# Study Data Tabulation Model

Version 1.5

**Prepared by the**

## CDISC Submission Data Standards Team and CDISC SDTM Governance Committee

**Notes to Readers**

This is version 1.5 of the Study Data Tabulation Model Document (SDTM). This document includes additional variables related to human clinical trials, animal studies, medical devices, pharmacogenomics/genetics, and other corrections and clarifications to the text. A full description of all changes from the prior version is provided in Section 7.

SDTM Governance is now tracking known issues for the SDTM. A description of these issues can be found on the CDISC Wiki at: http://wiki.cdisc.org/x/5cDdAQ.

**Revision History**

| Date | Version |
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*See Appendix A for Representations and Warranties, Limitations of Liability, and Disclaimers.*

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# TABLES

# 1 Introduction

## 1.1 Purpose

This document describes the Study Data Tabulation Model (SDTM), which defines a standard structure for study data tabulations that are to be submitted as part of a product application to a regulatory authority such as the United States Food and Drug Administration (FDA). This document is based on material originally prepared by the Submissions Data Standards (SDS) Team of the Clinical Data Interchange Standards Consortium (CDISC), but is now maintained by the SDTM Governance Committee (SGC) of CDISC. This document, which supersedes all prior versions, includes numerous changes from the prior version 1.4, which are described in Section 7.1.

Data tabulation datasets are one of four ways to represent the human subject Case Report Tabulation (CRT) and equivalent animal data submitted to the FDA. CRTs are also submitted in the format of subject profiles, data listings, and analysis datasets. One benefit to industry of submitting data tabulation datasets that conform to the standard structure is that it minimizes the need to submit the same data in multiple formats.

The availability of standard submission data may provide many benefits to regulatory reviewers. Reviewers can now be trained in the principles of standardized datasets and the use of standard software tools, and thus be able to work with the data more effectively with less preparation time. Another benefit of the standardized datasets is that they can provide support for the FDA's efforts to develop a repository for all submitted studies and a suite of standard review tools to access, manipulate, and view the study data.

This document is intended for companies and individuals involved in the collection, preparation, and analysis of study data submitted to regulatory authorities. Guidance, specifications, and regulations for the application of this model will be provided separately by regulatory authorities. Audiences 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 of what was known in prior versions as the CDISC Submission Data Standards or Submission Domain Models. While Version 1.0 SDTM 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 non-clinical 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 v1.5 should be fully compatible with prior versions. 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.

In addition to including several text corrections and clarifications, v1.5 has been expanded to include the following:

- New tables to relay data about disease milestones at the subject and trial level
- Domain-specific variables
- New variables in the general observation classes

The following new sections and tables have been added:

- Section and Table 2.2.10 Subject Disease Milestones
- Section and Table 2.2.11 Domain-Specific Variables for the General Observation Class
- Section and Table 3.6 Trial Disease Milestones

New variables have been added to the following sections:

- Table 2.2.1 Interventions
- Table 2.2.2 Events
- Table 2.2.3 Findings
- Table 2.2.4 Identifiers
- Table 2.2.5 Timing 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 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 five 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 (such as the name of a lab test).
- Timing variables, which describe the timing of an observation (such as start date and end date).
- Qualifier variables, which include additional illustrative text, or numeric values that describe the results or additional traits of the observation (such as units or descriptive adjectives).
- 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. Table 2.2.11 lists the proposed domain-specific variables.

The set of Qualifier variables can be further categorized into five sub-classes:

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

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", while 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, APs) who can be associated with the study, a particular study

subject, or a device used in the study. Associated Persons may or may not have a familial relationship to a study subject.

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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, two-character code that should be used consistently throughout the submission. This code, which is stored in the SDTM variable named DOMAIN, is used in four ways: as the dataset name, 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 metadata are described in a data definition document named "define" that is submitted with the data to regulatory authorities (see the Define-XML Specification, available at www.CDISC.org/define-xml). Define-XML specifies variable metadata attributes such as: name, label, data type, etc.

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 version 5 transport files. The Define-XML provides more descriptive data types (e.g. integer, float, date, datetime). Please see the Define-XML specification for information about how to represent SDTM types using Define-XML data types.

When creating submissions, a sponsor may drop certain variables (those defined as permissible in the 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, which 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 three general observation classes: Interventions, Events, or Findings:

- The Interventions class, described in Table 2.2.1, 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 (such as alcohol, tobacco, or caffeine).
- The Events class, described in Table 2.2.2, 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 class, described in Table 2.2.3, captures the 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 sub-type "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 Identifier variables used is described in Table 2.2.4. The set of Timing variables that should be used for all three general observation classes is included in Table 2.2.5. 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 two hyphens before the variable name (e.g., --TRT) is used to indicate the required use of a prefix based on the two-character domain code. The domain code is used as a variable prefix to minimize the risk of difficulty when merging/joining domains for reporting purposes.

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

- A Demographics special-purpose domain is included with human and animal studies, described in Section 2.2.6.
- Other special purpose domains such as Comments (Section 2.2.7), Subject Elements (Section 2.2.8), Subject Visits (Section 2.2.9), Subject Disease Milestones (Section 2.2.10).
- Domain-Specific Variables (Section 2.2.11)
- Datasets to describe the design of a trial, described in Section 3.
- Datasets to represent the relationships between datasets and records described in Section 4.
- Applying model fundamentals to associated persons in Section 5.

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. Not all variables described in the tables in this document (SDTM tables) are appropriate for all implementations. Please refer to the implementation guides for specific information on any restrictions.

