Study Data Tabulation Model

Version 1.8 (Final)

Prepared by the
CDISC Submission Data Standards Team and
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Notes to Readers

- This is Version 1.8 of the Study Data Tabulation Model Document (SDTM). This document includes additional variables related to the Standard for Exchange of Nonclinical Data Implementation Guide: Animal Rule (SENDIG-AR) Version 1.0, released concurrently.
- A full description of all changes from the prior version is provided in Section 8.1.1, Variable, Dataset, and Section Changes and Additions.

Revision History

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See Appendix A for Representations and Warranties, Limitations of Liability, and Disclaimers.

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1 Introduction

1.1 Purpose

This document describes the Study Data Tabulation Model (SDTM), which defines a standard structure for study data tabulations. This document, which supersedes all prior versions, includes numerous changes from the prior SDTM v1.7, described in Section 8.1, Changes from SDTM v1.7 to SDTM v1.8.

This document is intended for companies and individuals involved in the collection, preparation, and analysis of study data which may be submitted to regulatory authorities. Guidance, specifications, and regulations for the application of this model are provided separately in the implementation guides (IGs) and by regulatory authorities. Readers are advised to refer to these documents before preparing a regulatory submission based on the SDTM.

1.2 Relationship to Prior CDISC Models

This document is a successor to what was known in prior versions as the CDISC Submission Data Standards or Submission Domain Models. Whereas SDTM v1.0 was designated as the first implementation-ready version for clinical studies involving human drug products, improvements and enhancements have been incorporated in subsequent versions to support a broader range of regulated products, including the needs of nonclinical animal toxicity studies. Efforts will continue to further evaluate the model for human and animal studies involving other regulated products including food additives; therapeutic biologics; blood derivatives; vaccines; cellular, tissue, and gene therapy; and devices. Implementation guides for applying the model to each type of data and guidance on controlled terminology will be published separately.

1.3 Significant Changes from Prior Versions

The SDTM has been designed for backward compatibility; datasets prepared with prior versions should be compatible with v1.8. In most cases, this means that later versions may add new variables or correct textual errors, but do not eliminate variables or structures incorporated in prior versions. There are, however, isolated instances where some older variables may be deprecated in favor of newer, more functional variables. SDTM v1.8 does not identify any proposed deprecated variables, as there are no variables to be deprecated at this time.

The following new sections and tables have been added:

- Section 3.6, Challenge Agent Characterization
  - Table 3.6.1, Challenge Agent Characterization

New variables have been added to the following tables:

- Table 2.2.1.1 Interventions—Topic and Qualifier Variables
- Table 2.2.3.1 Findings—Topic and Qualifier Variables
- Table 2.2.5.1 All Observation Classes—Timing Variables
- Table 2.2.6.1 Subject Demographics Domain Variables

2 Model Fundamentals

2.1 Model Concepts and Terms

The SDTM provides a general framework for describing the organization of information collected during human and animal studies and submitted to regulatory authorities. The model is built around the concept of observations, which consist of discrete pieces of information collected during a study. Observations normally correspond to rows in a dataset. A collection of observations on a particular topic is considered a domain. For example, "Subject 101 had an adverse event of mild nausea starting on study day 6" is an observation belonging to the Adverse Events domain in a clinical trial.

Each observation can be described by a series of named variables. Each variable, which normally corresponds to a column in a dataset, can be classified according to its role. A *role* describes the type of information conveyed by the variable about each distinct observation and how it can be used. SDTM variables can be classified into 5 major roles:

- Identifier variables, such as those that identify the study, the subject (individual human or animal or group of individuals) involved in the study, the domain, and the sequence number of the record;
- Topic variables, which specify the focus of the observation (e.g., the name of a lab test);
- Timing variables, which describe the timing of an observation (e.g., start date, end date);
- Qualifier variables, which include additional illustrative text or numeric values that describe the results or additional traits of the observation (e.g., units, descriptive adjectives); and
- Rule variables, which express an algorithm or executable method to define start, end, or looping conditions in the Trial Design model.

Domain-specific variables, a concept introduced in SDTM v1.5, are for use in a limited number of designated domains and will be identified in the appropriate implementation guide. The variable names include the specific domain prefix. Section 2.2.12, Domain-specific Variables for the General Observation Classes, lists the domain-specific variables.

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

- Grouping Qualifiers used to group together a collection of observations within the same domain (e.g., --CAT and --SCAT);
- Result Qualifiers, which describe the specific results associated with the topic variable in a Findings dataset and which answer the question raised by the topic variable (e.g., --ORRES, --STRESC, --STRESN);
- Synonym Qualifiers specifying an alternative name for a particular variable in an observation (e.g., --MODIFY and --DECOD, which are equivalent terms for a --TRT or --TERM Topic variable; --TEST for --TESTCD);
- Record Qualifiers, which define additional attributes of the observation record as a whole, rather than describing a particular variable within a record (e.g., AESLIFE, and all other Serious Adverse Event flag variables in the AE domain; AGE, SEX, and RACE in the Demographics domain; --REASND, --POS, --LOC, --SPEC, and --NAM in a Findings domain); and
- Variable Qualifiers used to further modify or describe a specific variable within an observation and which are only meaningful in the context of the variable they qualify (e.g., --ORRESU, --ORNRHI, and --ORNRLO, all of which are Variable Qualifiers of --ORRES; --DOSU, which is a Variable Qualifier of --DOSE).

For example, in the observation "Subject 101 had mild nausea starting on study day 6," the Topic variable value is the term for the adverse event, "NAUSEA". The Identifier variable is the subject identifier, "101". The Timing variable is the study day of the start of the event, which captures the information "starting on study day 6", whereas an example of a Record Qualifier is the severity, the value for which is "MILD". Additional Timing and Qualifier variables could be included to provide the necessary detail to adequately describe an observation.

Most of the data collected in a study is about the subjects who are enrolled in the study. Sometimes, however, data is collected about other persons (Associated Persons, AP) who can be associated with the study, a particular study subject, or a device used in the study. An AP may or may not have a familial relationship to a study subject.

Observations about study subjects are normally collected for all subjects in a series of 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 trial. Each domain dataset is distinguished by a unique 2-character code that should be used consistently throughout the submission. This code, which is stored 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.

All datasets are structured as flat files with rows representing observations and columns representing variables; each dataset is described by metadata definitions that provide information about the variables used in the dataset. The Define.XML specification provides additional information.

The SDTM describes the name, label, role, and type for the standard variables. Note that the SDTM type specified in this document is either character or numeric, as these are the only types supported by SAS v.5 transport files. Define-XML provides more descriptive data types (e.g., integer, float, date, datetime); see the Define.XML specification for information about how to represent SDTM types using Define.XML data types.

A sponsor may drop certain variables (those defined as permissible in the relevant implementation guide) from the dataset and the corresponding descriptions from the Define.XML (i.e., the applicable "ItemRef" must be removed from the "ItemGroupDef" representing the dataset, as long as no data were collected for these variables). New sponsor-defined variables must not be added, and existing variables must not be renamed or modified for novel usage. Sponsors should consult the appropriate implementation guide; the implementation guides specifically describe which variables are required, expected, or permissible to use in specific domains based on the general observation classes.

2.2 The General Observation Classes

The majority of observations collected during a study can be divided among 3 general observation classes: Interventions, Events, or Findings.

- The Interventions Observation Class, described in Table 2.2.1.1, captures investigational, therapeutic, and other treatments that are administered to the subject (with some actual or expected physiological effect) either as specified by the study protocol (e.g., "exposure"), coincident with the study assessment period (e.g., "concomitant medications"), or other substances self-administered by the subject (e.g., "alcohol", "tobacco", "caffeine").
- The Events Observation Class, described in Table 2.2.2.1, captures planned protocol milestones such as randomization and study completion and occurrences, conditions, or incidents independent of planned study evaluations occurring during the trial (e.g., adverse events) or prior to the trial (e.g., medical history).
- The Findings Observation Class, described in Table 2.2.3.1, captures observations resulting from planned evaluations to address specific tests or questions such as laboratory tests, ECG testing, and questions listed on questionnaires. The Findings class also includes a subtype, "Findings About", which is used to record findings related to observations in the Interventions or Events class.

Datasets based on any of the general observation classes share a set of common Identifier and Timing variables. The set of Identifiers for All Classes variables used is described in Table 2.2.4.1. The set of Timing Variables for All Classes variables that should be used for all 3 general observation classes is included in Table 2.2.5.1. As a general rule, any valid Identifier or Timing variable is permissible for use in any submission dataset based on a general observation class.

In the tables in this section, the presence of 2 hyphens before the variable name (e.g., --TRT) is used to indicate the required use of a prefix based on the 2-character domain code. The domain code is used as a variable prefix to minimize the risk of difficulty when merging or joining domains for reporting purposes.

In addition to the 3 general observation classes, a submission will generally include a set of other special-purpose datasets of specific standardized structures to represent additional important information. For example:

- A Demographics special-purpose domain is included with human and animal studies (see Demographics).
- Other special-purpose domains may be included, such as Comments, Subject Elements, Subject Visits, Subject Disease Milestones, and Subject Repro Stages.
- Submissions may include Domain-specific Variables for the General Observation Classes.
- Submissions may include datasets to describe the design of a trial (see Section 3, The Trial Design Model).
- Submissions may include datasets to represent the relationships between datasets and records (see Section 4, Representing Relationships Among Datasets and Records).
- Submissions may include datasets illustrating how to apply the model fundamentals to associated persons (see Section 6, Applying Model Fundamentals to Associated Persons).

The SDTM is the foundation for many implementations. Examples include the SDTM Implementation Guide for Human Clinical Trials and the SEND (Standard for the Exchange of Nonclinical Data) Implementation Guide, available on the CDISC website at: https://www.cdisc.org/standards. Not all variables described in the tables in this document (SDTM tables) are appropriate for all implementations. Refer to the implementation guides for specific information on any restrictions.

2.2.1 The Interventions Observation Class

Table 2.2.1.1 Interventions—Topic and Qualifier Variables—One Record per Constant-dosing Interval or Intervention Episode

Variable Name	Variable Label	Type	Role	Description
--TRT	Name of Treatment	Char	Topic	The topic for the intervention observation, usually the verbatim name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.

#	Variable Name	Variable Label	Type	Role	Description
1	--MODIFY	Modified Treatment Name	Char	Synonym Qualifier of --TRT	If the value for --TRT is modified for coding purposes, then the modified text is placed here.
2	--DECOD	Standardized Treatment Name	Char	Synonym Qualifier of --TRT	Standardized or dictionary-derived name of the topic variable, --TRT, or the modified topic variable (--MODIFY), if applicable. Equivalent to the generic drug name in WHODrug, or a term in SNOMED, ICD-9, or other published or sponsor-defined dictionaries.
3	--MOOD	Mood	Char	Record Qualifier	Mode or condition of the record (e.g., "SCHEDULED", "PERFORMED").
4	--CAT	Category	Char	Grouping Qualifier	Used to define a category of topic-variable values.
5	--SCAT	Subcategory	Char	Grouping Qualifier	Used to define a further categorization of --CAT values.
6	--PRESP	Pre-specified	Char	Variable Qualifier of --TRT	Used when a specific intervention is prespecified on a CRF. Values should be "Y" or null.
7	--OCCUR	Occurrence Indicator	Char	Record Qualifier	Used to record whether a prespecified intervention occurred when information about the occurrence of a specific intervention is solicited.
8	--STAT	Completion Status	Char	Record Qualifier	Used to indicate when a question about the occurrence of a prespecified intervention was not answered. Should be null or have a value of "NOT DONE".
9	--REASND	Reason Not Done	Char	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is "NOT DONE".
10	--INDC	Indication	Char	Record Qualifier	Denotes the indication for the intervention (e.g., why the therapy was taken or administered).

