0001	PCSEQ	4		1
5	ABC-123	PC	ABC-123-0001	PCSEQ	5		1
6	ABC-123	PC	ABC-123-0001	PCSEQ	6		1
7	ABC-123	PC	ABC-123-0001	PCSEQ	7		1
8	ABC-123	PC	ABC-123-0001	PCSEQ	10		1
9	ABC-123	PC	ABC-123-0001	PCSEQ	11		1
10	ABC-123	PC	ABC-123-0001	PCSEQ	12		1
11	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX		1

Method C (Many to one, using PCGRPID and PPSEQ)

Day 8 relationships are the same as those shown in Example 1.

RELID 1 Indicates records with a PCGRPID value of DY1_DRGX are related to records with PPSEQ values of 1-7.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCGRPID	DY1_DRGX		1
2	ABC-123	PP	ABC-123-0001	PPSEQ	1		1
3	ABC-123	PP	ABC-123-0001	PPSEQ	2		1
4	ABC-123	PP	ABC-123-0001	PPSEQ	3		1
5	ABC-123	PP	ABC-123-0001	PPSEQ	4		1
6	ABC-123	PP	ABC-123-0001	PPSEQ	5		1
7	ABC-123	PP	ABC-123-0001	PPSEQ	6		1
8	ABC-123	PP	ABC-123-0001	PPSEQ	7		1

Method D (One to one, using PCSEQ and PPSEQ)

Day 8 relationships are the same as those shown in Example 1.

RELID 1 Indicates records with PCSEQ values of 1-7 and 10-12 are related to records with PPSEQ values of 1-7.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCSEQ	1		1
2	ABC-123	PC	ABC-123-0001	PCSEQ	2		1
3	ABC-123	PC	ABC-123-0001	PCSEQ	3		1
4	ABC-123	PC	ABC-123-0001	PCSEQ	4		1
5	ABC-123	PC	ABC-123-0001	PCSEQ	5		1
6	ABC-123	PC	ABC-123-0001	PCSEQ	6		1
7	ABC-123	PC	ABC-123-0001	PCSEQ	7		1

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
8	ABC-123	PC	ABC-123-0001	PCSEQ	10		1
9	ABC-123	PC	ABC-123-0001	PCSEQ	11		1
10	ABC-123	PC	ABC-123-0001	PCSEQ	12		1
11	ABC-123	PP	ABC-123-0001	PPSEQ	1		1
12	ABC-123	PP	ABC-123-0001	PPSEQ	2		1
13	ABC-123	PP	ABC-123-0001	PPSEQ	3		1
14	ABC-123	PP	ABC-123-0001	PPSEQ	4		1
15	ABC-123	PP	ABC-123-0001	PPSEQ	5		1
16	ABC-123	PP	ABC-123-0001	PPSEQ	6		1
17	ABC-123	PP	ABC-123-0001	PPSEQ	7		1

Example 3

Only some records in PC used to calculate some parameters: Time points 8 and 9 on day 1 were not used for half-life calculations, but were used for other parameters.

Method A (Many to many, using PCGRPID and PPGRPID)

Day 8 relationships are the same as those shown in Example 1.

RELID 1 Indicates that all time points on Day 1 (PCGRPID = DY1_DRGX_A and DY1_DRGX_B) were used to calculate all parameters (PPGRPID = DY1DRGX_A) except half-lives.

RELID 2 Indicates only the values for PCGRPID = DY1_DRGX_A were used to calculate the half-lives (PPGRPID = DY1DRGX_HALF).

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCGRPID	DY1_DRGX_A		1
2	ABC-123	PC	ABC-123-0001	PCGRPID	DY1_DRGX_B		1
3	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX_A		1
4	ABC-123	PC	ABC-123-0001	PCGRPID	DY1_DRGX_A		2
5	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX_HALF		2

Method B (One to many, using PCSEQ and PPGRPID)

Day 8 relationships are the same as those shown in Example 1.

RELID 1 Indicates records with PCSEQ values of 1-12 are related to records with PPGRPID = DY1DRGX_A

RELID 2 Indicates records with PCSEQ values of 1-7 and 10-12 are related to records with PPGRPID = DY1DRGX_HALF.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCSEQ	1		1
2	ABC-123	PC	ABC-123-0001	PCSEQ	2		1
3	ABC-123	PC	ABC-123-0001	PCSEQ	3		1
4	ABC-123	PC	ABC-123-0001	PCSEQ	4		1
5	ABC-123	PC	ABC-123-0001	PCSEQ	5		1
6	ABC-123	PC	ABC-123-0001	PCSEQ	6		1
7	ABC-123	PC	ABC-123-0001	PCSEQ	7		1
8	ABC-123	PC	ABC-123-0001	PCSEQ	8		1
9	ABC-123	PC	ABC-123-0001	PCSEQ	9		1
10	ABC-123	PC	ABC-123-0001	PCSEQ	10		1
11	ABC-123	PC	ABC-123-0001	PCSEQ	11		1
12	ABC-123	PC	ABC-123-0001	PCSEQ	12		1
13	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX_A		1
14	ABC-123	PC	ABC-123-0001	PCSEQ	1		2
15	ABC-123	PC	ABC-123-0001	PCSEQ	2		2
16	ABC-123	PC	ABC-123-0001	PCSEQ	3		2

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
17	ABC-123	PC	ABC-123-0001	PCSEQ	4		2
18	ABC-123	PC	ABC-123-0001	PCSEQ	5		2
19	ABC-123	PC	ABC-123-0001	PCSEQ	6		2
20	ABC-123	PC	ABC-123-0001	PCSEQ	7		2
21	ABC-123	PC	ABC-123-0001	PCSEQ	10		2
22	ABC-123	PC	ABC-123-0001	PCSEQ	11		2
23	ABC-123	PC	ABC-123-0001	PCSEQ	12		2
24	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX_HALF		2

Method C (Many to one, using PCGRPID and PPSEQ)

Day 8 relationships are the same as those shown in Example 1.

RELID 1 Indicates records with a PCGRPID value of DY1_DRGX_A and DY1_DRGX_B are related to records with PPSEQ values of 1-7.

RELID 2 Indicates records with a PCGRPID value of DY1_DRGX_A are related to records with PPSEQ values of 4 and 5.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCGRPID	DY1_DRGX_A		1
2	ABC-123	PC	ABC-123-0001	PCGRPID	DY1_DRGX_B		1
3	ABC-123	PP	ABC-123-0001	PPSEQ	1		1
4	ABC-123	PP	ABC-123-0001	PPSEQ	2		1
5	ABC-123	PP	ABC-123-0001	PPSEQ	3		1
6	ABC-123	PP	ABC-123-0001	PPSEQ	6		1
7	ABC-123	PP	ABC-123-0001	PPSEQ	7		1
8	ABC-123	PC	ABC-123-0001	PCGRPID	DY1_DRGX_A		2
9	ABC-123	PP	ABC-123-0001	PPSEQ	4		2
10	ABC-123	PP	ABC-123-0001	PPSEQ	5		2

Method D (One to one, using PCSEQ and PPSEQ)

Day 8 relationships are the same as those shown in Example 1.

RELID 1 Indicates records with PCSEQ values of 1-12 are related to records with PPSEQ values of 1-7.

RELID 2 Indicates records with PCSEQ values of 1-7 and 10-12 are related to records with PPSEQ values of 4 and 5.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCSEQ	1		1
2	ABC-123	PC	ABC-123-0001	PCSEQ	2		1
3	ABC-123	PC	ABC-123-0001	PCSEQ	3		1
4	ABC-123	PC	ABC-123-0001	PCSEQ	4		1
5	ABC-123	PC	ABC-123-0001	PCSEQ	5		1
6	ABC-123	PC	ABC-123-0001	PCSEQ	6		1
7	ABC-123	PC	ABC-123-0001	PCSEQ	7		1
8	ABC-123	PC	ABC-123-0001	PCSEQ	8		1
9	ABC-123	PC	ABC-123-0001	PCSEQ	9		1
10	ABC-123	PC	ABC-123-0001	PCSEQ	10		1
11	ABC-123	PC	ABC-123-0001	PCSEQ	11		1
12	ABC-123	PC	ABC-123-0001	PCSEQ	12		1
13	ABC-123	PP	ABC-123-0001	PPSEQ	1		1
14	ABC-123	PP	ABC-123-0001	PPSEQ	2		1
15	ABC-123	PP	ABC-123-0001	PPSEQ	3		1
16	ABC-123	PP	ABC-123-0001	PPSEQ	6		1
17	ABC-123	PP	ABC-123-0001	PPSEQ	7		1

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
18	ABC-123	PC	ABC-123-0001	PCSEQ	1		2
19	ABC-123	PC	ABC-123-0001	PCSEQ	2		2
20	ABC-123	PC	ABC-123-0001	PCSEQ	3		2
21	ABC-123	PC	ABC-123-0001	PCSEQ	4		2
22	ABC-123	PC	ABC-123-0001	PCSEQ	5		2
23	ABC-123	PC	ABC-123-0001	PCSEQ	6		2
24	ABC-123	PC	ABC-123-0001	PCSEQ	7		2
25	ABC-123	PC	ABC-123-0001	PCSEQ	10		2
26	ABC-123	PC	ABC-123-0001	PCSEQ	11		2
27	ABC-123	PC	ABC-123-0001	PCSEQ	12		2
28	ABC-123	PP	ABC-123-0001	PPSEQ	4		2
29	ABC-123	PP	ABC-123-0001	PPSEQ	5		2

Example 4

Only some records in PC used to calculate parameters: Time point 5 was excluded from Tmax, 6 from Cmax, and 11 and 12 from AUC.

Method A (Many to many, using PCGRPID and PPGRPID)

Day 8 relationships are the same as those shown in Example 1.

RELID 1 Indicates that Tmax used records with PCGRPID values DY1DRGX_A, DY1DRGX_C, and DY1DRGX_D.

RELID 2 Indicates that Cmax used records with PCGRPID values DY1DRGX_A, DY1DRGX_B, and DY1DRGX_D.

RELID 3 Indicates that AUC used PCGRPID values DY1DRGX_A, DY1DRGX_B, and DY1DRGX_C.

RELID 4 Indicates that all other parameters (PPGRPID = OTHER) used all PC time points: PCGRPID values DY1DRGX_A, DY1DRGX_B, DY1DRGX_C, and DY1DRGX_D.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PP	ABC-123-0001	PPGRPID	TMAX		1
2	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_A		1
3	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_C		1
4	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_D		1
5	ABC-123	PP	ABC-123-0001	PPGRPID	CMAX		2
6	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_A		2
7	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_B		2
8	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_D		2
9	ABC-123	PP	ABC-123-0001	PPGRPID	AUC		3
10	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_A		3
11	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_B		3
12	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_C		3
13	ABC-123	PP	ABC-123-0001	PPGRPID	OTHER		4
14	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_A		4
15	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_B		4
16	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_C		4
17	ABC-123	PC	ABC-123-0001	PCGRPID	DY1DRGX_D		4

Note that in this RELREC table, the single records in rows 1, 3, 5, 7, and 9, represented by their --GRPIDs (Tmax, DY1DRGX_C, Cmax, DY1DRGX_B, AUC) could have been referenced by their SEQ values, as both identify the records sufficiently. At least 2 other hybrid approaches would have been acceptable as well: using PPSEQ and PCGRPIDs whenever possible or using PPGRPID and PCSEQ values whenever possible. Method D uses only SEQ values.

Method D (One to one, using PCSEQ and PPSEQ)

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Day 8 relationships are the same as those shown in Example 1.

RELID 1 Indicates records with PCSEQ values of 1-4 and 6-12 are related to the record with a PPSEQ value of 1.

RELID 2 Indicates records with PCSEQ values of 1-5 and 7-12 are related to the record with a PPSEQ value of 2.

RELID 3 Indicates records with PCSEQ values of 1-10 are related to the record with a PPSEQ value of 3.

RELID 4 Indicates records with PCSEQ values of 1-12 are related to the records with PPSEQ values of 4-7.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC-123	PC	ABC-123-0001	PCSEQ	1		1
2	ABC-123	PC	ABC-123-0001	PCSEQ	2		1
3	ABC-123	PC	ABC-123-0001	PCSEQ	3		1
4	ABC-123	PC	ABC-123-0001	PCSEQ	4		1
5	ABC-123	PC	ABC-123-0001	PCSEQ	6		1
6	ABC-123	PC	ABC-123-0001	PCSEQ	7		1
7	ABC-123	PC	ABC-123-0001	PCSEQ	8		1
8	ABC-123	PC	ABC-123-0001	PCSEQ	9		1
9	ABC-123	PC	ABC-123-0001	PCSEQ	10		1
10	ABC-123	PC	ABC-123-0001	PCSEQ	11		1
11	ABC-123	PC	ABC-123-0001	PCSEQ	12		1
12	ABC-123	PP	ABC-123-0001	PPSEQ	1		1
13	ABC-123	PC	ABC-123-0001	PCSEQ	1		2
14	ABC-123	PC	ABC-123-0001	PCSEQ	2		2
15	ABC-123	PC	ABC-123-0001	PCSEQ	3		2
16	ABC-123	PC	ABC-123-0001	PCSEQ	4		2
17	ABC-123	PC	ABC-123-0001	PCSEQ	5		2
18	ABC-123	PC	ABC-123-0001	PCSEQ	7		2
19	ABC-123	PC	ABC-123-0001	PCSEQ	8		2
20	ABC-123	PC	ABC-123-0001	PCSEQ	9		2
21	ABC-123	PC	ABC-123-0001	PCSEQ	10		2
22	ABC-123	PC	ABC-123-0001	PCSEQ	11		2
23	ABC-123	PC	ABC-123-0001	PCSEQ	12		2
24	ABC-123	PP	ABC-123-0001	PPSEQ	2		2
25	ABC-123	PC	ABC-123-0001	PCSEQ	1		3
26	ABC-123	PC	ABC-123-0001	PCSEQ	2		3
27	ABC-123	PC	ABC-123-0001	PCSEQ	3		3
28	ABC-123	PC	ABC-123-0001	PCSEQ	4		3
29	ABC-123	PC	ABC-123-0001	PCSEQ	5		3
30	ABC-123	PC	ABC-123-0001	PCSEQ	6		3
31	ABC-123	PC	ABC-123-0001	PCSEQ	7		3
32	ABC-123	PC	ABC-123-0001	PCSEQ	8		3
33	ABC-123	PC	ABC-123-0001	PCSEQ	9		3
34	ABC-123	PC	ABC-123-0001	PCSEQ	10		3
35	ABC-123	PP	ABC-123-0001	PPSEQ	3		3
36	ABC-123	PC	ABC-123-0001	PCSEQ	1		4
37	ABC-123	PC	ABC-123-0001	PCSEQ	2		4
38	ABC-123	PC	ABC-123-0001	PCSEQ	3		4
39	ABC-123	PC	ABC-123-0001	PCSEQ	4		4
40	ABC-123	PC	ABC-123-0001	PCSEQ	5		4
41	ABC-123	PC	ABC-123-0001	PCSEQ	6		4
42	ABC-123	PC	ABC-123-0001	PCSEQ	7		4
43	ABC-123	PC	ABC-123-0001	PCSEQ	8		4
44	ABC-123	PC	ABC-123-0001	PCSEQ	9		4

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
45	ABC-123	PC	ABC-123-0001	PCSEQ	10		4
46	ABC-123	PC	ABC-123-0001	PCSEQ	11		4
47	ABC-123	PC	ABC-123-0001	PCSEQ	12		4
48	ABC-123	PP	ABC-123-0001	PPSEQ	4		4
49	ABC-123	PP	ABC-123-0001	PPSEQ	5		4
50	ABC-123	PP	ABC-123-0001	PPSEQ	6		4
51	ABC-123	PP	ABC-123-0001	PPSEQ	7		4

6.3.12.4 Suggestions for Implementing RELREC in the Submission of Pharmacokinetic Data

If a sponsor decides to create RELREC records, determine which of the scenarios best reflects how PP data are related to PC data. Questions that should be considered include:

1. Do all parameters for each pharmacokinetic profile use all concentrations for all subjects? If so, and you decide to create RELREC records showing this explicitly, create a PPGRPID value for all PP records and a PCGRPID value for all PC records for each profile for each subject, analyte, and reference time point. Decide whether to relate datasets (Section 8.1, Relating Groups of Records Within a Domain Using the --GRPID Variable) or records (Section 8.2, Relating Records - RELREC, and Example 1). If choosing the latter, create records in RELREC for each PCGRPID value and each PPGRPID value (Method A). Use RELID to show which PCGRPID and PPGRPID records are related. Consider RELREC Methods B, C, and D as applicable.
2. Do all parameters use the same concentrations, although maybe not all of them (Example 2)? If so, create a single PPGRPID value for all PP records, and 2 PCGRPID values for the PC records: a PCGRPID value for ones that were used and a PCGRPID value for those that were not used. Create records in RELREC for each PCGRPID value and each PPGRPID value (Method A). Use RELID to show which PCGRPID and PPGRPID records are related. Consider RELREC Methods B, C, and D as applicable.
3. Do any parameters use the same concentrations, but not as consistently as shown in Examples 1 and 2? If so, refer to Example 3. Assign a GRPID value to the PP records that use the same concentrations. More than one PPGRPID value may be necessary. Assign as many PCGRPID values in the PC domain as needed to group these records. Create records in RELREC for each PCGRPID value and each PPGRPID value (Method A). Use RELID to show which PCGRPID and PPGRPID records are related. Consider RELREC Methods B, C, and D as applicable.

If none of these applies, or the data become difficult to group, then start with Example 4, and decide which RELREC method would be easiest to implement and represent.

6.3.12.5 Conclusions

Relating the datasets (as described in Section 8, Representing Relationships and Data) is the simplest method; however, all time-point concentrations in PC must be used to calculate all parameters for all subjects. If datasets cannot be related, then individual subject records must be related. In either case, the values of PCGRPID and PPGRPID must take into account multiple analytes and multiple reference time points, if these exist.

Method A is clearly the most efficient in terms of having the least number of RELREC records, but it does require the assignment of --GRPID values (which are optional) in both the PC and PP datasets. Method D, in contrast, does not require the assignment of --GRPID values, but relies instead on the required --SEQ values in both datasets to relate the records. Although Method D results in the largest number of RELREC records compared to the other methods, it may be the easiest to implement consistently across the range of complexities shown in the examples. Two additional methods, Methods B and C, are also shown for Examples 1-3, representing hybrid approaches using --GRPID values in only one dataset (PP and PC, respectively) and --SEQ values for the other. These methods are best suited for sponsors who want to minimize the number of RELREC records while not having to assign --GRPID values in both domains. Methods B and C would not be ideal, however, if one expected complex scenarios as shown in Example 4.

Please note that an attempt has been made to approximate real pharmacokinetic data; however, the example values are not intended to reflect data used for actual analysis. When certain time-point concentrations have been omitted

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from PP calculations in Examples 2-4, the actual parameter values in the PP dataset have not been recalculated from those in Example 1 to reflect those omissions.

6.3.13 PC PP Cross-domain Examples

This version of SENDIG provides cross-domain examples for pharmacokinetic data. These new examples are provided to show 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.

6.3.13.1 PC PP Cross-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 PCRFTDTC 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 sponsor chose to populate PCTPTNUM with a value representing the number of hours postdose. The sponsor 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 PCSTRESC, PCLLOQ should be populated, and PCSTRESU must be populated.

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Rows 2-8, 11-18, 21-36: Show measurements where all result variables (PCORRES, PCSTRESC, 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

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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
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	2017-06-26T09:08:40
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	2017-06-26T09:08:40
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	2017-06-26T09:08:40
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	2017-06-26T09:08:40
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	PPSTRESC	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		

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PC PP Cross-domain Example 1: 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-123-1001	PCSTRESC	BLQ	PCCALCN	Numeric Interpretation for Calculations	0	DERIVED

6.3.13.2 PC PP Cross-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 PCELTM; 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 sponsor 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 PCSTRESC, 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	PCSTRESC	PCSTRESN	PCSTRESU	PCSTAT	PCREASND	PCNAM	PCSPEC	PCBLFL	PCLLOQ	PCEXCLFL	PCREASEX	PCNOMDY	PCDTC	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
1	5311016	PC	5311016-101	1	A9876543	ABC9876543	PARENT	3000	ng/mL	3000	3000	ng/mL			ACME INC	PLASMA		1			1		0H30MIN	1	PT30M	Day 1 dose	2018-01-01
2	5311016	PC	5311016-101	3	A9876543	ABC9876543	PARENT	6240	ng/mL	6240	6240	ng/mL			ACME INC	PLASMA		1			1		1H	2	PT1H	Day 1 dose	2018-01-01
3	5311016	PC	5311016-101	5	A9876543	ABC9876543	PARENT	6950	ng/mL	6950	6950	ng/mL			ACME INC	PLASMA		1			1		2H	3	PT2H	Day 1 dose	2018-01-01
4	5311016	PC	5311016-101	7	A9876543	ABC9876543	PARENT	3630	ng/mL	3630	3630	ng/mL			ACME INC	PLASMA		1			1		4H	4	PT4H	Day 1 dose	2018-01-01
5	5311016	PC	5311016-101	9	A9876543	ABC9876543	PARENT		ng/mL			ng/mL	NOT DONE	MISSING SAMPLE	ACME INC	PLASMA		1			1		8H	5	PT8H	Day 1 dose	2018-01-01
6	5311016	PC	5311016-101	11	A9876543	ABC9876543	PARENT	27	ng/mL	27	27	ng/mL			ACME INC	PLASMA		1			1		24H	6	PT24H	Day 1 dose	2018-01-01
7	5311016	PC	5311016-101	2	A9871234	ABC9871234	METABOLITE	6680	ng/mL	6680	6680	ng/mL			ACME INC	PLASMA		1			1		0H30MIN	1	PT30M	Day 1 dose	2018-01-01
8	5311016	PC	5311016-101	4	A9871234	ABC9871234	METABOLITE	11700	ng/mL	11700	11700	ng/mL			ACME INC	PLASMA		1			1		1H	2	PT1H	Day 1 dose	2018-01-01
9	5311016	PC	5311016-101	6	A9871234	ABC9871234	METABOLITE	14200	ng/mL	14200	14200	ng/mL			ACME INC	PLASMA		1			1		2H	3	PT2H	Day 1 dose	2018-01-01