## 2.2.1 The Interventions Observations Class

**Table 2.2.1 Interventions — Topic and Qualifier Variables — One Record per Constant-Dosing Interval or Intervention Episode**

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| **Topic Variable** | | | | |
| --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. |
| **Qualifier Variables** | | | | |
| --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. |
| --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 WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries. |
| --MOOD | Mood | Char | Record Qualifier | Mode or condition of the record (e.g., SCHEDULED, PERFORMED). |
| --CAT | Category | Char | Grouping Qualifier | Used to define a category of topic-variable values. |
| --SCAT | Subcategory | Char | Grouping Qualifier | Used to define a further categorization of --CAT values. |
| --PRESP | Pre-specified | Char | Variable Qualifier of --TRT | Used when a specific intervention is pre-specified on a CRF. Values should be "Y" or null. |
| --OCCUR | Occurrence | Char | Record Qualifier | Used to record whether a pre-specified intervention occurred when information about the occurrence of a specific intervention is solicited. |
| --STAT | Completion Status | Char | Record Qualifier | Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE. |
| --REASND | Reason Not Done | Char | Record Qualifier | Reason not done. Used in conjunction with --STAT when value is NOT DONE. |
| --INDC | Indication | Char | Record Qualifier | Denotes the indication for the intervention (e.g., why the therapy was taken or administered). |
| --CLAS | Class | Char | Variable Qualifier of --TRT | Class for a medication or treatment, often obtained from a coding dictionary. |

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| --CLASCD | Class Code | Char | Variable Qualifier of --TRT | Used to represent code for --CLAS. |
| --DOSE | Dose | Num | Record Qualifier | Amount of --TRT given. Not populated when --DOSTXT is populated. |
| --DOSTXT | Dose Description | Char | Record Qualifier | Dosing information collected in text form. Examples: <1 per day, 200-400. Not populated when --DOSE is populated. |
| --DOSU | Dose Units | Char | Variable Qualifier of --DOSE, --DOSTXT or --DOSTOT | Units for --DOSE, --DOSTOT, or --DOSTXT (Examples: ng, mg, mg/kg). |
| --DOSFRM | Dose Form | Char | Variable Qualifier of --DOSE, --DOSTXT or --DOSTOT | Dose form for the treatment. Examples: TABLET, CAPSULE. |
| --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. |
| --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. |
| --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. |
| --ROUTE | Route of Administration | Char | Variable Qualifier of --TRT | Route of administration for the intervention. Examples: ORAL, INTRAVENOUS. |
| --LOT | Lot Number | Char | Record Qualifier | Lot number for the intervention described in --TRT. |
| --LOC | Location of Dose Administration | Char | Record Qualifier | Anatomical location of an intervention, such as an injection site. Example: ARM for an injection. |
| --LAT | Laterality | Char | Variable Qualifier of --LOC | Qualifier for anatomical location further detailing laterality of intervention administration. Examples: RIGHT, LEFT, BILATERAL |
| --DIR | Directionality | Char | Variable Qualifier of --LOC | Qualifier for anatomical location further detailing directionality of intervention administration. Examples: ANTERIOR, LOWER, PROXIMAL |
| --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. |
| --FAST | Fasting Status | Char | Record Qualifier | Indicator used to identify fasting status. Valid values include Y, N, U or null if not relevant. |
| --PSTRG | Pharmaceutical Strength | Num | Variable 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. Example: 50 mg/TABLET, 300 mg/L |
| --PSTRGU | Pharmaceutical Strength Units | Char | Variable Qualifier | Unit for --PSTRG. Example: mg/TABLET, mg/mL |
| --TRTV | Treatment Vehicle | Char | Record Qualifier | Vehicle for administration of treatment, such as a liquid in which the treatment drug is dissolved. Example: SALINE. |
| --VAMT | Treatment Vehicle Amount | Num | Record Qualifier | Amount of the prepared product (treatment + vehicle) administered or given. Note: should not be diluent amount alone. |
| --VAMTU | Treatment Vehicle Amount Units | Char | Variable Qualifier of --VAMT | Units for the prepared product (treatment + vehicle). Examples: mL, mg. |

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| --ADJ | Reason for Dose Adjustment | Char | Record Qualifier | Describes reason or explanation of why a dose is adjusted. Examples ADVERSE EVENT, INSUFFICIENT RESPONSE, NON-MEDICAL REASON. |
| --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. |

## 2.2.2 The Events Observation Class

**Table 2.2.2 Events — Topic and Qualifier Variables — One Record per Event**

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| **Topic Variable** | | | | |
| --TERM | Reported Term | Char | Topic | Topic variable for an event observation, which is the verbatim or pre-specified name of the event. |
| **Qualifier Variables** | | | | |
| --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. |
| --LLT | Lowest Level Term | Char | Variable Qualifier of --TERM | MedDRA Lowest Level Term. |
| --LLTCD | Lowest Level Term Code | Num | Variable Qualifier of --LLT | MedDRA Lowest Level Term code. |
| --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). |
| --PTCD | Preferred Term Code | Num | Variable Qualifier of --DECOD | MedDRA Preferred Term code. |
| --HLT | High Level Term | Char | Variable Qualifier of --TERM | MedDRA High Level Term from the primary path. |
| --HLTCD | High Level Term Code | Num | Variable Qualifier of --HLT | MedDRA High Level Term code from the primary path. |
| --HLGT | High Level Group Term | Char | Variable Qualifier of --TERM | MedDRA High Level Group Term from the primary path. |
| --HLGTCD | High Level Group Term Code | Num | Variable Qualifier of --HLGT | MedDRA High Level Group Term code from the primary path. |
| --CAT | Category | Char | Grouping Qualifier | Used to define a category of topic-variable values. |
| --SCAT | Subcategory | Char | Grouping Qualifier | Used to define a further categorization of --CAT values. |
| --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. |
| --OCCUR | Occurrence | Char | Record Qualifier | Used to record whether a pre-specified event occurred when information about the occurrence of a specific event is solicited. |
| --STAT | Completion Status | Char | Record Qualifier | Used to indicate when a question about the occurrence of a pre-specified event was not answered. Should be null or have a value of NOT DONE. |