#	Variable Name	Variable Label	Type	Role	Description
11	--CLAS	Class	Char	Variable Qualifier of --TRT	Class for a medication or treatment, often obtained from a coding dictionary.
12	--CLASCD	Class Code	Char	Variable Qualifier of --TRT	Used to represent code for --CLAS.
13	--DOSE	Dose	Num	Record Qualifier	Amount of --TRT given. Not populated when --DOSTXT is populated.
14	--DOSTXT	Dose Description	Char	Record Qualifier	Dosing information collected in text form. Examples: <1 per day, 200-400. Not populated when --DOSE is populated.
15	--DOSU	Dose Units	Char	Variable Qualifier of --DOSE, --DOSTXT or --DOSTOT	Units for --DOSE, --DOSTOT, or --DOSTXT. Examples: "ng", "mg", "mg/kg".
16	--TDOSD	Toxic/Physiologic Dose Descr	Char	Record Qualifier	NEW A description of a statistically derived estimate of a dose with a certain toxicological or physiological effect in a population, based on data from a dose-response study. Examples: "LD50", "ED90".
17	--FTDOSD	Factor for Toxic/Physiologic Dose Descr	Num	Variable Qualifier of --TDOSD	NEW The quantity given for the multiplier of --TDOSD. For example, if --TDOSD = "LD50" and --FTDOSD = "5", then the value represented by --DOSE and --DOSU is 5 times the LD50.
18	--DOSFRM	Dose Form	Char	Variable Qualifier of --DOSE, --DOSTXT or --DOSTOT	Dose form for the treatment. Examples: "TABLET", "CAPSULE".
19	--DOSFRQ	Dosing Frequency per Interval	Char	Variable Qualifier of --DOSE, --DOSTXT or --DOSTOT	Usually expressed as the number of doses given per a specific interval. Examples: "Q2H", "QD", "PRN".
20	--DOSTOT	Total Daily Dose	Num	Record Qualifier	Total daily dose of --TRT using the units in --DOSU. Used when dosing is collected as Total Daily Dose.
21	--DOSRGM	Intended Dose Regimen	Char	Variable Qualifier of --DOSE, --DOSTXT or --DOSTOT	Text description of the (intended) schedule or regimen for the Intervention. Example: "TWO WEEKS ON, TWO WEEKS OFF".
22	--ROUTE	Route of Administration	Char	Variable Qualifier of --TRT	Route of administration for the intervention. Examples: "ORAL", "INTRAVENOUS".
23	--LOT	Lot Number	Char	Record Qualifier	Lot number for the intervention described in --TRT.
24	--LOC	Location of Dose Administration	Char	Record Qualifier	Anatomical location of an intervention, such as an injection site. Example: "ARM" for an injection.
25	--LAT	Laterality	Char	Variable Qualifier of --LOC	Qualifier for anatomical location further detailing laterality of intervention administration. Examples: "RIGHT", "LEFT", "BILATERAL".
26	--DIR	Directionality	Char	Variable Qualifier of --LOC	Qualifier for anatomical location further detailing directionality of intervention administration. Examples: "ANTERIOR", "LOWER", "PROXIMAL".
27	--PORTOT	Portion or Totality	Char	Variable Qualifier of --LOC	Qualifier for anatomical location further detailing the distribution, which means arrangement of, apportioning of the intervention administration. Examples: "ENTIRE", "SINGLE", "SEGMENT", "MANY".
28	--FAST	Fasting Status	Char	Record Qualifier	Indicator used to identify fasting status. Valid values include "Y", "N", "U", or null if not relevant.
29	--PSTRG	Pharmaceutical Strength	Num	Record Qualifier	Amount of an active ingredient expressed quantitatively per dosage unit, per unit of volume, or per unit of weight, according to the pharmaceutical dose form. Examples: "50 mg/TABLET", "300 mg/L".
30	--PSTRGU	Pharmaceutical Strength Units	Char	Variable Qualifier of --PSTRG	Unit for --PSTRG. Examples: "mg/TABLET", "mg/mL".
31	--TRTV	Treatment Vehicle	Char	Record Qualifier	Vehicle for administration of treatment, such as a liquid in which the treatment drug is dissolved. Example: "SALINE".
32	--VAMT	Treatment Vehicle Amount	Num	Record Qualifier	Amount of the prepared product (treatment + vehicle) administered or given. Note: should not be diluent amount alone.

#	Variable Name	Variable Label	Type	Role	Description
33	--VAMTU	Treatment Vehicle Amount Units	Char	Variable Qualifier of --VAMT	Units for the prepared product (treatment + vehicle). Examples: "mL", "mg".
34	--ADJ	Reason for Dose Adjustment	Char	Record Qualifier	Describes reason for or explanation of why a dose is adjusted. Examples "ADVERSE EVENT", "INSUFFICIENT RESPONSE", "NON-MEDICAL REASON".
35	--RSDISC	Reason for Treatment Discontinuation	Char	Record Qualifier	Reason why the treatment was discontinued.
36	--USCHFL	Unscheduled Flag	Char	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. Not to be used with human clinical trials. This variable would not be needed when information on planned assessments is provided, such as when the Trial Visits (TV) and Subject Visits (SV) domains are used.
37	--RSTIND	Restraint Indicator	Char	Record Qualifier	NEW An indicator as to whether the animal subject was restrained during the intervention period. Expected values are "Y" or null. Not to be used with human clinical trials.
38	--RSTMOD	Restraint Mode	Char	Record Qualifier	NEW A description of whether the restraint was physical and/or chemical. Not to be used with human clinical trials.

2.2.2 The Events Observation Class

Table 2.2.2.1 Events—Topic and Qualifier Variables—One Record per Event

Variable Name	Variable Label	Type	Role	Description
--TERM	Reported Term	Char	Topic	Topic variable for an event observation, which is the verbatim or prespecified name of the event.

#	Variable Name	Variable Label	Type	Role	Description
1	--MODIFY	Modified Reported Term	Char	Synonym Qualifier of --TERM	If the value for --TERM is modified for coding purposes, then the modified text is placed here.
2	--LLT	Lowest Level Term	Char	Variable Qualifier of --TERM	MedDRA Lowest Level Term.
3	--LLTCD	Lowest Level Term Code	Num	Variable Qualifier of --LLT	MedDRA Lowest Level Term code.
4	--DECOD	Dictionary-Derived Term	Char	Synonym Qualifier of --TERM	Dictionary or sponsor-defined derived text description of the topic variable, --TERM, or the modified topic variable (--MODIFY), if applicable. Equivalent to the Preferred Term (PT in MedDRA).
5	--PTCD	Preferred Term Code	Num	Variable Qualifier of --DECOD	MedDRA Preferred Term code.
6	--HLT	High Level Term	Char	Variable Qualifier of --TERM	MedDRA High Level Term from the primary path.
7	--HLTCD	High Level Term Code	Num	Variable Qualifier of --HLT	MedDRA High Level Term code from the primary path.
8	--HLGT	High Level Group Term	Char	Variable Qualifier of --TERM	MedDRA High Level Group Term from the primary path.
9	--HLGTCD	High Level Group Term Code	Num	Variable Qualifier of --HLGT	MedDRA High Level Group Term code from the primary path.

#	Variable Name	Variable Label	Type	Role	Description
10	--CAT	Category	Char	Grouping Qualifier	Used to define a category of topic-variable values.
11	--SCAT	Subcategory	Char	Grouping Qualifier	Used to define a further categorization of --CAT values.
12	--PRESP	Pre-Specified	Char	Variable Qualifier of --TERM	Used to indicate whether the event described by --TERM was pre-specified on a CRF. Value is Y for pre-specified events, null for spontaneously reported events.
13	--OCCUR	Occurrence Indicator	Char	Record Qualifier	Used to record whether a prespecified event occurred when information about the occurrence of a specific event is solicited.
14	--STAT	Completion Status	Char	Record Qualifier	Used to indicate when a question about the occurrence of a prespecified event was not answered. Should be null or have a value of NOT DONE.
15	--REASND	Reason Not Done	Char	Record Qualifier	Reason not done. Used in conjunction with --STAT when its value is "NOT DONE".
16	--BODSYS	Body System or Organ Class	Char	Record Qualifier	Body system or system organ class assigned for analysis from a standard hierarchy (e.g., MedDRA) associated with an event. Example: "GASTROINTESTINAL DISORDERS".
17	--BDSYCD	Body System or Organ Class Code	Num	Variable Qualifier of --BODSYS	MedDRA System Organ Class code corresponding to --BODSYS assigned for analysis.
18	--SOC	Primary System Organ Class	Char	Variable Qualifier of --TERM	MedDRA primary System Organ Class associated with the event.
19	--SOCCD	Primary System Organ Class Code	Num	Variable Qualifier of --SOC	MedDRA primary System Organ Class code.
20	--LOC	Location of Event	Char	Record Qualifier	Describes anatomical location relevant for the event. Example: "ARM" for skin rash.
21	--LAT	Laterality	Char	Variable Qualifier of --LOC	Qualifier for anatomical location further detailing laterality. Examples: "RIGHT", "LEFT", "BILATERAL".
22	--DIR	Directionality	Char	Variable Qualifier of --LOC	Qualifier for anatomical location further detailing directionality. Examples: "ANTERIOR", "LOWER", "PROXIMAL".
23	--PORTOT	Portion or Totality	Char	Variable Qualifier of --LOC	Qualifier for anatomical location further detailing the distribution, which means arrangement of, apportioning of. Examples: "ENTIRE", "SINGLE", "SEGMENT", "MANY".
24	--PARTY	Accountable Party	Char	Record Qualifier	Party accountable for the transferable object (e.g., device, specimen) as a result of the activity performed in the associated --TERM variable. The party could be an individual (e.g., subject), an organization (e.g., sponsor), or a location that is a proxy for an individual or organization (e.g., site). It is usually a somewhat general term that is further identified in the --PRTYID variable.
25	--PRTYID	Identification of Accountable Party	Char	Record Qualifier	Identification of the specific party accountable for the transferable object (e.g., device, specimen) after the action in --TERM is taken. Used in conjunction with --PARTY.
26	--SEV	Severity/Intensity	Char	Record Qualifier	The severity or intensity of the event. Examples: "MILD", "MODERATE", "SEVERE".
27	--SER	Serious Event	Char	Record Qualifier	Is this is a serious event? Valid values are "Y" and "N".
28	--ACN	Action Taken with Study Treatment	Char	Record Qualifier	Describes changes made to the study treatment as a result of the event. Examples: "DOSE INCREASED", "DOSE NOT CHANGED".
29	--ACNOTH	Other Action Taken	Char	Record Qualifier	Describes other actions taken as a result of the event that are unrelated to dose adjustments of study treatment.
30	--ACNDEV	Action Taken with Device	Char	Record Qualifier	Action taken with respect to a device in a study, which may or may not be the device under study.
31	--REL	Causality	Char	Record Qualifier	Records the investigator's opinion as to the causality of the event to the treatment. ICH E2A and E2B examples include "NOT RELATED", "UNLIKELY RELATED", "POSSIBLY RELATED", "RELATED".

#	Variable Name	Variable Label	Type	Role	Description
32	--RELNST	Relationship to Non-Study Treatment	Char	Record Qualifier	An opinion as to whether the event may have been due to a treatment other than study drug. Example: "MORE LIKELY RELATED TO ASPIRIN USE".
33	--PATT	Pattern of Event	Char	Record Qualifier	Used to indicate the pattern of the event over time. Examples: "INTERMITTENT", "CONTINUOUS", "SINGLE EVENT".
34	--OUT	Outcome of Event	Char	Record Qualifier	Description of the outcome of an event. Examples: "RECOVERED/RESOLVED", "FATAL".
35	--SCAN	Involves Cancer	Char	Record Qualifier	Was the event associated with the development of cancer? Valid values are "Y", "N", and null.
36	--SCONG	Congenital Anomaly or Birth Defect	Char	Record Qualifier	Was the event associated with congenital anomaly or birth defect? Valid values are "Y", "N", and null.
37	--SDISAB	Persist or Signif Disability/Incapacity	Char	Record Qualifier	Did the event result in persistent or significant disability/incapacity? Valid values are "Y", "N", and null.
38	--SDTH	Results in Death	Char	Record Qualifier	Did the event result in death? Valid values are "Y", "N", and null.
39	--SHOSP	Requires or Prolongs Hospitalization	Char	Record Qualifier	Did the event require or prolong hospitalization? Valid values are "Y", "N", and null.
40	--SLIFE	Is Life Threatening	Char	Record Qualifier	Was the event life threatening? Valid values are "Y", "N", and null.
41	--SOD	Occurred with Overdose	Char	Record Qualifier	Did the event occur with an overdose? Valid values are "Y", "N", and null.
42	--SMIE	Other Medically Important Serious Event	Char	Record Qualifier	Do additional categories for seriousness apply? Valid values are "Y", "N", and null.
43	--CONTRT	Concomitant or Additional Trtmnt Given	Char	Record Qualifier	Was another treatment given because of the occurrence of the event? Valid values are "Y", "N", and null.
44	--TOX	Toxicity	Char	Variable Qualifier of --TOXGR	Description of toxicity quantified by --TOXGR such as NCI CTCAE Short Name. Examples: "HYPERCALCEMIA", "HYPOCALCEMIA". Sponsor should specify which scale and version is used in the Sponsor Comments column of the Define-XML document.
45	--TOXGR	Toxicity Grade	Char	Record Qualifier	Records toxicity grade using a standard toxicity scale (such as the NCI CTCAE). Sponsor should specify which scale and version is used in the Sponsor Comments column of the Define-XML document.
46	--USCHFL	Unscheduled Flag	Char	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. Not to be used with human clinical trials. This variable would not be needed when information on planned assessments is provided, such as when the Trial Visits (TV) and Subject Visits (SV) domains are used.

2.2.3 The Findings Observation Class

Table 2.2.3.1 Findings—Topic and Qualifier Variables—One Record per Finding

Variable Name	Variable Label	Type	Role	Description
--TESTCD	Short Name of Measurement, Test, or Exam	Char	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: "PLAT", "SYSBP", "RRMIN", "EYEEXAM".

#	Variable Name	Variable Label	Type	Role	Description
1	--TEST	Name of Measurement, Test, or Exam	Char	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: "Platelets", "Systolic Blood Pressure", "Summary (Min) RR Duration", "Eye Examination".

