Study Data Tabulation Model

Version 1.4

Prepared by the

CDISC Submission Data Standards Team

[redacted]

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Notes to Readers

This is Version 1.4 of the Study Data Tabulation Model Document (SDTM). This document includes additional variables related to human clinical trials and animal studies, and other corrections and clarifications to the text. A full description of all changes from the prior version is provided in Section 7.1.

Revision History

Date	Version	Summary of Changes
2013-11-26	Version 1.4 Final	Final Version
2012-07-16	Version 1.3 Final	Final Version
2008-11-12	Version 1.2 Final	Final Version
2005-04-28	Version 1.1 Final	Final version incorporating minor corrections to address comments submitted during public review period.
2004-06-25	Version 1.0	First released version reflecting all changes identified during comment periods.

Note: Please see Appendix A for Representations and Warranties, Limitations of Liability, and Disclaimers.

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1 Introduction

1.1 Purpose

This document describes the Study Data Tabulation Model (SDTM), which defines a standard structure for study data tabulations 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 prepared by the Submissions Data Standards (SDS) Team of the Clinical Data Interchange Standards Consortium (CDISC). This document, which will supersede all prior versions, includes numerous changes from the prior Version 1.3, 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. Structured evaluation pilots of the SDTM are planned for these products, and the lessons learned from these pilots would be used in developing future enhancements to the standard. 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 V1.4 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 more recently added SDTM variables are recognized as being more functional than older ones. In order to help ensure more consistency in implementations, the less functional variables are deprecated. Section 7.2 lists planned variable deprecations to take effect in a future SDTM release. In addition to including several text corrections and clarifications, V1.4 has been expanded to include 1) new tables to relay data about persons who are not the "subjects" of a study (referred to as Associated Persons), an additional Trial Design table to describe the disease assessment schedule in some oncology trials, and 2) new variables in the general observation class tables.

The following new sections have been added:

- Section 3.5 - The Trial Disease Assessments

- Section 5 - Applying Model Fundamentals to Associated Persons

The following sections have been re-numbered within SDTM V1.4:

- Section 6 “Using the Model for Regulatory Submissions” - was previously “Section 5” in SDTM V1.3
- Section 7 “SDTM Version History” - was previously “Section 6” in SDTM V1.3

The following new tables have been included in Version 1.4:

- Table 3.5.1 - Trial Disease Assessments
- Table 5.1.1 - Associated Persons Data – Identifier Variables
- Table 5.2.1 - APRELSUB Table

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.

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 --BLFL, --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.

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 Case Report Tabulation Data Definition Specification [Define-XML], available at www.CDISC.org). Define-XML specifies seven distinct metadata attributes to describe SDTM data:

- The Variable Name (limited to 8 characters for compatibility with the SAS Transport format)
- A descriptive Variable Label, using up to 40 characters, which should be unique for each variable in the dataset
- The data Type (e.g., whether the variable value is a character or numeric)
- The set of controlled terminology for the value or the presentation format of the variable (Controlled Terms or Format)
- The Origin of each variable
- The Role of the variable, which determines how the variable is used in the dataset. Roles include Identifiers, Topic, Timing, and the five types of Qualifiers.
- Comments or other relevant information about the variable or its data included by the sponsor as necessary to communicate information about the variable or its contents to a regulatory agency.

Data stored in these variables include both raw (as captured by the data provider) and derived values (e.g., converted into standard units or computed, such as age). The SDTM describes the name, label, role, and type for the standard variables.. The origin attribute has controlled terminology defined by CDISC as do values for many of the SDTM variables. Note that current types are restricted to character and number for compatibility with SAS Version 5 transport files; it is expected that additional, more descriptive data types (e.g., integer, float, date, date/time) will be used in the future when the SAS v5 transport requirement is changed to a newer version or to a different format such as XML.

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, as long as no data was 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).
- 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.

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.

Variable Name	Variable Label	Type	Role	Description
--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.
--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.

Variable Name	Variable Label	Type	Role	Description
--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.
--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.

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.

Variable Name	Variable Label	Type	Role	Description
--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.
--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.

Variable Name	Variable Label	Type	Role	Description
--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”.

Variable Name	Variable Label	Type	Role	Description
--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”.
--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.

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.