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Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCTESTCD	PCTEST	PCCAT	PCORRES	PCORRESU	PCSTRESC	PCSTRESN	PCSTRESU	PCSTAT	PCREASND	PCNAM	PCSPEC	PCBLFL	PCLLOQ	PCEXCLFL	PCREASEX	PCNOMDY	PCDTC	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
10	5311016	PC	5311016-101	8	A9871234	ABC9871234	METABOLITE	13900	ng/mL	13900	13900	ng/mL			ACME INC	PLASMA		1			1		4H	4	PT4H	Day 1 dose	2018-01-01
11	5311016	PC	5311016-101	10	A9871234	ABC9871234	METABOLITE		ng/mL			ng/mL	NOT DONE	MISSING SAMPLE	ACME INC	PLASMA		1			1		8H	5	PT8H	Day 1 dose	2018-01-01
12	5311016	PC	5311016-101	12	A9871234	ABC9871234	METABOLITE	90.1	ng/mL	90.1	90.1	ng/mL			ACME INC	PLASMA		1			1		24H	6	PT24H	Day 1 dose	2018-01-01
13	5311016	PC	5311016-101	13	A9876543	ABC9876543	PARENT	<1	ng/mL	BLQ		ng/mL			ACME INC	PLASMA		1			14		PREDOSE	1	PT0H	Day 14 dose	2018-01-14
14	5311016	PC	5311016-101	15	A9876543	ABC9876543	PARENT	2970	ng/mL	2970	2970	ng/mL			ACME INC	PLASMA		1			14		0H30MIN	2	PT30M	Day 14 dose	2018-01-14
15	5311016	PC	5311016-101	17	A9876543	ABC9876543	PARENT	6270	ng/mL	6270	6270	ng/mL			ACME INC	PLASMA		1			14		1H	3	PT1H	Day 14 dose	2018-01-14
16	5311016	PC	5311016-101	19	A9876543	ABC9876543	PARENT	6290	ng/mL	6290	6290	ng/mL			ACME INC	PLASMA		1			14		2H	4	PT2H	Day 14 dose	2018-01-14
17	5311016	PC	5311016-101	21	A9876543	ABC9876543	PARENT	3170	ng/mL	3170	3170	ng/mL			ACME INC	PLASMA		1			14		4H	5	PT4H	Day 14 dose	2018-01-14
18	5311016	PC	5311016-101	23	A9876543	ABC9876543	PARENT	1550	ng/mL	1550	1550	ng/mL			ACME INC	PLASMA		1			14		8H	6	PT8H	Day 14 dose	2018-01-14
19	5311016	PC	5311016-101	25	A9876543	ABC9876543	PARENT	49.5	ng/mL	49.5	49.5	ng/mL			ACME INC	PLASMA		1			14		24H	7	PT24H	Day 14 dose	2018-01-14
20	5311016	PC	5311016-101	14	A9871234	ABC9871234	METABOLITE	<1	ng/mL	BLQ		ng/mL			ACME INC	PLASMA		1			14		PREDOSE	1	PT0H	Day 14 dose	2018-01-14
21	5311016	PC	5311016-101	16	A9871234	ABC9871234	METABOLITE	3350	ng/mL	3350	3350	ng/mL			ACME INC	PLASMA		1			14		0H30MIN	2	PT30M	Day 14 dose	2018-01-14
22	5311016	PC	5311016-101	18	A9871234	ABC9871234	METABOLITE	8370	ng/mL	8370	8370	ng/mL			ACME INC	PLASMA		1			14		1H	3	PT1H	Day 14 dose	2018-01-14
23	5311016	PC	5311016-101	20	A9871234	ABC9871234	METABOLITE	14800	ng/mL	14800	14800	ng/mL			ACME INC	PLASMA		1			14		2H	4	PT2H	Day 14 dose	2018-01-14
24	5311016	PC	5311016-101	22	A9871234	ABC9871234	METABOLITE	11900	ng/mL	11900	11900	ng/mL			ACME INC	PLASMA		1			14		4H	5	PT4H	Day 14 dose	2018-01-14
25	5311016	PC	5311016-101	24	A9871234	ABC9871234	METABOLITE	8610	ng/mL	8610	8610	ng/mL			ACME INC	PLASMA		1			14		8H	6	PT8H	Day 14 dose	2018-01-14
26	5311016	PC	5311016-101	26	A9871234	ABC9871234	METABOLITE	124	ng/mL	124	124	ng/mL			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	PPSTRESC	PPSTRESN	PPSTRESU	PPSPEC	PPNOMDY	PPTPTREF	PPRFTDTC	PPSTINT	PPENINT
1	5311016	PP	5311016-101	1	AUCINT	AUC from T1 to T2	ABC9876543	PARENT	56805	h*ng/mL	56805	56805	h*ng/mL	PLASMA	1	Day 1 dose	2018-01-01	PT0H	PT24H
2	5311016	PP	5311016-101	2	CMAX	Max Conc	ABC9876543	PARENT	6950	ng/mL	6950	6950	ng/mL	PLASMA	1	Day 1 dose	2018-01-01		
3	5311016	PP	5311016-101	3	TMAX	Max Conc	ABC9876543	PARENT	2	h	2	2	h	PLASMA	1	Day 1 dose	2018-01-01		
4	5311016	PP	5311016-101	4	AUCINTD	AUC from T1 to T2 Norm by Dose	ABC9876543	PARENT	5681	h*ng/mL/(mg/kg)	5681	5681	h*ng/mL/(mg/kg)	PLASMA	1	Day 1 dose	2018-01-01	PT0H	PT24H
5	5311016	PP	5311016-101	5	CMAXD	Max Conc Norm by Dose	ABC9876543	PARENT	695	ng/mL/(mg/kg)	695	695	ng/mL/(mg/kg)	PLASMA	1	Day 1 dose	2018-01-01		
6	5311016	PP	5311016-101	6	AUCINT	AUC from T1 to T2	ABC9876543	PARENT	41029	h*ng/mL	41029	41029	h*ng/mL	PLASMA	14	Day 14 dose	2018-01-01	PT0H	PT24H
7	5311016	PP	5311016-101	7	CMAX	Max Conc	ABC9876543	PARENT	6290	ng/mL	6290	6290	ng/mL	PLASMA	14	Day 14 dose	2018-01-01		
8	5311016	PP	5311016-101	8	TMAX	Time of CMAX	ABC9876543	PARENT	2	h	2	2	h	PLASMA	14	Day 14 dose	2018-01-01		

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Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPTESTCD	PPTEST	PPCAT	PPSCAT	PPORRES	PPORRESU	PPSTRESC	PPSTRESN	PPSTRESU	PPSPEC	PPNOMDY	PPTPTREF	PPRFTDTC	PPSTINT	PPENINT
9	5311016	PP	5311016-101	9	AUCINTD	AUC from T1 to T2 Norm by Dose	ABC9876543	PARENT	4103	h*ng/mL/(mg/kg)	4103	4103	h*ng/mL/(mg/kg)	PLASMA	14	Day 14 dose	2018-01-01	PT0H	PT24H
10	5311016	PP	5311016-101	10	CMAXD	Max Conc Norm by Dose	ABC9876543	PARENT	629	ng/mL/(mg/kg)	629	629	ng/mL/(mg/kg)	PLASMA	14	Day 14 dose	2018-01-01		
11	5311016	PP	5311016-101	11	AUCINT	AUC from T1 to T2	ABC9871234	METABOLITE	187216	h*ng/mL	187216	187216	h*ng/mL	PLASMA	1	Day 1 dose	2018-01-01	PT0H	PT24H
12	5311016	PP	5311016-101	12	CMAX	Max Conc	ABC9871234	METABOLITE	14200	ng/mL	14200	14200	ng/mL	PLASMA	1	Day 1 dose	2018-01-01		
13	5311016	PP	5311016-101	13	TMAX	Time of CMAX	ABC9871234	METABOLITE	2	h	2	2	h	PLASMA	1	Day 1 dose	2018-01-14		
14	5311016	PP	5311016-101	14	AUCINTD	AUC from T1 to T2 Norm by Dose	ABC9871234	METABOLITE	18722	h*ng/mL/(mg/kg)	18722	18722	h*ng/mL/(mg/kg)	PLASMA	1	Day 1 dose	2018-01-14	PT0H	PT24H
15	5311016	PP	5311016-101	15	CMAXD	Max Conc Norm by Dose	ABC9871234	METABOLITE	1420	ng/mL/(mg/kg)	1420	1420	ng/mL/(mg/kg)	PLASMA	1	Day 1 dose	2018-01-14		
16	5311016	PP	5311016-101	16	AUCINT	AUC from T1 to T2	ABC9871234	METABOLITE	152945	h*ng/mL	152945	152945	h*ng/mL	PLASMA	14	Day 14 dose	2018-01-14	PT0H	PT24H
17	5311016	PP	5311016-101	17	CMAX	Max Conc	ABC9871234	METABOLITE	14800	ng/mL	14800	14800	ng/mL	PLASMA	14	Day 14 dose	2018-01-14		
18	5311016	PP	5311016-101	18	TMAX	Time of CMAX	ABC9871234	METABOLITE	2	h	2	2	h	PLASMA	14	Day 14 dose	2018-01-14		
19	5311016	PP	5311016-101	19	AUCINTD	AUC from T1 to T2 Norm by Dose	ABC9871234	METABOLITE	15295	h*ng/mL/(mg/kg)	15295	15295	h*ng/mL/(mg/kg)	PLASMA	14	Day 14 dose	2018-01-14	PT0H	PT24H
20	5311016	PP	5311016-101	20	CMAXD	Max Conc Norm by Dose	ABC9871234	METABOLITE	1480	ng/mL/(mg/kg)	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

6.3.13.3 PC PP Cross-domain Example 3

This cross-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	PCORRES	PCORRESU	PCSTRESC	PCSTRESN	PCSTRESU	PCNAM	PCSPEC	PCMETHOD	PCBLFL	PCLLOQ	PCNOMDY	PCDTC	PCDY	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
1	ABC-123	PC	ABC-123-2001	1	LMN123	LMN-123			0.856	ug/mL	0.856	0.856	ug/mL	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
2	ABC-123	PC	ABC-123-2001	2	LMN123	LMN-123			28.9	ug/mL	28.9	28.9	ug/mL	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	ABC-123	PC	ABC-123-2001	3	LMN123	LMN-123			0.559	ug/mL	0.559	0.559	ug/mL	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	ABC-123	PC	ABC-123-2002	1	LMN123	LMN-123			1.76	ug/mL	1.76	1.76	ug/mL	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

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Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCTESTCD	PCTEST	PCCAT	PCSCAT	PCORRES	PCORRESU	PCSTRESC	PCSTRESN	PCSTRESU	PCNAM	PCSPEC	PCMETHOD	PCBLFL	PCLLOQ	PCNOMDY	PCDTC	PCDY	PCTPT	PCTPTNUM	PCELTM	PCTPTREF	PCRFTDTC
5	ABC-123	PC	ABC-123-2002	2	LMN123	LMN-123			39	ug/mL	39	39	ug/mL	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	ABC-123	PC	ABC-123-2002	3	LMN123	LMN-123			2.89	ug/mL	2.89	2.89	ug/mL	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	ABC-123	PC	ABC-123-2003	1	LMN123	LMN-123			0.646	ug/mL	0.646	0.646	ug/mL	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	ABC-123	PC	ABC-123-2003	2	LMN123	LMN-123			33.9	ug/mL	33.9	33.9	ug/mL	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	ABC-123	PC	ABC-123-2003	3	LMN123	LMN-123			0.39	ug/mL	0.39	0.39	ug/mL	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	ABC-123	PC	ABC-123-2004	1	LMN123	LMN-123			18.9	ug/mL	18.9	18.9	ug/mL	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	ABC-123	PC	ABC-123-2004	2	LMN123	LMN-123			16.1	ug/mL	16.1	16.1	ug/mL	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	ABC-123	PC	ABC-123-2004	3	LMN123	LMN-123			1.28	ug/mL	1.28	1.28	ug/mL	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	ABC-123	PC	ABC-123-2005	1	LMN123	LMN-123			20.8	ug/mL	20.8	20.8	ug/mL	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	ABC-123	PC	ABC-123-2005	2	LMN123	LMN-123			18	ug/mL	18	18	ug/mL	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	ABC-123	PC	ABC-123-2005	3	LMN123	LMN-123			17.8	ug/mL	17.8	17.8	ug/mL	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	ABC-123	PC	ABC-123-2006	1	LMN123	LMN-123			23.9	ug/mL	23.9	23.9	ug/mL	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	ABC-123	PC	ABC-123-2006	2	LMN123	LMN-123			22.4	ug/mL	22.4	22.4	ug/mL	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	ABC-123	PC	ABC-123-2006	3	LMN123	LMN-123			0.520	ug/mL	0.520	0.520	ug/mL	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	ABC-123	PC	ABC-123-2007	1	LMN123	LMN-123			46.9	ug/mL	46.9	46.9	ug/mL	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	ABC-123	PC	ABC-123-2007	2	LMN123	LMN-123			3.45	ug/mL	3.45	3.45	ug/mL	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	ABC-123	PC	ABC-123-2007	3	LMN123	LMN-123			BLQ (<0.200)	ug/mL	BLQ		ug/mL	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	ABC-123	PC	ABC-123-2008	1	LMN123	LMN-123			39.4	ug/mL	39.4	39.4	ug/mL	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	ABC-123	PC	ABC-123-2008	2	LMN123	LMN-123			4.44	ug/mL	4.44	4.44	ug/mL	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	ABC-123	PC	ABC-123-2008	3	LMN123	LMN-123			BLQ (<0.200)	ug/mL	BLQ		ug/mL	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	ABC-123	PC	ABC-123-2009	1	LMN123	LMN-123			45.1	ug/mL	45.1	45.1	ug/mL	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	ABC-123	PC	ABC-123-2009	2	LMN123	LMN-123			3.16	ug/mL	3.16	3.16	ug/mL	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	ABC-123	PC	ABC-123-2009	3	LMN123	LMN-123			BLQ (<0.200)	ug/mL	BLQ		ug/mL	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

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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 sponsor 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

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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

6.3.14 Subject Characteristics – SC

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

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 treatment 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 (http://www.cdisc.org/terminology) list.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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
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	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 sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

6.3.14.1 Assumptions for Subject Characteristics (SC) Domain Model

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. Sponsors 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 sponsor 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.

6.3.14.2 Example for Subject Characteristics (SC) Domain Model

Example 1

This example shows data that are collected once per subject and which do not fit into the 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

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Row	STUDYID	DOMAIN	USUBJID	SCSEQ	SCTESTCD	SCTEST	SCORRES	SCSTRESC	SCDTC	SCDY
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

6.3.14.3 List of Tests for Subject Characteristics (SC) Domain Model

The following table lists example tests for the SC domain, including descriptions of usage and any controlled terminology codelists associated with their values.

SCTESTCD	SCTEST	Type	Controlled Terms, Codelist or Format	Notes
HAIRCOLR	Hair Coat Color	Char		Used to designate the hair coat color of the animal
PHYMARK	Physical Marking	Char		Used to identify any physical markings present on the animal
ALTID	Alternate Identifier	Char		Used to record any alternate identifiers for the animal (e.g., a tattoo number which differs from the SUBJID)
USDANUM	USDA Number	Char		May be used when a USDA number has been assigned to the animal
SPLRNAM	Test Subject Supplier	Char		The name of the test subject supplier for this subject
SPLRLOC	Test Subject Supplier Site	Char		City, state, and country of the test subject supplier for this subject
FEEDREG	Feeding Regimen	Char		Describes the feeding regimen for this subject

6.3.15 Tumor Findings – TF

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

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 treatment 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 such as MASS 1 or 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
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	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					valid). TFTESTCD cannot contain characters other than letters, numbers, or underscores. Example: TUMEX.	
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, SPONSOR PATHOLOGIST.	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	Timing	For a specimen collected or observed post mortem, this is the date/time of subject disposition, in ISO 8601 format.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 sponsor-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

6.3.15.1 Assumptions for Tumor Findings (TF) Domain Model

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. This domain is necessary if the SEND datasets are the basis for creation of the tumor.xpt dataset (as described in the FDA *Study Data Technical Conformance Guide*). See Appendix C, Mapping to Tumor xpt File.
3. One subject may have multiple records for any organ, if multiple tumors were found.
4. The TFDETECT variable is the number of days relative to the first day of treatment 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.
5. 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).

6.3.15.2 Examples for Tumor Findings (TF) Domain Model

Example 1

This example shows some tumor findings for subject ABC-113.

Row 1: The original descriptive text by the pathologist is in the original result field (TFORRES), whereas the standardized result field (TFSTRESC) contain the CDISC submission value from the codelist NEOPLASM. This is a record for a "BENIGN" tumor (TFRESCAT) that did not cause the death of the animal (TFDTHREL).

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Row 2: The animal also had a malignant tumor in a kidney. This record is linked to row 4 via the TFGRPID value of 1 to relate the primary tumor with its metastasis to the ovaries.

Row 3: Another tumor was diagnosed in the subcutis (TFANTREG) of the skin. Because could not be determined if this tumor caused death, TFDTHREL is "U" (Unknown).

Row 4: The tumor in row 2 was identified to have metastasized to the ovaries. Therefore, TFSTRESC is the same value as row 2, and TFRESCAT is METASTATIC. This record is linked to row 2 via the TFGRPID value of 1 to relate the metastasis to the finding at the primary site identified for the tumor.

Rows 5-7: These rows represent a tumor that was discovered in multiple tissues and for which the primary site was not able to be determined. In this case, the sponsor decided to represent this case by labeling each of the contributing findings (rows 5 and 6) as metastatic (TFRESCAT="METASTATIC"), with a row for the multicentric neoplasm with a TFSPEC value of "SITE, UNCERTAIN PRIMARY" (row 7). All 3 rows are related via the TFGRPID value of 2. Note: the use of "SITE, UNCERTAIN PRIMARY" is sponsor-specific; an alternative (based on how the data are collected) would be to exclude this row and label each site with TFRESCAT value of "MALIGNANT".

tf.xpt

Row	STUDYID	DOMAIN	USUBJID	TFSEQ	TFGRPID	TFSPID	TFTESTCD	TFTEST	TFORRES	TFSTRESC	TFRESCAT	TFSPEC	TFANTREG	TFLAT	TFDTHREL	TFDETECT
1	ABC	TF	ABC-113	1		MASS A	TUMEX	Tumor Examination	ACINAR CELL ADENOMA, PRIMARY	ADENOMA, ACINAR CELL, BENIGN	BENIGN	PANCREAS			N	699
2	ABC	TF	ABC-113	2	1	MASS B	TUMEX	Tumor Examination	HISTIOCYTIC SARCOMA, PRIMARY	SARCOMA, HISTIOCYTIC, MALIGNANT	MALIGNANT	KIDNEY		LEFT	N	699
3	ABC	TF	ABC-113	3		MASS C	TUMEX	Tumor Examination	FIBROSARCOMA, PRIMARY	FIBROSARCOMA, MALIGNANT	MALIGNANT	SKIN	SUBCUTIS		U	699
4	ABC	TF	ABC-113	4	1	MASS D	TUMEX	Tumor Examination	HISTIOCYTIC SARCOMA, SECONDARY	SARCOMA, HISTIOCYTIC, MALIGNANT	METASTATIC	OVARY		BILATERAL	N	699
5	ABC	TF	ABC-113	5	2	MASS E	TUMEX	Tumor Examination	LYMPHOMA, MALIGNANT, MULTICENTRIC	LYMPHOMA, MALIGNANT	METASTATIC	LIVER	PORTAL TRIAD		Y	673
6	ABC	TF	ABC-113	6	2	MASS F	TUMEX	Tumor Examination	LYMPHOMA, MALIGNANT, MULTICENTRIC	LYMPHOMA, MALIGNANT	METASTATIC	SPLEEN			Y	673
7	ABC	TF	ABC-113	7	2	MASS G	TUMEX	Tumor Examination	LYMPHOMA, MALIGNANT, MULTICENTRIC	LYMPHOMA, MALIGNANT	MALIGNANT	SITE, UNCERTAIN PRIMARY			Y	673

These rows show the supplemental qualifier records for the modifiers associated with the findings in Example 1.

supptf.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	ABC	TF	ABC-113	TFSEQ	1	TFRESMOD	Result Modifiers	PRIMARY	COLLECTED
2	ABC	TF	ABC-113	TFSEQ	2	TFRESMOD	Result Modifiers	PRIMARY	COLLECTED
3	ABC	TF	ABC-113	TFSEQ	3	TFRESMOD	Result Modifiers	PRIMARY	COLLECTED
4	ABC	TF	ABC-113	TFSEQ	4	TFRESMOD	Result Modifiers	SECONDARY	COLLECTED
5	ABC	TF	ABC-113	TFSEQ	5	TFRESMOD	Result Modifiers	MULTICENTRIC	COLLECTED
6	ABC	TF	ABC-113	TFSEQ	6	TFRESMOD	Result Modifiers	MULTICENTRIC	COLLECTED
7	ABC	TF	ABC-113	TFSEQ	7	TFRESMOD	Result Modifiers	MULTICENTRIC	COLLECTED

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Example 2

This example shows a single tumor finding for subject ABC-101 in a carcinogenicity study.This tumor was not the cause of death (TFDTHREL="N") and it was not discovered during the in-life phase, so TFDETECT is populated with death day. However, the finding relates to a necropsy finding of raised focus of the lung, so a RELREC record is created for this relationship.

tf.xpt

Row	STUDYID	DOMAIN	USUBJID	TFSEQ	TFSPID	TFTESTCD	TFTEST	TFORRES	TFSTRESC	TFRESCAT	TFSPEC	TFLAT	TFDTHREL	TFDETECT
1	ABC	TF	ABC-101	1	MASS A	TUMEX	Tumor Examination	BRONCHIOLO-ALVEOLAR CARCINOMA	CARCINOMA, BRONCHIOLOALVEOLAR, MALIGNANT	MALIGNANT	LUNG	LEFT	N	702

This RELREC example is included as part of the comment in row 1.

Row 1: This record points to 1 record in the TF domain, describing the tumor.

Row 2: This record points to 1 record in the MA domain, describing the related necropsy finding.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	TF	ABC-101	TFSEQ	1		1
2	ABC	MA	ABC-101	MASEQ	10		1

Example 3

This example shows a tumor finding for subject ABC-245.

This record shows a malignant (TFRESCAT) tumor that was the cause of death for the animal (TFDTHREL="Y"). In addition, this tumor was palpated during the experimental phase. It was determined that the earliest onset day for this tumor was study day 653 for this subject. This record is related to records in other domains as indicated by the RELREC example that follows.

tf.xpt

Row	STUDYID	DOMAIN	USUBJID	TFSEQ	TFSPID	TFTESTCD	TFTEST	TFORRES	TFSTRESC	TFRESCAT	TFSPEC	TFDTHREL	TFDETECT
1	ABC	TF	ABC-245	45	MASS 4	TUMEX	Tumor Examination	HISTIOCYTIC SARCOMA	SARCOMA, HISTIOCYTIC, MALIGNANT	MALIGNANT	BONE, FEMUR	Y	653

This RELREC example is included as part of the comment in row 1.

Row 1: This record points to 1 record in the TF domain, describing the tumor.

Row 2: This record points to all the records in the CL domain that pertain to the specific tumor (identified by "MASS 4" in --SPID), since the tumor was discovered (and observations recorded in CL) during the experimental phase of the study.

Row 3: This record points to all the records in the PM domain that pertain to the specific tumor (identified by "MASS 4" in --SPID), since the tumor was discovered (and observations recorded in PM) during the experimental phase of the study.

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Row 4: This record points to all the records in the MI domain that pertain to the specific tumor (identified by "MASS 4" in --SPID), since the tumor was discovered (and had observations in MI).

Row 5: This record points to all the records in the MA domain that pertain to the specific tumor (identified by "MASS 4" in --SPID), since the tumor was discovered (and had observations in MA).

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	TF	ABC-245	TFSPID	MASS 4		2
2	ABC	CL	ABC-245	CLSPID	MASS 4		2
3	ABC	PM	ABC-245	PMSPID	MASS 4		2
4	ABC	MI	ABC-245	MISPID	MASS 4		2
5	ABC	MA	ABC-245	MASPID	MASS 4		2

6.3.16 Vital Signs – VS

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

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 treatment group number.	Perm
VSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference identifier	Perm
VSTESTCD	Vital Signs Test Short Name	Char	(SVSTSTCD)	Topic	Short name of the measurement described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). VSTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
VSTEST	Vital Signs Test Name	Char	(SVSTST)	Synonym Qualifier	Long name for VSTESTCD. The value in VSTEST 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 (example SITTING or STANDING).	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 (http://www.cdisc.org/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 submited in numeric format in VSSTRESN.	Exp
VSSTRESN	Standardized Result in Numeric Format	Num		Result Qualifier	Used for numeric results or findings in standard format; contains the numeric form of VSSTRESC. VSSTRESN 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 VSSTRESN.	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
VSBLFL	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 sponsor 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	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	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	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	
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 sponsor-defined RFSTDTC variable in the Demographics (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-Treatment, 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
VSELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	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 or '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, 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
VSRFTDTC	Date/Time of Time Point Reference	Char	ISO 8601	Timing	Date/Time of the reference time point, VSTPTREF.	Perm

6.3.16.1 Assumptions for Vital Signs (VS) Domain Model

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.

