



**Study Data Tabulation Model
Implementation Guide:
Human Clinical Trials**

Version 3.2

Prepared by the
CDISC Submission Data Standards Team

Notes to Readers

- This is the implementation guide for Human Clinical Trials corresponding to Version 1.4 of the CDISC Study Data Tabulation Model.
- This Implementation Guide comprises version 3.2 (V3.2) of the CDISC Submission Data Standards and domain models.

Revision History

Date	Version	Summary of Changes
2013-11-26	3.2 Final	<p>Contains the following major updates to the SDTMIG document structure in previous releases:</p> <ul style="list-style-type: none"> • Document has been split into smaller, more granular documents, and re-packaged as a PDF Portfolio • Domains in Section 5 & 6 are now individual documents with clearly identified Definition, Specification, Assumptions & Examples sub-sections; numbering schema at the sub-section level has been removed for these domains. • Main TOC does not contain page numbers • Page numbering is relative to individual document, with clear notation of document content • A small TOC has been inserted for Sections 5, 6.1, 6.2 and 6.3 • New HO Domain in Section 6.2 • New DD, IS, SR, RP, PR, MO, MI Domains in Section 6.3 • Other more granular updates as captured in Appendix E
2012-07-16	3.1.3 Final	<p>Released version the following updates:</p> <ul style="list-style-type: none"> • The incorporation of the content previously published in the SDTM Amendment 1; • Changes to the Trial Design section; • Document formatting updates; • Inclusion of the domains developed as the Oncology Disease-specific Therapeutic Area Supplement

Date	Version	Summary of Changes
2008-11-12	3.1.2 Final	Released version reflecting all changes and corrections identified during comment period.
2007-07-25	3.1.2 Draft	Draft for comment.
2005-08-26	3.1.1 Final	Released version reflecting all changes and corrections identified during comment period.
2004-07-14	3.1	Released version reflecting all changes and corrections identified during comment periods.

Please see [Appendix F](#) for Representations and Warranties, Limitations of Liability, and Disclaimers.

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1 Introduction

1.1 Purpose

This document comprises the CDISC Version 3.2 (V3.2) Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG), which has been prepared by the Submissions Data Standards (SDS) team of the Clinical Data Interchange Standards Consortium (CDISC). Like its predecessors, V3.2 is intended to guide the organization, structure, and format of standard clinical trial tabulation datasets submitted to a regulatory authority such as the US Food and Drug Administration (FDA). V3.2 supersedes all prior versions of the Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG).

The SDTMIG should be used in close concert with the current version of the CDISC Study Data Tabulation Model (SDTM, available at <http://www.cdisc.org/sdtm>) that describes the general conceptual model for representing clinical study data that is submitted to regulatory authorities and should be read prior to reading the SDTMIG. V3.2 provides specific domain models, assumptions, business rules, and examples for preparing standard tabulation datasets that are based on the SDTM.

Tabulation datasets, which are electronic listings of individual observations for a subject that comprise the essential data reported from a clinical trial, are one of four types of data currently submitted to the FDA along with patient profiles, listings, and analysis files. By submitting tabulations that conform to the standard structure, sponsors may benefit by no longer having to submit separate patient profiles or listings with a product marketing application. SDTM datasets are not intended to fully meet the needs supported by analysis datasets, which will continue to be submitted separately in addition to the tabulations. Since July 2004, the FDA has referenced use of the SDTM in the [Study Data Specifications for the Electronic Common Technical Document](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/), available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/>.

The availability of standard submission data will provide many benefits to regulatory reviewers. Reviewers can 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 will support 1) the FDA's efforts to develop a repository for all submitted trial data, and 2) a suite of standard review tools to access, manipulate, and view the tabulations. Use of these data standards is also expected to benefit industry by streamlining the flow of data from collection through submission, and facilitating data interchange between partners and providers. Note that the SDTM represents an interchange standard, rather than a presentation format. It is assumed that tabulation data will be transformed by software tools to better support viewing and analysis.

This document is intended for companies and individuals involved in the collection, preparation, and analysis of clinical data that will be submitted to regulatory authorities.

1.2 Organization of this Document

This document is organized into the following sections:

- **Section 1 - Introduction**, provides an overall introduction to the V3.2 models and describes changes from prior versions.
- **Section 2 - Fundamentals of the SDTM**, recaps the basic concepts of the SDTM, and describes how this implementation guide should be used in concert with the SDTM.
- **Section 3 – Submitting Data in Standard Format**, explains how to describe metadata for regulatory submissions, and how to assess conformance with the standards.
- **Section 4 – Assumptions for Domain Models**, describes basic concepts, business rules, and assumptions that should be taken into consideration before applying the domain models.

- **Section 5 – Models for Special-Purpose Domains**, describes special-purpose domains, including Demographics, Comments, Subject Visits, and Subject Elements.
- **Section 6 – Domain Models Based on the General Observation Classes**, provides specific metadata models based on the three general observation classes, along with assumptions and example data.
- **Section 7 - Trial Design Datasets**, provides specific metadata models, assumptions, and examples.
- **Section 8 – Representing Relationships and Data**, describes how to represent relationships between separate domains, datasets, and/or records, and information to help sponsors determine where data belongs in the SDTM.
- **Appendices** provide additional background material and describe other supplemental material relevant to implementation.

1.3 Relationship to Prior CDISC Documents

This document, together with the SDTM, represents the most recent version of the CDISC Submission Data Domain Models. Since all updates are intended to be backward compatible the term “V3.x” is used to refer to Version 3.1 and all subsequent versions. The most significant changes since the prior version, V3.1.3, include:

- Conversion of SDTMIG from a single document to a [PDF Portfolio](#), or a collection of multiple files assembled into an integrated PDF unit. Not all PDF viewers can display a PDF portfolio, but any PDF viewer which supports Flash should display the PDF portfolio as intended. The “At A Glance” file offers a few options.
- Breakup of Sections 5 and 6 into Domain or topic documents (one per domain or one per set of specialty domains)
- For the individual Domain Documents, the numbering schema has been replaced by a clear and consistent organization with smaller sub-sections such as “Description/Overview”, “Specification”, “Assumptions”, and “Examples”; this approach will enable:
 - Domains to be listed in alphabetical order (by their two-letter domain code)
 - Group related domains into single document where it makes sense to describe them together (e.g., Microbiology domains MS and MB, Pharmacokinetics domains PP and PC)
 - Insert new domains in the future without having to renumber those from previous releases
- Cross-referencing of Sections, sub-sections, assumptions, examples, appendices have all been harmonized with the following format:
 - **Section/Appendix-number: sub-section-number, [segment header], title**
where *[segment header]* may be a named example or assumption
title is the actual title of the document, section or sub-section being referenced
- An enhanced **Exposure (EX)** domain in Section 6.1
- The following new domains in Section 6.1 - Interventions: **Exposure as Collected (EC)** and **Procedures (PR)**
- The following new domain in Section 6.2 - Events: **Healthcare Encounters (HO)**
- The following new domains in Section 6.3 Findings:
 - **Death Details (DD)**
 - Immunogenicity Domain: **Immunogenicity Specimen Assessment (IS)**
 - **Microscopic Findings (MI)**
 - **Morphology (MO)**
 - **Reproductive System Findings (RP)**
 - **Subject Status (SS)**
- The following new Immunogenicity domain: **Section 6.4 – Skin Response (SR)**
- A complete re-design of Section 7, where In the same way that Sections 5 & 6 have been turned into a collection of more granular documents, each describing a single domain, or a collection of related ones, Section 7 is now a set of smaller documents that better organizes the Trial Design datasets
- The following new domain in Section 7 - Trial Design: **Trial Disease Assessment (TD)**
- Updated Controlled Terminology for applicable variables across all domains, if available.

- Reduction of Appendix C to contain only **Trial Summary Codes** and **Supplemental Qualifiers Name Codes**; this is being done as CDISC Terminology is centrally managed by the CDISC Controlled Terminology Team, and up-to-date CDISC Terminology information is best found at the [NCI Enterprise Vocabulary Services](#) website
- Removed the References column from all domain models specifications.

A detailed list of changes between versions is provided in *Appendix E - Revision History*.

V3.1 was the first fully implementation-ready version of the CDISC Submission Data Standards that was directly referenced by the FDA for use in human clinical studies involving drug products. However, future improvements and enhancements such as V3.2 will continue to be made as sponsors gain more experience submitting data in this format. Therefore, CDISC will be preparing regular updates to the implementation guide to provide corrections, clarifications, additional domain models, examples, business rules, and conventions for using the standard domain models. CDISC will produce further documentation for controlled terminology as separate publications, so sponsors are encouraged to check the CDISC website (<http://www.cdisc.org/terminology>) frequently for additional information. See *Section 4: 4.1.3, Coding and Controlled Terminology Assumptions* for the most up-to-date information on applying Controlled Terminology.

1.4 How to Read this Implementation Guide

This SDTM Implementation Guide (SDTMIG) is best read online, so the reader can benefit from the many hyperlinks included to both internal and external references. The following guidelines may be helpful in reading this document:

1. First, read the *SDTM* to gain a general understanding of SDTM concepts.
2. Next, read Sections 1-3 of this document to review the key concepts for preparing domains and submitting data to regulatory authorities. Refer to the Glossary in *Appendix B - Glossary And Abbreviations* as necessary.
3. Read the *Section 4 - Assumptions For Domain Models*.
4. Review *Section 5 – Models For Special-Purpose Domains* and *Section 6 – Domain Models Based On The General Observation Classes* in detail, referring back to Assumptions as directed (hyperlinks are provided). Note the implementation examples for each domain to gain an understanding of how to apply the domain models for specific types of data.
5. Read *Section 7 - Trial Design Datasets* to understand the fundamentals of the Trial Design Model and consider how to apply the concepts for typical protocols. New extensions to the trial design model will be published separately on the CDISC website.
6. Review *Section 8 - Representing Relationships and Data* to learn advanced concepts of how to express relationships between datasets, records and additional variables not specifically defined in the models.
7. Finally, review the *Appendices* as appropriate. *Appendix C – Controlled Terminology*, in particular, describes how CDISC Terminology is centrally managed by the CDISC Controlled Terminology Team; efforts are made at publication time to ensure all SDTMIG domain/dataset specification tables and/or examples reflect the latest CDISC Terminology; users, however, should frequently refer to *Appendix C – Controlled Terminology* as CDISC terminology is updated on a quarterly.

1.5 Submitting Comments

Comments on this document can be submitted through the [CDISC Discussion Forum](#).

2 Fundamentals of the SDTM

2.1 Observations and Variables

The V3.x Submission Data Standards are based on the SDTM's general framework for organizing clinical trials information that is to be submitted to the FDA. The SDTM is built around the concept of observations collected about subjects who participated in a clinical study. Each observation can be described by a series of variables, corresponding to a row in a dataset or table. Each variable can be classified according to its *Role*. A Role determines the type of information conveyed by the variable about each distinct observation and how it can be used. Variables can be classified into five major roles:

- *Identifier* variables, such as those that identify the study, subject, domain, and 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 the 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, and branching 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, --TEST and --LOINC which are equivalent terms for a --TESTCD.
- *Record Qualifiers* define additional attributes of the observation record as a whole (rather than describing a particular variable within a record). Examples include --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.

2.2 Datasets and Domains

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 is represented by a single dataset.

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 [*Section 8 - Representing Relationships and Data*].

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, Codelist, or Format*)
- The *Origin* of each variable [*see Section 4: 4.1.1.8, Origin Metadata*]
- The *Role* of the variable, which determines how the variable is used in the dataset. For the V3.x domain models, Roles are used to represent the categories of variables such as Identifier, Topic, Timing, or 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 SDTM datasets include both raw (as originally collected) and derived values (e.g., converted into standard units, or computed on the basis of multiple values, such as an average). The *SDTM* lists only the name, label, and type, with a set of brief CDISC guidelines that provide a general description for each variable used for a general observation class.

The domain dataset models included in *Section 5 – Models For Special-Purpose Domains* and *Section 6 – Domain Models Based On The General Observation Classes* of this document provide additional information about Controlled Terms or Format, notes on proper usage, and examples. Controlled terminology (CT) is now represented one of four ways:

- A single asterisk when there is no specific CT available at the current time, but the SDS Team expects that sponsors may have their own CT and/or the CDISC Controlled Terminology Team may be developing CT.
- A list of controlled terms for the variable when values are not yet maintained externally
- The name of an external codelist whose values can be found via the hyperlinks in either the domain or by accessing the CDISC Controlled Terminology as outlined in *Appendix C – Controlled Terminology*.
- A common format such as ISO 8601

The CDISC Controlled Terminology team will be publishing additional guidance on use of controlled terminology separately.

2.3 Special-Purpose Datasets

The SDTM includes three types of special-purpose datasets:

- Domain datasets, consisting of Demographics (DM), Comments (CO), Subject Elements (SE), and Subject Visits (SV)¹, all of which include subject-level data that do not conform to one of the three general observation classes. These are described in *Section 5 – Models For Special-Purpose Domains*.
- Trial Design Model (TDM) datasets, such as Trial Arms (TA) and Trial Elements (TE), which represent information about the study design but do not contain subject data. These are described in *Section 7 - Trial Design Datasets*.
- Relationship datasets, which include the RELREC and SUPP-- datasets described in *Section 8 - Representing Relationships and Data*.

2.4 The General Observation Classes

Most subject-level observations collected during the study should be represented according to one of the three SDTM general observation classes: Interventions, Events, or Findings. The lists of variables allowed to be used in each of these can be found in the *SDTM*.

- The *Interventions* class captures investigational, therapeutic and other treatments that are administered to the subject (with some actual or expected physiological effect) either as specified by the study protocol (e.g., exposure to study drug), coincident with the study assessment period (e.g., concomitant medications), or self-administered by the subject (such as use of alcohol, tobacco, or caffeine).
- The *Events* class 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 captures the observations resulting from planned evaluations to address specific tests or questions such as laboratory tests, ECG testing, and questions listed on questionnaires.

In most cases, the choice of observation class appropriate to a specific collection of data can be easily determined according to the descriptions provided above. The majority of data, which typically consists of measurements or responses to questions usually at specific visits or time points, will fit the Findings general observation class. Additional guidance on choosing the appropriate general observation class is provided in *Section 8: 8.6.1, Guidelines For Determining The General Observation Class*.

General assumptions for use with all domain models and custom domains based on the general observation classes are described in *Section 4 - Assumptions For Domain Models* of this document; specific assumptions for individual domains are included with the domain models.

¹ SE and SV were included as part of the Trial Design Model in earlier versions of the SDTMIG.

2.5 The SDTM Standard Domain Models

The following standard domains, listed in alphabetical order by Domain Code, with their respective domain codes have been defined or referenced by the CDISC SDS Team in this document. Note that other domain models may be posted separately for comment after this publication.

Special-Purpose Domains (defined in Section 5 – Models For Special-Purpose Domains):

- Comments (CO)
- Subject Elements (SE)
- Demographics (DM)
- Subject Visits (SV)

Interventions General Observation Class (defined in Section 6.1 - Interventions):

- Concomitant Medications (CM)
- Exposure (EX)
- Procedures (PR)
- Exposure as Collected (EC)
- Substance Use (SU)

Events General Observation Class (defined in Section 6.2 - Events):

- Adverse Events (AE)
- Disposition (DS)
- Healthcare Encounters (HO)
- Clinical Events (CE)
- Protocol Deviations (DV)
- Medical History (MH)

Findings General Observation Class (defined in Section 6.3 - Findings):

- Drug Accountability (DA)
- ECG Test Results (EG)
- Immunogenicity Specimen Assessments (IS)
- Microbiology Specimen (MB)
- Morphology (MO)
- PK Concentrations (PC)
- Physical Examination (PE)
- Reproductive System Findings (RP)
- Subject Characteristics (SC)
- Tumor Identification (TU)
- Vital Signs (VS)
- Death Details (DD)
- Inclusion/Exclusion Criterion Not Met (IE)
- Laboratory Test Results (LB)
- Microscopic Findings (MI)
- Microbiology Susceptibility Test (MS)
- PK Parameters (PP)
- Questionnaires (QS)
- Disease Response (RS)
- Subject Status (SS)
- Tumor Results (TR)

Findings About (defined in Section 6.4 - FA Domain)

- Findings About (FA)
- Skin Response (SR)

Trial Design Domains (defined in Section 7 - Trial Design Datasets):

- Trial Arms (TA)
- Trial Elements (TE)
- Trial Inclusion/Exclusion Criteria (TI)
- Trial Disease Assessment (TD)
- Trial Visits (TV)
- Trial Summary (TS)

Relationship Datasets (defined in Section 8 - Representing Relationships and Data):

- Supplemental Qualifiers (SUPP-- datasets)
- Related Records (RELREC)

A sponsor should only submit domain datasets that were actually collected (or directly derived from the collected data) for a given study. Decisions on what data to collect should be based on the scientific objectives of the study, rather than the SDTM. Note that any data that was collected and will be submitted in an analysis dataset must also appear in a tabulation dataset.

The collected data for a given study may use some or all of the SDS standard domains as well as additional custom domains based on the three general observation classes. A list of standard domain codes for many commonly used

domains is provided in . Additional standard domain models will be published by CDISC as they are developed, and sponsors are encouraged to check the CDISC website for updates.

These general rules apply when determining which variables to include in a domain:

- The Identifier variables, STUDYID, USUBJID, DOMAIN, and --SEQ are required in all domains based on the general observation classes. Other Identifiers may be added as needed.
- Any Timing variables are permissible for use in any submission dataset based on a general observation class except where restricted by specific domain assumptions.
- Any additional Qualifier variables from the same general observation class may be added to a domain model except where restricted by specific domain assumptions.
- Sponsors may not add any other variables than those described in the preceding three bullets. The addition of non-standard variables will compromise the FDA's abilities to populate the data repository and to use standard tools. The SDTM allows for the inclusion of the sponsors non-SDTM variables using the Supplemental Qualifiers special-purpose dataset structure, described in **Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain**. As the SDTM continues to evolve over time, certain additional standard variables may be added to the general observation classes. Therefore, Sponsors wishing to nominate such variables for future consideration should provide a rationale and description of the proposed variable(s) along with representative examples to the [CDISC Public Discussion Forum](#).
- Standard variables must not be renamed or modified for novel usage. Their metadata should not be changed.
- As long as no data was collected for Permissible variables, a sponsor is free to drop them and the corresponding descriptions from the Define-XML.

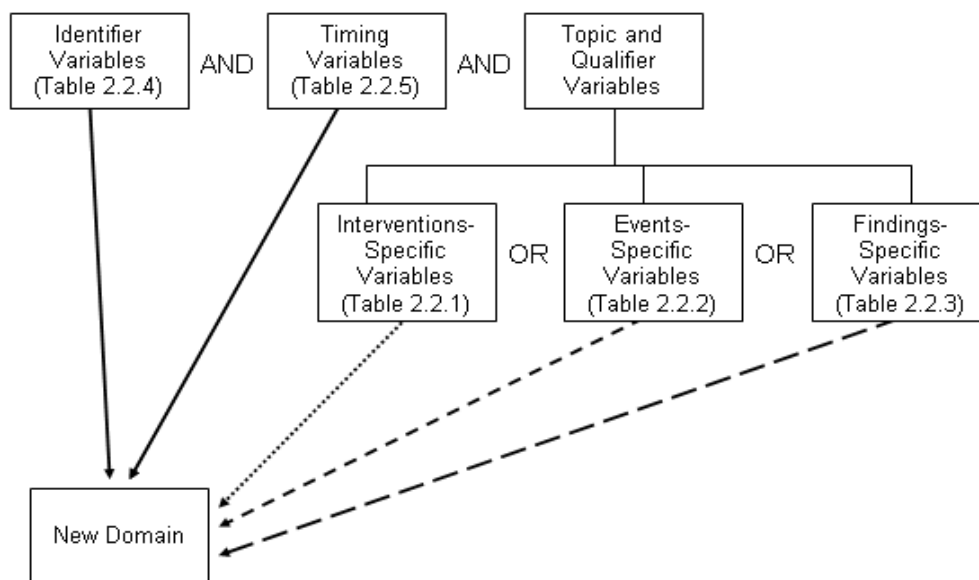
2.6 Creating a New Domain

This section describes the overall process for creating a custom domain, which must be based on one of the three SDTM general observation classes. The number of domains submitted should be based on the specific requirements of the study. Follow the process below to create a custom domain:

1. Confirm that none of the existing published domains will fit the need. A custom domain may only be created if the data are different in nature and do not fit into an existing published domain.
 - Establish a domain of a common topic (i.e., where the nature of the data is the same), rather than by a specific method of collection (e.g. electrocardiogram - EG). Group and separate data within the domain using --CAT, --SCAT, --METHOD, --SPEC, --LOC, etc. as appropriate. Examples of different topics are: microbiology, tumor measurements, pathology/histology, vital signs, and physical exam results.
 - Do not create separate domains based on time, rather represent both prior and current observations in a domain (e.g., CM for all non-study medications). Note that AE and MH are an exception to this best practice because of regulatory reporting needs.
 - How collected data are used (e.g., to support analyses and/or efficacy endpoints) must not result in the creation of a custom domain. For example, if blood pressure measurements are endpoints in a hypertension study, they must still be represented in the VS (Vital Signs) domain as opposed to a custom "efficacy" domain. Similarly, if liver function test results are of special interest, they must still be represented in the LB (Laboratory Tests) domain.
 - Data that were collected on separate CRF modules or pages may fit into an existing domain (such as separate questionnaires into the QS domain, or prior and concomitant medications in the CM domain).
 - If it is necessary to represent relationships between data that are hierarchical in nature (e.g., a parent record must be observed before child records), then establish a domain pair (e.g., MB/MS, PC/PP). Note, domain pairs have been modeled for microbiology data (MB/MS domains) and PK data (PC/PP domains) to enable dataset-level relationships to be described using RELREC. The domain pair uses DOMAIN as an Identifier to group parent records (e.g., MB) from child records (e.g., MS) and enables a dataset-level relationship to be described in RELREC. Without using DOMAIN to facilitate description of the data relationships, RELREC, as currently defined could not be used without introducing a variable that would group data like DOMAIN.

2. Check the Submission Data Standards area of the CDISC website ([Hhttp://www.cdisc.org/](http://www.cdisc.org/)) for models added after the last publication of the SDTMIG.
3. Look for an existing, relevant domain model to serve as a prototype. If no existing model seems appropriate, choose the general observation class (Interventions, Events, or Findings) that best fits the data by considering the topic of the observation. The general approach for selecting variables for a custom domain is as follows (also see [Figure 2.6, Creating A New Domain](#) below)
 - a. Select and include the required Identifier variables (e.g., STUDYID, DOMAIN, USUBJID, --SEQ) and any permissible Identifier variables from *SDTM: Table 2.2.4*.
 - b. Include the Topic variable from the identified general observation class (e.g., --TESTCD for Findings) [*SDTM: Tables 2.2.1, 2.2.2, or 2.2.3*].
 - c. Select and include the relevant Qualifier variables from the identified general observation class [*SDTM: Tables 2.2.1, 2.2.2, or 2.2.3*]. Variables belonging to other general observation classes must not be added.
 - d. Select and include the applicable Timing variables [*see SDTM: Table 2.2.5*]. Determine the domain code. Check the CDISC Controlled Terminology [*see Appendix C – Controlled Terminology*] for reserved two-character domain identifiers or abbreviations. If one has not been assigned by CDISC, then the sponsor may select the unique two-character domain code to be used consistently throughout the submission.
 - e. Apply the two-character domain code to the appropriate variables in the domain. Replace all variable prefixes (shown in the models as two hyphens "--") with the domain code. If no domain code exists in the CDISC Controlled Terminology [*see Appendix C – Controlled Terminology*] for this data and if it is desired to have this domain code as part of CDISC controlled terminology then submit a request to add the new domain via the CDISC website. Requests for new domain codes must include:
 - 1) Two-letter domain code and description
 - 2) Rationale for domain code
 - 3) Domain model with assumptions
 - 4) ExamplesUpon receipt, the SDS Domain Code Subteam will review the package. If accepted, then the proposal will be submitted to the SDS Team for review. Upon approval, a response will be sent to the requestor and package processing will begin (i.e., prepare for inclusion in a next release of the SDTM and SDTMIG, mapping concepts to BRIDG, and posting an update to the CDISC website). If declined, then the Domain Code Subteam will draft a response for SDS Team review. Upon agreement, the response will be sent to the requestor and also posted to the CDISC website.
 - f. Set the order of variables consistent with the order defined in *SDTM: Tables 2.2.1, 2.2.2, or 2.2.3*, depending upon the general observation class the custom domain is based on.
 - g. Adjust the labels of the variables only as appropriate to properly convey the meaning in the context of the data being submitted in the newly created domain. Use title case for all labels (title case means to capitalize the first letter of every word except for articles, prepositions, and conjunctions).
 - h. Ensure that appropriate standard variables are being properly applied by comparing the use of variables in standard domains.
 - i. Describe the dataset within the define.xml document [*see Section 3: 3.2, Using The CDISC Domain Models In Regulatory Submissions - Dataset Metadata*].
 - j. Place any non-standard (SDTM) variables in a Supplemental Qualifier dataset. Mechanisms for representing additional non-standard Qualifier variables not described in the general observation classes and for defining relationships between separate datasets or records are described in [Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain](#) of this document.

Figure 2.6. Creating a New Domain



2.7 SDTM variables Allowed in SDTMIG

This section identifies those SDTM variables that either 1) should not be used in SDTM-compliant data tabulations of clinical trials data or 2) have not yet been evaluated for use in human clinical trials.

The following SDTM variables, defined for use in non-clinical studies (SEND), must **NEVER** be used in the submission of SDTM-based data for human clinical trials:

- --DTHREL (Findings)
- --EXCLFL (Findings)
- --REASEX (Findings)
- --DETECT (Findings)

The following variables can be used for non-clinical studies (SEND) but must **NEVER** be used in the Demographics domain for human clinical trials. However, the use of these variables is currently being evaluated in Findings general observation class domains being developed for use in the tabulations of virology data:

- SPECIES (Demographics)
- STRAIN (Demographics)
- SBSTRAIN (Demographics)

The following variables have not been evaluated for use in human clinical trials and must therefore be used with extreme caution:

- --ANTREG (Findings)
- SETCD (Demographics)

[Note: The use of SETCD additionally requires the use of the Trials Sets domain]

The following identifier variable can be used for non-clinical studies (SEND), and may be used in human clinical trials when appropriate:

- POOLID

[Note: The use of POOLID additionally requires the use of the Pool Definition dataset]

Other variables defined in the SDTM are allowed for use as defined in this SDTMIG except when explicitly stated. Custom domains, created following the guidance in [Section 2.6, Creating A New Domain](#), may utilize any appropriate Qualifier variables from the selected general observation class.

3 Submitting Data in Standard Format

3.1 Standard Metadata for Dataset Contents and Attributes

The SDTMIG provides standard descriptions of some of the most commonly used data domains, with metadata attributes. The descriptive metadata attributes that should be included in a define.xml as applied in the domain models are:

- The SDTMIG -standard variable name (standardized for all submissions, even though sponsors may be using other variable names internally in their operational database)
- The SDTMIG -standard variable label
- Expected data types (the SDTMIG uses character or numeric to conform to the data types consistent with SAS V5 transport file format, but define.xml allows for more descriptive data types, such as integer or float)
- The actual controlled terms and formats used by the sponsor (do not include the asterisk (*) included in the CDISC domain models to indicate when controlled terminology applies)
- The origin or source of the data (e.g., CRF, derived; see definitions in *Section 4: 4.1.1.8, Origin Metadata*)
- The role of the variable in the dataset corresponding to the role in the SDTM if desired. Since these roles are predefined for all standard domains that follow the general observation classes, they do not need to be specified by sponsors in their define.xml for these domains.
- Any Comments provided by the sponsor that may be useful to the Reviewer in understanding the variable or the data in it.

In addition to these metadata attributes, the CDISC domain models include three other shaded columns that are not sent to the FDA. These columns assist sponsors in preparing their datasets:

- "CDISC Notes" is for notes to the sponsor regarding the relevant to the use of each variable
- "Core" indicates how a variable is classified as a CDISC Core Variable [*see Section 4: 4.1.1.5, CDISC Core Variables*]
- "References" provides references to relevant section of the SDTM or the SDTMIG.), and one to provide references to relevant section of the SDTM or the SDTMIG.

The domain models in *Section 6.1 – Interventions*, *Section 6.2 – Events*, *Section 6.3 – Findings*, and *Section 6.4 - FA Domain* illustrate how to apply the SDTM when creating a specific domain dataset. In particular, these models illustrate the selection of a subset of the variables offered in one of the general observation classes along with applicable timing variables. The models also show how a standard variable from a general observation class should be adjusted to meet the specific content needs of a particular domain, including making the label more meaningful, specifying controlled terminology, and creating domain-specific notes and examples. Thus the domain models demonstrate not only how to apply the model for the most common domains, but also give insight on how to apply general model concepts to other domains not yet defined by CDISC.

3.2 Using the CDISC Domain Models in Regulatory Submissions — Dataset Metadata

The define.xml that accompanies a submission should also describe each dataset that is included in the submission and describe the natural key structure of each dataset. While most studies will include DM and a set of safety domains based on the three general observation classes (typically including EX, CM, AE, DS, MH, IE, LB, and VS), the actual choice of which data to submit will depend on the protocol and the needs of the regulatory reviewer. Dataset definition metadata should include dataset filenames, descriptions, locations, structures, class, purpose, keys, and comments as described below in Table 3.2.1.

In the event that no records are present in a dataset (e.g., a small PK study where no subjects took concomitant medications), the empty dataset should not be submitted and should not be described in the define.xml document. The annotated CRF will show the data that would have been submitted had data been received; it need not be re-annotated to indicate that no records exist.

3.2.1 Table 3.2.1 SDTM Submission Dataset-Definition Metadata Example

Dataset	Description	Class	Structure	Purpose	Keys*	Location
DM	Demographics	Special Purpose Domains	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt
CO	Comments	Special Purpose Domains	One record per comment per subject	Tabulation	STUDYID, USUBJID, COSEQ	co.xpt
SE	Subject Elements	Special Purpose Domains	One record per actual Element per subject	Tabulation	STUDYID, USUBJID, ETCD, SESTDTC	se.xpt
SV	Subject Visits	Special Purpose Domains	One record per actual visit per subject	Tabulation	STUDYID, USUBJID, VISITNUM	sv.xpt
CM	Concomitant Medications	Interventions	One record per recorded medication occurrence or constant-dosing interval per subject.	Tabulation	STUDYID, USUBJID, CMTRT, CMSTDTC	cm.xpt
EX	Exposure	Interventions	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC	ex.xpt
SU	Substance Use	Interventions	One record per substance type per reported occurrence per subject	Tabulation	STUDYID, USUBJID, SUTRT, SUSTDTC	su.xpt
AE	Adverse Events	Events	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AEDECOD, AESTDTC	ae.xpt
DS	Disposition	Events	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD, DSSTDTC	ds.xpt
MH	Medical History	Events	One record per medical history event per subject	Tabulation	STUDYID, USUBJID, MHDECOD	mh.xpt
DV	Protocol Deviations	Events	One record per protocol deviation per subject	Tabulation	STUDYID, USUBJID, DVTERM, DVSTDTC	dv.xpt

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Dataset	Description	Class	Structure	Purpose	Keys*	Location
CE	Clinical Events	Events	One record per event per subject	Tabulation	STUDYID, USUBJID, CETERM, CESTDTC	ce.xpt
EG	ECG Test Results	Findings	One record per ECG observation per time point per visit per subject	Tabulation	STUDYID, USUBJID, EGTESTCD, VISITNUM, EGTPTREF, EGTPTNUM	eg.xpt
IE	Inclusion/ Exclusion Criteria Not Met	Findings	One record per inclusion/exclusion criterion not met per subject	Tabulation	STUDYID, USUBJID, IETESTCD	ie.xpt
LB	Laboratory Test Results	Findings	One record per analyte per planned time point number per time point reference per visit per subject	Tabulation	STUDYID, USUBJID, LBTESTCD, LBSPEC, VISITNUM, LBTPTRF, LBTPPTNUM	lb.xpt
PE	Physical Examination	Findings	One record per body system or abnormality per visit per subject	Tabulation	STUDYID, USUBJID, PETESTCD, VISITNUM	pe.xpt
QS	Questionnaire	Findings	One record per questionnaire per question per time point per visit per subject	Tabulation	STUDYID, USUBJID, QSCAT, QSTESTCD, VISITNUM, QSTPTREF, QSTPTNUM	qs.xpt
SC	Subject Characteristics	Findings	One record per characteristic per subject	Tabulation	STUDYID, USUBJID, SCTESTCD	sc.xpt
VS	Vital Signs	Findings	One record per vital sign measurement per time point per visit per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VISITNUM, VSTPTREF, VSTPTNUM	vs.xpt
DA	Drug Accountability	Findings	One record per drug accountability finding per subject	Tabulation	STUDYID, USUBJID, DATESTCD, DADTC	da.xpt
MB	Microbiology Specimen	Findings	One record per microbiology specimen finding per time point per visit per subject	Tabulation	STUDYID, USUBJID, MBTESTCD, VISITNUM, MBTPTRF, MBTPPTNUM	mb.xpt
MS	Microbiology Susceptibility	Findings	One record per microbiology susceptibility test (or other organism-related finding) per organism found in MB	Tabulation	STUDYID, USUBJID, MSTESTCD, VISITNUM, MSTPTREF, MSTPTNUM	ms.xpt

Dataset	Description	Class	Structure	Purpose	Keys*	Location
PC	Pharmacokinetic Concentrations	Findings	One record per analyte per planned time point number per time point reference per visit per subject"	Tabulation	STUDYID, USUBJID, PCTESTCD, VISITNUM, PCTPTREF, PCTPTNUM	pc.xpt
PP	Pharmacokinetic Parameters	Findings	One record per PK parameter per time-concentration profile per modeling method per subject	Tabulation	STUDYID, USUBJID, PPTESTCD, PPCAT, VISITNUM, PPTPTREF	pp.xpt
FA	Findings About Events or Interventions	Findings	One record per finding per object per time point per time point reference per visit per subject	Tabulation	STUDYID, USUBJID, FATESTCD, FAOBJ, VISITNUM, FATPTREF, FATPTNUM	fa.xpt
TA	Trial Arms	Trial Design	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt
TE	Trial Elements	Trial Design	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt
TV	Trial Visits	Trial Design	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD	tv.xpt
TI	Trial Inclusion/ Exclusion Criteria	Trial Design	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xpt
TS	Trial Summary	Trial Design	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt
RELREC	Related Records	Special Purpose Datasets	One record per related record, group of records or datasets	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, RELID	relrec.xpt
SUPP-- **	Supplemental Qualifiers for [domain name]	Special-Purpose Datasets	One record per IDVAR, IDVARVAL, and QNAM value per subject	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	supp--.xpt or suppqual.xpt

* Note that the key variables shown in this table are examples only. A sponsor's actual key structure may be different.

** Separate Supplemental Qualifier datasets of the form supp--.xpt are recommended. See *Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain*.

3.2.1.1 Primary Keys

[Table 3.2.1, SDTM Submission Dataset-Definition Metadata Example](#) above shows examples of what a sponsor might submit as variables that comprise the primary key for SDTM datasets. Since the purpose of this column is to aid reviewers in understanding the structure of a dataset, sponsors should list all of the natural keys (see definition below) for the dataset. These keys should define uniqueness for records within a dataset, and may define a record sort order. The naming of these keys should be consistent with the description of the structure in the Structure column. For all the general-observation-class domains (and for some special-purpose domains), the --SEQ variable was created so that a unique record could be identified consistently across all of these domains via its use, along with STUDYID,

USUBJID, DOMAIN. In most domains, --SEQ will be a surrogate key (see definition below) for a set of variables which comprise the natural key. In certain instances, a Supplemental Qualifier (SUPP--) variable might also contribute to the natural key of a record for a particular domain. See **Section 4: 4.1.1.9, Assigning Natural Keys In The Metadata** for how this should be represented, and for additional information on keys.

A *natural key* is a piece of data (one or more columns of an entity) that uniquely identify that entity, and distinguish it from any other row in the table. The advantage of natural keys is that they exist already, and one does not need to introduce a new “unnatural” value to the data schema. One of the difficulties in choosing a natural key is that just about any natural key one can think of has the potential to change. Because they have business meaning, natural keys are effectively coupled to the business, and they may need to be reworked when business requirements change. An example of such a change in clinical trials data would be the addition of a position or location that becomes a key in a new study, but wasn’t collected in previous studies.

A *surrogate key* is a single-part, artificially established identifier for a record. Surrogate key assignment is a special case of derived data, one where a portion of the primary key is derived. A surrogate key is immune to changes in business needs. In addition, the key depends on only one field, so it’s compact. A common way of deriving surrogate key values is to assign integer values sequentially. The --SEQ variable in the SDTM datasets is an example of a surrogate key for most datasets; in some instances, however, --SEQ might be a part of a natural key as a replacement for what might have been a key (e.g. a repeat sequence number) in the sponsor’s database

3.2.1.2 CDISC Submission Value-Level Metadata

In general, the CDISC V3.x Findings data models are closely related to normalized, relational data models in a vertical structure of one record per observation. Since the V3.x data structures are fixed, sometimes information that might have appeared as columns in a more horizontal (denormalized) structure in presentations and reports will instead be represented as rows in an SDTM Findings structure. Because many different types of observations are all presented in the same structure, there is a need to provide additional metadata to describe the expected differences that differentiate, for example, hematology lab results from serum chemistry lab results in terms of data type, standard units and other attributes.

For example, the Vital Signs data domain could contain subject records related to diastolic and systolic blood pressure, height, weight, and body mass index (BMI). These data are all submitted in the normalized SDTM Findings structure of one row per vital signs measurement. This means that there could be five records per subject (one for each test or measurement) for a single visit or time point, with the parameter names stored in the Test Code/Name variables, and the parameter values stored in result variables. Since the unique Test Code/Names could have different attributes (i.e., different origins, roles, and definitions) there would be a need to provide value-level metadata for this information.

The value-level metadata should be provided as a separate section of the Case Report Tabulation Data Definition Specification (Define-XML). This information, which historically has been submitted as a pdf document named “define.pdf”, should henceforth be submitted in an XML format. For details on the CDISC specification for submitting define.xml, see <http://www.cdisc.org/define-xml>

3.2.2 Conformance

Conformance with the SDTMIG Domain Models is minimally indicated by:

- Following the complete metadata structure for data domains
- Following SDTMIG domain models wherever applicable
- Using SDTM-specified standard domain names and prefixes where applicable
- Using SDTM-specified standard variable names
- Using SDTM-specified variable labels for all standard domains
- Using SDTM-specified data types for all variables
- Following SDTM-specified controlled terminology and format guidelines for variables, when provided

- Including all collected and relevant derived data in one of the standard domains, special-purpose datasets, or general-observation-class structures
- Including all Required and Expected variables as columns in standard domains, and ensuring that all Required variables are populated
- Ensuring that each record in a dataset includes the appropriate Identifier and, Timing variables, as well as a Topic variable
- Conforming to all business rules described in the CDISC Notes column and general and domain-specific assumptions.

4 Assumptions for Domain Models

4.1 General Assumptions for All Domains

4.1.1 General Domain Assumptions

4.1.1.1 Review Study Data Tabulation and Implementation Guide

Review the Study Data Tabulation Model as well as this Implementation Guide before attempting to use any of the individual domain models. See the Case Report Tabulation Data Definition Specification (*see Define-XML 2.0*), available on the CDISC website, for information about an xml representation of the define.xml document.

4.1.1.2 Relationship to Analysis Datasets

Specific guidance on preparing analysis datasets can be found in the CDISC Analysis Data Model (ADaM) Implementation Guide and other ADaM documents, available at <http://www.cdisc.org/adam>

4.1.1.3 Additional Timing Variables

Additional Timing variables can be added as needed to a standard domain model based on the three general observation classes except where discouraged in [Assumption 4.1.4.8](#) and specific domain assumptions. Timing variables can be added to special-purpose domains only where specified in the SDTMIG domain model assumptions. Timing variables cannot be added to SUPPQUAL datasets or to RELREC (described in *Section 8 - Representing Relationships and Data*).

4.1.1.4 Order of the Variables

The order of variables in the define.xml must reflect the order of variables in the dataset. The order of variables in the CDISC domain models has been chosen to facilitate the review of the models and application of the models. Variables for the three general observation classes must be ordered with Identifiers first, followed by the Topic, Qualifier, and Timing variables. Within each role, variables must be ordered as shown in *SDTM: Tables 2.2.1, 2.2.2, 2.2.3, 2.2.3.1, 2.2.4, and 2.2.5*.

4.1.1.5 CDISC Core Variables

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

- A **Required** variable is any variable that is basic to the identification of a data record (i.e., essential key variables and a topic variable) or is necessary to make the record meaningful. Required variables must always be included in the dataset and cannot be null for any record.
- An **Expected** variable is any variable necessary to make a record useful in the context of a specific domain. Expected variables may contain some null values, but in most cases will not contain null values for every record. When no data has been collected for an expected variable, however, a null column must still be included in the dataset, and a comment must be included in the define.xml to state that data was not collected.
- A **Permissible** variable should be used in a domain as appropriate when collected or derived. Except where restricted by specific domain assumptions, any SDTM Timing and Identifier variables, and any Qualifier variables from the same general observation class are permissible for use in a domain based on that general observation class. The Sponsor can decide whether a Permissible variable should be included as a column when all values for that variable are null. The sponsor does not have the discretion to exclude permissible variables when they contain data.

4.1.1.6 Additional Guidance on Dataset Naming

SDTM datasets are normally named to be consistent with the domain code; for example, the Demographics dataset (DM) is named dm.xpt (see *Appendix C – Controlled Terminology* regarding Controlled Terminology information

that includes a list of standard domain codes). Exceptions to this rule are described in [Section 4.1.1.7, Splitting Domains](#) for general-observation-class datasets and in [Section 8 - Representing Relationships and Data](#) for the RELREC and SUPP-- datasets.

In some cases, sponsors may need to define new custom domains other than those represented in the SDTMIG or found in the CDISC Terminology [as described in [Appendix C – Controlled Terminology](#)], and may be concerned that CDISC domain codes defined in the future will conflict with those they choose to use. To eliminate any risk of a sponsor using a name that CDISC later determines to have a different meaning, domain codes beginning with the letters X, Y, or Z have been reserved for the creation of custom domains. Any letter or number may be used in the second position. Note the use of codes beginning with X, Y, or Z is optional, and not required for custom domains.

4.1.1.7 Splitting Domains

Sponsors may choose to split a domain of topically related information into physically separate datasets. In such cases, one of two approaches should be implemented:

- 1) For a domain based on a general observation class, splitting should be according to values in --CAT (which must not be null).
- 2) The Findings About (FA) domain [[Section 6.4 - FA Domain](#)] can be split either by --CAT values (per the bullet above) or relative to the parent domain of the value in --OBJ. For example, FACM would store Findings About CM records. See [Section 6.4: 6.4.2, Naming FINDINGS ABOUT Domains](#) for more details.

The following rules must be adhered to when splitting a domain into separate datasets to ensure they can be appended back into one domain dataset:

- 1) The value of DOMAIN must be consistent across the separate datasets as it would have been if they had not been split (e.g., QS, FA).
- 2) All variables that require a domain prefix (e.g., --TESTCD, --LOC) must use the value of DOMAIN as the prefix value (e.g., QS, FA).
- 3) --SEQ must be unique within USUBJID for all records across all the split datasets. If there are 1000 records for a USUBJID across the separate datasets, all 1000 records need unique values for --SEQ.
- 4) When relationship datasets (e.g., SUPPxx, FAxx, CO, RELREC) relate back to split parent domains, IDVAR should generally be --SEQ. When IDVAR is a value other than --SEQ (e.g., --GRPID, --REFID, --SPID), care should be used to ensure that the parent records across the split datasets have unique values for the variable specified in IDVAR, so that related children records do not accidentally join back to incorrect parent records.
- 5) Permissible variables included in one split dataset need not be included in all split datasets. Should the datasets be appended in SAS, permissible variables not used in some split datasets will have null values in the appended datasets. Care is advised, however, when considering variable order. Should a permissible variable used in one (or more) split datasets not be included in the first dataset used in a SAS Set statement, the order of variables could be compromised.
- 6) Split dataset names can be up to four characters in length. For example, if splitting by --CAT, then dataset names would be the domain name plus up to two additional characters (e.g., QS36 for SF-36). If splitting Findings About by parent domain, then the dataset name would be the domain name plus the two-character domain code describing the parent domain code (e.g., FACM). The four-character dataset-name limitation allows the use of a Supplemental Qualifier dataset associated with the split dataset.
- 7) Supplemental Qualifier datasets for split domains would also be split. The nomenclature would include the additional one-to-two characters used to identify the split dataset (e.g., SUPPQS36, SUPPFACM). The value of RDOMAIN in the SUPP-- datasets would be the two-character domain code (e.g., QS, FA).
- 8) In RELREC, if a dataset-level relationship is defined for a split Findings About domain, then RDOMAIN may contain the four-character dataset name, as shown in the following example.

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC	CM		CMSPID		ONE	1
ABC	FACM		FASPID		MANY	1

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- 9) See the SDTM Metadata Implementation Guide for guidance on how to represent the metadata for a set of split domain datasets in the define.xml.

Note that submission of split SDTM domains may be subject to additional dataset splitting conventions as defined by regulators via technical specifications (e.g., Study Data Specifications) and/or as negotiated with regulatory reviewers.

4.1.1.7.1 Example of Splitting Questionnaires

This example shows the split QS domain data into three datasets: Clinical Global Impression (QSCG), Cornell Scale for Depression in Dementia (QSCS) and Mini Mental State Examination (QSM). Each dataset represents a subset of the QS domain data and has only one value of QSCAT.