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| --REASND | Reason Not Done | Char | Record Qualifier | Reason not done. Used in conjunction with --STAT when its value is NOT DONE. |
| --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. |
| --BDSYCD | Body System or Organ Class Code | Num | Variable Qualifier of --BODSYS | MedDRA System Organ Class code corresponding to --BODSYS assigned for analysis. |
| --SOC | Primary System Organ Class | Char | Variable Qualifier of --TERM | MedDRA primary System Organ Class associated with the event. |
| --SOCCD | Primary System Organ Class Code | Num | Variable Qualifier of --SOC | MedDRA primary System Organ Class code. |
| --LOC | Location of Event | Char | Record Qualifier | Describes anatomical location relevant for the event. Example: ARM for skin rash. |
| --LAT | Laterality | Char | Variable Qualifier of --LOC | Qualifier for anatomical location further detailing laterality. Examples: RIGHT, LEFT, BILATERAL |
| --DIR | Directionality | Char | Variable Qualifier of --LOC | Qualifier for anatomical location further detailing directionality. Examples: ANTERIOR, LOWER, PROXIMAL |
| --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. |
| --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. |
| --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. |
| --SEV | Severity/Intensity | Char | Record Qualifier | The severity or intensity of the event. Examples: MILD, MODERATE, SEVERE. |
| --SER | Serious Event | Char | Record Qualifier | Is this is a serious event? Valid values are "Y" and "N". |
| --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. |
| --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. |
| --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 |
| --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. |
| --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." |
| --PATT | Pattern of Event | Char | Record Qualifier | Used to indicate the pattern of the event over time. Examples: INTERMITTENT, CONTINUOUS, SINGLE EVENT. |
| --OUT | Outcome of Event | Char | Record Qualifier | Description of the outcome of an event. Examples: RECOVERED/RESOLVED, FATAL. |
| --SCAN | Involves Cancer | Char | Record Qualifier | Was the event associated with the development of cancer? Valid values are "Y" and "N". |
| --SCONG | Congenital Anomaly or Birth Defect | Char | Record Qualifier | Was the event associated with congenital anomaly or birth defect? Valid values are "Y" and "N". |

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| --SDISAB | Persist or Signif Disability/Incapacity | Char | Record Qualifier | Did the event result in persistent or significant disability/incapacity? Valid values are "Y" and "N". |
| --SDTH | Results in Death | Char | Record Qualifier | Did the event result in death? Valid values are "Y" and "N". |
| --SHOSP | Requires or Prolongs Hospitalization | Char | Record Qualifier | Did the event require or prolong hospitalization? Valid values are "Y" and "N". |
| --SLIFE | Is Life Threatening | Char | Record Qualifier | Was the event life threatening? Valid values are "Y" and "N". |
| --SOD | Occurred with Overdose | Char | Record Qualifier | Did the event occur with an overdose? Valid values are "Y" and "N". |
| --SMIE | Other Medically Important Serious Event | Char | Record Qualifier | Do additional categories for seriousness apply? Valid values are "Y" and "N". |
| --CONTRT | Concomitant or Additional Trtmnt Given | Char | Record Qualifier | Was another treatment given because of the occurrence of the event? Valid values are "Y" and "N". |
| --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. |
| --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. |
| --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 Findings — Topic and Qualifier Variables — One Record per Finding**

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| **Topic Variable** | | | | |
| --TESTCD | Short Name of Measurement, Test or Examination | 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. |
| **Qualifier Variables** | | | | |
| --TEST | Name of Measurement, Test or Examination | Char | Synonym Qualifier of --TESTCD | Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination. |
| --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. |
| --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. |
| --CAT | Category | Char | Grouping Qualifier | Used to define a category of topic-variable values. Examples: HEMATOLOGY, URINALYSIS, CHEMISTRY, HAMILTON DEPRESSION SCALE, SF36, EGFR MUTATION ANALYSIS. |
| --SCAT | Subcategory | Char | Grouping Qualifier | Used to define a further categorization of --CAT values. Example: WBC DIFFERENTIAL. |

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| --POS | Position of Subject During Observation | Char | Record Qualifier | Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING. |
| --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. |
| --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. |
| --ORRESU | Original Units | Char | Variable Qualifier of --ORRES | Unit for --ORRES. Examples: in, LB, kg/L. |
| --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. |
| --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. |
| --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. |
| --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". |
| --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. |
| --STRESU | Standard Units | Char | Variable Qualifier of --STRESC and --STRESN | Standardized units used for --STRESC and --STRESN. Example: mol/L. |
| --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). |
| --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). |
| --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. |
| --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. |
| --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. |
| --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. |

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| --RESCAT | Result Category | Char | Variable Qualifier of --ORRES | Used to categorize the result of a finding. Example: MALIGNANT or BENIGN for tumor findings. RESISTANCE VARIANT for genetic variation. |
| --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. |
| --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. |
| --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. |
| --REASND | Reason Not Done | Char | Record Qualifier | Reason not done. Used in conjunction with --STAT when value is NOT DONE. |
| --XFN | External File Path | Char | Record Qualifier | Filename for an external file, such as one for an ECG waveform or a medical image. |
| --NAM | Laboratory/Vendor Name | Char | Record Qualifier | Name or identifier of the vendor (e.g., laboratory) that provided the test results. |
| --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. |
| --SPEC | Specimen Material Type | Char | Record Qualifier | Defines the type of specimen used for a measurement. Examples: SERUM, PLASMA, URINE, DNA, RNA. |
| --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 |
| --SPCCND | Specimen Condition | Char | Record Qualifier | Defines the condition of the specimen. Example: CLOUDY. |
| --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. |
| --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. |
| --LAT | Laterality | Char | Variable Qualifier of --LOC | Qualifier for anatomical location or specimen further detailing laterality. Examples: RIGHT, LEFT, BILATERAL |
| --DIR | Directionality | Char | Variable Qualifier of --LOC | Qualifier for anatomical location or specimen further detailing directionality. Examples: ANTERIOR, LOWER, PROXIMAL |
| --PORTOT | Portion or Totality | Char | Variable Qualifier of --LOC | Qualifier for anatomical location or specimen further detailing the distribution, which means arrangement of, apportioning of. Examples: ENTIRE, SINGLE, SEGMENT, MANY. |
| --METHOD | Method of Test or Examination | Char | Record Qualifier | Method of the test or examination. Examples: EIA (Enzyme Immunoassay), ELECTROPHORESIS, DIPSTICK |
| --RUNID | Run ID | Char | Record Qualifier | A unique identifier for a particular run of a test on a particular batch of samples. |
| --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). |
| --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. |
| --CSTATE | Consciousness State | Char | Record Qualifier | The consciousness state of the subject at the time of measurement. Examples: CONSCIOUS, SEMI-CONSCIOUS, UNCONSCIOUS |

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| --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. |
| --BLFL | Baseline Flag | Char | Record Qualifier | Indicator used to identify a baseline value. Should be Y or null. |
| --FAST | Fasting Status | Char | Record Qualifier | Indicator used to identify fasting status. Valid values include Y, N, U or null if not relevant. |
| --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. |
| --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. |
| --EVALID | Evaluator Identifier | Char | Variable Qualifier of --EVAL | Used to distinguish multiple evaluators with the same role recorded in --EVAL. Examples: RADIOLOGIST1, RADIOLOGIST2. |
| --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 |
| --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. |
| --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. |
| --SEV | Severity | Char | Record Qualifier | Describes the severity or intensity of a particular finding. Examples: MILD, MODERATE, SEVERE. |
| --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. |
| --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. |
| --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. |
| --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. |
| --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. |
| --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 |

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| | | | | planned assessments is provided, such as when the Trial Visits (TV) and Subject Visits (SV) domains are used. |
| --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. |

#### 2.2.3.1 Findings About Events or Interventions

**Table 2.2.3.1.1 Findings — Topic and Qualifier Variables — One Record per Finding**

| 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 three general observation classes. STUDYID, DOMAIN and --SEQ are required in all domains based on one of the three general observation classes. Each general class domain must also include at least one of the following subject identifiers: USUBJID, APID, SPDEVID, or POOLID.