#	Variable Name	Variable Label	Type	Role	Description
2	--MODIFY	Modified Term	Char	Synonym Qualifier of --ORRES	If the value of --ORRES is modified for coding purposes, then the modified text is placed here.
3	--TSTDTL	Measurement, Test, or Examination Detail	Char	Variable Qualifier of --TESTCD and --TEST	Further description of --TESTCD and --TEST. Example: "The percentage of cells with +1 intensity of staining" when MITEST="Thyroid Transcription Factor 1".
4	--CAT	Category	Char	Grouping Qualifier	Used to define a category of topic-variable values. Examples: "HEMATOLOGY", "URINALYSIS", "CHEMISTRY", "HAMD 17", "SF36 V2.0 ACUTE", "EGFR MUTATION ANALYSIS".
5	--SCAT	Subcategory	Char	Grouping Qualifier	Used to define a further categorization of --CAT values. Example: "WBC DIFFERENTIAL".
6	--POS	Position of Subject During Observation	Char	Record Qualifier	Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".
7	--BODSYS	Body System or Organ Class	Char	Record Qualifier	Body System or Organ Class that is involved for a finding from the standard hierarchy for dictionary-coded results. Example: MedDRA SOC.
8	--ORRES	Result or Finding in Original Units	Char	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: "120", "<1", "POS".
9	--ORRESU	Original Units	Char	Variable Qualifier of --ORRES and --ORREF	Unit for --ORRES and --ORREF. Examples: "in", "LB", "kg/L".
10	--ORNRLO	Normal Range Lower Limit-Original Units	Char	Variable Qualifier of --ORRES	Lower end of normal range or reference range for results stored in --ORRES.
11	--ORNRHI	Normal Range Upper Limit-Original Units	Char	Variable Qualifier of --ORRES	Upper end of normal range or reference range for results stored in --ORRES.
12	--ORREF	Reference Result in Original Units	Char	Variable Qualifier of --ORRES	Reference value for the result or finding as originally received or collected. --ORREF uses the same units as --ORRES, if applicable. Examples: value from predicted normal value in spirometry tests.
13	--STRESC	Result or Finding in Standard Format	Char	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
14	--STRESN	Numeric Result/Finding in Standard Units	Num	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from --STRESC. --STRESN should store all numeric test results or findings.
15	--STRESU	Standard Units	Char	Variable Qualifier of --STRESC and --STRESN and --STREFC and --STREFN	Standardized units used for --STRESC, --STRESN, --STREFC, and --STREFN. Example: "mol/L".
16	--STNRLO	Normal Range Lower Limit-Standard Units	Num	Variable Qualifier of --STRESC and --STRESN	Lower end of normal range or reference range for standardized results (e.g., --STRESC, --STRESN) represented in standardized units (--STRESU).
17	--STNRHI	Normal Range Upper Limit-Standard Units	Num	Variable Qualifier of --STRESC and --STRESN	Upper end of normal range or reference range for standardized results (e.g., --STRESC, --STRESN) represented in standardized units (--STRESU).
18	--STNRC	Normal Range for Character Results	Char	Variable Qualifier of --STRESC	Normal range or reference range for results stored in --STRESC that are character in ordinal or categorical scale. Example: "Negative to Trace".

#	Variable Name	Variable Label	Type	Role	Description
19	--STREFC	Reference Result in Standard Format	Char	Variable Qualifier of --STRESC	Reference value for the result or finding copied or derived from --ORREF in a standard format.
20	--STREFN	Numeric Reference Result in Std Units	Num	Variable Qualifier of --STRESN	Reference value for continuous or numeric results or findings in standard format or in standard units. --STREFN uses the same units as --STRESN, if applicable.
21	--NRIND	Normal/Reference Range Indicator	Char	Variable Qualifier of --ORRES	Used to indicate the value is outside the normal range or reference range. May be defined by --ORNRLO and --ORNRHI or other objective criteria. Examples: "Y", "N"; "HIGH", "LOW"; "NORMAL", "ABNORMAL".
22	--RESCAT	Result Category	Char	Variable Qualifier of --ORRES	Used to categorize the result of a finding. Example: "MALIGNANT" or "BENIGN" for tumor findings.
23	--CHRON	Chronicity of Finding	Char	Variable Qualifier of --STRESC	Characterization of the duration of a biological process resulting in a particular finding. Examples: "ACUTE", "CHRONIC", "SUBACUTE".
24	--DISTR	Distribution Pattern of Finding	Char	Variable Qualifier of --STRESC	Description of the distribution pattern of a finding within the examined area. Examples: "FOCAL", "MULTIFOCAL", "DIFFUSE", "FOCAL", "MULTIFOCAL".
25	--RESLOC	Result Location of Finding	Char	Result Qualifier	Location where the result was observed (as opposed to the location specified for examination). This location may have a higher degree of specificity than the location specified for examination. Not to be used with human clinical trials.
26	--STAT	Completion Status	Char	Record Qualifier	Used to indicate that a question was not asked or 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".
27	--REASND	Reason Not Done	Char	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is "NOT DONE".
28	--XFN	External File Path	Char	Record Qualifier	Filename for an external file, such as one for an ECG waveform or a medical image.
29	--NAM	Laboratory/Vendor Name	Char	Record Qualifier	Name or identifier of the vendor (e.g., laboratory) that provided the test results.
30	--LOINC	LOINC Code	Char	Synonym Qualifier of --TESTCD	Logical Observation Identifiers Names and Codes (LOINC) code for the topic variable such as a lab test.
31	--SPEC	Specimen Material Type	Char	Record Qualifier	Defines the type of specimen used for a measurement. Examples: "SERUM", "PLASMA", "URINE", "DNA", "RNA".
32	--ANTREG	Anatomical Region	Char	Variable Qualifier of --SPEC	Defines the specific anatomical or biological region of a tissue, organ specimen or the region from which the specimen is obtained, as defined in the protocol, such as a section or part of what is described in the --SPEC variable. Examples: "CORTEX", "MEDULLA", "MUCOSA".
33	--SPCCND	Specimen Condition	Char	Record Qualifier	Defines the condition of the specimen. Example: "CLOUDY".
34	--SPCUFL	Specimen Usability for the Test	Char	Record Qualifier	Describes the usability of the specimen for the test. The value will be "N" if the specimen is not usable, and null if the specimen is usable.
35	--LOC	Location Used for the Measurement	Char	Record Qualifier	Anatomical location of the subject relevant to the collection of the measurement. Examples: "RECTAL" for temperature, "ARM" for blood pressure.
36	--LAT	Laterality	Char	Variable Qualifier of --LOC	Qualifier for anatomical location or specimen further detailing laterality. Examples: "RIGHT", "LEFT", "BILATERAL".
37	--DIR	Directionality	Char	Variable Qualifier of --LOC	Qualifier for anatomical location or specimen further detailing directionality. Examples: "ANTERIOR", "LOWER", "PROXIMAL".
38	--PORTOT	Portion or Totality	Char	Variable Qualifier of --LOC	Qualifier for anatomical location or specimen further detailing the distribution, which means arrangement or apportioning of. Examples: "ENTIRE", "SINGLE", "SEGMENT", "MANY".
39	--METHOD	Method of Test or Examination	Char	Record Qualifier	Method of the test or examination. Examples: "EIA" (enzyme immunoassay), "ELECTROPHORESIS", "DIPSTICK".

#	Variable Name	Variable Label	Type	Role	Description
40	--RUNID	Run ID	Char	Record Qualifier	A unique identifier for a particular run of a test on a particular batch of samples.
41	--ANMETH	Analysis Method	Char	Record Qualifier	Analysis method applied to obtain a summarized result. Analysis method describes the method of secondary processing applied to a complex observation result (e.g., an image or a genetic sequence).
42	--LEAD	Lead Identified to Collect Measurements	Char	Record Qualifier	Lead or leads identified to capture the measurement for a test from an instrument. Examples: "LEAD I", "LEAD V2", "LEAD CM5".
43	--CSTATE	Consciousness State	Char	Record Qualifier	The consciousness state of the subject at the time of measurement. Examples: "CONSCIOUS", "SEMI-CONSCIOUS", "UNCONSCIOUS".
44	--LOBXFL	Last Observation Before Exposure Flag	Char	Record Qualifier	Operationally-derived indicator used to identify the last non-missing value prior to RFXSTDTC. Should be "Y" or null.
45	--BLFL	Baseline Flag	Char	Record Qualifier	Indicator used to identify a baseline value. Should be "Y" or null.
46	--FAST	Fasting Status	Char	Record Qualifier	Indicator used to identify fasting status. Valid values include "Y", "N", "U", or null if not relevant.
47	--DRVFL	Derived Flag	Char	Record Qualifier	Used to indicate a derived record (e.g., a record that represents the average of other records such as a computed baseline). Should be "Y" or null.
48	--EVAL	Evaluator	Char	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Examples: "ADJUDICATION COMMITTEE", "INDEPENDENT ASSESSOR", "RADIOLOGIST".
49	--EVALID	Evaluator Identifier	Char	Variable Qualifier of --EVAL	Used to distinguish multiple evaluators with the same role recorded in --EVAL. Examples: "RADIOLOGIST1", "RADIOLOGIST2".
50	--ACPTFL	Accepted Record Flag	Char	Record Qualifier	In cases where more than one assessor provides an evaluation of a result or response, this flag identifies the record that is considered to be the accepted evaluation. Expected values can include "Y", "N", or null. This is not intended to be an analysis flag to indicate acceptability for a given analysis.
51	--TOX	Toxicity	Char	Variable Qualifier of --TOXGR	Description of toxicity quantified by --TOXGR such as NCI CTCAE Short Name. Examples: "HYPERCALCEMIA", "HYPOCALCEMIA". Sponsor should specify which scale and version is used in the Sponsor Comments column of the Define-XML document.
52	--TOXGR	Toxicity Grade	Char	Record Qualifier	Records toxicity grade using a standard toxicity scale (such as the NCI CTCAE). Sponsor should specify which scale and version is used in the Sponsor Comments column of the Define data definition document. Example: "2".
53	--SEV	Severity	Char	Record Qualifier	Describes the severity or intensity of a particular finding. Examples: "MILD", "MODERATE", "SEVERE".
54	--DTHREL	Relationship to Death	Char	Record Qualifier	Describes the relationship of a particular finding to the death of a subject. Examples: "Y", "N", or "U". Not to be used with human clinical trials.
55	--LLOQ	Lower Limit of Quantitation	Num	Variable Qualifier of --STRESC and --STRESN	Indicates the lower limit of quantitation for an assay. Units will be those used for --STRESU.
56	--ULOQ	Upper Limit of Quantitation	Num	Variable Qualifier of --STRESC and --STRESN	Indicates the upper limit of quantitation for an assay. Units will be those used for --STRESU.
57	--EXCLFL	Exclude from Statistics	Char	Record Qualifier	Indicates whether the values in the result variables for this record should be excluded from summary statistical calculations such as Mean, Standard Deviation, and Count (and others). Expected to be "Y" or null. --EXCLFL should not be used when --STAT is "NOT DONE". Not to be used with human clinical trials.
58	--REASEX	Reason for Exclusion from Statistics	Char	Record Qualifier	Reason excluded from statistics. Used in conjunction with --EXCLFL when its value is "Y". Not to be used with human clinical trials.

#	Variable Name	Variable Label	Type	Role	Description
59	--USCHFL	Unscheduled Flag	Char	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. Not to be used with human clinical trials. This variable would not be needed when information on planned assessments is provided, such as when the Trial Visits (TV) and Subject Visits (SV) domains are used.
60	--REPNUM	Repetition Number	Num	Record Qualifier	The instance number of a test that is repeated within a given timeframe for the same test. The level of granularity can vary (e.g., within a time point or within a visit). For example, multiple measurements of blood pressure or multiple analyses of a sample.
61	--RSTIND	Restraint Indicator	Char	Record Qualifier	NEW An indicator as to whether the animal was restrained during the observation period. Expected values are "Y" or null. Not to be used with human clinical trials.
62	--RSTMOD	Restraint Mode	Char	Record Qualifier	NEW A description of whether the restraint was physical and/or chemical. Not to be used with human clinical trials.

2.2.3.1 Findings About Events or Interventions

Findings About Events or Interventions utilizes the Findings General Observation Class variables with the addition of the --OBJ variable, as described in the following table. Note that the --OBJ variable must only be used in Findings About Events or Interventions.

Table 2.2.3.1.1 Findings About—Additional Qualifiers

Variable Name	Variable Label	Type	Role	Description
--OBJ	Object of the Observation	Char	Record Qualifier	Used in domains modeled as Findings About Events or Findings About Interventions. Describes the event or intervention whose property is being measured in --TESTCD/--TEST. Example: an event of vomiting which has findings, where --OBJ="VOMIT" and the volume of VOMIT is being measured where --TESTCD="VOLUME".

2.2.4 Identifiers for All Classes

All of the following identifier variables are available for use in any domain based on one of the 3 general observation classes. STUDYID, DOMAIN, and --SEQ are required in all domains based on one of the 3 general observation classes. Each general class domain must also include at least 1 of the following subject identifiers: USUBJID, APID, SPDEVID, or POOLID.

All identifier variables are allowed for all implementation guides.

Table 2.2.4.1 All Observation Classes—Identifiers

#	Variable Name	Variable Label	Type	Description
1	STUDYID	Study Identifier	Char	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char	2-character abbreviation for the domain most relevant to the observation. The domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged.
3	USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
4	APID	Associated Persons Identifier	Char	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist for each associated person. (See Table 4.1.3.1, POOLDEF Dataset, and Section 6, Applying Model Fundamentals to Associated Persons).
5	POOLID	Pool Identifier	Char	An identifier used to identify a result from a group of subjects that is not assignable to a specific subject.
6	SPDEVID	Sponsor Device Identifier	Char	Sponsor-defined identifier for a device.