QS Domains

qscg.xpt (Clinical Global Impressions)

Row	STUDYID	DOMAIN	USUBJID	QSEQ	QSPID	QSTESTCD	QSTEST	QSCAT
1	CDISC01	QS	CDISC01.100008	1	CGI-CGI-I	CGIGLOB	Global Improvement	Clinical Global Impressions
2	CDISC01	QS	CDISC01.100008	2	CGI-CGI-I	CGIGLOB	Global Improvement	Clinical Global Impressions
3	CDISC01	QS	CDISC01.100014	1	CGI-CGI-I	CGIGLOB	Global Improvement	Clinical Global Impressions
4	CDISC01	QS	CDISC01.100014	2	CGI-CGI-I	CGIGLOB	Global Improvement	Clinical Global Impressions

Row	QSORRES	QSSTRESC	QSSTRESN	QSBFLF	VISITNUM	VISIT	VISITDY	QSDTC	QSDY
1 (cont)	No change	4	4		3	WEEK 2	15	2003-05-13	15
2 (cont)	Much Improved	2	2		10	WEEK 24	169	2003-10-13	168
3 (cont)	Minimally Improved	3	3		3	WEEK 2	15	2003-10-31	17
4 (cont)	Minimally Improved	3	3		10	WEEK 24	169	2004-03-30	168

qscs.xpt (Cornell Scale for Depression in Dementia)

Row	STUDYID	DOMAIN	USUBJID	QSEQ	QSPID	QSTESTCD	QSTEST	QSCAT
1	CDISC01	QS	CDISC01.100008	3	CSDD-01	CSDD01	Anxiety	Cornell Scale for Depression in Dementia
2	CDISC01	QS	CDISC01.100008	23	CSDD-01	CSDD01	Anxiety	Cornell Scale for Depression in Dementia
3	CDISC01	QS	CDISC01.100014	3	CSDD-01	CSDD01	Anxiety	Cornell Scale for Depression in Dementia
4	CDISC01	QS	CDISC01.100014	28	CSDD-06	CSDD06	Retardation	Cornell Scale for Depression in Dementia

Row	QSORRES	QSSTRESC	QSSTRESN	QSBFLF	VISITNUM	VISIT	VISITDY	QSDTC	QSDY
1 (cont)	Severe	2	2		1	SCREEN	-13	2003-04-15	-14
2 (cont)	Severe	2	2	Y	2	BASELINE	1	2003-04-29	1
3 (cont)	Severe	2	2		1	SCREEN	-13	2003-10-06	-9
4 (cont)	Mild	1	1	Y	2	BASELINE	1	2003-10-15	1

qsmm.xpt (Mini Mental State Examination)

Row	STUDYID	DOMAIN	USUBJID	QSEQ	QSPID	QSTESTCD	QSTEST	QSCAT
1	CDISC01	QS	CDISC01.100008	81	MMSE-A.1	MMSEA1	Orientation Time Score	Mini Mental State Examination
2	CDISC01	QS	CDISC01.100008	88	MMSE-A.1	MMSEA1	Orientation Time Score	Mini Mental State Examination
3	CDISC01	QS	CDISC01.100014	81	MMSE-A.1	MMSEA1	Orientation Time score	Mini Mental State Examination
4	CDISC01	QS	CDISC01.100014	88	MMSE-A.1	MMSEA1	Orientation Time score	Mini Mental State Examination

Row	QSORRES	QSSTRESC	QSSTRESN	QSBFLF	VISITNUM	VISIT	VISITDY	QSDTC	QSDY
1 (cont)	4	4	4		1	SCREEN	-13	2003-04-15	-14
2 (cont)	3	3	3	Y	2	BASELINE	1	2003-04-29	1
3 (cont)	2	2	2		1	SCREEN	-13	2003-10-06	-9
4 (cont)	2	2	2	Y	2	BASELINE	1	2003-10-15	1

SUPPOS Domains

suppqscg.xpt: Supplemental Qualifiers for QSCG

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	CDISC01	QS	CDISC01.100008	QSCAT	Clinical Global Impressions	QSLANG	Questionnaire Language	GERMAN	CRF	
2	CDISC01	QS	CDISC01.100014	QSCAT	Clinical Global Impressions	QSLANG	Questionnaire Language	FRENCH	CRF	

suppqscs.xpt: Supplemental Qualifiers for QSCS

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	CDISC01	QS	CDISC01.100008	QSCAT	Cornell Scale for Depression in Dementia	QSLANG	Questionnaire Language	GERMAN	CRF	
2	CDISC01	QS	CDISC01.100014	QSCAT	Cornell Scale for Depression in Dementia	QSLANG	Questionnaire Language	FRENCH	CRF	

suppqsmm.xpt: Supplemental Qualifiers for QSMM

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	CDISC01	QS	CDISC01.100008	QSCAT	Mini Mental State Examination	QSLANG	Questionnaire Language	GERMAN	CRF	
2	CDISC01	QS	CDISC01.100014	QSCAT	Mini Mental State Examination	QSLANG	Questionnaire Language	FRENCH	CRF	

4.1.1.8 Origin Metadata

4.1.1.8.1 Origin Metadata for Variables

The Origin column of the define.xml is used to indicate where the data originated. Its purpose is to unambiguously communicate to the reviewer whether data was collected on a CRF (and thus should be traceable to an annotated CRF), derived (and thus traceable to some derivation algorithm), or assigned by some subjective process (and thus traceable to some external evaluator). The SDTMIG defines the following controlled terms for specifying Origin (note that other values may be defined by other standards):

CRF: The designation of "CRF" (along with a reference) as an origin in the define.xml means that data was collected as part of a CRF and that there is an annotated CRF associated with the variable. Sponsors may specify additional details about the origin that may be helpful to the Reviewer (e.g., electronic diary) in the Comments section of the define.xml. An origin of "CRF" includes information that is preprinted on the CRF (e.g., "RESPIRATORY SYSTEM DISORDERS" for MHCAT).

eDT: The designation of "eDT" as an origin in the define.xml means that the data are received via an electronic Data Transfer (eDT) and usually does not have associated annotations. An origin of eDT refers to data collected via data streams such as laboratory, ECG, or IVRS. Sponsors may specify additional details about the origin that may be helpful to the Reviewer in the Comments section of the define.xml.

Derived: Derived data are not directly collected on the CRF but are calculated by an algorithm or reproducible rule, which is dependent upon other data values. This algorithm is applied across all values and may reference other SDTM datasets. The derivation is assumed to be performed by the Sponsor. This does not apply to derived lab test results performed directly by labs (or by devices).

Examples illustrating the distinction between collected and derived values include the following:

- A value derived by an eCRF system from other entered fields has an origin of "Derived," since the sponsor controls the derivation.
- A value derived from collected data by the sponsor, or a CRO working on their behalf, has an origin of "Derived."
- A value derived by an investigator and written/entered on a CRF has an origin of "CRF" (along with a reference) rather than "derived".
- A value derived by a vendor (e.g., a central lab) according to their procedures is considered collected rather than derived, and would have an origin of "eDT".

Assigned: A value that is determined by individual judgment (by an evaluator other than the subject or investigator), rather than collected as part of the CRF or derived based on an algorithm. This may include third party attributions by an adjudicator. Coded terms that are supplied as part of a coding process (as in --DECOD) are considered to have an Origin of “Assigned”. Values that are set independently of any subject-related data values in order to complete SDTM fields such as DOMAIN and --TESTCD are considered to have an Origin of “Assigned”.

Protocol: A value that is defined as part of the Trial Design preparation [see Section 7 – Trial Design Datasets]. An example would be VSPOS (Vital Signs Position), which may be specified only in the protocol and not appear on a CRF.

The term “Sponsor Defined” was used in earlier versions of the SDTMIG to advise the Sponsor to supply the appropriate Origin value in the metadata. The text “Sponsor Defined” was not intended to be used in the define.xml and is no longer used in V3.1.2 and later.

4.1.1.8.2 Origin Metadata for Records

Sponsors are cautioned to recognize that an Origin of “Derived” means that all values for that variable were derived, and that “CRF” (along with a reference) means that all were collected. In some cases, both collected and derived values may be reported in the same field. For example, some records in a Findings dataset such as QS contain values collected from the CRF and other records may contain derived values such as a total score. When both derived and collected values are reported in a field, the value-level metadata origin will indicate at the test level if the value is “Derived” or “CRF” and the variable-level metadata origin will list all types for that variable separated by commas (e.g., “Derived, CRF”).

4.1.1.9 Assigning Natural Keys in the Metadata

Section 3: 3.2, Using the CDISC Domain Models in Regulatory Submissions - Dataset Metadata indicates that a sponsor should include in the metadata the variables that contribute to the natural key for a domain. In a case where a dataset includes a mix of records with different natural keys, the natural key that provides the most granularity is the one that should be provided. The following examples are illustrations of how to do this, and include a case where a Supplemental Qualifier variable is referenced because it forms part of the natural key.

Physical Examination (PE) domain example:
Sponsor A chooses the following natural key for the PE domain:

STUDYID, USUBJID, VISTNUM, PETESTCD

Sponsor B collects data in such a way that the location (PELOC) and method (PEMETHOD) variables need to be included in the natural key to identify a unique row, but they do not collect a visit variable; instead they use the visit date (PEDTC) to sequence the data. Sponsor B then defines the following natural key for the PE domain.

STUDYID, USUBJID, PEDTC, PETESTCD, PELOC, PEMETHOD

In certain instances a Supplemental Qualifier variable (i.e., a QNAM value, see **Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain**) might also contribute to the natural key of a record, and therefore needs to be referenced as part of the natural key for a domain. The important concept here is that a domain is not limited by physical structure. A domain may be comprised of more than one physical dataset, for example the main domain dataset and its associated Supplemental Qualifiers dataset. Supplemental Qualifiers variables should be referenced in the natural key by using a two-part name. The word QNAM must be used as the first part of the name to indicate that the contributing variable exists in a dataset (and this can be either a domain-specific SUPP-- dataset or the general SUPPQUAL dataset) and the second part is the value of QNAM that ultimately becomes a column reference (e.g., QNAM.XVAR when the SUPP-- record has a QNAM of “XVAR”) when the SUPPQUAL records are joined on to the main domain dataset.

Continuing with the PE domain example above, Sponsor B might have used ultrasound as a method of measurement and might have collected additional information such as the makes and models of ultrasound equipment employed. The sponsor considers the make and model information to be essential data that contributes to the uniqueness of the

test result, and so creates Supplemental Qualifier variables for make (QNAM=PEMAKE) and model (QNAM=PEMODEL). The natural key is then defined as follows (this example is for displaying natural keys only actual data modeling should follow the SDTMIG-MD):

STUDYID, USUBJID, PEDTC, PETESTCD, PELOC, PEMETHOD, QNAM.PEMAKE, QNAM.PEMODEL

This approach becomes very useful in a Findings domain when a sponsor might choose to employ generic --TESTCD values rather than compound --TESTCD values. The use of generic test codes helps to create distinct lists of manageable controlled terminology for --TESTCD. In studies where multiple repetitive tests or measurements are being made, for example in a rheumatoid arthritis study where repetitive measurements of bone erosion in the hands and wrists might be made using both X-ray and MRI equipment, one approach to recording this data might be to create an individual --TESTCD value for each measurement. Taking just the phalanges, a sponsor might want to express the following in a test code in order to make it unique:

- Left or Right hand
- Phalange position (proximal / distal / middle)
- Rotation of the hand
- Method of measurement (X-ray / MRI)
- Machine Make
- Machine Model

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

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

As a result, the preferred approach would be to use a generic (or simple) test code that requires associated qualifier variables to fully express the test detail. Using this approach in the above example, a generic --TESTCD value might be “EROSION” and the additional components of the compound test codes discussed above would be represented in a number of distinct qualifier variables. These may include domain variables (--LOC, --METHOD, etc.) and Supplemental Qualifier variables (QNAM.MAKE, QNAM.MODEL, etc.). Expressing the natural key becomes very important in this situation in order to communicate the variables that contribute to the uniqueness of a test.

If a generic --TESTCD was used the following variables would be used to fully describe the test. The test is “EROSION”, the location is “Left MCP I”, the method of measurement is “Ultrasound”, the make of the ultrasound machine is “ACME” and the model of the ultrasound machine is “u 2.1”. This domain includes both domain variables and Supplemental Qualifier variables that contribute to the natural key of each row and to describe the uniqueness of the test.

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

4.1.2 General Variable Assumptions

4.1.2.1 Variable-Naming Conventions

SDTM variables are named according to a set of conventions, using fragment names (defined in *Appendix D - CDISC Variable-Naming Fragments*). Variables with names ending in “CD” are “short” versions of associated variables that do not include the “CD” suffix (e.g., --TESTCD is the short version of --TEST).

Values of --TESTCD must be limited to 8 characters, and cannot start with a number, nor can they contain characters other than letters, numbers, or underscores. This is to avoid possible incompatibility with SAS V5 Transport files.

This limitation will be in effect until the use of other formats (such as SDS-XML) becomes acceptable to regulatory authorities.

QNAM serves the same purpose as --TESTCD within supplemental qualifier datasets, and so values of QNAM are subject to the same restrictions as values of --TESTCD.

Values of other “CD” variables are not subject to the same restrictions as --TESTCD.

- ETCD (the companion to ELEMENT) and TSPARMCD (the companion to TSPARM) are limited to 8 characters and do not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that they will need to serve as variable names.
- ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than for other “short” variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20. This same rule applies to the ACTARMCD variable also.

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

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

4.1.2.2 Two-Character Domain Identifier

In order to minimize the risk of difficulty when merging/joining domains for reporting purposes, the two-character Domain Identifier is used as a prefix in most variable names.

Special-Purpose domains [*see Section 5 – Models for Special-Purpose Domains*], Standard domains [*see Section 6 – Domain Models Based on the General Observation Classes*], Trial Design domains [*see Section 7 - Trial Design Datasets*] and Relationship datasets [*see Section 8 - Representing Relationships and Data*] already specify the complete variable names, so no action is required. When creating custom domains based on the General Observation Classes, sponsors must replace the -- (two hyphens) prefix in the General Observation Class, Timing, and Identifier variables with the two-character Domain Identifier (DOMAIN) variable value for that domain/dataset. The two-character domain code is limited to A to Z for the first character, and A-Z, 0 to 9 for the 2nd character. No special characters are allowed for compatibility with SAS version 5 transport files, and with file naming for the Electronic Common Technical Document (eCTD).

The philosophy applied to determine which variable names use a prefix was that all variable names are prefixed with the Domain Identifier in which they originate except the following:

- a. Required Identifiers (STUDYID, DOMAIN, USUBJID)
- b. Commonly used grouping and merge Keys (VISIT, VISITNUM, VISITDY), and many of the variables in trial design (such as ELEMENT and ARM)
- c. All Demographics domain (DM) variables other than DMDTC and DMDY
- d. All variables in RELREC and SUPQUAL, and some variables in Comments and Trial Design datasets.

Required Identifiers are not prefixed because they are usually used as keys when merging/joining observations. The --SEQ and the optional Identifiers --GRPID and --REFID are prefixed because they may be used as keys when relating observations across domains.

4.1.2.3 Use of “Subject” and USUBJID

“Subject” should be used where applicable to generically refer to both “patients” and “healthy volunteers” in order to be consistent with the recommendation in FDA guidance. The term “Subject” should be used consistently in all labels and Define-XML comments. To identify a subject uniquely across all studies for all applications or submissions involving the product, a unique identifier (USUBJID) should be assigned and included in all datasets.

The unique subject identifier (USUBJID) is required in all datasets containing subject-level data. USUBJID values must be unique for each trial participant (subject) across all trials in the submission. This means that no two (or more) subjects, across all trials in the submission, may have the same USUBJID. Additionally, the same person who participates in multiple clinical trials (when this is known) must be assigned the same USUBJID value in all trials.

The below dm.xpt sample rows illustrate a single subject who participates in two studies, first in ACME01 and later in ACME14. Note that this is only one example of the possible values for USUBJID. CDISC does not recommend any specific format for the values of USUBJID, only that the values need to be unique for all subjects in the submission, and across multiple submissions for the same compound. Many sponsors concatenate values for the Study, Site and Subject into USUBJID, but this is not a requirement. It is acceptable to use any format for USUBJID, as long as the values are unique across all subjects per FDA guidance.

Study ACME01 dm.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	SITEID	INVNAM
ACME01	DM	ACME01-05-001	001	05	John Doe

Study ACME14 dm.xpt

STUDYID	DOMAIN	USUBJID	SUBJID	SITEID	INVNAM
ACME14	DM	ACME01-05-001	017	14	Mary Smith

4.1.2.4 Case Use of Text in Submitted Data

It is recommended that text data be submitted in upper case text. Exceptions may include long text data (such as comment text); values of --TEST in Findings datasets (which may be more readable in title case if used as labels in transposed views); and certain controlled terminology [see [Section 4.1.3.2, Controlled Terminology Text Case](#)] that are already in mixed case. The case used in the text data must match the case used in the Controlled Terminology provided in the Define-XML.

4.1.2.5 Convention for Missing Values

Missing values for individual data items should be represented by nulls. This is a change from previous versions of the SDTMIG, which allowed sponsors to define their conventions for missing values. Conventions for representing observations not done using the SDTM --STAT and --REASND variables are addressed in [Section 4.1.5.1.2, Tests Not Done](#) and the individual domain models.

4.1.2.6 Grouping Variables and Categorization

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

1. Hierarchy of Grouping Variables

```
STUDYID
DOMAIN
  --CAT
    --SCAT
      USUBJID
        --GRPID
        --LNKID
        --LNKGRP
```

2. How Grouping Variables Group Data

A. For the subject

1. All records with the same USUBJID value are a group of records that describe that subject.

B. Across subjects (records with different USUBJID values)

1. All records with the same STUDYID value are a group of records that describe that study
2. All records with the same DOMAIN value are a group of records that describe that domain
3. --CAT (Category) and --SCAT (Sub-category) values further subset groups within the domain. Generally, --CAT/--SCAT values have meaning within a particular domain. However, it is possible to use the same values for --CAT/--SCAT in related domains (e.g., MH and AE). When values are used across domains, the meanings should be the same. Examples of where --CAT/--SCAT may have meaning across domains/datasets:
 - a. Some limited cases where they will have meaning across domains within the same general observation class, because those domains contain similar conceptual information. Adverse Events (AE), Medical History (MH) and Clinical Events (CE), for example, are conceptually the same data, the only differences being when the event started relative to the study start and whether the event is considered a regulatory reportable adverse event in the study. Neurotoxicities collected in Oncology trials both as separate Medical History CRFs (MH domain) and Adverse Event CRFs (AE domain) could both identify/collect "Paresthesia of the left Arm." In both domains, the --CAT variable could have the value of NEUROTOXICITY.
 - b. Cases where multiple datasets are necessary to capture data in the same domain. As an example, perhaps the existence, start and stop date of "Paresthesia of the left Arm" is reported as an Adverse Event (AE domain), but the severity of the event is captured at multiple visits and recorded as Findings About (FA dataset). In both cases the --CAT variable could have a value of NEUROTOXICITY.
 - c. Cases where multiple domains are necessary to capture data that was collected together and have an implicit relationship, perhaps identified in the Related Records (RELREC) special purpose dataset. Stress Test data collection, for example, may capture the following:
 - i. Information about the occurrence, start, stop, and duration of the test in an Events or Interventions custom general observation class dataset
 - ii. Vital Signs recorded during the stress test (VS domain)
 - iii. Treatments (e.g., oxygen) administered during the stress test (in an Interventions domain).

In such cases, the data collected during the stress tests recorded in three separate domains may all have --CAT/--SCAT values (STRESS TEST) that identify this data was collected during the stress test.

C. Within subjects (records with the same USUBJID values)

1. --GRPID values further group (subset) records within USUBJID. All records in the same domain with the same --GRPID value are a group of records within USUBJID. Unlike --CAT and --SCAT, --GRPID values are not intended to have any meaning across subjects and are usually assigned during or after data collection.
2. Although --SPID and --REFID are Identifier variables, usually not considered to be grouping variables, they may have meaning across domains.
3. --LNKID is a grouping identifier used to link a feature initially recorded as a result in one findings domain to assessments of that feature in another findings domain essentially forming a one-to-many relationship. LNKID values group records within USUBJID.
4. --LNKGRP is a grouping identifier used to identify a group of assessment results in one domain that are evaluated, as a group, and contribute to a (summary) result in another domain essentially forming a many-to-one relationship.
5. --LNKID and --LNKGRP express values that are used to link records in separate domains. As such these variables are often used in IDVAR in a RELREC relationship when there is a dataset to dataset relationship.

3. Differences between Grouping Variables

The primary distinctions between --CAT/--SCAT and --GRPID are:

- --CAT/--SCAT are known (identified) about the data before it is collected
- --CAT/--SCAT values group data across subjects
- --CAT/--SCAT may have some controlled terminology
- --GRPID is usually assigned during or after data collection at the discretion of the Sponsor
- --GRPID groups data only within a subject
- --GRPID values are sponsor-defined, and will not be subject to controlled terminology.

Therefore, data that would be the same across subjects is usually more appropriate in --CAT/--SCAT, and data that would vary across subjects is usually more appropriate in --GRPID. For example, a Concomitant Medication administered as part of a known combination therapy for all subjects (Mayo Clinic Regimen for example) would more appropriately use --CAT/--SCAT to identify the medication as part of that regimen. 'Groups of medications recorded on an SAE form as treatments for the SAE would more appropriately use --GRPID as the groupings are likely to differ across subjects.

In domains based on the Findings general observation class, the --RESCAT variable can be used to categorize results after the fact. --CAT and --SCAT by contrast, are generally pre-defined by the Sponsor or used by the investigator at the point of collection, not after assessing the value of Findings results.

4.1.2.7 Submitting Free Text from the CRF

Sponsors often collect free text data on a CRF to supplement a standard field. This often occurs as part of a list of choices accompanied by "Other, specify." The manner in which these data are submitted will vary based on their role.

4.1.2.7.1 "Specify" Values for Non-Result Qualifier Variables

When free-text information is collected to supplement a standard non-result Qualifier field, the free-text value should be placed in the SUPP-- dataset described in **Section 8: 8.4, Relating Non-Standard Variables Values to a Parent Domain**. When applicable, controlled terminology should be used for SUPP-- field names (QNAM) and their associated labels (QLABEL) (see **Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain** and **Appendix C2 - Supplemental Qualifier Name Codes**). For example, when a description of "Other Medically Important Serious Adverse Event" category is collected on a CRF, the free text description should be stored in the SUPPAE dataset.

- AESMIE=Y
- SUPPAE QNAM=AESOSP, QLABEL= Other Medically Important SAE, QVAL=HIGH RISK FOR ADDITIONAL THROMBOSIS

Another example is a CRF that collects reason for dose adjustment with additional free-text description:

Reason for Dose Adjustment (EXADJ)	Describe
<input type="checkbox"/> Adverse event	_____
<input type="checkbox"/> Insufficient response	_____
<input type="checkbox"/> Non-medical reason	_____

The free text description should be stored in the SUPPEX dataset.

- EXADJ=NONMEDICAL REASON
- SUPPEX QNAM=EXADJDSC, QLABEL= Reason For Dose Adjustment, QVAL=PATIENT MISUNDERSTOOD INSTRUCTIONS
 - Note that QNAM references the "parent" variable name with the addition of "DSC". Likewise, the label is a modification of the parent variable label.

- 2) If the sponsor wishes to maintain controlled terminology in the standard result field, but will expand the terminology based on values seen in the specify field, then the free text is placed in --ORRES and the value of --STRESC will reflect the sponsor's coding decision.
 - SCTEST=Eye Color, SCORRES=BLUEISH GRAY, SCSTRESC=GRAY
- 3) If the sponsor does not require that controlled terminology be maintained, the verbatim value will be copied to --STRESC.
 - SCTEST=Eye Color, SCORRES=BLUEISH GRAY, SCSTRESC=BLUEISH GRAY

Note that rules for the use of “Other, Specify” for the Result Qualifier variable, --OBJ, is discussed in **Section 6.4: 6.4.3, Variables Unique to FINDINGS ABOUT**.

4.1.2.7.3 “Specify” Values for Topic Variables

Interventions: If a list of specific treatments is provided along with “Other, Specify”, --TRT should be populated with the name of the treatment found in the specified text. If the sponsor wishes to distinguish between the pre-specified list of treatments and those recorded under “Other, Specify,” the --PRES variable could be used. For example:

Indicate which of the following concomitant medications was used to treat the subject's headaches:

- Acetaminophen
- Aspirin
- Ibuprofen
- Naproxen
- Other: _____

If ibuprofen and diclofenac were reported, the CM dataset would include the following:

- CMTRT=IBUPROFEN, CMPRESP=Y
- CMTRT=DICLOFENAC, CMPRESP is null.

Events: “Other, Specify” for Events may be handled similarly to Interventions. --TERM should be populated with the description of the event found in the specified text and --PRES could be used to distinguish between pre-specified and free text responses.

Findings: “Other, Specify” for tests may be handled similarly to Interventions. --TESTCD and --TEST should be populated with the code and description of the test found in the specified text. If specific tests are not prespecified on the CRF and the investigator has the option of writing free text for tests, then the name of the test would have to be coded to ensure that all --TESTCD and --TEST values are controlled terminology and are not free text. For example, a lab CRF has tests of Hemoglobin, Hematocrit and “Other, specify”. The value the investigator wrote for “Other, specify” is Prothrombin time with an associated result and units. The sponsor would submit the controlled terminology for this test which is LBTESTCD = PT and LBTEST = Prothrombin Time.

4.1.2.8 Multiple Values for a Variable

4.1.2.8.1 Multiple Values for an Intervention or Event Topic Variable

If multiple values are reported for a topic variable (i.e., --TRT in an Interventions general-observation-class dataset or --TERM in an Events general-observation-class dataset), it is assumed that the sponsor will split the values into multiple records or otherwise resolve the multiplicity as per the sponsor's standard data management procedures. For example, if an adverse event term of “Headache and Nausea” or a concomitant medication of “Tylenol and Benadryl” is reported, sponsors will often split the original report into separate records and/or query the site for clarification. By the time of submission, the datasets should be in conformance with the record structures described in the SDTMIG. Note that the Disposition dataset (DS) is an exception to the general rule of splitting multiple topic values into separate records. For DS, one record for each disposition or protocol milestone is permitted according to the domain structure. For cases of multiple reasons for discontinuation see **Section 6.2 - DS Domain: Assumption 5, DS - Assumptions for DISPOSITION Domain Model** for additional information.

4.1.2.8.2 Multiple Values for a Findings Result Variable

If multiple result values (--ORRES) are reported for a test in a Findings class dataset, multiple records should be submitted for that --TESTCD. Example:

- EGTESTCD=RHYRATE, EGTEST=Rhythm and Rate, EGORRES=ATRIAL FIBRILLATION
- EGTESTCD=RHYRATE, EGTEST=Rhythm and Rate, EGORRES=ATRIAL FLUTTER

Note that in this case, the sponsor’s operational database may have a result-sequence variable as part of the natural key. Some sponsors may elect to keep this variable in a Supplemental Qualifier record, while others may decide to use --SPID or --SEQ to replace it. Dependent variables such as result Qualifiers should never be part of the natural key.

4.1.2.8.3 Multiple Values for a Non-Result Qualifier Variable

The SDTM permits one value for each Qualifier variable per record. If multiple values exist (e.g., due to a “Check all that apply” instruction on a CRF), then the value for the Qualifier variable should be “MULTIPLE” and SUPP-- should be used to store the individual responses. It is recommended that the SUPP-- QNAM value reference the corresponding standard domain variable with an appended number or letter. In some cases, the standard variable name will be shortened to meet the 8 character variable name requirement or it may be clearer to append a meaningful character string as shown in the 2nd AE example below where the 1st 3 characters of the drug name are appended. Likewise the QLABEL value should be similar to the standard label. The values stored in QVAL should be consistent with the controlled terminology associated with the standard variable. See **Section 8: 8.4, Relating Non-Standard Variables Values to a Parent Domain** for additional guidance on maintaining appropriately unique QNAM values. The following example includes selected variables from the ae.xpt and suppaexpt datasets for a rash whose locations are the face, neck, and chest.

AE Dataset

AETERM	AELOC
RASH	MULTIPLE

SUPPAE Dataset

QNAM	QLABEL	QVAL
AELOC1	Location of the Reaction 1	FACE
AELOC2	Location of the Reaction 2	NECK
AELOC3	Location of the Reaction 3	CHEST

In some cases, values for QNAM and QLABEL more specific than those above may be needed. For example, a sponsor might conduct a study with two study drugs (e.g., open-label study of Abcicin + Xyzamin), and may require the investigator assess causality and describe action taken for each drug for the rash:

AE Dataset

AETERM	AEREL	AEACN
RASH	MULTIPLE	MULTIPLE

SUPPAE Dataset

QNAM	QLABEL	QVAL
AERELABC	Causality of Abcicin	POSSIBLY RELATED
AERELXYZ	Causality of Xyzamin	UNLIKELY RELATED
AEACNABC	Action Taken with Abcicin	DOSE REDUCED
AEACNXYZ	Action Taken with Xyzamin	DOSE NOT CHANGED

In each of the above examples, the use of SUPPAE should be documented in the metadata and the annotated CRF. The controlled terminology used should be documented as part of value-level metadata.

If the sponsor has clearly documented that one response is of primary interest (e.g., in the CRF, protocol, or analysis plan), the standard domain variable may be populated with the primary response and SUPP-- may be used to store the secondary response(s). For example, if Abcicin is designated as the primary study drug in the example above:

AE Dataset

AETERM	AEREL	AEACN
RASH	POSSIBLY RELATED	DOSE REDUCED

SUPPAE Dataset

QNAM	QLABEL	QVAL
AERELX	Causality of Xyzamin	UNLIKELY RELATED
AEACNX	Action Taken with Xyzamin	DOSE NOT CHANGED

Note that in the latter case the label for standard variables AEREL and AEACN will have no indication that they pertain to Abcicin. This association must be clearly documented in the metadata and annotated CRF.

4.1.2.9 Variable Lengths

Very large transport files have become an issue for FDA to process. One of the main contributors to the large file sizes has been sponsors using the maximum length of 200 for character variables. To help rectify this situation:

- The maximum SAS Version 5 character variable length of 200 characters should not be used unless necessary.
- Sponsors should consider the nature of the data, and apply reasonable, appropriate lengths to variables. For example:
 - The length of flags will always be 1
 - –TESTCD and IDVAR will never be more than 8, so length can always be set to 8
 - The length for variables which use controlled terminology can be set to the length of the longest term.

4.1.3 Coding and Controlled Terminology Assumptions

PLEASE NOTE: Examples provided in the column “CDISC Notes” are only examples and not intended to imply controlled terminology. Please check current controlled terminology at this link:

<http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>

4.1.3.1 Types of Controlled Terminology

As of V3.1.2, controlled terminology is represented one of three ways:

- A single asterisk when there is no specific CT available at the current time, but the SDS Team expects that sponsors may have their own CT and/or the CDISC Controlled Terminology Team may be developing CT.
- A list of controlled terms for the variable when values are not yet maintained externally
- The name of an external codelist whose values can be found via the hyperlinks in either the domain or as described in *Appendix C – Controlled Terminology*.

In addition, the “Controlled Terms Codelist or Format” column has been used to indicate a common format such as ISO 8601.

4.1.3.2 Controlled Terminology Text Case

It is recommended that controlled terminology be submitted in upper case text for all cases other than those described as exceptions below. Deviations to this rule should be described in the define.xml.

- a. If the external reference for the controlled terminology is not in upper case then the data should conform to the case prescribed in the external reference (e.g., MedDRA and LOINC).
- b. Units, which are considered symbols rather than abbreviated text (e.g., mg/dL).

The text case used in the definition of the controlled terminology in the Define-XML should match the text case used in the data.

4.1.3.3 Controlled Terminology Values

The controlled terminology or a link to the controlled terminology should be included in the define.xml wherever applicable. All values in the permissible value set for the study should be included, whether they are represented in the submitted data or not. Note that a null value should not be included in the permissible value set. A null value is

implied for any list of controlled terms unless the variable is “Required” [see [Section 4.1.1.5, CDISC Core Variables](#)].

4.1.3.4 Use of Controlled Terminology and Arbitrary Number Codes

Controlled terminology or decoded text should be used instead of arbitrary number codes in order to reduce ambiguity for submission reviewers. For example, for concomitant medications, the verbatim term and/or dictionary term should be presented, rather than numeric codes. Separate code values may be submitted as Supplemental Qualifiers and may be necessary in analysis datasets.

4.1.3.5 Storing Controlled Terminology for Synonym Qualifier Variables

- For events such as AEs and Medical History, populate --DECOD with the dictionary’s preferred term and populate --BODSYS with the preferred body system name. If a dictionary is multi-axial, the value in --BODSYS should represent the system organ class (SOC) used for the sponsor’s analysis and summary tables, which may not necessarily be the primary SOC. Populate --SOC with the dictionary derived primary SOC. When the primary SOC was used for analysis the values of --BODSYS and --SOC will be the same.
- If the MedDRA dictionary was used to code events the intermediate levels in the MedDRA hierarchy should also be represented in the dataset. A pair of variables has been defined for each of the remaining levels of the hierarchy, one to represent the text description and the other to represent the code value associated with it. For example, --LLT should be used to represent the Lowest Level Term text description and --LLTCD should be used to represent the Lowest Level Term code value.
- For concomitant medications, populate CMDECOD with the drug’s generic name and populate CMCLAS with the drug class used for the sponsor’s analysis and summary tables. If coding to multiple classes, follow [Section 4.1.2.8.1, Multiple Values for an Intervention or Event Topic Variable](#) or omit CMCLAS.
- For concomitant medications, supplemental qualifiers (see [Section 8: 8.4, Relating Non-Standard Variables Values to a Parent Domain](#) and [Appendix C2 - Supplemental Qualifier Name Codes](#) for more information) may be used to represent additional coding dictionary information, e.g. a drug’s ATC codes from the WHO Drug dictionary. However, by knowing the dictionary and version used, the reviewer will be able to obtain additional coding dictionary information.

Note: The sponsor is expected to provide the dictionary name and version used to map the terms by utilizing the define.xml external codelist attributes.

4.1.3.6 Storing Topic Variables for General Domain Models

The topic variable for the Interventions and Events general-observation-class models is often stored as verbatim text. For an Events domain, the topic variable is --TERM. For an Interventions domain, the topic variable is --TRT. For a Findings domain, the topic variable, --TESTCD, should use Controlled Terminology (e.g., SYSBP for Systolic Blood Pressure). If CDISC standard controlled terminology exists, it should be used; otherwise sponsors should define their own controlled list of terms. If the verbatim topic variable in an Interventions or Event domain is modified to facilitate coding, the modified text is stored in --MODIFY. In most cases (other than PE), the dictionary-coded text is derived into --DECOD. Since the PEORRES variable is modified instead of the topic variable for PE, the dictionary-derived text would be placed in PESTRESC. The variables used in each of the defined domains are:

Domain	Original Verbatim	Modified Verbatim	Standardized Value
AE	AETERM	AEMODIFY	AEDECOD
DS	DSTERM		DSDECOD
CM	CMTRT	CMMODIFY	CMDECOD
MH	MHTERM	MHMODIFY	MHDECOD
PE	PEORRES	PEMODIFY	PESTRESC

4.1.3.7 Use of “Yes” and “No” Values

Variables where the response is “Yes” or “No” (“Y” or “N”) should normally be populated for both “Y” and “N” responses. This eliminates confusion regarding whether a blank response indicates “N” or is a missing value. However, some variables are collected or derived in a manner that allows only one response, such as when a single check box indicates “Yes”. In situations such as these, where it is unambiguous to only populate the response of

interest, it is permissible to only populate one value (“Y” or “N”) and leave the alternate value blank. An example of when it would be acceptable to use only a value of “Y” would be for Baseline Flag (--BLFL) variables, where “N” is not necessary to indicate that a value is not a baseline value.

Note: Permissible values for variables with controlled terms of “Y” or “N” may be extended to include “U” or “NA” if it is the sponsor’s practice to explicitly collect or derive values indicating “Unknown” or “Not Applicable” for that variable.

4.1.4 Actual and Relative Time Assumptions

Timing variables (*SDTM: Table 2.2.5* of the SDTM) are an essential component of all SDTM subject-level domain datasets. In general, all domains based on the three general observation classes should have at least one Timing variable. In the Events or Interventions general observation class this could be the start date of the event or intervention. In the Findings observation class where data are usually collected at multiple visits, at least one Timing variable must be used.

The SDTMIG requires dates and times of day to be stored according to the international standard ISO 8601 (<http://www.iso.org>). ISO 8601 provides a text-based representation of dates and/or times, intervals of time, and durations of time.

4.1.4.1 Formats for Date/Time Variables

An SDTM DTC variable may include data that is represented in ISO 8601 format as a complete date/time, a partial date/time, or an incomplete date/time.

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

- o YYYY-MM-DDThh:mm:ss

where:

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

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

- o [-] (hyphen): to separate the time Elements "year" from "month" and "month" from "day" and to represent missing date components.
- o [:] (colon): to separate the time Elements "hour" from "minute" and "minute" from "second"
- o [/] (solidus): to separate components in the representation of date/time intervals
- o [P] (duration designator): precedes the components that represent the duration
- o NOTE: Spaces are not allowed in any ISO 8601 representations

Key aspects of the ISO 8601 standard are as follows:

- ISO 8601 represents dates as a text string using the notation YYYY-MM-DD.
- ISO 8601 represents times as a text string using the notation hh:mm:ss.
- The SDTM and SDTMIG require use of the ISO 8601 Extended format, which requires hyphen delimiters for date components and colon delimiters for time components. The ISO 8601 basic format, which does not require delimiters, should not be used in SDTM datasets.
- When a date is stored with a time in the same variable (as a date/time), the date is written in front of the time and the time is preceded with “T” using the notation YYYY-MM-DDThh:mm:ss (e.g. 2001-12-26T00:00:01).

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

4.1.4.2 Date/Time Precision

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

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

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

This date and date/time model also provides for imprecise or estimated dates, such as those commonly seen in Medical History. To represent these intervals while applying the ISO 8601 standard, it is recommended that the sponsor concatenate the date/time values (using the most complete representation of the date/time known) that describe the beginning and the end of the interval of uncertainty and separate them with a solidus as shown in the table below:

	Interval of Uncertainty	ISO 8601 Date/Time
1	Between 10:00 and 10:30 on the Morning of December 15, 2003	2003-12-15T10:00/2003-12-15T10:30
2	Between the first of this year (2003) until "now" (February 15, 2003)	2003-01-01/2003-02-15
3	Between the first and the tenth of December, 2003	2003-12-01/2003-12-10
4	Sometime in the first half of 2003	2003-01-01/2003-06-30

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

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

Note that Row 6 above where a time is reported with no date information represents a very unusual situation. Since most data is collected as part of a visit, when only a time appears on a CRF, it is expected that the date of the visit would usually be used as the date of collection.

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

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

4.1.4.3.1 Intervals of time and Use of Duration for --DUR variables

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

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

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

While the above would represent the interval (by providing the start date/time and end date/time to "bound" the interval of time), it does not provide the value of the duration (the quantity of time).

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

Both duration and duration units can be provided in the single --DUR variable, in accordance with the ISO 8601 standard. The values provided in --DUR should follow one of the following ISO 8601 duration formats:

PnYnMnDnHnMnS or PnW

where:

- [P] (duration designator): precedes the alphanumeric text string that represents the duration. NOTE: The use of the character P is based on the historical use of the term "period" for duration.
- [n] represents a positive -number or zero
- [W] is used as week designator, preceding a data Element that represents the number of calendar weeks within the calendar year (e.g., P6W represents 6 weeks of calendar time).

The letter "P" must precede other values in the ISO 8601 representation of duration. The "n" preceding each letter represents the number of Years, Months, Days, Hours, Minutes, Seconds, or the number of Weeks. As with the date/time format, "T" is used to separate the date components from time components.

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

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

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

The table below provides some examples of ISO-8601-compliant representations of durations:

Duration as originally recorded	ISO 8601 Duration
2 Years	P2Y
10 weeks	P10W
3 Months 14 days	P3M14D
3 Days	P3D
6 Months 17 Days 3 Hours	P6M17DT3H
14 Days 7 Hours 57 Minutes	P14DT7H57M
42 Minutes 18 Seconds	PT42M18S
One-half hour	PT0.5H
5 Days 12¼ Hours	P5DT12.25H
4 ½ Weeks	P4.5W

Note that a leading zero is required with decimal values less than one.

4.1.4.3.2 Interval with Uncertainty

When an interval of time is an amount of time (duration) following an event whose start date/time is recorded (with some level of precision, i.e. when one knows the start date/time and the duration following the start date/time), the correct ISO 8601 usage to represent this interval is as follows:

YYYY-MM-DDThh:mm:ss/PnYnMnDTnHnMnS

where the start date/time is represented before the solidus [/], the "Pn...", following the solidus, represents a "duration", and the entire representation is known as an "interval". NOTE: This is the recommended representation of elapsed time, given a start date/time and the duration elapsed.

When an interval of time is an amount of time (duration) measured prior to an event whose start date/time is recorded (with some level of precision, i.e. where one knows the end date/time and the duration preceding that end date/time), the syntax is:

PnYnMnDTnHnMnS/YYYY-MM-DDThh:mm:ss

where the duration, "Pn...", is represented before the solidus [/], the end date/time is represented following the solidus, and the entire representation is known as an "interval".

4.1.4.4 Use of the "Study Day" Variables

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

The Subject Reference Start Date (RFSTDTC) is designated as Study Day 1. The Study Day value is incremented by 1 for each date following RFSTDTC. Dates prior to RFSTDTC are decreased by 1, with the date preceding RFSTDTC designated as Study Day -1 (there is no Study Day 0). This algorithm for determining Study Day is consistent with how people typically describe sequential days relative to a fixed reference point, but creates problems if used for mathematical calculations because it does not allow for a Day 0. As such, Study Day is not suited for use in subsequent numerical computations, such as calculating duration. The raw date values should be used rather than Study Day in those calculations.

All Study Day values are integers. Thus, to calculate Study Day:

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

--DY = (date portion of --DTC) - (date portion of RFSTDTC) if --DTC precedes RFSTDTC

This algorithm should be used across all domains.

4.1.4.5 Clinical Encounters and Visits

All domains based on the three general observation classes should have at least one timing variable. For domains in the Events or Interventions observations classes, and for domains in the Findings observation class for which data are collected only once during the study, the most appropriate timing variable may be a date (e.g., --DTC, --STDTC) or some other timing variable. For studies that are designed with a prospectively defined schedule of visit-based activities, domains for data that are to be collected more than once per subject (e.g., Labs, ECG, Vital Signs) are expected to include VISITNUM as a timing variable.

Clinical encounters are described by the CDISC Visit variables. For planned visits, values of VISIT, VISITNUM, and VISITDY must be those defined in the Trial Visits dataset, see *Section 7.3 - Schedule for Assessments: Trial Visits (TV)*. For planned visits:

- Values of VISITNUM are used for sorting and should, wherever possible, match the planned chronological order of visits. Occasionally, a protocol will define a planned visit whose timing is unpredictable (e.g., one planned in response to an adverse event, a threshold test value, or a disease event), and completely chronological values of VISITNUM may not be possible in such a case.
- There should be a one-to-one relationship between values of VISIT and VISITNUM.
- For visits that may last more than one calendar day, VISITDY should be the planned day of the start of the visit.

Sponsor practices for populating visit variables for unplanned visits may vary across sponsors.

- VISITNUM should generally be populated, even for unplanned visits, as it is expected in many Findings domains, as described above. The easiest method of populating VISITNUM for unplanned visits is to assign the same value (e.g., 99) to all unplanned visits, but this method provides no differentiation between the unplanned visits and does not provide chronological sorting. Methods that provide a one-to-one relationship between visits and values of VISITNUM, that are consistent across domains, and that assign VISITNUM values that sort chronologically require more work and must be applied after all of a subject's unplanned visits are known.
- VISIT may be left null or may be populated with a generic value (e.g., "Unscheduled") for all unplanned visits, or individual values may be assigned to different unplanned visits.
- VISITDY must not be populated for unplanned visits, since VISITDY is, by definition, the planned study day of visit, and since the actual study day of an unplanned visit belongs in a --DY variable.

The following table shows an example of how the visit identifiers might be used for lab data:

USUBJID	VISIT	VISITNUM	VISITDY	LBDY
001	Week 1	2	7	7
001	Week 2	3	14	13
001	Week 2 Unscheduled	3.1		17

4.1.4.6 Representing Additional Study Days

The SDTM allows for --DTC values to be represented as study days (--DY) relative to the RFSTDTC reference start date variable in the DM dataset, as described above in [Section 4.1.4.4, Use Of the “Study Day” Variables](#). The calculation of additional study days within subdivisions of time in a clinical trial may be based on one or more sponsor-defined reference dates not represented by RFSTDTC. In such cases, the Sponsor may define Supplemental Qualifier variables and the define.xml should reflect the reference dates used to calculate such study days. If the sponsor wishes to define “day within element” or “day within epoch,” the reference date/time will be an element start date/time in the Subject Elements dataset [see *Section 5 - SE Domain*].

4.1.4.7 Use of Relative Timing Variables

--STRF and --ENRF

The variables --STRF and --ENRF represent the timing of an observation relative to the sponsor-defined reference period when information such as "BEFORE", "PRIOR", "ONGOING", or "CONTINUING" is collected in lieu of a date and this collected information is in relation to the sponsor-defined reference period. The sponsor-defined reference period is the

continuous period of time defined by the discrete starting point (RFSTDTC) and the discrete ending point (RFENDTC) for each subject in the Demographics dataset.

--STRF is used to identify the start of an observation relative to the sponsor-defined reference period.

--ENRF is used to identify the end of an observation relative to the sponsor-defined reference period.

Allowable values for --STRF and --ENRF are “BEFORE”, “DURING”, “DURING/AFTER”, “AFTER”, “COINCIDENT”, “ONGOING”, and “U” (for unknown).

As an example, a CRF checkbox that identifies concomitant medication use that began prior to the study treatment period would translate into CMSTRF = “BEFORE” if selected; similarly, a CRF checkbox that identifies concomitant medication use that continues after the study treatment period would translate into CMENRF = “ONGOING” if selected. Note that in this example, the information collected is with respect to the start of the concomitant medication use only and therefore the collected data corresponds to variable CMSTRF, not CMENRF. Note also that the information collected is relative to the study treatment period, which meets the definition of CMSTRF.

Some sponsors may wish to derive --STRF and --ENRF for analysis or reporting purposes even when dates are collected. Sponsors are cautioned that doing so in conjunction with directly collecting or mapping data such as “BEFORE”, “PRIOR”, “ONGOING”, etc. to --STRF and --ENRF will blur the distinction between collected and derived values within the domain. Sponsors wishing to do such derivations are instead encouraged to use supplemental variables or analysis datasets for this derived data.

In general, sponsors are cautioned that representing information using variables --STRF and --ENRF may not be as precise as other methods, particularly because information is often collected relative to a point in time or to a period of time other than the one defined as the study reference period. SDTMIG V3.1.2 has attempted to address these limitations by the addition of four new relative timing variables, which are described in the following paragraph. Sponsors should use the set of variables that allows for accurate representation of the collected data. In many cases, this will mean using these new relative timing variables in place of --STRF and --ENRF.

--STRTPT, --STTPT, --ENRTPT, and --ENTPT

While the variables --STRF and --ENRF are useful in the case when relative timing assessments are made coincident with the start and end of the study reference period, these may not be suitable for expressing relative timing assessments such as “Prior” or “Ongoing” that are collected at other times of the study. As a result, four new timing variables have been added in V3.1.2 to express a similar concept at any point in time. The variables --STRTPT and --ENRTPT contain values similar to --STRF and --ENRF, but may be anchored with any timing description or date/time value expressed in the respective --STTPT and --ENTPT variables, and not be limited to the study reference period. Unlike the variables --STRF and --ENRF, which for all domains are defined relative to one study reference period, the timing variables --STRTPT, --STTPT, --ENRTPT, and --ENTPT are defined to be unique. Allowable values for --STRTPT and --ENRTPT are as follows:

If the reference time point corresponds to the date of collection or assessment:

- Start values: an observation can start BEFORE that time point, can start COINCIDENT with that time point, or it is unknown (U) when it started
- End values: an observation can end BEFORE that time point, can end COINCIDENT with that time point, can be known that it didn't end but was ONGOING, or it is unknown (U) at all when it ended or if it was ongoing.
- AFTER is not a valid value in this case because it would represent an event after the date of collection.

If the reference time point is prior to the date of collection or assessment:

- Start values: an observation can start BEFORE the reference point, can start COINCIDENT with the reference point, can start AFTER the reference point, or it may not be known (U) when it started
- End values: an observation can end BEFORE the reference point, can end COINCIDENT with the reference point, can end AFTER the reference point, can be known that it didn't end but was ONGOING, or it is unknown (U) when it ended or if it was ongoing.