All identifier variables are allowed for all implementation guides.

**Table 2.2.4 All Observation Classes — Identifiers**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain most relevant to the observation. The Domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged. |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. |
| 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 for POOLDEF and Section 5 for Associated Persons data). |
| POOLID | Pool Identifier | Char | An identifier used to identify a result from a group of subjects that is not assignable to a specific subject. |
| SPDEVID | Sponsor Device Identifier | Char | Sponsor-defined identifier for a device. |
| 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. |
| 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) or "Upper left quadrant of the back". The value in this variable should have inherent semantic meaning. |
| --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. |
| --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 dataset (Section 3.4). |

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| --REFID | Reference ID | Char | Optional internal or external identifier such as lab specimen ID, or UUID for an ECG waveform or a medical image. |
| --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. |
| --SPID | Sponsor-Defined Identifier | Char | Sponsor-defined identifier. Example: pre-printed line identifier on a Concomitant Medications page. |
| --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. |
| --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

All of the following timing variables are available for use in any domain based on one of the three general observation classes except where restricted in implementation guide standard-domain-model assumptions.

All timing variables are allowed for all implementation guides.

**Table 2.2.5 All Observation Classes — Timing Variables**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| VISITNUM | Visit Number | Num | Clinical encounter number. Numeric version of VISIT, used for sorting. |
| VISIT | Visit Name | Char | Protocol-defined description of a clinical encounter. |
| VISITDY | Planned Study Day of Visit | Num | Planned study day of VISIT. Should be an integer. |
| TAETORD | Planned Order of Element within Arm | Num | Number that gives the planned order of the Element within the Arm (see .Timing v1.5, Section 3.2.2). |
| EPOCH | Epoch | Char | Epoch associated with the start date/time of the observation, or the date/time of collection if start date/time is not collected. (See Section 3.2.2). |
| --DTC | Date/Time of Collection | Char | Collection date and time of an observation represented in IS0 8601 character format. |
| --STDTC | Start Date/Time of Observation | Char | Start date/time of an observation represented in IS0 8601 character format. |
| --ENDTC | End Date/Time of Observation | Char | End date/time of the observation represented in IS0 8601 character format. |
| --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. |
| --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. |
| --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. |
| --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 (such as for output on a tabulation report). Not to be used with human clinical trials. |
| --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. |
| --DUR | Duration | Char | Collected duration of an event, intervention, or finding represented in ISO 8601 character format. Used only if collected on the CRF and not derived. |
| --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, such as time of last dose. See --TPTNUM and --TPTREF. |

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| --TPTNUM | Planned Time Point Number | Num | Numeric version of planned time point used in sorting. |
| --ELTM | Planned Elapsed Time from Time Point Ref | Char | Planned Elapsed time in ISO 8601 character format 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, represented as ISO duration. |
| --TPTREF | Time Point Reference | Char | Description of the fixed reference point referred to by --ELTM, --TPTNUM, and --TPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL. |
| --RFTDTC | Date/Time of Reference Time Point | Char | Date/time for a fixed reference time point defined by --TPTREF in ISO 8601 character format. |
| --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. |
| --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. |
| --EVLINT | Evaluation Interval | Char | Duration of interval associated with an observation such as a finding --TESTCD, represented in ISO 8601 character format. Example: -P2M to represent a period of the past 2 months as the evaluation interval for a question from a questionnaire such as SF-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. |
| --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. |
| --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" or "VISIT 1". |
| --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. |
| --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" or "VISIT 2". |
| 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). This should be unique within a subject. Used only in conjunction with RELMIDS and MIDSDTC. |
| 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. |
| MIDSDTC | Disease Milestone Instance Date/Time | Char | The start date/time of the Disease Milestone Instance Name in MIDS, in ISO8601 format. |
| --STINT | Planned Start of Assessment Interval | Char | The start of a planned evaluation or assessment interval in ISO 8601 character format relative to the Time Point Reference (--TPTREF).* |
| --ENINT | Planned End of Assessment Interval | Char | The end of a planned evaluation or assessment interval in ISO 8601 character format relative to the Time Point Reference (--TPTREF).* |
| --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. |

## 2.2.6 Demographics

Each study must include one standardized set of observations in a specific structure; this is the Demographics domain described in Table 2.2.6. Demographics is the parent domain for all other observations for subjects, and should be identified with the domain code of "DM". The Demographics domain describes the essential characteristics of the study subjects, and is used by reviewers for selecting subsets of subjects for analysis. The Demographics domain, as with other datasets, includes Identifiers, a Topic variable, Timing variables, and Qualifiers. Since DM has a fixed structure, only certain variables may be added as appropriate. See the implementation guides for guidance on which additional variables can be added to this domain.