6.3.16.2 Examples for Vital Signs (VS) Domain Model

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.

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vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	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 sponsor chose to show this as a planned elapsed time of 4 hours in VSELTM.

vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSBLFL	VSDTC	VSDY	VSNOMDY	VSTPT	VSTPTNUM	VSELTM	VSTPTREF
1	ABC	VS	ABC-001-001	1	TEMP	Temperature	34.7	C	34.7	34.7	C	Y	2012-10-25	1	1	PREDOSE	1	PT0H	Day 1 Dose
2	ABC	VS	ABC-001-001	2	TEMP	Temperature	36.2	C	36.2	36.2	C		2012-10-25	1	1	30 MIN	2	PT0.5H	Day 1 Dose
3	ABC	VS	ABC-001-001	3	TEMP	Temperature	37.1	C	37.1	37.1	C		2012-10-25	1	1	1H	3	PT1H	Day 1 Dose
4	ABC	VS	ABC-001-001	4	TEMP	Temperature	34.3	C	34.3	34.3	C		2012-10-25	1	1	4H-6H	4	PT4H	Day 1 Dose
5	ABC	VS	ABC-001-001	5	TEMP	Temperature	35.2	C	35.2	35.2	C		2012-11-01	8	8	PREDOSE	1	PT0H	Day 2 Dose
6	ABC	VS	ABC-001-001	6	TEMP	Temperature	35.9	C	35.9	35.9	C		2012-11-01	8	8	30 MIN	2	PT0.5H	Day 2 Dose
7	ABC	VS	ABC-001-001	7	TEMP	Temperature	36.5	C	36.5	36.5	C		2012-11-01	8	8	1H	3	PT1H	Day 2 Dose
8	ABC	VS	ABC-001-001	8	TEMP	Temperature	34.9	C	34.9	34.9	C		2012-11-01	8	8	4H-6H	4	PT4H	Day 2 Dose

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6.3.17 ECG Test Results – EG

eg.xpt, ECG - Findings. One record per test per ECG reference per observation time per subject, Tabulation.

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 treatment group number.	Perm
EGREFID	ECG Reference Identifier	Char		Identifier	Internal or external ECG identifier. Example: UUID.	Perm
EGSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-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 results are numeric, they should also be stored in numeric format in EGSTRESN.	Exp
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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 sponsor 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 sponsor 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	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	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 sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 sponsor-defined RFSTDTC variable in the Demographics (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-Treatment, 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 EGTPTNUM and EGTPTREF. Examples: Predose, 1 Hour Postdose.	Perm
EGTPTNUM	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	Timing	Planned elapsed time (in ISO 8601 format) relative to a fixed time point reference (EGTPTREF). 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 EGTPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by EGTPTREF.	Perm
EGTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by EGELTM, if used for EGTPTNUM, and EGTPT. It is recommended that EGTPTREF 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	Timing	Date/Time of the reference time point, EGTPTREF.	Perm
EGEVLINT	Evaluation Interval	Char	ISO 8601	Timing	Length of evaluation interval in ISO 8601 duration format. Used in place of EGSTINT and EGENINT when EGTPTREF is not available.	Perm
EGSTINT	Planned Start of Assessment Interval	Char	ISO 8601	Timing	Planned Start of an asessment interval relative to Time Point Reference (EGTPTREF) in ISO 8601 duration format.	Perm
EGENINT	Planned End of Assessment Interval	Char	ISO 8601	Timing	Planned End of an assessment interval relative to Time Point Reference (EGTPTREF) in ISO 8601 duration format.	Perm

6.3.17.1 Assumptions for ECG Test Results (EG) Domain Model

1. The EG domain captures electrocardiographic (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.

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6.3.17.2 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	EGSTRESC	EGSTRESN	EGSTRESU	EGLEAD	EGMETHOD	EGCSTATE	EGBLFL	EGDTC	EGDY	EGNOMDY	EGTPT	EGTPTNUM	EGELTM	EGTPTREF	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

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Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGTESTCD	EGTEST	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU	EGLEAD	EGMETHOD	EGCSTATE	EGBLFL	EGDTC	EGDY	EGNOMDY	EGTPT	EGTPTNUM	EGELTM	EGTPTREF	EGRFTDTC
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 EGTPTREF, 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 (EGENINT) of the evaluation relative to the referenced dose (EGTPTREF). Each of the 6 intervals has a text label (e.g., "Predose", "1 hr Postdose") indicated in the EGTPT variable. The sponsor has defined the labels to be the end of the interval relative to the referenced dose. The entry in EGTPT is represented 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.

eg.xpt

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGTESTCD	EGTEST	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU	EGLEAD	EGMETHOD	EGCSTATE	EGBLFL	EGDTC	EGDY	EGENDTC	EGENDY	EGNOMDY	EGTPT	EGTPTNUM	EGELTM	EGTPTREF	EGRFTDTC	EGSTINT	EGENINT
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	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	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	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	XYZ	EG	XYZ-001-001	3	QTAG	QT Interval, Aggregate	UNCONSTRAINED	132.17	msec	132.17	132.17	msec	LEAD I	12 LEAD STANDARD	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	XYZ	EG	XYZ-001-001	4	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	211.91	msec	211.91	211.91	msec	LEAD I	12 LEAD STANDARD	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	XYZ	EG	XYZ-001-001	5	RRAG	RR Interval, Aggregate	UNCONSTRAINED	354.13	msec	354.13	354.13	msec	LEAD I	12 LEAD STANDARD	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	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	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	XYZ	EG	XYZ-001-001	7	QTAG	QT Interval, Aggregate	UNCONSTRAINED	150.19	msec	150.19	150.19	msec	LEAD I	12 LEAD STANDARD	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	XYZ	EG	XYZ-001-001	8	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	213.34	msec	213.34	213.34	msec	LEAD I	12 LEAD STANDARD	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	XYZ	EG	XYZ-001-001	9	RRAG	RR Interval, Aggregate	UNCONSTRAINED	363.43	msec	363.43	363.43	msec	LEAD I	12 LEAD STANDARD	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	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	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

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Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGTESTCD	EGTEST	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU	EGLEAD	EGMETHOD	EGCSTATE	EGBLFL	EGDTC	EGDY	EGENDTC	EGENDY	EGNOMDY	EGTPT	EGTPTNUM	EGELTM	EGTPTREF	EGRFTDTC	EGSTINT	EGENINT
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	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	XYZ	EG	XYZ-001-001	12	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	212.35	msec	212.35	212.35	msec	LEAD I	12 LEAD STANDARD	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	XYZ	EG	XYZ-001-001	13	RRAG	RR Interval, Aggregate	UNCONSTRAINED	361.04	msec	361.04	361.04	msec	LEAD I	12 LEAD STANDARD	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	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	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	XYZ	EG	XYZ-001-001	15	QTAG	QT Interval, Aggregate	UNCONSTRAINED	149.01	msec	149.01	149.01	msec	LEAD I	12 LEAD STANDARD	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	XYZ	EG	XYZ-001-001	16	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	210.76	msec	210.76	210.76	msec	LEAD I	12 LEAD STANDARD	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	XYZ	EG	XYZ-001-001	17	RRAG	RR Interval, Aggregate	UNCONSTRAINED	360.23	msec	360.23	360.23	msec	LEAD I	12 LEAD STANDARD	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	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	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	XYZ	EG	XYZ-001-001	19	QTAG	QT Interval, Aggregate	UNCONSTRAINED	147.98	msec	147.98	147.98	msec	LEAD I	12 LEAD STANDARD	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	XYZ	EG	XYZ-001-001	20	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	209.40	msec	209.40	209.40	msec	LEAD I	12 LEAD STANDARD	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	XYZ	EG	XYZ-001-001	21	RRAG	RR Interval, Aggregate	UNCONSTRAINED	259.89	msec	259.89	259.89	msec	LEAD I	12 LEAD STANDARD	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	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	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	XYZ	EG	XYZ-001-001	23	QTAG	QT Interval, Aggregate	UNCONSTRAINED	133.67	msec	133.67	133.67	msec	LEAD I	12 LEAD STANDARD	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	XYZ	EG	XYZ-001-001	24	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	210.99	msec	210.99	210.99	msec	LEAD I	12 LEAD STANDARD	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 sponsor has defined the interval labels to be the end of the interval relative to the referenced dose. However, sponsors 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 (EGELTM).

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.

eg.xpt

Row	EGDTC	EGDY	EGENDTC	EGENDY	EGNOMDY	EGTPT	EGTPTNUM	EGELTM	EGTPTREF	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

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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

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

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

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	

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).

eg.xpt

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGGRPID	EGTESTCD	EGTEST	EGCAT	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU	EGLEAD	EGMETHOD	EGCSTATE	EGBLFL	EGEVAL	EGDTC	EGDY	EGNOMDY	EGTPT	EGTPTNUM	EGTPTREF	EGRFTDTC
1	XYZ	EG	XYZ-001-001	1	1	QTAG	QT Interval, Aggregate	MEASUREMENT	UNCONSTRAINED	132.172	msec	132.172	132.172	msec	LEAD I	12 LEAD STANDARD	CONSCIOUS			2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
2	XYZ	EG	XYZ-001-001	2	1	INTP	Interpretation	INTERPRETATION	UNCONSTRAINED	QT MEAN POSSIBLY ABNORMAL		QT MEAN POSSIBLY ABNORMAL							TECHNICIAN	2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
3	XYZ	EG	XYZ-001-001	3	1	INTP	Interpretation	DIAGNOSIS	UNCONSTRAINED	PROLONGED QT		PROLONGED QT							CARDIOLOGIST	2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
4	XYZ	EG	XYZ-001-002	1	2	TWARAG	T Wave Area, Aggregate	MEASUREMENT	UNCONSTRAINED	-211.905	msec	-211.905	-211.905	msec	LEAD I	12 LEAD STANDARD	CONSCIOUS			2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
5	XYZ	EG	XYZ-001-002	2	2	INTP	Interpretation	INTERPRETATION	UNCONSTRAINED	T WAVE INVERSION		T WAVE ABNORMALITY							ECG ANALYST	2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
6	XYZ	EG	XYZ-001-002	3	2	INTP	Interpretation	DIAGNOSIS	UNCONSTRAINED	LEFT VENTRICULAR HYPERTROPHY		LEFT VENTRICULAR HYPERTROPHY							CARDIOLOGIST	2009-01-15T06:00	1	1	Predose	0	Day 1 Dose	2009-01-15T07:00
7	XYZ	EG	XYZ-001-002	4	2	INTP	Interpretation	DIAGNOSIS	UNCONSTRAINED	JUNCTIONAL TACHYCARDIA		JUNCTIONAL TACHYCARDIA							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 time points. 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.

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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.

eg.xpt

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGTESTCD	EGTEST	EGPOS	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU	EGLEAD	EGMETHOD	EGCSTATE	EGBLFL	EGDTC	EGDY	EGNOMDY	EGTPT	EGTPTNUM	EGELTM	EGTPTREF	EGRFTDTC	EGSTINT	EGENINT
1	XYZ	EG	XYZ-101-101	1	RRAG	RR Interval, Aggregate	UNCONSTRAINED	248.105	msec	248.105	248.105	msec	LEAD CV5RL	6 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
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	6 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
3	XYZ	EG	XYZ-101-101	3	QTAG	QT Interval, Aggregate	UNCONSTRAINED	132.172	msec	132.172	132.172	msec	LEAD CV5RL	6 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
4	XYZ	EG	XYZ-101-101	4	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	211.905	msec	211.905	211.905	msec	LEAD CV5RL	6 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
5	XYZ	EG	XYZ-201-201	5	RRAG	RR Interval, Aggregate	STANDING	354.13	msec	354.13	354.13	msec	LEAD II	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
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	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
7	XYZ	EG	XYZ-201-201	7	QTAG	QT Interval, Aggregate	STANDING	150.19	msec	150.19	150.19	msec	LEAD II	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
8	XYZ	EG	XYZ-201-201	8	QTCFAG	QTcF Interval, Aggregate	STANDING	213.335	msec	213.335	213.335	msec	LEAD II	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
9	XYZ	EG	XYZ-301-301	9	RRAG	RR Interval, Aggregate	UNCONSTRAINED	363.428	msec	363.428	363.428	msec	LEAD I	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
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	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
11	XYZ	EG	XYZ-301-301	11	QTAG	QT Interval, Aggregate	UNCONSTRAINED	150.819	msec	150.819	150.819	msec	LEAD I	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H
12	XYZ	EG	XYZ-301-301	12	QTCFAG	QTcF Interval, Aggregate	UNCONSTRAINED	212.351	msec	212.351	212.351	msec	LEAD I	12 LEAD STANDARD	CONSCIOUS		2009-04-15T07:00	1	1	1H POSTDOSE	1	PT1H	Day 1 Dose	2009-04-15T06:00	PT0H	PT1H

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6.3.18 Cardiovascular Test Results – CV

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

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 treatment group number.	Perm
CVSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-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 (example SITTING or 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
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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 sponsor 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	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	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 sponsor-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 sponsor-defined RFSTDTC variable in the Demographics (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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
CVELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	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
CVRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/Time of the reference time point, CVTPTREF.	Perm
CVEVLINT	Evaluation Interval	Char	ISO 8601	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	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	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

6.3.18.1 Assumptions for Cardiovascular (CV) Domain Model

1. The DV 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.

6.3.18.2 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.

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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	CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVMETHOD	CVCSTATE	CVBLFL	CVDRVFL	CVDTC	CVDY	CVNOMDY	CVTPT	CVTPTNUM	CVELTM	CVTPTREF	CVSTINT	CVENINT
1	ABC	CV	ABC-001-001	1	SYSBP	Systolic Blood Pressure	SITTING	154	mmHg	154	154	mmHg	External Cuff	CONSCIOUS			1999-06-19T08:45	1	1	8 hours postdose	1	PT8H	Day 1 Dose		
2	ABC	CV	ABC-001-001	2	SYSBP	Systolic Blood Pressure	SITTING	152	mmHg	152	152	mmHg	External Cuff	CONSCIOUS			1999-06-19T09:00	1	1	8 hours postdose	1	PT8H	Day 1 Dose		
3	ABC	CV	ABC-001-001	3	SYSBP	Systolic Blood Pressure	SITTING	153	mmHg	153	153	mmHg	External Cuff	CONSCIOUS	Y	Y	1999-06-19	1	1	8 hours postdose	1	PT8H	Day 1 Dose		
4	ABC	CV	ABC-001-001	4	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg	External Cuff	CONSCIOUS			1999-06-19T08:45	1	1	8 hours postdose	1	PT8H	Day 1 Dose		
5	ABC	CV	ABC-001-001	5	DIABP	Diastolic Blood Pressure	SITTING	48	mmHg	48	48	mmHg	External Cuff	CONSCIOUS			1999-06-19T09:00	1	1	8 hours postdose	1	PT8H	Day 1 Dose		
6	ABC	CV	ABC-001-001	6	DIABP	Diastolic Blood Pressure	SITTING	46	mmHg	46	46	mmHg	External Cuff	CONSCIOUS	Y	Y	1999-06-19	1	1	8 hours postdose	1	PT8H	Day 1 Dose		
7	ABC	CV	ABC-001-001	7	PULSEPR	Pulse Pressure	SITTING	107	mmHg	72	72	mmHg	External Cuff	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 time points (baseline, 120 minutes, 240 minutes) relative to the administration of the third dose level of a Latin square design (with CVTPTREF as "Dose 3"). At each time point, 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	CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVMETHOD	CVCSTATE	CVBLFL	CVDTC	CVDY	CVNOMDY	CVTPT	CVTPTNUM	CVELTM	CVTPTREF	CVRFTDTC	CVSTINT	CVENINT
1	AA222	CV	1003	1	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	50.94	mmHg	50.94	50.94	mmHg	Intravascular	CONSCIOUS	Y	2006-09-15	15	15	0 min	0	PT0M	Dose 3	2006-09-15T10:30	-PT60M	PT0M
2	AA222	CV	1003	2	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	50.68	mmHg	50.68	50.68	mmHg	Intravascular	CONSCIOUS		2006-09-15	15	15	120 min	120	PT120M	Dose 3	2006-09-15T10:30	PT60M	PT120M
3	AA222	CV	1003	3	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	49.37	mmHg	49.37	49.37	mmHg	Intravascular	CONSCIOUS		2006-09-15	15	15	240 min	240	PT240M	Dose 3	2006-09-15T10:30	PT180M	PT240M
4	AA222	CV	1003	4	HR	Heart Rate	UNCONSTRAINED	139.2	beats/min	139.2	139.2	beats/min	Intravascular	CONSCIOUS	Y	2006-09-15	15	15	0 min	0	PT0M	Dose 3	2006-09-15T10:30	-PT60M	PT0M
5	AA222	CV	1003	5	HR	Heart Rate	UNCONSTRAINED	128.3	beats/min	128.3	128.3	beats/min	Intravascular	CONSCIOUS		2006-09-15	15	15	120 min	120	PT120M	Dose 3	2006-09-15T10:30	PT60M	PT120M

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Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVMETHOD	CVCSTATE	CVBLFL	CVDTC	CVDY	CVNOMDY	CVTPT	CVTPTNUM	CVELTM	CVTPTREF	CVRFTDTC	CVSTINT	CVENINT
6	AA222	CV	1003	6	HR	Heart Rate	UNCONSTRAINED	118.4	beats/min	118.4	118.4	beats/min	Intravascular	CONSCIOUS		2006-09-15	15	15	240 min	240	PT240M	Dose 3	2006-09-15T10:30	PT180M	PT240M
7	AA222	CV	1003	7	MAP	Mean Arterial Pressure	UNCONSTRAINED	66.96	mmHg	66.96	66.96	mmHg	Intravascular	CONSCIOUS	Y	2006-09-15	15	15	0 min	0	PT0M	Dose 3	2006-09-15T10:30	-PT60M	PT0M
8	AA222	CV	1003	8	MAP	Mean Arterial Pressure	UNCONSTRAINED	66.66	mmHg	66.66	66.66	mmHg	Intravascular	CONSCIOUS		2006-09-15	15	15	120 min	120	PT120M	Dose 3	2006-09-15T10:30	PT60M	PT120M
9	AA222	CV	1003	9	MAP	Mean Arterial Pressure	UNCONSTRAINED	65.99	mmHg	65.99	65.99	mmHg	Intravascular	CONSCIOUS		2006-09-15	15	15	240 min	240	PT240M	Dose 3	2006-09-15T10:30	PT180M	PT240M
10	AA1111	CV	1008	10	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	34.11	mmHg	34.11	34.11	mmHg	Intravascular	CONSCIOUS	Y	2006-09-01	1	1	0 min	0	PT0M	Dose 3	2006-09-01T10:30	-PT60M	PT0M
11	AA1111	CV	1008	11	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	28.63	mmHg	28.63	28.63	mmHg	Intravascular	CONSCIOUS		2006-09-01	1	1	120 min	120	PT120M	Dose 3	2006-09-01T10:30	PT60M	PT120M
12	AA1111	CV	1008	12	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	28.96	mmHg	28.96	28.96	mmHg	Intravascular	CONSCIOUS		2006-09-01	1	1	240 min	240	PT240M	Dose 3	2006-09-01T10:30	PT180M	PT240M
13	AA1111	CV	1008	13	HR	Heart Rate	UNCONSTRAINED	186.1	beats/min	186.1	186.1	beats/min	Intravascular	CONSCIOUS	Y	2006-09-01	1	1	0 min	0	PT0M	Dose 3	2006-09-01T10:30	-PT60M	PT0M
14	AA1111	CV	1008	14	HR	Heart Rate	UNCONSTRAINED	168.3	beats/min	168.3	168.3	beats/min	Intravascular	CONSCIOUS		2006-09-01	1	1	120 min	120	PT120M	Dose 3	2006-09-01T10:30	PT60M	PT120M
15	AA1111	CV	1008	15	HR	Heart Rate	UNCONSTRAINED	150.8	beats/min	150.8	150.8	beats/min	Intravascular	CONSCIOUS		2006-09-01	1	1	240 min	240	PT240M	Dose 3	2006-09-01T10:30	PT180M	PT240M
16	AA1111	CV	1008	16	MAP	Mean Arterial Pressure	UNCONSTRAINED	53.48	mmHg	53.48	53.48	mmHg	Intravascular	CONSCIOUS	Y	2006-09-01	1	1	0 min	0	PT0M	Dose 3	2006-09-01T10:30	-PT60M	PT0M
17	AA1111	CV	1008	17	MAP	Mean Arterial Pressure	UNCONSTRAINED	47.67	mmHg	47.67	47.67	mmHg	Intravascular	CONSCIOUS		2006-09-01	1	1	120 min	120	PT120M	Dose 3	2006-09-01T10:30	PT60M	PT120M
18	AA1111	CV	1008	18	MAP	Mean Arterial Pressure	UNCONSTRAINED	46.48	mmHg	46.48	46.48	mmHg	Intravascular	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 sponsor chose to label its time points (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	CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVMETHOD	CVCSTATE	CVBLFL	CVDTC	CVDY	CVNOMDY	CVTPT	CVTPTNUM	CVELTM	CVTPTREF	CVRFTDTC	CVSTINT	CVENINT
1	ABC-123	CV	101	1	HR	Heart Rate	UNCONSTRAINED	162	beats/min	162	162	beats/min	Intravascular	CONSCIOUS	Y	2012-03-22	1	1	00:00:00	1	PT0M	Day 1 Dose	2012-03-22T09:52	-PT1H	PT0M
2	ABC-123	CV	101	2	HR	Heart Rate	UNCONSTRAINED	158	beats/min	158	158	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	00:15:00	2	PT15M	Day 1 Dose	2012-03-22T09:52	PT0M	PT15M
3	ABC-123	CV	101	3	HR	Heart Rate	UNCONSTRAINED	152	beats/min	152	152	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	00:30:00	3	PT30M	Day 1 Dose	2012-03-22T09:52	PT15M	PT30M
4	ABC-123	CV	101	4	HR	Heart Rate	UNCONSTRAINED	141	beats/min	141	141	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	00:45:00	4	PT45M	Day 1 Dose	2012-03-22T09:52	PT30M	PT45M
5	ABC-123	CV	101	5	HR	Heart Rate	UNCONSTRAINED	120	beats/min	120	120	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	01:00:00	5	PT1H	Day 1 Dose	2012-03-22T09:52	PT45M	PT1H
6	ABC-123	CV	101	6	HR	Heart Rate	UNCONSTRAINED	113	beats/min	113	113	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	01:15:00	6	PT1H15M	Day 1 Dose	2012-03-22T09:52	PT1H	PT1H15M
7	ABC-123	CV	101	7	HR	Heart Rate	UNCONSTRAINED	123	beats/min	123	123	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	01:30:00	7	PT1H30M	Day 1 Dose	2012-03-22T09:52	PT1H15M	PT1H30M
8	ABC-123	CV	101	8	HR	Heart Rate	UNCONSTRAINED	143	beats/min	143	143	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	01:45:00	8	PT1H45M	Day 1 Dose	2012-03-22T09:52	PT1H30M	PT1H45M
9	ABC-123	CV	101	9	HR	Heart Rate	UNCONSTRAINED	146	beats/min	146	146	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	02:00:00	9	PT2H	Day 1 Dose	2012-03-22T09:52	PT1H45M	PT2H

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Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVMETHOD	CVCSTATE	CVBLFL	CVDTC	CVDY	CVNOMDY	CVTPT	CVTPTNUM	CVELTM	CVTPTREF	CVRFTDTC	CVSTINT	CVENINT
10	ABC-123	CV	101	10	HR	Heart Rate	UNCONSTRAINED	166	beats/min	166	166	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	03:00:00	10	PT3H	Day 1 Dose	2012-03-22T09:52	PT2H	PT3H
11	ABC-123	CV	101	11	HR	Heart Rate	UNCONSTRAINED	146	beats/min	146	146	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	04:00:00	11	PT4H	Day 1 Dose	2012-03-22T09:52	PT3H	PT4H
12	ABC-123	CV	101	12	HR	Heart Rate	UNCONSTRAINED	149	beats/min	149	149	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	05:00:00	12	PT5H	Day 1 Dose	2012-03-22T09:52	PT4H	PT5H
13	ABC-123	CV	101	13	HR	Heart Rate	UNCONSTRAINED	123	beats/min	123	123	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	06:00:00	13	PT6H	Day 1 Dose	2012-03-22T09:52	PT5H	PT6H
14	ABC-123	CV	101	14	HR	Heart Rate	UNCONSTRAINED	105	beats/min	105	105	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	08:00:00	14	PT8H	Day 1 Dose	2012-03-22T09:52	PT6H	PT8H
15	ABC-123	CV	101	15	HR	Heart Rate	UNCONSTRAINED	100	beats/min	100	100	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	10:00:00	15	PT10H	Day 1 Dose	2012-03-22T09:52	PT8H	PT10H
16	ABC-123	CV	101	16	HR	Heart Rate	UNCONSTRAINED	113	beats/min	113	113	beats/min	Intravascular	CONSCIOUS		2012-03-22	1	1	12:00:00	16	PT12H	Day 1 Dose	2012-03-22T09:52	PT10H	PT12H

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6.3.19 Respiratory Test Results – RE

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

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 treatment group number.	Perm
RESPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-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 (http://www.cdisc.org/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

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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
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 sponsor 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
REDTC	Date/Time of Respiratory Measurement	Char	ISO 8601	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
REENDTC	End Date/Time of Respiratory Measurement	Char	ISO 8601	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 sponsor-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 sponsor-defined RFSTDTC variable in the Demographics (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	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

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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 others variables. Example: DAY 1 FIRST DOSE.	Exp
RERFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/Time of the reference time point, RETPTREF.	Perm
REEVLINT	Evaluation Interval	Char	ISO 8601	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	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
REENINT	Planned End of Assessment Interval	Char	ISO 8601	Timing	Planned end 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 PT2H.	Exp

6.3.19.1 Assumptions for Respiratory Test Results (RE) Domain Model

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 (RETPTREF).
4. REMETHOD and RECSTATE are considered important for comparison purposes and should be populated whenever available or collected.