#	Variable Name	Variable Label	Type	Description
7	NHOID	Non-Host Organism Identifier	Char	Sponsor-defined identifier for a non-host organism. This variable should be populated with an intuitive name based on the identity of the non-host organism as reported by the lab. Example: "A/California/7/2009 (H1N1)".
8	FETUSID	Fetus Identifier	Char	Identifier used to identify a fetus from a maternal subject for prenatal evaluations. FETUSID uniquely identifies a fetus within a subject. Not to be used with human clinical trials.
9	FOCID	Focus of Study-Specific Interest	Char	Identification of a focus of study-specific interest on or within a subject or specimen as called out 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"), or a more specific focus (e.g., "OD" (right eye), "Upper left quadrant of the back"). The value in this variable should have inherent semantic meaning.
10	--SEQ	Sequence Number	Num	Sequence number to ensure uniqueness of records within a dataset for a subject (or within a parameter, in the case of the Trial Summary domain). May be any valid number (including decimals) and does not have to start at 1.
11	--GRPID	Group ID	Char	Optional group identifier, used to link together a block of related records within a subject in a domain. Also used to link together a block of related records in the Trial Summary Information (Section 3.3).
12	--REFID	Reference ID	Char	Optional internal or external identifier such as lab specimen ID, or UUID for an ECG waveform or a medical image.
13	--RECID	Invariant Record Identifier	Char	Identifier for a record that is unique within a domain for a study and that 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.
14	--SPID	Sponsor-Defined Identifier	Char	Sponsor-defined identifier. Example: preprinted line identifier on a Concomitant Medications page.
15	--LNKID	Link ID	Char	Identifier used to link related records across domains. This may be a one-to-one or a one-to-many relationship. For example, a single tumor may have multiple measurements/assessments performed at each study visit.
16	--LNKGRP	Link Group ID	Char	Identifier used to link related records across domains. This will usually be a many-to-one relationship. For example, multiple tumor measurements/assessments will contribute to a single response to therapy determination record.

2.2.5 Timing Variables for All Classes

The following timing variables are available for use in any domain based on one of the 3 general observation classes, except where restricted in the assumptions for the standard domain models in the implementation guides. See Sections 2.2.6-2.2.11 for additional guidance relating to special-purpose domains.

Table 2.2.5.1 All Observation Classes—Timing Variables

#	Variable Name	Variable Label	Type	Format	Description
1	VISITNUM	Visit Number	Num		Clinical encounter number. Numeric version of VISIT, used for sorting.
2	VISIT	Visit Name	Char		Protocol-defined description of a clinical encounter.
3	VISITDY	Planned Study Day of Visit	Num		Planned study day of VISIT. Should be an integer.
4	TAETORD	Planned Order of Element Within Arm	Num		Number that gives the planned order of the Element within the Arm (see Section 3.1.2, Trial Arms).
5	EPOCH	Epoch	Char		Epoch associated with the start date or start date and time of the observation, or the date/time of collection if start date/time is not collected (see Section 3.1.2, Trial Arms).
6	RPHASE	Repro Phase	Char		Reproductive Phase with which the Reproductive Stage of the Reproductive Path is associated. Defined in Trial Paths domain. The

#	Variable Name	Variable Label	Type	Format	Description
					RPHASE variable is Required when any Reproductive Phase Day variable is used. Not to be used with human clinical trials.
7	RPPLDY	Planned Repro Phase Day of Observation	Num		The planned day within the Reproductive Phase on which the observation was scheduled to occur. Expressed as an integer. Not to be used with human clinical trials.
8	RPPLSTDY	Planned Repro Phase Day of Obs Start	Num		The planned day within the Reproductive Phase of the start of the observation. Expressed as an integer. Not to be used with human clinical trials.
9	RPPLENDY	Planned Repro Phase Day of Obs End	Num		The planned day within the Reproductive Phase of the end of the observation. Expressed as an integer. Not to be used with human clinical trials.
10	--DTC	Date/Time of Collection	Char	ISO 8601	Collection date and time of an observation.
11	--STDTC	Start Date/Time of Observation	Char	ISO 8601	Start date/time of an observation.
12	--ENDTC	End Date/Time of Observation	Char	ISO 8601	End date/time of the observation.
13	--DY	Study Day of Visit/Collection/Exam	Num		Actual study day of visit/collection/exam expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
14	--STDY	Study Day of Start of Observation	Num		Actual study day of start of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
15	--ENDY	Study Day of End of Observation	Num		Actual study day of end of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
16	--NOMDY	Nominal Study Day for Tabulations	Num		The nominal study day used by data-collection and reporting systems for grouping records for observations that may be scheduled to occur on different days into a single study day (e.g., output on a tabulation report). Not to be used with human clinical trials.
17	--NOMLBL	Label for Nominal Study Day	Char		A label for a given value of --NOMDY, within a domain, as presented in the study report. Not to be used with human clinical trials.
18	--RPDY	Actual Repro Phase Day of Observation	Num		The actual day within the Reproductive Phase on which the observation occurred. Expressed as an integer. Not to be used with human clinical trials.
19	--RPSTDY	Actual Repro Phase Day of Obs Start	Num		The actual day within the Reproductive Phase of the start of the observation. Expressed as an integer. Not to be used with human clinical trials.
20	--RPENDY	Actual Repro Phase Day of Obs End	Num		The actual day within the Reproductive Phase of the end of the observation. Expressed as an integer. Not to be used with human clinical trials.
21	--XDY	Day of Obs Relative to Exposure	Num		NEW The actual study day of an intervention, event, or finding, derived relative to the first exposure to any protocol-specified treatment. Expressed in integer days relative to RFXSTDTC in Demographics.
22	--XSTDY	Start Day of Obs Relative to Exposure	Num		NEW The actual study day of the start of an intervention or event, derived relative to the first exposure to any protocol-specified treatment. Expressed in integer days relative to RFXSTDTC in Demographics.
23	--XENDY	End Day of Obs Relative to Exposure	Num		NEW The actual study day of the end of an intervention, event, or finding, derived relative to the first exposure to any protocol-specified treatment. Expressed in integer days relative to RFXSTDTC in Demographics.
24	--CHDY	Day of Obs Rel to Challenge Agent	Num		NEW The actual study day of an intervention, event, or finding, derived relative to the first exposure to the challenge agent that induces the disease or condition that the investigational treatment is intended to cure, mitigate, treat, or prevent. Expressed in integer days relative to RFCSTDTC in Demographics.
25	--CHSTDY	Start Day of Obs Rel to Challenge Agent	Num		NEW The actual study day of the start of an intervention or event derived relative to the first exposure to the challenge agent that induces the disease or condition that the investigational treatment is intended to cure, mitigate, treat, or prevent. Expressed in integer days relative to RFCSTDTC in Demographics.

#	Variable Name	Variable Label	Type	Format	Description
26	--CHENDY	End Day of Obs Rel to Challenge Agent	Num		NEW The actual study day of the end of an intervention, event, or finding derived relative to the first exposure to the challenge agent that induces the disease or condition that the investigational treatment is intended to cure, mitigate, treat, or prevent. Expressed in integer days relative to RFCSTDTC in Demographics.
27	--DUR	Duration	Char	ISO 8601	Collected duration of an event, intervention, or finding. Used only if collected on the CRF and not derived.
28	--TPT	Planned Time Point Name	Char		Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point (e.g., time of last dose). See --TPTNUM and --TPTREF.
29	--TPTNUM	Planned Time Point Number	Num		Numeric version of planned time point used in sorting.
30	--ELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Planned elapsed time relative to a planned fixed reference (--TPTREF) such as "Previous Dose" or "Previous Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval.
31	--TPTREF	Time Point Reference	Char		Description of the fixed reference point referred to by --ELTM, --TPTNUM, --TPT, --STINT, and --ENINT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".
32	--RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Date/time for a fixed reference time point defined by --TPTREF.
33	--STRF	Start Relative to Reference Period	Char		Identifies the start of the observation as being before, during, or after the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by RFSTDTC and RFENDTC in Demographics.
34	--ENRF	End Relative to Reference Period	Char		Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by RFSTDTC and RFENDTC in Demographics.
35	--EVLINT	Evaluation Interval	Char	ISO 8601	Duration of interval associated with an observation such as a finding --TESTCD. Usually used with --DTC to describe an interval of this duration that ended at the time represented in --DTC. Example: "-P2M" to represent a period of the past 2 months as the evaluation interval for a question from a questionnaire.
36	--EVINTX	Evaluation Interval Text	Char		Evaluation interval associated with an observation, where the interval is not able to be represented in ISO 8601 format. Examples: "LIFETIME", "LAST NIGHT", "RECENTLY", "OVER THE LAST FEW WEEKS".
37	--STRTPT	Start Relative to Reference Time Point	Char		Identifies the start of the observation as being before or after the sponsor-defined reference time point defined by variable --STTPT.
38	--STTPT	Start Reference Time Point	Char		Description or date/time in ISO 8601 or other character format of the sponsor-defined reference point referred to by --STRTPT. Examples: "2003-12-15", "VISIT 1".
39	--ENRTPT	End Relative to Reference Time Point	Char		Identifies the end of the observation as being before or after the sponsor-defined reference time point defined by variable --ENTPT.
40	--ENTPT	End Reference Time Point	Char		Description or date/time in ISO 8601 or other character format of the sponsor-defined reference point referred to by --ENRTPT. Examples: "2003-12-25", "VISIT 2".
41	MIDS	Disease Milestone Instance Name	Char		The name of a specific instance of a Disease Milestone Type (MIDSTYPE) described in the Trial Disease Milestones dataset (see Section 3.5, Trial Disease Milestones). This should be unique within a subject. Used only in conjunction with RELMIDS and MIDSDTC.
42	RELMIDS	Temporal Relation to Milestone Instance	Char		The temporal relationship of the observation to the Disease Milestone Instance Name in MIDS. Examples: "IMMEDIATELY BEFORE", "AT TIME OF", "AFTER".
43	MIDSDTC	Disease Milestone Instance Date/Time	Char	ISO 8601	The start date/time of the Disease Milestone Instance Name in MIDS.

#	Variable Name	Variable Label	Type	Format	Description
44	--STINT	Planned Start of Assessment Interval	Char	ISO 8601	The start of a planned evaluation or assessment interval relative to the Time Point Reference (--TPTREF).
45	--ENINT	Planned End of Assessment Interval	Char	ISO 8601	The end of a planned evaluation or assessment interval relative to the Time Point Reference (--TPTREF).
46	--DETECT	Time in Days to Detection	Num		The number of days from the start of dosing to the earliest detection of a condition or pathogen. Not to be used with human clinical trials.

2.2.6 Demographics

Each study must include 1 standardized set of observations in a specific structure; this is the Demographics domain described in Table 2.2.6.1. Demographics is the parent domain for all other observations for subjects and should be identified with the domain code of "DM". The DM domain describes the essential characteristics of the study subjects, and is used by reviewers for selecting subsets of subjects for analysis. The DM domain, as with other datasets, includes Identifiers, a Topic variable, Timing variables, and Qualifiers. See the respective implementation guides for further guidance regarding use of additional Identifier and Timing variables.

Table 2.2.6.1 Subject Demographics Domain Variables

#	Variable Name	Variable Label	Type	Format	Role	Description
1	STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char		Identifier	2-character abbreviation for the domain, which must be "DM".
3	USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
4	SUBJID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.
5	RFSTDTC	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference start date or start date and time for the subject. Usually equivalent to date/time when subject was first exposed to study treatment. Required for all randomized subjects; will be null for all subjects who did not meet the milestone the date requires, such as screen failures or unassigned subjects.
6	RFENDTC	Subject Reference End Date/Time	Char	ISO 8601	Record Qualifier	Reference end date/time for the subject. Usually equivalent to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects.
7	RFXSTDTC	Date/Time of First Study Treatment	Char	ISO 8601	Record Qualifier	First date/time of exposure to any protocol-specified treatment or therapy for the subject.
8	RFXENDTC	Date/Time of Last Study Treatment	Char	ISO 8601	Record Qualifier	Last date/time of exposure to any protocol-specified treatment or therapy for the subject.
9	RFCSTDTC	Date/Time of First Challenge Agent Admin	Char	ISO 8601	Record Qualifier	NEW The start date or date and time of the first exposure to any protocol-specified challenge agent that induces the disease or condition that the investigational treatment is intended to cure, mitigate, treat, or prevent, represented in a standardized character format. Equal to the earliest value of AGSTDTC for the challenge agent.
10	RFCENDTC	Date/Time of Last Challenge Agent Admin	Char	ISO 8601	Record Qualifier	NEW The end date or date and time of the last exposure to any protocol-specified challenge agent that induces the disease or condition that the investigational treatment is intended to cure, mitigate, treat, or prevent, represented in a standardized character format. Equal to the latest value of AGENDTC for the challenge agent.
11	RFICDTC	Date/Time of Informed Consent	Char	ISO 8601	Record Qualifier	Date/time of informed consent.
12	RFPENDTC	Date/Time of End of Participation	Char	ISO 8601	Record Qualifier	Date/time when subject ended participation or follow-up in a trial. Should correspond to the last known date of contact.