Examples of --STRTPT, --STTPT, --ENRTPT, and --ENTPT

1. Medical History

Assumptions:

- CRF contains "Year Started" and check box for "Active"
- "Date of Assessment" is collected

Example when "Active" is checked:

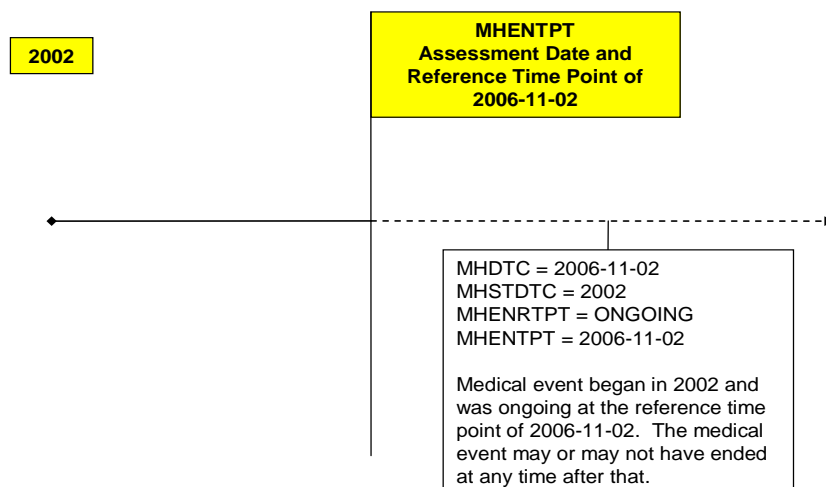
MHDTTC = date of assessment value, ex. "2006-11-02"

MHSTDTC = year of condition start, e.g., "2002"

MHENRTPT = "ONGOING"

MHENTPT = date of assessment value, e.g., "2006-11-02"

Figure 4.1.4.7: Example of --ENRTPT and --ENTPT for Medical History



Prior and Concomitant Medications

Assumptions:

- CRF contains "Start Date", "Stop Date", and check boxes for "Prior" if unknown or uncollected Start Date, and "Continuing" if no Stop Date was collected. Prior refers to screening visit and Continuing refers to final study visit.

Example when both "Prior" and "Continuing" are checked:

CMSTDTC = [null]

CMENDTC = [null]

CMSTRTPT = "BEFORE"

CMSTTPT = screening date, e.g., "2006-10-21"

CMENRTPT = "ONGOING"

CMENPT = final study visit date, e.g., "2006-11-02"

2. Adverse Events

Assumptions:

- CRF contains "Start Date", "Stop Date", and "Outcome" with check boxes including "Continuing" and "Unknown" (Continuing and Unknown are asked at the end of the subject's study participation)
- No assessment date or visit information is collected

Example when "Unknown" is checked:

AESTDTC = start date, e.g., "2006-10-01"

AEENDTC = [null]

AEENRTPT = "U"

4.1.4.8 AEENTPT = final subject contact date, e.g., "2006-11-02" Date and Time Reported in a Domain Based on Findings

When the date/time of collection is reported in any domain, the date/time should go into the --DTC field (e.g., EGDTC for Date/Time of ECG). For any domain based on the Findings general observation class, such as lab tests which are based on a specimen, the collection date is likely to be tied to when the specimen or source of the finding was captured, not necessarily when the data was recorded. In order to ensure that the critical timing information is always represented in the same variable, the --DTC variable is used to represent the time of specimen collection. For example, in the LB domain the LBDTC variable would be used for all single-point blood collections or spot urine collections. For timed lab collections (e.g., 24-hour urine collections) the LBDTC variable would be used for the start date/time of the collection and LBENDTC for the end date/time of the collection. This approach will allow the single-point and interval collections to use the same date/time variables consistently across all datasets for the Findings general observation class. The table below illustrates the proper use of these variables. Note that --STDTC is not used for collection dates over an interval, so is blank in the following table.

Collection Type	--DTC	--STDTC	--ENDTC
Single-Point Collection	X		
Interval Collection	X		X

4.1.4.9 Use of Dates as Result Variables

Dates are generally used only as timing variables to describe the timing of an event, intervention, or collection activity, but there may be occasions when it may be preferable to model a date as a result (--ORRES) in a Findings dataset. Note that using a date as a result to a Findings question is unusual and atypical, and should be approached with caution, but this situation may occasionally occur when a) a group of questions (each of which has a date response) is asked and analyzed together; or b) the Event(s) and Intervention(s) in question are not medically significant (often the case when included in questionnaires). Consider the following cases:

- Calculated due date
- Date of last day on the job
- Date of high school graduation

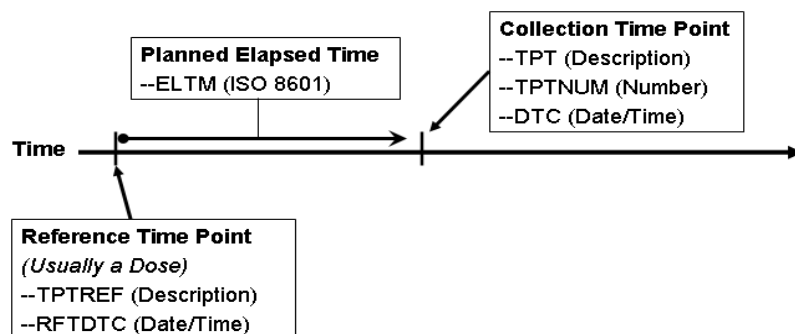
One approach to modeling these data would be to place the text of the question in --TEST and the response to the question, a date represented in ISO 8601 format, in --ORRES and --STRESC as long as these date results do not contain the dates of medically significant events or interventions.

Again, use extreme caution when storing dates as the results of Findings. Remember, in most cases, these dates should be timing variables associated with a record in an Intervention or Events dataset.

4.1.4.10 Representing Time Points

Time points can be represented using the time point variables, --TPT, --TPTNUM, --ELTM, and the time point anchors, --TPTREF (text description) and --RFTDTC (the date/time). Note that time-point data will usually have an associated --DTC value. The interrelationship of these variables is shown in Figure 4.1.4.10 below.

Figure 4.1.4.10



Values for these variables for Vital Signs measurements taken at 30, 60, and 90 minutes after dosing would look like the following.

VSTPTNUM	VSTPT	VSELTM	VSTPTREF	VSRFTDTC	VSDTC
1	30 MIN	PT30M	DOSE ADMINISTRATION	2006-08-01T08:00	2006-08-01T08:30
2	60 MIN	PT1H	DOSE ADMINISTRATION	2006-08-01T08:00	2006-08-01T09:01
3	90 MIN	PT1H30M	DOSE ADMINISTRATION	2006-08-01T08:00	2006-08-01T09:32

Note that the **actual** elapsed time is not an SDTM variable, but can be derived by an algorithm representing VSDTC-VSRFTDTC.

Values for these variables for Urine Collections taken pre-dose, and from 0-12 hours and 12-24 hours after dosing would look like the following.

LBTPNUM	LBTP	LBELTM	LBTPREF	LBRFTDTC	LBDC
1	15 MIN PRE-DOSE	-PT15M	DOSE ADMINISTRATION	2006-08-01T08:00	2006-08-01T08:30
2	0-12 HOURS	PT12H	DOSE ADMINISTRATION	2006-08-01T08:00	2006-08-01T20:35
3	12-24 HOURS	PT24H	DOSE ADMINISTRATION	2006-08-01T08:00	2006-08-02T08:40

Note that the value in LBELTM represents the end of the interval at which the collection ends.

When time points are used, --TPTNUM is expected. Time points may or may not have an associated --TPTREF. Sometimes, --TPTNUM may be used as a key for multiple values collected for the same test within a visit; as such, there is no dependence upon an anchor such as --TPTREF, but there will be a dependency upon the VISITNUM. In such cases, VISITNUM will be required to confer uniqueness to values of --TPTNUM.

If the protocol describes the scheduling of a dose using a reference intervention or assessment, then --TPTREF should be populated, even if it does not contribute to uniqueness. The fact that time points are related to a reference time point, and what that reference time point is, are important for interpreting the data collected at the time point.

Not all time points will require all three variables to provide uniqueness. In fact, in some cases a time point may be uniquely identified without the use of VISIT, or without the use of --TPTREF, or, rarely, without the use of either one. For instance:

- A trial might have time points only within one visit, so that the contribution of VISITNUM to uniqueness is trivial.
- A trial might have time points that do not relate to any visit, such as time points relative to a dose of drug self-administered by the subject at home.
- A trial may have only one reference time point per visit, and all reference time points may be similar, so that only one value of --TPTREF (e.g., "DOSE") is needed.
- A trial may have time points not related to a reference time point. For instance, --TPTNUM values could be used to distinguish first, second, and third repeats of a measurement scheduled without any relationship to dosing.

For trials with many time points, the requirement to provide uniqueness using only VISITNUM, --TPTREF, and --TPTNUM may lead to a scheme where multiple natural keys are combined into the values of one of these variables. For instance, in a crossover trial with multiple doses on multiple days within each period, either of the following options could be used. VISITNUM might be used to designate period, --TPTREF might be used to designate the day and the dose, and --TPTNUM might be used to designate the timing relative to the reference time point. Alternatively, VISITNUM might be used to designate period and day within period, --TPTREF might be used to designate the dose within the day, and --TPTNUM might be used to designate the timing relative to the reference time point.

Option 1

VISIT	VISITNUM	--TPT	--TPTNUM	--TPTREF
PERIOD 1	3	PRE-DOSE	1	DAY 1, AM DOSE
		1H	2	
		4H	3	
		PRE-DOSE	1	DAY 1, PM DOSE
		1H	2	
		4H	3	
		PRE-DOSE	1	DAY 5, AM DOSE
		1H	2	
		4H	3	
		PRE-DOSE	1	DAY 5, PM DOSE
		1H	2	
		4H	3	
PERIOD 2	4	PRE-DOSE	1	DAY 1, AM DOSE
		1H	2	
		4H	3	
		PRE-DOSE	1	DAY 1, PM DOSE
		1H	2	
		4H	3	

Option 2

VISIT	VISITNUM	--TPT	--TPTNUM	--TPTREF
PERIOD 1, DAY 1	3	PRE-DOSE	1	AM DOSE
		1H	2	
		4H	3	
		PRE-DOSE	1	PM DOSE
		1H	2	
		4H	3	
PERIOD 1, DAY 5	4	PRE-DOSE	1	AM DOSE
		1H	2	
		4H	3	
		PRE-DOSE	1	PM DOSE
		1H	2	
		4H	3	
PERIOD 2, DAY 1	5	PRE-DOSE	1	AM DOSE
		1H	2	
		4H	3	
		PRE-DOSE	1	PM DOSE
		1H	2	
		4H	3	

Within the context that defines uniqueness for a time point, which may include domain, visit, and reference time point, there must be a one-to-relationship between values of --TPT and --TPTNUM. In other words, if domain, visit, and reference time point uniquely identify subject data, then if two subjects have records with the same values of DOMAIN, VISITNUM, --TPTREF, and --TPTNUM, then these records may not have different time point descriptions in --TPT.

Within the context that defines uniqueness for a time point, there is likely to be a one-to-one relationship between most values of --TPT and --ELTM. However, since --ELTM can only be populated with ISO 8601 periods of time (as described in [Section 4.1.4.3, Intervals of Time and Use of Duration for --DUR Variables](#)), --ELTM may not be populated for all time points. For example, --ELTM is likely to be null for time points described by text such as "pre-dose" or "before breakfast." When --ELTM is populated, if two subjects have records with the same values of DOMAIN, VISITNUM, --TPTREF, and --TPTNUM, then these records may not have different values in --ELTM.

When the protocol describes a time point with text such as "4-6 hours after dose" or "12 hours +/- 2 hours after dose" the sponsor may choose whether and how to populate --ELTM. For example, a time point described as "4-6 hours after dose" might be associated with an --ELTM value of PT4H. A time point described as "12 hours +/- 2 hours after dose" might be associated with an --ELTM value of PT12H. Conventions for populating --ELTM should be consistent (the examples just given would probably not both be used in the same trial). It would be good practice to indicate the range of intended timings by some convention in the values used to populate --TPT.

Sponsors may, of course, use more stringent requirements for populating --TPTNUM, --TPT, and --ELTM. For instance, a sponsor could decide that all time points with a particular --ELTM value would have the same values of --TPTNUM and --TPT, across all visits, reference time points, and domains.

4.1.5 Other Assumptions

4.1.5.1 Original and Standardized Results of Findings and Tests Not Done

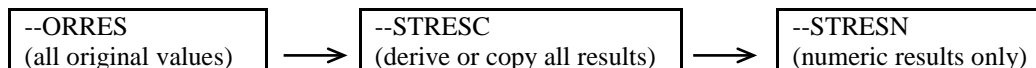
4.1.5.1.1 Original and Standardized Results

The --ORRES variable contains the result of the measurement or finding as originally received or collected. --ORRES is an expected variable and should always be populated, with two exceptions:

- When --STAT = "NOT DONE"
- --ORRES should generally not be populated for derived records

Derived records are flagged with the --DRVFL variable. When the derived record comes from more than one visit, the sponsor must define the value for VISITNUM, addressing the correct temporal sequence. If a new record is derived for a dataset, and the source is not eDT, then that new record should be flagged as derived. For example in ECG data, if QTc Intervals are derived in-house by the sponsor, then the derived flag is set to "Y". If the QTc Intervals are received from a vendor the derived flag is not populated.

When --ORRES is populated, --STRESC must also be populated, regardless of whether the data values are character or numeric. The variable, --STRESC, is derived either by the conversion of values in --ORRES to values with standard units, or by the assignment of the value of --ORRES (as in the PE Domain, where --STRESC could contain a dictionary-derived term). A further step is necessary when --STRESC contains numeric values. These are converted to numeric type and written to --STRESN. Because --STRESC may contain a mixture of numeric and character values, --STRESN may contain null values, as shown in the flowchart below.



When the original measurement or finding is a selection from a defined codelist, in general, the --ORRES and --STRESC variables contain results in decoded format, that is, the textual interpretation of whichever code was selected from the codelist. In some cases where the code values in the codelist are statistically meaningful standardized values or scores, which are defined by sponsors or by valid methodologies such as SF36 questionnaires, the --ORRES variables will contain the decoded format, whereas, the --STRESC variables as well as the --STRESN variables will contain the standardized values or scores.

Occasionally data that are intended to be numeric are collected with characters attached that cause the character-to-numeric conversion to fail. For example, numeric cell counts in the source data may be specified with a greater than (>) or less than (<) sign attached (e.g. >10,000 or <1). In these cases the value with the greater than (>) or less than (<) sign attached should be moved to the --STRESC variable, and --STRESN should be null. The rules for modifying the value for analysis purposes should be defined in the analysis plan and only changed in the ADaM datasets. If the value in --STRESC has different units, the greater than (>) or less than (<) sign should be maintained. An example is included in [Section 4.1.5.1.3, Examples of Original and Standard Units and Test Not Done](#), Rows 11 and 12.

4.1.5.1.2 Tests Not Done

When an entire examination (Laboratory draw, ECG, Vital Signs, or Physical Examination), or a group of tests (hematology or urinalysis), or an individual test (glucose, PR interval, blood pressure, or hearing) is not done, and this information is explicitly captured on the CRF with a yes/no or done/not done question, this information should be presented in the dataset. The reason for the missing information may or may not have been collected. A sponsor has two options; one is to submit individual records for each test not done or to submit one record for a group of tests that were not done. See the examples below for submitting groups of tests not done.

If the data on the CRF is missing and yes/no or done/not done was not explicitly captured a record should not be created to indicate that the data was not collected.

If a group of tests were not done:

- --TESTCD should be --ALL
- --TEST should be <Name of the Module>
- --CAT should be <Name of Group of Tests>
- --ORRES should be null
- --STAT should be "NOT DONE"
- --REASND, if collected, might be "Specimen lost"

For example, if urinalysis is not done then:

- LBTESTCD should be "LBALL"
- LBTEST should be "Labs Data"
- LBCAT should be "URINALYSIS"
- LBORRES should be NULL
- LBSTAT should be "NOT DONE"
- LBREASND, if collected, might be "Subject could not void"

4.1.5.1.3 Examples of Original and Standard Units and Test Not Done

The following examples are meant to illustrate the use of Findings results variables, and are not meant as comprehensive domain examples. Certain required and expected variables are omitted, and the samples may represent data for more than one subject.

Lab Data Example

- Row 1:** Numeric values that have been converted
- Row 2:** A character result that has been copied
- Row 3:** Numeric values that have been copied
- Row 4:** A result of "TRACE" shows "TRACE" in LBSTRESC and LBSTRESN is null
- Row 5:** Value of 1+ in LBORRES, 1+ in LBSTRESC and LBSTRESN is null
- Row 6:** A result of "BLQ" was collected. That value was copied to LBSTRESC and LBSTRESN is null. Note that the standard units are populated by sponsor decision, but could be left null
- Row 7:** A result is missing because the observation was "NOT DONE", as reflected in the --STAT variable; neither LBORRES nor LBSTRESC are populated
- Row 8:** A result is derived from multiple records such as an average of baseline measurements for a baseline value, so LBDRVFL = Y. Note that the original collected data are not shown in this example
- Row 9:** None of the scheduled tests were completed as planned
- Row 10:** A category of tests was not completed as planned
- Row 11:** Shows when LBSTRESC has been standardized and the less than (<) sign has been maintained
- Row 12:** Shows when LBSTRESC has been standardized and the less than (<) sign has been maintained

Row	LBTESTCD	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSTAT	LBDRVFL
1	GLUC	CHEMISTRY	6.0	mg/dL	60.0	60.0	mg/L		
2	BACT	URINALYSIS	MODERATE		MODERATE				
3	ALT	CHEMISTRY	12.1	mg/L	12.1	12.1	mg/L		
4	RBC	URINALYSIS	TRACE		TRACE				

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Row	LBTESTCD	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSTAT	LBDRVFL
5	WBC	URINALYSIS	1+		1+				
6	KETONES	CHEMISTRY	BLQ	mg/L	BLQ		mg/L		
7	HCT	HEMATOLOGY						NOT DONE	
8	MCHC	HEMATOLOGY			33.8	33.8	g/dL		Y
9	LBALL							NOT DONE	
10	LBALL	HEMATOLOGY						NOT DONE	
11	WBC	HEMATOLOGY	<4,000	/mm3	<4,000		/mm3		
12	BILI	CHEMISTRY	<0.1	mg/dL	<1.71		umol/L		

ECG Example:

Rows 2 & 3: Numeric and character values that have been converted

Rows 1 & 4: Numeric and character values that have been copied

Row 5: A result is missing because the test was "NOT DONE", as reflected in the EGSTAT variable; neither EGORRES nor EGSTRESC is populated

Row 6: The overall interpretation is included as a new record

Row 7: The entire ECG was not done

Row	EGTESTCD	EGORRES	EGORRESU	EGSTRESC	EGSTRESN	EGSTRESU	EGSTAT	EGDRVFL
1	QRS DUR	0.362	sec	0.362	0.362	sec		
2	QTMEAN	221	msec	.221	.221	sec		
3	QT CB	412	msec	.412	.412	sec		
4	RHYM RATE	ATRIAL FLUTTER		ATRIAL FLUTTER				
5	PRMEAN						NOT DONE	
6	INTP	ABNORMAL		ABNORMAL				
7	EGALL						NOT DONE	

Vital Signs Example:

Rows 1-2: Numeric values that have converted

Row 3: A result is missing because the Vital Signs test was "NOT DONE", as reflected in the VSSTAT variable; neither VSORRES nor VSSTRESC is populated

Rows 4-5: The result is derived by having multiple records for one measurement

Row 6: The derived value is recorded in a new row with the derived record flagged

Row 7: The entire examination was not done

Row	VSTESTCD	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSSTAT	VSDRVFL
1	HEIGHT	60	IN	152	152	cm		
2	WEIGHT	110	LB	50	50	kg		
3	HR						NOT DONE	
4	SYSBP	96	mmHg	96	96	mmHg		
5	SYSBP	100	mmHg	100	100	mmHg		
6	SYSBP			98	98	mmHg		Y
7	VSALL						NOT DONE	

Questionnaire Example:

Note that this is for a standard instrument for which no subjectivity is involved in representing the original result as a numeric value

- **Rows 1, 5 & 6:** A Character value that has been converted to a standard score
- **Row 2:** A result is derived from multiple records (Row 2). The records for the original collected results are not shown in this example
- **Row 3:** A result is missing because the observation was “NOT DONE”, as reflected in the QSSTAT variable; neither QSORRES nor QSSTRESC is populated
- **Row 4:** The entire questionnaire was not done
- **Row 7:** Shows when a summary score in Row 7 is derived from the data in Rows 5 and 6 and QSORRES should not be populated because the character values cannot be added to give a meaningful result (Rows 5, 6, and 7)

Row	QSTESTCD	QSTEST	QSORRES	QSSTRESC	QSSTRESN	QSSTAT	QSDRVFL
1	QS1	Health	VERY GOOD	4.4	4.4		
2	QS2	Health Perceptions (0-100)		82	82		Y
3	QS1	Health				NOT DONE	
4	QSALL	Questionnaire				NOT DONE	
5	QSP10	Healthy As Anyone	MOSTLY TRUE	4	4		
6	QSP11	Expect Health To Get Better	DEFINITELY TRUE	5	5		
7	QSPSUM	Total of Scores		9	9		Y

4.1.5.2 Linking of Multiple Observations

See *Section 8 - Representing Relationships and Data* for guidance on expressing relationships among multiple observations.

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

4.1.5.3.1 Test Name (--TEST) Greater than 40 Characters

Sponsors may have test descriptions (--TEST) longer than 40 characters in their operational database. Since the --TEST variable is meant to serve as a label for a --TESTCD when a Findings dataset is transposed to a more horizontal format, the length of --TEST is normally limited to 40 characters to conform to the limitations of the SAS V5 Transport format currently used for submission datasets. Therefore, sponsors have the choice to either insert the first 40 characters or a text string abbreviated to 40 characters in --TEST. Sponsors should include the full description for these variables in the study metadata in one of two ways:

- If the annotated CRF contains the full text, provide a link to the annotated CRF page containing the full test description in the define.xml Origin column for --TEST.
- If the annotated CRF does not specify the full text, then create a pdf document to store full-text descriptions. In the define.xml Comments column for --TEST insert a link to the full test description in the pdf.

The convention above should also be applied to the Qualifier Value Label (QLABEL) in Supplemental Qualifiers (SUPP--) datasets. IETEST values in IE and TI are exceptions to the above 40-character rule and are limited to 200 characters since they are not expected to be transformed to a column labels. Values of IETEST that exceed 200 characters should be described in study metadata as per the convention above. For further details see *Section 6.3 - IE Domain: Assumption 4, IE - Assumptions for Inclusion/Exclusion Criteria Not Met Domain Model* and *Section 7.4 - Trial Summary and Eligibility: TI - Assumptions for Trial Inclusion/Exclusion Criteria Dataset: Assumption 5.*

4.1.5.3.2 Text Strings > 200 Characters in Other Variables

Some sponsors may collect data values longer than 200 characters for some variables. Because of the current requirement for Version 5 SAS transport file format, it will not be possible to store those long text strings using only one variable. Therefore, the SDTMIG has defined a convention for storing a long text string by using a combination of the standard domain dataset and the Supplemental Qualifiers (SUPP--) datasets, which applies to all domains based on a general observation class. Note that the Comments domain is not based on a general observation class and has different rules. See *Section 5 - CO Domain* for information on handling comment text more than 200 characters long.

The first 200 characters of text should be stored in the standard domain variable and each additional 200 characters of text should be stored as a record in the SUPP-- dataset [see *Section 8: 8.4, Relating Non-Standard Variables Values to a Parent Domain*]. In this dataset, the value for QNAM should contain a sequential variable name, which is formed by appending a one-digit integer, beginning with 1, to the original standard domain variable name. When splitting a text string into several records, the text should be split between words to improve readability.

As an example, if there was a verbatim response for a Medical History Reported Term (MHTERM) of 500 characters in length, the sponsor would put the first 200 characters of text in the standard domain variable and dataset (MHTERM in MH), the next 200 characters of text as a first supplemental record in the SUPPMH dataset, and the final 100 characters of text as a second record in the SUPPMH dataset (see Example 1 below). Variable QNAM would have the values MHTERM1 and MHTERM2 for these two records in SUPPMH, respectively, for this one particular text string. Sponsors should place the text itself into variable QVAL and the label of the original standard domain variable into variable QLABEL. In this case, IDVAR and IDVARVAL should be used in SUPPMH to relate the associated supplemental text records to the parent record containing the first 200 characters of text in the standard domain.

In cases where the standard domain variable name is already 8 characters in length, sponsors should replace the last character with a digit when creating values for QNAM. As an example, for Other Action Taken in Adverse Events (AEACNOTH), values for QNAM for the SUPPAE records would have the values AEACNOT1, AEACNOT2, and so on.

Example 1: MHTERM with 500 characters.

suppmh.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
12345	MH	99-123	MHSEQ	6	MHTERM1	Reported Term for the Medical History	2nd 200 chars of text	CRF	
12345	MH	99-123	MHSEQ	6	MHTERM2	Reported Term for the Medical History	last 100 chars of text	CRF	

Example 2: AEACN with 400 characters.

suppae.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
12345	AE	99-123	AESEQ	4	AEACNOT1	Other Action Taken	2nd 200 chars of text	CRF	

The only exceptions to the above rules are Comments (CO) and TS (Trial Summary). Please see *Section 5 - CO Domain: CO - Assumptions for the COMMENTS Domain Model* for Comments and *Section 7.4 - Trial Summary and Eligibility: Trial Summary Dataset (TS)* for Trial Summary. **NOTE:** Only the Comments (CO) and Trial Summary (TS) domains are allowed to add variables for the purpose of handling text exceeding 200 characters. All other domains must use SUPPQUAL variables as noted in the examples above.

4.1.5.4 Evaluators in the Interventions and Events Observation Classes

The observations recorded in the Findings class include the --EVAL qualifier because the observation may originate from more than one source (e.g., an Investigator or Central Reviewer). For the Interventions and Events observation classes, which do not include the --EVAL variable, all data are assumed to be attributed to the Principal Investigator. The QEVAL variable can be used to describe the evaluator for any data item in a SUPP-- dataset [Section 8: 8.4.1, Supplemental Qualifiers: SUPP-- Datasets], but is not required when the data are objective. For observations that have primary and supplemental evaluations of specific qualifier variables, sponsors should put data from the primary

evaluation into the standard domain dataset and data from the supplemental evaluation into the Supplemental Qualifier datasets (SUPP--). Within each SUPP-- record, the value for QNAM should be formed by appending a "1" to the corresponding standard domain variable name. In cases where the standard domain variable name is already eight characters in length, sponsors should replace the last character with a "1" (incremented for each additional attribution). The following is an example of how to represent the case where an adjudication committee evaluates an adverse event in SUPPAE. See *Section 8: 8.4, Relating Non-Standard Variables Values to a Parent Domain* for additional details on how to use SUPP--.

Note that QNAM takes on the value AERELNS1, as the corresponding standard domain variable AERELNST is already eight characters in length. The adverse event data as determined by the primary investigator would reside in the standard AE dataset.

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
12345	AE	99-123	AESEQ	3	AESEV1	Severity/ Intensity	MILD	CRF	ADJUDICATION COMMITTEE
12345	AE	99-123	AESEQ	3	AEREL1	Causality	POSSIBLY RELATED	CRF	ADJUDICATION COMMITTEE
12345	AE	99-123	AESEQ	3	AERELNS1	Relationship to Non-Study Treatment	Possibly related to aspirin use	CRF	ADJUDICATION COMMITTEE

4.1.5.5 Clinical Significance for Findings Observation Class Data

For assessments of clinical significance when the overall interpretation is a record in the domain, use Supplemental Qualifier (SUPP--) record (with QNAM = --CLSIG) linked to the record that contains the overall interpretation or a particular result. An example would be a QNAM value of EGCLSIG in SUPPEG with a value of "Y", indicating that an ECG result of ATRIAL FIBRILLATION was clinically significant.

Separate from clinical significance are results of NORMAL or ABNORMAL, or lab values which are out of range. Examples of the latter include the following:

- An ECG test with EGTESTCD=INTP addresses the ECG as a whole should have a result of NORMAL or ABNORMAL. A record for EGTESTCD=INTP may also have a record in SUPPEG indicating whether the result is clinically significant.
- A record for a vital signs measurement (e.g., systolic blood pressure) or a lab test (e.g., hematocrit) that contains a measurement may have a normal range and a normal range indicator. It could also have a SUPP-- record indicating whether the result was clinically significant.

4.1.5.6 Supplemental Reason Variables

The SDTM general observation classes include the --REASND variable to submit the reason an observation was not collected. However, sponsors sometimes collect the reason that something was done. For the Interventions general observation class, --INDC and --ADJ are available to indicate the reason for the intervention or for the dose adjustment. For the Findings general observation class, if the sponsor collects the reason for performing a test or examination, it should be placed in the SUPP-- dataset as described in *Section 8: 8.4.1, Supplemental Qualifiers: SUPPQUAL Or SUPP-- Datasets*. The standard SUPP-- QNAM value of --REAS should be used as described in *Appendix C2 - Supplemental Qualifier Name Codes*. If multiple reasons are reported, refer to [Section 4.1.2.8.3, Multiple Values for a Non-Result Qualifier Variable](#).

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

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

4.1.5.7 Presence or Absence of Pre-Specified Interventions and Events

Interventions (e.g., concomitant medications) and Events (e.g., medical history) can generally be collected in two different ways, by recording either verbatim free text or the responses to a pre-specified list of treatments or terms. Since the method of solicitation for information on treatments and terms may affect the frequency at which they are reported, whether they were pre-specified may be of interest to reviewers. The --PRESP variable is used to indicate whether a specific intervention (--TRT) or event (--TERM) was solicited. The --PRESP variable has controlled terminology of Y (for “Yes”) or a null value. It is a permissible variable, and should only be used when the topic variable values come from a pre-specified list. Questions such as “Did the subject have any concomitant medications?” or “Did the subject have any medical history?” should not have records in SDTM domain because 1) these are not valid values for the respective topic variables of CMTRT and MHTERM, and 2) records whose sole purpose is to indicate whether or not a subject had records are not meaningful.

The --OCCUR variable is used to indicate whether a pre-specified intervention or event occurred or did not occur. It has controlled terminology of Y and N (for “Yes” and “No”). It is a permissible variable and may be omitted from the dataset if no topic-variable values were pre-specified.

If a study collects both pre-specified interventions and events as well as free-text events and interventions, the value of --OCCUR should be “Y” or “N” for all pre-specified interventions and events, and null for those reported as free-text.

The --STAT and --REASND variables can be used to provide information about pre-specified interventions and events for which there is no response (e.g., investigator forgot to ask). As in Findings, --STAT has controlled terminology of NOT DONE.

Situation	Value of --PRESP	Value of --OCCUR	Value of --STAT
Spontaneously reported event occurred			
Pre-specified event occurred	Y	Y	
Pre-specified event did not occur	Y	N	
Pre-specified event has no response	Y		NOT DONE

Refer to the standard domains in the Events and Interventions General Observation Classes for additional assumptions and examples.

4.1.5.8 Accounting for Long-Term Follow-up

Studies often include long-term follow-up assessments to monitor a subject's condition. Examples include studies in terminally ill populations that periodically assess survival and studies involving chronic disease that include follow up to assess relapse. Long-term follow-up is often conducted via telephone calls rather than clinic visits. Regardless of the method of contact, the information should be stored in the appropriate topic-based domain.

Overall study conclusion in the Disposition (DS) domain occurs once all contact with the subject ceases. If a study has a clinical treatment phase followed by a long-term follow-up phase, these two segments of the study can be represented as separate epochs within the overall study, each with its own epoch disposition record.

The recommended SDTM approach to storing these data can be described by an example. Assume an oncology study encompasses two months of clinical treatment and assessments followed by once-monthly telephone contacts. The contacts continue until the subject dies. During the telephone contact, the investigator collects information on the subject's survival status and medication use. The answers to certain questions may trigger other data collection. For example, if the subject's survival status is "dead" then this indicates that the subject has ceased participation in the study so a study discontinuation record would need to be created. In SDTM, the data related to these follow-up telephone contacts should be stored as follows:

1. Concomitant medications reported during the contact should be stored in the CM (Concomitant Medications) domain.
2. The subject's survival status should be stored in the SS (Subject Status) domain.
3. The disposition of the subject at the time of the final follow-up contact should be stored in DS (Disposition). Note that overall study conclusion is the point where any contact with the subject ceases, which in this example is also the conclusion of long-term follow-up. The disposition of the subject at the conclusion of the two-month clinical treatment phase would be stored in DS as the conclusion to that epoch. Long-term follow-up would be represented as a separate epoch. Therefore, in this example the subject could have three disposition records in DS, with both the follow-up epoch disposition and the overall study conclusion disposition being collected at the final telephone contact.
4. If the subject's survival status is "dead", the Demographics (DM) variables DTHDTC and DTHFL must be appropriately populated.
5. The long-term follow-up phase would be represented in Trial Arms (TA), Trial Elements (TE) and Trial Visits (TV).
6. The contacts would be recorded in Subject Visits (SV) and Subject Elements (SE) consistent with the way they are represented in TV and TE.

5 Models for Special-Purpose Domains

Special Purpose Domains is an SDTM category in its own right as they provide specific standardized structures to represent additional important information that does not fit any of the General Observation Classes.

The below table provides a short index for documents where each listed Domain/Dataset is described in full detail.

Please note that this is a change from previous SDTMIG versions (prior to SDTMIG 3.2), where all domains were contained within a single document. This approach has been taken with the goal to simplify SDTMIG maintenance and to assist users in accessing the specific section/domain of interest without having to search a single and much larger document. The Table of Contents for the entire SDTMIG should reflect all domains (old and new) that make up this new release.

Domain Code	Domain Description	Domain Document Name
CO	<p><u>Comments</u> The Comments dataset accommodates two sources of comments: 1) those collected alongside other data on topical case report form (CRF) pages such as Adverse Events and 2) those collected on a separate page specifically dedicated to comments.</p>	Section 5 – CO Domain
DM	<p><u>Demographics</u> The Demographics domain includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects.</p>	Section 5 - DM Domain
SE	<p><u>Subject Elements</u> The subject element table describes the actual order of elements followed by the subject, together with the start date/time and end date/time for each element.</p>	Section 5 – SE Domain
SV	<p><u>Subject Visits</u> The subject visits table describes the actual start and end data/time for each visit of each individual subject.</p>	Section 5 - SV Domain

5 Models for Special-Purpose Domains

Comments (CO)

CO – Description/Overview for the Comments Domain Model

The Comments dataset accommodates two sources of comments: 1) those collected alongside other data on topical case report form (CRF) pages such as Adverse Events and 2) those collected on a separate page specifically dedicated to comments

CO – Specification for the Comments Domain Model

co.xpt, Comments —Version 3.2, One record per comment per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	CO	Identifier	Two-character abbreviation for the domain.	Req
RDOMAIN	Related Domain Abbreviation	Char	*	Record Qualifier	Two-character abbreviation for the domain of the parent record(s). Null for comments collected on a general comments or additional information CRF page.	Perm
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
COSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
IDVAR	Identifying Variable	Char	*	Record Qualifier	Identifying variable in the parent dataset that identifies the record(s) to which the comment applies. Examples AESEQ or CMGRPID. Used only when individual comments are related to domain records. Null for comments collected on separate CRFs.	Perm
IDVARVAL	Identifying Variable Value	Char		Record Qualifier	Value of identifying variable of the parent record(s). Used only when individual comments are related to domain records. Null for comments collected on separate CRFs.	Perm
COREF	Comment Reference	Char		Record Qualifier	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).	Perm
COVAL	Comment	Char		Topic	The text of the comment. Text over 200 characters can be added to additional columns COVAL1-COVALn. See Assumption 3 .	Req
COEVAL	Evaluator	Char	*	Record Qualifier	Used to describe the originator of the comment. Examples: CENTRAL, REVIEWER, ADJUDICATION COMMITTEE, PRINCIPAL INVESTIGATOR.	Perm
CODTC	Date/Time of Comment	Char	ISO 8601	Timing	Date/time of comment on dedicated comment form. Should be null if this is a child record of another domain or if comment date was not collected.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

CO - Assumptions for the Comments Domain Model

1. The Comments special-purpose domain provides a solution for submitting free-text comments related to data in one or more SDTM domains (as described in **Section 8: 8.5, Relating Comments To A Parent Domain**) or collected on a separate CRF page dedicated to comments. Comments are generally not responses to specific questions; instead, comments usually consist of voluntary, free-text or unsolicited observations.
2. The CO dataset accommodates three sources of comments:
 - a. Those unrelated to a specific domain or parent record(s), in which case the values of the variables RDOMAIN, IDVAR and IDVARVAL are null. CODTC should be populated if captured. See example, Rows 1.
 - b. Those related to a domain but not to specific parent record(s), in which case the value of the variable RDOMAIN is set to the DOMAIN code of the parent domain and the variables IDVAR and IDVARVAL are null. CODTC should be populated if captured. See example, Row 2.
 - c. Those related to a specific parent record or group of parent records, in which case the value of the variable RDOMAIN is set to the DOMAIN code of the parent record(s) and the variables IDVAR and IDVARVAL are populated with the key variable name and value of the parent record(s). Assumptions for populating IDVAR and IDVARVAL are further described in **Section 8: 8.5, Relating Comments To A Parent Domain**. CODTC should be null because the timing of the parent record(s) is inherited by the comment record. See example, Rows 3-5.
3. When the comment text is longer than 200 characters, the first 200 characters of the comment will be in COVAL, the next 200 in COVAL1, and additional text stored as needed to COVALn. See example, Rows 3-4.
4. Additional information about how to relate comments to parent SDTM records is provided in **Section 8: 8.5, Relating Comments To A Parent Domain**.
5. The variable COREF may be null unless it is used to identify the source of the comment. See example, Rows 1 and 5.
6. Only following Identifier and Timing variables that are permissible and may be added as appropriate when comments are not related to other domain records: COGRPID, COREFID, COSPID, VISIT, VISITNUM, VISITDY, TAETORD, CODY, COTPT, COTPTNUM, COELTM, COTPTREF, CORFTDTC.

CO - Examples for the Comments Domain Model

In the example below:

- **Row 1:** Shows a comment unrelated to any specific domain or record, because it was collected on a separate comments page...
- **Row 2:** Shows a comment related to a specific domain (PE in this example), but not to any specific record because it was collected on the bottom of the PE page without any indication of specific records it applies to. COREF is populated with the text “VISIT 7” to show this comment came from the VISIT 7 PE page.
- **Rows 3-5:** Show comments related to parent records in the AE, EX and VS domains.
 - Row 3 shows a comment related to a single AE record having its AESEQ=7.
 - Row 4 shows a comment related to multiple EX records having their EXGRPID=“COMBO1”.
 - Row 5 shows a comment related to multiple VS records having their VSGRPID=“VS2”
- **Rows 6-8:** Show three options for representing a comment unrelated to any specific general observation class record(s) because it was collected on a separate comments page, but the page was associated with a specific visit.
 - Row 6 shows the comment related to the Subject Visit record in SV. The RDOMAIN variable is populated with SV (the Subject Visits domain) and the variables IDVAR and IDVARVAL are populated with the key variable name and value of the parent Subject-Visit record.
 - Row 7 shows the comment unrelated to any parent records, RDOMAIN, IDVAR and IDVARVAL are not populated. COREF is populated to indicate that the comment reference is “VISIT 4”
 - Row 8 also shows the comment unrelated to any parent records, but instead of populating COREF, the VISITNUM Timing variable was added to the CO dataset and populated with 4 to indicate Visit 4.

Row	STUDYID	DOMAIN	RDOMAIN	USUBJID	COSEQ	IDVAR	IDVARVAL	COREF	COVAL	COVAL1	COVAL2
1	1234	CO		AB-99	1				Comment text		
2	1234	CO	PE	AB-99	2			VISIT 7	Comment text		
3	1234	CO	AE	AB-99	3	AESEQ	7	PAGE 650	First 200 characters	Next 200 characters	Remaining text
4	1234	CO	EX	AB-99	4	EXGRPID	COMBO1	PAGE 320-355	First 200 characters	Remaining text	
5	1234	CO	VS	AB-99	5	VSGRPID	VS2		Comment text		
6	1234	CO	SV	AB-99	6	VISITNUM	4		Comment Text		
7	1234	CO		AB-99	7			VISIT 4	Comment Text		
8	1234	CO		AB-99	8				Comment Text		

Row	COEVAL	VISITNUM	CODTC
1 (cont)	PRINCIPAL INVESTIGATOR		2003-11-08
2 (cont)	PRINCIPAL INVESTIGATOR		2004-01-14
3 (cont)	PRINCIPAL INVESTIGATOR		
4 (cont)	PRINCIPAL INVESTIGATOR		
5 (cont)	PRINCIPAL INVESTIGATOR		
6 (cont)	PRINCIPAL INVESTIGATOR		
7 (cont)	PRINCIPAL INVESTIGATOR		
8 (cont)	PRINCIPAL INVESTIGATOR	4	

5 Models for Special-Purpose Domains

Demographics (DM)

DM – Description/Overview for the Demographics Domain Model

The Demographics domain includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects.

DM – Specification for the Demographics Domain Model

dm.xpt, Demographics — Version 3.2. One record per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	Req
SUBJID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req
RFSTDTC	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study 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.	Exp
RFENDTC	Subject Reference End Date/Time	Char	ISO 8601	Record Qualifier	Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the 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.	Exp
RFXSTDTC	Date/Time of First Study Treatment	Char	ISO 8601	Record Qualifier	First date of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC.	Exp
RFXENDTC	Date/Time of Last Study Treatment	Char	ISO 8601	Record Qualifier	Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing).	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
RFICDTC	Date/Time of Informed Consent	Char	ISO 8601	Record Qualifier	Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent.	Exp
RFPENDTC	Date/Time of End of Participation	Char	ISO 8601	Record Qualifier	Date/time when subject ended participation or follow-up in a trial, as defined in the protocol, in ISO 8601 character format. Should correspond to the last known date of contact. Examples include completion date, withdrawal date, last follow-up, date recorded for lost to follow up, or death date.	Exp
DTHDTC	Date/Time of Death	Char	ISO 8601	Record Qualifier	Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-trial database.	Exp
DTHFL	Subject Death Flag	Char	(NY)	Record Qualifier	Indicates the subject died. Should be Y or null. Should be populated even when the death date is unknown.	Exp
SITEID	Study Site Identifier	Char		Record Qualifier	Unique identifier for a site within a study.	Req
INVID	Investigator Identifier	Char		Record Qualifier	An identifier to describe the Investigator for the study. May be used in addition to SITEID. Not needed if SITEID is equivalent to INVID.	Perm
INVNAM	Investigator Name	Char		Synonym Qualifier	Name of the investigator for a site.	Perm
BRTHDTC	Date/Time of Birth	Char	ISO 8601	Record Qualifier	Date/time of birth of the subject.	Perm
AGE	Age	Num		Record Qualifier	Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns).	Exp
AGEU	Age Units	Char	(AGEU)	Variable Qualifier	Units associated with AGE.	Exp
SEX	Sex	Char	(SEX)	Record Qualifier	Sex of the subject.	Req
RACE	Race	Char	(RACE)	Record Qualifier	Race of the subject. 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/RegulatoryInformation/Guidances/ucm126340.htm) See Assumption below regarding RACE.	Exp
ETHNIC	Ethnicity	Char	(ETHNIC)	Record Qualifier	The ethnicity of the subject. Sponsors should refer to “Collection of Race and Ethnicity Data in Clinical Trials” (FDA, September 2005) for guidance regarding the collection of ethnicity (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm).	Perm
ARMCD	Planned Arm Code	Char	*	Record Qualifier	ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than for other “short” variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20.	Req
ARM	Description of Planned Arm	Char	*	Synonym Qualifier	Name of the Arm to which the subject was assigned.	Req

CDISC SDTM Implementation Guide (Version 3.2)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
ACTARMCD	Actual Arm Code	Char	*	Record Qualifier	Code of actual Arm. When an Arm is not planned (not in Trial Arms), ACTARMCD will be UNPLAN. Randomized subjects who were not treated will be given a value of NOTTRT. Values should be "SCRNFAIL" for screen failures and "NOTASSGN" for subjects not assigned to treatment. Restricted to values in Trial Arms in all other cases. ACTARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ACTARMCD is longer than for other short variables to accommodate the kind of values that are likely to be needed for crossover trials.	Req
ACTARM	Description of Actual Arm	Char	*	Synonym Qualifier	Description of actual Arm. When an Arm is not planned (not in Trial Arms), ACTARM will be "Unplanned Treatment". Randomized subjects who were not treated will be given a value of "Not Treated". Values should be "Screen Failure" for screen failures and "Not Assigned" for subjects not assigned to treatment. Restricted to values in Trial Arms in all other cases.	Req
COUNTRY	Country	Char	(COUNTRY) ISO 3166	Record Qualifier	Country of the investigational site in which the subject participated in the trial.	Req
DMDTC	Date/Time of Collection	Char	ISO 8601	Timing	Date/time of demographic data collection.	Perm
DMDY	Study Day of Collection	Num		Timing	Study day of collection measured as integer days.	Perm

* Indicates variable may be subject to controlled terminology. (Parenthesis indicates CDISC/NCI codelist code value)

DM – Assumptions for the Demographics Domain Model

1. Investigator and site identification: Companies use different methods to distinguish sites and investigators. CDISC assumes that SITEID will always be present, with INVID and INVNAM used as necessary. This should be done consistently and the meaning of the variable made clear in the define.xml.
2. Every subject in a study must have a subject identifier (SUBJID). In some cases a subject may participate in more than one study. To identify a subject uniquely across all studies for all applications or submissions involving the product, a unique identifier (USUBJID) must be included in all datasets. Subjects occasionally change sites during the course of a clinical trial. The sponsor must decide how to populate variables such as USUBJID, SUBJID and SITEID based on their operational and analysis needs, but only one DM record should be submitted for the subject. The Supplemental Qualifiers dataset may be used if appropriate to provide additional information.
3. Concerns for subject privacy suggest caution regarding the collection of variables like BRTHDTC. This variable is included in the Demographics model in the event that a sponsor intends to submit it; however, sponsors should follow regulatory guidelines and guidance as appropriate.
4. The values of ARM and ARMCD in DM must match entries in the Trial Arms (TA) dataset, except for subjects who were not fully assigned to an Arm. Subjects who did not receive the treatments to which they were assigned will still have the values of ARM and ARMCD to which they were assigned. SE/DM Examples 1 and 2 in **Section 5 - SE Domain: SE - Examples for the SUBJECT ELEMENTS Domain Model** show examples of subjects whose actual treatment did not match their planned treatment.

Some subjects may leave the trial before they can be assigned to an Arm, or, in the case of trials where Arm is assigned by two or more successive allocation processes, may leave before the last of these processes. Such subjects will not be assigned to one of the planned Arms described in the Trial Arms dataset, and must have special values of ARM and ARMCD assigned.

- Data for screen failure subjects, if submitted, should be included in the Demographics dataset, with ARMCD = "SCRNFAIL" and ARM = "Screen Failure". Sponsors may include a record in the Disposition dataset indicating when the screen failure event occurred. DM/SE Example 6 shows an example of data submitted for a screen failure subject.
 - Some trial designs include Elements after screening but before Arm assignments are made, and so may have subjects who are not screen failures, but are not assigned to an Arm. Subjects withdrawn from a trial before assignment to an Arm, if they are not screen failures, should have ARMCD = "NOTASSGN" and ARM = "Not Assigned". Example Trial 1 in **Section 7.2 - Experimental Design: Example Trial 1, A Parallel Trial, TA – Examples For Trial Arms Dataset**, which includes a screening Epoch and a run-in Epoch before randomization, is an example of such a trial; data for a subject who passed screening but was not randomized in this trial are shown in DM/SE Example 6.
 - In trials where Arm assignment is done by means of two or more allocation processes at separate points in time, subjects who drop out after the first allocation process but before the last allocation process, should be assigned values of ARMCD that reflect only the allocation processes they underwent. Example Trial 3, **Section 7.2 - Experimental Design: Example Trial 3, A Trial With Multiple Branch Points, TA - Examples for Trial Arms Dataset**, is such a trial. DM/SE Example 7 shows sample data for subjects in this trial.
5. When study population flags are included in SDTM, they are treated as Supplemental Qualifiers [*see Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain*] to DM and placed in the SUPPDM dataset. Controlled terms for these subject-level population flags, (e.g., COMPLT, SAFETY, ITT and PPROT) are listed in **Appendix C2 - Supplemental Qualifier Name Codes**. See ICH E9 for more information and definitions. Note that the ADaM subject-level analysis dataset (ADSL) includes population flags; consult the ADaM Implementation Guide for more information about these variables.