**Table 2.2.6 Subject Demographics Domain Variables**

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| STUDYID | Study Identifier | Char | Identifier | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Identifier | Two-character abbreviation for the domain which must be DM. |
| USUBJID | Unique Subject Identifier | Char | Identifier | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. |
| 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. |
| RFSTDTC | Subject Reference Start Date/Time | Char | Qualifier | Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study 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. |
| RFENDTC | Subject Reference End Date/Time | Char | Qualifier | Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the 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. |
| RFXSTDTC | Date/Time of First Study Treatment | Char | Qualifier | First date/time of exposure to any protocol-specified treatment or therapy for the subject in ISO 8601 character format. |
| RFXENDTC | Date/Time of Last Study Treatment | Char | Qualifier | Last date/time of exposure to any protocol-specified treatment or therapy for the subject in ISO 8601 character format. |
| RFICDTC | Date/Time of Informed Consent | Char | Qualifier | Date/time of informed consent in ISO 8601 character format. |
| RFPENDTC | Date/Time of End of Participation | Char | Qualifier | Date/time when subject ended participation or follow-up in a trial, in ISO 8601 character format. Should correspond to the last known date of contact. |
| DTHDTC | Date/Time of Death | Char | 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. |
| DTHFL | Subject Death Flag | Char | Qualifier | A value of 'Y' indicates the subject died. Should be Y or null. Should be populated even when the death date is unknown. |
| SITEID | Study Site Identifier | Char | Qualifier | Unique identifier for a site within a study. |
| INVID | Investigator Identifier | Char | 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. |
| INVNAM | Investigator Name | Char | Qualifier | Name of the investigator for a site. |
| BRTHDTC | Date/Time of Birth | Char | Qualifier | Date/time of birth of the subject in ISO 8601 character format. |
| AGE | Age | Num | 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). |
| AGETXT | Age Text | Char | 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. |
| AGEU | Age Units | Char | Qualifier | Units associated with AGE or AGETXT. |
| SEX | Sex | Char | Qualifier | Sex of the subject. |
| RACE | Race | Char | Qualifier | Race of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of race |

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| | | | | (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126396.pdf). |
| ETHNIC | Ethnicity | Char | Qualifier | The ethnicity of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of ethnicity (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126396.pdf). |
| SPECIES | Species | Char | Qualifier | Used to identify the common species name of the subject (i.e., test system) under study (e.g., MOUSE, RAT, DOG, MONKEY). |
| STRAIN | Strain/Substrain | Char | 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). |
| SBSTRAIN | Strain/Substrain Details | Char | Qualifier | 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. |
| ARMCD | Planned Arm Code | Char | Qualifier | Short name for the Arm to which the subject was assigned, limited to 20 characters. |
| ARM | Description of Planned Arm | Char | Qualifier | Name of the Arm to which the subject was assigned. |
| ACTARMCD | Actual Arm Code | Char | Qualifier | Short name for the actual Arm in which the subject participated during the trial, limited to 20 characters. |
| ACTARM | Description of Actual Arm | Char | Qualifier | Description of the actual Arm in which the subject participated during the trial. |
| SETCD | Set Code | Char | Qualifier | Short name of a specific Trial Set (see Table 3.2.4), as defined by the sponsor. Maximum of 8 characters. This represents the code for the Trial Set for which parameters are being submitted. |
| COUNTRY | Country | Char | Qualifier | Country of the investigational site at which the subject participated in the trial in ISO 3166 three-character format. |
| DMDTC | Date/Time of Collection | Char | Timing | Date/time of collection of the demographic information in ISO 8601 character format. |
| 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. |

## 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.

Please see Implementation Guide for further guidance regarding use of additional Identifier and Timing variables.

**Table 2.2.7 Comments Domain Variables**

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| STUDYID | Study Identifier | Char | Identifier | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Identifier | Two-character abbreviation for the domain which must be CO. |
| 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. |
| USUBJID | Unique Subject Identifier | Char | Identifier | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. |
| POOLID | Pool Identifier | Char | Identifier | Used to identify a result for pooled subjects that is not assignable to any one individual within the pool. |
| COSEQ | Sequence Number | Num | Identifier | Sequence number to ensure uniqueness within a domain. Should be assigned to be in a consistent chronological order. |
| 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. |
| IDVARVAL | Identifying Variable Value | Char | Record Qualifier | Value of identifying variable of the parent record(s). Null for comments collected on separate CRFs. |
| 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). |
| COVAL | Comment | Char | Topic | The text of the comment. Text over 200 characters can be added to additional columns COVAL1-COVALn. |
| COEVAL | Evaluator | Char | Record Qualifier | Used to describe the originator of the comment. Example: CENTRAL REVIEWER. |
| CODTC | Date/Time of Comment | Char | Timing | Date/time of comment on dedicated comment form, if collected. Represented in ISO 8601 character format. Should be null if this is a child record of another domain or if comment date was not collected. |

## 2.2.8 Subject Elements

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

Please see the specific implementation guides for further guidance regarding use of additional Identifier and Timing variables.

**Table 2.2.8 Subject Elements — One Record per Actual Element per Subject**

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| STUDYID | Study Identifier | Char | Identifier | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Identifier | Two-character abbreviation for the domain which must be SE. |
| USUBJID | Unique Subject Identifier | Char | Identifier | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. |
| SESEQ | Sequence Number | Num | Identifier | Sequence number to ensure uniqueness within dataset. Should be assigned to be in a consistent chronological order. |

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| 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. |
| ELEMENT | Description of Element | Char | Qualifier | The name of the Element. If ETCD has a value of "UNPLAN" then ELEMENT should be null. |
| SESTDTC | Start Date/Time of Element | Char | Timing | Start date/time for an Element for each subject, represented in ISO 8601 character format. |
| SEENDTC | End Date/Time of Element | Char | Timing | End date/time of an Element for each subject, represented in ISO 8601 character format. |
| TAETORD | Planned Order of Element within Arm | Num | Timing | Number that gives the planned order of the Element within the subject's assigned ARM. |
| EPOCH | Epoch | Char | Timing | Epoch associated with the Element in the planned sequence of Elements for the ARM to which the subject was assigned |
| SEUPDES | Description of Unplanned Element | Char | Optional Qualifier* | Description of what happened to the subject during an unplanned Element. Used only if ETCD has the value of "UNPLAN". |

** Optional additional qualifier variables are placed at the end because they are seldom used.*

### 2.2.9 Subject Visits

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

Please see the Implementation Guides for further guidance regarding use of additional Identifier and Timing variables.