#	Variable Name	Variable Label	Type	Format	Role	Description
13	DTHDTC	Date/Time of Death	Char	ISO 8601	Record Qualifier	Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-trial database.
14	DTHFL	Subject Death Flag	Char		Record Qualifier	A value of "Y" indicates the subject died. Should be "Y" or null. Should be populated even when the death date is unknown.
15	SITEID	Study Site Identifier	Char		Record Qualifier	Unique identifier for a site within a study.
16	INVID	Investigator Identifier	Char		Record Qualifier	An identifier to describe the Investigator for the study. May be used in addition to the SITEID. Not needed if SITEID is equivalent to INVID.
17	INVNAM	Investigator Name	Char		Synonym Qualifier of INVID	Name of the investigator for a site.
18	BRTHDTC	Date/Time of Birth	Char	ISO 8601	Record Qualifier	Date/time of birth of the subject.
19	AGE	Age	Num		Record Qualifier	Age expressed in AGEU. May be derived as (RFSTDTC-BRTHDTC), but BRTHDTC may not be available in all cases (due to subject privacy concerns).
20	AGETXT	Age Text	Char	number-number	Record Qualifier	The age of the subject 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, but not both.
21	AGEU	Age Units	Char		Variable Qualifier of AGE or AGETXT	Units associated with AGE or AGETXT.
22	SEX	Sex	Char		Record Qualifier	Sex of the subject.
23	RACE	Race	Char		Record Qualifier	Race of the subject. Sponsors should refer to the FDA guidance regarding the collection of race data.[1]
24	ETHNIC	Ethnicity	Char		Record Qualifier	The ethnicity of the subject. Sponsors should refer to the FDA guidance regarding the collection of ethnicity data.[1]
25	SPECIES	Species	Char		Record Qualifier	Used to identify the common species name of the subject (i.e., test system) under study (e.g., "MOUSE", "RAT", "DOG", "MONKEY"). Not to be used with human clinical trials.
26	STRAIN	Strain/Substrain	Char		Record Qualifier	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"). Not to be used with human clinical trials.
27	SBSTRAIN	Strain/Substrain Details	Char		Variable Qualifier of STRAIN	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. Not to be used with human clinical trials.
28	ARMCD	Planned Arm Code	Char		Record Qualifier	Short name for the Arm to which the subject was assigned, limited to 20 characters.
29	ARM	Description of Planned Arm	Char		Synonym Qualifier of ARMCD	Name of the Arm to which the subject was assigned.
30	ACTARMCD	Actual Arm Code	Char		Record Qualifier	Short name for the actual Arm in which the subject participated during the trial, limited to 20 characters.
31	ACTARM	Description of Actual Arm	Char		Synonym Qualifier of ACTARMCD	Description of the actual Arm in which the subject participated during the trial.

#	Variable Name	Variable Label	Type	Format	Role	Description
32	ARMNRS	Reason Arm and/or Actual Arm is Null	Char		Record Qualifier	The reason why the actual arm variables are null or why both the planned and actual arm variables are null. Examples: "SCREEN FAILURE", "NOT ASSIGNED", "NOT TREATED", "UNPLANNED TREATMENT". It is assumed that if the arm and actual arm variables are null, the same reason applies to both.
33	ACTARMUD	Description of Unplanned Actual Arm	Char		Record Qualifier	A description of actual treatment for a subject who did not receive treatment described in one of the planned trial arms.
34	SETCD	Set Code	Char		Record Qualifier	Short name of a specific Trial Set, as defined by the sponsor (see Section 3.1.4, Trial Sets). Maximum of 8 characters. This represents the code for the Trial Set for which parameters are being submitted.
35	RPATHCD	Planned Repro Path Code	Char		Record Qualifier	Short name for the planned Repro Path to which the subject was assigned. Limited to 20 characters. Not to be used with human clinical trials.
36	COUNTRY	Country	Char	ISO 3166-1 Alpha-3	Record Qualifier	Country of the investigation site at which the subject participated in the trial.
37	DMDTC	Date/Time of Collection	Char	ISO 8601	Timing	Date/time of collection of the demographic information.
38	DMDY	Study Day of Collection	Num		Timing	Study day of collection measured as integer days. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC in Demographics.

[1]US Department of Health and Human Services, Food and Drug Administration. Collection of race and ethnicity data in clinical trials. Guidance for industry and Food and Drug Administration staff. https://www.fda.gov/media/75453/download. Published October 26, 2016. Accessed August 26, 2019.

2.2.7 Comments

Comments are collected during the conduct of many studies. These are normally supplied by a principal investigator, but might also be collected from other sources such as central reviewers. When collected, comments should be submitted in a single Comments domain, which is defined in Table 2.2.7.1.

See the implementation guides for further guidance regarding use of additional Identifier and Timing variables.

Table 2.2.7.1 Comments Domain Variables

#	Variable Name	Variable Label	Type	Format	Role	Description
1	STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char		Identifier	2-character abbreviation for the domain, which must be "CO".
3	RDOMAIN	Related Domain Abbreviation	Char		Record Qualifier	Domain Abbreviation of the parent record(s). Null for records collected on general comments or additional information CRF page.
4	USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
5	POOLID	Pool Identifier	Char		Identifier	Used to identify a result for pooled subjects that is not assignable to any one individual within the pool.
6	COSEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness within the dataset. Should be assigned to be in a consistent chronological order.
7	IDVAR	Identifying Variable	Char		Record Qualifier	Identifying variable in the parent dataset that identifies the record(s) to which the comment applies. Examples: AESEQ or CMGRPID. Used only when individual comments are related to domain records. Null for comments collected on separate CRFs.

#	Variable Name	Variable Label	Type	Format	Role	Description
8	IDVARVAL	Identifying Variable Value	Char		Record Qualifier	Value of identifying variable of the parent record(s). Null for comments collected on separate CRFs.
9	COREF	Comment Reference	Char		Record Qualifier	Sponsor-defined reference associated with the comment. May be the CRF page number (e.g., 650), or a module name (e.g., "DEMOG"), or a combination of information that identifies the reference (e.g., "650-VITALS-VISIT 2").
10	COVAL	Comment	Char		Topic	The text of the comment. Text over 200 characters can be added to additional columns COVAL1-COVALn.
11	COEVAL	Evaluator	Char		Record Qualifier	Used to describe the originator of the comment. Example: "CENTRAL REVIEWER".
12	COEVALID	Evaluator Identifier	Char		Variable Qualifier of COEVAL	Used to distinguish multiple evaluators with the same role recorded in --EVAL. Examples: "RADIOLOGIST1", "RADIOLOGIST2".
13	CODTC	Date/Time of Comment	Char	ISO 8601	Timing	Date or date and time of comment on dedicated comment form, if collected. Should be null if this is a child record of another domain or if comment date was not collected.
14	CODY	Study Day of Comment	Num		Timing	Actual study day of the comment, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.

2.2.8 Subject Elements

Subject Elements describes the actual order of Elements that were traversed by the subject, together with the start date or start date and time and end date/time for each Element (see Table 2.2.8.1). Planned Elements are described in the Trial Design Model (see Section 3.1.1, Trial Elements). Because actual data does not always follow the plan, the SDTM allows for descriptions of an unplanned Element for subjects (SEUPDES).

See the implementation guides for further guidance regarding use of additional Identifier and Timing variables.

Table 2.2.8.1 Subject Elements—One Record per Actual Element per Subject

#	Variable Name	Variable Label	Type	Format	Role	Description
1	STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char		Identifier	2-character abbreviation for the domain, which must be "SE".
3	USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
4	SESEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness within the dataset. Should be assigned to be in a consistent chronological order.
5	ETCD	Element Code	Char		Topic	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that ETCD will need to serve as a variable name.
6	ELEMENT	Description of Element	Char		Synonym Qualifier of ETCD	The name of the Element. If ETCD has a value of "UNPLAN" then ELEMENT should be null.
7	TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the Element within the subject's assigned Arm.

#	Variable Name	Variable Label	Type	Format	Role	Description
8	EPOCH	Epoch	Char		Timing	Epoch associated with the Element in the planned sequence of Elements for the Arm to which the subject was assigned.
9	SESTDTC	Start Date/Time of Element	Char	ISO 8601	Timing	Start date or start date and time for an Element for each subject.
10	SEENDTC	End Date/Time of Element	Char	ISO 8601	Timing	End date/time of an Element for each subject.
11	SEUPDES	Description of Unplanned Element	Char		Synonym Qualifier of ETCD	Description of what happened to the subject during an unplanned Element. Used only if ETCD has the value of "UNPLAN".

2.2.9 Subject Visits

Subject Visits describes the actual start and end date/time for each visit of each individual subject (see Table 2.2.9.1). Planned trial visits are described in the Trial Design Model (see Section 3.1.3, Trial Visits). Because actual data does not always follow the plan, the SDTM allows for descriptions of unplanned visits for subjects (SVUPDES).

See the implementation guides for further guidance regarding use of additional Identifier and Timing variables.

Table 2.2.9.1 Subject Visits—One Record per Subject Visit, per Subject

#	Variable Name	Variable Label	Type	Format	Role	Description
1	STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char		Identifier	2-character abbreviation for the domain, which must be "SV".
3	USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
4	VISITNUM	Visit Number	Num		Topic	Clinical encounter number. (Decimal numbering may be useful for inserting unplanned visits.) Numeric version of VISIT, used for sorting.
5	VISIT	Visit Name	Char		Timing	Protocol-defined description of clinical encounter or description of unplanned visit. May be used in addition to VISITNUM and/or VISITDY as a text description of the clinical encounter.
6	VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the start of the visit based upon RFSTDTC in Demographics.
7	SVSTDTC	Start Date/Time of Visit	Char	ISO 8601	Timing	Start date or start date and time for a subject's visit.
8	SVENDTC	End Date/Time of Visit	Char	ISO 8601	Timing	End date/time of a subject's visit.
9	SVSTDY	Study Day of Start of Visit	Num		Timing	Study day of start of visit relative to the sponsor-defined RFSTDTC.
10	SVENDY	Study Day of End of Visit	Num		Timing	Study day of end of visit relative to the sponsor-defined RFSTDTC.
11	SVUPDES	Description of Unplanned Visit	Char		Synonym Qualifier of VISITNUM	Description of what happened to the subject during an unplanned visit. Null for protocol-defined visits.

2.2.10 Subject Disease Milestones

Subject Disease Milestones (see Table 2.2.10.1) is designed to record the timing, for each subject, of Disease Milestones that have been defined in the Trial Disease Milestones (see Section 3.5, Trial Disease Milestones).

Table 2.2.10.1 Subject Disease Milestones—One Record per Disease Milestone, per Subject

#	Variable Name	Variable Label	Type	Format	Role	Description
1	STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.
2	DOMAIN	Domain	Char		Identifier	2-character abbreviation for the domain, which must be "SM".
3	USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
4	SMSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records. Should be assigned to be consistent with chronological order.
5	MIDS	Disease Milestone Instance Name	Char		Topic	Name of the specific Disease Milestone. For types of Disease Milestones that can occur multiple times, the name will end with a sequence number. Example: "HYPO1".
6	MIDSTYPE	Disease Milestone Type	Char		Record Qualifier	The type of Disease Milestone. Example:"HYPOGLYCEMIC EVENT".
7	SMSTDTC	Start Date/Time of Milestone	Char	ISO 8601	Timing	Start date or start date and time of Milestone Instance, if Milestone is an intervention or event, or date of Milestone if Milestone is a finding.
8	SMENDTC	End Date/Time of Milestone	Char	ISO 8601	Timing	End date/time of Disease Milestone Instance.
9	SMSTDY	Study Day of Start of Milestone	Num		Timing	Study day of start of Disease Milestone Instance, relative to the sponsor-defined RFSTDTC.
10	SMENDY	Study Day of End of Milestone	Num		Timing	Study day of end of Disease Milestone Instance, relative to the sponsor-defined RFSTDTC.

2.2.11 Subject Repro Stages

Subject Repro Stages (not for use with human clinical trials; see Table 2.2.11.1) describes the actual order of Repro Stages experienced by the subject, together with the start date or start date and time and end date/time for each Repro Stage. The planned Repro Stages are described in the Trial Design Model (see Section 3.1.5, Trial Repro Stages). Because actual data does not always follow the plan, the SDTM allows for descriptions of an unplanned Repro Stage for subjects (SJUPDES).

Table 2.2.11.1 Subject Repro Stages—One Record per Actual Repro Stage per Subject

#	Variable Name	Variable Label	Type	Format	Role	Description
1	STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char		Identifier	2-character abbreviation for the domain, which must be "SJ".
3	USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
4	SJSEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness within the dataset. Should be assigned to be in a consistent chronological order.
5	RSTGCD	Repro Stage Code	Char		Topic	Short name of the Repro Stage used for programming and sorting. Maximum 8 characters.
6	RSTAGE	Description of Repro Stage	Char		Synonym Qualifier of RSTGCD	The name of the Repro Stage. If RSTGCD has a value of "UNPLAN" then RSTAGE should be null.

#	Variable Name	Variable Label	Type	Format	Role	Description
7	SJSTDTC	Start Date/Time of Repro Stage	Char	ISO 8601	Timing	Start date or start date and time for a Repro Stage for each subject.
8	SJENDTC	End Date/Time of Repro Stage	Char	ISO 8601	Timing	End date/time for a Repro Stage for each subject.
9	RPHASE	Repro Phase	Char		Timing	Name of the reproductive phase with which this Repro Stage of the Repro Path is associated.
10	SJUPDES	Description of Unplanned Repro Stage	Char		Synonym Qualifier of RSTGCD	Description of what happened to the subject during an unplanned Repro Stage. Used only if RSTGCD has the value of "UNPLAN".

2.2.12 Domain-specific Variables for the General Observation Classes

The concept of domain-specific variables was first introduced in SDTM v1.5. These variables are for use only in a specific domain and will be identified in the appropriate implementation guide. The variable names include the specific domain prefix. Table 2.2.12.1 lists the proposed domain-specific variables.