6. Submission of multiple race responses should be represented in the Demographics domain and Supplemental Qualifiers (SUPPDM) dataset as described in **Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable**. If multiple races are collected then the value of RACE should be “MULTIPLE” and the additional information will be included in the Supplemental Qualifiers dataset. Controlled terminology for RACE should be used in both DM and SUPPDM so that consistent values are available for summaries regardless of whether the data are found in a column or row. If multiple races were collected and one was designated as primary, RACE in DM should be the primary race and additional races should be reported in SUPPDM. When additional free text information is reported about subject's RACE using “Other, Specify”, Sponsors should refer to **Section 4: 4.1.2.7.1, “Specify” Values For Non-Result Qualifier Variables**. If the race was collected via an “Other, Specify” field and the sponsor chooses not to map the value as described in the current FDA guidance (see CDISC Notes for RACE) then the value of RACE should be “OTHER”. If a subject refuses to provide race information, the value of RACE could be “UNKNOWN”. Examples are provided below in [Section 5 - DM Domain: DM - Examples for the DEMOGRAPHICS Domain Model](#).
7. RFSTDTC, RFENDTC, RFXSTDTC, RFXENDTC, RFICDTC, RFPENDTC and BRTHDTC represent date/time values, but they are considered to have a Record Qualifier role in DM. They are not considered to be Timing Variables because they are not intended for use in the general observation classes.
8. Additional Permissible Identifier, Qualifier and Timing Variables
Only the following Timing variables are permissible and may be added as appropriate: VISITNUM, VISIT, VISITDY. The Record Qualifier DMXFN (External File Name) is the only additional qualifier variable that may be added, which is adopted from the Findings general observation class, may also be used to refer to an external file, such as a patient narrative.
9. The order of these new variables within the domain should follow the rules as described in **Section 4: 4.1.1.4, Order Of The Variables** and the order described in **Section 4: 1.2, Organization Of This Document**.
10. As described in **Section 4: 4.1.1.4, Order Of The Variables**, RFSTDTC is used to calculate study day variables. RFSTDTC is usually defined as the date/time when a subject was first exposed to study drug. This definition applies for most interventional studies, when the start of treatment is the natural and preferred starting point for study day variables and thus the logical value for RFSTDTC. In such studies, when data are submitted for subjects who are ineligible for treatment (e.g., screen failures with ARMCD=SCRNFAIL), subjects who were enrolled but not assigned to an arm (ARMCD=NOTASSGN), or subjects who were randomized but not treated (ACTARMCD=NOTTRT), RFSTDTC will be null. For studies with designs that include a substantial portion of subjects who are not expected to be treated, a different protocol milestone may be chosen as the starting point for study day variables. Some examples include non-interventional or observational studies, studies with a no-treatment arm, or studies where there is a delay between randomization and treatment.
11. RFXSTDTC may be the same as RFSTDTC, but it might be different for some studies. An example of the latter would be when RFSTDTC was defined as the date the informed consent was signed. RFXSTDTC should be the same as SESTDTC for the first treatment Element described in the SE dataset.
12. RFXENDTC may often be the same as the SEENDTC for the last treatment Element described in the SE dataset. RFXENDTC may or may not be the same as RFENDTC, the date defined as the reference end for a subject.
13. RFICDTC should correspond to the date of the informed consent protocol milestone in DS, if that protocol milestone is documented in DS. In the event that there are multiple informed consents, this will be the date of the first one.

14. RFPENDTC will be the last date of participation for a subject for data included in a submission. This should be the last date of any record for the subject in the database at the time it's locked for submission. As such, it may not be the last date of participation in the study if the submission includes interim data.

DM – Examples for the Demographics Domain Model

Examples of using the DM domain for typical scenarios are provided below. Example 1 displays the all Required and Expected variables; in examples 2 - 6, certain Required or Expected variables have been omitted in consideration of space and clarity. Example 1 is a general Demographics example showing typical data recorded for a clinical trial. Examples 2 through 5 display various scenarios for representing race and ethnicity information. Example 6 shows the handling of ARMCD for Subjects Withdrawn before Assignment to an Arm, and Example 7 shows the handling ARMCD for Subjects Withdrawn when assignment to an Arm is Incomplete.

DM Example 1 – General Demographics

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICTTC	RFPENDTC
1	ABC123	DM	ABC12301001	001	2006-01-12	2006-03-10	2006-01-12	2006-03-10	2006-01-03	2006-04-01
2	ABC123	DM	ABC12301002	002	2006-01-15	2006-02-28	2006-01-15	2006-02-28	2006-01-04	2006-03-26
3	ABC123	DM	ABC12301003	003	2006-01-16	2006-03-19	2006-01-16	2006-03-19	2006-01-02	2006-03-19
4	ABC123	DM	ABC12301004	004					2006-01-07	2006-01-08
5	ABC123	DM	ABC12302001	001	2006-02-02	2006-03-31	2006-02-02	2006-03-31	2006-01-15	2006-04-12
6	ABC123	DM	ABC12302002	002	2006-02-03	2006-04-05	2006-02-03	2006-04-05	2006-01-10	2006-04-25

Row	SITEID	INVNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC
1 (cont)	01	JOHNSON, M	1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO
2 (cont)	01	JOHNSON, M	1955-03-22	50	YEARS	M	WHITE	NOT HISPANIC OR LATINO
3 (cont)	01	JOHNSON, M	1938-01-19	68	YEARS	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO
4 (cont)	01	JOHNSON, M	1941-07-02			M	ASIAN	NOT HISPANIC OR LATINO
5 (cont)	02	GONZALEZ, E	1950-06-23	55	YEARS	F	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO
6 (cont)	02	GONZALEZ, E	1956-05-05	49	YEARS	F	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDERS	NOT HISPANIC OR LATINO

Row	ARMCD	ARM	ACTARMCD	ACTARM	COUNTRY
1 (cont)	A	Drug A	A	Drug A	USA
2 (cont)	P	Placebo	P	Placebo	USA
3 (cont)	P	Placebo	P	Placebo	USA
4 (cont)	SCRNFAIL	Screen Failure	SCRNFAIL	Screen Failure	USA
5 (cont)	P	Placebo	P	Placebo	USA
6 (cont)	A	Drug A	A	Drug A	USA

DM Example 2 – Single Race/Single Ethnicity Choice

Sample CRF:

Ethnicity	Check one
Hispanic or Latino	<input type="checkbox"/>
Not Hispanic or Latino	<input type="checkbox"/>

Race	Check one
American Indian or Alaska Native	<input type="checkbox"/>
Asian	<input type="checkbox"/>
Black or African American	<input type="checkbox"/>
Native Hawaiian or Other Pacific Islander	<input type="checkbox"/>
White	<input type="checkbox"/>

Row 1: Subject 001 was Not-Hispanic and Asian.

Row 2: Subject 002 was Hispanic and White.

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Row	STUDYID	DOMAIN	USUBJID	RACE	ETHNIC
1	ABC	DM	001	ASIAN	NOT HISPANIC OR LATINO
2	ABC	DM	002	WHITE	HISPANIC OR LATINO

DM Example 3 - Multiple Race Choices

In this example, the subject is permitted to check all applicable races.

Sample CRF:

Race	Check all that apply
American Indian or Alaska Native	<input type="checkbox"/>
Asian	<input type="checkbox"/>
Black or African American	<input type="checkbox"/>
Native Hawaiian or Other Pacific Islander	<input type="checkbox"/>
White	<input type="checkbox"/>
Other, Specify: _____	<input type="checkbox"/>

Row 1 (DM) and

Row 1 (SUPPDM): Subject 001 checked “Other, Specify:” and entered “Brazilian” as race.

Row 2 (DM) and

Rows 2, 3, 4, 5 (SUPPDM): Subject 002 checked three races, including an “Other, Specify” value. The three values are reported in SUPPDM using QNAM values RACE1 - RACE3. The specified information describing other race for is submitted in the same manner as subject 001.

Row 3 (DM): Subject 003 refused to provide information on race.

Row 4 (DM): Subject 004 checked “Asian” as their only race.

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Row	STUDYID	DOMAIN	USUBJID	RACE
1	ABC	DM	001	OTHER
2	ABC	DM	002	MULTIPLE
3	ABC	DM	003	
4	ABC	DM	004	ASIAN

suppdm.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	DM	001			RACEOTH	Race, Other	BRAZILIAN	CRF	
2	ABC	DM	002			RACE1	Race 1	BLACK OR AFRICAN AMERICAN	CRF	
3	ABC	DM	002			RACE2	Race 2	AMERICAN INDIAN OR ALASKA NATIVE	CRF	
4	ABC	DM	002			RACE3	Race 3	OTHER	CRF	
5	ABC	DM	002			RACEOTH	Race, Other	ABORIGINE	CRF	

DM Example 4: Mapping Predefined Races

In this example, the sponsor has chosen to map some of the predefined races to other races, specifically Japanese and Non-Japanese to Asian. Note: Sponsors may choose not to map race data, in which case the previous examples should be followed.

Sample CRF

Race	Check One
American Indian or Alaska Native	<input type="checkbox"/>
Asian	<input checked="" type="checkbox"/>
Japanese	<input type="checkbox"/>
Non-Japanese	<input type="checkbox"/>
Black or African American	<input type="checkbox"/>
Native Hawaiian or Other Pacific Islander	<input type="checkbox"/>
White	<input type="checkbox"/>

Row 1 (DM), Row 1 (SUPPDM): Subject 001 checked “Non-Japanese” which was mapped by the sponsor to “Asian”.

Row 2 (DM), Row 2 (SUPPDM): Subject 002 checked “Japanese” which was mapped by the sponsor to “Asian”.

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Row	STUDYID	DOMAIN	USUBJID	RACE
1	ABC	DM	001	ASIAN
2	ABC	DM	002	ASIAN

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	DM	001			RACEOR	Original Race	NON-JAPANESE	CRF	
2	ABC	DM	002			RACEOR	Original Race	JAPANESE	CRF	

DM Example 5: Mapping “Other, Specify” Races

In this example, the sponsor has chosen to map the values entered into the “Other, Specify” field to one of the preprinted races.
 Note: Sponsors may choose not to map race data, in which case the first two examples should be followed.

Sample CRF and Data:

Race	Check One
American Indian or Alaska Native	<input type="checkbox"/>
Asian	<input type="checkbox"/>
Black or African American	<input type="checkbox"/>
Native Hawaiian or Other Pacific Islander	<input type="checkbox"/>
White	<input type="checkbox"/>
Other, Specify: _____	<input type="checkbox"/>

Row 1 (DM), Row 1 (SUPPDM): Subject 001 checked “Other, Specify” and entered “Japanese” which was mapped to “Asian” by the sponsor.

Row 2 (DM), Row 2 (SUPPDM): Subject 002 checked “Other, Specify” and entered “Swedish” which was mapped to “White” by the sponsor.

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Row	STUDYID	DOMAIN	USUBJID	RACE
1	ABC	DM	001	ASIAN
2	ABC	DM	002	WHITE

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	DM	001			RACEOR	Original Race	JAPANESE	CRF	
2	ABC	DM	002			RACEOR	Original Race	SWEDISH	CRF	

DM/SE Example 6

The following examples illustrate values of ARMCD for subjects in Example Trial 1, described in *Section 7.2 - Experimental Design: Example Trial 1, A Parallel Trial, TA – Examples For Trial Arms Dataset*. The sponsor is submitting data on screen-failure subjects.

Row 1: Subject 001 was randomized to Arm A. Rows 1-3 of SE dataset show that the subject completed all the Elements for Arm A.

Row 2: Subject 002 was randomized to Arm B. Rows 4-6 of SE dataset show that the subject completed all the Elements for Arm B.

Row 3: Subject 003 was a screen failure. Row 7 of SE dataset shows that they passed through only the Screen Element.

Row 4: Subject 004 withdrew during the Run-in Element. They were not considered a screen failure, but they were not randomized, so they have been given the special ARMCD value NOTASSGN. Rows 8-9 of the SE dataset show the two Elements (Screen and Run-in) this subject passed through.

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Row	STUDYID	DOMAIN	USUBJID	ARMCD
1	ABC	DM	001	A
2	ABC	DM	002	B
3	ABC	DM	003	SCRNFAIL
4	ABC	DM	004	NOTASSGN

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Row	STUDYID	DOMAIN	USUBJID	SESEQ	ETCD	ELEMENT	SESTDTC	SEENDTC
1	ABC	SE	001	1	SCRN	Screen	2006-06-01	2006-06-07
2	ABC	SE	001	2	RI	Run-In	2006-06-07	2006-06-21
3	ABC	SE	001	3	A	Drug A	2006-06-21	2006-07-05
4	ABC	SE	002	1	SCRN	Screen	2006-05-03	2006-05-10
5	ABC	SE	002	2	RI	Run-In	2006-05-10	2006-05-24
6	ABC	SE	002	3	B	Drug B	2006-05-24	2006-06-07
7	ABC	SE	003	1	SCRN	Screen	2006-06-27	2006-06-30
8	ABC	SE	004	1	SCRN	Screen	2006-05-14	2006-05-21
9	ABC	SE	004	2	RI	Run-In	2006-05-21	2006-05-26

DM/SE Example 7:

The following example illustrates values of ARMCD for subjects in Example Trial 3, described in *Section 7.2 - Experimental Design: Example Trial 3, A Trial With Multiple Branch Points, TA - Examples for Trial Arms Dataset*

Row 1: Subject 001 was randomized to Drug A. At the end of the Double Blind Treatment Epoch, they were assigned to Open Label A. Thus their ARMCD is AA. Rows 1-3 of the SE dataset show that subject passed through all three Elements for the AA Arm.

Row 2: Subject 002 was randomized to Drug A. They were lost to follow-up during the Double Blind Epoch, so never reached the Open Label Epoch, when they would have been assigned to either the Open Drug A or the Rescue Element. Their ARMCD is A. Note that A is not one of the Arm code values in the Trial Arms dataset for this trial. See *Section 7.2 - Experimental Design: Issue 2, Subjects Not Assigned To An Arm, TA – Issues In Trial Arms Dataset* for more information on handling subjects who do not reach all branch points in the trial design. Rows 4-5 of the SE dataset show the two Elements (Screen and Treatment A) the subject passed through.

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Row	STUDYID	DOMAIN	USUBJID	ARMCD	ARM
1	DEF	DM	001	AA	A-OPEN A
2	DEF	DM	002	A	A

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Row	STUDYID	DOMAIN	USUBJID	SESEQ	ETCD	ELEMENT	SESTDTC	SEENDTC
1	DEF	SE	001	1	SCRN	Screen	2006-01-07	2006-01-12
2	DEF	SE	001	2	DBA	Treatment A	2006-01-12	2006-04-10
3	DEF	SE	001	3	OA	Open Drug A	2006-04-10	2006-07-05
4	DEF	SE	002	1	SCRN	Screen	2006-02-03	2006-02-10
5	DEF	SE	002	2	DBA	Treatment A	2006-02-10	2006-03-24

5 Models for Special-Purpose Domains

Subject Elements (SE) and Subject Visits (SV)

The Trial Elements, Trial Arms, and Trial Visits datasets in the Trial Design model describe the planned design of the study (see *Section 7.2 - Experimental Design: Trial Elements (TE)*, *Section 7.2 - Experimental Design: Trial Arms (TA)* and *Section 7.3 - Schedule for Assessments: Trial Visits (TV)*), but it is also necessary to collect the corresponding actual data. Subject assignment to an Arm is reported in the ARM variable in Demographics. Actual Elements and Visits data for each subject are described in two additional datasets:

- The Subject Elements dataset [*Section 5 - SE Domain*]
- The Subject Visits dataset [*Section 5 - SV Domain*]

Subject Elements (SE)

SE – Description/Overview for the Subject Elements Domain Model

The Subject Elements dataset consolidates information about the timing of each subject's progress through the Epochs and Elements of the trial. For Elements that involve study treatments, the identification of which Element the subject passed through (e.g., Drug X vs. placebo) is likely to derive from data in the Exposure domain or another Interventions domain. The dates of a subject's transition from one Element to the next will be taken from the Interventions domain(s) and from other relevant domains, according to the definitions (TESTRL values) in the Trial Elements dataset [*see Section 7.2 - Experimental Design: Trial Elements (TE)*].

The Subject Elements dataset is particularly useful for studies with multiple treatment periods, such as crossover studies. The Subject Elements dataset contains the date/times at which a subject moved from one Element to another, so when the Trial Arms [*Section 7.2 - Experimental Design: Trial Arms (TA)*], Trial Elements [*Section 7: 7.3, Trial Elements (TE)*], and Subject Elements datasets are included in a submission, reviewers can relate all the observations made about a subject to that subject's progression through the trial.

- Comparison of the --DTC of a finding observation to the Element transition dates (values of SESTDTC and SEENDTC) tells which Element the subject was in at the time of the finding. Similarly, one can determine the Element during which an event or intervention started or ended.
- “Day within Element” or “day within Epoch” can be derived. Such variables relate an observation to the start of an Element or Epoch in the same way that study day (--DY) variables relate it to the reference start date (RFSTDTC) for the study as a whole. See *Section 4: 4.1.4.4, Use Of The “Study Day” Variables*
- Having knowledge of Subject Element start and end dates can be helpful in the determination of baseline values.

SE – Specification for the for the Subject Elements Domain Model

se.xpt, Subject Elements — Version 3.2. One record per actual Element per subject.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SESEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. Should be assigned to be consistent chronological order.	Req
ETCD	Element Code	Char	*	Topic	1. ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that ETCD will need to serve as a variable name. 2. If an encountered Element differs from the planned Element to the point that it is considered a new Element, then use “UNPLAN” as the value for ETCD to represent this Element.	Req
ELEMENT	Description of Element	Char	*	Synonym Qualifier	The name of the Element. If ETCD has a value of “UNPLAN” then ELEMENT should be Null.	Perm
SESTDTC	Start Date/Time of Element	Char	ISO 8601	Timing	Start date/time for an Element for each subject.	Req
SEENDTC	End Date/Time of Element	Char	ISO 8601	Timing	End date/time for an Element for each subject.	Exp
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the Element within the subject's assigned ARM.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the Element in the planned sequence of Elements for the ARM to which the subject was assigned	Perm
SEUPDES	Description of Unplanned Element	Char		Synonym Qualifier	Description of what happened to the subject during this unplanned Element. Used only if ETCD has the value of “UNPLAN”.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

SE – Assumptions for the for the Subject Elements Domain Model

1. Submission of the Subject Elements dataset is strongly recommended, as it provides information needed by reviewers to place observations in context within the study. The Trial Elements and Trial Arms datasets should also be submitted, as they define the design and the terms referenced by the Subject Elements dataset.
2. The Subject Elements domain allows the submission of data on the timing of the trial Elements a subject actually passed through in their participation in the trial. Please read *Section 7.2 - Experimental Design: Trial Elements (TE)*, on the Trial Elements dataset and *Section 7.2 - Experimental Design: Trial Arms (TA)*, on the Trial Arms dataset, as these datasets define a trial's planned Elements, and describe the planned sequences of Elements for the Arms of the trial.

3. For any particular subject, the dates in the subject Elements table are the dates when the transition events identified in the Trial Elements table occurred. Judgment may be needed to match actual events in a subject's experience with the definitions of transition events (the events that mark the starts of new Elements) in the Trial Elements table, since actual events may vary from the plan. For instance, in a single dose PK study, the transition events might correspond to study drug doses of 5 and 10 mg. If a subject actually received a dose of 7 mg when they were scheduled to receive 5 mg, a decision will have to be made on how to represent this in the SE domain.
4. If the date/time of a transition Element was not collected directly, the method used to infer the Element start date/time should be explained in the Comments column of the define.xml.
5. Judgment will also have to be used in deciding how to represent a subject's experience if an Element does not proceed or end as planned. For instance, the plan might identify a trial Element which is to start with the first of a series of 5 daily doses and end after 1 week, when the subject transitions to the next treatment Element. If the subject actually started the next treatment Epoch [see Section 7 - Introduction: 7.1.2, Definitions Of Trial Design Concepts] after 4 weeks, the sponsor will have to decide whether to represent this as an abnormally long Element, or as a normal Element plus an unplanned non-treatment Element.
6. If the sponsor decides that the subject's experience for a particular period of time cannot be represented with one of the planned Elements, then that period of time should be represented as an unplanned Element. The value of ETCD for an unplanned Element is "UNPLAN" and SEUPDES should be populated with a description of the unplanned Element.
7. The values of SESTDTC provide the chronological order of the actual subject Elements. SESEQ should be assigned to be consistent with the chronological order. Note that the requirement that SESEQ be consistent with chronological order is more stringent than in most other domains, where --SEQ values need only be unique within subject.
8. When TAETORD is included in the SE domain, it represents the planned order of an Element in an Arm. This should not be confused with the actual order of the Elements, which will be represented by their chronological order and SESEQ. TAETORD will not be populated for subject Elements that are not planned for the Arm to which the subject was assigned. Thus, TAETORD will not be populated for any Element with an ETCD value of "UNPLAN". TAETORD will also not be populated if a subject passed through an Element that, although defined in the TE dataset, was out of place for the Arm to which the subject was assigned. For example, if a subject in a parallel study of Drug A vs. Drug B was assigned to receive Drug A, but received Drug B instead, then TAETORD would be left blank for the SE record for their Drug B Element. If a subject was assigned to receive the sequence of Elements A, B, C, D, and instead received A, D, B, C, then the sponsor would have to decide for which of these subject Element records TAETORD should be populated. The rationale for this decision should be documented in the Comments column of the define.xml.
9. For subjects who follow the planned sequence of Elements for the Arm to which they were assigned, the values of EPOCH in the SE domain will match those associated with the Elements for the subject's Arm in the Trial Arms dataset. The sponsor will have to decide what value, if any, of EPOCH to assign SE records for unplanned Elements and in other cases where the subject's actual Elements deviate from the plan. The sponsor's methods for such decisions should be documented in the define.xml, in the row for EPOCH in the SE dataset table.
10. Since there are, by definition, no gaps between Elements, the value of SEENDTC for one Element will always be the same as the value of SESTDTC for the next Element.
11. Note that SESTDTC is required, although --STDTC is not required in any other subject-level dataset. The purpose of the dataset is to record the Elements a subject actually passed through. We assume that if it is known that a subject passed through a particular Element, then there must be some information on when it started, even if that information is imprecise. Thus, SESTDTC may not be null, although some records may not have all the components (e.g., year, month, day, hour, minute) of the date/time value collected.
12. The following Identifier variables are permissible and may be added as appropriate: --GRPID, --REFID, --SPID.
13. Care should be taken in adding additional Timing variables:

- The purpose of --DTC and --DY in other domains with start and end dates (Event and Intervention Domains) is to record the date and study day on which data was collected. The starts and ends of elements are generally “derived” in the sense that they are a secondary use of data collected elsewhere, and it is not generally useful to know when those date/times were recorded.
- --DUR could be added only if the duration of an element was collected, not derived.
- It would be inappropriate to add the variables that support time points (--TPT, --TPTNUM, --ELTM, --TPTREF, and --RFTDTC), since the topic of this dataset is Elements.

SE – Examples for the for the Subject Elements Domain Model

STUDYID and DOMAIN, which are required in the SE and DM domains, have not been included in the following examples, to improve readability.

Example 1

This example shows data for two subjects for a crossover trial with four Epochs.

Row 1: The record for the SCREEN Element for subject 789. Note that only the date of the start of the SCREEN Element was collected, while for the end of the Element, which corresponds to the start of IV dosing, both date and time were collected.

Row 2: The record for the IV Element for subject 789. The IV Element started with the start of IV dosing and ended with the start of oral dosing, and full date/times were collected for both.

Row 3: The record for the ORAL Element for subject 789. Only the date, and not the time, of start of Follow-up was collected.

Row 4: The FOLLOWUP Element for subject 789 started and ended on the same day. Presumably, the Element had a positive duration, but no times were collected.

Rows 5-8: Subject 790 was treated incorrectly, as shown by the fact that the values of SESEQ and TAETORD do not match. This subject entered the IV Element before the Oral Element, but the planned order of Elements for this subject was ORAL, then IV. The sponsor has assigned EPOCH values for this subject according to the actual order of Elements, rather than the planned order. The correct order of Elements is the subject's ARMCD, shown in Row 2 of the DM dataset.

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Row	USUBJID	SESEQ	ETCD	SESTDTC	SEENDTC	SEUPDES	TAETORD	EPOCH
1	789	1	SCREEN	2006-06-01	2006-06-03T10:32		1	SCREENING
2	789	2	IV	2006-06-03T10:32	2006-06-10T09:47		2	TREATMENT 1
3	789	3	ORAL	2006-06-10T09:47	2006-06-17		3	TREATMENT 2
4	789	4	FOLLOWUP	2006-06-17	2006-06-17		4	FOLLOW-UP
5	790	1	SCREEN	2006-06-01	2006-06-03T10:14		1	SCREENING
6	790	2	IV	2006-06-03T10:14	2006-06-10T10:32		3	TREATMENT 1
7	790	3	ORAL	2006-06-10T10:32	2006-06-17		2	TREATMENT 2
8	790	4	FOLLOWUP	2006-06-17	2006-06-17		4	FOLLOW-UP

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Row	USUBJID	SUBJID	RFSTDTCT	RFENDTCT	SITEID	INVTNAM	BIRTHDTCT	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	COUNTRY
1	789	001	2006-06-03	2006-06-17	01	SMITH, J	1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO	IO	IV-ORAL	USA
2	790	002	2006-06-03	2006-06-17	01	SMITH, J	1955-03-22	51	YEARS	M	WHITE	NOT HISPANIC OR LATINO	OI	ORAL-IV	USA

Example 2

The data below represent two subjects enrolled as described in *Section 7.2 - Experimental Design: Example Trial 3, A Trial With Multiple Branch Points, TA - Examples for Trial Arms Dataset*.

Rows 1-2: Subject 123 completed only two Elements of the trial. The double-blind treatment Epoch starts with the start of dosing, but in this trial only the date, and not the time, of the start of dosing has been collected. Note that, for this subject, events that occurred on, or data collected on, 2006-06-03 cannot be assigned to an Element or an Epoch on the basis of dates alone. When sponsors choose to collect only dates, they must deal with such ambiguity in the algorithms they use to assign data to Elements or Epochs. Row 1 of the Demographics dataset shows that this subject has an ARMCD value of A. See DM/SE Example 6 in *Section 5 - DM Domain: DM - Examples for the DEMOGRAPHICS Domain Model* for other examples of ARM and ARMCD values for this trial.

Rows 3-6: Subject 456 completed the trial, but received the wrong drug for the last 2 weeks of the double-blind treatment period. This has been represented by treating the period when the subject received the wrong drug as an unplanned Element. Note that TAETORD, which represents the planned order of Elements within an Arm, has not been populated for this unplanned Element. However, even though this Element was unplanned, the sponsor assigned a value of BLINDED TREATMENT to EPOCH. Row 2 of the Demographics dataset shows that the values of ARM and ARMCD for this subject reflect their planned treatment, and are not affected by the fact that their treatment deviated from plan.

se.xpt

Row	USUBJID	SESEQ	ETCD	SESTDTCT	SEENDTCT	SEUPDES	TAETORD	EPOCH
1	123	1	SCRN	2006-06-01	2006-06-03		1	SCREENING
2	123	2	DBA	2006-06-03	2006-06-10		2	BLINDED TREATMENT
3	456	1	SCRN	2006-05-01	2006-05-03		1	SCREENING
4	456	2	DBA	2006-05-03	2006-05-31		2	BLINDED TREATMENT
5	456	3	UNPLAN	2006-05-31	2006-06-13	Drug B dispensed in error		BLINDED TREATMENT
6	456	4	RSC	2006-06-13	2006-07-30		3	OPEN LABEL TREATMENT

dm.xpt

Row	USUBJID	SUBJID	RFSTDTCT	RFENDTCT	SITEID	INVTNAM	BIRTHDTCT	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	COUNTRY
1	123	012	2006-06-03	2006-06-10	01	JONES, D	1943-12-08	62	YEARS	M	ASIAN	HISPANIC OR LATINO	A	A	USA
2	456	103	2006-05-03	2006-07-30	01	JONES, D	1950-05-15	55	YEARS	F	WHITE	NOT HISPANIC OR LATINO	AR	A-Rescue	USA

5 Models for Special-Purpose Domains

Subject Elements (SE) and Subject Visits (SV)

The Trial Elements, Trial Arms, and Trial Visits datasets in the Trial Design model describe the planned design of the study (see *Section 7.2 - Experimental Design: Trial Elements (TE)*, *Section 7.2 - Experimental Design: Trial Arms (TA)* and *Section 7.3 - Schedule for Assessments: Trial Visits (TV)*), but it is also necessary to collect the corresponding actual data. Subject assignment to an Arm is reported in the ARM variable in Demographics. Actual Elements and Visits data for each subject are described in two additional datasets:

- The Subject Elements dataset [*Section 5 - SE Domain*]
- The Subject Visits dataset [*Section 5 - SV Domain*]

Subject Visits (SV)

SV – Description/Overview for the Subject Visits Domain Model

The Subject Visits domain consolidates information about the timing of subject visits that is otherwise spread over domains that include the visit variables (VISITNUM and possibly VISIT and/or VISITDY). Unless the beginning and end of each visit is collected, populating the Subject Visits dataset will involve derivations. In a simple case, where, for each subject visit, exactly one date appears in every such domain, the Subject Visits dataset can be created easily, by populating both SVSTDTC and SVENDTC with the single date for a visit. When there are multiple dates and/or date/times for a visit for a particular subject, the derivation of values for SVSTDTC and SVENDTC may be more complex. The method for deriving these values should be consistent with the visit definitions in the Trial Visits dataset [*see Section 7.3 - Schedule for Assessments: Trial Visits (TV)*]. For some studies, a visit may be defined to correspond with a clinic visit that occurs within one day, while for other studies, a visit may reflect data collection over a multi-day period.

The Subject Visits dataset provides reviewers with a summary of a subject's Visits. Comparison of an individual subject's SV dataset with the TV dataset [*Section 7.3 - Schedule for Assessments: Trial Visits (TV)*], which describes the planned Visits for the trial, quickly identifies missed Visits and "extra" Visits. Comparison of the values of STVSDY and SVENDY to VISIT and/or VISITDY can often highlight departures from the planned timing of Visits.

SV – Specification for the SUBJECT VISITS Domain Model

sv.xpt, Subject Visits — Version 3.2., One record per subject per actual visit.

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

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VISITNUM	Visit Number	Num		Topic	1. Clinical encounter number. (Decimal numbering may be useful for inserting unplanned visits.) 2. Numeric version of VISIT, used for sorting.	Req
VISIT	Visit Name	Char		Synonym Qualifier	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY as a text description of the clinical encounter.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the start of the visit based upon RFSTDTC in Demographics.	Perm
SVSTDTC	Start Date/Time of Visit	Char	ISO 8601	Timing	Start date/time for a Visit.	Exp
SVENDTC	End Date/Time of Visit	Char	ISO 8601	Timing	End date/time of a Visit.	Exp
SVSTDY	Study Day of Start of Visit	Num		Timing	Study day of start of visit relative to the sponsor-defined RFSTDTC.	Perm
SVENDY	Study Day of End of Visit	Num		Timing	Study day of end of visit relative to the sponsor-defined RFSTDTC.	Perm
SVUPDES	Description of Unplanned Visit	Char		Synonym Qualifier	Description of what happened to the subject during an unplanned visit.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

SV – Assumptions for the SUBJECT VISITS Domain Model

1. The Subject Visits domain allows the submission of data on the timing of the trial visits a subject actually passed through in their participation in the trial. Please read *Section 7.3 - Schedule for Assessments: Trial Visits (TV)* on the Trial Visits dataset, as the Trial Visits dataset defines the planned visits for the trial.
2. The identification of an actual visit with a planned visit sometimes calls for judgment. In general, data collection forms are prepared for particular visits, and the fact that data was collected on a form labeled with a planned visit is sufficient to make the association. Occasionally, the association will not be so clear, and the sponsor will need to make decisions about how to label actual visits. The sponsor's rules for making such decisions should be documented in the define.xml document.
3. Records for unplanned visits should be included in the SV dataset. For unplanned visits, SVUPDES should be populated with a description of the reason for the unplanned visit. Some judgment may be required to determine what constitutes an unplanned visit. When data are collected outside a planned visit, that act of collecting data may or may not be described as a "visit." The encounter should generally be treated as a visit if data from the encounter are included in any domain for which VISITNUM is included, since a record with a missing value for VISITNUM is generally less useful than a record with VISITNUM populated. If the occasion is considered a visit, its date/times must be included in the SV table and a value of VISITNUM must be assigned. See *Section 4: 4.1.4.5, Clinical Encounters And Visits* for information on the population of visit variables for unplanned visits.

4. VISITDY is the Planned Study Day of a visit. It should not be populated for unplanned visits.
5. If SVSTDY is included, it is the actual study day corresponding to SVSTDTC. In studies for which VISITDY has been populated, it may be desirable to populate SVSTDY, as this will facilitate the comparison of planned (VISITDY) and actual (SVSTDY) study days for the start of a visit.
6. If SVENDY is included, it is the actual day corresponding to SVENDTC.
7. For many studies, all visits are assumed to occur within one calendar day, and only one date is collected for the Visit. In such a case, the values for SVENDTC duplicate values in SVSTDTC. However, if the data for a visit is actually collected over several physical visits and/or over several days, then SVSTDTC and SVENDTC should reflect this fact. Note that it is fairly common for screening data to be collected over several days, but for the data to be treated as belonging to a single planned screening visit, even in studies for which all other visits are single-day visits.
8. Differentiating between planned and unplanned visits may be challenging if unplanned assessments (e.g., repeat labs) are performed during the time period of a planned visit.
9. Algorithms for populating SVSTDTC and SVENDTC from the dates of assessments performed at a visit may be particularly challenging for screening visits since baseline values collected at a screening visit are sometimes historical data from tests performed before the subject started screening for the trial
10. The following Identifier variables are permissible and may be added as appropriate: --SEQ, --GRPID, --REFID, and --SPID.
11. Care should be taken in adding additional Timing variables:
 - If TAETORD and/or EPOCH are added, then the values must be those at the start of the visit.
 - The purpose of --DTC and --DY in other domains with start and end dates (Event and Intervention Domains) is to record the data on which data was collected. It seems unnecessary to record the date on which the start and end of a visit were recorded.
 - --DUR could be added if the duration of a visit was collected.
 - It would be inappropriate to add the variables that support time points (--TPT, --TPTNUM, --ELTM, --TPTREF, and --RFTDTC), since the topic of this dataset is visits.
 - --STRF and --ENRF could be used to say whether a visit started and ended before, during, or after the study reference period, although this seems unnecessary.
 - --STRTPT, --STTPT, --ENRTPT, and --ENTPT could be used to say that a visit started or ended before or after particular dates, although this seems unnecessary.

SV – Examples for the SUBJECT VISITS Domain Model

Example

The data below represents the visits for a single subject.

Row 1: Data for the screening visit was actually gathered over the course of six days.

Row 2: The visit called DAY 1 actually started and ended as planned, on Day 1.

Row 3: The visit scheduled for Day 8 occurred one day early, on Day 7.

Row 4: The visit called WEEK 2 actually started and ended as planned, on Day 15.

Row 5: Shows an unscheduled visit. SVUPDES provides the information that this visit dealt with evaluation of an adverse event. Since this visit was not planned, VISITDY was not populated. The sponsor chose not to populate VISIT. VISITNUM was populated, probably because the data collected at this encounter is in a Findings domain such as EG, LB, or VS, in which VISIT is treated as an important timing variable.

Row 6: This subject had their last visit, a follow-up visit on study Day 26, eight days after the unscheduled visit, but well before the scheduled visit day of 71.

Row	STUDYID	DOMAIN	USUBJID	VISITNUM	VISIT	VISITDY	SVSTDTC	SVENDTC	SVSTDY	SVENDY	SVUPDES
1	123456	SV	101	1	SCREEN	-7	2006-01-15	2006-01-20	-6	-1	
2	123456	SV	101	2	DAY 1	1	2006-01-21	2006-01-21	1	1	
3	123456	SV	101	3	WEEK 1	8	2006-01-27	2006-01-27	7	7	
4	123456	SV	101	4	WEEK 2	15	2006-02-04	2006-02-04	15	15	
5	123456	SV	101	4.1			2006-02-07	2006-02-07	18	18	Evaluation of AE
6	123456	SV	101	8	FOLLOW-UP	71	2006-02-15	2006-02-15	26	26	

6 Domain Models Based on the General Observation Classes

Most subject-level observations collected during the study should be represented according to one of the three SDTM general observation classes. The lists of variables allowed to be used in each of these can be found in the SDTM. For detailed definitions, please refer to *SDTM: Section 2.2.1, The Interventions Observations Class*.

The below table provides links to individual documents where each listed Domain/Dataset is described in full detail.

Please note that this is a change from previous SDTMIG versions (prior to SDTMIG 3.2), where all domains were contained within a single document. This approach has been taken with the goal to simplify SDTMIG maintenance and to assist users in accessing the specific section/domain of interest without having to search a single and much larger document. The Table of Contents for the entire SDTMIG should reflect all domains (old and new) that make up this new release.

6.1 Interventions

Domain Code	Domain Description	Domain Document Name
CM	<p><u>Concomitant and Prior Medications</u> Case report form (CRF) data that captures the Concomitant and Prior Medications/Therapies used by the subject. Examples are the Concomitant Medications/Therapies given on an as needed basis and the usual Background Medications/Therapies given for a condition.</p>	Section 6.1 - CM Domain
EX and EC	<p><u>Exposure Domains</u></p> <p><u>Exposure (EX)</u> The Exposure domain model records the details of a subject's exposure to protocol-specified study treatment. Study treatment may be any intervention that is prospectively defined as a test material within a study, and is typically but not always supplied to the subject.</p> <p><u>Exposure as Collected (EC)</u> The Exposure as Collected domain model reflects protocol-specified study treatment administrations, as collected.</p>	Section 6.1 – EX and EC Domains
PR	<p><u>Procedures</u> The Procedures domain model reflects collected details describing a subject's therapeutic and diagnostic procedures.</p>	Section 6.1 – PR Domain
SU	<p><u>Substance Use</u> The intent of the domain is to capture substance use information that may be used to assess the efficacy and/or safety of therapies that look to mitigate the effects of chronic substance use.</p>	Section 6.1 - SU Domain

6 Domain Models Based on the General Observation Classes

6.1 Interventions

Concomitant/Prior Medications (CM)

CM – Description/Overview for the Concomitant/Prior Medication Domain Model

Case report form (CRF) data that captures the concomitant and prior medications/therapies used by the subject. Examples are the concomitant medications/therapies given on an as needed basis and the usual background medications/therapies given for a condition.

CM – Specification for the Concomitant/Prior Medication Domain Model

cm.xpt, Concomitant Medications — Interventions, Version 3.2. One record per recorded intervention occurrence or constant-dosing interval per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	CM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
CMSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
CMGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
CMSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Examples: a number pre-printed on the CRF as an explicit line identifier or record identifier defined in the sponsor's operational database. Example: line number on a concomitant medication page.	Perm
CMTRT	Reported Name of Drug, Med, or Therapy	Char		Topic	Verbatim medication name that is either pre-printed or collected on a CRF.	Req
CMMODIFY	Modified Reported Name	Char		Synonym Qualifier	If CMTRT is modified to facilitate coding, then CMMODIFY will contain the modified text.	Perm

CDISC SDTM Implementation Guide (Version 3.2)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
CMDECOD	Standardized Medication Name	Char	*	Synonym Qualifier	Standardized or dictionary-derived text description of CMTRT or CMMODIFY. Equivalent to the generic medication name in WHO Drug. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes. If an intervention term does not have a decode value in the dictionary then CMDECOD will be left blank.	Perm
CMCAT	Category for Medication	Char	*	Grouping Qualifier	Used to define a category of medications/treatments. Examples: PRIOR, CONCOMITANT, ANTI-CANCER MEDICATION, or GENERAL CONMED.	Perm
CMSCAT	Subcategory for Medication	Char	*	Grouping Qualifier	A further categorization of medications/ treatment. Examples: CHEMOTHERAPY, HORMONAL THERAPY, ALTERNATIVE THERAPY.	Perm
CMPRESP	CM Pre-Specified	Char	(NY)	Variable Qualifier	Used to indicate whether (Y/null) information about the use of a specific medication was solicited on the CRF.	Perm
CMOCCUR	CM Occurrence	Char	(NY)	Record Qualifier	When the use of specific medications is solicited, CMOCCUR is used to indicate whether or not (Y/N) use of the medication occurred. Values are null for medications not specifically solicited.	Perm
CMSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a question about a pre-specified medication was not answered. Should be null or have a value of NOT DONE.	Perm
CMREASND	Reason Medication Not Collected	Char		Record Qualifier	Describes the reason concomitant medication was not collected. Used in conjunction with CMSTAT when value is NOT DONE.	Perm
CMINDC	Indication	Char		Record Qualifier	Denotes why a medication was taken or administered. Examples: NAUSEA, HYPERTENSION.	Perm
CMCLAS	Medication Class	Char	*	Variable Qualifier	Drug class. May be obtained from coding. When coding to a single class, populate with class value. If using a dictionary and coding to multiple classes, then follow Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable or omit CMCLAS.	Perm
CMCLASCD	Medication Class Code	Char	*	Variable Qualifier	Class code corresponding to CMCLAS. Drug class. May be obtained from coding. When coding to a single class, populate with class code. If using a dictionary and coding to multiple classes, then follow Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable or omit CMCLASCD.	Perm
CMDOSE	Dose per Administration	Num		Record Qualifier	Amount of CMTRT taken. Not populated when CMDOSTXT is populated.	Perm
CMDOSTXT	Dose Description	Char		Record Qualifier	Dosing amounts or a range of dosing information collected in text form. Units may be stored in CMDOSU. Example: 200-400, 15-20. Not populated when CMDOSE is populated.	Perm
CMDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for CMDOSE, CMDOSTOT, and CMDOSTXT. Examples: ng, mg, or mg/kg.	Perm
CMDOSEFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for CMTRT. Examples: TABLET, LOTION.	Perm
CMDOSEFRQ	Dosing Frequency per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of CMDOSE within a specific time period. Examples: BID (twice daily), Q12H (every 12 hours).	Perm

CDISC SDTM Implementation Guide (Version 3.2)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
CMOSTOT	Total Daily Dose	Num		Record Qualifier	Total daily dose of CMTRT using the units in CMDOSU. Used when dosing is collected as Total Daily Dose. Total dose over a period other than day could be recorded in a separate Supplemental Qualifier variable.	Perm
CMDOSRGM	Intended Dose Regimen	Char		Variable Qualifier	Text description of the (intended) schedule or regimen for the Intervention. Examples: TWO WEEKS ON, TWO WEEKS OFF.	Perm
CMROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for CMTRT. Examples: ORAL, INTRAVENOUS.	Perm
CMSTDTC	Start Date/Time of Medication	Char	ISO 8601	Timing		Perm
CMENDTC	End Date/Time of Medication	Char	ISO 8601	Timing		Perm
CMSTDY	Study Day of Start of Medication	Num		Timing	Study day of start of medication relative to the sponsor-defined RFSTDTC.	Perm
CMENDY	Study Day of End of Medication	Num		Timing	Study day of end of medication relative to the sponsor-defined RFSTDTC.	Perm
CMDUR	Duration of Medication	Char	ISO 8601	Timing	Collected duration for a treatment episode. Used only if collected on the CRF and not derived from start and end date/times.	Perm
CMSTRF	Start Relative to Reference Period	Char	(STENRF)	Timing	Describes the start of the medication relative to 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). If information such as "PRIOR", ONGOING or "CONTINUING" was collected, this information may be translated into CMSTRF.	Perm
CMENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the medication relative to the 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). If information such as "PRIOR", ONGOING, or "CONTINUING" was collected, this information may be translated into CMENRF.	Perm
CMSTRTPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the start of the medication as being before or after the reference time point defined by variable CMSTTPT.	Perm
CMSTTPT	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by CMSTRTPT. Examples: "2003-12-15" or "VISIT 1".	Perm
CMENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the medication as being before or after the reference time point defined by variable CMENRTPT.	Perm
CMENRTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by CMENRTPT. Examples: "2003-12-25" or "VISIT 2".	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

CM – Assumptions for the Concomitant/Prior Medication Domain Model

1. CM Definition and Structure
 - a. CRF data that captures the Concomitant and Prior Medications/Therapies used by the subject. Examples are the Concomitant Medications/Therapies given on an as-needed basis and the usual and background medications/therapies given for a condition.
 - b. The structure of the CM domain is one record per medication intervention episode, constant-dosing interval, or pre-specified medication assessment per subject. It is the sponsor's responsibility to define an intervention episode. This definition may vary based on the sponsor's requirements for review and analysis. The submission dataset structure may differ from the structure used for collection. One common approach is to submit a new record when there is a change in the dosing regimen. Another approach is to collapse all records for a medication to a summary level with either a dose range or the highest dose level. Other approaches may also be reasonable as long as they meet the sponsor's evaluation requirements.
2. Concomitant Medications Description and Coding
 - a. CMTRT captures the name of the Concomitant Medications/Therapy and it is the topic variable. It is a required variable and must have a value. CMTRT should only include the medication/therapy name and should not include dosage, formulation, or other qualifying information. For example, "ASPIRIN 100MG TABLET" is not a valid value for CMTRT. This example should be expressed as CMTRT= "ASPIRIN", CMDOSE= "100", CMDOSU= "MG", and CMDOSFRM= "TABLET".
 - b. CMMODIFY should be included if the sponsor's procedure permits modification of a verbatim term for coding.
 - c. CMDECOD is the standardized medication/therapy term derived by the sponsor from the coding dictionary. It is expected that the reported term (CMTRT) or the modified term (CMMODIFY) will be coded using a standard dictionary. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.
3. Pre-specified Terms; Presence or Absence of Concomitant Medications
 - a. Information on concomitant medications is generally collected in two different ways, either by recording free text or using a pre-specified list of terms. Since the solicitation of information on specific concomitant medications may affect the frequency at which they are reported, the fact that a specific medication was solicited may be of interest to reviewers. CMPRESP and CMOCCUR are used together to indicate whether the intervention in CMTRT was pre-specified and whether it occurred, respectively.
 - b. CMOCCUR is used to indicate whether a pre-specified medication was used. A value of Y indicates that the medication was used and N indicates that it was not.
 - c. If a medication was not pre-specified the value of CMOCCUR should be null. CMPRESP and CMOCCUR is a permissible fields and may be omitted from the dataset if all medications were collected as free text. Values of CMOCCUR may also be null for pre-specified medications if no Y/N response was collected; in this case, CMSTAT = NOT DONE, and CMREASND could be used to describe the reason the answer was missing.
4. Additional Timing Variables
 - a. CMSTRTPT, CMSTTPT, CMENRTPT and CMENTPT may be populated as necessary to indicate when a medication was used relative to specified time points. For example, assume a subject uses birth control medication. The subject has used the same medication for many years and continues to do so. The date the subject began using the medication (or at least a partial date) would be stored in CMSTDTC. CMENDTC is null since the end date is unknown (it hasn't happened yet). This fact can be recorded by setting CMENTPT="2007-04-30" (the date the assessment was made) and CMENRTPT="ONGOING".
5. Additional Permissible Interventions Qualifiers
 - a. Any additional Qualifiers from the Interventions Class may be added to this domain.