6.3.19.2 Examples for Respiratory Test Results (RE) Domain Model

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.

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Row	STUDYID	DOMAIN	USUBJID	RESEQ	RETESTCD	RETEST	REPOS	REORRES	REORRESU	RESTRESC	RESTRESN	RESTRESU	REMETHOD	RECSTATE	REBLFL	REDTC	REDY	RENOMDY	RETPT	RETPTNUM	REELTM	RETPTREF	RERFTDTC	RESTINT	REENINT
1	AA1111	RE	AA111-3	1	RESPRATE	Respiratory Rate	SITTING	115.25	breaths/min	115.25	115.25	breaths/min	plethysmograph	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
2	AA1111	RE	AA111-3	2	RESPRATE	Respiratory Rate	SITTING	127.11	breaths/min	127.11	127.11	breaths/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
3	AA1111	RE	AA111-3	3	RESPRATE	Respiratory Rate	SITTING	111.57	breaths/min	111.57	111.57	breaths/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
4	AA1111	RE	AA111-3	4	RESPRATE	Respiratory Rate	SITTING	140.28	breaths/min	140.28	140.28	breaths/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
5	AA1111	RE	AA111-3	5	RESPRATE	Respiratory Rate	SITTING	109.87	breaths/min	109.87	109.87	breaths/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
6	AA1111	RE	AA111-3	6	RESPRATE	Respiratory Rate	SITTING	85.84	breaths/min	85.84	85.84	breaths/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	4 Hours	16	PT4H	Day 1 Dose	2005-12-15T10:00	P225M	PT4H
7	AA1111	RE	AA111-3	7	TIDALVOL	Tidal Volume	SITTING	1.48	mL	1.48	1.48	mL	plethysmograph	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
8	AA1111	RE	AA111-3	8	TIDALVOL	Tidal Volume	SITTING	1.46	mL	1.46	1.46	mL	plethysmograph	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
9	AA1111	RE	AA111-3	9	TIDALVOL	Tidal Volume	SITTING	1.34	mL	1.34	1.34	mL	plethysmograph	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
10	AA1111	RE	AA111-3	10	TIDALVOL	Tidal Volume	SITTING	1.11	mL	1.11	1.11	mL	plethysmograph	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
11	AA1111	RE	AA111-3	11	TIDALVOL	Tidal Volume	SITTING	1.29	mL	1.29	1.29	mL	plethysmograph	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
12	AA1111	RE	AA111-3	12	TIDALVOL	Tidal Volume	SITTING	1.58	mL	1.58	1.58	mL	plethysmograph	CONSCIOUS		2005-12-15	1	1	4 Hours	16	PT4H	Day 1 Dose	2005-12-15T10:00	P225M	PT4H
13	AA1111	RE	AA111-3	13	MV	Minute Volume	SITTING	170.43	mL/min	170.43	170.43	mL/min	plethysmograph	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
14	AA1111	RE	AA111-3	14	MV	Minute Volume	SITTING	184.98	mL/min	184.98	184.98	mL/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
15	AA1111	RE	AA111-3	15	MV	Minute Volume	SITTING	149.27	mL/min	149.27	149.27	mL/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
16	AA1111	RE	AA111-3	16	MV	Minute Volume	SITTING	155.19	mL/min	155.19	155.19	mL/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
17	AA1111	RE	AA111-3	17	MV	Minute Volume	SITTING	141.95	mL/min	141.95	141.95	mL/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
18	AA1111	RE	AA111-3	18	MV	Minute Volume	SITTING	135.34	mL/min	135.34	135.34	mL/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	4 Hours	16	PT4H	Day 1 Dose	2005-12-15T10:00	P225M	PT4H
19	AA1111	RE	AA111-7	19	RESPRATE	Respiratory Rate	SITTING	123.06	breaths/min	123.06	123.06	breaths/min	plethysmograph	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
20	AA1111	RE	AA111-7	20	RESPRATE	Respiratory Rate	SITTING	149.42	breaths/min	149.42	149.42	breaths/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
21	AA1111	RE	AA111-7	21	RESPRATE	Respiratory Rate	SITTING	122.17	breaths/min	122.17	122.17	breaths/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
22	AA1111	RE	AA111-7	22	RESPRATE	Respiratory Rate	SITTING	140.47	breaths/min	140.47	140.47	breaths/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
23	AA1111	RE	AA111-7	23	RESPRATE	Respiratory Rate	SITTING	117.75	breaths/min	117.75	117.75	breaths/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
24	AA1111	RE	AA111-7	24	RESPRATE	Respiratory Rate	SITTING	116.00	breaths/min	116.00	116	breaths/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	4 Hours	16	PT4H	Day 1 Dose	2005-12-15T10:00	P225M	PT4H
25	AA1111	RE	AA111-7	25	TIDALVOL	Tidal Volume	SITTING	1.24	mL	1.24	1.24	mL	plethysmograph	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
26	AA1111	RE	AA111-7	26	TIDALVOL	Tidal Volume	SITTING	1.33	mL	1.33	1.33	mL	plethysmograph	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
27	AA1111	RE	AA111-7	27	TIDALVOL	Tidal Volume	SITTING	1.45	mL	1.45	1.45	mL	plethysmograph	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
28	AA1111	RE	AA111-7	28	TIDALVOL	Tidal Volume	SITTING	1.27	mL	1.27	1.27	mL	plethysmograph	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
29	AA1111	RE	AA111-7	29	TIDALVOL	Tidal Volume	SITTING	1.42	mL	1.42	1.42	mL	plethysmograph	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
30	AA1111	RE	AA111-7	30	TIDALVOL	Tidal Volume	SITTING	1.50	mL	1.50	1.5	mL	plethysmograph	CONSCIOUS		2005-12-15	1	1	4 Hours	16	PT4H	Day 1 Dose	2005-12-15T10:00	P225M	PT4H
31	AA1111	RE	AA111-7	31	MV	Minute Volume	SITTING	153.09	mL/min	153.09	153.09	mL/min	plethysmograph	CONSCIOUS	Y	2005-12-15	1	1	baseline	0	-PT15M	Day 1 Dose	2005-12-15T10:00	-PT30M	-PT15M
32	AA1111	RE	AA111-7	32	MV	Minute Volume	SITTING	198.06	mL/min	198.06	198.06	mL/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	30 Minutes	2	PT30M	Day 1 Dose	2005-12-15T10:00	P15M	PT30M
33	AA1111	RE	AA111-7	33	MV	Minute Volume	SITTING	176.67	mL/min	176.67	176.67	mL/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	60 Minutes	4	PT60M	Day 1 Dose	2005-12-15T10:00	P45M	PT60M
34	AA1111	RE	AA111-7	34	MV	Minute Volume	SITTING	178.20	mL/min	178.20	178.2	mL/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	90 Minutes	6	PT90M	Day 1 Dose	2005-12-15T10:00	P75M	PT90M
35	AA1111	RE	AA111-7	35	MV	Minute Volume	SITTING	167.47	mL/min	167.47	167.47	mL/min	plethysmograph	CONSCIOUS		2005-12-15	1	1	2 Hours	8	PT2H	Day 1 Dose	2005-12-15T10:00	P105M	PT2H
36	AA1111	RE	AA111-7	36	MV	Minute Volume	SITTING	174.18	mL/min	174.18	174.18	mL/min	plethysmograph	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 time points 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" time point.

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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" time point.

re.xpt

Row	STUDYID	DOMAIN	USUBJID	RESEQ	RETESTCD	RETEST	REPOS	REORRES	REORRESU	RESTRESC	RESTRESN	RESTRESU	REMETHOD	RECSTATE	REBLFL	REDTC	REDY	RENOMDY	RETPT	RETPTNUM	REELTM	RETPTREF	RERFTDTC	RESTINT	REENINT
1	XY123	RE	XY123_101	1	RESPRATE	Respiratory Rate	UNCONSTRAINED	115.25	breaths/min	115.25	115.25	breaths/min	plethysmograph	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:32:58	-PT1H	PT0H
2	XY123	RE	XY123_101	2	RESPRATE	Respiratory Rate	UNCONSTRAINED	127.11	breaths/min	127.11	127.11	breaths/min	plethysmograph	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:32:58	PT0H	PT1H
3	XY123	RE	XY123_101	3	RESPRATE	Respiratory Rate	UNCONSTRAINED	111.57	breaths/min	111.57	111.57	breaths/min	plethysmograph	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:32:58	PT1H	PT2H
4	XY123	RE	XY123_101	4	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.48	mL	1.48	1.48	mL	plethysmograph	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:32:58	-PT1H	PT0H
5	XY123	RE	XY123_101	5	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.46	mL	1.46	1.46	mL	plethysmograph	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:32:58	PT0H	PT1H
6	XY123	RE	XY123_101	6	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.34	mL	1.34	1.34	mL	plethysmograph	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:32:58	PT1H	PT2H
7	XY123	RE	XY123_101	7	MV	Minute Volume	UNCONSTRAINED	170.43	mL/min	170.43	170.43	mL/min	plethysmograph	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:32:58	-PT1H	PT0H
8	XY123	RE	XY123_101	8	MV	Minute Volume	UNCONSTRAINED	184.98	mL/min	184.98	184.98	mL/min	plethysmograph	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:32:58	PT0H	PT1H
9	XY123	RE	XY123_101	9	MV	Minute Volume	UNCONSTRAINED	149.27	mL/min	149.27	149.27	mL/min	plethysmograph	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:32:58	PT1H	PT2H
10	XY123	RE	XY123_102	10	RESPRATE	Respiratory Rate	UNCONSTRAINED	123.06	breaths/min	123.06	123.06	breaths/min	plethysmograph	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:33:02	-PT1H	PT0H
11	XY123	RE	XY123_102	11	RESPRATE	Respiratory Rate	UNCONSTRAINED	149.42	breaths/min	149.42	149.42	breaths/min	plethysmograph	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:33:02	PT0H	PT1H
12	XY123	RE	XY123_102	12	RESPRATE	Respiratory Rate	UNCONSTRAINED	122.17	breaths/min	122.17	122.17	breaths/min	plethysmograph	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:33:02	PT1H	PT2H
13	XY123	RE	XY123_102	13	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.24	mL	1.24	1.24	mL	plethysmograph	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:33:02	-PT1H	PT0H
14	XY123	RE	XY123_102	14	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.33	mL	1.33	1.33	mL	plethysmograph	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:33:02	PT0H	PT1H
15	XY123	RE	XY123_102	15	TIDALVOL	Tidal Volume	UNCONSTRAINED	1.45	mL	1.45	1.45	mL	plethysmograph	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:33:02	PT1H	PT2H
16	XY123	RE	XY123_102	16	MV	Minute Volume	UNCONSTRAINED	153.09	mL/min	153.09	153.09	mL/min	plethysmograph	CONSCIOUS	Y	2010-04-06	1	1	Predose	0	-PT1H	Day 1 Dose	2010-04-06T11:33:02	-PT1H	PT0H
17	XY123	RE	XY123_102	17	MV	Minute Volume	UNCONSTRAINED	198.06	mL/min	198.06	198.06	mL/min	plethysmograph	CONSCIOUS		2010-04-06	1	1	0 Hour	1	PT0H	Day 1 Dose	2010-04-06T11:33:02	PT0H	PT1H
18	XY123	RE	XY123_102	18	MV	Minute Volume	UNCONSTRAINED	176.67	mL/min	176.67	176.67	mL/min	plethysmograph	CONSCIOUS		2010-04-06	1	1	1 Hour	2	PT1H	Day 1 Dose	2010-04-06T11:33:02	PT1H	PT2H

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7 Trial Design Model Datasets

7.1 Introduction to Trial Design Model Datasets

7.1.1 Purpose of Trial Design Model

The Trial Design Model in the SENDIG provides a standardized way to describe those aspects of the planned conduct of a nonclinical study, as shown in the study design diagram examples within this section. The Trial Design Model in the SENDIG is equivalent to the Trial Design Model within the SDTMIG for clinical trials. Trial Design datasets contain study-level, rather than subject-level, information. Note that generally the term "trial" is equivalent to "study" in the nonclinical context. In addition, "subjects" are equivalent to "animals."

The Trial Design datasets will allow:

- Clear and quick understanding of the design of nonclinical studies (or trials)
- Comparison of the designs of different studies (or trials)
- Comparison of planned and actual treatments and sponsor-defined groups for subjects (or animals) in a study (or trial)

Modeling a nonclinical study in this standardized way requires the explicit statement of certain decision rules that may not be addressed or may not be as explicit in the textual description of the approved study protocol (or study plan). Prospective modeling of the design of a study could contribute to a more complete and wholly representative protocol. Retrospective modeling of the study design provides a reviewer with a clear description of how the study was conducted.

7.1.2 Definitions of Trial Design Concepts

A *nonclinical study* is a scientific experiment, typically involving animal subjects, which is intended to address certain scientific questions that are the objectives of the study.

Branch	In a study with multiple arms, the protocol plans for each subject to be assigned to 1 arm. The time within the study at which this assignment takes place is often the point at which arms with common elements diverge into uncommon or nonshared elements, and is referred to as a "branch point." Many studies have a single branch point. Subjects are assigned to an arm all at the same time. For other studies, there may be 2 or more branches that collectively assign a subject to individual arms. The process that makes this assignment may be a randomization, but this is not always the case, as branch points are protocol-defined.
Element	An *element* is a basic building block in the study design. All elements are related to the administration of planned interventions, which may involve treatment or no treatment, during a period of time. Elements for which the planned intervention does not involve treatment would include screening, wash-out, and recovery.
Epoch	As part of the design of a study, the planned periods or phases of subjects' participation in the study 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 treatment, or to prepare for such a treatment period (e.g., pretreatment or screening period, wash-out previous treatments) or to gather data on subjects after a treatment has ended (e.g., recovery phase). It is possible for epochs to span multiple elements for some or all trial arms present on a study. For example, there may be 2 sequential (but different) treatment elements planned for a group; the sponsor might choose to include both of these in a single treatment epoch.
Treatment	The word "treatment" may be used in connection with epochs or elements, but has somewhat different meanings in each context: • Because epochs cut across arms, an epoch involving treatment is a higher-level concept that may not specify anything that differs between arms. For example, in a 3-period crossover study of 3 doses of compound X, each treatment epoch is associated with compound X, but not with a specific dose. In this case, EPOCH may be populated as "Study Treatment". • An element may be fairly detailed. For example, for an element representing repeated dosing, an element treatment might specify twice-daily dosing of 100-mg/kg doses of compound X. In this case, ELEMENT may be populated as "Study Drug 100 mg/kg Administered Twice Daily".

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Trial arm	A *trial arm* is a planned path through the study based upon a planned sequence of elements. This path covers the entire time of the study. Each sponsor-defined protocol group may contain subjects from several arms, 1 arm, or part of an arm. Each subject is assigned to 1 and only 1 planned arm.
Trial design	The design of a study is a plan outlining the activities subjects will experience and what data will be collected during the course of the study in order to address the study's objectives.
Trial group	A "group" describes the sponsor-defined protocol structure commonly used in nonclinical studies, where study subjects 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 receiving different treatments, but there may be other considerations involved in the design of any particular study. For purposes of SEND, a *trial group* is a collection of subjects which have been designated with the same sponsor-defined protocol group code. A trial group consists of 1 or more trial sets.
Trial set	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 (e.g., diet restriction), treatment parameters, and/or sponsor-defined attributes (e.g., control-group designation). There should be no planned parameters of interest that could further subdivide a trial set. Each subject must be assigned to 1 and only 1 trial set. Each trial set should be assigned to a single group. Each set should be assigned to a single trial arm.
Trial summary	As part of the Trial Design datasets, trial summary provides important or key study-level information.

7.2 Trial Elements

7.2.1 Trial Elements – TE

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

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	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

7.2.1.1 Assumptions for Trial Elements (TE) Domain Model

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 treatment. Therefore, an element is defined by the treatment (or lack of treatment) 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 treatment but different durations are different elements). The same applies to nontreatment 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).

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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 treatment, start rule, and either end rule or duration do not distinguish separate elements. For example, a restricted vs. ad libitum diet for the same treatment does not necessarily imply different treatment 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 treatment being administered during an element. If no treatment is administered, as is often the case with a screening element, the other activities that define this period of time (as related to a treatment 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 treatment element).
8. For treatment elements, the ELEMENT variable may include the following information (if appropriate for the element): treatment amount; treatment frequency; and total daily dose, if different from treatment 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 treatment, TESTRL is usually populated with a value that indicates treatment 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 treatment element may be thought of as active while the start rule for a nontreatment element, particularly a recovery or wash-out element, may be passive. The start of a treatment 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 treatment, TESTRL can be more difficult to define. For wash-out and recovery elements, which often follow treatment elements, the start of the element may be defined relative to the end of a preceding treatment. For example, a wash-out period might be defined as starting after the last dose of drug for the preceding treatment 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 nontreatment element that always follows another nontreatment 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.

7.2.1.2 Examples for Trial Elements (TE) Domain Model

Example 1: Simple Parallel Design

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This is a simple study design example, including element start (TESTRL) and end (TEENRL) rules as well as element duration (TEDUR).

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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 (see Section 7.3, Trial Arms, and Section 7.4, Trial Sets).

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	EXP7	TE	PRETEST	Pretreatment Feeding Period	Start of pretreatment 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 treatment or vehicle control	14 days after start of Element	P14D

See also Section 7.5, Additional Examples of Trial Elements, Trial Arms, and Trial Sets.

7.3 Trial Arms

7.3.1 Trial Arms – TA

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

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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
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 control group).	Perm
TATRANS	Transition Rule	Char		Rule	If the study 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 Treatment 2').	Perm
EPOCH	Trial Epoch	Char		Timing	Name of the study Epoch with which this Element of the Arm is associated (e.g., Treatment, Screen). Equivalent to 'Phase' or 'Period.'	Exp

7.3.1.1 Assumptions for Trial Arms (TA) Domain Model

1. The Trial Arms (TA) dataset provides a record of the complete planned sequence of elements for each arm.
2. 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).
3. 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 treatment 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 treatment 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 treatment 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 treatment 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.

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10. There is usually some gap in time between the performance of a randomization and the start of randomized treatment. However, in many studies this gap in time is small and it is not intended that subjects will leave the study between randomization and treatment. In these circumstances, the study does not need to be modeled with this time period between randomization and start of treatment 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="Treatment", where specific treatments may be different across arms but the subjects are all being treated in some manner).

7.3.1.2 Example for Trial Arms (TA) Domain Model

Example 1: Simple Parallel Design, No Recovery

This example assumes a simple parallel design in which the sponsor-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. This example corresponds to TE Example 1 (see Section 7.2.1.2, Examples for Trial Elements (TE) Domain Model) and TS Example 1 (Section 7.4.1.2, Example for Trial Sets (TX) Domain Model). 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	Screen
2	EXP1	TA	1	Control	2	TRT01	Vehicle Control		Treatment
3	EXP1	TA	2	100 mg/kg	1	SCRN	Screen	Randomized to Group 2	Screen
4	EXP1	TA	2	100 mg/kg	2	TRT02	100 mg/kg Drug A		Treatment
5	EXP1	TA	3	500 mg/kg	1	SCRN	Screen	Randomized to Group 3	Screen
6	EXP1	TA	3	500 mg/kg	2	TRT03	500 mg/kg Drug A		Treatment

See also Section 7.5, Additional Examples of Trial Elements, Trial Arms, and Trial Sets.

7.4 Trial Sets

The Trial Sets (TS) domain is intended to allow the sponsor to define the planned sets of subjects that result as a combination of the experimental factors of interest on a study (including experimental parameters, treatment strategies, inherent characteristics, and sponsor-defined attributes). By providing a list of these sets in the submission, the sponsor can provide information on which sets have various combinations of experimental factors as defined in the trial protocol. This also allows the sponsor to include information about the groups defined in the protocol.

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, treatment strategies, inherent characteristics (such as strain)

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parameters, and/or sponsor-defined attributes (e.g., control group designation). There should be no planned parameters of interest that could further subdivide a trial set. Each trial set can be assigned to a group. Each trial set can be assigned to an arm, and several trial sets can be assigned to 1 trial arm.

A *trial group* is a collection of subjects that have been designated with the same sponsor-defined protocol group code. A group consists of 1 or more sets, so this relationship is hierarchical. Note that the relationship between a group and an arm is not hierarchical: A group may contain subjects from several arms, 1 arm, or part of 1 arm. As a result, each group cannot always be assigned to a single arm.