Table 2.2.12.1 Domain-specific Variables for General Observation Class Domains

Observation Class	Domain	Variable Name	Variable Label	Type	Role	Description	Position
Events	MH	MHEVDTYP	Medical History Event Date Type	Char	Variable Qualifier of MHSTDTC and/or MHENDTC	Specifies the aspect of the medical condition or event by which MHSTDTC and/or the MHENDTC is defined. Examples: "DIAGNOSIS", "SYMPTOMS", "RELAPSE", "INFECTION".	After MHDECOD
Interventions	EX	EXMETHOD	Method of Administration	Char	Record Qualifier	Method of administration of the treatment. Not to be used with human clinical trials.	After EXLOC
Findings	EG	EGBEATNO	ECG Beat Number	Num	Variable Qualifier of EGORRES	A sequence number that identifies the beat within an ECG.	After EGPOS
Findings	IC	ICIMPLBL	Implantation Site Label	Char	Record Qualifier	Label or identifier that describes the location or position of a fetal implantation site in the uterus (or uterine horn) when classifying implantations during a uterine examination in a reproductive toxicology study. Not to be used with human clinical trials.	After ICSTRESC
Findings	MS	MSAGENT	Agent Name	Char	Record Qualifier	The name of the drug or other material for which resistance is tested. The agent may be used for in vitro testing or may be used in tests for genetic markers or in direct phenotypic drug-sensitivity testing.	After MSTEST
Findings	MS	MSCONC	Agent Concentration	Num	Variable Qualifier of MSAGENT	The amount of drug or other material listed in MSAGENT per unit volume or weight. Used when the agent is part of the prespecified test. Not to be used when the concentration is a result of a test such as minimal inhibitory concentration, IC50, or EC50.	After MSAGENT
Findings	MS	MSCONCU	Agent Concentration Units	Char	Variable Qualifier of MSCONC	Unit of measure for MSCONC.	After MSCONC

3 The Trial Design Model

The Trial Design Model defines a standard structure for representing the planned sequence of activities and the treatment plan for the trial. The model provides a standard way to define the treatment groups and planned visits and assessments that will be experienced by trial subjects.

The model is built upon the concepts of Elements, Arms, Epochs, and Visits. The variables corresponding to these concepts are used in many domains. The implementation guides define specific details and examples for Trial Design.

3.1 Planned Elements, Arms, Visits, Sets, Repro Stages, and Repro Paths

Under the model, planned information is presented in a series of up to 6 tables:

- Trial Elements describes the Element code (unique for each Element), the Element description, and the rules for starting and ending an Element.
- Trial Arms describes each planned Arm in the trial. An Arm is an ordered sequence of Elements; the same Element may occur more than once in a given Arm. In order to accommodate complex Trial Designs, this dataset allows for rules for branching from one Element to another when a choice is available, and a rule for transitions to allow a subject to skip ahead to another Element rather than proceed linearly.
- Trial Visits describes the planned order and number of visits in the study. In the case where visits vary for each Arm, there would be a separate record per Visit per Arm. Trial Visits also describes the allowable or planned values for VISIT, VISITNUM, and VISITDY in the trial (which are subsequently used as Timing Variables for the collected study data), and rules for starting and ending each visit. In most blinded trials, the timing of visits is the same for all subjects in all Arms.
- Trial Sets allows the submission of detailed information about planned groups of subjects that results as a combination of experimental factors of interest for a study (including experimental parameters, inherent characteristics, and sponsor-defined attributes). A Set may be a planned subdivision of a Trial Arm, or may comprise one or more Trial Arms. These datasets are essential to determining whether data comparisons are feasible across different studies.
- Trial Repro Stages describes the unique Repro Stages in a study, with Repro Stage description, code (short name), and rules for start and end. Note: Not for use with human clinical trials.
- Trial Repro Paths describes each planned Repro Path in a Repro study, with the ordered sequence of Repro Stages that comprise each Repro Path, as well as specification of Repro Phase and reference start day of the Repro Phase applicable to the Repro Stage within the Repro Path. Note: Not for use with human clinical trials.

3.1.1 Trial Elements

Trial Elements describes the Element code (unique for each Element), the Element description, and the rules for starting and ending an Element (see Table 3.1.1.1).

Table 3.1.1.1 Trial Elements—One Record per Trial Element

#	Variable Name	Variable Label	Type	Format	Role	Description
1	STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char		Identifier	2-character abbreviation for the domain, which must be "TE".
3	ETCD	Element Code	Char		Topic	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that ETCD will need to serve as a variable name.
4	ELEMENT	Description of Element	Char		Synonym Qualifier of ETCD	The name of the Element.
5	TESTRL	Rule for Start of Element	Char		Rule	Expresses the rule for beginning the Element.
6	TEENRL	Rule for End of Element	Char		Rule	Expresses the rule for ending the Element. Either TEENRL or TEDUR must be present for each Element.
7	TEDUR	Planned Duration of Element	Char	ISO 8601	Timing	Planned Duration of Element. Used when the rule for ending the Element is applied after a fixed duration.

3.1.2 Trial Arms

Trial Arms describes each planned Arm in the trial (see Table 3.1.2.1). An Arm is an ordered sequence of Elements; the same Element may occur more than once in a given Arm. In order to accommodate complex trial designs, this dataset allows for rules for branching from one Element to another when a choice is available, and a rule for transitions to allow a subject to skip ahead to another Element rather than proceed linearly.

Note that although the same Element may occur more than once within an Arm, each occurrence would have a different value for TAETORD and EPOCH, and may have different values for TABRANCH and TATRANS.

Table 3.1.2.1 Trial Arms—One Record per Planned Element per Arm

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain, which must be "TA".
3	ARMCD	Planned Arm Code	Char	Topic	ARMCD is limited to 20 characters and does not have special character restrictions.
4	ARM	Description of Planned Arm	Char	Synonym Qualifier of ARMCD	Name given to Arm or treatment group.
5	TAETORD	Planned Order of Element within Arm	Num	Timing	Number that gives the order of the Element within the Arm.
6	ETCD	Element Code	Char	Record Qualifier	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that ETCD will need to serve as a variable name.
7	ELEMENT	Description of Element	Char	Synonym Qualifier of ETCD	The name of the Element.

#	Variable Name	Variable Label	Type	Role	Description
8	TABRANCH	Branch	Char	Rule	Condition subjects meet, at a "branch" in the Trial Design at the end of this Element, to be included in this Arm. Example: Randomization to DRUG X.
9	TATRANS	Transition Rule	Char	Rule	If the trial design allows a subject to transition to an Element other than the next Element in sequence, then the conditions for transitioning to those other Elements, and the alternative Element sequences, are specified in this rule (e.g., Responders go to washout).
10	EPOCH	Epoch	Char	Timing	Name of the Trial Epoch with which this Element of the Arm is associated.

3.1.3 Trial Visits

Trial Visits describes the planned order and number of visits in the study. In the case where visits vary for each Arm, there would be a separate record per Visit per Arm. Trial Visits also describes the allowable or planned values for VISIT, VISITNUM, and VISITDY in the trial (which are subsequently used as Timing Variables for the collected study data), and rules for starting and ending each visit (see Table 3.1.3.1). In most blinded trials, the timing of visits is the same for all subjects in all Arms.

Table 3.1.3.1 Trial Visits—One Record per Planned Trial Visit

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain, which must be "TV".
3	VISITNUM	Visit Number	Num	Topic	Clinical encounter number. Numeric version of VISIT can be used for sorting.
4	VISIT	Visit Name	Char	Synonym Qualifier of VISITNUM	Protocol-defined description of the clinical encounter. May be used in addition to VISITNUM and/or VISITDY as a text description of the clinical encounter.
5	VISITDY	Planned Study Day of Visit	Num	Timing	Planned study day of VISIT. Due to its sequential nature can be used for sorting.
6	ARMCD	Planned Arm Code	Char	Record Qualifier	ARMCD is limited to 20 characters and does not have special character restrictions. If the timing of visits for a trial does not depend on which Arm a subject is in, then ARMCD should be null.
7	ARM	Description of Planned Arm	Char	Synonym Qualifier of ARMCD	Name given to Arm or treatment group.
8	TVSTRL	Visit Start Rule	Char	Rule	Rule describing when the visit starts, in relation to the sequence of Elements.
9	TVENRL	Visit End Rule	Char	Rule	Rule describing when the visit ends, in relation to the sequence of Elements.

3.1.4 Trial Sets

Trial Sets allows the submission of detailed information about planned groups of subjects that results as a combination of experimental factors of interest for a study (including experimental parameters, inherent characteristics, and sponsor-defined attributes; see Table 3.1.4.1). A Set may be a planned subdivision of a Trial Arm, or may comprise one or more Trial Arms. These datasets are essential to determining whether data comparisons are feasible across different studies.

Table 3.1.4.1 Trial Sets—One Record per Trial Set Parameter

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain, which must be "TX".
3	SETCD	Set Code	Char	Identifier	Short name of a specific Trial Set, as defined by the sponsor. Maximum 8 characters. This represents the Trial Set for which parameters are being submitted.
4	SET	Set Description	Char	Synonym Qualifier of SETCD	Long description of a specific Trial Set, as defined by the sponsor.
5	TXSEQ	Sequence Number	Num	Identifier	Unique number for this record within this dataset.
6	TXPARMCD	Trial Set Parameter Short Name	Char	Topic	Short character value for the Trial Set parameter described in TXPARM. Maximum 8 characters.
7	TXPARM	Trial Set Parameter	Char	Synonym Qualifier of TXPARMCD	Term for the Trial Set parameter. Maximum 40 characters.
8	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.

3.1.5 Trial Repro Stages

Note: Not for use with human clinical trials.

Trial Repro Stages describes the unique Repro Stages in a study, with Repro Stage description, code (short name), and rules for start and end (see Table 3.1.5.1).

Table 3.1.5.1 Trial Repro Stages—One Record per Planned Repro Stage

#	Variable Name	Variable Label	Type	Format	Role	Description
1	STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char		Identifier	2-character abbreviation for the domain, which must be "TT".
3	RSTGCD	Repro Stage Code	Char		Topic	Short name of the Repro Stage used for programming and sorting. Maximum 8 characters.
4	RSTAGE	Description of Repro Stage	Char		Synonym Qualifier of RSTGCD	The name of the Repro Stage.
5	TTSTRL	Rule for Start of Repro Stage	Char		Rule	Expresses the rule for beginning the Repro Stage.
6	TTENRL	Rule for End of Repro Stage	Char		Rule	Expresses the rule for ending the Repro Stage. Either TTENRL or TTDUR must be present for each Repro Stage.
7	TTDUR	Planned Duration of Repro Stage	Char	ISO 8601	Timing	Planned Duration of Repro Stage. Used when the rule for ending the Repro Stage is applied after a fixed duration.

3.1.6 Trial Repro Paths

Note: Not for use with human clinical trials.

Trial Repro Paths describes each planned Repro Path in a Repro study, with the ordered sequence of Repro Stages that comprise each Repro Path, as well as specification of Repro Phase and reference start day of the Repro Phase applicable to the Repro Stage within the Repro Path (see Table 3.1.6.1).

Table 3.1.6.1 Trial Repro Paths—One Record per Planned Repro Stage per Repro Path

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain, which must be "TP".
3	RPATHCD	Planned Repro Path Code	Char	Topic	Short name for the planned Repro Path. Limited to 20 characters. Should be populated in Demographics when Repro Paths have been defined in this domain.
4	RPATH	Description of Planned Repro Path	Char	Synonym Qualifier of RPATHCD	Name of the planned Repro Path.
5	TPSTGORD	Order of Repro Stage within Repro Path	Num	Timing	Number that gives the planned order of the Repro Stage within the Repro Path.
6	RSTGCD	Repro Stage Code	Char	Topic	Short name of the Repro Stage used for programming and sorting. Maximum 8 characters. The values of RSTGCD used in the Trial Paths dataset must match values for the same Repro Stage in the Trial Stages dataset.
7	RSTAGE	Description of Repro Stage	Char	Synonym Qualifier of RSTGCD	The name of the Repro Stage.
8	TPBRANCH	Branch	Char	Rule	Conditions subjects meet, occurring at the end of a Repro Stage, which cause a Repro Path to branch off from another Repro Path.
9	RPHASE	Repro Phase	Char	Timing	Name of the reproductive phase with which this Repro Stage of the Repro Path is associated.
10	RPRFDY	Repro Phase Start Reference Day	Num	Timing	Sponsor Protocol-defined first day of Repro Phase. Should be zero or 1.

3.2 Trial Inclusion/Exclusion Criteria

Trial Inclusion/Exclusion contains 1 record for each of the inclusion and exclusion criteria for the trial.

Table 3.2.1 Trial Inclusion/Exclusion—One Record per Trial Inclusion or Exclusion Criterion

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain, which must be "TI".
3	IETESTCD	Inclusion/Exclusion Criterion Short Name	Char	Topic	Short name IETEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in IETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). IETESTCD cannot contain characters other than letters, numbers, or underscores. The prefix "IE" is used to ensure consistency with the IE domain.