Variable Name	Variable Label	Type	Role	Description
--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 MITESTCD = TTF1.
--CAT	Category	Char	Grouping Qualifier	Used to define a category of topic-variable values. Examples: HEMATOLOGY, URINALYSIS, CHEMISTRY, HAMILTON DEPRESSION SCALE, SF36, MICRO ARRAY, EGFR MUTATION ANALYSIS
--SCAT	Subcategory	Char	Grouping Qualifier	Used to define a further categorization of --CAT values. Example: DIFFERENTIAL.
--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.
--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).

Variable Name	Variable Label	Type	Role	Description
--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.
--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.
--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.
--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

Variable Name	Variable Label	Type	Role	Description
--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
--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 or 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, by an independent assessor, to be the accepted evaluation. Expected to be Y or null.
--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.
--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.

Variable Name	Variable Label	Type	Role	Description
--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

2.2.3.1 "Findings About" Events or Interventions

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

Table 2.2.3.1: Findings About, Additional Qualifiers

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

2.2.4 Identifiers for All Classes

All of the following Identifier variables are available for use in any domain based on one of the three general observation classes. STUDYID, DOMAIN, USUBJID (or POOLID), and --SEQ are required in all domains based on one of the three general observation classes.

All identifier variables are allowed for both SDTMIG and SENDIG.

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.
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

Variable Name	Variable Label	Type	Description
--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).
--REFID	Reference ID	Char	Optional internal or external identifier such as lab specimen ID, or UUID for an ECG waveform or a medical image.
--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 both SDTMIG and SENDIG.

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 Trial Arms, 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.

Variable Name	Variable Label	Type	Description
--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.
--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.
--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. Note: This variable will be deprecated (phased out) in a future (post SDTM v1.4) release. The functionality of this variable can be replaced by the use of --STRTPT with --STTPT = RFSTDTC.
--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. Note: This variable will be deprecated (phased out) in a future (post SDTM v1.4) release. The functionality of this variable can be replaced by the use of --ENRTPT with --ENTPT = RFENDTC.
--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.

Variable Name	Variable Label	Type	Description
--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".
--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 The Demographics Domain

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	Description
Identifier Variables			
STUDYID	Study Identifier	Char	Unique identifier for a study.
DOMAIN	Domain Abbreviation	Char	Two-character abbreviation for the domain which must be DM.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
Topic Variables			
SUBJID	Subject Identifier for the Study	Char	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.
Qualifier Variables			
RFSTDTC	Subject Reference Start Date/Time	Char	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	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	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	Last date/time of exposure to any protocol-specified treatment or therapy for the subject in ISO 8601 character format.

Variable Name	Variable Label	Type	Description
RFICDTC	Date/Time of Informed Consent	Char	Date/time of informed consent in ISO 8601 character format.
RFPENDTC	Date/Time of End of Participation	Char	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	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	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	Unique identifier for a site within a study.
INVID	Investigator Identifier	Char	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	Unique identifier for a site within a study.
BRTHDTC	Date/Time of Birth	Char	Date/time of birth of the subject in ISO 8601 character format.
AGE	Age	Num	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	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	Units associated with AGE or AGETXT.
SEX	Sex	Char	Sex of the subject.
RACE	Race	Char	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 (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126396.pdf)
ETHNIC	Ethnicity	Char	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	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	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	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	Short name for the Arm to which the subject was assigned, limited to 20 characters.
ARM	Description of Planned Arm	Char	Name of the Arm to which the subject was assigned.

Variable Name	Variable Label	Type	Description
ACTARMCD	Actual Arm Code	Char	Short name for the actual Arm in which the subject participated during the trial, limited to 20 characters.
ACTARM	Description of Actual Arm	Char	Description of the actual Arm in which the subject participated during the trial.
SETCD	Set Code	Char	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	Country of the investigational site at which the subject participated in the trial in ISO 3166 three-character format.
Timing Variables			
DMDTC	Date/Time of Collection	Char	Date/time of collection of the demographic information in ISO 8601 character format.
DMDY	Study Day of Collection	Num	Study day of collection measured as integer days. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC in Demographics.

2.2.7 The Comments Domain

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).