CM – Examples for the Concomitant/Prior Medication Domain Model

Example 1: Spontaneous concomitant medications with dosing information

Sponsors collect the timing of concomitant medication use with varying specificity, depending on the pattern of use; the type, purpose, and importance of the medication; and the needs of the study. It is often unnecessary to record every unique instance of medication use, since the same information can be conveyed with start and end dates and frequency of use. If appropriate, medications taken as needed (intermittently or sporadically over a time period) may be reported with a start and end date and a frequency of “PRN”.

The example below shows three subjects who took the same medication on the same day.

Rows 1-6: For the first subject (USUBJID=ABC-0001, each instance is recorded separately, and frequency (CMDOSFRQ) is ONCE.

Rows 7-9: For the second subject (USUBJID=ABC-0002, the second record (CMSEQ=2) shows that aspirin was taken twice on January 7th, so the frequency is BID. The frequency is also included for the other daily records to avoid confusion.

Row 10: Records for the third subject are collapsed (this is shown as an example only, not as a recommendation) into a single entry that spans the relevant time period, with a frequency of PRN. This approach assumes that knowing exactly when aspirin was used is not important for evaluating safety and efficacy in this study.

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMDOSE	CMDOSU	CMDOSFRQ	CMSTDTC	CMENDTC
1	ABC	CM	ABC-0001	1	ASPIRIN	100	MG	ONCE	2004-01-01	2004-01-01
2	ABC	CM	ABC-0001	2	ASPIRIN	100	MG	ONCE	2004-01-02	2004-01-02
3	ABC	CM	ABC-0001	3	ASPIRIN	100	MG	ONCE	2004-01-03	2004-01-03
4	ABC	CM	ABC-0001	4	ASPIRIN	100	MG	ONCE	2004-01-07	2004-01-07
5	ABC	CM	ABC-0001	5	ASPIRIN	100	MG	ONCE	2004-01-07	2004-01-07
6	ABC	CM	ABC-0001	6	ASPIRIN	100	MG	ONCE	2004-01-09	2004-01-09
7	ABC	CM	ABC-0002	1	ASPIRIN	100	MG	Q24H	2004-01-01	2004-01-03
8	ABC	CM	ABC-0002	2	ASPIRIN	100	MG	BID	2004-01-07	2004-01-07
9	ABC	CM	ABC-0002	3	ASPIRIN	100	MG	Q24H	2004-01-09	2004-01-09
10	ABC	CM	ABC-0003	1	ASPIRIN	100	MG	PRN	2004-01-01	2004-01-09

Example 2: Spontaneous concomitant medications without dosing information

The example below is for a study that has a particular interest in whether subjects use any anticonvulsant medications. The medication history, dosing, etc. is not of interest; the study only asks for the anticonvulsants to which subjects are being exposed.

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMCAT
1	ABC123	CM	1	1	LITHIUM	ANTI-CONVULSANT
2	ABC123	CM	2	1	VPA	ANTI-CONVULSANT

Example 3: Pre-specified concomitant medications using CMPRESP, CMOCCUR, CMSTAT, and CMREASND

Sponsors often are interested in whether subjects are exposed to specific concomitant medications, and collect this information using a checklist. The example below is for a study that has a particular interest in the antidepressant medications that subjects use. For the study’s purposes, the absence is just as important as the presence of a medication. This can be clearly shown by using CMOCCUR.

In this example, CMPRESP shows that the subjects were specifically asked if they use any of three antidepressants (Zoloft, Prozac, or Paxil). The value of CMOCCUR indicates the response to the pre-specified medication question. CMSTAT indicates whether the response was missing for a pre-specified medication, and CMREASND shows the reason for missing response. The medication details (e.g., dose, frequency) were not of interest in this study.

- Row 1:** Medication was solicited on CRF and was taken.
- Row 2:** Medication use solicited in CRF and was not taken.
- Row 3:** Medication use solicited in CRF but data was not collected.

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMPRESP	CMOCCUR	CMSTAT	CMREASND
1	ABC123	CM	1	1	ZOLOFT	Y	Y		
2	ABC123	CM	1	2	PROZAC	Y	N		
3	ABC123	CM	1	3	PAXIL	Y		NOT DONE	Didn't ask due to interruption

6 Domain Models Based on the General Observation Classes

6.1 Interventions

Exposure Domains: EX and EC

Clinical trial study designs can range from open label (where subjects and investigators know which product each subject is receiving) to blinded (where the subject, investigator, or anyone assessing the outcome is unaware of the treatment assignment(s) to reduce potential for bias). To support standardization of various collection methods and details, as well as process differences between open-label and blinded studies, two SDTM domains based on the Interventions General Observation Class are available to represent details of subject exposure to protocol-specified study treatment(s).

The two domains are introduced below.

Exposure (EX)

EX – Description/Overview for the Exposure Domain Model

The Exposure domain model records the details of a subject's exposure to protocol-specified study treatment. Study treatment may be any intervention that is prospectively defined as a test material within a study, and is typically but not always supplied to the subject.

EX – Specification for the Exposure Domain Model

ex.xpt, Exposure - Interventions, Version 3.2. One record per protocol-specified study treatment, constant-dosing interval, per subject, Tabulation

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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
					subject.	
EXREFID	Reference ID	Char		Identifier	Internal or external identifier (e.g., kit number, bottle label, vial identifier).	Perm
EXSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a CRF Page.	Perm
EXLNKID	Link ID	Char		Identifier	Identifier used to link related records across domains.	Perm
EXLNKGRP	Link Group ID	Char		Identifier	Identifier used to link related, grouped records across domains.	Perm
EXTRT	Name of Treatment	Char	*	Topic	Name of the protocol-specified study treatment given during the dosing period for the observation.	Req
EXCAT	Category of Treatment	Char	*	Grouping Qualifier	Used to define a category of EXTRT values.	Perm
EXSCAT	Subcategory of Treatment	Char	*	Grouping Qualifier	A further categorization of EXCAT values.	Perm
EXDOSE	Dose	Num		Record Qualifier	Amount of EXTRT when numeric. Not populated when EXDOSTXT is populated.	Exp
EXDOSTXT	Dose Description	Char		Record Qualifier	Amount of EXTRT when non-numeric. Dosing amounts or a range of dosing information collected in text form. Example: 200-400. Not populated when EXDOSE is populated.	Perm
EXDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for EXDOSE, EXDOSTOT, or EXDOSTXT representing protocol-specified values. Examples: ng, mg, mg/kg, mg/m2.	Exp
EXDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for EXTRT. Examples: TABLET, LOTION.	Exp
EXDOSFRQ	Dosing Frequency per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of EXDOSE within a specific time period. Examples: Q2H, QD, BID.	Perm
EXDOSRGM	Intended Dose Regimen	Char		Variable Qualifier	Text description of the intended schedule or regimen for the intervention. Example: TWO WEEKS ON, TWO WEEKS OFF.	Perm
EXROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for the intervention. Examples: ORAL, INTRAVENOUS.	Perm
EXLOT	Lot Number	Char		Record Qualifier	Lot Number of the intervention product.	Perm
EXLOC	Location of Dose Administration	Char	(LOC)	Record Qualifier	Specifies location of administration. Examples: ARM, LIP.	Perm
EXLAT	Laterality	Char	(LAT)	Variable Qualifier	Qualifier for anatomical location further detailing laterality of the intervention administration. Examples: LEFT, RIGHT.	Perm
EXDIR	Directionality	Char	(DIR)	Variable Qualifier	Qualifier for anatomical location further detailing directionality. Examples: ANTERIOR, LOWER, PROXIMAL, UPPER.	Perm
EXFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status. Examples: Y, N.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
EXADJ	Reason for Dose Adjustment	Char	*	Record Qualifier	Describes reason or explanation of why a dose is adjusted.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Trial Epoch of the Exposure record. Examples: RUN-IN, TREATMENT.	Perm
EXSTDTC	Start Date/Time of Treatment	Char	ISO 8601	Timing	The date/time when administration of the treatment indicated by EXTRT and EXDOSE began.	Exp
EXENDTC	End Date/Time of Treatment	Char	ISO 8601	Timing	The date/time when administration of the treatment indicated by EXTRT and EXDOSE ended. For administrations considered given at a point in time (e.g., oral tablet, pre-filled syringe injection), where only an administration date/time is collected, EXSTDTC should be copied to EXENDTC as the standard representation.	Exp
EXSTDY	Study Day of Start of Treatment	Num		Timing	Study day of EXSTDTC relative to DM.RFSTDTC.	Perm
EXENDY	Study Day of End of Treatment	Num		Timing	Study day of EXENDTC relative to DM.RFSTDTC.	Perm
EXDUR	Duration of Treatment	Char	ISO 8601	Timing	Collected duration of administration represented in ISO 8601 duration format. Used only if collected on the CRF and not derived from start and end date/times.	Perm
EXTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when administration should occur. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See EXTPTNUM and EXTPTREF.	Perm
EXTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of EXTPT to aid in sorting.	Perm
EXELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601 format) relative to the planned fixed reference (EXTPTREF). This variable is useful where there are repetitive measures. Not a clock time. Represented in ISO 8601 duration format.	Perm
EXTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by EXELTM, EXTPTNUM, and EXTPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
EXRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time for a fixed reference time point defined by EXTPTREF in ISO 8601 character format.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI code list code value)

EX – Assumptions for the Exposure Domain Model

1 EX Definition

- a. The Exposure domain model reflects details of a subject’s exposure to protocol-specified study treatment(s), in protocol-specified unit(s). Study treatment may be an intervention that is prospectively defined as a test material within a study, and is typically but not always supplied to the subject. Examples include but are not limited to placebo, active comparators, and investigational products. Treatments that are not protocol-specified should be represented in the Concomitant Medication (CM) or another Interventions domain as appropriate.
- b. The EX domain is recognized in most cases as a derived dataset where EXDOSU reflects the protocol-specified unit per study treatment. Collected data points (e.g., number of tablets, total volume infused) along with additional inputs (e.g., randomization file, concentration, dosage strength, drug accountability) are used to derive records in the EX domain.
- c. The EX domain is required for all studies that include protocol-specified study treatment. Exposure records may be directly or indirectly determined; metadata should describe how the records were derived. Common methods for determining exposure (from most direct to least direct) include the following:
 1. Derived from actual observation of the administration of drug by the investigator
 2. Derived from automated dispensing device which records administrations
 3. Derived from subject recall
 4. Derived from drug accountability data
 5. Derived from the protocol

When a study is still masked and protocol-specified study treatment doses cannot yet be reflected in the protocol-specified unit due to blinding requirements, then the EX domain is not expected to be populated.

- d. The EX domain should contain one record per constant-dosing interval per subject. “Constant-dosing interval” is sponsor defined, and may include any period of time that can be described in terms of a known treatment given at a consistent dose, frequency, infusion rate, etc. For example, for a study with once-a-week administration of a standard dose for 6 weeks, exposure may be represented as one of the following:
 1. If information about each dose is not collected, there would be a single record per subject, spanning the entire 6-week treatment phase.
 2. If the sponsor monitors each treatment administration, there could be up to six records (one for each weekly administration).

2 Exposure Treatment Description

- a. EXTRT captures the name of the protocol-specified study treatment and is the topic variable. It is a Required variable and must have a value. EXTRT must only include the treatment name and must not include dosage, formulation or other qualifying information. For example, “ASPIRIN 100MG TABLET” is not a valid value for EXTRT. This example should be expressed as EXTRT = ‘ASPIRIN’, EXDOSE = 100, EXDOSU = ‘mg’, and EXDOSFRM = ‘TABLET’.
- b. Doses of placebo should be represented by EXTRT = ‘PLACEBO’ and EXDOSE = 0 (indicating 0 mg of active ingredient was taken or administered).

3 Categorization and Grouping

- a. EXCAT and EXSCAT may be used when appropriate to categorize treatments into categories and subcategories. For example, if a study contains several active comparator medications, EXCAT may be set to ‘ACTIVE COMPARATOR’. Such categorization may not be useful in all studies, so these variables are permissible.

- 4 Timing Variables
 - a. The timing of exposure to study treatment is captured by the start/end date and start/end time of each constant-dosing interval. If the subject is only exposed to study medication within a clinical encounter (e.g., if an injection is administered at the clinic), VISITNUM may be added to the domain as an additional Timing variable. VISITDY and VISIT would then also be permissible Qualifiers. However, if the beginning and end of a constant-dosing interval is not confined within the time limits of a clinical encounter (e.g., if a subject takes pills at home), then it is not appropriate to include VISITNUM in the EX domain. This is because EX is designed to capture the timing of exposure to treatment, not the timing of dispensing treatment. Furthermore, VISITNUM should not be used to indicate that treatment began at a particular visit and continued for a period of time. The SDTM does not have any provision for recording “start visit” and “end visit” of exposure.
 - b. For administrations considered given at a point in time (e.g., oral tablet, pre-filled syringe injection), where only an administration date/time is collected, EXSTDTC should be copied to EXENDTC as the standard representation.
- 5 Collected exposure data points are to be represented in the EC domain (See Section 6.1.2.3). When the relationship between EC and EX records can be described in RELREC, then it should be defined. EX derivations must be described in the define.xml.
- 6 Additional Interventions Qualifiers
 - a. The variables --PRESP, --OCCUR, --STAT, and --REASND from the Interventions General Observation Class would generally not be used in the EX domain. EX contains medications received; the inclusion of administrations not taken, not given or missed is under evaluation.
 - b. --DOSTOT is under evaluation for potential deprecation and replacement with a mechanism to describe total dose over any interval of time (e.g., day, week, month). Sponsors considering use of EXDOSTOT may want to consider using other dose amount variables (EXDOSE or EXDOSTXT) in combination with frequency (EXDOSFRQ) and timing variables to represent the data.
 - c. When the EC domain (See Section 6.1.2.3) is implemented in conjunction with the EX domain, EXVAMT and EXVAMTU should not be used in EX; collected values instead would be represented in ECDOSE and ECDOSE.
 - d. Other additional Qualifiers from the SDTM Interventions General Observation Class may be added to this domain.

Exposure as Collected (EC)

EC – Description/Overview for the Exposure as Collected Domain Model

The Exposure as Collected domain model reflects protocol-specified study treatment administrations, as collected.

EC – Specification for the Exposure as Collected Domain Model

ec.xpt, Exposure as Collected - Interventions, Version 3.2. One record per protocol-specified study treatment, collected-dosing interval, per subject, per mood
Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	EC	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
ECSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
ECGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
ECREFID	Reference ID	Char		Identifier	Internal or external identifier (e.g., kit number, bottle label, vial identifier).	Perm
ECSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a CRF Page.	Perm
ECLNKID	Link ID	Char		Identifier	Identifier used to link related records across domains.	Perm
ECLNKGRP	Link Group ID	Char		Identifier	Identifier used to link related, grouped records across domains.	Perm
ECTRT	Name of Treatment	Char	*	Topic	Name of the intervention treatment known to the subject and/or administrator.	Req
ECMOOD	Mood	Char	*	Record Qualifier	Mode or condition of the record specifying whether the intervention (activity) is intended to happen or has happened. Values align with BRIDG pillars (e.g., scheduled context, performed context) and HL7 activity moods (e.g., intent, event). Examples: SCHEDULED, PERFORMED. CDISC Controlled Terminology request for MOOD codelist with values of SCHEDULED and PERFORMED has been submitted.	Perm
ECCAT	Category of Treatment	Char	*	Grouping Qualifier	Used to define a category of related ECTRT values.	Perm
ECSCAT	Subcategory of Treatment	Char	*	Grouping Qualifier	A further categorization of ECCAT values.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
ECPRESP	Pre-Specified	Char	(NY)	Record Qualifier	Used when a specific intervention is pre-specified. Values should be “Y” or null.	Perm
ECOCCUR	Occurrence	Char	(NY)	Record Qualifier	Used to indicate whether a treatment occurred when information about the occurrence is solicited. ECOCCUR = ‘N’ when a treatment was not taken, not given, or missed.	Perm
ECDOSE	Dose	Num		Record Qualifier	Amount of ECTRT when numeric. Not populated when ECDOSTXT is populated.	Exp
ECDOSTXT	Dose Description	Char		Record Qualifier	Amount of ECTRT when non-numeric. Dosing amounts or a range of dosing information collected in text form. Example: 200-400. Not populated when ECDOSE is populated.	Perm
ECDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for ECDOSE, ECDOSTOT, or ECDOSTXT.	Exp
ECDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for ECTRT. Examples: TABLET, LOTION.	Exp
ECDOSFRQ	Dosing Frequency per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of ECDOSE within a specific time period. Examples: Q2H, QD, BID.	Perm
ECDOSTOT	Total Daily Dose	Char		Record Qualifier	Total daily dose of ECTRT using the units in ECDOSU. Used when dosing is collected as Total Daily Dose.	Perm
ECDOSRGM	Intended Dose Regimen	Char		Variable Qualifier	Text description of the intended schedule or regimen for the Intervention. Example: TWO WEEKS ON, TWO WEEKS OFF.	Perm
ECROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for the intervention. Examples: ORAL, INTRAVENOUS.	Perm
ECLLOT	Lot Number	Char		Record Qualifier	Lot Number of the ECTRT product.	Perm
ECLOC	Location of Dose Administration	Char	(LOC)	Record Qualifier	Specifies location of administration. Example: ARM, LIP.	Perm
ECLAT	Laterality	Char	(LAT)	Record Qualifier	Qualifier for anatomical location further detailing laterality of the intervention administration. Examples: LEFT, RIGHT.	Perm
ECDIR	Directionality	Char	(DIR)	Variable Qualifier	Qualifier for anatomical location further detailing directionality. Examples: ANTERIOR, LOWER, PROXIMAL, UPPER.	Perm
ECPOROT	Portion or Totality	Char	(PORTOT)	Variable Qualifier	Qualifier for anatomical location further detailing distribution, which means arrangement of, apportioning of. Examples: ENTIRE, SINGLE, SEGMENT.	Perm
ECFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status. Examples: Y, N.	Perm
ECPSTRG	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.	Perm
ECPSTRGU	Pharmaceutical Strength Units	Char	*	Variable Qualifier	Unit for ECPSTRG. Examples: mg/TABLET, mg/mL.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
ECADJ	Reason for Dose Adjustment	Char	*	Record Qualifier	Describes reason or explanation of why a dose is adjusted.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Trial Epoch of the exposure as collected record. Examples: RUN-IN, TREATMENT.	Perm
ECSTDTC	Start Date/Time of Treatment	Char	ISO 8601	Timing	The date/time when administration of the treatment indicated by ECTRT and ECDOSE began.	Exp
ECENDTC	End Date/Time of Treatment	Char	ISO 8601	Timing	The date/time when administration of the treatment indicated by ECTRT and ECDOSE ended. For administrations considered given at a point in time (e.g., oral tablet, pre-filled syringe injection), where only an administration date/time is collected, ECSTDTC should be copied to ECENDTC as the standard representation.	Exp
ECSTDY	Study Day of Start of Treatment	Num		Timing	Study day of ECSTDTC relative to the sponsor-defined DM.RFSTDTC.	Perm
ECENDY	Study Day of End of Treatment	Num		Timing	Study day of ECENDTC relative to the sponsor-defined DM.RFSTDTC.	Perm
ECDUR	Duration of Treatment	Char	ISO 8601	Timing	Collected duration of administration represented in ISO 8601 duration format. Used only if collected on the CRF and not derived from start and end date/times.	Perm
ECTPT	Planned Time Point Name	Char		Timing	Text Description of time when administration should occur. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See ECTPTNUM and ECTPTREF.	Perm
ECTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of ECTPT to aid in sorting.	Perm
ECELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601 format) relative to the planned fixed reference (ECTPTREF). This variable is useful where there are repetitive measures. Not a clock time. Represented in ISO 8601 duration format.	Perm
ECTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by ECELTM, ECTPTNUM, and ECTPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
ECRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time for a fixed reference time point defined by ECTPTREF in ISO 8601 character format.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI code list code value)

EC – Assumptions for the Exposure as Collected Domain Model

1 EC Definition

- a. The Exposure as Collected domain model reflects protocol-specified study treatment administrations, as collected.
 1. EC should be used in all cases where collected exposure information cannot or should not be directly represented in EX. For example, administrations collected in tablets but protocol-specified unit is mg, administrations collected in mL but protocol-specified unit is mg/kg. Drug accountability details (e.g., amount dispensed, amount returned) are represented in DA and not in EC.
 2. Collected exposure data are in most cases represented in a combination of one or more of EC, DA, or FA domains. If the entire EC dataset is an exact duplicate of the entire EX dataset, then EC is optional and at the sponsor's discretion.
- b. Collected exposure log data points descriptive of administrations typically reflect amounts at the product-level (e.g., number of tablets, number of mL).

2. Treatment Description

- a. ECTRT is sponsor defined and should reflect how the protocol-specified study treatment is known or referred to in data collection. In an open-label study, ECTRT should store the treatment name. In a masked study, if treatment is collected and known as Tablet A to the subject or administrator, then ECTRT = 'TABLET A'. If in a masked study the treatment is not known by a synonym and the data are to be exchanged between sponsors, partners and/or regulatory agency(s), then assign ECTRT the value of 'MASKED'.

3. ECMOOD is permissible; when implemented, it must be populated for all records.

- a. Values of ECMOOD, to date include:
 1. 'SCHEDULED' (for collected subject-level intended dose records)
 2. 'PERFORMED' (for collected subject-level actual dose records)
- b. Qualifier variables should be populated with equal granularity across Scheduled and Performed records when known. For example, if ECDOSU and ECDOSFRQ are known at scheduling and administration, then the variables would be populated on both records. If ECLOC is determined at the time of administration, then it would be populated on the performed record only.
- c. Appropriate Timing variable(s) should be populated. Note: Details on Scheduled records may describe timing at a higher level than Performed records.
- d. ECOCCUR is generally not applicable for Scheduled records.
- e. An activity may be rescheduled or modified multiple times before being performed. Representation of Scheduled records is dependent on the collected, available data. If each rescheduled or modified activity is collected, then multiple Scheduled records may be represented. If only the final Scheduled activity is collected, then it would be the only scheduled record represented.

4. Doses Not Taken, Not Given, or Missed

- a. The record qualifier --OCCUR, with value of 'N', is available in domains based on the Interventions and Events General Observation Classes as the standard way to represent whether an intervention or event did not happen. In the EC domain, ECOCCUR value of 'N' indicates a dose was not taken, not given, or missed. For example, if 0 tablets are taken within a timeframe or 0 mL infused at a visit, then ECOCCUR = 'N' is the standard representation of the collected doses not taken, not given, or missed. Dose amount variables (e.g., ECDOSE, ECDOSTXT) must not be set to zero (0) as an alternative method for indicating doses not taken, not given, or missed.
- b. The population of Qualifier variables (e.g., Grouping, Record, Variable) and additional Timing variables (e.g., date of collection, visit, time point) for records representing information collected about doses not taken, not given, or missed should be populated with equal granularity as administered

records, when known and/or applicable. Qualifiers that indicate dose amount (e.g., ECDOSE, ECDOSTXT) may be populated with positive (non-zero) values in cases where the sponsor feels it is necessary and/or appropriate to represent specific dose amounts not taken, not given, or missed.

5. Timing Variables

- a. Timing variables in the EC domain should reflect administrations by the intervals they were collected (e.g., constant-dosing intervals, visits, targeted dates like first dose, last dose).
- b. For administrations considered given at a point in time (e.g., oral tablet, pre-filled syringe injection), where only an administration date/time is collected, ECSTDTTC should be copied to ECENDTTC.

6. The degree of summarization of records from EC to EX is sponsor defined to support study purpose and analysis. When the relationship between EC and EX records can be described in RELREC, then it should be defined. EX derivations must be described in the define.xml.

7. Additional Interventions Qualifiers

- a. The variables --STAT, --REASND, --VAMT, and --VAMTU from the Interventions General Observation Class are generally not used in the EC domain.
- b. --DOSTOT is under evaluation for potential deprecation and replacement with a mechanism to describe total dose over any interval of time (e.g., day, week, month). Sponsors considering ECDOSTOT may want to consider using other dose amount variables (ECDOSE or ECDOSTXT) in combination with frequency (ECDOSFRQ) and timing variables to represent the data.
- c. Other additional Qualifiers from the SDTM Interventions General Observation Class may be added to this domain.

EX-EC – Examples for Exposure and Exposure as Collected Domain Models

Example 1

This is an example of a double-blind study comparing Drug X extended release (ER) (two 500-mg tablets once daily) vs. Drug Z (two 250-mg tablets once daily). Per example CRFs, Subject ABC1001 took 2 tablets from 2011-01-14 to 2011-01-28 and Subject ABC2001 took 2 tablets within the same timeframe but missed dosing on 2011-01-24.

Exposure CRF:

Subject: ABC1001

Bottle	Number of Tablets Taken Daily	Reason for Variation	Start Date	End Date
A	2		2011-01-14	2011-01-28

Subject: ABC2001

Bottle	Number of Tablets Taken Daily	Reason for Variation	Start Date	End Date
A	2		2011-01-14	2011-01-23
A	0	Patient mistake	2011-01-24	2011-01-24
A	2		2011-01-25	2011-01-28

Upon unmasking, it became known that Subject ABC1001 received Drug X and Subject ABC2001 received Drug Z.

SDTM Dataset Examples:

Rows 1-4: Show the administrations as collected.

Row 3: The '0' collected Number of Tablets Taken is standardized as ECOCCUR = 'N'.

ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECLNKID	ECTRT	ECPRESP	ECOCCUR	ECDOSE	ECDOSU	ECDOSFRQ
1	ABC	EC	ABC1001	1	A2-20110114	BOTTLE A	Y	Y	2	TABLET	QD
2	ABC	EC	ABC2001	1	A2-20110114	BOTTLE A	Y	Y	2	TABLET	QD
3	ABC	EC	ABC2001	2	A0-20110124	BOTTLE A	Y	N		TABLET	QD
4	ABC	EC	ABC2001	3	A2-20110125	BOTTLE A	Y	Y	2	TABLET	QD

Row	EPOCH	ECSTDTC	ECENDTC	ECSTDY	ECENDY
1 (cont)	TREATMENT	2011-01-14	2011-01-28	1	15
2 (cont)	TREATMENT	2011-01-14	2011-01-23	1	10
3 (cont)	TREATMENT	2011-01-24	2011-01-24	11	11
4 (cont)	TREATMENT	2011-01-25	2011-01-28	12	15

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suppec.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
ABC	EC	ABC2001	ECSEQ	2	ECREASOC	Reason for Occur Value	PATIENT MISTAKE	CRF	

Rows 1-3: Show the unmasked administrations where Subject ABC1001 took 1000 mg of Drug X extended release tablets daily and Subject ABC2001 took 500 mg of Drug Z tablets daily.

Not Shown: The dose Subject ABC2001 did not take on 2001-01-24 is not represented as a record in the EX dataset; it is reflected as a gap in time between Row 2 (EXENDY relative day '10') and Row 3 (EXSTDY relative day '12'). The collected reason for the dose variation is represented in the EC domain.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXLNKID	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE
1	ABC	EX	ABC1001	1	A2-20110114	DRUG X	1000	mg	TABLET, EXTENDED RELEASE	QD	ORAL
2	ABC	EX	ABC2001	1	A2-20110114	DRUG Z	500	mg	TABLET	QD	ORAL
3	ABC	EX	ABC2001	2	A2-20110125	DRUG Z	500	mg	TABLET	QD	ORAL

Row	EPOCH	EXSTDTC	EXENDTC	EXSTDY	EXENDY
1 (cont)	TREATMENT	2011-01-14	2011-01-28	1	15
2 (cont)	TREATMENT	2011-01-14	2011-01-23	1	10
3 (cont)	TREATMENT	2011-01-25	2011-01-28	12	15

The relrec.xpt example reflects a one-to-one dataset-level relationship between EC and EX using --LNKID.

relrec.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC	EC		ECLNKID		ONE	1
ABC	EX		EXLNKID		ONE	1

Example 2

This is an example of an open-label study design where Drug X (20 mg/mL solution) is administered across 3 injection sites to deliver a dose of 3 mg/kg.

Exposure CRF:

Visit	3
Date	2009-05-10
Injection 1	
Volume Given (mL)	5
Location	ABDOMEN
Side	LEFT
Injection 2	
Volume Given (mL)	5
Location	ABDOMEN
Side	CENTER
Injection 3	

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Volume Given (mL)	5
Location	ABDOMEN
Side	RIGHT

SDTM Dataset Examples:

Rows 1-3: Show the collected administration amounts (mL) associated with their respective locations.

ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECSPID	ECLNKID	ECTRT	ECPRESP	EOCCUR	ECDOSE	ECDOSU	ECDOSFRM
1	ABC	EC	ABC3001	1	INJ1	V3	DRUG X	Y	Y	5	mL	INJECTION
2	ABC	EC	ABC3001	2	INJ2	V3	DRUG X	Y	Y	5	mL	INJECTION
3	ABC	EC	ABC3001	3	INJ3	V3	DRUG X	Y	Y	5	mL	INJECTION

Row	ECDOSFRQ	ECROUTE	ECLOC	ECLAT	VISITNUM	VISIT	EPOCH	ECSTDTC	ECENDTC	ECSTDY	ECENDY
1 (cont)	ONCE	SUBCUTANEOUS	ABDOMEN	LEFT	3	VISIT 3	TREATMENT	2009-05-10	2009-05-10	21	21
2 (cont)	ONCE	SUBCUTANEOUS	ABDOMEN	CENTER	3	VISIT 3	TREATMENT	2009-05-10	2009-05-10	21	21
3 (cont)	ONCE	SUBCUTANEOUS	ABDOMEN	RIGHT	3	VISIT 3	TREATMENT	2009-05-10	2009-05-10	21	21

Row 1: Shows the calculated administrations in protocol-specified unit (mg/kg). A single EX record is reflected because the sponsor considered the 3 injections as a single administration. In this example, EX laterality values are not represented because the record is related to the EC records. But if the sponsor chose to represent the values, then the General Assumption for handling multiple values for a non-result qualifier variable (SDTMIG v3.1.2 Section 4.1.2.8.3) should be followed. The subject's weight was 100 kg.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXSPID	EXLNKID	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ
1	ABC	EX	ABC3001	1		V3	DRUG X	3	mg/kg	INJECTION	ONCE

Row	EXROUTE	EXLOC	VISITNUM	VISIT	EPOCH	EXSTDTC	EXENDTC	EXSTDY	EXENDY
1 (cont)	SUBCUTANEOUS	ABDOMEN	3	VISIT 3	TREATMENT	2009-05-10	2009-05-10	21	21

The relrec.xpt example reflects a many-to-one dataset-level relationship between EC and EX using --LNKID.

relrec.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC	EC		ECLNKID		MANY	1
ABC	EX		EXLNKID		ONE	1

Example 3

This is an example of a double-blind study design comparing 10, 20, 30 mg of Drug X once daily vs Placebo. A tablet from Bottles A, B and C is to be taken together, daily.

Subject ABC4001 took

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- 1 tablet from Bottles A, B and C from 2011-01-14 to 2011-01-20
- 0 tablets from Bottle B on 2011-01-21, then 2 tablets on 2011-01-22
- 1 tablet from Bottles A and C on 2011-01-21 and 2011-01-22
- 1 tablet from Bottles A, B and C from 2011-01-23 to 2011-01-28

Upon unmasking, it became known that Subject ABC4001 was randomized to Drug X 20 mg where

- Bottle A contained 10 mg/tablet
- Bottle B contained 10 mg/tablet
- Bottle C contained Placebo (i.e., 0 mg of active ingredient/tablet).

SDTM Dataset Examples:

Rows 1-6: Show the administrations as collected.

ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECTRTR	ECPRESP	ECOCCUR	ECDOSE	ECDOSU	ECDOSFRQ	EPOCH
1	ABC	EC	ABC4001	1	BOTTLE A	Y	Y	1	TABLET	QD	TREATMENT
2	ABC	EC	ABC4001	2	BOTTLE C	Y	Y	1	TABLET	QD	TREATMENT
3	ABC	EC	ABC4001	3	BOTTLE B	Y	Y	1	TABLET	QD	TREATMENT
4	ABC	EC	ABC4001	4	BOTTLE B	Y	N		TABLET	QD	TREATMENT
5	ABC	EC	ABC4001	5	BOTTLE B	Y	Y	2	TABLET	QD	TREATMENT
6	ABC	EC	ABC4001	6	BOTTLE B	Y	Y	1	TABLET	QD	TREATMENT

Row	ECSTDTC	ECENDTC	ECSTDY	ECENDY
1 (cont)	2011-01-14	2011-01-28	1	15
2 (cont)	2011-01-14	2011-01-28	1	15
3 (cont)	2011-01-14	2011-01-20	1	7
4 (cont)	2011-01-21	2011-01-21	8	8
5 (cont)	2011-01-22	2011-01-22	9	9
6 (cont)	2011-01-23	2011-01-28	10	15

Rows 1-4: Show the calculated administration in protocol-specified unit (mg). The sponsor considered an administration as a tablet from Bottles A, B and C. In this example, the derivation of EX from EC should be described in the define.xml due to the summing and collapse of records across the domains.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EPOCH
1	ABC	EX	ABC4001	1	DRUG X	20	mg	TABLET	QD	ORAL	TREATMENT
2	ABC	EX	ABC4001	2	DRUG X	10	mg	TABLET	QD	ORAL	TREATMENT
3	ABC	EX	ABC4001	3	DRUG X	30	mg	TABLET	QD	ORAL	TREATMENT
4	ABC	EX	ABC4001	4	DRUG X	20	mg	TABLET	QD	ORAL	TREATMENT

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Row	EXSTDTC	EXENDTC	EXSTDY	EXENDY
1 (cont)	2011-01-14	2011-01-20	1	7
2 (cont)	2011-01-21	2011-01-21	8	8
3 (cont)	2011-01-22	2011-01-22	9	9
4 (cont)	2011-01-23	2011-01-28	10	15

Example 4

This is an example of an Exposure dataset for an open-label study examining the tolerability of different doses of Drug A. Study drug was taken orally, daily for three months. Dose adjustments were allowed as needed in response to tolerability or efficacy issues.

Rows 1-6: Show the open-label administrations collected in the protocol-specified unit.

Not Shown: The EC domain is not shown since the open-label administrations were collected in the protocol-specified unit; EC would be an exact duplicate of the entire EX domain.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXADJ	EPOCH	EXSTDTC	EXENDTC
1	37841	EX	37841001	1	DRUG A	20	mg	TABLET	QD	ORAL		TREATMENT	2002-07-01	2002-10-01
2	37841	EX	37841002	1	DRUG A	20	mg	TABLET	QD	ORAL		TREATMENT	2002-04-02	2002-04-21
3	37841	EX	37841002	2	DRUG A	15	mg	TABLET	QD	ORAL	Reduced due to toxicity	TREATMENT	2002-04-22	2002-07-01
4	37841	EX	37841003	1	DRUG A	20	mg	TABLET	QD	ORAL		TREATMENT	2002-05-09	2002-06-01
5	37841	EX	37841003	2	DRUG A	25	mg	TABLET	QD	ORAL	Increased due to suboptimal efficacy	TREATMENT	2002-06-02	2002-07-01
6	37841	EX	37841003	3	DRUG A	30	mg	TABLET	QD	ORAL	Increased due to suboptimal efficacy	TREATMENT	2002-07-02	2002-08-01

Example 5

This is an example of a double-blind study design comparing 10 and 20 mg of Drug X vs Placebo taken daily, morning and evening, for a week.

Subject ABC5001

Bottle	Time Point	Number of Tablets Taken	Start Date	End Date
A	AM	1	2012-01-01	2012-01-08
B	PM	1	2012-01-01	2012-01-08

Subject ABC5002

Bottle	Time Point	Number of Tablets Taken	Start Date	End Date
A	AM	1	2012-02-01	2012-02-08
B	PM	1	2012-02-01	2012-02-08

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Subject ABC5003

Bottle	Time Point	Number of Tablets Taken	Start Date	End Date
A	AM	1	2012-03-01	2012-03-08
B	PM	1	2012-03-01	2012-03-08

SDTM Dataset Examples:

Rows 1-6: Show the administrations as collected. The use of Time Point variables to describe the time of day intervals of constant dosing occurred is novel. The concept of 'Time of Day' will be explored and in a future version may replace the use of ECTPT in this example.

ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECLNKID	ECTRT	ECPRESP	ECOCCUR	ECDOSE	ECDOSU	ECDOSFRQ	EPOCH
1	ABC	EC	ABC5001	1	20120101-20120108-AM	BOTTLE A	Y	Y	1	TABLET	QD	TREATMENT
2	ABC	EC	ABC5001	2	20120101-20120108-PM	BOTTLE B	Y	Y	1	TABLET	QD	TREATMENT
3	ABC	EC	ABC5002	1	20120201-20120208-AM	BOTTLE A	Y	Y	1	TABLET	QD	TREATMENT
4	ABC	EC	ABC5002	2	20120201-20120208-PM	BOTTLE B	Y	Y	1	TABLET	QD	TREATMENT
5	ABC	EC	ABC5003	1	20120301-20120308-AM	BOTTLE A	Y	Y	1	TABLET	QD	TREATMENT
6	ABC	EC	ABC5003	2	20120301-20120308-PM	BOTTLE B	Y	Y	1	TABLET	QD	TREATMENT

Row	ECSTDTC	ECENDTC	ECSTDY	ECENDY	ECTPT	ECTPTNUM
1 (cont)	2012-01-01	2012-01-08	1	8	AM	1
2 (cont)	2012-01-01	2012-01-08	1	8	PM	2
3 (cont)	2012-02-01	2012-02-08	1	8	AM	1
4 (cont)	2012-02-01	2012-02-08	1	8	PM	2
5 (cont)	2012-03-01	2012-03-08	1	8	AM	1
6 (cont)	2012-03-01	2012-03-08	1	8	PM	2

Rows 1-6: Show the unmasked administrations. The sponsor chose to represent the administrations at the time-point level. The use of Time Point variables to describe the time of day intervals of constant dosing occurred is novel. The concept of 'Time of Day' will be explored and in a future version may replace the use of EXTPT in this example.

Rows 1-2: Show Subject ABC5001 who was randomized to the 20 mg Drug X arm.

Rows 3-4: Show Subject ABC5002 who was randomized to the 10 mg Drug X arm.

Rows 5-6: Show Subject ABC5003 who was randomized to the Placebo arm.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXLNKID	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE
1	ABC	EX	ABC5001	1	20120101-20120108-AM	DRUG X	10	mg	TABLET	QD	ORAL
2	ABC	EX	ABC5001	2	20120101-20120108-PM	DRUG X	10	mg	TABLET	QD	ORAL
3	ABC	EX	ABC5002	1	20120201-20120208-AM	DRUG X	10	mg	TABLET	QD	ORAL
4	ABC	EX	ABC5002	2	20120201-20120208-PM	PLACEBO	0	mg	TABLET	QD	ORAL
5	ABC	EX	ABC5003	1	20120301-20120308-AM	PLACEBO	0	mg	TABLET	QD	ORAL
6	ABC	EX	ABC5003	2	20120301-20120308-PM	PLACEBO	0	mg	TABLET	QD	ORAL

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Row	EPOCH	EXSTDTC	EXENDTC	EXSTDY	EXENDY	EXTPT	EXTPTNUM
1 (cont)	TREATMENT	2012-01-01	2012-01-08	1	8	AM	1
2 (cont)	TREATMENT	2012-01-01	2012-01-08	1	8	PM	2
3 (cont)	TREATMENT	2012-02-01	2012-02-08	1	8	AM	1
4 (cont)	TREATMENT	2012-02-01	2012-02-08	1	8	PM	2
5 (cont)	TREATMENT	2012-03-01	2012-03-08	1	8	AM	1
6 (cont)	TREATMENT	2012-03-01	2012-03-08	1	8	PM	2

The relrec.xpt example reflects a one-to-one dataset-level relationship between EC and EX using --LNKID.

relrec.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC	EC		ECLNKID		ONE	1
ABC	EX		EXLNKID		ONE	1

Example 6

This is an example of an Exposure dataset for a single-crossover study comparing once daily oral administration of Drug A 20 mg capsules with Drug B 30 mg coated tablets. Study drug was taken for 3 consecutive mornings 30 minutes prior to a standardized breakfast. There was a 6-day washout period between treatments.

Exposure CRF:

Subject 56789001

Period 1					Period 2				
Day	Bottle 1 # of capsules	Bottle 2 # of tablets	Start Date/Time	End Date/Time	Day	Bottle 1 # of capsules	Bottle 2 # of tablets	Start Date/Time	End Date/Time
1	1	1	2002-07-01T07:30	2002-07-01T07:30	1	1	1	2002-07-09T07:30	2002-07-09T07:30
2	1	1	2002-07-02T07:30	2002-07-02T07:30	2	1	1	2002-07-10T07:30	2002-07-10T07:30
3	1	1	2002-07-03T07:32	2002-07-03T07:32	3	1	1	2002-07-11T07:34	2002-07-11T07:34

Subject 56789003

Period 1					Period 2				
Day	Bottle 1 # of capsules	Bottle 2 # of tablets	Start Date/Time	End Date/Time	Day	Bottle 1 # of capsules	Bottle 2 # of tablets	Start Date/Time	End Date/Time
1	1	1	2002-07-03T07:30	2002-07-03T07:30	1	1	1	2002-07-11T07:30	2002-07-11T07:30
2	1	1	2002-07-04T07:24	2002-07-04T07:24	2	1	1	2002-07-12T07:43	2002-07-12T07:43
3	1	1	2002-07-05T07:24	2002-07-05T07:24	3	1	1	2002-07-13T07:38	2002-07-13T07:38

SDTM Dataset Examples:

Rows 1 to 24: Show the administrations as collected.

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ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECTRT	ECPRESP	ECOCCUR	ECDOSE	ECDOSU	ECDOSFRM	ECDOSFRQ	ECROUTE
1	56789	EC	56789001	1	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
2	56789	EC	56789001	2	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL
3	56789	EC	56789001	3	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
4	56789	EC	56789001	4	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL
5	56789	EC	56789001	5	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
6	56789	EC	56789001	6	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL
7	56789	EC	56789001	7	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
8	56789	EC	56789001	8	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL
9	56789	EC	56789001	9	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
10	56789	EC	56789001	10	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL
11	56789	EC	56789001	11	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
12	56789	EC	56789001	12	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL
13	56789	EC	56789003	1	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
14	56789	EC	56789003	2	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL
15	56789	EC	56789003	3	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
16	56789	EC	56789003	4	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL
17	56789	EC	56789003	5	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
18	56789	EC	56789003	6	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL
19	56789	EC	56789003	7	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
20	56789	EC	56789003	8	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL
21	56789	EC	56789003	9	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
22	56789	EC	56789003	10	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL
23	56789	EC	56789003	11	BOTTLE 1	Y	Y	1	CAPSULE	CAPSULE	QD	ORAL
24	56789	EC	56789003	12	BOTTLE 2	Y	Y	1	TABLET, COATED	TABLET, COATED	QD	ORAL

Row	EPOCH	ECSTDT	ECENDTC	ECSTDY	ECENDY	ECTPT	ECELTM	ECTPTREF
1 (cont)	TREATMENT PERIOD 1	2002-07-01T07:30	2002-07-01T07:30	1	1	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
2 (cont)	TREATMENT PERIOD 1	2002-07-01T07:30	2002-07-01T07:30	1	1	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
3 (cont)	TREATMENT PERIOD 1	2002-07-02T07:30	2002-07-02T07:30	2	2	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
4 (cont)	TREATMENT PERIOD 1	2002-07-02T07:30	2002-07-02T07:30	2	2	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
5 (cont)	TREATMENT PERIOD 1	2002-07-03T07:32	2002-07-03T07:32	3	3	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
6 (cont)	TREATMENT PERIOD 1	2002-07-03T07:32	2002-07-03T07:32	3	3	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
7 (cont)	TREATMETN PERIOD 2	2002-07-09T07:30	2002-07-09T07:30	9	9	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
8 (cont)	TREATMETN PERIOD 2	2002-07-09T07:30	2002-07-09T07:30	9	9	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
9 (cont)	TREATMENT PERIOD 2	2002-07-10T07:30	2002-07-10T07:30	10	10	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
10 (cont)	TREATMENT PERIOD 2	2002-07-10T07:30	2002-07-10T07:30	10	10	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
11 (cont)	TREATMENT PERIOD 2	2002-07-11T07:34	2002-07-11T07:34	11	11	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
12 (cont)	TREATMENT PERIOD 2	2002-07-11T07:34	2002-07-11T07:34	11	11	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
13 (cont)	TREATMENT PERIOD 1	2002-07-03T07:30	2002-07-03T07:30	1	1	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
14 (cont)	TREATMENT PERIOD 1	2002-07-03T07:30	2002-07-03T07:30	1	1	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
15 (cont)	TREATMETN PERIOD 1	2002-07-04T07:24	2002-07-04T07:24	2	2	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
16 (cont)	TREATMETN PERIOD 1	2002-07-04T07:24	2002-07-04T07:24	2	2	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
17 (cont)	TREATMENT PERIOD 1	2002-07-05T07:24	2002-07-05T07:24	3	3	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
18 (cont)	TREATMENT PERIOD 1	2002-07-05T07:24	2002-07-05T07:24	3	3	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
19 (cont)	TREATMETN PERIOD 2	2002-07-11T07:30	2002-07-11T07:30	9	9	30 MINUTES PRIOR	-PT30M	STD BREAKFAST

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Row	EPOCH	ECSTDTC	ECENDTC	ECSTDY	ECENDY	ECTPT	ECELTM	ECTPTREF
20 (cont)	TREATMETN PERIOD 2	2002-07-11T07:30	2002-07-11T07:30	9	9	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
21 (cont)	TREATMENT PERIOD 2	2002-07-12T07:43	2002-07-12T07:43	10	10	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
22 (cont)	TREATMENT PERIOD 2	2002-07-12T07:43	2002-07-12T07:43	10	10	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
23 (cont)	TREATMENT PERIOD 2	2002-07-13T07:38	2002-07-13T07:38	11	11	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
24 (cont)	TREATMENT PERIOD 2	2002-07-13T07:38	2002-07-13T07:38	11	11	30 MINUTES PRIOR	-PT30M	STD BREAKFAST

Rows 1 to 24: Show the unblinded administrations.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EPOCH	EXSTDTC
1	56789	EX	56789001	1	DRUG A	20	mg	CAPSULE	QD	ORAL	TREATMENT PERIOD 1	2002-07-01T07:30
2	56789	EX	56789001	2	PLACEBO	0	mg	TABLET, COATED	QD	ORAL	TREATMENT PERIOD 1	2002-07-01T07:30
3	56789	EX	56789001	3	DRUG A	20	mg	CAPSULE	QD	ORAL	TREATMENT PERIOD 1	2002-07-02T07:30
4	56789	EX	56789001	4	PLACEBO	0	mg	TABLET, COATED	QD	ORAL	TREATMENT PERIOD 1	2002-07-02T07:30
5	56789	EX	56789001	5	DRUG A	20	mg	CAPSULE	QD	ORAL	TREATMENT PERIOD 1	2002-07-03T07:32
6	56789	EX	56789001	6	PLACEBO	0	mg	TABLET, COATED	QD	ORAL	TREATMENT PERIOD 1	2002-07-03T07:32
7	56789	EX	56789001	7	PLACEBO	0	mg	CAPSULE	QD	ORAL	TREATMETN PERIOD 2	2002-07-09T07:30
8	56789	EX	56789001	8	DRUG B	30	mg	TABLET, COATED	QD	ORAL	TREATMETN PERIOD 2	2002-07-09T07:30
9	56789	EX	56789001	9	PLACEBO	0	mg	CAPSULE	QD	ORAL	TREATMENT PERIOD 2	2002-07-10T07:30
10	56789	EX	56789001	10	DRUG B	30	mg	TABLET, COATED	QD	ORAL	TREATMENT PERIOD 2	2002-07-10T07:30
11	56789	EX	56789001	11	PLACEBO	0	mg	CAPSULE	QD	ORAL	TREATMENT PERIOD 2	2002-07-11T07:34
12	56789	EX	56789001	12	DRUG B	30	mg	TABLET, COATED	QD	ORAL	TREATMENT PERIOD 2	2002-07-11T07:34
13	56789	EX	56789003	1	PLACEBO	0	mg	CAPSULE	QD	ORAL	TREATMENT PERIOD 1	2002-07-03T07:30
14	56789	EX	56789003	2	DRUG B	30	mg	TABLET, COATED	QD	ORAL	TREATMENT PERIOD 1	2002-07-03T07:30
15	56789	EX	56789003	3	PLACEBO	0	mg	CAPSULE	QD	ORAL	TREATMETN PERIOD 1	2002-07-04T07:24
16	56789	EX	56789003	4	DRUG B	30	mg	TABLET, COATED	QD	ORAL	TREATMETN PERIOD 1	2002-07-04T07:24
17	56789	EX	56789003	5	PLACEBO	0	mg	CAPSULE	QD	ORAL	TREATMENT PERIOD 1	2002-07-05T07:24
18	56789	EX	56789003	6	DRUG B	30	mg	TABLET, COATED	QD	ORAL	TREATMENT PERIOD 1	2002-07-05T07:24
19	56789	EX	56789003	7	DRUG A	20	mg	CAPSULE	QD	ORAL	TREATMETN PERIOD 2	2002-07-11T07:30
20	56789	EX	56789003	8	PLACEBO	0	mg	TABLET, COATED	QD	ORAL	TREATMETN PERIOD 2	2002-07-11T07:30
21	56789	EX	56789003	9	DRUG A	20	mg	CAPSULE	QD	ORAL	TREATMENT PERIOD 2	2002-07-12T07:43
22	56789	EX	56789003	10	PLACEBO	0	mg	TABLET, COATED	QD	ORAL	TREATMENT PERIOD 2	2002-07-12T07:43
23	56789	EX	56789003	11	DRUG A	20	mg	CAPSULE	QD	ORAL	TREATMENT PERIOD 2	2002-07-13T07:38
24	56789	EX	56789003	12	PLACEBO	0	mg	TABLET, COATED	QD	ORAL	TREATMENT PERIOD 2	2002-07-13T07:38

Row	EXENDTC	EXSTDY	EXENDY	EXTPT	EXELTM	EXTPTREF
1 (cont)	2002-07-01T07:30	1	1	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
2 (cont)	2002-07-01T07:30	1	1	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
3 (cont)	2002-07-02T07:30	2	2	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
4 (cont)	2002-07-02T07:30	2	2	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
5 (cont)	2002-07-03T07:32	3	3	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
6 (cont)	2002-07-03T07:32	3	3	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
7 (cont)	2002-07-09T07:30	9	9	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
8 (cont)	2002-07-09T07:30	9	9	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
9 (cont)	2002-07-10T07:30	10	10	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
10 (cont)	2002-07-10T07:30	10	10	30 MINUTES PRIOR	-PT30M	STD BREAKFAST

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Row	EXENDTC	EXSTDY	EXENDY	EXTPT	EXELTM	EXPTREF
11 (cont)	2002-07-11T07:34	11	11	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
12 (cont)	2002-07-11T07:34	11	11	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
13 (cont)	2002-07-03T07:30	1	1	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
14 (cont)	2002-07-03T07:30	1	1	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
15 (cont)	2002-07-04T07:24	2	2	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
16 (cont)	2002-07-04T07:24	2	2	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
17 (cont)	2002-07-05T07:24	3	3	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
18 (cont)	2002-07-05T07:24	3	3	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
19 (cont)	2002-07-11T07:30	9	9	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
20 (cont)	2002-07-11T07:30	9	9	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
21 (cont)	2002-07-12T07:43	10	10	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
22 (cont)	2002-07-12T07:43	10	10	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
23 (cont)	2002-07-13T07:38	11	11	30 MINUTES PRIOR	-PT30M	STD BREAKFAST
24 (cont)	2002-07-13T07:38	11	11	30 MINUTES PRIOR	-PT30M	STD BREAKFAST

Example 7

This is an example of a study design involving weekly infusions of Drug Z 10 mg/kg. In the event a subject experiences a dose-limiting toxicity (DLT), the intended dose may be reduced to 7.5 mg/kg.