A well-defined trial set has the following characteristics:

- A trial set is a planned set of one or more subjects, possessing experimental factors, treatment factors, or sponsor-defined attributes that differentiate the set from other trial sets on the same trial.
- Any subject that is selected for the study will be in one and only one trial set (i.e., trial sets are mutually exclusive and do not overlap).
- The trial set is associated with a single trial arm (the set of subjects assigned to a treatment strategy). More than 1 trial set may be associated with the same arm; however, any trial set should be associated with only 1 arm. If a trial set appears to be associated with multiple trial arms, then it should be further subdivided into trial sets, each of which is associated with 1 arm through the use of treatment strategy as an experimental factor.

7.4.1 Trial Sets – TX

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

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 sponsor.	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. See the Controlled Terms, Codelist, or Format column in Section 7.4.2 that lists all defined Trial Set parameters.	Req

7.4.1.1 Assumptions for Trial Sets (TX) Domain Model

1. The Trial Sets (TX) domain provides the list of distinct sets of subjects having different experimental factors, treatment factors, inherent characteristics, or distinct sponsor 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 sponsor.

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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. Sponsors should consider utilizing values that will sort alphabetically in an order intended by the sponsor.
5. Trial sets should be designed so that each individual subject shall participate in 1 and only 1 trial set.
6. 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.
7. The TXPARMCD and TXPARM list may be extended by the sponsor as needed to provide the information on experimental factors that differentiate trial sets.
8. 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.
9. The sponsor 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.
10. The TXPARMCD values marked as "Yes" in the Should Include column in Section 7.4.2, Trial Set Codes, should be included in a well-formed TX domain submission. These TXPARMCD values are expected to occur in almost all studies and may be necessary for clear interpretation of the data package.
11. 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.

7.4.1.2 Example for Trial Sets (TX) Domain Model

Example 1: Simple Parallel Design, No Recovery

This example assumes a simple parallel design in which the sponsor-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. This example corresponds to Trial Elements Example 1 (see Section 7.2.1.2, Examples for Trial Elements (TE) Domain Model) and the Trial Arms example (see Section 7.3.1.2, Example for Trial Arms (TA) Domain Model). There are only 3 trial sets in this scenario, because there are no nontreatment factors to consider. In this example, the sponsor has chosen to provide a small amount of additional information about each trial set, including the associated arm code, sponsor-defined protocol group number, control group type, group label, and dose level and units, and the sponsor 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	Sponsor-Defined Group Code	1

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Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
3	EXP1	TX	1	Control Group, Vehicle Control once daily	3	TCNTRL	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	Sponsor-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	Sponsor-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 7.5, Additional Examples of Trial Elements, Trial Arms, and Trial Sets.

7.4.2 Trial Set Codes

The following is an extensible list of parameters that may be used to describe a Trial Set. The parameters listed as "Yes" in the "Should Include" column provide a relationship between Trial Sets and other information (the trial protocol or the Trial Arms dataset) and should be included in a well-formed TX domain submission. These TXPARMCD values are expected to occur in almost all studies and may be necessary for clear interpretation of the data package.

Should Include	TXPARMCD	TXPARM	Type	Controlled Terms, Codelist, or Format	CDISC Notes
Yes	ARMCD	Arm Code	Char		The Arm Code of the Trial Arm that is associated with this Trial Set. Each Trial Set should be associated with a single Trial Arm.
Yes	SPGRPCD	Sponsor-Defined Group Code	Char		The identifier for the sponsor-defined group (usually a number) to which this Trial Set belongs. In many cases, there will be multiple Trial Sets with the same value of the SPGRPCD variable. This value may be used by the recipient of the submission to reference an external protocol/report document or information submitted in other forms (e.g., summary tables in a PDF submission).
Yes	GRPLBL	Group Label	Char		The reporting label for the associated SPGRPCD group.
Yes	TRTDOS	Dose Level	Char		Numeric representation of the planned test article dose level. For dose levels that vary over time within a set, a semicolon-delimited string without spaces can be used (e.g., 100;150;7). For more complex dosing regimens, sponsor should enter "SEE PROTOCOL."
Yes	TRTDOSU	Dose Units	Char	(UNIT)	Dose level unit for TRTDOS. For more complex dosing regimens, sponsor should enter "SEE PROTOCOL" to match the associated TRTDOS value.

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See CDISC Notes	TCNTRL	Control Type	Char		This parameter should be included if the Trial Set is considered to be a control for this study (or part of a control). This parameter should be used to define the type of control (e.g., Vehicle Control, Positive Control, etc.).
	BEDCHNG	Bedding Change	Char		Describes the planned frequency of bedding changes for the subjects in this Set (e.g., Every other day, Every 5 days, Every week, etc.).
	BEDDING	Bedding	Char		Planned type of bedding material available to the subjects in this Set (e.g., Straw, Corn cob, Shavings, etc.).
	DIET	Basal Diet	Char		Describes the planned type of diet to be offered to the subjects in this Set (e.g., Standard diet, Nutrient restricted, etc.).
	DOSENDTC	End Date/Time of Dose Interval	Char	ISO 8601	The planned end date of the dosing interval for this Set, in ISO 8601 format.
	DOSSTDTC	Start Date/Time of Dose Interval	Char	ISO 8601	The planned start date of the dosing interval for this Set, in ISO 8601 format.
	ENVTEMP	Environmental Temperature	Char		The planned environmental temperature for the subjects in this Set. Can be expressed as a single value (80), or a range (75-80).
	ENVTEMPU	Environmental Temperature Units	Char	(UNIT)	The units associated with the environmental temperature. Only "C" or "F" is acceptable.
	FEEDREG	Feeding Regimen	Char		Describes the planned subject feeding regimen for this Set (e.g., Fed ad libitum, Restricted Feeding, Entire Study Fasted, etc.).
	HOUSEGRP	Housing Group	Char		The planned grouping of subjects in housing for this Set (e.g., Single-housed, Pair-housed, Triple-housed, Group-housed, etc.).
	HOUSETYP	Housing Type	Char		Describes the planned type of housing provided for the subjects in this Set (e.g., Ventilated caging system (IVC), Plastic caging (suspended), Stainless steel caging (suspended), Plastic Micro-barrier caging, Primate Horizontal caging, Primate Vertical caging, Kennel, Pen, Stable, Feline Colony housing, Battery cages, Egg Laying cages, Poultry isolators, Bio-containment Unit, Other, etc.).
	HUMIDT	Housing Humidity	Char		The planned housing humidity for the test subjects in this Set. Can be expressed as a single value (75), or as a range (60-70).
	HUMIDTU	Housing Humidity Units	Char	(UNIT)	The units associated with the housing humidity.
	IDMETH	Method of Identification	Char		Describes the planned method of uniquely identifying the subjects for this Set (e.g., Ear tag, Tattoo, Collar, Microchip, etc.).
	LIGHT	Light Cycle	Char		Defines the planned light/dark hour cycle for the subjects in this Set. E.g., an entry of "12 / 12" indicates that the subjects will be exposed to 12 hours of light and 12 hours of darkness. Text entry field in the format of nn / nn or nn/nn where n = number.
	MTHTRM	Method of Termination	Char	(MTHTRM)	Describes the planned sacrifice procedure for subjects in this Set (e.g., CO2, ANESTHETIZED CERVICAL DISLOCATION, ANESTHETIZED EXSANGUINATION, etc.).
	PLANFSUB	Planned Number of Female Subjects	Num		Defined as the planned number of Female subjects that will be part of this Set.
	PLANMSUB	Planned Number of Male Subjects	Num		Defined as the planned number of Male subjects that will be part of this Set.
	SPLANSUB	Planned Number of Subjects	Num		Defined as the planned number of subjects that will be part of this Set.
	SETLBL	Set Label	Char		Sponsor-defined label for this Trial Set. This may be used to provide a concise or summary version of the information in the SET variable.
	SEXPOP	Sex of Participants	Char	(SEXPOP)	Identifies which sexes of subjects are planned to participate in this Set.
	SPECIES	Species	Char	(SPECIES)	Used to identify the common species name of the subject (i.e., test system) under study (e.g., MOUSE, RAT, DOG, MONKEY) for this Set.
	STRAIN	Strain/Substrain	Char	(STRAIN)	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-

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					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 and genertically modified strains. It is extensible to accommodate strains not listed and genetically modified substrains for the subjects in this Set. Country or origin for non-human primates should not go into STRAIN. In geneneral, details related to coat color (e.g., White and Red designations for New Zealand Rabbits) should not go into STRAIN.
	SBSTRAIN	Strain/Substrain Details	Char		Free-text field that allows the sponsor to enter additional details regarding the subject (i.e., test system) under study, such as a 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). At a subject level, this is recorded in the Demographics (DM) domain.
	SPLRLOC	Test Subject Supplier Site	Char		City, state, and country of the subject supplier for subjects in this Set.
	SPLRNAM	Test Subject Supplier	Char		The name of the subject supplier for subjects in this Set.
	TKDESC	Toxicokinetic Description	Char		This parameter allows the sponsor to provide additional information about whether this Set will (or will not) have samples drawn for toxicokinetic analysis. The text may be simple (TK or NON-TK) or descriptive (Sampled at six time points on Day 1 and end of dosing period).
	WATER	Drinking Water	Char		The type of drinking water that is planned to be provided to the subjects in this Set (e.g., Tap water, Acidified, Reverse osmosis, etc.).
	WTRDLVRY	Water Delivery	Char		Describes the methods of water delivery systems available for the test subjects in this Set (e.g., Bottled water, Ad lib, Restricted, etc.)

7.5 Additional Examples of Trial Elements, Trial Arms, and Trial Sets

The following examples are intended to show how a variety of study designs would be represented in the Trial Elements, Trial Arms, and Trial Sets domains.

7.5.1 Example 1. Parallel Design with Some Subjects Moving To Recovery

This example assumes a design in which the sponsor-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

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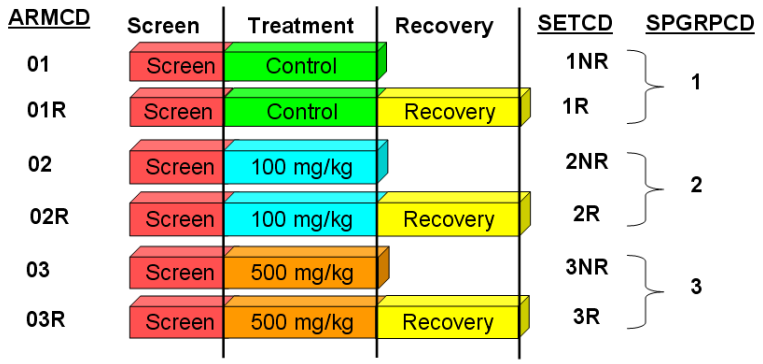
There are no other experimental factors of interest specified in the study design. In this case, the design consists of 6 trial arms, because there are 6 distinct sequences of elements, as depicted in the following figure.

Figure. Example Trial 1 Design



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 Pretreatment	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	Screen
2	TDM1	TA	01	Control	2	TRT01	Vehicle Control		Treatment
3	TDM1	TA	01R	Control w/ Recovery	1	SCRN	Screen	Randomized to Group 1, planned for recovery	Screen
4	TDM1	TA	01R	Control w/ Recovery	2	TRT01	Vehicle Control		Treatment
5	TDM1	TA	01R	Control w/ Recovery	3	RECO	Recovery		Recovery
6	TDM1	TA	02	Low Dose	1	SCRN	Screen	Randomized to Group 2	Screen
7	TDM1	TA	02	Low Dose	2	TRT02	100 mg/kg Drug A		Treatment
8	TDM1	TA	02R	Low Dose w/ Recovery	1	SCRN	Screen	Randomized to Group 2, planned for recovery	Screen
9	TDM1	TA	02R	Low Dose w/ Recovery	2	TRT02	100 mg/kg Drug A		Treatment
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	Screen
12	TDM1	TA	03	High Dose	2	TRT03	500 mg/kg Drug A		Treatment

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Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	EPOCH
13	TDM1	TA	03R	High Dose w/ Recovery	1	SCRN	Screen	Randomized to Group 3, planned for recovery	Screen
14	TDM1	TA	03R	High Dose w/ Recovery	2	TRT03	500 mg/kg Drug A		Treatment
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 treatment period and whether the subjects are planned for termination on day 28 or will enter a recovery period.

In this example, the sponsor is providing the arm code, sponsor-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	Sponsor-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	Sponsor-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	Sponsor-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

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Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
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	Sponsor-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	Sponsor-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
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	Sponsor-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

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7.5.2 Example 2. Study With Tk Subjects Within Same Protocol Group and Scheduled Necropsy

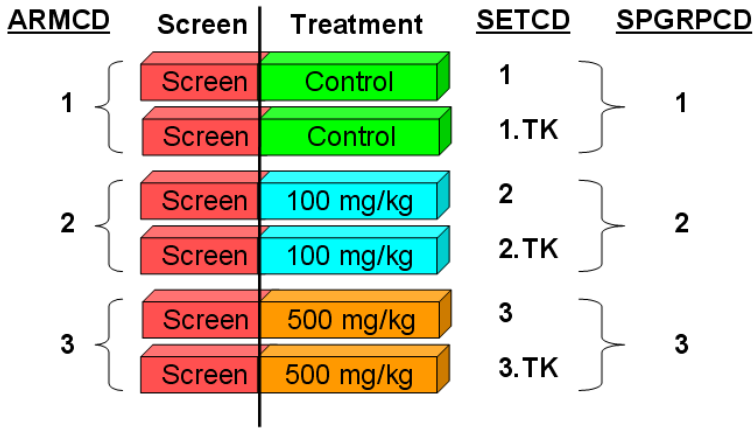
This example assumes a design in which the sponsor-defined protocol specifies the following information. All subjects are to be screened for 7 days prior to randomization into 3 protocol groups:

- 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.

Figure. Example Trial 2 Design



Trial Elements

In this study, treatment started on one date and the necropsy is scheduled, for an individual animal, after 28 to 30 days of treatment. The necropsy for a subset of animals per treatment 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 Pretreatment	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	

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Trial Arms

There are three 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 treatment 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	Screen
2	TDM2	TA	1	Control	2	TRT01	Vehicle Control		Treatment
3	TDM2	TA	2	100 mg/kg	1	SCRN	Screen	Randomized to Group 2	Screen
4	TDM2	TA	2	100 mg/kg	2	TRT02	100 mg/kg Drug A		Treatment
5	TDM2	TA	3	500 mg/kg	1	SCRN	Screen	Randomized to Group 3	Screen
6	TDM2	TA	3	500 mg/kg	2	TRT03	500 mg/kg Drug A		Treatment

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 treatment levels and whether the subject is sampled for TK analysis; this leads to 6 trial sets.

The sponsor has chosen to provide the associated arm code, sponsor-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	Sponsor-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	Sponsor-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

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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	Sponsor-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	Sponsor-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	Sponsor-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	Sponsor-Defined Group Code	3

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Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
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

7.5.3 Example 3. Study With Tk Subjects in Separate Protocol Groups

This example assumes a design in which the sponsor-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 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.

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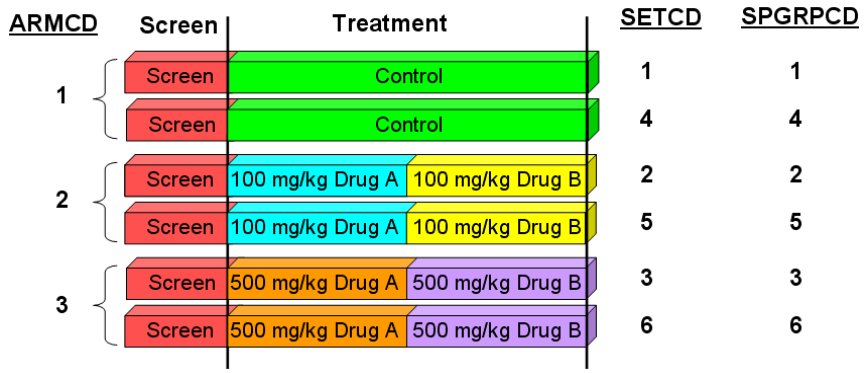
Figure. Example Trial 3 Design



Trial Elements

The TK blood collection has no effect on the structure of the treatment elements.

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	TDM3	TE	SCRN	Screen	Start of Pretreatment	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 treatment being received; see the TS example. The sponsor-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 sponsor considers all treatment elements for the study to be part of a single treatment 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	Screen
2	TDM3	TA	1	Control	2	TRT01	Vehicle Control		Treatment
3	TDM3	TA	2	100 mg/kg	1	SCRN	Screen	Randomized to Group 2 or Group 5	Screen
4	TDM3	TA	2	100 mg/kg	2	TRT02A	100 mg/kg Compound A, once daily		Treatment
5	TDM3	TA	2	100 mg/kg	3	TRT02B	100 mg/kg Compound B, once daily		Treatment
6	TDM3	TA	3	500 mg/kg	1	SCRN	Screen	Randomized to Group 3 or Group 5	Screen
7	TDM3	TA	3	500 mg/kg	2	TRT03A	500 mg/kg Compound A, once daily		Treatment
8	TDM3	TA	3	500 mg/kg	3	TRT03B	500 mg/kg Compound B, once daily		Treatment

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Trial Sets

In this case, there are 6 trial sets, corresponding to the following experimental factors: treatment level (3 separate treatment levels) and whether the subjects will be used for TK analysis.

The sponsor has chosen to provide the associated arm code, sponsor-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	Sponsor-Defined Group Code	1
3	TDM3	TX	1	Control Group, Vehicle Control, once daily	3	GRPLBL	Group Label	Group 1, Control
3	TDM3	TX	1	Control Group, Vehicle Control, once daily	4	SETLBL	Set Label	Group 1, Control
4	TDM3	TX	1	Control Group, Vehicle Control, once daily	5	TRTDOS	Dose Level	0
5	TDM3	TX	1	Control Group, Vehicle Control, once daily	6	TRTDOSU	Dose Units	mg/kg/day
6	TDM3	TX	1	Control Group, Vehicle Control, once daily	7	TCNTRL	Control Type	Vehicle Control
7	TDM3	TX	1	Control Group, Vehicle Control, once daily	8	TKDESC	Toxicokinetic Description	NON-TK
8	TDM3	TX	1	Control Group, Vehicle Control, once daily	9	PLANMSUB	Planned Number of Male Subjects	10
9	TDM3	TX	1	Control Group, Vehicle Control, once daily	10	PLANFSUB	Planned Number of Female Subjects	10
10	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	11	ARMCD	Arm Code	2
11	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	12	SPGRPCD	Sponsor-Defined Group Code	2
12	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
13	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
14	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	15	TRTDOS	Dose Level	100
15	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
16	TDM3	TX	2	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily	17	TKDESC	Toxicokinetic Description	NON-TK
17	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
18	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
19	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	20	ARMCD	Arm Code	3
20	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	21	SPGRPCD	Sponsor-Defined Group Code	3
21	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

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Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
22	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
23	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	24	TRTDOS	Dose Level	500
24	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
25	TDM3	TX	3	High-Dose Group, 500 mg/kg Compound A, 500 mg/kg Compound B, once daily	26	TKDESC	Toxicokinetic Description	NON-TK
26	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
27	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
28	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	29	ARMCD	Arm Code	1
29	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	30	SPGRPCD	Sponsor-Defined Group Code	4
30	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	31	GRPLBL	Group Label	Group 4, Control
31	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	32	SETLBL	Set Label	Group 4, Control - TK
32	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	33	TRTDOS	Dose Level	0
33	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	34	TRTDOSU	Dose Units	mg/kg/day
34	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	35	TCNTRL	Control Type	Vehicle Control
35	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	36	TKDESC	Toxicokinetic Description	TK
36	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	37	PLANMSUB	Planned Number of Male Subjects	3
37	TDM3	TX	4	Control Group, Vehicle Control once daily, TK	38	PLANFSUB	Planned Number of Female Subjects	3
38	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	39	ARMCD	Arm Code	2
39	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	40	SPGRPCD	Sponsor-Defined Group Code	5
40	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
41	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
42	TDM3	TX	5	Low-Dose Group, 100 mg/kg Compound A, 100 mg/kg Compound B, once daily, TK	43	TRTDOS	Dose Level	100
43	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
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

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Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
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	Sponsor-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

7.5.4 Example 4. Study With Multiple Experimental Factors

The example depicts a complex multifactorial trial design. The sponsor-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 treatment period (day 30).

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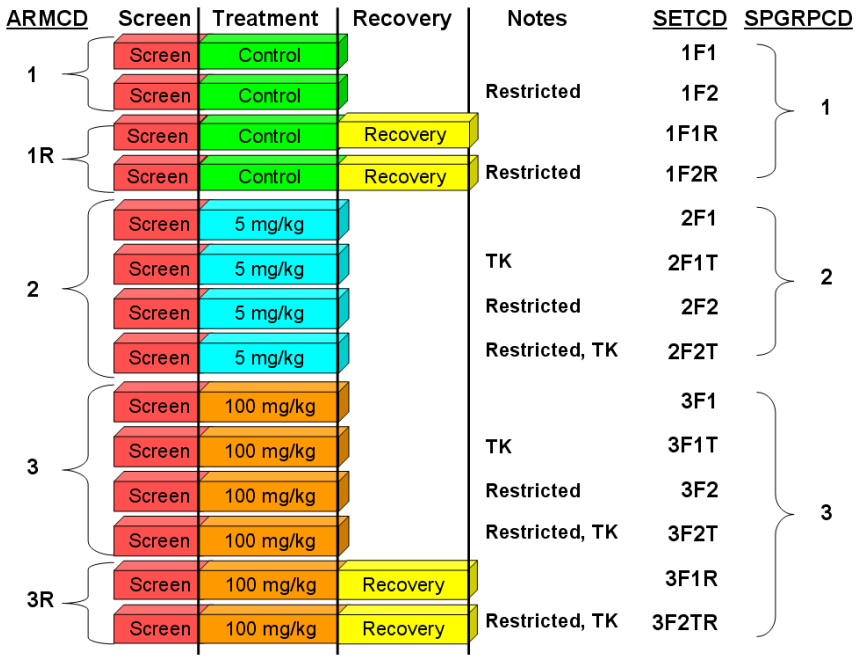
Group Number	Group Label	Dose Level	Number of Animals (Both Sexes Combined)							
			Fed Ad Libitum				Restricted Feeding			
			Non-toxicokinetic		Toxicokinetic		Non-toxicokinetic		Toxicokinetic	
			Nonrecovery	Recovery	Nonrecovery	Recovery	Nonrecovery	Recovery	Nonrecovery	Recovery
1	Group 1, Control	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.