Variable Name	Variable Label	Type	Role	Description
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 The Subject Elements Table

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. These correspond to the planned Elements described in the Trial Elements (Section 3.2.1) 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 Implementation Guide 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	Description
STUDYID	Study Identifier	Char	Unique identifier for a study.
DOMAIN	Domain Abbreviation	Char	Two-character abbreviation for the domain which must be SE.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
SESEQ	Sequence Number	Num	Sequence number to ensure uniqueness within dataset. Should be assigned to be in a consistent chronological order.
Topic Variable			
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.
Qualifier Variables			
ELEMENT	Description of Element	Char	The name of the Element. If ETCD has a value of “UNPLAN” then ELEMENT should be null.
Timing Variables			
SESTDTC	Start Date/Time of Element	Char	Start date/time for an Element for each subject, represented in ISO 8601 character format.
SEENDTC	End Date/Time of Element	Char	End date/time of an Element for each subject, represented in ISO 8601 character format.
TAETORD	Planned Order of Element within Arm	Num	Number that gives the planned order of the Element within the subject's assigned ARM.
EPOCH	Epoch	Char	Epoch associated with the Element in the planned sequence of Elements for the ARM to which the subject was assigned

Variable Name	Variable Label	Type	Description
Qualifier Variables			
SEUPDES	Description of Unplanned Element	Char	Description of what happened to the subject during an unplanned Element. Used only if ETCD has the value of "UNPLAN".

2.2.9 The Subject Visits Table

The Subject Visits table describes the actual start and end date/time for each visit of each individual subject. These correspond to the planned visits described in the Trial Design Model Trial Visits table (see Section 3.2.3). Because actual data does not always follow the plan, the model allows for descriptions of unplanned visits for subjects.

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

3 The Trial Design Model

3.1 Introduction

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.

3.2 Planned Elements, Arms, and Visits

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

- The Trial Elements table (Table 3.2.1) 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 (Table 3.2.2) 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 (Table 3.2.3) 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) 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.

3.2.1 Trial Elements Table

Table 3.2.1: 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.

Variable Name	Variable Label	Type	Description
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.

3.2.2 Trial Arms Table

Table 3.2.2: 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.

3.2.3 Trial Visits Table

Table 3.2.3: 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.

Variable Name	Variable Label	Type	Description
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.

3.2.4 Trial Sets Table

Table 3.2.4: 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 TV.
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.

3.3 Trial Inclusion/Exclusion Criteria

The Trial Inclusion Exclusion Domain (TI) contains one record for each of the inclusion and exclusion criteria for the trial.

3.3.1 Trial Inclusion/Exclusion Table

Table 3.3.1: 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.

Variable Name	Variable Label	Type	Description
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.

3.4 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.

3.4.1 Trial Summary Table

Table 3.4.1: 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.
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. 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.

Variable Name	Variable Label	Type	Description
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 from which TSVALCD is taken. For example; CDISC, SNOMED, ISO 8601.
TSVCDVER	Version of the Reference Terminology	Char	The version number of the Reference Terminology cited in TSVCDREF, if applicable.

3.5 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 within oncology and 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.

3.5.1 Trial Disease Assessments Table

Table 3.5.1: 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.
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.

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 2.4)
- A relationship between subjects in a study who are not part of 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 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.

Variable Name	Variable Label	Type	Description
RELID	Relationship Identifier	Char	Unique value within USUBJID that identifies the relationship. All records for the same USUBJID that have the same RELID are considered "related/associated." RELID can be any value the sponsor chooses, and is only meaningful within the RELREC dataset to identify the related/associated Domain records.

4.1.2 Supplemental Qualifiers 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 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 who can be associated with a study, a particular study subject or a device used in the study. An AP may or may not have a familial relationship to a study subject. 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 will 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	CDISC Notes
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.
RSUBJID	Related Subject	Char	Identifier for a related study subject or pool of study subjects. The subject(s) may be human or animal. RSUBJID will be populated with the USUBJID of the related subject or the POOLID of the related pool. RSUBJID will be null for data about associated persons who are related to the study but not to any of the study subjects.
RDEVID	Related Device	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. If RDEVID is populated, describes the relationship of the associated person(s) identified in APID to the device identified in RDEVID. If RSUBJID and RDEVID are null, SREL describes the relationship of the associated person(s) identified in APID to the study identified in STUDYID.