Per CRF example, Subject ABC123-0201's first administration of Drug Z was on 2009-02-13; the intended dose was 10 mg/kg and the calculated actual dose was 9.9 mg/kg. The subject's second administration of Drug Z occurred on 2009-02-20; the intended dose was reduced to 7.5 mg/kg due to dose limiting toxicity, the infusion was stopped early due to an injection site reaction and the calculated actual dose was 2.6 mg/kg. The subject's third administration was intended to occur on 2009-02-27; the intended dose was 7.5 mg/kg but due to a personal reason, the administration did not occur.

Exposure CRF:

Subject ABC123-0201

Visit	1	2	3
Intended Dose	<ul style="list-style-type: none"> ● 10 mg/kg ○ 7.5 mg/kg 	<ul style="list-style-type: none"> ○ 10 mg/kg ● 7.5 mg/kg 	<ul style="list-style-type: none"> ○ 10 mg/kg ● 7.5 mg/kg
Reason for Dose Adjustment	○ Dose limiting toxicity	● Dose limiting toxicity	○ Dose limiting toxicity
Dose Administered	<ul style="list-style-type: none"> ● Yes ○ No If no, give reason: <ul style="list-style-type: none"> ○ Treatment discontinued due to disease progression ○ Other, specify: _____ 	<ul style="list-style-type: none"> ● Yes ○ No If no, give reason: <ul style="list-style-type: none"> ○ Treatment discontinued due to disease progression ○ Other, specify: _____ 	<ul style="list-style-type: none"> ○ Yes ● No If no, give reason: <ul style="list-style-type: none"> ○ Treatment discontinued due to disease progression ● Other, specify: Personal reason
Date	13-FEB-2009	20-FEB-2009	27-FEB-2009
Start Time (24 hour clock)	10:00	11:00	
End Time (24 hour clock)	10:45	11:20	
Amount (mL)	99 mL	35 mL	0 mL
Concentration	5.5 mg/mL	4.12 mg/mL	4.12 mg/mL
If dose was adjusted, what was the reason:	<ul style="list-style-type: none"> ○ Injection site reaction ○ Adverse event 	<ul style="list-style-type: none"> ● Injection site reaction ○ Adverse event 	<ul style="list-style-type: none"> ○ Injection site reaction ○ Adverse event

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Visit	1	2	3
	o Other, specify: _____	o Other, specify: _____	o Other, specify: _____

SDTM Dataset Examples:

Rows 1, 3, 5: Show the collected intended dose levels (mg/kg) and ECMOOD is 'SCHEDULED'.

Rows 2, 4, 6: Show the collected actual administration amounts (mL) and ECMOOD is 'PERFORMED'.

ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECLNKID	ECLNKGRP	ECTRT	ECMOOD	ECPRESP	ECOCCUR	ECDOSE	ECDOSU	ECPSTRG	ECPSTRGU
1	ABC123	EC	ABC123-0201	1		V1	DRUG Z	SCHEDULED			10	mg/kg		
2	ABC123	EC	ABC123-0201	2	20090213 T1000	V1	DRUG Z	PERFORMED	Y	Y	99	mL	5.5	mg/mL
3	ABC123	EC	ABC123-0201	3		V2	DRUG Z	SCHEDULED			7.5	mg/kg		
4	ABC123	EC	ABC123-0201	4	20090220 T1100	V2	DRUG Z	PERFORMED	Y	Y	35	mL	4.12	mg/mL
5	ABC123	EC	ABC123-0201	5		V3	DRUG Z	SCHEDULED			7.5	mg/kg		
6	ABC123	EC	ABC123-0201	6	20090227	V3	DRUG Z	PERFORMED	Y	N		mL	4.12	mg/mL

Row	ECADJ	VISITNUM	VISIT	EPOCH	ECSTDTC	ECENDTC	EXSTDY	EXENDY
1 (cont)		1	VISIT 1	TREATMENT	2009-02-13	2009-02-13	1	1
2 (cont)		1	VISIT 1	TREATMENT	2009-02-13T10:00	2009-02-13T10:45	1	1
3 (cont)	Dose limiting toxicity	2	VISIT 2	TREATMENT	2009-02-20	2009-02-20	8	8
4 (cont)		2	VISIT 2	TREATMENT	2009-02-20T11:00	2009-02-20T11:20	8	8
5 (cont)		3	VISIT 3	TREATMENT	2009-02-27	2009-02-27	15	15
6 (cont)		3	VISIT 3	TREATMENT	2009-02-27	2009-02-27	15	15

suppec.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
ABC	EC	ABC123-0201	ECSEQ	6	ECREASOC	Reason for Occur Value	PERSONAL REASON	CRF	

Rows 1-3: Show the calculated administrations in protocol-specified unit (mg/kg). The subject's weight was 55 kg.

Row 2: Shows the collected explanation for the adjusted dose amount administered at Visit 2 in EXADJ. The scheduled dose was 7.5 mg/kg, as noted in EC, and the performed dose in mg/kg was 2.6 as seen in EX.

Not Shown: The visit 3 dose that was not performed is not represented as a record in the EX dataset. The collected reason for the not performed dose is represented in the EC domain.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXLNKID	EXLNKGRP	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE
1	ABC123	EX	ABC123-0201	1	20090213T1000	V1	DRUG Z	9.9	mg/kg	SOLUTION	CONTINUOUS	INTRAVENOUS
2	ABC123	EX	ABC123-0201	2	20090220T1100	V2	DRUG Z	2.6	mg/kg	SOLUTION	CONTINUOUS	INTRAVENOUS

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Row	EXADJ	VISITNUM	VISIT	EPOCH	EXSTDTC	EXSTDTC	EXSTDY	EXENDY
1 (cont)		1	VISIT 1	TREATMENT	2009-02-13T10:00	2009-02-13T10:00	1	1
2 (cont)	Injection site reaction	2	VISIT 2	TREATMENT	2009-02-20T11:00	2009-02-20T11:00	8	8

Rows 1-2: Show the sponsor chose to calculate the administered doses in the alternative unit of 'mg' and represented the amounts in the FA domain.

fa.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU
1	ABC123	FA	ABC123-0201	1	20090213T1000	DOSEALT	Dose in Alternative Unit	DRUG Z	522.5	mg	522.5	522.5	mg
2	ABC123	FA	ABC123-0201	2	20090220T1100	DOSEALT	Dose in Alternative Unit	DRUG Z	144.2	mg	144.2	144.2	mg

Row	VISITNUM	VISIT	EPOCH
1 (cont)	1	VISIT 1	TREATMENT
2 (cont)	2	VISIT 2	TREATMENT

The relrec.xpt example reflects two types of relationships between EC and EX. --LNKID is used to represent the one-to-one relationship of the Performed records across the domains and --LNKGRP is used to represent the many-to-one relationship of the Scheduled and Performed records in EC with the Performed records in EX. Lastly, a one-to-one relationship between EX and FA is defined at the dataset-level by --LNKID.

relrec.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC123	EC		ECLNKID		ONE	1
ABC123	EX		EXLNKID		ONE	1
ABC123	EC		ECLNKGRP		MANY	2
ABC123	EX		EXLNKGRP		ONE	2
ABC123	EX		EXLNKID		ONE	3
ABC123	FA		FALNKID		ONE	3

Example 8

This is an example where a 100 mg tablet is scheduled to be taken daily. The overall dosing interval is collected (first dose date, last dose date) and the date and amount of any unplanned doses. Note: This example collection design does not map from current CDASH standards.

First Dose Date	Last Dose Date
2012-01-13	2012-01-20

Date	Number of Doses Daily If/When Deviated from Plan
2012-01-15	0
2012-01-16	2

SDTM Dataset Examples:

Rows 1-3: Show the administrations as collected.

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- Row 1:** Shows the overall dosing interval from first dose date to last dose date.
Row 2: Shows the missed dose on 2012-01-15 which falls within the overall dosing interval.
Row 3: Shows a doubled dose on 2012-01-16 which also falls within the overall dosing interval.

ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECTRTR	ECCAT	ECPRESP	ECOCCUR	ECDOSE	ECDOSU	ECDOSFRQ
1	ABC	EC	ABC7001	1	BOTTLE A	FIRST TO LAST DOSE INTERVAL	Y	Y	1	TABLET	QD
2	ABC	EC	ABC7001	2	BOTTLE A	EXCEPTION DOSE	Y	N		TABLET	QD
3	ABC	EC	ABC7001	3	BOTTLE A	EXCEPTION DOSE	Y	Y	2	TABLET	QD

Row	EPOCH	ECSTDTC	ECENDTC	ECSTDY	ECENDY
1 (cont)	TREATMENT	2012-01-13	2012-01-20	1	8
2 (cont)	TREATMENT	2012-01-15	2012-01-15	3	3
3 (cont)	TREATMENT	2012-01-16	2012-01-16	4	4

- Rows 1-3:** Show the unmasked administrations in non-overlapping intervals of time.
Row 1: Shows the administration from first dose date to the day before the missed dose.
Row 2: Shows the doubled dose.
Row 3: Shows the remaining administrations to the last dose date.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EPOCH	EXSTDTC
1	ABC	EX	ABC7001	1	DRUG X	100	mg	TABLET	QD	ORAL	TREATMENT	2012-01-13
2	ABC	EX	ABC7001	2	DRUG X	200	mg	TABLET	QD	ORAL	TREATMENT	2012-01-16
3	ABC	EX	ABC7001	3	DRUG X	100	mg	TABLET	QD	ORAL	TREATMENT	2012-01-17

Row	EXENDTC	EXSTDY	EXENDY
1 (cont)	2012-01-14	1	2
2 (cont)	2012-01-16	4	4
3 (cont)	2012-01-20	5	8

6 Domain Models Based on the General Observation Classes

6.1 Interventions

Procedures (PR)

PR – Description/Overview for the Procedures Domain Model

The Procedures domain model reflects collected details describing a subject's therapeutic and diagnostic procedures.

PR – Specification for the Procedures Domain Model

pr.xpt, Procedures — Interventions, Version 3.2. One record per recorded procedure per occurrence per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	PR	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
PRSEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness of records within a dataset for a subject. Should be assigned to be in a consistent chronological order.	Req
PRGRPID	Group ID	Char		Identifier	Used to link together a block of related records within a subject in a domain.	Perm
PRSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier. Example: pre-printed line identifier on a CRF or record identifier defined in the sponsor's operational database.	Perm
PRLNKID	Link ID	Char		Identifier	Used to facilitate identification of relationships between records.	Perm
PRLNKGRP	Link Group ID	Char		Identifier	Used to facilitate identification of relationships between records.	Perm
PRTRT	Reported Name of Procedure	Char		Topic	Name of procedure performed, either pre-printed or collected on a CRF.	Req
PRDECOD	Standardized Procedure Name	Char	*	Synonym Qualifier	Standardized or dictionary-derived name of PRTRT. The sponsor is expected to provide the dictionary name and version used to map the terms in the define.xml external codelist attributes. If an intervention term does not have a decode value in the dictionary then PRDECOD will be null.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
PRCAT	Category	Char	*	Grouping Qualifier	Used to define a category of procedure values.	Perm
PRSCAT	Subcategory	Char	*	Grouping Qualifier	Used to define a further categorization of PRCAT values.	Perm
PRPRESP	Pre-specified	Char	(NY)	Record Qualifier	Used when a specific procedure is pre-specified on a CRF. Values should be “Y” or null.	Perm
PROCCUR	Occurrence	Char	(NY)	Record Qualifier	Used to record whether a pre-specified procedure occurred when information about the occurrence of a specific procedure is solicited.	Perm
PRINDC	Indication	Char		Record Qualifier	Denotes the indication for the procedure (e.g., why the procedure was performed).	Perm
PRDOSE	Dose	Num		Record Qualifier	Amount of PRTRT administered. Not populated when PRDOSTXT is populated.	Perm
PRDOSTXT	Dose Description	Char		Record Qualifier	Dosing information collected in text form. Examples: <1, 200-400. Not populated when PRDOSE is populated.	Perm
PRDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for PRDOSE, PRDOSTOT, or PRDOSTXT.	Perm
PRDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for PRTRT.	Perm
PRDOSFRQ	Dosing Frequency per Interval	Char	(FRQ)	Variable Qualifier	Usually expressed as the number of doses given per a specific interval.	Perm
PRDOSRGM	Intended Dose Regimen	Char		Variable Qualifier	Text description of the intended schedule or regimen for the procedure.	Perm
PRROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for PRTRT.	Perm
PRLOC	Location of Procedure	Char	(LOC)	Record Qualifier	Anatomical location of a procedure.	Perm
PRLAT	Laterality	Char	(LAT)	Variable Qualifier	Qualifier for anatomical location or specimen further detailing laterality.	Perm
PRDIR	Directionality	Char	(DIR)	Variable Qualifier	Qualifier for anatomical location or specimen further detailing directionality.	Perm
PRPORTOT	Portion or Totality	Char	(PORTOT)	Variable Qualifier	Qualifier for anatomical location or specimen further detailing the distribution, which means arrangement of, apportioning of.	Perm
VISITNUM	Visit Number	Num		Timing	Clinical encounter number. Numeric version of VISIT, used for sorting.	Perm
VISIT	Visit Name	Char		Timing	Protocol-defined description of a clinical encounter.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of VISIT. Should be an integer.	Perm
PRSTDTC	Start Date/Time of Procedure	Char	ISO 8601	Timing	Start date/time of the procedure represented in ISO 8601 character format.	Exp
PRENDTC	End Date/Time of Procedure	Char	ISO 8601	Timing	End date/time of the procedure represented in ISO 8601 character format.	Perm
PRSTDY	Study Day of Start of Procedure	Num		Timing	Study day of start of procedure expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.	Perm
PRENDY	Study Day of End of Procedure	Num		Timing	Study day of end of procedure expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.	Perm
PRDUR	Duration of Procedure	Char	ISO 8601	Timing	Collected duration of a procedure represented in ISO 8601 character format. Used only if collected on the CRF and not derived from start and end date/times.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
PRTPT	Planned Time Point Name	Char		Timing	Text description of time when a procedure should be performed. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See PRTPTNUM and PRTPTREF.	Perm
PRTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of planned time point used in sorting.	Perm
PRELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time in ISO 8601 format relative to a planned fixed reference (PRTPTREF). 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.	Perm
PRTPTREF	Time Point Reference	Char		Timing	Description of the fixed reference point referred to by PRELTM, PRTPTNUM, and PRTPT.	Perm
PRRFDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time for a fixed reference time point defined by PRTPTREF in ISO 8601 character format.	Perm
PRSTRTPT	Start Relative to Reference Time Point	Char	BEFORE, COINCIDENT, AFTER, U	Timing	Identifies the start of the observation as being before or after the sponsor-defined reference time point defined by variable PRTPT.	Perm
PRSTTPT	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by PRSTRTPT. Examples: "2003-12-15" or "VISIT 1".	Perm
PRENRTPT	End Relative to Reference Time Point	Char	BEFORE, COINCIDENT, AFTER, ONGOING, U	Timing	Identifies the end of the observation as being before or after the sponsor-defined reference time point defined by variable PRTPT.	Perm
PRENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by PRENRTPT. Examples: "2003-12-25" or "VISIT 2".	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

PR – Assumptions for the Procedures Domain Model

1. PR Definition

The Procedures domain model reflects collected details describing a subject's therapeutic and diagnostic procedures. Some example procedures by type include the following:

- a. disease screening (e.g., mammogram, pap smear)
- b. endoscopic examinations (e.g., arthroscopy, diagnostic colonoscopy, therapeutic colonoscopy, diagnostic laparoscopy, therapeutic laparoscopy)
- c. diagnostic tests (e.g., amniocentesis, biopsy, catheterization, cutaneous oximetry, finger stick, fluorophotometry, imaging techniques (e.g., DXA scan, CT scan, MRI), phlebotomy, pulmonary function test, skin test, stress test, tympanometry)
- d. therapeutic procedures (e.g., ablation therapy, catheterization, cryotherapy, mechanical ventilation, phototherapy, radiation therapy/radiotherapy, thermotherapy)
- e. surgical procedures (e.g., curative surgery, diagnostic surgery, palliative surgery, therapeutic surgery, prophylactic surgery, resection, stenting, hysterectomy, tubal ligation, implantation)

The Procedures domain is based on the Interventions Observation Class. The extent of physiological effect may range from observable to microscopic. Regardless of the extent of effect or whether it is collected in the study, all collected procedures are represented in this domain. The protocol design should pre-specify whether procedure information will be collected.

Measurements obtained from procedures are to be represented in their respective Findings domain(s). For example, a biopsy may be performed to obtain a tissue sample that is then evaluated histopathologically. In this case, details of the biopsy procedure can be represented in the PR domain and the histopathology findings in the MI domain. Describing the relationship between PR and MI records (in RELREC) in this example is dependent on whether the relationship is collected, either explicitly or implicitly.

2. In the Findings Observation Class, the test method is represented in the --METHOD variable (e.g., electrophoresis, gram stain, polymerase chain reaction). At times, the test method overlaps with diagnostic/therapeutic procedures (e.g., ultrasound, MRI, x-ray) in-scope for the PR domain. The following is recommended: If timing (start, end or duration) or an indicator populating PROCCUR, PRSTAT or PRREASND is collected, then a PR record should be created. If only the findings from a procedure are collected, then --METHOD in the Findings domain(s) may be sufficient to reflect the procedure and a related PR record is optional. It is at the sponsor's discretion whether to represent the procedure as both a test method (--METHOD) and related PR record.
3. Additional Interventions Qualifiers
 - a. Other additional Qualifiers from the SDTM Interventions Class may be added to this domain.

PR – Examples for the Procedures Domain Model

Example 1

A procedures log CRF may solicit verbatim values and date performed. The example below shows a subject who had five procedures collected and represented in pr.xpt.

Rows 1-5: Represent procedures where verbatim values and the date they occurred were collected.

pr.xpt

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTRT	PRSTDTC	PRENDTC
1	XYZ	PR	XYZ789-002	1	Wisdom Teeth Extraction	2010-06-08	2010-06-08
2	XYZ	PR	XYZ789-002	2	Reset Broken Arm	2010-08-06	2010-08-06
3	XYZ	PR	XYZ789-002	3	Prostate Examination	2010-12-12	2010-12-12
4	XYZ	PR	XYZ789-002	4	Endoscopy	2010-12-12	2010-12-12
5	XYZ	PR	XYZ789-002	5	Heart Transplant	2011-08-29	2011-08-29

Example 2

A 24-hour holter monitor data scenario is below. This ambulatory electrocardiography technique records a continuous electrocardiographic rhythm pattern for 24 hours to detect heart arrhythmias. Monitoring started at 2011-01-01T08:00 and ended 2011-01-02T09:45. Minimum, maximum and mean heart rate results are represented in eg.xpt.

Row 1: Represents the occurrence of a 24-hour holter monitor, from its start to its end.

pr.xpt

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRLNKID	PRTRT	PRPRES	PROCCUR	PRSTDTC	PRENDTC
1	ABC123	PR	ABC123-001	1	20110101_20110102	24-HOUR HOLTER MONITOR	Y	Y	2011-01-01T08:00	2011-01-02T09:45

Rows 1-3: The heart rate findings from the procedure are represented in the EG domain.

eg.xpt

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGLNKID	EGTESTCD	EGTEST	EGORRES	EGORRESU	EGMETHOD
1	ABC123	EG	ABC123-001	1	20110101_20110102	HRMIN	Summary (Min) Heart Rate	70	BEATS/MIN	24-HOUR HOLTER MONITOR
2	ABC123	EG	ABC123-001	2	20110101_20110102	HRMAX	Summary (Max) Heart Rate	100	BEATS/MIN	24-HOUR HOLTER MONITOR
3	ABC123	EG	ABC123-001	3	20110101_20110102	HRMEAN	Summary (Mean) Heart Rate	75	BEATS/MIN	24-HOUR HOLTER MONITOR

Row	EGDTC	EGENDTC
1 (cont)	2011-01-01T08:00	2011-01-02T09:45
2 (cont)	2011-01-01T08:00	2011-01-02T09:45
3 (cont)	2011-01-01T08:00	2011-01-02T09:45

Row 1: The relrec.xpt reflects a one-to-many dataset-level relationship between PR and EG using --LNKID.

relrec.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC123	PR		PRLNKID		ONE	1
ABC123	EG		EGLNKID		MANY	1

Example 3:

A six-minute walk procedure is below. At Visit 3, the six-minute walk was performed and Heart Rate measured at the beginning and end. The six-minute walk was also scheduled at Visit 4, but was not performed.

Was it performed	<input type="checkbox"/> No <input type="checkbox"/> Yes
Date Performed	YYYY-MM-DD
Start Time	HH:MM
Completed Time	HH:MM
Beginning Heart Rate (beats/min)	nnn
Ending Heart Rate (beats/min)	nnn

Row 1: Represents the occurrence of a six-minute walk procedure, from its start to its end.

Row 2: Represents a six-minute walk procedure that was solicited but did not occur.

Not Shown: The heart rate measurements from the beginning and end of the procedure should be represented in an appropriate Findings domain; this currently is under discussion by the Functional Tests Subteam. Additionally, collected relationships across the datasets should be represented in RELREC.

pr.xpt

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTRT	PRPRES	PROCCUR	VISIT	PRSTDTC	PRENDTC
1	ABC123	PR	ABC123-001	1	6-MINUTE WALK TEST	Y	Y	VISIT 3	2011-06-01T10:01	2001-06-01T10:07
2	ABC123	PR	ABC123-001	2	6-MINUTE WALK TEST	Y	N	VISIT 4		

Example 4:

Data for three subjects who had on-study radiotherapy are below.

Rows 1-3: Represent radiotherapy procedures with Qualifiers of dose, dose unit and location represented, in addition to Timing variables.

pr.xpt

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTRT	PRDOSE	PRDOSU	PRLOC	PRLAT	PRSTDTC	PRENDTC
1	ABC123	PR	ABC123-1001	1	External beam radiation therapy	70	Gy	BREAST	RIGHT	2011-06-01	2011-06-25
2	ABC123	PR	ABC123-2002	1	Brachytherapy	25	Gy	PROSTATE		2011-07-15	2011-07-15
3	ABC123	PR	ABC123-3003	1	Radiotherapy	300	cGy	BONE		2011-08-19	2011-08-22

6 Domain Models Based on the General Observation Classes

6.1 Interventions

Substance Use (SU)

SU – Description/Overview for the Substance Use Domain Model

The intent of the domain is to capture substance use information that may be used to assess the efficacy and/or safety of therapies that look to mitigate the effects of chronic substance use.

SU – Specification for the Substance Use Domain Model

su.xpt, Substance Use — Interventions, Version 3.2. One record per substance type per reported occurrence per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SU	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SUSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
SUGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
SUSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a Tobacco & Alcohol use CRF page.	Perm
SUTRT	Reported Name of Substance	Char		Topic	Substance name. Examples: Cigarettes, Coffee.	Req
SUMODIFY	Modified Substance Name	Char		Synonym Qualifier	If SUTRT is modified, then the modified text is placed here.	Perm
SUDECOD	Standardized Substance Name	Char	*	Synonym Qualifier	Standardized or dictionary-derived text description of SUTRT or SUMODIFY if the sponsor chooses to code the substance use. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
SUCAT	Category for Substance Use	Char	*	Grouping Qualifier	Used to define a category of related records. Examples: TOBACCO, ALCOHOL, or CAFFEINE.	Perm
SUSCAT	Subcategory for Substance Use	Char	*	Grouping Qualifier	A further categorization of substance use. Examples: CIGARS, CIGARETTES, BEER, WINE	Perm
SUPRESP	SU Pre-Specified	Char	(NY)	Variable Qualifier	Used to indicate whether (Y/null) information about the use of a specific substance was solicited on the CRF.	Perm
SUOCCUR	SU Occurrence	Char	(NY)	Record Qualifier	When the use of specific substances is solicited, SUOCCUR is used to indicate whether or not (Y/N) a particular pre-specified substance was used. Values are null for substances not specifically solicited.	Perm
SUSTAT	Completion Status	Char	(ND)	Record Qualifier	When the use of pre-specified substances is solicited, the completion status indicates that there was no response to the question about the pre-specified substance. When there is no pre-specified list on the CRF, then the completion status indicates that substance use was not assessed for the subject.	Perm
SUREASND	Reason Substance Use Not Collected	Char		Record Qualifier	Describes the reason substance use was not collected. Used in conjunction with SUSTAT when value of SUSTAT is NOT DONE.	Perm
SUCLAS	Substance Use Class	Char	*	Variable Qualifier	Substance use class. May be obtained from coding. When coding to a single class, populate with class value. If using a dictionary and coding to multiple classes, then follow <i>Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable</i> or omit SUCLAS.	Perm
SUCLASCD	Substance Use Class Code	Char	*	Variable Qualifier	Code corresponding to SUCLAS. May be obtained from coding.	Perm
SUDOSE	Substance Use Consumption	Num		Record Qualifier	Amount of SUTRT consumed. Not populated if SUDOSTXT is populated.	Perm
SUDOSTXT	Substance Use Consumption Text	Char		Record Qualifier	Substance use consumption amounts or a range of consumption information collected in text form. Not populated if SUDOSE is populated.	Perm
SUDOSU	Consumption Units	Char	(UNIT)	Variable Qualifier	Units for SUDOSE, SUDOSTOT, or SUDOSTXT. Examples: OUNCES, CIGARETTE EQUIVALENTS, GRAMS.	Perm
SUDOSFRM	Dose Form	Char	*	Variable Qualifier	Dose form for SUTRT. Examples: INJECTABLE, LIQUID, or POWDER.	Perm
SUDOSFRQ	Use Frequency Per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of SUDOSE within a specific time period. Example: Q24H (every day)	Perm
SUDOSTOT	Total Daily Consumption	Num		Record Qualifier	Total daily use of SUTRT using the units in SUDOSU. Used when dosing is collected as Total Daily Dose. If sponsor needs to aggregate the data over a period other than daily, then the aggregated total could be recorded in a Supplemental Qualifier variable.	Perm
SUROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for SUTRT. Examples: ORAL, INTRAVENOUS.	Perm
SUSTDTC	Start Date/Time of Substance Use	Char	ISO 8601	Timing		Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
SUENDTC	End Date/Time of Substance Use	Char	ISO 8601	Timing		Perm
SUSTDY	Study Day of Start of Substance Use	Num		Timing	Study day of start of substance use relative to the sponsor-defined RFSTDTC.	Perm
SUENDY	Study Day of End of Substance Use	Num		Timing	Study day of end of substance use relative to the sponsor-defined RFSTDTC.	Perm
SUDUR	Duration of Substance Use	Char	ISO 8601	Timing	Collected duration of substance use in ISO 8601 format. Used only if collected on the CRF and not derived from start and end date/times.	Perm
SUSTRF	Start Relative to Reference Period	Char	(STENRF)	Timing	Describes the start of the substance use relative to the 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). If information such as "PRIOR", "ONGOING", or "CONTINUING" was collected, this information may be translated into SUSTRF.	Perm
SUENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the substance use with relative to the 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). If information such as "PRIOR", "ONGOING", or "CONTINUING" was collected, this information may be translated into SUENRF.	Perm
SUSTRTPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the start of the substance as being before or after the reference time point defined by variable SUSTTPT.	Perm
SUSTTPT	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by SUSTRTPT. Examples: "2003-12-15" or "VISIT 1".	Perm
SUENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the substance as being before or after the reference time point defined by variable SUENTPT.	Perm
SUENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by SUENRTPT. Examples: "2003-12-25" or "VISIT 2".	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

SU – Assumptions for the Substance Use Domain Model

1. The intent of the domain is to capture substance use information that may be used to assess the efficacy and/or safety of therapies that look to mitigate the effects of chronic substance use, or that could be used as covariates in other efficacy and/or safety analyses.
2. SU Definition
 - a. This information may be independent of planned study evaluations, or may be a key outcome (e.g., planned evaluation) of a clinical trial.
 - b. In many clinical trials, detailed substance use information as provided for in the domain model above may not be required (e.g., the only information collected may be a response to the question “Have you ever smoked tobacco?”); in such cases, many of the Qualifier variables would not be submitted.
 - c. SU may contain responses to questions about use of pre-specified substances as well as records of substance use collected as free text.
3. Substance Use Description and Coding
 - a. SUTRT captures the verbatim or the pre-specified text collected for the substance. It is the topic variable for the SU dataset. SUTRT is a required variable and must have a value.
 - b. SUMODIFY is a permissible variable and should be included if coding is performed and the sponsor’s procedure permits modification of a verbatim substance use term for coding. The modified term is listed in SUMODIFY. The variable may be populated as per the sponsor’s procedures.
 - c. SUDECOD is the preferred term derived by the sponsor from the coding dictionary if coding is performed. It is a permissible variable. Where deemed necessary by the sponsor, the verbatim term (SUTRT) should be coded using a standard dictionary such as WHO Drug. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.
4. Additional Categorization and Grouping
 - a. SUCAT and SUSCAT should not be redundant with the domain code or dictionary classification provided by SUDECOD, or with SUTRT. That is, they should provide a different means of defining or classifying SU records. For example, a sponsor may be interested in identifying all substances that the investigator feels might represent opium use, and to collect such use on a separate CRF page. This categorization might differ from the categorization derived from the coding dictionary.
 - b. SUGRPID may be used to link (or associate) different records together to form a block of related records within SU at the subject level [*see Section 4: 4.1.2.6, Grouping Variables and Categorization*]. It should not be used in place of SUCAT or SUSCAT.
5. Timing Variables
 - a. SUSTDTC and SUENDTC may be populated as required.
 - b. If substance use information is collected more than once within the CRF (indicating that the data are visit-based) then VISITNUM would be added to the domain as an additional timing variable. VISITDY and VISIT would then be permissible variables.
6. Additional Permissible Interventions Qualifiers
 - a. Any additional Qualifiers from the Interventions Class may be added to this domain.

SU – Examples for the Substance Use Domain Model

Example 1

The example below illustrates how typical substance use data could be populated. Here, the CRF collected smoking data (smoking status: previous, current, never; if a current or past smoker, how many packs per day; if a former smoker, what year did the subject quit) and current caffeine use (what caffeine drinks have been consumed today; how many cups today). SUCAT allows the records to be grouped into smoking-related data and caffeine-related data. In this example, the treatments are pre-specified on the CRF page so SUTRT does not require a standardized SUDECOD equivalent.

- Row 1:** Subject 1234005 is a 2-pack/day current smoker. “Current” implies that smoking started sometime before the time the question was asked (SUSTTPT = 2006-01-01, SUSTRTPT = BEFORE) and will end sometime after that date (SUENRTPT = ONGOING). See *Section 4: 4.1.4.7, Use of Relative Timing Variables* for the use of these variables. Both the beginning and ending reference time points for this question are the date of the assessment.
- Row 2:** The same subject drank three cups of coffee on the day of the assessment.
- Row 3:** Subject 1234006 is a former smoker. The date the subject began smoking is unknown but we know that it was sometime before the assessment date. This is shown by the values of SUSTTPT and SUSTRTPT (taken from the timing variables for all classes). The end date of smoking was collected so SUENTPT and SUENRTPT are not populated. Instead, the end date is in SUENDTC.
- Rows 4-5:** The same subject drank tea (Row 4) and coffee (Row 5) on the day of the assessment.
- Row 6:** Subject 1234007 has missing data for the smoking questions. This is indicated by SUSTAT=NOT DONE. The reason is in SUREASND.
- Row 7:** The same subject also had missing data for all of the caffeine questions.
- Not shown:** Subject 1234008 has never smoked, so does not have a tobacco record. Alternatively, a row for the subject could have been included with SUOCCUR=N and not populating the dosing and timing fields; the interpretation would be the same. The subject did not drink any caffeinated drinks on the day of the assessment so does not have any caffeine records. Therefore this subject does not appear in the data.

Row	STUDYID	DOMAIN	USUBJID	SUSEQ	SUTRT	SUCAT	SUSTAT	SUREASND	SUDOSE	SUDOSU	SUDOSFRQ
1	1234	SU	1234005	1	CIGARETTES	TOBACCO			2	PACK	PER DAY
2	1234	SU	1234005	2	COFFEE	CAFFEINE			3	CUP	PER DAY
3	1234	SU	1234006	1	CIGARETTES	TOBACCO			1	PACK	PER DAY
4	1234	SU	1234006	2	TEA	CAFFEINE			1	CUP	PER DAY
5	1234	SU	1234006	3	COFFEE	CAFFEINE			2	CUP	PER DAY
6	1234	SU	1234007	1	CIGARETTES	TOBACCO	NOT DONE	Subject left office before CRF was completed			
7	1234	SU	1234007	2	CAFFEINE	CAFFEINE	NOT DONE	Subject left office before CRF was completed			

Row	SUSTDTC	SUENDTC	SUSTTPT	SUSTRTPT	SUENTPT	SUENRTPT
1 (cont)			2006-01-01	BEFORE	2006-01-01	ONGOING
2 (cont)	2006-01-01	2006-01-01				
3 (cont)		2003	2006-03-15	BEFORE		
4 (cont)	2006-03-15	2006-03-15				
5 (cont)	2006-03-15	2006-03-15				
6 (cont)						
7 (cont)						

6 Domain Models Based on the General Observation Classes

Most subject-level observations collected during the study should be represented according to one of the three SDTM general observation classes. The lists of variables allowed to be used in each of these can be found in the STDM. For detailed definitions, please refer to *SDTM: Section 2.2.2, The Events Observations Class*.

The below table provides a short index for documents where each listed Domain/Dataset is described in full detail.

Please note that this is a change from previous SDTMIG versions (prior to SDTMIG 3.2), where all domains were contained within a single document. This approach has been taken with the goal to simplify SDTMIG maintenance and to assist users in accessing the specific section/domain of interest without having to search a single and much larger document. The Table of Contents for the entire SDTMIG should reflect all domains (old and new) that make up this release.

6.2 Events

Domain Code	Domain Description	Domain Document Name
AE	<u>Adverse Events</u> Adverse events may be captured either as free text or a pre-specified list of terms.	Section 6.2 – AE Domain
CE	<u>Clinical Events</u> A dataset used to capture clinical events of interest that would not be classified as adverse events.	Section 6.2 – CE Domain
DS	<u>Disposition</u> A subject domain utilized for the submission of information encompassing and representing data, vocabulary or records related to disposition. (NCI)	Section 6.2 – DS Domain
DV	<u>Protocol Deviations</u> The intent of the domain is to capture protocol violations and deviations during the course of the study and will store only those criteria violation by or deviated from by the subject and not a response to each violation or deviation.	Section 6.2 – DV Domain
HO	<u>Healthcare Encounters</u> The Healthcare Encounters dataset includes inpatient and outpatient healthcare events (e.g., hospitalizations, nursing home stay, rehabilitation facility stays, ambulatory surgery).	Section 6.2 – HO Domain
MH	<u>Medical History</u> The medical history dataset includes the subject's prior history at the start of the trial. Examples of subject medical history information could include general medical history, gynecological history, and primary diagnosis.	Section 6.2 – MH Domain

6 Domain Models Based on the General Observation Classes

6.3 Events

Adverse Events (AE)

AE - Description/Overview for Adverse Events Domain Model

Adverse events may be captured either as free text or a pre-specified list of terms.

AE - Specification for Adverse Events Domain Model

ae.xpt, Adverse Events — Events, Version 3.2, One record per adverse event per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	AE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
AESEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
AEGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
AEREFID	Reference ID	Char		Identifier	Internal or external identifier such as a serial number on an SAE reporting form.	Perm
AESPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier. It may be pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on an Adverse Events page.	Perm
AETERM	Reported Term for the Adverse Event	Char		Topic	Verbatim name of the event.	Req
AEMODIFY	Modified Reported Term	Char		Synonym Qualifier	If AETERM is modified to facilitate coding, then AEMODIFY will contain the modified text.	Perm
AELLT	Lowest Level Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the Lowest Level Term.	Exp
AELLTCD	Lowest Level Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the Lowest Level Term.	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
AEDECOD	Dictionary-Derived Term	Char	MedDRA	Synonym Qualifier	Dictionary-derived text description of AETERM or AEMODIFY. Equivalent to the Preferred Term (PT in MedDRA). The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.	Req
AEPTCD	Preferred Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the Preferred Term.	Exp
AEHLT	High Level Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the High Level Term for the primary System Organ Class.	Exp
AEHLTCD	High Level Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the High Level Term for the primary System Organ Class.	Exp
AEHLGT	High Level Group Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the High Level Group Term for the primary System Organ Class.	Exp
AEHLGTCD	High Level Group Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the High Level Group Term for the primary System Organ Class.	Exp
AECAT	Category for Adverse Event	Char	*	Grouping Qualifier	Used to define a category of related records. Example: BLEEDING, NEUROPSYCHIATRIC.	Perm
AESCAT	Subcategory for Adverse Event	Char	*	Grouping Qualifier	A further categorization of adverse event. Example: NEUROLOGIC.	Perm
AEPRESP	Pre-Specified Adverse Event	Char	(NY)	Variable Qualifier	A value of "Y" indicates that this adverse event was pre-specified on the CRF. Values are null for spontaneously reported events (i.e., those collected as free-text verbatim terms)	Perm
AEBODSYS	Body System or Organ Class	Char	*	Record Qualifier	Dictionary derived. Body system or organ class used by the sponsor from the coding dictionary (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables which may not necessarily be the primary SOC.	Exp
AEBDSYCD	Body System or Organ Class Code	Num	MedDRA	Variable Qualifier	Dictionary derived. Code for the body system or organ class used by the sponsor. When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables, which may not necessarily be the primary SOC.	Exp
AESOC	Primary System Organ Class	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the primary System Organ Class. Will be the same as AEBODSYS if the primary SOC was used for analysis.	Exp
AESOCDD	Primary System Organ Class Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the primary System Organ Class. Will be the same as AEBDSYCD if the primary SOC was used for analysis.	Exp
AELOC	Location of Event	Char	(LOC)	Record Qualifier	Describes anatomical location relevant for the event (e.g., ARM for skin rash).	Perm
AESEV	Severity/Intensity	Char	(AESEV)	Record Qualifier	The severity or intensity of the event. Examples: MILD, MODERATE, SEVERE.	Perm
AESER	Serious Event	Char	(NY)	Record Qualifier	Is this a serious event?	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
AEACN	Action Taken with Study Treatment	Char	(ACN)	Record Qualifier	Describes changes to the study treatment as a result of the event. AEACN is specifically for the relationship to study treatment. AEACNOTH is for actions unrelated to dose adjustments of study treatment. Examples of AEACN values include ICH E2B values: DRUG WITHDRAWN, DOSE REDUCED, DOSE INCREASED, DOSE NOT CHANGED, UNKNOWN or NOT APPLICABLE.	Exp
AEACNOTH	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. Usually reported as free text. Example: "TREATMENT UNBLINDED. PRIMARY CARE PHYSICIAN NOTIFIED."	Perm
AEREL	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. Controlled Terminology may be defined in the future. Check with regulatory authority for population of this variable.	Exp
AERELNST	Relationship to Non-Study Treatment	Char		Record Qualifier	Records the investigator's opinion as to whether the event may have been due to a treatment other than study drug. May be reported as free text. Example: "MORE LIKELY RELATED TO ASPIRIN USE."	Perm
AEPATT	Pattern of Adverse Event	Char	*	Record Qualifier	Used to indicate the pattern of the event over time. Examples: INTERMITTENT, CONTINUOUS, SINGLE EVENT.	Perm
AEOUT	Outcome of Adverse Event	Char	(OUT)	Record Qualifier	Description of the outcome of an event.	Perm
AESCAN	Involves Cancer	Char	(NY)	Record Qualifier	Was the serious event associated with the development of cancer?	Perm
AESCONG	Congenital Anomaly or Birth Defect	Char	(NY)	Record Qualifier	Was the serious event associated with congenital anomaly or birth defect?	Perm
AESDISAB	Persist or Signif Disability/Incapacity	Char	(NY)	Record Qualifier	Did the serious event result in persistent or significant disability/incapacity?	Perm
AESDTH	Results in Death	Char	(NY)	Record Qualifier	Did the serious event result in death?	Perm
AESHOSP	Requires or Prolongs Hospitalization	Char	(NY)	Record Qualifier	Did the serious event require or prolong hospitalization?	Perm
AESLIFE	Is Life Threatening	Char	(NY)	Record Qualifier	Was the serious event life threatening?	Perm
AESOD	Occurred with Overdose	Char	(NY)	Record Qualifier	Did the serious event occur with an overdose?	Perm
AESMIE	Other Medically Important Serious Event	Char	(NY)	Record Qualifier	Do additional categories for seriousness apply?	Perm
AECONTRT	Concomitant or Additional Trtmnt Given	Char	(NY)	Record Qualifier	Was another treatment given because of the occurrence of the event?	Perm
AETOXGR	Standard Toxicity Grade	Char	*	Record Qualifier	Toxicity grade according to a standard toxicity scale such as Common Terminology Criteria for Adverse Events v3.0 (CTCAE). Sponsor should specify name of the scale and version used in the metadata (see Assumption 6d). If value is from a numeric scale, represent only the number (e.g., "2" and not "Grade 2").	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
AESTDTC	Start Date/Time of Adverse Event	Char	ISO 8601	Timing		Exp
AEENDTC	End Date/Time of Adverse Event	Char	ISO 8601	Timing		Exp
AESTDY	Study Day of Start of Adverse Event	Num		Timing	Study day of start of adverse event relative to the sponsor-defined RFSTDTC.	Perm
AEENDY	Study Day of End of Adverse Event	Num		Timing	Study day of end of event relative to the sponsor-defined RFSTDTC.	Perm
AEDUR	Duration of Adverse Event	Char	ISO 8601	Timing	Collected duration and unit of an adverse event. Used only if collected on the CRF and not derived from start and end date/times. Example: P1DT2H (for 1 day, 2 hours).	Perm
AEENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the event relative to the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point (RFSTDTC) and a discrete ending point (RFENDTC) of the trial.	Perm
AEENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the event as being before or after the reference time point defined by variable AEENTPT.	Perm
AEENTPT	End Reference Time Point	Char		Timing	Description of date/time in ISO 8601 character format of the reference point referred to by AEENRTPT. Examples: "2003-12-25" or "VISIT 2".	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

AE - Assumptions for Adverse Events Domain Model

1. AE Definition

The Adverse Events dataset includes clinical data describing "any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment" (ICH E2A). In consultation with regulatory authorities, sponsors may extend or limit the scope of adverse event collection (e.g., collecting pre-treatment events related to trial conduct, not collecting events that are assessed as efficacy endpoints). The events included in the AE dataset should be consistent with the protocol requirements. Adverse events may be captured either as free text or via a pre-specified list of terms.