**Table 2.2.9 Subject Visits — One Record per Subject Visit, per Subject**

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| STUDYID | Study Identifier | Char | Identifier | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Identifier | Two-character abbreviation for the domain, which must be SV. |
| USUBJID | Unique Subject Identifier | Char | Identifier | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. |
| VISITNUM | Visit Number | Num | Topic | Clinical encounter number. (Decimal numbering may be useful for inserting unplanned visits.) Numeric version of VISIT, used for sorting. |
| 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. |
| VISITDY | Planned Study Day of Visit | Num | Timing | Planned study day of the start of the visit based upon RFSTDTC in Demographics. |
| SVSTDTC | Start Date/Time of Visit | Char | Timing | Start date/time for a subject's visit, represented in ISO 8601 character format. |
| SVENDTC | End Date/Time of Visit | Char | Timing | End date/time of a subject's visit, represented in ISO 8601 character format. |
| SVSTDY | Study Day of Start of Visit | Num | Timing | Study day of start of visit relative to the sponsor-defined RFSTDTC. |
| SVENDY | Study Day of End of Visit | Num | Timing | Study day of end of visit relative to the sponsor-defined RFSTDTC. |
| SVUPDES | Description of Unplanned Visit | Char | Optional Qualifier* | Description of what happened to the subject during an unplanned visit. Null for protocol-defined visits. |

** Optional additional Qualifier variables are placed at the end because they are seldom used.*

### 2.2.10 Subject Disease Milestones

The Subject Disease Milestones domain is designed to record the timing, for each subject, of Disease Milestones that have been defined in the Trial Disease Milestones (TM) dataset in Section 3.6.

**Table 2.2.10 Subject Disease Milestones — One Record per Disease Milestone, per Subject**

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| STUDYID | Study Identifier | Char | Identifier | Unique identifier for a study. |
| DOMAIN | Domain | Char | Identifier | Two-character abbreviation for the domain, which must be SM. |
| USUBJID | Unique Subject Identifier | Char | Identifier | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. |
| SMSEQ | Sequence Number | Num | Identifier | Sequence Number given to ensure uniqueness of subject records. Should be assigned to be consistent with chronological order. |
| 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: HYPO 1. |
| MIDSTYPE | Disease Milestone Type | Char | Qualifier | The type of Disease Milestone. Example: HYPOGLYCEMIC EVENT. |
| SMSTDTC | Start Date/Time of Milestone | Char | Timing | Start date/time of Milestone Instance, if Milestone is an intervention or event, or date of Milestone if Milestone is a finding. |
| SMENDTC | End Date/Time of Milestone | Char | Timing | End date/time of Disease Milestone Instance. |
| SMSTDY | Study Day of Start of Milestone | Num | Timing | Study day of start of Disease Milestone Instance, relative to the sponsor-defined RFSTDTC. |
| 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 Domain-Specific Variables for the General Observation Class

The concept of domain-specific variables is being 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 2.2.11 lists the proposed domain specific variables.

**Table 2.2.11 Domain-Specific Variables for General Observation Class Domains**

| Domain | Variable Name | Variable Label | Type | Role | Description | Position |
|---|---|---|---|---|---|---|
| EG | EGBEATNO | ECG Beat Number | Num | Variable Qualifier of EGORRES | A sequence number that identifies the beat within an ECG. | After EGPOS |
| EX | EXMETHOD | Method of Administration | Char | Record Qualifier | Method of administration of the treatment. Not to be used with human clinical trials. | After EXLOC |
| 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. | After ICSTRESC |

# 3 The Trial Design Model

The Trial Design Model defines a standard structure for representing the planned sequence of events 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, and Sets

Under the model, planned information is presented in a series of four tables:

- The Trial Elements table (TE) (Table 3.1.1) describes the Element code (unique for each Element), the Element description, and the rules for starting and ending an Element. A rule could be expressed as pseudo code or as executable code for determining transitions from one Element to another.
- The Trial Arms table (TA) (Table 3.1.2) describes each planned Arm in the trial. An Arm is described as an ordered sequence of Elements, and the same Element may occur more than once in a given Arm. In order to accommodate complex Trial Designs, this table 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 either skip ahead to another Element rather than proceed linearly.
- The Trial Visits table (TV) (Table 3.1.3) describes the planned order and number of visits in the study. In the case when visits vary for each Arm, there would be a separate record per Visit per Arm. It 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.
- The Trial Sets table (TX) (Table 3.1.4) allows the submission of detailed information about planned groups of subjects that result 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 consist of one or more Trial Arms. These datasets are essential to determine whether data comparisons are feasible across different studies.

### 3.1.1 Trial Elements

**Table 3.1.1 Trial Elements — One Record per Trial Element**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain, which must be TE. |
| ETCD | Element Code | Char | 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. |
| ELEMENT | Description of Element | Char | The name of the Element. |
| TESTRL | Rule for Start of Element | Char | Expresses the rule for beginning the Element. |
| TEENRL | Rule for End of Element | Char | Expresses the rule for ending the Element. Either TEENRL or TEDUR must be present for each Element. |
| TEDUR | Planned Duration of Element | Char | Planned Duration of Element in ISO 8601 format. Used when the rule for ending the Element is applied after a fixed duration. |

### 3.1.2 Trial Arms

**Table 3.1.2 Trial Arms — One Record per Planned Element per Arm**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain, which must be TA. |
| ARMCD | Planned Arm Code | Char | 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. |
| ARM | Description of Planned Arm | Char | Name given to Arm or treatment group. |
| TAETORD | Planned Order of Element within Arm | Num | Number that gives the order of the Element within the Arm. |
| ETCD | Element Code | Char | 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. |
| ELEMENT | Description of Element | Char | The name of the Element. |
| TABRANCH | Branch | Char | 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. |
| TATRANS | Transition Rule | Char | 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). |
| EPOCH | Epoch | Char | Name of the Trial Epoch with which this Element of the Arm is associated. |

*Note: The same Element may occur more than once within an Arm, but each occurrence would have a different value for TAETORD and EPOCH, and may have different values for TABRANCH and TATRANS.*

### 3.1.3 Trial Visits

**Table 3.1.3 Trial Visits — One Record per Planned Trial Visit**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain, which must be TV. |
| VISITNUM | Visit Number | Num | Clinical encounter number. Numeric version of VISIT can be used for sorting. |
| VISIT | Visit Name | Char | 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. |
| VISITDY | Planned Study Day of Visit | Num | Planned study day of VISIT. Due to its sequential nature, can be used for sorting. |
| ARMCD | Planned Arm Code | Char | 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. |
| ARM | Description of Planned Arm | Char | Name given to Arm or treatment group. |
| TVSTRL | Visit Start Rule | Char | Rule describing when the visit starts, in relation to the sequence of Elements. |
| TVENRL | Visit End Rule | Char | Rule describing when the visit ends, in relation to the sequence of Elements. |