5.2 Associated Person Relationships

5.2.1 Relationships between Associated Persons and Subjects

AP domains include relationship information because it is understood that a relationship must exist for a non-subject to be considered 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 table, which parallels the structure of the RELSUB table, was created as a more efficient and simpler way to record these multiple relationships. The APRELSUB table is required for studies in

which SREL values of MULTIPLE appear, but would not be needed if each AP has only one relationship to one subject.

Table 5.2.1: APRELSUB Dataset

Variable Name	Variable Label	Type	Role	CDISC Notes
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.
RSUBJID	Related Subject or Pool Identifier	Char	Identifier	Identifier for a related subject or pool of subjects. RSUBJID may be populated with the USUBJID of the related subject or the POOLID of the related pool. RSUBJID will be null for data about associated persons who are related to the study but not to any study subjects.
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. If RDEVID is populated, describes the relationship of the associated person(s) identified in APID to the subject or pool identified in RDEVID. If RSUBJID and RDEVID are null, SREL describes the relationship of the associated person(s) identified in APID to the study identified in STUDYID.

6 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)

7 SDTM Version History

Version 1.4 represents the fifth formal release of the Study Data Tabulation Model. The original version was released as the Study Data Tabulation Model Version 1.0 in June 2004. The last prior version was issued in July 2012.

7.1 Changes from SDTM V1.3 to SDTM V1.4

7.1.1 Additions

Table 2.2.1 - Interventions:

- --MOOD Mood
- --LAT Laterality
- --DIR Directionality
- --PORTOT Portion or Totality
- --FAST Fasting Status
- --PSTRG Pharmaceutical Strength
- --PSTRG Pharmaceutical Strength Unit

Table 2.2.2 - Events:

- --LAT Laterality
- --DIR Directionality
- --PORTOT Portion or Totality
- --PARTY Accountable Party
- --PRTYID Identification of Accountable Party
- --ACNDEV Action Taken with Device

Table 2.2.3 - Findings;

- --TSTDTL Measurement, Test or Examination Detail
- --RUNID Run ID
- --ANMETH Method of Analysis
- --ULOQ Upper Limit of Quantitation

Table 2.2.4 - Identifiers;

- SPDEVID Sponsor Device Identifier

Table 2.2.5 - Timing Variables;

- --EVINTX Evaluation Interval Text
- --STINT Planned Start of Assessment Interval
- --ENINT Planned End of Assessment Interval

Table 3.5.1 - Trial Disease Assessments: (New Table):

- STUDYID Study Identifier
- DOMAIN Domain Abbreviation
- TDORDER Sequence of Planned Assessment Schedule
- TDANCVAR Anchor Variable Name
- TDSTOFF Offset from the Anchor
- TDTGTPAI Planned Assessment Interval
- TDMINPAI Planned Assessment Interval Minimum
- TDMAXPAI Planned Assessment Interval Maximum
- TDNUMRPT Maximum Number of Actual Assessments

Table 4.1.1 – RELREC Dataset:
- APID Associated Persons Identifier
- POOLID Pool Identifier

Table 4.1.2 – SUPPQUAL Dataset:
- APID Associated Persons Identifier
- POOLID Pool Identifier

Table 4.1.3 – POOLDEF Dataset:
- APID Associated Persons Identifier

Table 4.1.4 – RELSUB Dataset: (New Table)
- STUDYID Study Identifier
- USUBJID Unique Subject Identifier
- POOLID Pool Identifier
- RSUBJID Related Subject
- SREL Subject, Device, or Study Relationship

Table 5.1.1 – Associated Persons – Identifier variables: (New Table)
- APID Associated Persons Identifier
- RSUBJID Related Subject
- RDEVID Related Device
- SREL Subject, Device, or Study Relationship

Table 5.2.1 – APRELSUB Dataset: (New Table)
- STUDYID Study Identifier
- APID Associated Persons Identifier
- RSUBJID Related Subject
- RDEVID Related Device
- SREL Subject, Device, or Study Relationship

7.2 Variables to be deprecated

7.2.1 Proposed deletions post SDTM V1.4

Table 2.2.5 – Timing variable for all classes:
- --STRF: The functionality of this variable can be replaced by the use of --STRTPT with --STTPT = RFSTDTC.
- --ENRF: The functionality of this variable can be replaced by the use of --ENRTPT with --ENTPT = RFENDTC.

Appendices

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

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