2. Adverse Event Description and Coding

- a. AETERM captures the verbatim term collected for the event. It is the topic variable for the AE dataset. AETERM is a required variable and must have a value.
- b. AEMODIFY is a permissible variable and should be included if the sponsor's procedure permits modification of a verbatim term for coding. The modified term is listed in AEMODIFY. The variable should be populated as per the sponsor's procedures.
- c. AEDECOD is the preferred term derived by the sponsor from the coding dictionary. It is a required variable and must have a value. It is expected that the reported term (AETERM) will be coded using a standard dictionary such as MedDRA. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.

- d. AEBODSYS is the system organ class from the coding dictionary associated with the adverse event by the sponsor. This value may differ from the primary system organ class designated in the coding dictionary's standard hierarchy. It is expected that this variable will be populated.
 - e. Sponsors may include the values of additional levels from the coding dictionary's hierarchy (i.e., High-Level Group Term, High-Level Term, Lower-Level Term) in the SUPPAE dataset as described in *Appendix C2 - Supplemental Qualifier Name Codes* and *Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain*.
3. Additional Categorization and Grouping
 - a. AECAT and AESCAT should not be redundant with the domain code or dictionary classification provided by AEDECOD and AEBODSYS (i.e., they should provide a different means of defining or classifying AE records). AECAT and AESCAT are intended for categorizations that are defined in advance. For example, a sponsor may have a separate CRF page for AEs of special interest and then another page for all other AEs. AECAT and AESCAT should not be used for after-the-fact categorizations such as clinically significant. In cases where a category of AEs of special interest resembles a part of the dictionary hierarchy (e.g., "CARDIAC EVENTS"), the categorization represented by AECAT and AESCAT may differ from the categorization derived from the coding dictionary.
 - b. AEGRPID may be used to link (or associate) different records together to form a block of related records at the subject level within the AE domain. See *Section 4: 4.1.2.6, Grouping Variables and Categorization* for discussion of grouping variables.
4. Pre-Specified Terms; Presence or Absence of Events
 - a. Adverse events are generally collected in two different ways, either by recording free text or using a pre-specified list of terms. In the latter case, the solicitation of information on specific adverse events may affect the frequency at which they are reported; therefore, the fact that a specific adverse event was solicited may be of interest to reviewers. An AEPRESP value of "Y" is used to indicate that the event in AETERM was pre-specified on the CRF.
 - b. If it is important to know which adverse events from a pre-specified list were not reported as well as those that did occur, these data should be submitted in a Findings class dataset such as Findings About Events and Interventions [*See Section 6.4 - FA Domain*]. A record should be included in that Findings dataset for each pre-specified adverse-event term. Records for adverse events that actually occurred should also exist in the AE dataset with AEPRESP set to "Y."
 - c. If a study collects both pre-specified adverse events as well as free-text events, the value of AEPRESP should be "Y" for all pre-specified events and null for events reported as free-text. AEPRESP is a permissible field and may be omitted from the dataset if all adverse events were collected as free text.
 - d. When adverse events are collected with the recording of free text, a record may be entered into the sponsor's data management system to indicate "no adverse events" for a specific subject. For these subjects, do not include a record in the AE submission dataset to indicate that there were no events. Records should be included in the submission AE dataset only for adverse events that have actually occurred.
5. Timing Variables
 - a. Relative timing assessment "Ongoing" is common in the collection of Adverse Event information. AEENRF may be used when this relative timing assessment is made coincident with the end of the study reference period for the subject represented in the Demographics dataset (RFENDTC). AEENRTPT with AEENTPT may be used when "Ongoing" is relative to another date such as the final safety follow-up visit date. See *Section 4: 4.1.4.7, Use of Relative Timing Variables*.
 - b. Additional timing variables (such as AEDTC) may be used when appropriate.
6. Other Qualifier Variables

- a. If categories of serious events are collected secondarily to a leading question, as in the example below, the values of the variables that capture reasons an event is considered serious (i.e., AESCAN, AESCONG, etc.) may be null. For example, if Serious is answered “No, “ the values for these variables may be null. However, if Serious is answered “Yes, “ at least one of them will have a “Y” response. Others may be N or null, according to the sponsor’s convention.
Serious? [] Yes [] No
If yes, check all that apply: [] Fatal [] Life-threatening [] Inpatient hospitalization... [] etc.
On the other hand, if the CRF is structured so that a response is collected for each seriousness category, all category variables (e.g., AESDTH, AESHOSP) would be populated and AESER would be derived.
 - b. The serious categories “Involves cancer” (AESCAN) and “Occurred with overdose” (AESOD) are not part of the ICH definition of a serious adverse event, but these categories are available for use in studies conducted under guidelines that existed prior to the FDA’s adoption of the ICH definition.
 - c. When a description of Other Medically Important Serious Adverse Events category is collected on a CRF, sponsors should place the description in the SUPPAE dataset using the standard supplemental qualifier name code AESOSP as described in **Section 8: 8.4, Relating Non-Standard Variables Values to a Parent Domain** and **Appendix C2 - Supplemental Qualifier Name Codes**.
 - d. In studies using toxicity grade according to a standard toxicity scale such as Common Terminology Criteria for Adverse Events v3.0 (CTCAE), published by the NCI (National Cancer Institute) at <http://ctep.cancer.gov/reporting/ctc.html>), AETOXGR should be used instead of AESEV. In most cases, either AESEV or AETOXGR is populated but not both. There may be cases when a sponsor may need to populate both variables. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes
 - e. AE Structure
The structure of the AE domain is one record per adverse event per subject. It is the sponsor's responsibility to define an event. This definition may vary based on the sponsor's requirements for characterizing and reporting product safety and is usually described in the protocol. For example, the sponsor may submit one record that covers an adverse event from start to finish. Alternatively, if there is a need to evaluate AEs at a more granular level, a sponsor may submit a new record when severity, causality, or seriousness changes or worsens. By submitting these individual records, the sponsor indicates that each is considered to represent a different event. The submission dataset structure may differ from the structure at the time of collection. For example, a sponsor might collect data at each visit in order to meet operational needs, but submit records that summarize the event and contain the highest level of severity, causality, seriousness, etc. Examples of dataset structure:
 1. One record per adverse event per subject for each unique event. Multiple adverse event records reported by the investigator are submitted as summary records “collapsed” to the highest level of severity, causality, seriousness, and the final outcome.
 2. One record per adverse event per subject. Changes over time in severity, causality, or seriousness are submitted as separate events. Alternatively, these changes may be submitted in a separate dataset based on the Findings About Events and Interventions model [*see Section 6.4 - FA Domain*].
 3. Other approaches may also be reasonable as long as they meet the sponsor's safety evaluation requirements and each submitted record represents a unique event. The domain-level metadata [*see Section 3: 3.2, Using The CDISC Domain Models In Regulatory Submissions - Dataset Metadata*] should clarify the structure of the dataset.
7. Use of EPOCH and TAETORD
When EPOCH is included in the Adverse Event domain, it should be the epoch of the start of the adverse event. In other words, it should be based on AESTDTC, rather than AEENDTC. The computational method for EPOCH in the define.xml should describe any assumptions made to handle cases where an adverse event starts on the same day that a subject starts an epoch, if AESTDTC and SESTDTC are not captured with enough precision to determine the epoch of the onset of the adverse event unambiguously. Similarly, if TAETORD is included in the Adverse Events domain, it should be the value for the start of the adverse event, and the computational method in the define.xml should describe any assumptions.

8. Additional Events Qualifiers

The following Qualifiers would not be used in AE: --OCCUR, --STAT, and--REASND. They are the only Qualifiers from the SDTM Events Class not in the AE domain. They are not permitted because the AE domain contains only records for adverse events that actually occurred. See Assumption 4b above for information on how to deal with negative responses or missing responses to probing questions for pre-specified adverse events.

9. Variable order in the domain should follow the rules as described in *Section 4: 4.1.1.4, Order Of The Variables* and the order described in *Section 1: 1.1, Purpose*.

10. The addition of AELLT, AELLTCD, AEPTCD, AEHLT, AEHLTCD, AEHLGT, AEHLGTCD, AEBDSYCD, AESOC, and AESOCCD is applicable to submissions coded in MedDRA only. Data items are not expected for non-MedDRA coding.

AE - Examples for Adverse Events Domain Model

Example 1

This is an example of data from an AE CRF that collects AE terms as free text. The first study drug was administered to the subject on October 13, 2006 at 12:00. Three AEs were reported. AEs were coded using MedDRA, and the sponsor’s procedures include the possibility of modifying the reported term to aid in coding. The CRF is structured so that seriousness category variables (e.g., AESDTH, AESHOSP) are checked only when AESER is answered “Y.”

Rows 1-2: Show the following: (1) an example of modifying the reported term for coding purposes. The modified value is in AEMODIFY. (2) An example of the overall seriousness question AESER answered with an “N” and corresponding seriousness category variables (e.g., AESDTH, AESHOSP) left blank.

Row 3: Shows an example of the overall seriousness question AESER answered with a “Y” and the relevant corresponding seriousness category variables (AESHOSP and AESLIFE) answered with a “Y”. The other seriousness category variables are left blank. This row also shows an example of AEENRF being populated because the AE was marked as “Continuing” as of the end of the study reference period for the subject [*see Section 4: 4.1.4.7, Use Of Relative Timing Variables*].

Row	STUDYID	DOMAIN	USUBJID	AESQ	AETERM	AESTDTC	AEENDTC	AEMODIFY	AEDECOD
1	ABC123	AE	123101	1	POUNDING HEADACHE	2005-10-12	2005-10-12	HEADACHE	Headache
2	ABC123	AE	123101	2	BACK PAIN FOR 6 HOURS	2005-10-13T13:05	2005-10-13T19:00	BACK PAIN	Back pain
3	ABC123	AE	123101	3	PULMONARY EMBOLISM	2005-10-21			Pulmonary embolism

Row	AEBODSYS	AESEV	AESER	AEACN	AEREL
1 (cont)	Nervous system disorders	SEVERE	N	NOT APPLICABLE	DEFINITELY NOT RELATED
2 (cont)	Musculoskeletal and connective tissue disorders	MODERATE	N	DOSE REDUCED	PROBABLY RELATED
3 (cont)	Vascular disorders	MODERATE	Y	DOSE REDUCED	PROBABLY NOT RELATED

Row	AEOUT	AESCONG	AESDISAB	AESDTH	AESHOSP	AESLIFE	AESMIE	AESTDY	AEENDY	AEENRF
1 (cont)	RECOVERED/RESOLVED							-1	-1	
2 (cont)	RECOVERED/RESOLVED							1	1	
3 (cont)	RECOVERING/RESOLVING				Y	Y		9		AFTER

Example 2

In this example, a CRF module occurring at several visits asks whether or not nausea, vomiting, or diarrhea occurred. The responses to the probing questions (Yes, No, or Not done) will be represented in the Findings About (FA) domain [see Section 6.4 - FA Domain]. If “Yes ” the investigator is instructed to complete the Adverse Event CRF. In the Adverse Events dataset, data on AEs solicited by means of pre-specified on the CRF will have an AEPRESP value of Y. For AEs solicited by a general question, AEPRESP will be null. RELREC may be used to relate AE records with FA records.

Rows 1-2: Show that nausea and vomiting were pre-specified on a CRF, as indicated by AEPRESP = “Y”. The subject did not experience diarrhea, so no record for that term exists in the AE dataset.

Row 3: Shows an example of an AE (headache) that is not pre-specified on a CRF as indicated by a blank for AEPRESP.

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AEPRESP	AEBODSYS	AESEV	AESER
1	ABC123	AE	123101	1	NAUSEA	Nausea	Y	Gastrointestinal disorders	SEVERE	N
2	ABC123	AE	123101	2	VOMITING	Vomiting	Y	Gastrointestinal disorders	MODERATE	N
3	ABC123	AE	123101	3	HEADACHE	Headache		Nervous system disorders	MILD	N

Row	AEACN	AEREL	AEOUT	AESTDTC	AEENDTC	AESTDY	AEENDY
1 (cont)	DOSE REDUCED	RELATED	RECOVERED/RESOLVED	2005-10-12	2005-10-13	2	3
2 (cont)	DOSE REDUCED	RELATED	RECOVERED/RESOLVED	2005-10-13T13:00	2005-10-13T19:00	3	3
3 (cont)	DOSE NOT CHANGED	POSSIBLY RELATED	RECOVERED/RESOLVED	2005-10-21	2005-10-21	11	11

Example 3

In this example, a CRF module occurs only once and asks whether or not nausea, vomiting, or diarrhea occurred. In the context of this study, the conditions that occurred are reportable as Adverse Events. No additional data about these events is collected. No other adverse event information is collected via general questions. The responses to the probing questions (Yes, No, or Not done) will be represented in the Findings About (FA) domain [see Section 6.4 - FA Domain]. Since all adverse events must be submitted in AE dataset, this represents an unusual case; the AE dataset will be populated with the term and the flag indicating that it was pre-specified, but timing information is limited to the date of collection, and other expected Qualifiers are not available. RELREC may be used to relate AE records with FA records.

Rows 1-2: Subject was found to have experienced nausea and vomiting by means of the probing questions. The subject did not experience diarrhea, so no record for that term exists in the AE dataset.

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AEPRESP	AEBODSYS	AESER	AEACN	AEREL	AEDTC	AESTDTC	AEENDTC	AEDY
1	ABC123	AE	123101	1	NAUSEA	Nausea	Y	Gastrointestinal disorders				2005-10-29			19
2	ABC123	AE	123101	2	VOMITING	Vomiting	Y	Gastrointestinal disorders				2005-10-29			19

Example 4

In this example, the investigator was instructed to create a new adverse-event record each time the severity of an adverse event changes. AEGRPID can be used to identify the group of records related to a single event for a subject.

Row 1: Shows an adverse event of nausea, whose severity was moderate.

Rows 2-6: Show how AEGRPID can be used to identify the group of records related to a single event for a subject.

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Row	STUDYID	DOMAIN	USUBJID	AESEQ	AEGRPID	AETERM	AEBODSYS	AESEV
1	ABC123	AE	123101	1		NAUSEA	Gastrointestinal disorders	MODERATE
2	ABC123	AE	123101	2	1	VOMITING	Gastrointestinal disorders	MILD
3	ABC123	AE	123101	3	1	VOMITING	Gastrointestinal disorders	SEVERE
4	ABC123	AE	123101	4	1	VOMITING	Gastrointestinal disorders	MILD
5	ABC123	AE	123101	5	2	DIARRHEA	Gastrointestinal disorders	SEVERE
6	ABC123	AE	123101	6	2	DIARRHEA	Gastrointestinal disorders	MODERATE

Row	AESER	AEACN	AEREL	AESTDTC	AEENDTC
1 (cont)	N	DOSE NOT CHANGED	RELATED	2005-10-13	2005-10-14
2 (cont)	N	DOSE NOT CHANGED	POSSIBLY RELATED	2005-10-14	2005-10-16
3 (cont)	N	DOSE NOT CHANGED	POSSIBLY RELATED	2005-10-16	2005-10-17
4 (cont)	N	DOSE NOT CHANGED	POSSIBLY RELATED	2005-10-17	2005-10-20
5 (cont)	N	DOSE NOT CHANGED	POSSIBLY RELATED	2005-10-16	2005-10-17
6 (cont)	N	DOSE NOT CHANGED	POSSIBLY RELATED	2005-10-17	2005-10-21

6 Domain Models Based on the General Observation Classes

6.2 Events

Clinical Events (CE)

CE - Description/Overview for Clinical Events Domain Model

A dataset used to capture clinical events of interest that would not be classified as adverse events.

CE - Specification for Clinical Events Domain Model

ce.xpt, Clinical Events — Events, Version 3.2. One record per event per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	CE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
CESEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
CEGRPID	Group ID	Char		Identifier	Used to tie together a block of related records for a subject within a domain.	Perm
CEREFID	Reference ID	Char		Identifier	Internal or external identifier.	Perm
CESPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a CRF page.	Perm
CETERM	Reported Term for the Clinical Event	Char		Topic	Term for the medical condition or event. Most likely pre-printed on CRF.	Req
CEDECOD	Dictionary-Derived Term	Char	*	Synonym Qualifier	Controlled terminology for the name of the clinical event. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes	Perm
CECAT	Category for Clinical Event	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
CESCAT	Subcategory for Clinical Event	Char	*	Grouping Qualifier	A further categorization of the condition or event.	Perm
CEPRES	Clinical Event Pre-Specified	Char	(NY)	Variable Qualifier	Used to indicate whether the Event in CETERM was pre-specified. Value is Y for pre-specified events, null for spontaneously reported events.	Perm
CEOCCUR	Clinical Event Occurrence	Char	(NY)	Record Qualifier	Used when the occurrence of specific events is solicited to indicate whether or not a clinical event occurred. Values are null for spontaneously reported events.	Perm
CESTAT	Completion Status	Char	(ND)	Record Qualifier	The status indicates that a question from a pre-specified list was not answered.	Perm
CEREASND	Reason Clinical Event Not Collected	Char		Record Qualifier	Describes the reason clinical event data was not collected. Used in conjunction with CESTAT when value is NOT DONE.	Perm
CEBODSYS	Body System or Organ Class	Char	*	Record Qualifier	Dictionary-derived. Body system or organ class that is involved in an event or measurement from a standard hierarchy (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables which may not necessarily be the primary SOC.	Perm
CESEV	Severity/Intensity	Char	*	Record Qualifier	The severity or intensity of the event. Examples: MILD, MODERATE, SEVERE	Perm
CEDTC	Date/Time of Event Collection	Char	ISO 8601	Timing		Perm
CESTDTC	Start Date/Time of Clinical Event	Char	ISO 8601	Timing		Perm
CEENDTC	End Date/Time of Clinical Event	Char	ISO 8601	Timing		Perm
CEDY	Study Day of Event Collection	Num		Timing	1. Study day of clinical event collection, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics. This formula should be consistent across the submission.	Perm
CESTRF	Start Relative to Reference Period	Char	(STENRF)	Timing	Describes the start of the clinical event relative to 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).	Perm
CEENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the event relative to 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).	Perm
CESTRTPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the start of the observation as being before or after the reference time point defined by variable CESTTPT.	Perm
CESTTPT	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by --STRTPT. Examples: "2003-12-15" or "VISIT 1".	Perm
CEENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the event as being before or after the reference time point defined by variable CEENTPT.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
CEENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by CEENRTPT. Examples: "2003-12-25" or "VISIT 2".	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

CE - Assumptions for Clinical Events Domain Model

- The intent of the domain model is to capture clinical events of interest that would not be classified as adverse events. The data may be data about episodes of symptoms of the disease under study (often known as signs and symptoms), or about events that do not constitute adverse events in themselves, though they might lead to the identification of an adverse event. For example, in a study of an investigational treatment for migraine headaches, migraine headaches may not be considered to be adverse events per protocol. The occurrence of migraines or associated signs and symptoms might be reported in CE. Other studies might track the occurrence of specific events as efficacy endpoints. For example, in a study of an investigational treatment for prevention of ischemic stroke, all occurrences of TIA, stroke and death might be captured as clinical events and assessed as to whether they meet endpoint criteria. Note that other information about these events may also be reported in other datasets. For example, the event leading to death would be reported in AE and death would also be a reason for study discontinuation in DS.
- CEOCCUR and CEPRESP are used together to indicate whether the event in CETERM was pre-specified, and whether it occurred. CEPRESP can be used to separate records that correspond to probing questions for pre-specified events from those that represent spontaneously reported events, while CEOCCUR contains the responses to such questions. The table below shows how these variables are populated in various situations.

Situation	Value of CEPRESP	Value of CEOCCUR	Value of CESTAT
Spontaneously reported event occurred			
Pre-specified event occurred	Y	Y	
Pre-specified event did not occur	Y	N	
Pre-specified event has no response	Y		NOT DONE

- The collection of write-in events on a Clinical Events CRF should be considered with caution. Sponsors must ensure that all adverse events are recorded in the AE domain.
- Timing Variables
 - Relative timing assessments "Prior" or "Ongoing" are common in the collection of Clinical Event information. CESTRF or CEENRF may be used when this timing assessment is relative to the study reference period for the subject represented in the Demographics dataset (RFENDTC). CESTRTPT with CESTTPT, and/or CEENRTPT with CEENTPT may be used when "Prior" or "Ongoing" are relative to specific dates other than the start and end of the study reference period. *See Section 4: 4.1.4.7, Use of Relative Timing Variables.*
 - Additional Timing variables may be used when appropriate.
- Additional Events Qualifiers

The following Qualifiers would generally not be used in CE: --SER, --ACN, --ACNOTH, --REL, --RELNST, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE.

CE - Examples for Clinical Events Domain Model

Example 1

Assumptions:

- CRF data are collected about pre-specified events that, in the context of this study, are not reportable as Adverse Events.
- The data being collected includes “event-like” timing and other Qualifiers.
- Data are collected about pre-specified clinical events in a log independent of visits, rather than in a visit-based CRF module.
- Note that data collected is the start date of the event, which is “event-like” data.
- No "yes/no" data on the occurrence of the event is collected.

CRF:

<i>Record start dates of any of the following signs that occur.</i>	
Clinical Sign	Start Date
Rash	
Wheezing	
Edema	
Conjunctivitis	

Data:

Rows 1-3: Show records for clinical events for which start dates were recorded. Since conjunctivitis was not observed, no start date was recorded and there is no CE record.

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CETERM	CEPRES	CEOCCUR	CESTDTC
1	ABC123	CE	123	1	Rash	Y	Y	2006-05-03
2	ABC123	CE	123	2	Wheezing	Y	Y	2006-05-03
3	ABC123	CE	123	3	Edema	Y	Y	2006-05-06

Example 2

Assumptions:

- CRF includes both questions about pre-specified clinical events (events not reportable as AEs in the context of this study) and spaces for the investigator to write in additional clinical events.
- Note that data being collected are start and end dates, which are "event-like," and severity, which is a Qualifier in the Events general observation class.

CRF:

Event	Yes	No	Date Started	Date Ended	Severity
Nausea	<input type="checkbox"/>	<input type="checkbox"/>			
Vomit	<input type="checkbox"/>	<input type="checkbox"/>			

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Event	Yes	No	Date Started	Date Ended	Severity
Diarrhea	<input type="checkbox"/>	<input type="checkbox"/>			
Other, Specify					

Data:

- Row 1:** Shows a record for a response to the pre-specified clinical event "Nausea." The CEPRESP value of "Y" indicates that there was a probing question, and the response to the probe (CEOCCUR) was "Yes."
- Row 2:** Shows a record for a response to the pre-specified clinical event "Vomit." The CEPRESP value of "Y" indicates that there was a probing question, and the response to the question (CEOCCUR) was "No".
- Row 3:** Shows a record for the pre-specified clinical event "Diarrhea." A value of Y for CEPRESP indicates it was pre-specified. The CESTAT value of NOT DONE indicates that there was either 1) no probing question (investigator error) or a probing question with no response.
- Row 4:** Shows a record for a write-in Clinical Event recorded in the "Other, Specify" space. Because this event was not pre-specified, CEPRESP and CEOCCUR are null [*Section 4: 4.1.2.7, Submitting Free Text from the CRF*] further information on populating the Topic variable when "Other, specify" is used on the CRF).

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CETERM	CEPRESP	CEOCCUR	CESTAT	CESEV	CESTDTC	CEENDTC
1	ABC123	CE	123	1	NAUSEA	Y	Y		MODERATE	2005-10-12	2005-10-15
2	ABC123	CE	123	2	VOMIT	Y	N				
3	ABC123	CE	123	3	DIARRHEA	Y		NOT DONE			
4	ABC123	CE	123	4	SEVERE HEAD PAIN				SEVERE	2005-10-09	2005-10-11

6 Domain Models Based on the General Observation Classes

6.2 Events

Disposition (DS)

DS - Description/Overview for Disposition Domain Model

DS - A subject domain utilized for the submission of information encompassing and representing data, vocabulary or records related to disposition. (NCI)

DS - Specification for Disposition Domain Model

ds.xpt, Disposition — Events, Version 3.2. One record per disposition status or protocol milestone per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
DSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
DSREFID	Reference ID	Char		Identifier	Internal or external identifier.	Perm
DSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a Disposition page.	Perm
DSTERM	Reported Term for the Disposition Event	Char		Topic	Verbatim name of the event or protocol milestone. Some terms in DSTERM will match DSDECOD, but others, such as "Subject moved" will map to controlled terminology in DSDECOD, such as "LOST TO FOLLOW-UP."	Req
DSDECOD	Standardized Disposition Term	Char	(NCOMPLT)	Synonym Qualifier	Controlled terminology for the name of disposition event or protocol milestone. Examples of protocol milestones: INFORMED CONSENT OBTAINED, RANDOMIZED	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
DSCAT	Category for Disposition Event	Char	(DSCAT)	Grouping Qualifier	Used to define a category of related records. DSCAT is now an “Expected” variable. DSCAT was permissible in SDTMIG 3.1.1 and earlier versions. The change from “permissible” to “expected” is based on the requirement to distinguish protocol milestones and/or other events from disposition events. DSCAT may be null if there are only “disposition events”; however, it is recommended that DSCAT always be populated.	Exp
DSSCAT	Subcategory for Disposition Event	Char	*	Grouping Qualifier	A further categorization of disposition event.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	EPOCH may be used when DSCAT = “DISPOSITION EVENT”. Examples: SCREENING, TREATMENT, FOLLOW-UP	Perm
DSDTC	Date/Time of Collection	Char	ISO 8601	Timing		Perm
DSSTDTC	Start Date/Time of Disposition Event	Char	ISO 8601	Timing		Exp
DSSTDY	Study Day of Start of Disposition Event	Num		Timing	Study day of start of event relative to the sponsor-defined RFSTDTC.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

DS - Assumption for Disposition Domain Model

1. DS Definition

The Disposition dataset provides an accounting for all subjects who entered the study and may include protocol milestones, such as randomization, as well as the subject's completion status or reason for discontinuation for the entire study or each phase or segment of the study, including screening and post-treatment follow-up. Sponsors may choose which disposition events and milestones to submit for a study. See ICH E3: Section 10.1 for information about disposition events.

2. Categorization

- a. DSCAT is used to distinguish between disposition events, protocol milestones and other events. The controlled terminology for DSCAT consists of “DISPOSITION EVENT,” “PROTOCOL MILESTONE,” and “OTHER EVENT.”
- b. A “DISPOSITION EVENT” describes whether a subject completed the study or portion of a study (Epoch) or the reason they did not complete. The subject's disposition is often described for each study Epoch (e.g., screening, initial treatment, washout, cross-over treatment, follow-up).
- c. A “PROTOCOL MILESTONE” is a protocol-specified, “point-in-time” event. The most common protocol milestones are “INFORMED CONSENT OBTAINED” and “RANDOMIZED.”
- d. Other important events that occur during a trial, but are not driven by protocol requirements and are not captured in another Events or Interventions class dataset, are classified as “OTHER EVENT.” “TREATMENT UNBLINDED” is an example of “OTHER EVENT.”

3. DS Description and Coding
 - a. DSTERM and DSDECOD are required. DSDECOD values are drawn from sponsor-defined controlled terminology. The controlled terminology will depend on the value of DSCAT. When DSCAT="DISPOSITION EVENT", DSTERM contains either "COMPLETED" or, if the subject did not complete, specific verbatim information about the disposition event.
 - b. When DSTERM = "COMPLETED", DSDECOD = "COMPLETED". When DSTERM contains verbatim text, DSDECOD will contain a standard term from a controlled terminology list. For example, DSTERM = "Subject moved" might map to "LOST TO FOLLOW-UP" in the sponsor's controlled terminology.
 - c. A sponsor may collect one disposition event for the trial as a whole, or they may collect disposition for each Epoch of the trial. When disposition is collected for each Epoch, the variable EPOCH should be included in the DS dataset. When EPOCH is populated for disposition events (records with DSCAT = DISPOSITION EVENT), EPOCH is the name of the Epoch for the disposition event described in the record. This is a subtly different meaning from that of EPOCH when it is used in other general-observation-class domains, where EPOCH, as a Timing variable, is the name of the Epoch during which --STDTC or --DTC falls. The values of EPOCH are drawn from the Trial Arms domain, **Section 7.2 - Experimental Design: Trial Arms (TA)**
 - d. When DSCAT="PROTOCOL MILESTONE", DSTERM and DSDECOD will contain the same value drawn from the sponsor's controlled terminology. Examples of controlled terms include "INFORMED CONSENT OBTAINED" and "RANDOMIZED." EPOCH should not be populated when DSCAT = "PROTOCOL MILESTONE".
 - e. Events that are not disposition or milestone related are classified as an "OTHER EVENT" (see Assumption 2d above). If a reason for the OTHER EVENT was collected, then the reason is in DSTERM. For example, treatment was unblinded due to investigator error. DSTERM = INVESTIGATOR ERROR and DSDECOD = TREATMENT UNBLINDED. IF no reason was collected then DSTERM = DSDECOD.
4. Timing Variables
 - a. DSSTDTC is expected and is used for the date/time of the disposition event. Disposition events do not have end dates since disposition events do not span an interval (e.g. randomization date) but occur at a single date/time (e.g., randomization date).
 - b. DSSTDTC documents the date/time that a protocol milestone, disposition event, or other event occurred. In the case of a disposition event, the reason for not completing the referenced study Epoch may be related to an event or intervention reported in another dataset. DSSTDTC is the date/time that the Epoch was completed and is not necessarily the same as the start or end date/time of the event or intervention that led to discontinuation. For example, a subject reported severe vertigo on June 1, 2006 (AESTDTC). After ruling out other possible causes, the investigator decided to discontinue study treatment on June 6, 2006 (DSSTDTC). The subject reported that the vertigo had resolved on June 8, 2006 (AEENDTC).
5. Reasons for Termination
 - a. ICH E3: Section 10.1 indicates that "the specific reason for discontinuation" should be presented, and that summaries should be "grouped by treatment and by major reason." The CDISC SDS Team interprets this guidance as requiring one standardized disposition term (DSDECOD) per disposition event. If multiple reasons are reported, the sponsor should identify a primary reason and use that to populate DSTERM and DSDECOD. Additional reasons should be submitted in SUPPDS. Example:

DSTERM= SEVERE NAUSEA
DSDECOD=ADVERSE EVENT

SUPPDS QNAM=DSTERM1

SUPPDS QLABEL= Reported Term for Disposition Event 1
SUPPDS QVAL=SUBJECT REFUSED FURTHER TREATMENT

SUPPDS QNAM=DSDECOD1
SUPPDS QLABEL= Standardized Disposition Term 1
SUPPDS QVAL=WITHDREW CONSENT

6. Additional Event Qualifiers

The following Qualifiers would generally not be used in DS: --PRESP, --OCCUR, --STAT, --REASND, --BODSYS, --LOC, --SEV, --SER, --ACN, --ACNOTH, --REL, --RELNST, --PATT, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE, --CONTRT, --TOXGR.

DS - Examples for Disposition Domain Model

Example 1

In this example, a DS CRF collected multiple disposition events at different time points in the study indicated by EPOCH. There are also several protocol milestones which are indicated by DSCAT = "PROTOCOL MILESTONE". DSTERM is populated with controlled terminology with the same value as DSDECOD except in the case when there is free text for DSTERM such as "Subject moved". In this case, the controlled terminology is only in DSDECOD (LOST TO FOLLOW-UP).

Rows 1-21: There are multiple disposition events and protocol milestones per subject. EPOCH is populated when DSCAT has a value of DISPOSITION EVENT and null when DSCAT has value of PROTOCOL MILESTONE.

Rows 2, 4, 5: Subject 123101 has 3 records to indicate the completion of 3 stages of the study, which are screening, treatment phase, and follow-up. The study also collected the protocol milestones of INFORMED CONSENT and RANDOMIZATION.

Row 7: Subject 123102 is a screen drop (also known as a screen failure). Screen drops are identified by a DSDECOD that is not equal to "COMPLETED" for the SCREENING stage. This is an example of the submission of the verbatim reason for discontinuation in DSTERM. Also note that although DSDECOD is "PROTOCOL VIOLATION", this record represents the disposition event for the SCREENING stage and documents the reason for not completing ("SUBJECT DENIED MRI PROCEDURE") and the corresponding date of discontinuation (DSSTDTC). A record describing the protocol deviation event itself should appear in the DV dataset.

Rows 9, 11: Subject 123103 completed the screening stage but did not complete the treatment stage.

Row 11: The verbatim reason the subject dropped is in DSTERM (SUBJECT MOVED) and the controlled term is in DSDECOD (LOST TO FOLLOW-UP).

Row 16: Subject 123104 died in an automobile accident on October 29, 2003 (see DSSTDTC) after the completion of treatment, but prior to the completion of follow-up. Note that the date of collection of the event information (DSDTC = October 31, 2003) was different from the date of the disposition event.

Rows 20, 21: Subject 123105 discontinued study treatment due to an AE, but went on to complete the follow-up phase of the trial.

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Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
1	ABC123	DS	123101	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-09-21	2003-09-21
2	ABC123	DS	123101	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2003-09-29	2003-09-29
3	ABC123	DS	123101	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2003-09-30	2003-09-30
4	ABC123	DS	123101	4	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT	2003-10-31	2003-10-31
5	ABC123	DS	123101	5	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2003-11-15	2003-11-15
6	ABC123	DS	123102	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-11-21	2003-11-21
7	ABC123	DS	123102	2	SUBJECT DENIED MRI PROCEDURE	PROTOCOL VIOLATION	DISPOSITION EVENT	SCREENING	2003-11-22	2003-11-20
8	ABC123	DS	123103	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-09-15	2003-09-15
9	ABC123	DS	123103	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2003-09-22	2003-09-22
10	ABC123	DS	123103	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2003-09-30	2003-09-30
11	ABC123	DS	123103	4	SUBJECT MOVED	LOST TO FOLLOW-UP	DISPOSITION EVENT	TREATMENT	2003-10-31	2003-10-31
12	ABC123	DS	123104	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-09-15	2003-09-15
13	ABC123	DS	123104	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2003-09-22	2003-09-22
14	ABC123	DS	123104	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2003-09-30	2003-09-30
15	ABC123	DS	123104	4	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT	2003-10-15	2003-10-15
16	ABC123	DS	123104	5	AUTOMOBILE ACCIDENT	DEATH	DISPOSITION EVENT	FOLLOW-UP	2003-10-31	2003-10-29
17	ABC123	DS	123105	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-09-28	2003-09-28
18	ABC123	DS	123105	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2003-10-02	2003-10-02
19	ABC123	DS	123105	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2003-10-02	2003-10-02
20	ABC123	DS	123105	4	ANEMIA	ADVERSE EVENT	DISPOSITION EVENT	TREATMENT	2003-10-17	2003-10-17
21	ABC123	DS	123105	5	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2003-11-02	2003-11-02

Example 2

In this example, the sponsor has chosen to simply submit whether or not the subject completed the study, so there is only one record per subject.

Row 1: Subject who completed the study

Rows 2, 3: Subjects who discontinued.

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	DSSTDTC
1	ABC456	DS	456101	1	COMPLETED	COMPLETED	DISPOSITION EVENT	2003-09-21
2	ABC456	DS	456102	1	SUBJECT TAKING STUDY MED ERRATICALLY	PROTOCOL VIOLATION	DISPOSITION EVENT	2003-09-29
3	ABC456	DS	456103	1	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP	DISPOSITION EVENT	2003-10-15

Example 3

Rows 1, 2: Subject completed the treatment and follow-up phase

Rows 3, 5: Subject did not complete the treatment phase but did complete the follow-up phase.

Row 4: Subject's treatment is unblinded. The date of the unblinding is represented in DSSTDTC. Maintaining the blind as per protocol is not considered to be an event since there is no change in the subject's state.

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSSTDTC
1	ABC789	DS	789101	1	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT	2004-09-12
2	ABC789	DS	789101	2	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2004-12-20
3	ABC789	DS	789102	1	SKIN RASH	ADVERSE EVENT	DISPOSITION EVENT	TREATMENT	2004-09-30

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Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSSTDTC
4	ABC789	DS	789102	2	SUBJECT HAD SEVERE RASH	TREATMENT UNBLINDED	OTHER EVENT	TREATMENT	2004-10-01
5	ABC789	DS	789102	3	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2004-12-28

Example 4

In this example, the CRF documents a link between the DS record and the AE record. This relationship is documented in the RELREC dataset.

Disposition (DS) Dataset

Row 1: Shows that Subject died of heart failure.

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
1	ABC123	DS	123102	1	Heart Failure	DEATH	DISPOSITION EVENT	TREATMENT	2003-09-29	2003-09-29

Adverse Event (AE) Dataset:

Row 1: Shows that Subject died due to heart failure.

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AESTDTC	AEENDTC	AEDECOD	AEBODSYS	AESEV	AESER	AEACN
1	ABC123	AE	123102	1	Heart Failure	2003-09-29	2003-09-29	HEART FAILURE	CARDIOVASCULAR SYSTEM	SEVERE	Y	NOT APPLICABLE

Row	AEREL	AEOUT	AESCAN	AESCONG	AESDISAB	AESDTH	AESHOSP	AESLIFE	AESOD	AESMIE
1 (cont)	DEFINITELY NOT RELATED	FATAL	N	N	N	Y	N	N	N	N

RELREC Dataset

Rows 1, 2: Show that the subject's disposition status that is related to the AE record.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC123	DS	123102	DSSEQ	1		1
2	ABC123	AE	123102	AESEQ	1		1

6 Domain Models Based on the General Observation Classes

6.2 Events

Protocol Deviations (DV)

DV - Description/Overview for Protocol Deviations Domain Model

The intent of the domain is to capture protocol violations and deviations during the course of the study and will store only those criteria violation by or deviated from by the subject and not a response to each violation or deviation.

DV - Specification for Protocol Deviations Domain Model

dv.xpt, Protocol Deviations — Events, Version 3.2. One record per protocol deviation per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DV	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
DVSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DVREFID	Reference ID	Char		Identifier	Internal or external identifier.	Perm
DVSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a CRF page.	Perm
DVTERM	Protocol Deviation Term	Char		Topic	Verbatim name of the protocol deviation criterion. Example: IVRS PROCESS DEVIATION - NO DOSE CALL PERFORMED. The DVTERM values will map to the controlled terminology in DVDECOD, such as TREATMENT DEVIATION.	Req
DVDECOD	Protocol Deviation Coded Term	Char	*	Synonym Qualifier	Controlled terminology for the name of the protocol deviation. Examples: SUBJECT NOT WITHDRAWN AS PER PROTOCOL, SELECTION CRITERIA NOT MET, EXCLUDED CONCOMITANT MEDICATION, TREATMENT DEVIATION.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
DVCAT	Category for Protocol Deviation	Char	*	Grouping Qualifier	Category of the protocol deviation criterion.	Perm
DVSCAT	Subcategory for Protocol Deviation	Char	*	Grouping Qualifier	A further categorization of the protocol deviation.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the start date/time of the deviation. Examples: TREATMENT PHASE, SCREENING, and FOLLOW-UP.	Perm
DVSTDTCT	Start Date/Time of Deviation	Char	ISO 8601	Timing	Start date/time of deviation represented in ISO 8601 character format.	Perm
DVENDTCT	End Date/Time of Deviation	Char	ISO 8601	Timing	End date/time of deviation represented in ISO 8601 character format.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

DV - Assumptions for Protocol Deviations Domain Model

1. The DV domain is an Events model for collected protocol deviations and not for derived protocol deviations that are more likely to be part of analysis. Events typically include what the event was, captured in --TERM (the topic variable), and when it happened (captured in its start and/or end dates). The intent of the domain model is to capture protocol deviations that occurred during the course of the study (see ICH E3: Section 10.2). Usually these are deviations that occur after the subject has been randomized or received the first treatment.
2. This domain should not be used to collect entry criteria information. Violated inclusion/exclusion criteria are stored in IE. The Deviations domain is for more general deviation data. A protocol may indicate that violating an inclusion/exclusion criterion during the course of the study (after first dose) is a protocol violation. In this case, this information would go into DV.
3. Additional Events Qualifiers
The following Qualifiers would generally not be used in DV: --PRESP, --OCCUR, --STAT, --REASND, --BODSYS, --LOC, --SEV, --SER, --ACN, --ACNOTH, --REL, --RELNST, --PATT, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE, --CONTRT, --TOXGR.

DV - Examples for Protocol Deviations Domain Model

Example 1

This is an example of data that was collected on a protocol-deviations CRF. The DVDECOD column is for controlled terminology whereas the DVTERM is free text.

Rows 1 & 3: Show examples of a TREATMENT DEVIATION type of protocol deviation.

Row 2: Shows an example of a deviation due to the subject taking a prohibited concomitant medication.

Row 4: Shows an example of a medication that should not be taken during the study.

Row	STUDYID	DOMAIN	USUBJID	DVSEQ	DVTERM	DVDECOD	EPOCH	DVSTDTCT
1	ABC123	DV	123101	1	IVRS PROCESS DEVIATION - NO DOSE CALL PERFORMED.	TREATMENT DEVIATION	TREATMENT PHASE	2003-09-21
2	ABC123	DV	123103	1	DRUG XXX ADMINISTERED DURING STUDY TREATMENT PERIOD	EXCLUDED CONCOMITANT MEDICATION	TREATMENT PHASE	2003-10-30
3	ABC123	DV	123103	2	VISIT 3 DOSE <15 MG	TREATMENT DEVIATION	TREATMENT PHASE	2003-10-30
4	ABC123	DV	123104	1	TOOK ASPIRIN	PROHIBITED MEDS	TREATMENT PHASE	2003-11-30

6 Domain Models Based on the General Observation Classes

6.2 Events

Healthcare Encounters (HO)

HO – Description/Overview for Healthcare Encounters Domain Model

The Healthcare Encounters dataset includes inpatient and outpatient healthcare events (e.g., hospitalizations, nursing home stay, rehabilitation facility stays, ambulatory surgery).

HO – Specification for Healthcare Encounters Domain Model

ho.xpt, Healthcare Encounters — Events, Version 3.2. One record per healthcare encounter per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	HO	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
HOSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
HOGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
HOREFID	Reference ID	Char		Identifier	Internal or external healthcare encounter identifier.	Perm
HOSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier. It may be pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a Healthcare encounters page.	Perm
HOTERM	Reported Term for the Healthcare Encounter	Char		Topic	Verbatim or preprinted CRF term for the healthcare encounter.	Req
HODECOD	Dictionary-Derived Term for the Healthcare Encounter	Char	*	Synonym Qualifier	Dictionary or sponsor-defined derived text description of HOTERM or the modified topic variable (HOMODIFY).	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
HOCAT	Category for Healthcare Encounter	Char	*	Grouping Qualifier	Used to define a category of topic-related values.	Perm
HOSCAT	Subcategory for Healthcare Encounter	Char	*	Grouping Qualifier	A further categorization of HOCAT values.	Perm
HOPRESP	Pre-Specified Healthcare Encounter	Char	(NY)	Record Qualifier	A value of "Y" indicates that this healthcare encounter event was pre-specified on the CRF. Values are null for spontaneously reported events (i.e., those collected as free-text verbatim terms)	Perm
HOCCUR	Healthcare Encounter Occurrence	Char	(NY)	Record Qualifier	Used when the occurrence of specific healthcare encounters is solicited to indicate whether or not an encounter occurred. Values are null for spontaneously reported events.	Perm
HOSTAT	Completion Status	Char	(ND)	Record Qualifier	The status indicates that the pre-specified question was not answered.	Perm
HOREASND	Reason Healthcare Encounter Not Done	Char		Record Qualifier	Describes the reason data for a pre-specified event was not collected. Used in conjunction with HOSTAT when value is NOT DONE.	Perm
HODTC	Date/Time of Event Collection	Char	ISO 8601	Timing	Collection date and time of the healthcare encounter.	Perm
HOSTDTC	Start Date/Time of Healthcare Encounter	Char	ISO 8601	Timing	Start date/time of the healthcare encounter (e.g., date of admission).	Exp
HOENDTC	End Date/Time of Healthcare Encounter	Char	ISO 8601	Timing	End date/time of the healthcare encounter (date of discharge).	Perm
HODY	Study Day of Event Collection	Num		Timing	Study day of event collection relative to the sponsor-defined RFSTDTC.	Perm
HOSTDY	Study Day of Start of Healthcare Encounter	Num		Timing	Study day of the start of the healthcare encounter relative to the sponsor-defined RFSTDTC.	Perm
HOENDY	Study Day of End of Healthcare Encounter	Num		Timing	Study day of the end of the healthcare encounter relative to the sponsor-defined RFSTDTC.	Perm
HODUR	Duration of Healthcare Encounter	Char	ISO 8601	Timing	Collected duration of the healthcare encounter. Used only if collected on the CRF and not derived from the start and end date/times. Example: P1DT2H (for 1 day, 2 hours).	Perm
HOSTRTPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the start of the observation as being before or after the sponsor-defined reference time point defined by variable --STTPT.	Perm
HOSTTPT	Start Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the sponsor-defined reference point referred to by STRTPT. Examples: "2003-12-15" or "VISIT 1".	Perm
HOENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end of the event as being before or after the reference time point defined by variable HOENTPT.	Perm
HOENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by HOENRTPT. Examples: "2003-12-25" or "VISIT 2".	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

HO – Assumptions for Healthcare Encounters Domain Model

1. **HO Definition**
The Healthcare Encounters dataset includes inpatient and outpatient healthcare events (e.g., hospitalizations, nursing home stay, rehabilitation facility stays, ambulatory surgery).
2. Values of HOTERM typically describe the location or place of the healthcare encounter (e.g., HOSPITAL instead of HOSPITALIZATION). HOSTDTC should represent the start or admission date and HOENDTC the end or discharge date. The supplemental qualifier, QNAM = 'HOINDC', should represent the indication or reason for the encounter.
3. **Additional Events Qualifiers**
The following Qualifiers would generally not be used in HO: --SER, --ACN, --ACNOTH, --REL, --RELNST, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE, --BODSYS, --LOC, --SEV, --TOX, --TOXGR, --PATT, --CONTRT.

HO – Examples for Healthcare Encounters Domain Model

Example 1

In this example, a healthcare encounter CRF collects verbatim descriptions of the encounter.

Rows 1-2: Subject ABC123101 was hospitalized and then moved to a nursing home.

Rows 3-5: Subject ABC123102 was in a hospital in the general ward and then in the intensive care unit. This same subject was transferred to a rehabilitation facility.

Rows 6-7: Subject ABC123103 has two hospitalization records.

Row 8: Subject ABC123104 was seen in the cardiac catheterization laboratory.

Rows 9-12: Subject ABC123105 and subject ABC123106 were each seen in the cardiac catheterization laboratory and then transferred to another hospital.

ho.xpt

Row	STUDYID	DOMAIN	USUBJID	HOSEQ	HOTERM	HOSTDTC	HOENDTC	HODUR
1	ABC	HO	ABC123101	1	HOSPITAL	2011-06-08	2011-06-13	
2	ABC	HO	ABC123101	2	NURSING HOME			P6D
3	ABC	HO	ABC123102	1	GENERAL WARD	2011-08-06	2011-08-08	
4	ABC	HO	ABC123102	2	INTENSIVE CARE	2011-08-08	2011-08-15	
5	ABC	HO	ABC123102	3	REHABILITATION FACILITY	2011-08-15	2011-08-20	
6	ABC	HO	ABC123103	1	HOSPITAL	2011-09-09	2011-09-11	
7	ABC	HO	ABC123103	2	HOSPITAL	2011-09-11	2011-09-15	
8	ABC	HO	ABC123104	1	CARDIAC CATHETERIZATION LABORATORY	2011-10-10	2011-10-10	
9	ABC	HO	ABC123105	1	CARDIAC CATHETERIZATION LABORATORY	2011-10-11	2011-10-11	
10	ABC	HO	ABC123105	2	HOSPITAL	2011-10-11	2011-10-15	
11	ABC	HO	ABC123106	1	CARDIAC CATHETERIZATION LABORATORY	2011-11-07	2011-11-07	
12	ABC	HO	ABC123106	2	HOSPITAL	2011-11-07	2011-11-09	

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Row 1: For the first encounter recorded for subject ABC123101, the reason for hospitalization was recorded.