### 3.1.4 Trial Sets

**Table 3.1.4 Trial Sets — One Record per Trial Set Parameter**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain, which must be TX. |
| SETCD | Set Code | Char | 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. |
| SET | Set Description | Char | Long description of a specific Trial Set, as defined by the sponsor. |
| TXSEQ | Sequence Number | Num | Unique number for this record within this dataset. |
| TXPARMCD | Trial Set Parameter Short Name | Char | Short character value for the Trial Set parameter described in TXPARM. Maximum 8 characters. |
| TXPARM | Trial Set Parameter | Char | Term for the Trial Set parameter. Maximum 40 characters. |
| TXVAL | Trial Set Parameter Value | Char | 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. |

## 3.2 Trial Inclusion Exclusion Criteria

The Trial Inclusion Exclusion Domain (TI) contains one 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 | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain, which must be TI. |
| IETESTCD | Inclusion/Exclusion Criterion Short Name | Char | 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 name "IE" prefix is used to ensure consistency with the IE domain |
| IETEST | Inclusion/Exclusion Criterion | Char | Full text of the inclusion or exclusion criterion. The prefix "IE" is used to ensure consistency with the IE domain. |
| IECAT | Inclusion/Exclusion Category | Char | Used for categorization of the Inclusion/Exclusion Criterion: INCLUSION, EXCLUSION. |
| IESCAT | Inclusion/Exclusion Subcategory | Char | 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. |
| TIRL | Inclusion/Exclusion Criterion Rule | Char | Rule that expresses the criterion in computer-executable form. |
| TIVERS | Protocol Criteria Versions | Char | The number of this version of the Inclusion/Exclusion criteria. May be omitted if there is only one version. |

## 3.3 Trial Summary Information

The Trial Summary Information Domain (TS) contains one record for each trial summary characteristic. Trial Summary is used to record basic information about the trial, such as trial phase, protocol title and design objectives.

**Table 3.3 Trial Summary — One Record per Trial Summary Parameter**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain, which must be TS. |
| TSSEQ | Sequence Number | Num | Sequence number to ensure uniqueness within the dataset. |
| TSGRPID | Group ID | Char | Used to tie together a group of related records. |

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| TSPARMCD | Trial Summary Parameter Short Name | Char | 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.<br>Examples: AGEMIN, AGEMAX |
| TSPARM | Trial Summary Parameter | Char | 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 |
| TSVAL | Parameter Value | Char | 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. |
| TSVALNF | Parameter Null Flavor | Char | Null flavor for the value of TSVAL describing the reason the value is null, to be populated if and only if TSVAL is null. |
| TSVALCD | Parameter Value Code | Char | Code of the term in TSVAL from Reference Terminology cited in TSVCDREF. |
| TSVCDREF | Name of the Reference Terminology | Char | The name of the reference terminology or standard format from which TSVALCD is taken. For example; CDISC, SNOMED, ISO8601. |
| TSVCDVER | Version of the Reference Terminology | Char | The version number of the Reference Terminology cited in TSVCDREF, if applicable. |

## 3.4 Trial Disease Assessments

The TD domain provides information on the planned protocol-specified disease assessment schedule. In oncology studies, good 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 a 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 Trial Disease Assessments — One Record per Planned Constant Assessment Period**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Unique identifier for a study. |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain, which must be TD. |
| TDORDER | Sequence of Planned Assessment Schedule | Num | A number given to ensure ordinal sequencing of the planned assessment schedules within a trial. |
| TDANCVAR | Anchor Variable Name | Char | 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. |
| TDSTOFF | Offset from the Anchor | Char | 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 and will be represented in ISO 8601 character format. |
| TDTGTPAI | Planned Assessment Interval | Char | The planned interval between disease assessments represented in ISO 8601 character format. |
| TDMINPAI | Planned Assessment Interval Minimum | Char | The lower limit of the allowed range for the planned interval between disease assessments represented in ISO 8601 character format. |

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| TDMAXPAI | Planned Assessment Interval Maximum | Char | The upper limit of the allowed range for the planned interval between disease assessments represented in ISO 8601 character format. |
| TDNUMRPT | Maximum Number of Actual Assessments | Num | 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

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

**Table 3.5 Trial Disease Milestones — One record per Disease Milestone type**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Unique identifier for a study. |
| DOMAIN | Domain | Char | Two-character abbreviation for the domain, which must be TM. |
| MIDSTYPE | Disease Milestone Type | Char | The type of Disease Milestone. Example: HYPOGLYCEMIC EVENT. |
| TMDEF | Disease Milestone Definition | Char | Definition of the Disease Milestone. |
| TMRPT | Disease Milestone Repetition Indicator | Char | 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). |

# 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 eight 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 two (or more) datasets where records of one (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 5.2)
- 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 RELREC Dataset**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Study Identifier of the domain record(s). |
| RDOMAIN | Related Domain Abbreviation | Char | Two-character abbreviation for the domain of the parent record(s). |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. |
| 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 for POOLDEF and Section 5 for Associated Persons data). |
| POOLID | Pool Identifier | Char | Identifier used for pooling subjects to assign a single finding to multiple subjects. |
| IDVAR | Identifying Variable | Char | Name of the identifying variable in the general-observation-class dataset that identifies the related record(s). Examples include --SEQ and --GRPID. |
| IDVARVAL | Identifying Variable Value | Char | Value of identifying variable described in IDVAR. If --SEQ is the variable being used to describe this record, then the value of --SEQ would be entered here. |
| RELTYPE | Relationship Type | Char | 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. |
| RELID | Relationship Identifier | Char | 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 SUPPQUAL Dataset**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Study Identifier of the parent record(s). |
| RDOMAIN | Related Domain Abbreviation | Char | Two-character abbreviation for the domain of the parent record(s). |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. |
| 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 for POOLDEF and Section 5 for Associated Persons data). |
| POOLID | Pool Identifier | Char | Identifier used for pooling subjects to assign a single finding to multiple subjects. |
| IDVAR | Identifying Variable | Char | Identifying variable in the parent dataset that identifies the related record(s). Examples: --SEQ, --GRPID. |
| IDVARVAL | Identifying Variable Value | Char | Value of identifying variable of the parent record(s). |
| QNAM | Qualifier Variable Name | Char | The short name of the Qualifier variable, which is used as a column name in a domain view with data from the parent domain. The value in QNAM cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). QNAM cannot contain characters other than letters, numbers, or underscores. This will often be the column name in the sponsor's operational dataset. |
| QLABEL | Qualifier Variable Label | Char | 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. |
| QVAL | Data Value | Char | Result of, response to, or value associated with QNAM. A value for this column is required; no records can be in a SUPP-- dataset with a null value for QVAL |
| QORIG | Origin | Char | Since QVAL can represent a mixture of collected (on a CRF), derived, or assigned items, QORIG is used to indicate the origin of this data. Examples include CRF, ASSIGNED, or DERIVED. |
| QEVAL | Evaluator | Char | 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. Some examples include ADJUDICATION COMMITTEE, STATISTICIAN, DATABASE ADMINISTRATOR, CLINICAL COORDINATOR, etc. |