Figure. Example Trial 4 Design



Trial Elements

The variety of feeding and TK analysis factors do not affect the TE dataset, which deals only with treatments. The fact that only some of the treatment 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	1 day after completion of SCRN Element	30 days after start of Element	P30D
3	TDM4	TE	T5	5 mg/kg Drug A	1 day after completion of SCRN Element	30 days after start of Element	P30D
4	TDM4	TE	T100	100 mg/kg Drug A	1 day after completion of SCRN Element	30 days after start of Element	P30D
5	TDM4	TE	RECO	Recovery	1 day after last dose with treatment or vehicle control	14 days after start of Element	P14D

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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 treatments; some of the subjects receiving the vehicle control or the medium dose are subject to a recovery period post-treatment. 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	Screen
2	TDM4	TA	1	Control	2	CONTROL	Control		Treatment
3	TDM4	TA	1R	Control + Recovery	1	SCRN	Screen	Randomized to Group 1 with Recovery	Screen
4	TDM4	TA	1R	Control + Recovery	2	CONTROL	Control		Treatment
5	TDM4	TA	1R	Control + Recovery	3	RECO	Recovery		Recovery
6	TDM4	TA	2	Low Dose	1	SCRN	Screen	Randomized to Group 2	Screen
7	TDM4	TA	2	Low Dose	2	T5	5 mg/kg Drug A		Treatment
8	TDM4	TA	3	High Dose	1	SCRN	Screen	Randomized to Group 3	Screen
9	TDM4	TA	3	High Dose	2	T100	100 mg/kg Drug A		Treatment
10	TDM4	TA	3R	High Dose + Recovery	1	SCRN	Screen	Randomized to Group 3 with Recovery	Screen
11	TDM4	TA	3R	High Dose + Recovery	2	T100	100 mg/kg Drug A		Treatment
12	TDM4	TA	3R	High Dose + Recovery	3	RECO	Recovery		Recovery

Trial Sets

In this study there are multiple experimental factors of interest: the treatment level given during the treatment 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 (3x2x2x2) 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

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This can be represented in the TS domain as follows. The sponsor is providing the following information for each set: arm code, sponsor-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	Sponsor-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	Sponsor-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	Sponsor-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

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Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
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	Sponsor-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
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	Sponsor-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	Sponsor-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

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Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
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	Sponsor-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	Sponsor-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	Sponsor-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
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	Sponsor-Defined Group Code	3

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Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
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	Sponsor-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	Sponsor-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	Sponsor-Defined Group Code	3

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Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
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	Sponsor-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
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

7.5.5 Example 5. Crossover Design (Latin Square)

This example assumes a crossover design in which the sponsor-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 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 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 once per day for 14 days, given a 7-day rest period, dosed at 50 mg/kg once per day for 14 days, given a second 7-day rest period, and dosed at 800 mg/kg 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 once per day for 14 days, given a 7-day rest period, dosed at 400 mg/kg once per day for 14 days, given a second 7-day rest period, and dosed at 50 mg/kg once per day for the final 14 days.

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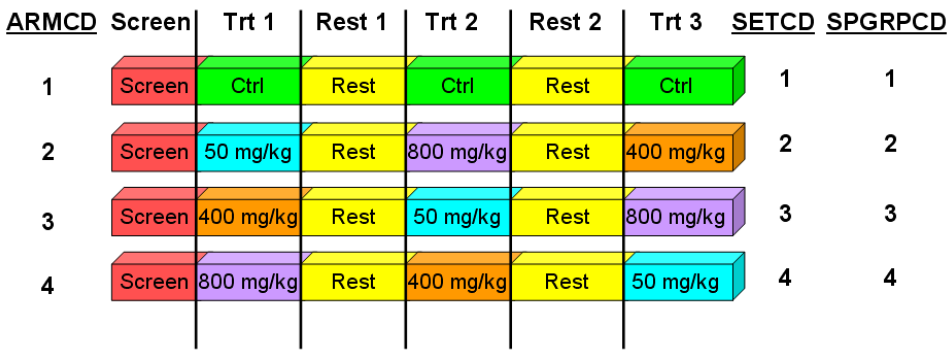
There are no other experimental factors of interest specified in the study design.

Figure. Example Trial 5 Design



Trial Elements

This example shows the start and end rules and durations for the different treatment elements, indicating whether they follow a treatment or nontreatment element.

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	TDM5	TE	SCRN	Screen	Start of Pretreatment	10 days after start of Element	P10D
2	TDM5	TE	CONTROL	Vehicle Control	First dosing with vehicle control following a nontreatment Element	14 days after start of Element	P14D
3	TDM5	TE	REST	Rest for 7 days	1 day after last dose in a treatment 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 nontreatment 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 nontreatment 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 nontreatment 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	Screen
2	TDM5	TA	1	Control	2	CONTROL	Vehicle Control		Trt 1
3	TDM5	TA	1	Control	3	REST	Rest for 7 days		Rest 1
4	TDM5	TA	1	Control	4	CONTROL	Vehicle Control		Trt 2
5	TDM5	TA	1	Control	5	REST	Rest for 7 days		Rest 2
6	TDM5	TA	1	Control	6	CONTROL	Vehicle Control		Trt 3
7	TDM5	TA	2	50-800-400	1	SCRN	Screen	Randomized to Group 2	Screen
8	TDM5	TA	2	50-800-400	2	50A	50 mg/kg Drug A		Trt 1
9	TDM5	TA	2	50-800-400	3	REST	Rest for 7 days		Rest 1
10	TDM5	TA	2	50-800-400	4	800A	800 mg/kg Drug A		Trt 2
11	TDM5	TA	2	50-800-400	5	REST	Rest for 7 days		Rest 2
12	TDM5	TA	2	50-800-400	6	400A	400 mg/kg Drug A		Trt 3
13	TDM5	TA	3	400-50-800	1	SCRN	Screen	Randomized to Group 3	Screen
14	TDM5	TA	3	400-50-800	2	400A	400 mg/kg Drug A		Trt 1
15	TDM5	TA	3	400-50-800	3	REST	Rest for 7 days		Rest 1
16	TDM5	TA	3	400-50-800	4	50A	50 mg/kg Drug A		Trt 2

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Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	EPOCH
17	TDM5	TA	3	400-50-800	5	REST	Rest for 7 days		Rest 2
18	TDM5	TA	3	400-50-800	6	800A	800 mg/kg Drug A		Trt 3
19	TDM5	TA	4	800-400-50	1	SCRN	Screen	Randomized to Group 4	Screen
20	TDM5	TA	4	800-400-50	2	800A	800 mg/kg Drug A		Trt 1
21	TDM5	TA	4	800-400-50	3	REST	Rest for 7 days		Rest 1
22	TDM5	TA	4	800-400-50	4	400A	400 mg/kg Drug A		Trt 2
23	TDM5	TA	4	800-400-50	5	REST	Rest for 7 days		Rest 2
24	TDM5	TA	4	800-400-50	6	50A	50 mg/kg Drug A		Trt 3

Trial Sets

In this example, there are 4 trial sets. The experimental factors considered are type of treatment (vehicle control or compound) and sequencing of treatment levels. The sponsor is providing the arm code, sponsor-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	Sponsor-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, (Compound 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, (Compound Name) once daily dosing in sequence: 50-800-400 mg/kg (14 days each) with 7-day rests between	9	SPGRPCD	Sponsor-Defined Group Code	2
10	TDM5	TX	2	Group 2, (Compound 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, (Compound Name) once daily dosing in sequence: 50-800-400 mg/kg (14 days each) with 7-day rests between	11	TRTDOS	Dose Level	SEE PROTOCOL
12	TDM5	TX	2	Group 2, (Compound Name) once daily dosing in sequence: 50-800-400 mg/kg (14 days each) with 7-day rests between	12	TRTDOSU	Dose Units	SEE PROTOCOL
13	TDM5	TX	2	Group 2, (Compound 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, (Compound 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, (Compound Name) once daily dosing in sequence: 400-50-800 mg/kg (14 days each) with 7-day rests between	15	SPGRPCD	Sponsor-Defined Group Code	3

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Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARM	TXVAL
16	TDM5	TX	3	Group 3, (Compound 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, (Compound Name) once daily dosing in sequence: 400-50-800 mg/kg (14 days each) with 7-day rests between	17	TRTDOS	Dose Level	SEE PROTOCOL
18	TDM5	TX	3	Group 3, (Compound Name) once daily dosing in sequence: 400-50-800 mg/kg (14 days each) with 7-day rests between	18	TRTDOSU	Dose Units	SEE PROTOCOL
19	TDM5	TX	3	Group 3, (Compound 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, (Compound 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, (Compound Name) once daily dosing in sequence: 800-400-50 mg/kg (14 days each) with 7-day rests between	21	SPGRPCD	Sponsor-Defined Group Code	4
22	TDM5	TX	4	Group 4, (Compound 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, (Compound Name) once daily dosing in sequence: 800-400-50 mg/kg (14 days each) with 7-day rests between	23	TRTDOS	Dose Level	SEE PROTOCOL
24	TDM5	TX	4	Group 4, (Compound Name) once daily dosing in sequence: 800-400-50 mg/kg (14 days each) with 7-day rests between	24	TRTDOSU	Dose Units	SEE PROTOCOL
25	TDM5	TX	4	Group 4, (Compound 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

7.6 Trial Summary

The Trial Summary (TS) dataset allows the sponsor to submit a summary of the study in a structured format. The TS dataset contains information about the planned study characteristics, identical for all animals 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. For example, TS is used to record basic information about the study such as study title, study type, and GLP status.

7.6.1 Trial Summary – TS

ts.xpt, Trial Summary - Trial Design. One record per Trial Summary parameter value, Tabulation.

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 sponsor-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	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
					terminology. See the Controlled Terms, Codelist, or Format column in Section 7.6.3 that lists all defined parameters. TSVAL can only be null if TSVALNF is populated.	
TSVALNF	Parameter Null Flavor	Char	(NULLFLAVOR)	Record Qualifier	Null flavor for the value of the TSPARMs, which should be included according to the trial summary code table below if and only if TSVAL is null.	Perm

7.6.1.1 Assumptions for Trial Summary (TS) Domain Model

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. For a list of example controlled terms for TSPARM and TSPARMCD, and whether they should be included in a submission, see Section 7.6.2, Trial Summary Codes. TSPARM and TSPARMCD are subject to controlled terminology.
3. TSVAL may have controlled terminology, depending on the value of TSPARMCD. For the controlled terminology list to be applied to TSVAL for a specific TSPARMCD, see Section 7.6.2, Trial Summary Codes.
4. 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.
5. 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."
6. 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.
7. 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.
8. The TSPARMCD values marked as "Yes" in the Should Include column in Section 7.6.3, Trial Summary Codes, following the examples should be included in a well-formed TS domain submission. These TSPARMCD values are expected to occur in almost all studies and may be necessary for clear interpretation of the data package. In the event that these values cannot be populated, the TSPARMCD should still be present in the dataset, with an empty (NULL) TSVAL and TSVALNF populated with the appropriate null flavor describing why the value cannot be populated.
9. 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.

7.6.1.2 Examples for Trial Summary (TS) Domain Model

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 recroded as an empty TSVAL and UNK in the corresponding TSVALNF.

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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		SPLRNAM	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 3.0	
15	XYZ	TS	1		SNDCTVER	SEND Controlled Terminology Version	SEND Terminology 2011-01-07	
16	XYZ	TS	1		STCAT	Study Category	TOX	
17	XYZ	TS	1		SSPONSOR	Sponsoring Organization	Example Sponsor 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 Nowhere 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		ASOCSTDY	Associated Study	Associated pharmacokinetic Study	
27	XYZ	TS	1		AGETXT	Age Text	6-8	
28	XYZ	TS	1		AGEU	Age Unit	WEEKS	
29	XYZ	TS	1		SPREFID	Sponsor's Reference ID	SP/StudyID	
30	XYZ	TS	1		STMON	Sponsor's Monitor	Dr. J. Smith	
31	XYZ	TS	1	1	STDIR	Study Director	Dr. H. Someone	
32	XYZ	TS	1	2	PINV	Principal Investigator	G. Person	
33	XYZ	TS	1		IDMETH	Method of Identification	MICROCHIP	
34	XYZ	TS	1		IACUC	IACUC Number	1234A	
35	XYZ	TS	1		WATER	Drinking Water	REVERSE OSMOSIS	
36	XYZ	TS	1		ENVTEMP	Environmental Temperature	70-75	
37	XYZ	TS	1		ENVTEMPU	Environmental Temperature Units	F	

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Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF
38	XYZ	TS	1		HUMIDT	Housing Humidity	10-30	
39	XYZ	TS	1		HUMIDTU	Housing Humidity Units	%	
40	XYZ	TS	1		LIGHT	Light Cycle	12/12	
41	XYZ	TS	1		HOUSEGRP	Housing Group	SINGLE	
42	XYZ	TS	1		BEDDING	Bedding	STRAW	
43	XYZ	TS	1		BEDCHNG	Bedding Change	WEEKLY	
44	XYZ	TS	1		MTHTRM	Method of Termination	CO2	
45	XYZ	TS	1		DIET	Basal Diet	STANDARD	
46	XYZ	TS	1		FEEDREG	Feeding Regimen	AD LIBITUM	
47	XYZ	TS	1		INTSAC	Time to Interim Sacrifice	P14D	
48	XYZ	TS	1		TRMSAC	Time to Terminal Sacrifice	P28D	
49	XYZ	TS	1		RECSAC	Recovery Period	P35D	
50	XYZ	TS	1		TRT	Investigational Therapy or Treatment	Example Compound Name	
51	XYZ	TS	1		TRTV	Treatment Vehicle	SALINE	
52	XYZ	TS	1		GLPFL	GLP Flag	Y	
53	XYZ	TS	1		TRTCAS	Primary Treatment CAS Registry Number		UNK

Example 2: Crossover Design (Latin Square)

This example reflects a dataset that has been reduced to only those parameters that should always be included.

ts.xpt

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF
1	EXP2	TS	1		SSTYP	Study Type	REPEAT DOSE TOXICITY	
2	EXP2	TS	1		SPECIES	Species	RAT	
3	EXP2	TS	1		STRAIN	Strain/Substrain	FISCHER 344	
4	EXP2	TS	1		SPLRNAM	Test Subject Supplier	HARLAN	
5	EXP2	TS	1		SDESIGN	Study Design	CROSSOVER	
6	EXP2	TS	1		ROUTE	Route of Administration	ORAL	
7	EXP2	TS	1		GLPTYP	Good Laboratory Practice Type	FDA	
8	EXP2	TS	1		EXPSTDTC	Experimental Start Date	2008-01-01	
9	EXP2	TS	1		EXPENDTC	Experimental End Date	2008-03-07	
10	EXP2	TS	1		TRMSAC	Time to Terminal Sacrifice	P42D	
11	EXP2	TS	1		STSTDTC	Study Start Date	2007-12-30	
12	EXP2	TS	1		DOSDUR	Dosing Duration	P42D	
13	EXP2	TS	1		STITLE	Study Title	Example of a Crossover study in the Rat with 3 dose levels and 3 dosing periods	
14	EXP2	TS	1		SNDIGVER	SEND Implementation Guide Version	SEND Implementation Guide Version 3.0	
15	EXP2	TS	1		SNDCTVER	SEND Controlled Terminology Version	SEND Terminology 2011-01-07	
16	EXP2	TS	1		STCAT	Study Category	TOX	

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Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF
17	EXP2	TS	1		SSPONSOR	Sponsor Organization	Example Sponsor Inc.	
18	EXP2	TS	1		SPREFID	Sponsor's Reference ID	NOT AVAILABLE	
19	EXP2	TS	1	1	TSTFNAM	Test Facility Name	Example Tox Lab Name	
20	EXP2	TS	1	1	TSTFLOC	Test Facility Location	10 Somewhere Street, Montgomery, AL 10000	
21	EXP2	TS	1	1	TFCNTRY	Test Facility Country	USA	
22	EXP2	TS	1		AGETXT	Age Text	6-8	
23	EXP2	TS	1		AGEU	Age Unit	WEEKS	
24	EXP2	TS	1	1	STDIR	Study Director	Dr. R. Smith	
25	EXP2	TS	1		TRT	Investigational Therapy or Treatment	Drug A	
26	EXP2	TS	1		TRTV	Treatment Vehicle	Saline	
27	EXP2	TS	1		GLPFL	GLP Flag	Y	
28	EXP2	TS	1		TRTCAS	Primary Treatment CAS Registry Number		NAV

7.6.2 Trial Summary Codes

The following table provides parameter codes (TSPARMCD) and parameter names (TSPARM) to be included in the Trial Summary (TS) dataset. They represent common types of trial summary information often included for a nonclinical study, at the discretion of the sponsor. The parameters listed as "Yes" in the Should Include column should always be included in the TS dataset, in order to provide proper study definition.

Should Include	TSPARMCD	TSPARM	Type	Controlled Terms, Codelist, or Format	CDISC Notes
See CDISC Notes	AGE	Age	Num		Age of subjects planned for the study populated as an integer. If the planned age of subjects is a range (e.g., "12-14 days"), then populate the age range in the AGETXT variable. Either the AGE or the AGETXT variable should be populated. Actual age of individual subjects at the start of the study is recorded in the Demographics (DM) domain AGE or AGETXT variable as appropriate.
See CDISC Notes	AGETXT	Age Text	Char		The age of the subjects at study start, as planned, expressed as a range. If an age integer value is available, then populate the AGE variable instead. Either the AGE or AGETXT variable should be populated. Actual age of individual subjects at the start of the study is recorded in the Demographics (DM) domain AGE or AGETXT variable as appropriate.
Yes	AGEU	Age Unit	Char	(AGEU)	Units associated with AGE and AGETXT (e.g., WEEKS, MONTHS, etc.). Individual AGEU of a USUBJID is recorded in the Demographics (DM) domain. A single AGEU for the study should be presented in the Trial Summary dataset. There is no requirement for AGEU in TS to be the same value as AGEU in DM..
Yes	SDESIGN	Study Design	Char	(DESIGN)	Describes the overall study plan/type, i.e., what will be done to the subjects, in order to answer certain questions about the Test Article to be administered, and how the Test Article is going to be administered (e.g., Cross-over, Latin Square, etc.). The most appropriate single value, as defined by the sponsor, should be included for Trial Summary purposes.
Yes	DOSDUR	Dosing Duration	Char	ISO 8601	The longest planned duration from the start of dosing to the first day of planned terminal disposition of the subjects (not including recovery) in ISO 8601 format.
Yes	EXPENDTC	Experimental End Date	Char	ISO 8601	Experimental completion date means the last date on which data are collected from the study (OECD). This date is sponsor defined, and is usually documented in the protocol.

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Should Include	TSPARMCD	TSPARM	Type	Controlled Terms, Codelist, or Format	CDISC Notes
Yes	EXPSTDTC	Experimental Start Date	Char	ISO 8601	Experimental starting date means the date on which the first study specific data are collected (OECD). This is sponsor defined, and is usually documented in the protocol.
Yes	GLPFL	GLP Flag	Char	(NY)	Indicates in the protocol whether a study was conducted according to Good Laboratory Practices (GLP).
Yes	ROUTE	Route of Administration	Char	(ROUTE)	The delivery method by which the Test Article is administered to the subjects. Subject-level dosing is recorded in the Exposure (EX) domain. TSGRPID may be used to relate ROUTE records to specific TRT records as needed.
Yes	SNDIGVER	SEND Implementation Guide Version	Char	(SNDIGVER)	The SEND Implementation Guide version used for the submission containing this dataset. Only a single record should be provided in the Trial Summary dataset.
Yes	SNDCTVER	SEND Controlled Terminology Version	Char		The SEND Controlled Terminology version used for the study dataset for this submission. An example of the appropriate format for TSVAL associated with this PARM/PARMCD combination is "SEND Terminology 2011-01-07" where "SEND Terminology" is the base name of the controlled terminology file, and "2011-01-07" is the publication date of the file in ISO 8601 format. The publication date can be found in the "SourceSystemVersion" attribute of the ODM tag in the ODM XML version of the controlled terminology file. Only a single record should be provided in the Trial Summary.
Yes	SPECIES	Species	Char	(SPECIES)	Used to identify the common species name of the subject (i.e., test system) under study (e.g., MOUSE, RAT, DOG, MONKEY). Individual species of a USUBJID is recorded in the Demographics (DM) domain.
Yes	SPLRNAM	Test Subject Supplier	Char		The name of the subject supplier. If there are multiple suppliers, individual SPLRNAM for a USUBJID may be recorded in the Subject Characteristics (SC) domain. TSGRPID may be used to relate SPLRNAM to specific SPLRLOC records.
Yes	SPREFID	Sponsor's Reference ID	Char		The reference identifier by which the study is known to the sponsor. This may be different from the STUDYID if the data were collected under a different identifier in the GLP protocol. For example, this would be used in a situation where a contract facility performs the study and provides a final report.
Yes	SSPONSOR	Sponsoring Organization	Char		The name of the company (or person) who initiates, supports, or submits the nonclinical study. The parameter contains the name of the specific sponsor or applicant.
Yes	STCAT	Study Category	Char	(STCAT)	Describes the general category of scientific study. The most appropriate single value, as defined by the sponsor, should be included for Trial Summary purposes.
Yes	STDIR	Study Director	Char		The Study Director is the individual responsible for the overall conduct of the nonclinical study. The parameter contains the name of the specific individual, e.g. "Dr. William Spock."
Yes	STRAIN	Strain/Substrain	Char	(STRAIN)	Used to identify the vendor-supplied strain/substrain designation for the subject (i.e., test system) under study. When applicable, it combines the root 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, CHIMPANZEE). The SEND Controlled Terminology codelist consists of commonly used wild-type and genetically modified strains. The codelist is extensible to accommodate strains not listed, as well as genetically modified substrains. Individual STRAIN of a USUBJID is recorded in the Demographics (DM) domain.
Yes	STSTDTC	Study Start Date	Char	ISO 8601	The Study Start Date, the date on which the study protocol or plan is approved (signed) by the Study Director. Also known as the study initiation date.