#	Variable Name	Variable Label	Type	Role	Description
4	IETEST	Inclusion/Exclusion Criterion	Char	Synonym Qualifier of IETESTCD	Full text of the inclusion or exclusion criterion. The prefix "IE" is used to ensure consistency with the IE domain.
5	IECAT	Inclusion/Exclusion Category	Char	Grouping Qualifier	Used for categorization of the Inclusion/Exclusion Criterion: "INCLUSION", "EXCLUSION".
6	IESCAT	Inclusion/Exclusion Subcategory	Char	Grouping Qualifier	A further categorization of the exception criterion. Can be used to distinguish criteria for a sub-study or for to categorize as a major or minor exceptions. Examples: "MAJOR", "MINOR".
7	TIRL	Inclusion/Exclusion Criterion Rule	Char	Rule	Rule that expresses the criterion in computer-executable form.
8	TIVERS	Protocol Criteria Versions	Char	Record Qualifier	The number of this version of the Inclusion/Exclusion criteria. May be omitted if there is only 1 version.

3.3 Trial Summary Information

Trial Summary Information contains 1 record for each trial summary characteristic. Trial Summary is used to record basic information about the trial (e.g., trial phase, protocol title, design objectives).

Table 3.3.1 Trial Summary—One Record per Trial Summary Parameter

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain, which must be "TS".
3	TSSEQ	Sequence Number	Num	Identifier	Sequence number to ensure uniqueness within the dataset.
4	TSGRPID	Group ID	Char	Identifier	Used to tie together a group of related records.
5	TSPARMCD	Trial Summary Parameter Short Name	Char	Topic	TSPARMCD (the companion to TSPARM) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that TSPARMCD will need to serve as variable names. Examples: AGEMIN, AGEMAX.
6	TSPARM	Trial Summary Parameter	Char	Synonym Qualifier of TSPARMCD	Term for the Trial Summary Parameter. The value in TSPARM cannot be longer than 40 characters. Examples: Planned Minimum Age of Subjects, Planned Maximum Age of Subjects.
7	TSVAL	Parameter Value	Char	Result Qualifier	Value of TSPARM. Example: "ASTHMA" when TSPARM value is "Trial Indications". If TSVAL is null; a value is required for TSVALNF. Text over 200 characters can be added to additional columns TSVAL1-TSVALn.
8	TSVALNF	Parameter Null Flavor	Char	Result Qualifier	Null flavor for the value of TSVAL describing the reason the value is null, to be populated only if TSVAL is null.
9	TSVALCD	Parameter Value Code	Char	Result Qualifier	Code of the term in TSVAL from Reference Terminology cited in TSVCDREF.
10	TSVCDREF	Name of the Reference Terminology	Char	Result Qualifier	The name of the reference terminology or standard format from which TSVALCD is taken. Examples: CDISC, SNOMED, ISO8601.
11	TSVCDVER	Version of the Reference Terminology	Char	Result Qualifier	The version number of the Reference Terminology cited in TSVCDREF, if applicable.

3.4 Trial Disease Assessments

Trial Disease Assessments provides information on the planned protocol-specified disease assessment schedule (see Table 3.4.1). In oncology studies, compliance with the disease-assessment schedule is essential to reduce the risk of assessment time bias. The TD domain makes possible an evaluation of assessment time bias from SDTM-based datasets by allowing comparison of the planned schedule of assessments against the actual occurrence of the efficacy assessments in order to determine the degree of compliance. TD has limited utility outside oncology (and indeed has limited utility within oncology studies). It was developed specifically with Response Evaluation Criteria in Solid Tumors (RECIST) in mind and, in particular, for studies with progression-free survival (PFS) endpoints where an assessment time bias analysis is appropriate.

Table 3.4.1 Trial Disease Assessments—One Record per Planned Constant Assessment Period

#	Variable Name	Variable Label	Type	Format	Role	Description
1	STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char		Identifier	2-character abbreviation for the domain, which must be "TD".
3	TDORDER	Sequence of Planned Assessment Schedule	Num		Timing	A number given to ensure ordinal sequencing of the planned assessment schedules within a trial.
4	TDANCVAR	Anchor Variable Name	Char		Timing	A reference to the date variable name that provides the start point from which the planned disease assessment schedule is measured. This must be referenced from the ADaM ADSL dataset (e.g., ANCH1DT). Note: TDANCVAR is to contain the name of a reference date variable name.
5	TDSTOFF	Offset from the Anchor	Char	ISO 8601	Timing	A fixed offset from the date provided by the variable referenced in TDANCVAR. This is used when the timing of planned cycles does not start on the exact day referenced in the variable indicated in TDANCVAR. The value of this variable will be either zero or a positive value.
6	TDTGTPAI	Planned Assessment Interval	Char	ISO 8601	Timing	The planned interval between disease assessments.
7	TDMINPAI	Planned Assessment Interval Minimum	Char	ISO 8601	Timing	The lower limit of the allowed range for the planned interval between disease assessments.
8	TDMAXPAI	Planned Assessment Interval Maximum	Char	ISO 8601	Timing	The upper limit of the allowed range for the planned interval between disease assessments.
9	TDNUMRPT	Maximum Number of Actual Assessments	Num		Record Qualifier	This variable must represent the maximum number of actual assessments for the analysis that this disease assessment schedule describes. In a trial where the maximum number of assessments is not defined explicitly in the protocol (e.g., assessments occur until death) TDNUMRPT should represent the maximum number of disease assessments that support the efficacy analysis, encountered by any subject across the trial at that point in time.

3.5 Trial Disease Milestones

Trial Disease Milestones is used to describe observations or activities expected to occur in the course of the disease under study, the timing of which is of interest for the study.

Table 3.5.1 Trial Disease Milestones—One Record per Disease Milestone Type

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique identifier for a study.

#	Variable Name	Variable Label	Type	Role	Description
2	DOMAIN	Domain	Char	Identifier	2-character abbreviation for the domain, which must be "TM".
3	MIDSTYPE	Disease Milestone Type	Char	Topic	The type of Disease Milestone. Example: "HYPOGLYCEMIC EVENT".
4	TMDEF	Disease Milestone Definition	Char	Rule	Definition of the Disease Milestone.
5	TMRPT	Disease Milestone Repetition Indicator	Char	Record Qualifier	Indicates whether this is a Disease Milestone that can occur only once ("N") or a type of Disease Milestone that can occur multiple times ("Y").

3.6 Challenge Agent Characterization

The Challenge Agent Characterization dataset allows the sponsor to provide information about challenge agents used in a trial in a structured format. Each record in the Challenge Agent Characterization dataset contains a parameter (a characteristic of the challenge agent) and its value.

Table 3.6.1 Challenge Agent Characterization—One Record per Challenge Agent Characterization Parameter Instance NEW

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique Identifier for a study.
2	DOMAIN	Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain, which must be "AC".
3	ACSEQ	Sequence Number	Num	Identifier	Sequence number given to ensure uniqueness within a dataset. Allows inclusion of multiple records for the same ACPARMCD.
4	ACGRPID	Group ID	Char	Identifier	Used to tie together a group of related records.
5	ACPARMCD	Challenge Agent Parameter Short Name	Char	Topic	ACPARMCD (the companion to ACPARM) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that ACPARMCD will need to serve as variable names.
6	ACPARM	Challenge Agent Parameter	Char	Synonym Qualifier of ACPARM	Term for the Challenge Agent Characterization Parameter. The value in ACPARM cannot be longer than 40 characters.
7	ACVAL	Parameter Value	Char	Result Qualifier	Value of ACPARM.
8	ACVALU	Parameter Units	Char	Variable Qualifier of ACVAL	Units for the value in ACVAL, if applicable.
9	ACVALNF	Parameter Null Flavor	Char	Result Qualifier	Null flavor for the value of ACPARM, to be populated if and only if ACVAL is null.
10	ACVALCD	Parameter Value Code	Char	Result Qualifier	This is the code of the term in ACVAL.
11	ACVCDREF	Name of the Reference Terminology	Char	Result Qualifier	The name of the Reference Terminology from which ACVALCD is taken. For example; CDISC, ISO 8601.
12	ACVCDVER	Version of the Reference Terminology	Char	Result Qualifier	The version number of the Reference Terminology cited in ACVCDREF, if applicable.

4 Representing Relationships Among Datasets and Records

There are many occasions when it is necessary or desirable to represent relationships among datasets or records. The SDTM identifies 8 distinct types of relationships:

- A relationship between a group of records for a given subject within the same dataset.
- A relationship between independent records (usually in separate datasets) for a subject, such as a concomitant medication taken to treat an adverse event.
- A relationship between 2 (or more) datasets where records of 1 (or more) dataset(s) are related to record(s) in another dataset (or datasets).
- A dependent relationship where data that cannot be represented by a standard variable within a general-observation class dataset record (or records) can be related back to that record.
- A dependent relationship between a comment in the Comments domain and a parent record (or records) in other datasets, such as a comment recorded in association with an adverse event.
- A relationship between a subject and a pool of subjects.
- A relationship between a subject and associated person(s). See Section 6.2, Associated Persons Relationships.
- A relationship between subjects in a study other than membership in a pool.

The implementation guides define specific details and examples for each of these relationships.

4.1 Datasets for Representing Relationships

4.1.1 Related Records Dataset

Table 4.1.1.1 RELREC Dataset

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Study Identifier of the domain record(s).
2	RDOMAIN	Related Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain of the parent record(s).
3	USUBJID	Unique Subject Identifier	Char	Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
4	APID	Associated Persons Identifier	Char	Identifier	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist for each associated person (see Section 4.1.3, Pool Definition Dataset, and Section 6.2, Associated Persons Relationships).
5	POOLID	Pool Identifier	Char	Identifier	Identifier used for pooling subjects to assign a single finding to multiple subjects.
6	IDVAR	Identifying Variable	Char	Identifier	Name of the identifying variable in the general-observation-class dataset that identifies the related record(s). Examples: --SEQ and --GRPID.
7	IDVARVAL	Identifying Variable Value	Char	Identifier	Value of identifying variable described in IDVAR. If --SEQ is the variable being used to describe this record, then the value of --SEQ is entered here.
8	RELTYPE	Relationship Type	Char	Record Qualifier	Identifies the hierarchical level of the records in the relationship. Values should be either ONE or MANY. However, values are only necessary when identifying a relationship between datasets.

#	Variable Name	Variable Label	Type	Role	Description
9	RELID	Relationship Identifier	Char	Record Qualifier	RELID value should be unique within the ID variable (e.g., USUBJID, APID, POOLID, SPDEVID) that is the subject of the relationship. All records with this ID variable that have the same RELID are considered "related/associated." RELID can be any value the sponsor chooses, and is only meaningful within the RELREC dataset to identify the related/associated Domain records.

4.1.2 Supplemental Qualifiers (SUPP--) Dataset

Table 4.1.2.1 SUPPQUAL Dataset

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Study Identifier of the parent record(s).
2	RDOMAIN	Related Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain of the parent record(s).
3	USUBJID	Unique Subject Identifier	Char	Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
4	APID	Associated Persons Identifier	Char	Identifier	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist for each associated person (see Section 4.1.3, Pool Definition Dataset, and Section 6.2, Associated Persons Relationships).
5	POOLID	Pool Identifier	Char	Identifier	Identifier used for pooling subjects to assign a single finding to multiple subjects.
6	IDVAR	Identifying Variable	Char	Identifier	Identifying variable in the parent dataset that identifies the related record(s). Examples: --SEQ, --GRPID.
7	IDVARVAL	Identifying Variable Value	Char	Identifier	Value of identifying variable of the parent record(s).
8	QNAM	Qualifier Variable Name	Char	Topic	The short name of the Qualifier variable, which is used as a column name in a domain view with data from the parent domain. The value in QNAM cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). QNAM cannot contain characters other than letters, numbers, or underscores. This will often be the column name in the sponsor's operational dataset. QNAM should not be the name of any standard ADaM variable.
9	QLABEL	Qualifier Variable Label	Char	Synonym Qualifier of QNAM	This is the long name or label associated with QNAM. The value in QLABEL cannot be longer than 40 characters. This will often be the column label in the sponsor's original dataset.
10	QVAL	Data Value	Char	Result Qualifier	Result of, response to, or value associated with QNAM. A value for this column is required; no records can be in a SUPP-- dataset with a null value for QVAL.
11	QORIG	Origin	Char	Record Qualifier	Because QVAL can represent a mixture of collected (on a CRF), derived, or assigned items, QORIG is used to indicate the origin of this data. Examples: CRF, ASSIGNED, DERIVED.
12	QEVAL	Evaluator	Char	Record Qualifier	Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain objectively collected or derived data. Examples: "ADJUDICATION COMMITTEE", "STATISTICIAN", "DATABASE ADMINISTRATOR", "CLINICAL COORDINATOR".

4.1.3 Pool Definition Dataset

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

Table 4.1.3.1 POOLDEF Dataset

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Study Identifier of the parent record(s).
2	POOLID	Pool Identifier	Char	Identifier	An identifier used to identify a result from a group of subjects that is not assignable to a specific subject.
3	USUBJID	Unique Subject Identifier	Char	Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
4	APID	Associated Persons Identifier	Char	Identifier	Identifier for a single associated person, a group of associated persons, or a pool of associated persons.

4.1.4 Related Subjects Dataset

Some studies include subjects who are related to each other, and in some cases it is important to record those relationships. Studies in which pregnant women are treated and both the mother and her child(ren) are study subjects are the most common case in which relationships between subjects are collected. There are also studies of genetically based diseases where subjects who are related to each other are enrolled, and the relationships between subjects are recorded.