### 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 POOLDEF Dataset**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Study Identifier of the parent record(s). |
| POOLID | Pool Identifier | Char | Identifier used for pooling subjects to assign a single finding to multiple subjects. |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. |
| APID | Associated Persons Identifier | Char | 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 RELSUB Dataset**

| Variable Name | Variable Label | Type | CDISC Notes |
|---|---|---|---|
| STUDYID | Study Identifier | Char | Unique identifier for a study. |
| USUBJID | Unique Subject Identifier | Char | 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. |
| POOLID | Pool Identifier | Char | 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. |
| RSUBJID | Related Subject or Pool Identifier | Char | 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. |
| SREL | Subject Relationship | Char | Describes the relationship of the subject identified in USUBJID or the pool identified in POOLID to the subject or pool identified in RSUBJID. |

# 5 Applying Model Fundamentals to Associated Persons

## 5.1 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 Study Data Tabulation Model Associate Persons Implementation Guide (SDTMIG-AP) provides implementation rules and advice. Unless an exception is described in this implementation guide, all other general assumptions about SDTM and SDTMIG variables and domains apply to AP data.

### 5.1.1 Variables Used in Associated Persons Data

**Table 5.1.1 Associated Persons Data — Identifier Variables**

| Variable Name | Variable Label | Type | Description |
|---|---|---|---|
| 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 for POOLDEF and Section 5 for Associated Persons data). |
| 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.<br>RSUBJID will be null for data about associated persons who are related to the study but not to any study subjects. |
| RDEVID | Related Device Identifier | Char | Identifier for a related device. RDEVID will be populated with the SPDEVID of the related device. |
| 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.<br>If RDEVID is populated, describes the relationship of the associated person(s) identified in APID to the subject or pool identified in RDEVID.<br>If RSUBJID and RDEVID are null, SREL describes the relationship of the associated person(s) identified in APID to the study identified in STUDYID. |

## 5.2 Associated Person Relationships

Some sort of a relationship is necessary between an AP and a study, a subject, or a device to justify collection of data for an AP. However, in cases where an AP has relationships to multiple subjects or devices and/or multiple relationships to a single subject or device, a single value in SREL is inadequate to describe these multiple relationships. In those cases, the value MULTIPLE should appear in SREL. If an AP has relationships with multiple subjects, MULTIPLE may also appear in RSUBJID. When other SDTM variables are populated with MULTIPLE, the multiple values are stored in Supplemental Qualifiers. However, this was found to be an indirect and cumbersome way to handle multiple relationships of an AP to subject(s). In addition, if an AP had 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 5.2.1 APRELSUB Dataset**

| Variable Name | Variable Label | Type | Role | Description |
|---|---|---|---|---|
| STUDYID | Study Identifier | Char | Identifier | Unique identifier for a study. |
| 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 for POOLDEF and Section 5 for Associated Persons data). |
| 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.<br>RSUBJID will be null for data about associated persons who are related to the study but not to any study subjects. |
| RDEVID | Related Device Identifier | Char | Identifier | Identifier for a related device. RDEVID will be populated with the SPDEVID of the related device. |
| 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.<br>If RDEVID is populated, describes the relationship of the associated person(s) identified in APID to the subject or pool identified in RDEVID.<br>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 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 structures of the model. Individual implementation guides 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 implementation guides also describe basic assumptions and business rules, and provide numerous examples for mapping data to the standard format. Any sponsor wishing to submit data in the standard formats should first consult the implementation guides before preparing a regulatory submission based on the SDTM. The following implementation guides have been published by CDISC:

1. The Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG)
2. The Standard for Exchange of Non-Clinical Data Implementation Guide (SENDIG)
3. The Study Data Tabulation Model Implementation Guide for Medical Devices (SDTMIG-MD)
4. The Study Data Tabulation Model Associated Persons Implementation Guide (SDTMIG-AP)
5. The Study Data Tabulation Model Pharmacogenomics/Genetics (SDTMIG-PGx)

# 7 SDTM Version History

## 7.1 Changes from SDTM v1.4 to SDTM v1.5

### 7.1.1 Variable and Dataset Additions

Table 2.2.1: Interventions:

- --USCHFL Unscheduled Flag

Table 2.2.2: Events:

- --USCHFL Unscheduled Flag

Table 2.2.3: Findings:

- --ORREF Reference Result in Original Units
- --STREFC Reference Result in Standard Format
- --STREFN Numeric Reference Result in Std Units
- --IMPLBL Implantation Site Label
- --CHRON Chronicity of Finding
- --DISTR Distribution Pattern of Finding
- --LOBXFL Last Observation Before Exposure Flag
- --USCHFL Unscheduled Flag
- --REPNUM Repetition Number

Table 2.2.4: Identifiers for All Classes:

- APID Associated Persons Identifier
- FETUSID Fetus Identifier
- FOCID Focus of Study Specific Interest
- --RECID Invariant Record Identifier

Table 2.2.5: Timing Variables for All Classes:

- --NOMDY Nominal Study Day for Tabulations
- --NOMLBL Label for Nominal Study Day
- MIDS Disease Milestone Instance Name
- RELMIDS Temporal Relation to Milestone Instance
- MIDSDTC Disease Milestone Instance Date/Time

Table 2.2.10: Subject Disease Milestones (new table)

Table 2.2.11: Domain-Specific Variables for the General Observation Class (new table)

Table 3.5.2: Trial Disease Milestones (new table)

### 7.1.2 Variables Not Deprecated

In SDTM v1.4, two timing variables, --STRF and --ENRF were identified as being under consideration for possible deprecation in a future (post SDTM v1.4) release. However, upon further consideration, these variables will be retained.

# Appendices

## Appendix A: Representations and Warranties, Limitations of Liability, and Disclaimers

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