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Should Include	TSPARMCD	TSPARM	Type	Controlled Terms, Codelist, or Format	CDISC Notes
Yes	STITLE	Study Title	Char		The title of the nonclinical study.
Yes	SSTYP	Study Type	Char	(SSTYP)	Generalized categorization of the kind of nonclinical study to be conducted (e.g., ABSORPTION, BIOAVAILABILITY, CARDIOVASCULAR PHARMACOLOGY, REPEAT DOSE TOXICITY, CNS PHARMACOLOGY, etc.). The most appropriate single value, as defined by the sponsor, should be included for Trial Summary purposes.
Yes	TRT	Investigational Therapy or Treatment	Char		The name of the planned Test Article, treatment, therapy administered during the study. Multiple entries may be included as multiple rows where applicable subject-level dosing is recorded in the Exposure (EX) domain.
Yes	TFCNTRY	Test Facility Country	Char	(COUNTRY)	The country where the Test Facility is located.
Yes	TSTFLOC	Test Facility Location	Char		The full postal address of the Test Facility.
Yes	TSTFNAM	Test Facility Name	Char		The name of the Test Facility responsible for the overall conduct of the nonclinical study, or the facility administering the Test Article to Test Subjects. TSGRPID may be used to relate this to specific TSVAL values when TSPARMCD = "TFCNTRY," "TSTFLOC," and "STDIR."
Yes	TRMSAC	Time to Terminal Sacrifice	Char	ISO 8601	The duration from the start of dosing to the first day of planned terminal disposition of the subjects in ISO 8601 format. Typically this will be the disposition at the end of the dosing period. TSVAL values associated with this TSPARMCD would be "P28D" for a duration of 28 days; "P4W" would be equally appropriate, if that is defined in the protocol. Multiple records should be used if more than one terminal sacrifice period is defined in the protocol.
Yes	TRTCAS	Primary Treatment CAS Registry Number	Char		Test Article Chemical Abstracts Service (CAS) Registry Number.
Yes	TRTUNII	Primary Treatment Unique Ingredient ID	Char		Test Article Unique Ingredient Identifier. For information related to the UNII, follow this link. http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/default.htm
Yes	TRTV	Treatment Vehicle	Char		Vehicle for administration of treatment, such as a liquid in which the treatment drug is dissolved (e.g., Saline). Individual TRTV for a USUBJID is recorded in the Exposure (EX) domain.
	ALTSTDID	Alternate Study ID	Char		Describes any other identities used for the nonclinical study, e.g. if the study is identified by multiple numbers for operational reasons.
	ASOCSTDY	Associated Study	Char		Identifies any other study or studies conducted in support of the primary study. The parameter would list the STUDYID of the associated studies. Examples of this would be STUDYID1, STUDYID2, etc.
	BEDCHNG	Bedding Change	Char		Describes the planned frequency of bedding changes for the subjects. TSVAL values associated with this TSPARMCD would be Every other day, Every 5 days, Every week, etc.
	BEDDING	Bedding	Char		Planned type of bedding material available to the subjects. TSVAL values associated with this TSPARMCD would be Straw, Corn cob, Shavings, etc.
	DIET	Basal Diet	Char		Describes the planned type of diet offered to the subject. TSVAL values associated with this TSPARMCD would be Standard Diet, Nutrient Restricted, etc. Individual DIET for a USUBJID may be recorded in the Subject Characteristics (SC) domain, if the diet is not varied during the course

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Should Include	TSPARMCD	TSPARM	Type	Controlled Terms, Codelist, or Format	CDISC Notes
					of the study. Amount of food and water consumed at the USUBJID level would be recorded in the FW domain.
	DOSENDTC	End Date/Time of Dose Interval	Char	ISO 8601	The end date of the dosing interval on the study, as defined by the protocol, in ISO 8601 format.
	DOSSTDTC	Start Date/Time of Dose Interval	Char	ISO 8601	The start date of the dosing interval on the study, as defined by the protocol, in ISO 8601 format.
	ENVTEMP	Environmental Temperature	Char		The planned environmental temperature for the test subjects. Can be expressed as either a single value (80), or a range (75-80).
	ENVTEMPU	Environmental Temperature Units	Char	(UNIT)	The units associated with the environmental temperature. Only "C" or "F" is acceptable.
	FEEDREG	Feeding Regimen	Char		Describes the subject-feeding regimen. TSVAL values associated with this TSPARMCD would be Fed ad libitum, Restricted Feeding, Entire Study Fasted, etc. Individual FEEDREG for a USUBJID may be recorded in the Subject Characteristics (SC) domain, if the feeding regimen is not varied during the course of the study.
	GLPTYP	Good Laboratory Practice Type	Char		The type of regulation to which the study will adhere. These regulations are generally described in the study protocol. Multiple records (with different TSSEQ values) may be used to describe multiple regulation types. This parameter may also be used to indicate if the study is exploratory and does not fall under a particular regulation (e.g., OECD, FDA, JMHW, EMEA, MHRA, NONE, etc.).
	HOUSEGRP	Housing Group	Char		The planned grouping of subjects housed in the same arrangement. TSVAL values associated with this TSPARMCD would be Single-housed, Pair-housed, Group-housed, etc.
	HOUSETYP	Housing Type	Char		Describes the planned type of housing provided for the subjects. TSVAL values associated with this TSPARMCD would be Ventilated caging system (IVC), Plastic caging (suspended), Stainless steel caging (suspended), Plastic Micro-barrier caging, Primate Horizontal caging, Primate Vertical caging, Kennel, Pen, Stable, Feline Colony housing, Battery cages, Egg Laying cages, Poultry isolators, Biocontainment Unit, etc.
	HUMIDT	Housing Humidity	Char		The planned housing humidity for the subjects. Can be expressed as a single value (75) or as a range (60–70).
	HUMIDTU	Housing Humidity Units	Char	(UNIT)	The units associated with the housing humidity.
	IACUC	IACUC Number	Char		Institutional Animal Care and Use Committee number.
	IDMETH	Method of Identification	Char		Describes the method of uniquely identifying the Test Subject. TSVAL values associated with this TSPARMCD would be Ear tag, Tattoo, Collar, Microchip, etc.
	INTERIM	Interim Study Flag	Char	(NY)	Indicates that the datasets for this study are interim datasets.
	INTSAC	Time to Interim Sacrifice	Char	ISO 8601	The duration from the start of dosing to the first day of planned interim disposition of the subjects in ISO 8601 format. TSVAL values associated with this TSPARMCD would be "P14D" for a duration of 14 days. Multiple records should be used if more than one interim sacrifice period is defined in the protocol.
	SLENGTH	Study Length	Char	ISO 8601	The planned length of time for a subject's participation in ISO 8601 format. TSVAL values associated with this TSPARMCD would be "P5M" for a duration of 5 months or "P2W" for a duration of 2 weeks.

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Should Include	TSPARMCD	TSPARM	Type	Controlled Terms, Codelist, or Format	CDISC Notes
	LIGHT	Light Cycle	Char		Defines the planned light/dark hour cycle for the subjects (e.g., TSVAL values associated with this TSPARMCD would be "12 / 12" indicating that the subjects will be exposed to 12 hours of light and 12 hours of darkness). Text entry field in the format of nn / nn or nn/nn where n = number.
	MTHTRM	Method of Termination	Char	(MTHTRM)	Describes the planned sacrifice procedure.
	PINV	Principal Investigator	Char		Name of the Principal Investigator. The TSVAL value contains the name of the specific individual, e.g., "Dr. William Spock."
	SPLANSUB	Planned Number of Subjects	Num		The planned total number of subjects that will participate in the study.
	PCLASS	Class of Compound	Char		Class for a treatment compound. TSVAL values associated with this TSPARMCD would be COX2, ACE inhibitor, etc.
	PPL	Project License Number	Char		Project License Number (specific to UK only).
	SRANDOM	Study is Randomized	Char	(NY)	Identifies whether the study is randomized. TSVAL values associated with this TSPARMCD would be "Y" or "N."
	RECSAC	Recovery Period	Char	ISO 8601	The duration from the end of dosing to the first day of planned disposition of the recovery subjects in ISO 8601 format. TSVAL values associated with this TSPARMCD would be "P35D" for a duration of 35 days. Multiple records should be used if more than one recovery sacrifice period is defined in the protocol.
	SEXPOP	Sex of Participants	Char	(SEXPOP)	Planned sex of subjects to participate in the study.
	SPLRLOC	Test Subject Supplier Site	Char		City, state and country of the subject supplier if only one site. If there are multiple supplier sites, individual SPLRLOC for a USUBJID may be recorded in the Subject Characteristics (SC) domain.
	STENDTC	Study End Date	Char	ISO 8601	The Study End Date: the date on which the final report is approved (signed) by Study Director. Also known as the study completion date.
	STMON	Sponsor's Monitor	Char		The individual responsible for the periodic follow-up regarding the conduct of the nonclinical study. TSVAL values associated with this TSPARMCD would be the specific name of an individual, e.g., "Dr. William Spock."
	SBSTRAIN	Strain/Substrain Details	Char		Free-text field that allows the sponsor to enter further details qualifiying 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).
	TSCNTRY	Test Site Country	Char	(COUNTRY)	The country where the Test Site is located (e.g., if the TK analysis is performed at a site other than the Test Facility, then this parameter's TSVAL would be the country of the site at which the TK analysis is performed).
	TSLOC	Test Site Location	Char		The full postal address of the site where the relevant part of the study is actually conducted (e.g., if the TK analysis is performed at a site other than the Test Facility, then this parameter's TSVAL would be the address of the site at which the TK analysis is performed).
	TSNAM	Test Site Name	Char		The name of the site where part(s) of the study is actually conducted. Can be used when part(s) of the nonclinical study is conducted at a different site than the Test Facility site (e.g., when a company has multiple site locations within the same country). This parameter could also be used

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Should Include	TSPARMCD	TSPARM	Type	Controlled Terms, Codelist, or Format	CDISC Notes
					to designate when a study was conducted at a contract site. TSGRPID may be used to relate this to specific TSLOC, TSCNTRY, and PINV records.
	WATER	Drinking Water	Char		The planned type of drinking water that is to be provided to the test subject. TSVAL values associated with this TSPARMCD would be Tap water, Acidified, Reverse osmosis, etc. Amount of food and water consumed at the USUBJID level would be recorded in the FW domain.
	WTRDLVRY	Water Delivery	Char		Describes the planned methods of water delivery available for the test subject. TSVAL values associated with this TSPARMCD would be Bottled water, Ad lib, Restricted, etc.

7.6.3 Use of Null Flavor

The variable TSVALNF is based on the idea of a "null flavor" as embodied in ISO 21090.[1] A null flavor is an ancillary piece of data that provides additional information when its primary piece of data is null (has a missing value). There is controlled terminology for the null flavor data item, which includes such familiar values as "Unknown", "Other", and "Not Applicable" among its 15 terms.

The proposal to include a null flavor variable to supplement the TSVAL variable in the Trial Summary (TS) dataset arose when the TS subteam realized that they did not have a good way to represent a protocol that placed no upper limit on the age of study subjects. When the trial summary parameter is AGEMAX, then TSVAL should have a value expressed as an ISO8601 time duration (e.g., P43Y for 43 years old, P6M for 6 months old). The team considered allowing a value such as "NONE" or "UNBOUNDED" to be entered in TSVAL, but realized that if this were allowed, then validation programs would have to recognize this special term as an exception to the expected data format. The team eventually chose to propose a separate null flavor variable that uses the ISO 21090 null flavor terminology.

The controlled terminology for null flavor is included below.

NullFlavor Enumeration. OID: 2.16.840.1.113883.5.1008			
1	NI	No information	The value is exceptional (missing, omitted, incomplete, improper). No information as to the reason for being an exceptional value is provided. This is the most general exceptional value. It is also the default exceptional value.
2	INV	Invalid	The value as represented in the instance is not a member of the set of permitted data values in the constrained value domain of a variable.
3	OTH	Other	The actual value is not a member of the set of permitted data values in the constrained value domain of a variable (e.g. concept not provided by required code system).
4	PINF	Positive infinity	Positive infinity of numbers.
4	NINF	Negative infinity	Negative infinity of numbers.
3	UNC	Unencoded	No attempt has been made to encode the information correctly but the raw source information is represented (usually in originalText).
3	DER	Derived	An actual value may exist, but it must be derived from the information provided (usually an expression is provided directly).
2	UNK	Unknown	A proper value is applicable, but not known.
3	ASKU	Asked but unknown	Information was sought but not found (e.g. patient was asked but didn't know).

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4	NAV	Temporarily unavailable	Information is not available at this time, but it is expected that it will be available later.
3	NASK	Not asked	This information has not been sought (e.g. patient was not asked).
3	QS	Sufficient quantity	The specific quantity is not known, but is known to be non-zero and is not specified because it makes up the bulk of the material. 'Add 10 mg of ingredient X, 50 mg of ingredient Y, and sufficient quantity of water to 100 ml.' the null flavor would be used to express the quantity of water
3	TRC	Trace	The content is greater than zero, but too small to be quantified.
2	MSK	Masked	There is information on this item available, but it has not been provided by the sender due to security, privacy or other reasons. There may be an alternate mechanism for gaining access to this information. **WARNING — Use of this null flavor does provide information that may be a breach of confidentiality, even though no detailed data are provided. Its primary purpose is for those circumstances where it is necessary to inform the receiver that the information does exist without providing any detail.**
2	NA	Not applicable	No proper value is applicable in this context (e.g. last menstrual period for a male).

The numbers in the first column of the table describe the hierarchy of these values:

- No information
  - Invalid
    - Other
      - Positive infinity
      - Negative infinity
    - Unencoded
    - Derived
  - Unknown
    - Asked but unknown
      - Temporarily unavailable
    - Not asked
    - Quantity sufficient
    - Trace
  - Masked
  - Not applicable

The "No information" is the least informative. It merely confirms that the primary piece of data is null.

The values at level 2 provide a little more information, distinguishing between situations where the primary piece of data is not applicable and those where it is applicable but masked, unknown, or "invalid" (i.e., not in the correct format to be represented in the primary piece of data).

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The values at levels 3 and 4 provide successively more information about the situation. For example, for the MAXAGE case that provided the impetus for the creation of the TSVALNF variable, the value PINF means that there is information about the maximum age but it is not something that can be expressed, as in the ISO8601 quantity of time format required for populating TSVAL. The null flavor PINF provides the most complete information possible in this case (i.e., that the maximum age for the study is unbounded).

References

1. International Organization for Standardization. *ISO 21090:2011. Health informatics — Harmonized data types for information interchange.* ISO; 2011. Accessed March 26, 2020. https://www.iso.org/standard/35646.html

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8 Representing Relationships and Data

The fixed structures of the SDTM general observation classes may restrict the ability of sponsors to represent all the data they wish to submit. Collected data that may not entirely fit includes relationships between records within a domain, records in separate domains, and sponsor-defined "variables." As a result, the SDTM has methods to represent distinct types of relationships, all of which are described in more detail in subsequent sections.

- Section 8.1, Relating Groups of Records Within a Domain Using the --GRPID Variable, describes representing a relationship between a group of records for a given subject within the same domain.
- Section 8.2, Relating Records - RELREC, describes relationships between records in separate domains, either at a record-to-record level or at a domain-to-domain level.
- Section 8.3, Supplemental Qualifiers - SUPP-- Datasets, describes a method for representing the dependent relationship where data that cannot be represented by a standard variable within a general observation class domain record (or records) can be related back to that record.
- Section 8.4, Relating Comments To a Parent Domain, describes a dependent relationship between a comment in the Comments domain (see Section 5.2, Comments) and a parent record (or records) in other datasets (e.g., a comment recorded in association with an adverse event).
- Section 8.5, Relating Findings To Multiple Subjects - Subject Pooling, describes a method for relating one finding for multiple subjects.
- Section 8.6, How To Determine Where Data Belong in SEND, discusses the concept of related datasets and whether to place additional data in a separate domain or a supplemental qualifier special-purpose dataset, and the concept of modeling findings data that refer to data in another general observation class dataset.

All relationships make use of the standard domain identifiers, STUDYID, DOMAIN, and sometimes USUBJID or POOLID. In addition, the variables IDVAR and IDVARVAL are used for identifying the record-level merge/join keys. These 5 variables are used to tie information together by linking records. The specific set of identifiers necessary to properly identify each type of relationship is described in detail in the following sections. Examples of variables that could be used in IDVAR include:

- The sequence number (--SEQ) variable, which uniquely identifies a record for a given USUBJID within a domain. The variable --SEQ is required in all domains except Demographics (DM). For example, if subject 1234-2003 has 25 food records in the Food and Water Consumption (FW) domain, FWSEQ values for this subject should be the numbers 1-25. The numbers in the --SEQ variable may not always be represented sequentially in cases where the sponsor assigns the numbers early in the process and subsequently deletes some records or uses blocks of numbers to sequence data coming from different sources, but they should always be unique at least within a subject.
- The reference identifier (--REFID) variable can be used to capture an internal or external identifier (e.g., an identifier provided in an electronic data transfer). Some examples are lab-specimen identifiers and slide identifiers. --REFID is permissible in all domains, but never required. Values for --REFID are sponsor-defined and can be any alphanumeric strings the site chooses, consistent with their internal practices.
- The grouping identifier (--GRPID) variable, used to link related records for a subject within a dataset, is explained in Section 8.1, Relating Groups of Records Within a Domain Using the --GRPID Variable.
- The invariant record identifier (--RECID) variable is described in Example 4 in Section 8.2.2, RELREC Examples for Record-To-Record Relationships.

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8.1 Relating Groups of Records Within a Domain Using the --GRPID Variable

The optional grouping identifier variable --GRPID is permissible in all domains that are based on the general observation classes. It is used to identify relationships between records within a USUBJID within a single domain. It is important to note that --GRPID is not the treatment group or the internal specimen ID. An example would be laboratory records for test results from the same sample. In such a case, the relationship is defined by assigning the same unique character value to the --GRPID variable. The values used for --GRPID can be any values the site chooses; however, if the site uses values with some embedded meaning (rather than arbitrary numbers), those values should be consistent across the submission to avoid confusion. It is important to note that --GRPID has no inherent meaning across subjects or across domains.

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

8.1.1 --GRPID Example

The following table illustrates how to use --GRPID in the Laboratory Test Results (LB) domain to identify a combination therapy. In this example, the clinical chemistry results were grouped together from 1 sample for subject ABC-001-001. Note this example does not represent a complete dataset.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBGRPID	LBTESTCD	LBTEST	LBCAT	LBSCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSPEC	LBMETHOD	LBBLFL	LBDTC	LBNOMDY
1	ABC	LB	ABC-001-001	1	1	ALB	Albumin	CLINICAL CHEMISTRY	LIVER FUNCTION	30	mg/mL	30	30	mg/mL	SERUM		Y	2006-07-19T08:30	1
2	ABC	LB	ABC-001-001	2		WBC	Leukocytes	HEMATOLOGY		5.9	10^3/uL	5.9	5.9	10^3/uL	WHOLE BLOOD		Y	2006-07-19T08:30	1
3	ABC	LB	ABC-001-001	3		LYMLE	Lymphocytes	HEMATOLOGY	DIFFERENTIAL	6.7	%	6.7	6.7	%	WHOLE BLOOD		Y	2006-07-19T08:30	1
4	ABC	LB	ABC-001-001	4		NEUT	Neutrophils	HEMATOLOGY	DIFFERENTIAL	5.1	10^3/uL	5.1	5.1	10^3/uL	WHOLE BLOOD		Y	2006-07-19T08:30	1
5	ABC	LB	ABC-001-001	5		PH	pH	URINALYSIS		7.5		7.5			URINE		Y	2006-07-19T08:30	1
6	ABC	LB	ABC-001-001	6	1	CREAT	Creatinine	CLINICAL CHEMISTRY		0.9	mg/dL	79.5618	79.5618	umol/L	SERUM		Y	2006-07-19T08:30	1
7	ABC	LB	ABC-001-001	7		WBC	Leukocytes	HEMATOLOGY		5.9	10^3/uL	5.9	5.9	10^3/uL	WHOLE BLOOD		Y	2006-07-19T08:30	1
8	ABC	LB	ABC-001-001	8	1	CHOL	Cholesterol	CLINICAL CHEMISTRY		2.29	mg/dL	2.29	2.29	mg/dL	SERUM		Y	2006-07-19T08:30	1

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8.2 Relating Records - RELREC

relrec.xpt, Related Records - Relationship Datasets. One record per related record, related group of records, or related domain, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	CDISC Notes	Core
STUDYID	Study Identifier	Char		Unique identifier for a study.	Req
RDOMAIN	Related Domain Abbreviation	Char		Two-character abbreviation for the domain of the parent record(s).	Req
USUBJID	Unique Subject Identifier	Char		Unique Subject Identifier of the Parent record(s). Either USUBJID or POOLID must be populated, except for certain domain-to-domain relationships (see Section 8.2.3).	Exp
POOLID	Pool Identifier	Char		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		Name of the identifying variable in the general observation class domain that identifies the related record(s). Examples include BWSEQ and BWGRPID.	Req
IDVARVAL	Identifying Variable Value	Char		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)	Identifies the hierarchical level of the records in the relationship. Values are only necessary when identifying a relationship between domains (as described in Section 8.4). Values should be either ONE or MANY.	Perm
RELID	Relationship Identifier	Char		Unique value within a study that identifies the relationship. RELID can be any value the sponsor chooses and is only meaningful within the df dataset to identify the related/associated domain records.	Req

8.2.1 Assumptions for Related Records (RELREC) Domain model

1. The Related Records (RELREC) special-purpose dataset is used to describe relationships between records in different domains and relationships between domains. Relationships represented in RELREC are either:
   a. Collected relationships (e.g., Microscopic Findings to Macroscopic Findings), or
   b. The relationship between Pharmacokinetics Concentrations (PC) and Pharmacokinetics Parameters (PP) records, or
   c. To indicate sponsor-defined identifier (--SPID) values are used consistently within subjects across a set of domains.
2. A relationship is defined by adding a record to RELREC for each record or group of records to be related and by assigning a unique character identifier value for the relationship (RELID). The value of RELID is chosen by the sponsor, but must be identical for all related records.
3. Record-to-record relationships (USUBJID or POOLID, and IDVARVAL are populated; RELTYPE is null)
   a. Records expressing a relationship are specified using the key variables STUDYID, RDOMAIN (the 2-letter domain code of the record in the relationship), and USUBJID or POOLID, along with IDVAR and IDVARVAL. Single records can be related by using a unique,record-identifying variable such as --SEQ in IDVAR. Groups of records can be related by using grouping variables such as --GRPID in IDVAR. IDVARVAL would contain the value of the variable described in IDVAR.
4. Domain-to-domain relationships (USUBJID, POOLID, and IDVARVAL are null; RELTYPE is populated)
   a. The RELREC special-purpose dataset can also be used to identify relationships between datasets (e.g., one-to-many relationship, parent-child relationship). The relationship is defined by including a single

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record for each related dataset that identifies the key(s) of the dataset that can be used to relate the respective records.

b. Records with POOLID populated cannot be included in domain-to domain relationships.

c. Note that it is not necessary to use the RELREC dataset to identify associations from data in the SUPP-- datasets or the Comments (CO) domain to their parent general-observation class domain records or special-purpose domain records, as both of these datasets include the key variable identifiers of the parent record(s) that are necessary to make the association.

d. The variable RELTYPE identifies the type of relationship between the domains. The allowable values are "ONE" and "MANY". This information defines how a merge/join would be written, and what would be the result of the merge/join. The possible combinations are:

   i. ONE and ONE. This combination indicates that **there is no hierarchical relationship between the domains** and the records in the domains. Only 1 record from each domain will potentially have the same value of the IDVAR within USUBJID.

   ii. ONE and MANY. This combination indicates that **there is a hierarchical (parent/child) relationship between the domains**. One record within USUBJID in the domain identified by RELTYPE = ONE will potentially have the same value of the IDVAR with many (one or more) records in the domain identified by RELTYPE = MANY.

   iii. MANY and 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 (e.g., see Section 6.3.12.3, Relating PP Records to PC Records – RELREC is Optional at this Time for SEND).

8.2.2 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	RELID
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	RELID
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.

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relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	POOLID	IDVAR	IDVARVAL	RELTYPE	RELID
1	EFC1234	CL		CAGE1	CLGRPID	FECES1		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	046GV2APCIu2	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

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RELREC Example Using --RECID

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELID
1	EFC5678	MA	ABC-101	MARECID	046GV2APCIu2	A
2	EFC5678	MI	ABC-101	MIRECID	2069gT4UnyRR	A

8.2.3 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
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 relevent 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

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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
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

8.2.4 Relating Nonstandard Variables Values To a Parent Domain

The SDTM does not allow the addition of new variables. Therefore, the supplemental qualifiers special-purpose dataset model is used to capture nonstandard variables and their association to parent records in general-observation class (Events, Findings, Interventions) datasets and Demographics (DM). Supplemental qualifiers are submitted via

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a separate SUPP-- dataset for each domain containing sponsor-defined variables (see Section 8.3, Supplemental Qualifiers - SUPP-- Datasets).

SUPP-- represents the metadata and data for each nonstandard variable/value combination. As the name "supplemental qualifiers" suggests, this dataset is intended to capture additional qualifiers for an observation. Data that represent separate observations should be treated as separate observations, either in this domain or another domain. The supplemental qualifiers dataset is structured similarly to the RELREC dataset in that it uses the same set of keys to identify parent records. Each SUPP-- record also includes the name of the qualifier variable being added (QNAM), the label for the variable (QLABEL), the actual value for each instance or record (QVAL), the origin (QORIG) of the value (see Sections 3.2.2.1, Origin Metadata, and 3.2.3, Value-level Metadata), and the evaluator (QEVAL) to specify the role of the individual assigning the value (e.g., pathologist, veterinarian).

SUPP-- datasets are also used to capture attributions. An *attribution* is typically an interpretation or subjective classification of 1 or more observations by a specific evaluator (e.g., a diagnosis provided by a pathologist or veterinarian). It is possible that different attributions may be necessary in some cases; SUPP-- provides a mechanism for incorporating as many attributions as are necessary. 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). 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 (e.g., "PATHOLOGIST", "VETERINARIAN").