Table 4.1.4.1 RELSUB Dataset

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique identifier for a study.
2	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.
3	POOLID	Pool Identifier	Char	Identifier	Identifier used to identify a pool of subjects. If POOLID is entered, POOLDEF records must exist for each subject in the pool and USUBJID must be null. Either USUBJID or POOLID must be populated.
4	RSUBJID	Related Subject or Pool Identifier	Char	Identifier	Identifier used to identify a related subject or pool of subjects. RSUBJID will be populated with either the USUBJID of the related subject or the POOLID of the related pool.
5	SREL	Subject Relationship	Char	Record Qualifier	Describes the relationship of the subject identified in USUBJID or the pool identified in POOLID to the subject or pool identified in RSUBJID.

4.1.5 Device-Subject Relationships Dataset

The Device-Subject Relationships (DR) domain is a special-purpose domain that links each subject to the associated devices. Information in this domain may have been collected and submitted in other domains (e.g., Device Exposure, Device Tracking and Disposition, Device Events). This domain, however, provides a single, consistent location to find the relationship between a subject and a device, regardless of the device or the domain in which subject-related data may have been collected or submitted.

Table 4.1.5.1 Device-Subject Relationships Dataset

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Study Identifier of the domain record(s).
2	DOMAIN	Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain, which must be "DR".
3	USUBJID	Unique Subject Identifier	Char	Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.

#	Variable Name	Variable Label	Type	Role	Description
4	SPDEVID	Sponsor Device Identifier	Char	Identifier	Sponsor-defined identifier for the device. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, combination of identifiers) as defined in DI.

5 Study References

There are occasions when it is necessary to establish study-specific identifiers that will be used in subject data. Two such situations have been identified thus far:

- Identifiers for devices
- Identifiers for non-host organisms

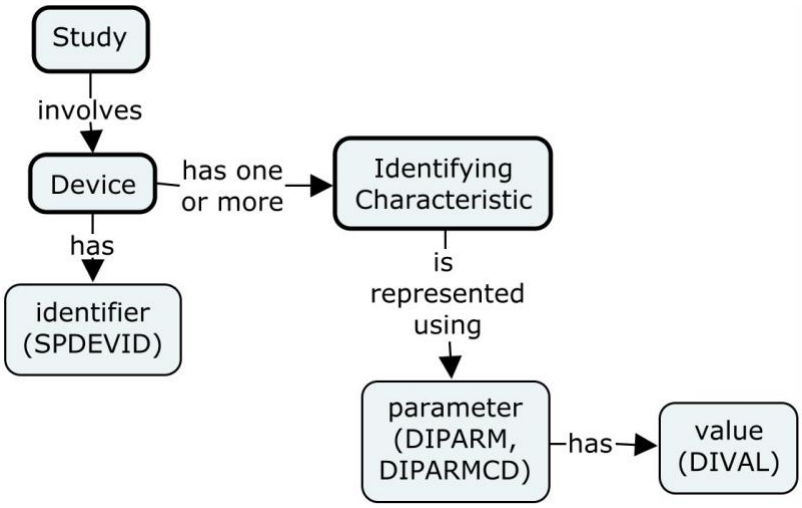
5.1 Datasets for Study References

5.1.1 Device Identifiers Dataset

The identity of a device is established by means of a number of parameters, then assigned an identifier. The parameters used for identification of a device depend on the kind of device and the needs of the study to distinguish among devices (see Table 5.1.1.1).

Table 5.1.1.1 Device Identifiers Dataset

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain, which must be "DI".
3	SPDEVID	Sponsor Device Identifier	Char	Identifier	Sponsor-defined identifier for the device.
4	DISEQ	Sequence Number	Num	Identifier	Sequence number given to ensure uniqueness within a parameter within a device (SPDEVID).
5	DIPARMCD	Device Identifier Element Short Name	Char	Topic	Short name of the identifier characteristic of the device.
6	DIPARM	Device Identifier Element Name	Char	Synonym Qualifier of DIPARMCD	Name of the identifier characteristic of the device.
7	DIVAL	Device Identifier Element Value	Char	Result Qualifier	Value for the parameter.

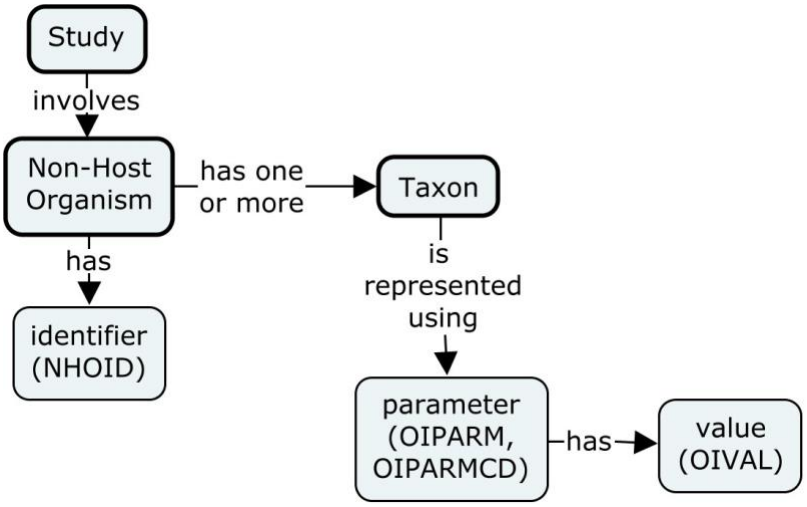


5.1.2 Non-host Organism Identifiers Dataset

The identity of a non-host organism is established by means of a number of *taxa* (categories used to classify living things), then assigned an identifier. The taxa used for identification of a non-host organism depend on the kind of organism and the needs of the study to distinguish among organisms.

Table 5.1.2.1 Non-host Organism Identifiers Dataset

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique identifier for a study.
2	DOMAIN	Domain Abbreviation	Char	Identifier	2-character abbreviation for the domain, which must be "OI".
3	NHOID	Non-Host Organism Identifier	Char	Identifier	Sponsor-defined identifier for a non-host organism.
4	OISEQ	Sequence Number	Num	Identifier	Sequence number given to ensure uniqueness within a parameter within an organism (NHOID).
5	OIPARMCD	Non-Host Organism ID Element Short Name	Char	Topic	Short name of the taxon being described.
6	OIPARM	Non-Host Organism ID Element Name	Char	Synonym Qualifier of OIPARMCD	Name of the taxon being described.
7	OIVAL	Non-Host Organism ID Element Value	Char	Result Qualifier	Value for the taxon in OIPARMCD/OIPARM for the organism identified by NHOID.



6 Applying Model Fundamentals to Associated Persons

6.1 Creating Associated Persons Domains

Associated Persons (AP) are persons other than study subjects who can be associated with a study, a particular study subject, or a device used in the study. AP domains are created using SDTM variables, with the application of specific AP rules, including:

- Implementers creating AP domains will follow the AP assumptions for the Identifier variables.
- AP will be the prefix for the domain and dataset name, and will identify the dataset as AP data.
- APID will be required in all AP datasets, and will identify records in a data warehouse as AP data.

The SDTM AP Implementation Guide (SDTMIG-AP; available at https://www.cdisc.org/standards/foundational/sdtmig) provides implementation rules, advice, and examples. Unless an exception is described in the SDTMIG-AP, all other general assumptions about SDTM and SDTMIG variables and domains apply to AP data.

6.1.1 Variables Used in Associated Persons Data

Table 6.1.1.1 Associated Persons Data—Identifier Variables

#	Variable Name	Variable Label	Type	Description
1	APID	Associated Persons Identifier	Char	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist for each associated person (see Section 4.1.3, Pool Definition Dataset, and Section 6, Applying Model Fundamentals to Associated Persons).
2	RSUBJID	Related Subject or Pool Identifier	Char	Identifier for a related subject or pool of subjects. RSUBJID may be populated with the USUBJID of the related subject or the POOLID of the related pool. RSUBJID will be null for data about associated persons who are related to the study but not to any study subjects.
3	RDEVID	Related Device Identifier	Char	Identifier for a related device. RDEVID will be populated with the SPDEVID of the related device.
4	SREL	Subject, Device, or Study Relationship	Char	If RSUBJID is populated, describes the relationship of the associated person(s) identified in APID to the subject or pool identified in RSUBJID. If RDEVID is populated, describes the relationship of the associated person(s) identified in APID to the subject or pool identified in RDEVID. If RSUBJID and RDEVID are null, SREL describes the relationship of the associated person(s) identified in APID to the study identified in STUDYID.

6.2 Associated Persons Relationships

To justify collection of AP data, some sort of a relationship is necessary between the AP and a study, a subject, or a device. However, a single value in SREL is inadequate to describe relationships to multiple subjects or devices and/or multiple relationships to a single subject or device. In such cases, the value MULTIPLE should appear in SREL. MULTIPLE may also appear in RSUBJID to describe relationships with multiple subjects. When other SDTM variables are populated with MULTIPLE, the multiple values are stored in Supplemental Qualifiers.

However, this approach has been found to be an indirect and cumbersome way to handle multiple AP-subject relationships. In addition, when there is AP data in multiple domains, the Supplemental Qualifier approach would require the same set of Supplemental Qualifiers to be repeated for each domain. The APRELSUB dataset, which parallels the structure of the RELSUB dataset, was created as a more efficient and simpler way to record these

multiple relationships. The APRELSUB dataset is required for studies in which SREL values of MULTIPLE appear, but would not be needed if each AP has only one relationship to a study, a subject, or a device.

Table 6.2.1 APRELSUB Dataset

#	Variable Name	Variable Label	Type	Role	Description
1	STUDYID	Study Identifier	Char	Identifier	Unique identifier for a study.
2	APID	Associated Persons Identifier	Char	Identifier	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist for each associated person (see Section 4.1.3, Pool Definition Dataset, and Section 6, Applying Model Fundamentals to Associated Persons).
3	RSUBJID	Related Subject or Pool Identifier	Char	Identifier	Identifier for a related subject or pool of subjects. RSUBJID may be populated with the USUBJID of the related subject or the POOLID of the related pool. RSUBJID will be null for data about associated persons who are related to the study but not to any study subjects.
4	RDEVID	Related Device Identifier	Char	Identifier	Identifier for a related device. RDEVID will be populated with the SPDEVID of the related device.
5	SREL	Subject, Device, or Study Relationship	Char	Record Qualifier	If RSUBJID is populated, describes the relationship of the associated person(s) identified in APID to the subject or pool identified in RSUBJID. If RDEVID is populated, describes the relationship of the associated person(s) identified in APID to the subject or pool identified in RDEVID. If RSUBJID and RDEVID are null, SREL describes the relationship of the associated person(s) identified in APID to the study identified in STUDYID.

7 Using the Model for Regulatory Submissions

The SDTM has been designed to accommodate the broadest range of human and animal study data in a standardized manner. This document describes the basic concepts and general structure of the model. Individual implementation guides (IGs) have been created to provide specific recommendations for numerous domains of data commonly collected in human, animal, and medical device studies, identifying which variables from a general observation class may apply. These IGs also describe basic assumptions and business rules, and provide numerous examples for mapping data to the standard format. Sponsors wishing to submit data in the standard formats should first consult the IGs before preparing a regulatory submission based on the SDTM. In addition to the IGs, multiple indication-specific therapeutic area user guides (TAUGs) provide examples and implementation advice for various therapeutic areas. The following implementation guides have been published by CDISC:

- The Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG)
- The Standard for Exchange of Nonclinical Data Implementation Guide (SENDIG)
- The Study Data Tabulation Model Implementation Guide for Medical Devices (SDTMIG-MD)
- The Study Data Tabulation Model Implementation Guide: Associated Persons (SDTMIG-AP)
- The Study Data Tabulation Model Implementation Guide: Pharmacogenomics/Genetics (SDTMIG-PGx)
- The Standard for Exchange of Nonclinical Data Implementation Guide: Developmental and Reproductive Toxicology (SENDIG-DART)

All current IGs and TAUGs are available on the CDISC website (https://www.cdisc.org).

8 SDTM Version History

8.1 Changes from SDTM v1.7 to SDTM v1.8

8.1.1 Variable, Dataset, and Section Changes and Additions

Variable Additions:

- Table 2.2.1.1 Interventions—Topic and Qualifier Variables
  - --TDOSD - Toxic/Physiologic Dose Descr
  - --FTDOSD - Factor for Toxic/Physiologic Dose Descr
  - --RSTIND - Restraint Indicator
  - --RSTMOD - Restraint Mode
- Table 2.2.3.1 Findings—Topic and Qualifier Variables
  - --RSTIND - Restraint Indicator
  - --RSTMOD - Restraint Mode
- Table 2.2.5.1 All Observation Classes—Timing Variables
  - --XDY - Day of Obs Relative to Exposure
  - --XSTDY - Day of Start of Obs Relative to Exposure
  - --XENDY - Day of End of Obs Relative to Exposure
  - --CHDY - Day of Obs Relative to Agent
  - --CHSTDY - Day of Start of Obs Relative to Agent
  - --CHENDY - Day of End of Obs Relative to Agent
- Table 2.2.6.1 Subject Demographics Domain Variables
  - RFCSTDTC - Date/Time of First Challenge Agent Admin
  - RFCENDTC - Date/Time of Last Challenge Agent Admin

Dataset Additions:

- Table 3.6.1 Challenge Agent Characterization

9 Appendices

Appendix A: Representations and Warranties, Limitations of Liability, and Disclaimer

CDISC Patent Disclaimers

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