The values for STUDYID, USUBJID, and POOLID should be unique for every record. There should not be multiple records in a SUPP-- dataset for the same QNAM value, as it relates to IDVAR/IDVARVAL for a USUBJID in a domain.

Just as use of the optional grouping identifier variable, --GRPID, can be a more efficient method of representing relationships in RELREC, it can also be used in a SUPP-- dataset to identify individual qualifier values (SUPP-- records) related to multiple general observation class domain records that could be grouped, such as relating an attribution to a group of laboratory measurements.

8.3 Supplemental Qualifiers - SUPP-- Datasets

supp--.xpt, Supplemental Qualifiers for (domain name) — Relationship Datasets. One record per supplemental qualifier per related parent domain record(s), Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	CDISC Notes	Core
STUDYID	Study Identifier	Char		Unique study identifier of the parent record(s).	Req
RDOMAIN	Related Domain Abbreviation	Char		Two-character abbreviation for the domain of the parent record(s).	Req
USUBJID	Unique Subject Identifier	Char		Unique subject identifier of the parent record(s). Either USUBJID or POOLID must be populated.	Exp
POOLID	Pool Identifier	Char		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		Identifying variable in the dataset that identifies the related record(s). Examples: BWSEQ, CLGRPID.	Exp
IDVARVAL	Identifying Variable Value	Char		Value of identifying variable of the parent record(s).	Exp
QNAM	Qualifier Variable Name	Char		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 sponsor'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

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QLABEL	Qualifier Variable Label	Char		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
QVAL	Data Value	Char		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		QORIG is used to indicate the origin of the data. Possible values are COLLECTED, DERIVED, OTHER, and NOT AVAILABLE. See Section 3.2.2.1.	Perm
QEVAL	Evaluator	Char		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. Some examples include PATHOLOGIST or VETERINARIAN, etc.	Perm

A record in a SUPP-- dataset relates back to its parent record(s) via the key identified by the STUDYID, RDOMAIN, USUBJID (or POOLID), and IDVAR/IDVARVAL variables. An exception are SUPP-- dataset records that are related to Demographics (DM) records where both IDVAR and IDVARVAL will be null because the key variables STUDYID, RDOMAIN, and USUBJID (or POOLID) are sufficient to identify the unique parent record in DM (DM has 1 record per USUBJID).

All records in the SUPP-- datasets must have a value for QVAL. Transposing source variables with missing/null values may generate SUPP-- records with null values for QVAL, causing the SUPP-- datasets to be extremely large. When this happens, the sponsor must delete the records where QVAL is null, prior to submission.

If the USUBJID and POOLID are null, then the contents apply to all subjects with the same IDVAR and IDVARVAL.

See Section 4.5.3, Biological Significance for Findings Observation Class Data, for information on representing information greater than 200 characters in length.

8.3.1 Submitting Supplemental Qualifiers

8.3.1.1 SUPP-- 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

8.3.1.2 When Not to Use Supplemental Qualifiers

The following data should ***not*** be submitted as supplemental qualifiers:

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- Subject-level objective data that fit in Subject Characteristics (SC)
- Comments related to a record or records contained within a parent dataset. Although they may have been collected in the same record by the sponsor, comments should instead be captured in the CO special-purpose domain.
- Data not directly related to records in a parent domain. Such records should instead be captured in either a separate general observation class or special-purpose domain.

8.3.1.3 Reserved Values for QNAM and QLABEL

Certain QNAM variables have been reserved for specific purposes, as described in previous sections of this document. Those values are as follows:

QNAM	QLABEL	SENDIG Section Reference
--CALCN	Numeric Interpretation for Calculations	4.5.1
--BIOSIG	Biological Significance	4.5.4
--REAS	Reason Test or Examination Was Performed	4.5.5
--RESMOD	Result Modifiers	6.3.3, 6.3.7, 6.3.8, 6.3.14

8.4 Relating Comments to a Parent Domain

The Comments special-purpose domain, which is also described in Section 5.2, Comments, 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 or POOLID, 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 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.

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 on this is that a single comment may only be related to 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.

See Section 5.2.1.2, Examples for Comments (CO) Domain Model.

8.5 Relating Findings to Multiple Subjects - Subject Pooling

In nonclinical studies it is common that a single finding may be captured for multiple subjects. The SENDIG specification handles this by introducing pools. The use of a POOLID column has been introduced to the Laboratory

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Test Results (LB), Food and Water Consumption (FW), Pharmacokinetics Concentrations (PC), Pharmacokinetics Parameters (PP), and Clinical Observation (CL) domains to support subject pooling in conjunction with the POOLDEF special-purpose domain described in this section.

POOLID and USUBJID are mutually exclusive. When POOLID is used, USUBJID will be null; if a USUBJID is recorded, the POOLID will be null.

It is important to note that POOLID values are unique for a given set of subjects. 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.

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

Domain	Example
Clinical Observations (CO)	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. See Section 6.3.3, Clinical Observations – CL.
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. See Section 6.3.6, Laboratory Test Results – LB.
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. See Section 6.3.5, Food and Water Consumption – FW.
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. See Section 6.3.11, Pharmacokinetics Concentrations – PC.
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 (see, e.g., Section 6.3.1.2, Examples for Body Weight (BW) Domain Model).

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 sponsor 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"

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8.5.1 Pool Definition - POOLDEF

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

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

8.5.1.1 Assumptions for Pool Definition (POOLDEF) Domain Model

1. POOLDEF Definition:
   a. This domain identifies the subjects that are included in a pool for which single finding records are captured.
   b. A "pool" must consist of at least 1 subject.
2. POOLID is unique for a given set of subjects.

8.5.1.2 Examples for Pool Definition (POOLDEF) Domain Model

Example 1

This example shows pools for group-housed food and water consumption pools and lab results.

Rows 1-3: Three subjects exist in pool "CAGE1 P1" for group-housed animals in the FW domain.

Rows 4-5: Two subjects were also used for a pooled blood sample in the LB domain.

pooldef.xpt

Row	STUDYID	POOLID	USUBJID
1	ABC1	CAGE1 P1	ABC1-1001
2	ABC1	CAGE1 P1	ABC1-1002
3	ABC1	CAGE1 P1	ABC1-1003
4	ABC1	POOL1	ABC1-1005
5	ABC1	POOL1	ABC1-1007

8.6 How To Determine Where Data Belong in SEND

Aside from a limited number of special-purpose domains, all subject-level SDTM datasets are based on 1 of the 3 general observation classes. When faced with a set of data that were collected and that "go together" in some sense, the first step is to identify SDTM observations within the data and the general observation class of each observation. Once these observations are identified at a high level, 2 other tasks remain:

- Determining whether the relationships between these observations need to be represented using GRPID within a dataset, as described in Section 8.1, Relating Groups of Records Within a Domain Using the --GRPID Variable, or using RELREC between datasets, as described in Section 8.3, Supplemental Qualifiers - SUPP-- Datasets
- Placing all the data items in 1 of the identified general observation class records, or in a SUPP-- dataset, as described in Section 8.5, Relating Findings To Multiple Subjects - Subject Pooling

In practice, considering the representation of relationships and placing individual data items may lead to reconsidering the identification of observations, so the whole process may require several iterations.

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9 Appendices

Appendix A: CDISC SEND Team

Based on participation on teams and in meetings throughout the development of this version.

SEND Leadership Team	
Name	**Company**
William Houser, SEND Team Leader	Bristol-Myers Squibb
Fred Wood, Cross-Team Governance	Data Standards Consulting Group
Mary Jo Brucker, DART Subteam Lead	Merck
Jamie Gilliam, Change Control Subteam Lead	Instem
Louis Norton, Cross-team Governance	Covance
Troy Smyrnios, Cross-team Governance	Zoetis
Audrey Walker, PCPP Subteam co-lead and Cross-team Governance	Charles River
Craig Zwickl, Controlled Terminology Subteam Lead	Independent consultant
SEND Extended Leadership Team	
Name (with indication of workstream or subteam led where applicable)	**Company**
Brian Argo, Dermal Ocular Lead	Charles River
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Susan DeHaven, PhUSE Liaison and SEND for CBER Co-lead	Sanofi
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Kevin Snyder	
Helena Sviglin	
Elaine Thompson	
Kendra Worthy	

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Appendix B: Glossary and Abbreviations

The following abbreviations and terms are used in this document. Additional definitions can be found throughout this document (see, e.g., Section 7.1.2, Definitions of Trial Design Concepts) and in the CDISC Glossary (available at http://www.cdisc.org/glossary/index.html).

CDISC	Clinical Data Interchange Standards Consortium
CRO	Contract research organization
CT	Controlled Terminology
Dataset	A collection of structured data in a single file
Domain	A collection of observations with a topic-specific commonality
eCDT	Electronic Common Technical Document
ECG	Electrocardiogram/electrocardiographic
eDT	Electronic data transfer
FDA	(US) Food and Drug Administration
GLP	Good laboratory practice
HPLC/MS	High performance liquid chromatography/mass spectrometer
INHAND	International Harmonization of Nomenclature and Diagnostic Criteria for Lesions in Rats and Mice
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.
MRI	Magnetic Resonance Imaging
NCI	National Cancer Institute (NIH)
NIH	(US) National Institutes of Health
SDS	Submission Data Standards. Also the name of the team that created the SDTM and SDTMIG.
SDTM	Study Data Tabulation Model
SDTMIG	Study Data Tabulation Model Implementation Guide
SEND	Standard for Exchange of Nonclinical Data
SENDIG	Standard for Exchange of Nonclinical Data Implementation Guide
TK	Toxicokinetics; the study of the absorption, distribution, metabolism and excretion of a drug (synonymous with pharmacokinetics)
USDA	US Department of Agriculture
XML	Extensible markup language

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Appendix C: Mapping To tumor.xpt File

The tumor.xpt file is a nonclinical analysis dataset. Specific assumptions regarding tabulating data from carcinogenicity studies were created with the intent that SEND datasets will contain the necessary information to derive a tumor.xpt file. It is the intent of the CDISC SEND Team that the data meet regulatory needs if submitted as SEND datasets.

The following assumptions must be met in to create a tumor.xpt file:

1. Every subject must have at least 1 record in the Exposure (EX) domain with EXSTDTC populated.
2. All organs scheduled for examination must have a record in the Microscopic Findings (MI) domain even if they were not analyzed. If a scheduled tissue is not examined, then a record for that tissue should be included with MISTAT = "NOT DONE". In any instance where a sample is found unusable (e.g., autolyzed), MISPCUFL must be "N."
3. If a sponsor chooses to include secondary or multicentric tumors in the tumor.xpt, they must map METASTATIC to MALIGNANT (=1) for the MALIGNST variable.
4. If a sponsor does not choose to include secondary or multicentric tumors in the tumor.xpt, the sponsor must exclude records with TFRESCAT = "METASTATIC."
5. Every tumor (including secondary and/or multicentric tumors) must have 1 record in the Tumor Findings (TF) domain.
6. Secondary tumors must have a MIRESCAT value of "METASTATIC".
7. When creating the TF domain, all secondary tumors must contain a value of "MALIGNANT" in the TFRESCAT variable.
8. TFDETECT (Time in Days to Detection of Tumor) is 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.

The following domains are required in order to create a tumor.xpt file:

- Demographics (DM)
- Disposition (DS)
- Exposure (EX)
- Microscopic Findings (MI)
- Tumor Findings (TF)
- Trial Sets (TX)

Appendix C1: tumor.xpt Mapping to SEND

This table describes the variables in the tumor.xpt and the SEND variables from which they are created.

Table. tumor.xpt Mapping to SEND

Tumor Dataset for Statistical Analysis 1,2 (tumor.xpt)					SEND Source - Domain	SEND Source - Variable	SEND Notes
SDS Variable	SDS Label	SDS Type	SDS Codes	SDS Comments			
STUDYNUM	Study number	Char		3	TF	STUDYID	This variable is mapped directly from the STUDYID variable in the TF domain.
ANIMLNUM	Animal number	Char		1,3	DM	USUBJID	This variable is mapped directly from the USUBJID variable in the DM domain. The 12-character limit does not apply.
SPECIES	Animal species	Char	M = mouse, R = rat		DM	SPECIES	This variable is mapped from the SPECIES variable in the DM domain. Defined mappings include M: MOUSE

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Tumor Dataset for Statistical Analysis 1,2 (tumor.xpt)					SEND Source - Domain	SEND Source - Variable	SEND Notes
SDS Variable	SDS Label	SDS Type	SDS Codes	SDS Comments			
							and R: RAT. There are no defined mappings for other species.
SEX	Sex	Char	M = male, F = female		DM	SEX	This variable is mapped directly from the SEX variable in the DM domain.
DOSEGP	Dose group	Num	Use 0, 1, 2, 3, 4,... In ascending order from control. Provide the dosing for each group.		DM -> TX	TXVAL	This variable is mapped from taking the SETCD value for a USUBJID in the DM domain and looking up the TXVAL value in the TX domain when TXPARMCD = "SPGRPCD." It is not required to use 0.
DTHSACTM	Time in days to death or sacrifice	Num			DS, EX	DSSTDTC - EXSTDTC + 1	This variable is calculated as the disposition date minus the first exposure start date for the subject, plus 1.
DTHSACST	Death or sacrifice status	Num	1 = Natural death or moribund sacrifice 2 = Terminal sacrifice 3 = Planned intermittent sacrifice 4 = Accidental death		DS	DSDECOD	This variable is mapped from the DSDECOD as specified in Table 2 below.
ANIMLEXM	Animal microscopic examination code	Num	0 = No tissues were examined 1 =At least one tissue was examined		MI	MISTAT	This variable is derived from all MI records for the subject. If all MI records for the animal have MISTAT= "NOT DONE," then this variable's value is 0. Otherwise, this variable's value is 1.
TUMORCOD	Tumor type code	Char		3,4		TFSTRESC Term's Code	The value of this variable is the code from the corresponding TFSTRESC codelist term.
TUMORNAM	Tumor name	Char		3,4	TF	TFSTRESC	This variable is mapped directly from the TFSTRESC variable.
ORGANCOD	Organ/tissue code	Char		3,5		SPEC Term's Code	The value of this variable is the code from the corresponding SPEC codelist term used for the TFSPEC variable.
ORGANNAM	Organ/tissue name	Char		3,5	TF	TFSPEC	This variable is mapped directly from the TFSPEC variable.
DETECTTM	Time in days to detection of tumor	Num			TF	TFDETECT	This variable is mapped from the TFDETECT variable.
MALIGNST	Malignancy status	Num	1 = Malignant2 = Benign3 = Undetermined	4	TF	TFRESCAT	This variable is mapped from the TFRESCAT as specified in Table 3 below.
DEATHCAU	Cause of death	Num	1 = Tumor caused death2 = Tumor did not cause death3 = Undetermined	4	TF	TFDTHREL	This variable is mapped from the TFDTHREL variable.1: TUMOR CAUSED DEATH2: TUMOR DID NOT CAUSE DEATH3: UNDETERMINED
ORGANEXM	Organ/Tissue microscopic examination code	Num	1 = Organ/Tissue was examined and was usable 2 = Organ/Tissue was examined but was not usable (e.g., autolyzed tissue) 3 = Organ/Tissue was not examined		MI	MISTAT, MISPCUFL	This variable is mapped from the MISTAT and MISPCUFL variables. 1: MISTAT is null and MISPCUFL is null 2: MISPCUFL value is "N" 3: MISTAT = "NOT DONE" and MISPCUFL is null

1. Each subject in the study should have at least 1 record even if it does not have a tumor.
2. Additional variables, as appropriate, can be added to the bottom of this dataset.
3. ORGANCOD and TUMORCOD limited to no more than 8 characters; ORGAN and TUMOR should be as concise as possible.
4. A missing value should be given for the variable MALIGNST, DEATHCAU, TUMOR, and TUMORCOD when the organ is unusable or not examined.

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5. Do not include a record for an organ that was usable and no tumor was found on examination. A record should be included for organs with a tumor, organs found unusable, and organs not examined.

Appendix C2: Mapping DSDECOD to DTHSACST

The tumor.xpt dataset's DTHSACST variable may be mapped from the Disposition (DS) domain's DSDECOD variable. The following table provides DSDECOD values and their DTHSACST equivalent.

Table. Mapping DSDECOD to DTHSACST

DSDECOD	DTHSACST	
Value	**Value**	**Meaning**
ACCIDENTAL DEATH	4	Accidental death
FOUND DEAD	1	Natural death or moribund sacrifice
MISSING	*	*
MORIBUND SACRIFICE	1	Natural death or moribund sacrifice
INTERIM SACRIFICE	3	Planned intermittent sacrifice
RECOVERY SACRIFICE	*	*
REMOVED FROM STUDY ALIVE	*	*
TERMINAL SACRIFICE	2	Terminal sacrifice
NON-MORIBUND SACRIFICE	*	*

There are no mappings to the DTHSACST variable for DSDECOD values listed with an asterisk (*). Subjects with these dispositions would not be relevant for tumor analysis.

Appendix C3: Mapping TFRESCAT to MALIGNST

The tumor.xpt dataset’s MALIGNST variable may be mapped from the TFRESCAT variable in the Tumor Findings (TF) domain. The following table provides TFRESCAT values and their MALIGNST equivalent.

Table. Mapping TFRESCAT to MALIGNST

TFRESCAT	MALIGNST		
Value	**Value**	**Meaning**	**Notes**
MALIGNANT	1	MALIGNANT	
METASTATIC	1	MALIGNANT	If the sponsor chooses to include secondary and multcentric tumors in the tumor.xpt
BENIGN	2	BENIGN	
UNDETERMINED	3	UNDETERMINED	

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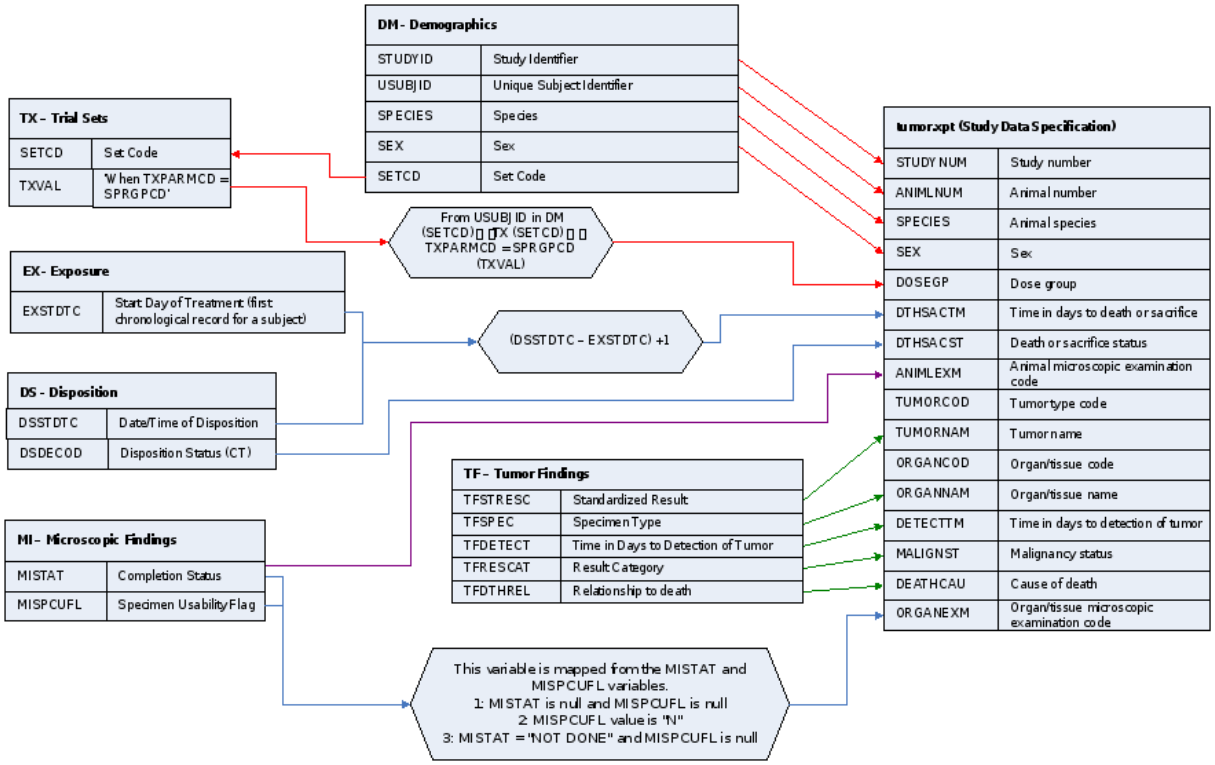
Appendix C4: Mapping of SEND Variables to tumor.xpt Variables

Figure. Mapping of SEND Variables to tumor.xpt Variables



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Appendix D: Revision History

This appendix lists all revisions since the last production version.

The changes made from SENDIG v3.1 to SENDIG v3.1.1 are as follows:

- PC domain
- PCBLFL changed to Perm (was Exp)
- PCDTC changed to Perm (was Exp)
- PCELTM changed to Exp (was Perm)
- PCTPTREF changed to Exp (was Perm)
- PCUSCHFL added (Perm)
- Assumption added to state intended purpose of PC domain
- Assumptions rewritten to emphasise importance of PCNOMDY, PCELTM and PCTPTREF in plotting concentration profiles
- All existing examples removed and replaced with cross-domain examples, plus 1 PC-specific example of how best to represent an unscheduled concentration sample
- PP domain
- Assumption added to describe relationship from PP back to PC
- Assumption 2 removed
- All existing examples removed and replaced with cross-domain examples, plus 1 PP-specific example of how best to qualify AUC tests
- Section 6.3.12.3.2, Relating Records, Example 3, Method C, typographical errors corrected in row descriptions
- Three cross-domain examples added
- Example 1 - EX, PC, PP and SUPPPC showing population of timing variables, when all timing information is readily available electronically
- Example 2 - PC, PP and SUPPPC showing population of timing variables, when only the minimum amount of timing information is readily available electronically
- Example 3 - PC, PP, SUPPPC and POOLDEF showing population of timing variables for a sparse sampling study.
- Dataset-level Metadata
- Table 3.2.1 Dataset Definition Metadata Example updated for PC to reflect changes to PC domain definition
- Table 3.2.1 Dataset Definition Metadata Example updated for PP to reflect changes to PP domain definition
- Section 4.5.1.1 Original and Standardized Results
  - Updated reference to PC examples for use of SUPP--
- Section numbering
  - Section 6.3.13, PC PP Cross-Domain Examples was inserted, meaning all subsequent sections within 6.3 were re-numbered
- Appendix A
  - CDISC SEND Team updated for SEND 3.1.1

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Appendix E: SDTM Variables to Never Use in SEND

The following SDTM variables, defined for use in human clinical trials, do not fit the SEND model and must **NEVER** be used in the submission of nonclinical studies :

Events variables

- BDSYCD
- HLT
- HLTCD
- HLGT
- LLT
- LLTCD
- PARTY
- PRTYID
- PTCD
- SCAN
- SCONG
- SDISAB
- SDTH
- SHOSP
- SLIFE
- SOD
- SMIE
- SOC
- SOCCD

Demographics variables

- ACTARMCD
- ACTARM
- COUNTRY
- DTHDTC
- DTHFL
- ETHNIC
- INVID
- INVNAM
- RACE
- RFICDTC
- RFPENDTC

Interventions variables

- PRESP

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Trial Summary variables

- TSVALCD
- TSVCDREF
- TSVCDVER

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