Rows 2-3: For the two encounters recorded for subject ABC123103, the name of the facilities were recorded.

Row 4: For the first encounter for subject ABC123105, the reason for the hospitalization was recorded.

Row 5: For the second encounter for subject ABC123105, the name of the hospital was recorded.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	HO	ABC123101	HOSEQ	1	HOINDC	Indication	CONGESTIVE HEART FAILURE	CRF	
2	ABC	HO	ABC123103	HOSEQ	1	HONAM	Provider Name	GENERAL HOSPITAL	CRF	
3	ABC	HO	ABC123103	HOSEQ	2	HONAM	Provider Name	EMERSON HOSPITAL	CRF	
4	ABC	HO	ABC123105	HOSEQ	1	HOINDC	Indication	ATRIAL FIBRILLATION	CRF	
5	ABC	HO	ABC123105	HOSEQ	2	HONAM	Provider Name	ROOSEVELT HOSPITAL	CRF	

Example 2

In this example, the dates of an initial hospitalization are collected as well as the date/time of ICU stay. Subsequent to discharge from the initial hospitalization, follow-up healthcare encounters, including admission to a rehabilitation facility, visits with healthcare providers, and home nursing visits were collected. Repeat hospitalizations are categorized separately.

ho.xpt

Row	STUDYID	DOMAIN	USUBJID	HOSEQ	HOTERM	HOCAT	HOSTDTC	HOENDTC	HOENRTPT	HOENTPT
1	ABC	HO	ABC123101	1	HOSPITAL	INITIAL HOSPITALIZATION	2011-06-08	2011-06-12		
2	ABC	HO	ABC123101	2	ICU	INITIAL HOSPITALIZATION	2011-06-08T11:00	2011-06-09T14:30		
3	ABC	HO	ABC123101	3	REHABILITATION FACILITY	FOLLOW-UP CARE	2011-06-12	2011-06-22		
4	ABC	HO	ABC123101	4	CARDIOLOGY UNIT	FOLLOW-UP CARE	2011-06-25	2011-06-25		
5	ABC	HO	ABC123101	5	OUTPATIENT PHYSICAL THERAPY	FOLLOW-UP CARE	2011-06-27	2011-06-27		
6	ABC	HO	ABC123101	6	OUTPATIENT PHYSICAL THERAPY	FOLLOW-UP CARE	2011-07-12	2011-07-12		
7	ABC	HO	ABC123101	7	HOSPITAL	REPEAT HOSPITALIZATION	2011-07-23	2011-07-24		
8	ABC	HO	ABC123102	1	HOSPITAL	INITIAL HOSPITALIZATION	2011-06-19	2011-07-02		
9	ABC	HO	ABC123102	2	ICU	INITIAL HOSPITALIZATION	2011-06-19T22:00	2011-06-23T09:30		
10	ABC	HO	ABC123102	3	ICU	INITIAL HOSPITALIZATION	2011-06-25T10:00	2011-06-29T19:30		
11	ABC	HO	ABC123102	4	SKILLED NURSING FACILITY	FOLLOW-UP CARE	2011-07-02		ONGOING	END OF STUDY

Row 1: The reason for subject ABC123101's repeat hospitalization was recorded.

suppho.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	HO	ABC123101	HOSEQ	7	HOINDC	Indication	STROKE	CRF	

6 Domain Models Based on the General Observation Classes

6.2 Events

Medical History (MH)

MH - Description/Overview for Medical History Domain Model

The medical history dataset includes the subject's prior history at the start of the trial. Examples of subject medical history information could include general medical history, gynecological history, and primary diagnosis.

MH - Specification for Medical History Domain Model

mh.xpt, Medical History — Events, Version 3.2. One record per medical history event per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	MH	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
MHSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MHGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
MHREFID	Reference ID	Char		Identifier	Internal or external medical history identifier.	Perm
MHSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a Medical History page.	Perm
MHTERM	Reported Term for the Medical History	Char		Topic	Verbatim or preprinted CRF term for the medical condition or event.	Req
MHMODIFY	Modified Reported Term	Char		Synonym Qualifier	If MHTERM is modified to facilitate coding, then MHMODIFY will contain the modified text.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MHDECOD	Dictionary-Derived Term	Char	*	Synonym Qualifier	Dictionary-derived text description of MHTERM or MHMODIFY. Equivalent to the Preferred Term (PT in MedDRA). The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes.	Perm
MHCAT	Category for Medical History	Char	*	Grouping Qualifier	Used to define a category of related records. Examples: CARDIAC or GENERAL	Perm
MHSCAT	Subcategory for Medical History	Char	*	Grouping Qualifier	A further categorization of the condition or event.	Perm
MHPRESP	Medical History Event Pre-Specified	Char	(NY)	Variable Qualifier of --TERM	A value of "Y" indicates that this medical history event was pre-specified on the CRF. Values are null for spontaneously reported events (i.e., those collected as free-text verbatim terms)	Perm
MHOCCUR	Medical History Occurrence	Char	(NY)	Record Qualifier	Used when the occurrence of specific medical history conditions is solicited to indicate whether or not (Y/N) a medical condition (MHTERM) had ever occurred. Values are null for spontaneously reported events.	Perm
MHSTAT	Completion Status	Char	(ND)	Record Qualifier	The status indicates that the pre-specified question was not asked/answered.	Perm
MHREASND	Reason Medical History Not Done or Not Occurred	Char		Record Qualifier	Reason the question was not asked/answered or an intervention did not occur. Used in conjunction with negation indicators --STAT of 'NOT DONE' or --OCCUR of 'N'	Perm
MHBODSYS	Body System or Organ Class	Char	*	Record Qualifier	Dictionary-derived. Body system or organ class that is involved in an event or measurement from a standard hierarchy (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables which may not necessarily be the primary SOC.	Perm
MHDTC	Date/Time of History Collection	Char	ISO 8601	Timing		Perm
MHSTDTC	Start Date/Time of Medical History Event	Char	ISO 8601	Timing		Perm
MHENDTC	End Date/Time of Medical History Event	Char	ISO 8601	Timing		Perm
MHDY	Study Day of History Collection	Num		Timing	1. Study day of medical history collection, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics. This formula should be consistent across the submission.	Perm
MHENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Describes the end of the event relative to the 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)	Perm
MHENRTPT	End Relative to Reference Time Point	Char	BEFORE, AFTER, COINCIDENT, ONGOING, U	Timing	Identifies the end of the event as being before or after the reference time point defined by variable MHENTPT.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MHENTPT	End Reference Time Point	Char		Timing	Description or date/time in ISO 8601 character format of the reference point referred to by MHENTPT. Examples: "2003-12-25" or "VISIT 2".	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

MH - Assumptions for Medical History Domain Model

1. MH Definition
 - a. The Medical History dataset generally includes the subject's prior and concomitant conditions at the start of the trial. Examples of subject medical history information could include general medical history and gynecological history, and primary diagnosis. Note that prior and concomitant medications should be submitted in an appropriate dataset from the Interventions class (e.g., CM).
2. Medical History Description and Coding
 - a. MHTERM captures the verbatim term collected for the condition or event. It is the topic variable for the MH dataset. MHTERM is a required variable and must have a value.
 - b. MHMODIFY is a permissible variable and should be included if the sponsor's procedure permits modification of a verbatim term for coding. The modified term is listed in MHMODIFY. The variable should be populated as per the sponsor's procedures; null values are permitted.
 - c. If the sponsor codes the reported term (MHTERM) using a standard dictionary, then MHDECOD will be populated with the preferred term derived from the dictionary. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes
 - d. MHBODSYS is the system organ class from the coding dictionary associated with the adverse event by the sponsor. This value may differ from the primary system organ class designated in the coding dictionary's standard hierarchy.
 - e. If a CRF collects medical history by pre-specified body systems and the sponsor also codes reported terms using a standard dictionary, then MHDECOD and MHBODSYS are populated using the standard dictionary. MHCAT and MHSCAT should be used for the pre-specified body systems.
3. Additional Categorization and Grouping
 - a. MHCAT and MHSCAT may be populated with the sponsor's pre-defined categorization of medical history events, which are often pre-specified on the CRF. Note that even if the sponsor uses the body system terminology from the standard dictionary, MHBODSYS and MHCAT may differ, since MHBODSYS is derived from the coding system, while MHCAT is effectively assigned when the investigator records a condition under the pre-specified category.
 - i. This categorization should not group all records (within the MH Domain) into one generic group such as "Medical History" or "General Medical History" because this is redundant information with the domain code. If no smaller categorization can be applied, then it is not necessary to include or populate this variable.
 - ii. Examples of MHCAT could include "General Medical History" (see above assumption since if "General Medical History" is an MHCAT value then there should be other MHCAT values), "Allergy Medical History," and "Reproductive Medical History."

- b. MHGRPID may be used to link (or associate) different records together to form a block of related records at the subject level within the MH domain. It should not be used in place of MHCAT or MHSCAT, which are used to group data across subjects. For example, if a group of syndromes reported for a subject were related to a particular disease then the MHGRPID variable could be populated with the appropriate text.
4. Pre-Specified Terms; Presence or Absence of Events
- a. Information on medical history is generally collected in two different ways, either by recording free text or using a pre-specified list of terms. The solicitation of information on specific medical history events may affect the frequency at which they are reported; therefore, the fact that a specific medical history event was solicited may be of interest to reviewers. MHPRESP and MHOCCUR are used together to indicate whether the condition in MHTERM was pre-specified and whether it occurred, respectively. A value of “Y” in MHPRESP indicates that the term was pre-specified.
 - b. MHOCCUR is used to indicate whether a pre-specified medical condition occurred; a value of Y indicates that the event occurred and N indicates that it did not.
 - c. If a medical history event was reported using free text, the values of MHPRESP and MHOCCUR should be null. MHPRESP and MHOCCUR are permissible fields and may be omitted from the dataset if all medical history events were collected as free text.
 - d. MHSTAT and MHREASND provide information about pre-specified medical history questions for which no response was collected. MHSTAT and MHREASND are permissible fields and may be omitted from the dataset if all medications were collected as free text or if all pre-specified conditions had responses in MHOCCUR.

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

- e. When medical history events are collected with the recording of free text, a record may be entered into the data management system to indicate “no medical history” for a specific subject or pre-specified body system category (e.g., Gastrointestinal). For these subjects or categories within subject, do not include a record in the MH dataset to indicate that there were no events.
5. Timing Variables
- a. Relative timing assessments such as “Ongoing” or "Active" are common in the collection of Medical History information. MHENRF may be used when this relative timing assessment is coincident with the start of the study reference period for the subject represented in the Demographics dataset (RFSTDTC). MHENRTPT and MHENTPT may be used when "Ongoing" is relative to another date such as the screening visit date. See examples below and *Section 4: 4.1.4.7, Use Of Relative Timing Variables*.
 - b. Additional timing variables (such as MHSTRF) may be used when appropriate.
6. Additional Events Qualifiers
- The following Qualifiers would generally not be used in MH: --SER, --ACN, --ACNOTH, --REL, --RELNST, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE.

MH - Examples for Medical History Domain Model

Example 1

In this example, a General Medical History CRF collects verbatim descriptions of conditions and events by body system (e.g., Endocrine, Metabolic) and asks whether or not the conditions were ongoing at the time of the visit. Another CRF page is used for Cardiac history events and for primary diagnosis; this page does not include the ongoing question.

Rows 1-3: MHSCAT displays the body systems specified on the General Medical History CRF. The reported events are coded using a standard dictionary. MHDECOD and MHBODSYS display the preferred term and body system assigned through the coding process.

Rows 1-3: MHENRTPT has been populated based on the response to the "Ongoing" question on the General Medical History CRF. MHENTPT displays the reference date for MHENRTPT - that is, the date the information was collected. If "Yes" is specified for Ongoing, MHENRTPT="ONGOING" if "No" is checked, MHENRTPT="BEFORE." See *Section 4: 4.1.4.7, Use of Relative Timing Variables* for further guidance.

Row 4: MHCAT indicates that this record displays the primary diagnosis, "ISCHEMIC STROKE". This term was not coded.

Row 5: MHCAT indicates that this term was reported on the Cardiac Medical History page.

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHDECOD	MHCAT	MHSCAT	MHBODSYS	MHSTDTC	MHENRTPT	MHENTPT
1	ABC123	MH	123101	1	ASTHMA	Asthma	GENERAL MEDICAL HISTORY	RESPIRATORY	Respiratory system disorders		ONGOING	2004-09-18
2	ABC123	MH	123101	2	FREQUENT HEADACHES	Headache	GENERAL MEDICAL HISTORY	CNS	Central and peripheral nervous system disorders		ONGOING	2004-09-18
3	ABC123	MH	123101	3	BROKEN LEG	Bone fracture	GENERAL MEDICAL HISTORY	OTHER	Musculoskeletal system disorders		BEFORE	2004-09-18
4	ABC123	MH	123101	4	ISCHEMIC STROKE		PRIMARY DIAGNOSIS			2004-09-17 T07:30		
5	ABC123	MH	123101	5	CHF	Cardiac failure congestive	CARDIAC MEDICAL HISTORY		Cardiac disorders	2004-06		

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Example 2

This is an example of a medical history CRF where the history of specific (pre-specified) conditions is solicited. The conditions are not coded using a standard dictionary. The data are collected as part of the Screening visit.

Rows 1-10 MHPRESP values of “Y” indicate that each condition was pre-specified on the CRF. The presence or absence of a condition is documented with MHOCCUR. The data are collected as part of the Screening visit.

Rows 1-3, 7, 9: The absence of a condition is documented with MHOCCUR.

Rows 4-6, 8: The presence of a condition is documented with MHOCCUR.

Row 10: The question regarding ASTHMA was not asked. MHSTAT is used to indicate this and MHOCCUR is null.

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHPRESP	MHOCCUR	MHSTAT	MHREASND	VISITNUM	VISIT	MHDTC	MHDY
1	ABC123	MH	101002	1	HISTORY OF EARLY CORONARY ARTERY DISEASE (<55 YEARS OF AGE)	Y	N			1	SCREEN	2006-04-22	-5
2	ABC123	MH	101002	2	CONGESTIVE HEART FAILURE	Y	N			1	SCREEN	2006-04-22	-5
3	ABC123	MH	101002	3	PERIPHERAL VASCULAR DISEASE	Y	N			1	SCREEN	2006-04-22	-5
4	ABC123	MH	101002	4	TRANSIENT ISCHEMIC ATTACK	Y	Y			1	SCREEN	2006-04-22	-5
5	ABC123	MH	101002	5	ASTHMA	Y	Y			1	SCREEN	2006-04-22	-5
6	ABC123	MH	101003	1	HISTORY OF EARLY CORONARY ARTERY DISEASE (<55 YEARS OF AGE)	Y	Y			1	SCREEN	2006-05-03	-3
7	ABC123	MH	101003	2	CONGESTIVE HEART FAILURE	Y	N			1	SCREEN	2006-05-03	-3
8	ABC123	MH	101003	3	PERIPHERAL VASCULAR DISEASE	Y	Y			1	SCREEN	2006-05-03	-3
9	ABC123	MH	101003	4	TRANSIENT ISCHEMIC ATTACK	Y	N			1	SCREEN	2006-05-03	-3
10	ABC123	MH	101003	5	ASTHMA	Y		NOT DONE	FORGOT TO ASK	1	SCREEN	2006-05-03	-3

Example 3

In this example, three CRFs related to medical history are collected:

- A General Medical History CRF collects descriptions of conditions and events by body system (e.g., Endocrine, Metabolic) and asks whether or not the conditions were ongoing at study start. The reported events are coded using a standard dictionary.
- A second CRF collects Stroke History.
- A third CRF asks whether or not the subject had any of a list of 4 specific risk factors.

Rows 1-3: MHSCAT displays the body systems specified on the General Medical History CRF. The reported events are coded using a standard dictionary.

Rows 1-3: MHENRF has been populated based on the response to the "Ongoing at Study Start" question on the General Medical History CRF. If "Yes" is specified, MHENRF="DURING/AFTER;" if "No" is checked, MHENRF="BEFORE" See *Section 4: 4.1.4.7, Use Of Relative Timing Variables* for further guidance on using --STRF and --ENRF.

Row 4: MHCAT indicates that this record displays Stroke History. This term is not coded.

Rows 1-4: MHPRESP and MHOCCUR are null for the conditions, which are not pre-specified.

Rows 5-8: MHCAT indicates that these terms were reported on the RISK FACTORS page. These terms are not coded.

Rows 5-8: MHPRESP values of "Y" indicate that each risk factor was pre-specified on the CRF. MHOCCUR is populated with Y or N corresponding to the CRF response to the questions for the 4 pre-specified risk factors.

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHDECOD	MHCAT	MHSCAT	MHPRESP
1	ABC123	MH	123101	1	ASTHMA	Asthma	GENERAL MEDICAL HISTORY	RESPIRATORY	
2	ABC123	MH	123101	2	FREQUENT HEADACHES	Headache	GENERAL MEDICAL HISTORY	CNS	
3	ABC123	MH	123101	3	BROKEN LEG	Bone fracture	GENERAL MEDICAL HISTORY	OTHER	
4	ABC123	MH	123101	4	ISCHEMIC STROKE		STROKE HISTORY		
5	ABC123	MH	123101	5	DIABETES		RISK FACTORS		Y
6	ABC123	MH	123101	6	HYPERCHOLESTEROLEMIA		RISK FACTORS		Y
7	ABC123	MH	123101	7	HYPERTENSION		RISK FACTORS		Y
8	ABC123	MH	123101	8	TIA		RISK FACTORS		Y

Row	MHOCCUR	MHBODSYS	MHSTDTC	MHENRF
1 (cont)		Respiratory system disorders		DURING/AFTER
2 (cont)		Central and peripheral nervous system disorders		DURING/AFTER
3 (cont)		Musculoskeletal system disorders		BEFORE
4 (cont)			2004-09-17T07:30	
5 (cont)	Y			
6 (cont)	Y			
7 (cont)	Y			
8 (cont)	N			

6 Domain Models Based on the General Observation Classes

Most subject-level observations collected during the study should be represented according to one of the three SDTM general observation classes. The lists of variables allowed to be used in each of these can be found in the STDM. For detailed definitions, please refer to *SDTM: Section 2.2.3, The Findings Observations Class*.

The below table provides a short index for documents where each listed Domain/Dataset is described in full detail.

Please note that this is a change from previous SDTMIG versions (prior to SDTMIG 3.2), where all domains were contained within a single document. This approach has been taken with the goal to simplify SDTMIG maintenance and to assist users in accessing the specific section/domain of interest without having to search a single and much larger document. The Table of Contents for the entire SDTMIG should reflect all domains (old and new) that make up this new release.

6.3 Findings

Domain Code	Domain Description	Domain Document Name
DA	<u>Drug Accountability</u> Data regarding the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.	Section 6.3 – DA Domain
DD	<u>Death Details</u> The domain is designed to hold supplemental data that are typically collected when a death occurs, such as the official cause of death. It does <u>not</u> replace existing data such as the SAE details in AE. Furthermore, it does <u>not</u> introduce a new requirement to collect information that is not already indicated as Good Clinical Practice or defined in regulatory guidelines. Instead, it provides a consistent place within SDTM to hold information that previously did not have a clearly defined home.	Section 6.3 – DD Domain
EG	<u>Electrocardiogram Results</u> Findings related to the collection of ECG data, including position of the subject, method of evaluation, all cycle measurements and all findings from the ECG including an overall interpretation if collected or derived.	Section 6.3 – EG Domain
IE	<u>Inclusion/Exclusion Criteria Not Met</u> The intent of the domain model is to only collect those criteria that cause the subject to be in violation of the inclusion/exclusion criteria not a response to each criterion.	Section 6.3 – IE Domain
IS	<u>The Immunogenicity Specimen Assessments (IS)</u> It is intended to be used only for data collected regarding the immunogenic potential of materials under study.	Section 6.3 – IS Domain
LB	<u>Laboratory Test Findings</u> Laboratory test findings including, but is not limited to hematology, clinical chemistry and urinalysis data. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.	Section 6.3 – LB Domain

Domain Code	Domain Description	Domain Document Name
MB and MS	<p><u>Microbiology</u> <u>MB</u> - Microbiology specimen findings, including gram stain results, and organisms found.</p> <p><u>MS</u> - This includes microbiology susceptibility test results, plus results of any other organism-related tests.</p>	Section 6.3 – MB & MS Domains
MI	<p><u>Microscopic Findings</u> Microbiology specimen findings, including gram stain results, and organisms found..</p>	Section 6.3 – MI Domain
MO	<p><u>Morphology</u> Macroscopic results (e.g. size, shape, color, and abnormalities of body parts or specimens) that are seen by the naked eye or observed via procedures such as imaging modalities, endoscopy, or other technologies. Many morphology results are obtained from a procedure, although information about the procedure may or may not be collected</p>	Section 6.3 – MO Domain
PC and PP	<p><u>Pharmacokinetics</u> <u>PC</u> - Concentrations of drugs/metabolites in fluids or tissues as a function of time.</p> <p><u>PP</u> - Pharmacokinetic parameters derived from pharmacokinetic concentration-time (PC) data.</p>	Section 6.3 – PC & PP Domains
PE	<p><u>Physical Exam</u> Findings collected during a physical examination of the subject. It has findings that are discovered that are related to body systems. Does not include vital signs measurements, which are stored in the vital signs domain.</p>	Section 6.3 – PE Domain
QS	<p><u>Questionnaires</u> Questionnaires are named, stand-alone instruments designed to provide an assessment of a concept.</p> <p>Questionnaires have a defined standard structure, format, and content; consist of conceptually related items that are typically scored; and have documented methods for administration and analysis.</p>	Section 6.3 – QS Domain
RP	<p><u>Reproductive System Findings</u> The Reproductive System Findings domain captures all Reproductive information related to a subject</p>	Section 6.3 – RP Domain
SC	<p><u>Subject Characteristics</u> The subject characteristics domain is for data not collected in other domains that is subject-related.</p>	Section 6.3 – SC Domain
SS	<p><u>Subject Status</u> Subject Status is for data relating to general subject characteristics that are evaluated periodically to determine if they have changed.</p>	Section 6.3 – SS Domain
TU, TR, and RS	<p><u>Oncology Domains TU, TR, and RS</u> Assessment of the change in tumor burden is an important feature of the clinical evaluation of cancer therapeutics: both tumor shrinkage (objective response) and disease progression are useful endpoints in cancer clinical trials.</p> <p>The tumor package consists of three SDTM domains based on the SDTM Findings Observation Class. The three domains are related but each has a distinct purpose.</p> <p><u>The Tumor Identification (TU)</u> - domain represents data that uniquely identifies tumors. The tumors are identified by</p>	Section 6.3 – TU TR and RS Domains

Domain Code	Domain Description	Domain Document Name
	<p>an investigator and/or independent assessor and classified according to the disease assessment criteria.</p> <p><u>The Tumor Response (TR)</u> - represents quantitative measurements and/or qualitative assessments of the tumors identified in the TU domain. These measurements are usually taken at baseline and then at each subsequent assessment to support response evaluations.</p> <p><u>The Disease Response (SR)</u> - domain represents the response evaluation(s) determined from the data in TR. Data from other sources (in other SDTM domains) might also be used in an assessment of response.</p>	
VS	<p><u>Vital Signs</u> Measurements including but not limited to blood pressure, temperature, respiration, body surface area, BMI, height and weight.</p>	Section 6.3 – VS Domain

6 Domain Models Based on the General Observation Classes

6.3 Findings

Drug Accountability (DA)

DA - Description/Overview for Drug Accountability Domain Model

Data regarding the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.

DA - Specification for Drug Accountability Domain Model

da.xpt, Drug Accountability — Findings, Version 3.2. One record per drug accountability finding per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study within the submission.	Req
DOMAIN	Domain Abbreviation	Char		Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Unique subject identifier within the submission.	Req
DASEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DAGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
DAREFID	Reference ID	Char		Identifier	Internal or external identifier such as label number.	Perm
DASPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Examples: Line number on the Drug Accountability page, drug label code.	Perm
DATESTCD	Short Name of Accountability Assessment	Char	*	Topic	Short character value for DATEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters and cannot begin with a number or contain characters other than letters, numbers or underscores. Example: DISPAMT, RETAMT.	Req
DATEST	Name of Accountability Assessment	Char	*	Synonym Qualifier	Verbatim name, corresponding to the topic variable, of the test or examination used to obtain the drug accountability assessment. The value in DATEST cannot be longer than 40 characters. Example: Dispensed Amount, Returned Amount.	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
DACAT	Category of Assessment	Char	*	Grouping Qualifier	Used to define a category of related records. Examples: STUDY MEDICATION, RESCUE MEDICATION.	Perm
DASCAT	Subcategory of Assessment	Char	*	Grouping Qualifier	Used to define a further categorization level for a group of related records.	Perm
DAORRES	Assessment Result in Original Units	Char		Result Qualifier	Result of the Drug Accountability assessment as originally received or collected.	Exp
DAORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Unit for DAORRES.	Perm
DASTRESC	Assessment Result in Std Format	Char		Result Qualifier	Contains the result value for all Drug Accountability assessments, copied or derived from DAORRES in a standard format or in standard units. DASTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in DASTRESN.	Exp
DASTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from DASTRESC. DASTRESN should store all numeric test results or findings.	Perm
DASTRESU	Assessment Standard Units	Char	(UNIT)	Variable Qualifier	Standardized units used for DASTRESC and DASTRESN.	Perm
DASTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a drug accountability assessment was not done. Should be null or have a value of NOT DONE.	Perm
DAREASND	Reason Not Performed	Char		Record Qualifier	Reason not done. Used in conjunction with DASTAT when value is NOT DONE.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter 2. May be used in addition to VISITNUM and/or VISITDY	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
DADTC	Date/Time of Accountability Assessment	Char	ISO 8601	Timing		Exp
DADY	Study Day of Accountability Assessment	Num		Timing	1. Study day of drug accountability assessment, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm

*indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

DA - Assumptions for Drug Accountability Domain Model

1. Definition: Drug Accountability is for data regarding the accountability of study drug, such as information on receipt, dispensing, return, and packaging.
2. One way a sponsor may choose to distinguish between different types of medications (e.g., study medication, rescue medication, run-in medication) is to use DACAT.
3. DAREFID and DASPID are both available for capturing label information.

4. The following Qualifiers would not generally be used in DA: --MODIFY, --POS, --BODSYS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STNRC, --NRIND, --RESCAT, --XFN, --NAM, --LOINC, --SPEC, --SPCCND, --METHOD, --BLFL, --FAST, --DRVRL, --TOX, --TOXGR, --SEV.

DA - Examples for Drug Accountability Domain Model

Example 1

Example 1 below shows drug accounting for a study with two study meds and one rescue med, all of which are measured in tablets. The sponsor has chosen to add EPOCH from the list of timing variables and to use DASPID and DAREFID for code numbers that appear on the label.

Row	STUDYID	DOMAIN	USUBJID	DASEQ	DAREFID	DASPID	DATESTCD	DATEST	DACAT	DASCAT	DAORRES	DAORRESU
1	ABC	DA	ABC/01001	1	XBYCC-E990A	A375827	DISPAMT	Dispensed Amount	Study Medication	Bottle A	30	TABLETS
2	ABC	DA	ABC/01001	2	XBYCC-E990A	A375827	RETAMT	Returned Amount	Study Medication	Bottle A	5	TABLETS
3	ABC	DA	ABC/01001	3	XBYCC-E990B	A227588	DISPAMT	Dispensed Amount	Study Medication	Bottle B	15	TABLETS
4	ABC	DA	ABC/01001	4	XBYCC-E990B	A227588	RETAMT	Returned Amount	Study Medication	Bottle B	0	TABLETS
5	ABC	DA	ABC/01001	5			DISPAMT	Dispensed Amount	Rescue Medication		10	TABLETS
6	ABC	DA	ABC/01001	6			RETAMT	Returned Amount	Rescue Medication		10	TABLETS

Row	DASTRESC	DASTRESN	DASTRESU	VISITNUM	EPOCH	DADTC
1 (cont)	30	30	TABLETS	1	Study Med Period 1	2004-06-15
2 (cont)	5	5	TABLETS	2	Study Med Period 1	2004-07-15
3 (cont)	15	15	TABLETS	1	Study Med Period 1	2004-06-15
4 (cont)	0	0	TABLETS	2	Study Med Period 1	2004-07-15
5 (cont)	10	10	TABLETS	1	Study Med Period 1	2004-06-15
6 (cont)	10	10	TABLETS	2	Study Med Period 1	2004-07-15

Example 2

Example 2 is for a study where drug containers, rather than their contents, are being accounted for and the sponsor did not track returns. In this case, the purpose of the accountability tracking is to verify that the containers dispensed were consistent with the randomization. The sponsor has chosen to use DASPID to record the identifying number of the container dispensed.

Row	STUDYID	DOMAIN	USUBJID	DASEQ	DASPID	DATESTCD	DATEST	DACAT	DASCAT	DAORRES	DAORRESU
1	ABC	DA	ABC/01001	1	AB001	DISPAMT	Dispensed Amount	Study Medication	Drug A	1	CONTAINER
2	ABC	DA	ABC/01001	2	AB002	DISPAMT	Dispensed Amount	Study Medication	Drug B	1	CONTAINER

Row	DASTRESC	DASTRESN	DASTRESU	VISITNUM	DADTC
1 (cont)	1	1	CONTAINER	1	2004-06-15
2 (cont)	1	1	CONTAINER	1	2004-06-15

6 Domain Models Based on the General Observation Classes

6.3 Findings

Death Details (DD)

DD - Description/Overview for Death Details Domain Model

The domain is designed to hold supplemental data that are typically collected when a death occurs, such as the official cause of death. It does not replace existing data such as the SAE details in AE. Furthermore, it does not introduce a new requirement to collect information that is not already indicated as Good Clinical Practice or defined in regulatory guidelines. Instead, it provides a consistent place within SDTM to hold information that previously did not have a clearly defined home.

DD - Specification for Death Details Domain Model

dd.xpt, Death Details — Findings, Version 3.2. One record per finding per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DD	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
DDSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
DDTESTCD	Death Detail Assessment Short Name	Char	*	Topic	Short name of the measurement, test, or examination described in DDTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DDTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). DDTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: DIAGPRIM, DIAGSEC, DTHWIT	Req
DDTEST	Death Detail Assessment Name	Char	*	Synonym Qualifier	Long name for DDTESTCD. The value in DDTEST cannot be longer than 40 characters. Examples: Primary Diagnosis, Secondary Diagnosis, Was Death Witnessed?	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
DDORRES	Result or Finding as Collected	Char		Result Qualifier	Result of the test defined in DDTEST, as originally received or collected.	Exp
DDSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result or finding copied or derived from DDORRES in a standard format.	Exp
DDRESCAT	Result Category	Char	*	Variable Qualifier	Used to categorize the result of a finding. Examples: TREATMENT RELATED, NONTREATMENT RELATED, UNDETERMINED, ACCIDENTAL	Perm
DDEVAL	Evaluator	Char	EVAL	Record Qualifier	Role of the person who provided the evaluation.	Perm
DDDTC	Date/Time of Collection	Char	ISO 8601	Timing	Date/time of collection of the diagnosis or other death assessment data in ISO 8601 format. This is not necessarily the date of death.	Exp
DDDY	Study Day of Collection	Num		Timing	Study day of the collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

DD - Assumptions for Death Details Domain Model

- 1 DD Definition: This domain captures information pertaining to the death of a subject, including the causes of death. There may be more than one causes. If so, these may be separated into primary and secondary causes and/or other appropriate designations. DD may also include other details about the death, such as where the death occurred and whether it was witnessed.
- 2 Death details are typically collected on designated CRF pages. The DD domain is not intended to collate data that are collected in standard variables in other domains, such as AE.AEOUT (Outcome of Adverse Event), AE.AESDTH (Results in Death) or DS.DSTERM (Reported Term for the Disposition Event). Data from other domains that relates to the death can be linked to DD using RELREC.
- 3 This domain is not intended to include data obtained from autopsy. An autopsy is a procedure from which there will usually be findings. Autopsy information should be handled as per recommendations in the Procedures domain.

DD – Examples for Death Details Domain Model

Example 1

This example shows the primary cause of death for three subjects. The CRF also collects the location of the subject's death and a secondary cause of death.

Rows 1, 2, 5-7: For subjects ABC12301001 and ABC12301023, the primary cause of death is known and the date reflects the date of this assessment. A secondary cause of death was recorded for subject ABC12301023.

Rows 3, 4: For subject ABC12301002, the primary cause of death was not known. DDDTC shows the date on which this assessment was made.

CDISC SDTM Implementation Guide (Version 3.2)

Row	STUDYID	DOMAIN	USUBJID	DDSEQ	DDTESTCD	DDTEST	DDORRES	DDSTRESC	DDTTC
1	ABC123	DD	ABC12301001	1	PRCDTH	Primary Cause of Death	SUDDEN CARDIAC DEATH	SUDDEN CARDIAC DEATH	2011-01-12
2	ABC123	DD	ABC12301001	2	LOCPTH	Location of Death	HOME	HOME	2011-01-12
3	ABC123	DD	ABC12301002	1	PRCDTH	Primary Cause of Death	UNKNOWN	UNKNOWN	2011-03-15
4	ABC123	DD	ABC12301002	2	LOCPTH	Location of Death	UNKNOWN	UNKNOWN	2011-03-15
5	ABC123	DD	ABC12301023	1	PRCDTH	Primary Cause of Death	CARDIAC ARRHYTHMIA	CARDIAC ARRHYTHMIA	2011-09-09
6	ABC123	DD	ABC12301023	2	SECDTH	Secondary Cause of Death	CHF	CONGESTIVE HEART FAILURE	2011-09-09
7	ABC123	DD	ABC12301023	3	LOCPTH	Location of Death	MEMORIAL HOSPITAL	HOSPITAL	2011-09-09

Example 2

This example illustrates how the DD, DS and AE data for subject ABC12301001 are linked using RELREC. Note that each of these domains serve a different purpose even though the information is related. DS (row 4) contains the disposition status of the subject with respect to the treatment phase. AE contains an adverse event term which in this case is coincidentally the same as the primary cause of death in DD. DD contains information that is specifically collected with respect to the death.

dd.xpt

Row	STUDYID	DOMAIN	USUBJID	DDSEQ	DDTESTCD	DDTEST	DDORRES	DDSTRESC	DDTTC
1	ABC123	DD	ABC12301001	1	PRCDTH	Primary Cause of Death	SUDDEN CARDIAC DEATH	SUDDEN CARDIAC DEATH	2011-01-12

Rows 1-3: Show typical protocol milestones and disposition events.

Row 4: Shows the date the death event occurred (DSSTDTTC) and was recorded (DSDTTC).

ds.xpt

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	DSDTTC	DSSTDTTC
1	ABC123	DS	ABC12301001	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	2011-01-02	2011-01-02
2	ABC123	DS	ABC12301001	2	COMPLETED	COMPLETED	DISPOSITION EVENT	2011-01-03	2011-01-03
3	ABC123	DS	ABC12301001	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE	2011-01-03	2011-01-03
4	ABC123	DS	ABC12301001	4	SUDDEN CARDIAC DEATH	DEATH	DISPOSITION EVENT	2011-01-10	2011-01-10

ae.xpt (selected fields)

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AESTDTC	AEENDTC	AEDECOD	AEBODSYS	AEOUT	AESER	AESDTH
1	ABC123	AE	ABC12301001	6	SUDDEN CARDIAC DEATH	2011-01-10	2011-01-10	SUDDEN CARDIAC DEATH	CARDIOVASCULAR SYSTEM	FATAL	Y	Y

Rows 1-3: Show that the subject's disposition event (DEATH) in DS is related to the AE "SUDDEN CARDIAC DEATH" event and the death details in DD.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC123	DS	ABC12301001	DSSEQ	4		1
2	ABC123	AE	ABC12301001	AESEQ	6		1
3	ABC123	DD	ABC12301001	DDSEQ	1		1

6 Domain Models Based on the General Observation Classes

6.3 Findings

ECG Test Results (EG)

EG - Description/Overview for ECG Test Results Domain Model

Findings related to the collection of ECG data, including position of the subject, method of evaluation, all cycle measurements and all findings from the ECG including an overall interpretation if collected or derived.

EG - Specification for ECG Test Results Domain Model

eg.xpt, ECG — Findings, Version 3.2. One record per ECG observation per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	EG	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
EGSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
EGGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
EGREFID	ECG Reference ID	Char		Identifier	Internal or external ECG identifier. Example: UUID.	Perm
EGSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number from the ECG page.	Perm
EGTESTCD	ECG Test or Examination Short Name	Char	(EGTESTCD)	Topic	Short name of the measurement, test, or examination described in EGTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in EGTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). EGTESTCD cannot contain characters other than letters, numbers, or underscores. Examples :PRMEAN, QTMEAN	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
EGTEST	ECG Test or Examination Name	Char	(EGTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in EGTEST cannot be longer than 40 characters. Examples: Summary (Mean) PR Duration, Summary (Mean) QT Duration	Req
EGCAT	Category for ECG	Char	*	Grouping Qualifier	Used to categorize ECG observations across subjects. Examples: MEASUREMENT, FINDING, INTERVAL	Perm
EGSCAT	Subcategory for ECG	Char	*	Grouping Qualifier	A further categorization of the ECG.	Perm
EGPOS	ECG Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.	Perm
EGORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the ECG measurement or finding as originally received or collected. Examples of expected values are 62 or 0.151 when the result is an interval or measurement, or "ATRIAL FIBRILLATION" or "QT PROLONGATION" when the result is a finding.	Exp
EGORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for EGORRES. Examples: sec or msec.	Perm
EGSTRESC	Character Result/Finding in Std Format	Char	(EGSTRESC)	Result Qualifier	Contains the result value for all findings, copied or derived from EGORRES in a standard format or standard units. EGSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in EGSTRESN. For example, if a test has results of "NONE", "NEG", and "NEGATIVE" in EGORRES and these results effectively have the same meaning, they could be represented in standard format in EGSTRESC as "NEGATIVE". For other examples, see general assumptions. Additional examples of result data: SINUS BRADYCARDIA, ATRIAL FLUTTER, ATRIAL FIBRILLATION.	Exp
EGSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from EGSTRESC. EGSTRESN should store all numeric test results or findings.	Perm
EGSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for EGSTRESC or EGSTRESN.	Perm
EGSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate an ECG was not done, or an ECG measurement was not taken. Should be null if a result exists in EGORRES.	Perm
EGREASND	Reason ECG Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: BROKEN EQUIPMENT or SUBJECT REFUSED. Used in conjunction with EGSTAT when value is NOT DONE.	Perm
EGFXN	ECG External File Path	Char		Record Qualifier	File name and path for the external ECG Waveform file.	Perm
EGNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor who provided the test results.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
EGLEAD	Lead Location Used for Measurement	Char	(LOC)	Record Qualifier	The lead used for the measurement, examples, V1, V6, aVR, I, II, III.	Perm
EGMETHOD	Method of ECG Test	Char	(EGMETHOD)	Record Qualifier	Method of the ECG test. Examples: 12 LEAD STANDARD.	Perm
EGBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be “Y” or null.	Exp
EGDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records which represent the average of other records, or that do not come from the CRF, or are not as originally collected or received are examples of records that would be derived for the submission datasets. If EGDRVFL=Y, then EGORRES could be null, with EGSTRESC, and (if numeric) EGSTRESN having the derived value.	Perm
EGEVAL	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). Should be null for records that contain collected or derived data. Examples: INVESTIGATOR, ADJUDICATION COMMITTEE, VENDOR.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
EGDTC	Date/Time of ECG	Char	ISO 8601	Timing	Date of ECG.	Exp
EGDY	Study Day of ECG	Num		Timing	1. Study day of the ECG, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm
EGTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when measurement should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See EGTPTNUM and EGTPTREF. Examples: Start, 5 min post.	Perm
EGTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of EGTPT to aid in sorting.	Perm
EGELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a fixed time point reference (EGTPTREF). Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: “-PT15M” to represent the period of 15 minutes prior to the reference point indicated by EGTPTREF, or “PT8H” to represent the period of 8 hours after the reference point indicated by EGTPTREF.	Perm
EGTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by EGELTM, EGTPTNUM, and EGTPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm

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

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

EG - Assumptions for ECG Test Results Domain Model

1. EG Definition: CRF data that captures interval measurements and summary information from an ECG. This domain captures ECG data collected on the CRF or received from a central provider or vendor.
2. EGREFID is intended to store an identifier (e.g., UUID) for the associated ECG tracing. EGXFN is intended to store the name of and path to the ECG waveform file when it is submitted.
3. The method for QT interval correction is specified in the test name by controlled terminology: EGTESTCD = QTcF and EGTEST = QTcF for Fridericia's Correction Formula; EGTESTCD=QTcB and EGTEST = QTcB for Bazett's Correction Formula.
4. EGNRIND can be added to indicate where a result falls with respect to reference range defined by EGORNRL0 and EGORNRI. Examples: HIGH, LOW. Clinical significance would be represented as described in **Section 4: 4.1.5.5, Clinical Significance for Findings Observation Class Data**, as a record in SUPPEG with a QNAM of EGCLSIG (see also ECG Example 1 below).
5. When QTcF and QTcB are derived by the sponsor, the derived flag (EGDRVFL) is set to Y. However, when the QTcF or QTcB is received from a central provider or vendor, the value would go into EGORRES and EGDRVFL would be null [See **Section 4: 4.1.1.8.1, Origin Metadata for Variables**].
6. The following Qualifiers would not generally be used in EG: --MODIFY, --BODSYS, --SPEC, --SPCCND, --FAST, --SEV. It is recommended that --LOINC not be used.

EG - Examples for ECG Test Results Domain Model

Example 1

Rows 1-6: Show how ECG measurements are represented.

Row 1: Shows a measurement of ventricular rate. The Supplemental Qualifier record related to this EG record, Row 1 in the SUPPEG dataset, has QNAM = EGCLSIG and QVAL = "N". This indicates that the ventricular rate of 62 bpm was assessed as not being clinically significant. See **Section 4: 4.1.5.5, Clinical Significance for Findings Observation Class Data** for more on clinical significance.

Rows 2-4: Show the data in original units of measure in EGORRES, EGSTRESC, and EGSTRESN. See **Section 4: 4.1.5.1, Original and Standardized Results of Findings and Test Not Done** for additional examples for the population of Result Qualifiers.

Row 2: The TEST "Summary (Mean) PR Duration" has a result of 0.15 sec. The Supplemental Qualifier record related to this EG record, Row 2 in the SUPPEG dataset, has QNAM = CLSIG and QVAL = "Y". This indicates that the PR interval of 0.15 sec was assessed as being clinically significant. See **Section 4: 4.1.5.5, Clinical Significance for Findings Observation Class Data** for more on clinical significance.

Rows 2-10: Show how EGCAT could be used to group the intervals and the findings.

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Rows 5-6: Show QTcB and QTcF. The data shows a “Y” in the EGDRVFL column since these results are derived by the sponsor in this example. Note that EGORRES is null for these derived records.

Rows 7-10: Show how ECG findings are represented.

Row 11: Shows a way of representing technical problems that are important to the overall understanding of the ECG, but which are not truly findings or interpretations.

Row 12: The TEST "Interpretation" (i.e., the interpretation of the ECG strip as a whole), is "ABNORMAL".

eg.xpt

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGCAT	EGREFID	EGTESTCD	EGTEST	EGPOS	EGORRES	EGORRESU
1	XYZ	EG	XYZ-US-701-002	1	MEASUREMENT	334PT89	HRMEAN	Summary (Mean) Heart Rate	SUPINE	62	BEATS/MIN
2	XYZ	EG	XYZ-US-701-002	2	INTERVAL	334PT89	PRMEAN	Summary (Mean) PR Duration	SUPINE	0.15	sec
3	XYZ	EG	XYZ-US-701-002	3	INTERVAL	334PT89	QRS DUR	Summary (Mean) QRS Duration	SUPINE	0.103	sec
4	XYZ	EG	XYZ-US-701-002	4	INTERVAL	334PT89	QTMEAN	Summary (Mean) QT Duration	SUPINE	0.406	sec
5	XYZ	EG	XYZ-US-701-002	5	INTERVAL	334PT89	QTcB	QTcB – Bazett's Correction Formula	SUPINE		
6	XYZ	EG	XYZ-US-701-002	6	INTERVAL	334PT89	QTcF	QTcF – Fridericia's Correction Formula	SUPINE		
7	XYZ	EG	XYZ-US-701-002	7	FINDING	334PT89	RHYRATE	Rhythm and Rate	SUPINE	ATRIAL FIBRILLATION	
8	XYZ	EG	XYZ-US-701-002	8	FINDING	334PT89	RHYRATE	Rhythm and Rate	SUPINE	ATRIAL FLUTTER	
9	XYZ	EG	XYZ-US-701-002	9	FINDING	334PT89	QTABN	QT Abnormalities	SUPINE	PROLONGED QT	
10	XYZ	EG	XYZ-US-701-002	10	FINDING	334PT89	VCABN	Ventricular Conduction Abnormalities	SUPINE	LEFT VENTRICULAR HYPERTROPHY	
11	XYZ	EG	XYZ-US-701-002	11		334PT89	TECHPROB	Technical Problems	SUPINE	INCORRECT ELECTRODE PLACEMENT	
12	XYZ	EG	XYZ-US-701-002	12		334PT89	INTP	Interpretation	SUPINE	ABNORMAL	

Row	EGSTRESC	EGSTRESN	EGSTRESU	EGXFN	EGNAM	EGDRVFL	EGEVAL	VISITNUM	VISIT	EGDTC	EGDY
1 (cont)	62	62	BEATS/MIN	PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
2 (cont)	150	150	msec	PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
3 (cont)	103	103	msec	PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
4 (cont)	406	406	msec	PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
5 (cont)	469	469	msec	PQW436789-07.xml	Test Lab	Y		1	Screening 1	2003-04-15T11:58	-36
6 (cont)	446	446	msec	PQW436789-07.xml	Test Lab	Y		1	Screening 1	2003-04-15T11:58	-36
7 (cont)	ATRIAL FIBRILLATION			PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
8 (cont)	ATRIAL FLUTTER			PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
9 (cont)	PROLONGED QT			PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
10 (cont)	LEFT VENTRICULAR HYPERTROPHY			PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
11 (cont)	INCORRECT ELECTRODE PLACEMENT			PQW436789-07.xml	Test Lab			1	Screening 1	2003-04-15T11:58	-36
12 (cont)	ABNORMAL						PRINCIPAL INVESTIGATOR	1	Screening 1	2003-04-15T11:58	-36

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Row 1: Shows that the record in the EG dataset with value of EGSEQ of 1 has Supplemental Qualifier record indicating that the ventricular rate of 62 bpm was assessed as not being clinically significant.

Row 2: Shows that the record in the EG dataset with value of EGSEQ of 2 has Supplemental Qualifier record indicating that the PR interval of 0.15 sec was assessed as being clinically significant.

suppeg.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	XYZ	EG	XYZ-US-701-002	EGSEQ	1	EGCLSIG	Clinically Significant	N	CRF	
2	XYZ	EG	XYZ-US-701-002	EGSEQ	2	EGCLSIG	Clinically Significant	Y	CRF	

Example 2

Example 2 shows results for one subject across multiple visits where only the overall assessment was collected. In addition the ECG done at Visit 4 was read by the principal investigator and a cardiologist. In this example the EGGRPID is the same number and the EGSEQ increments by one.

Rows 1-5: Show that when an interpretation is collected the evaluator is stored in EGEVAL.

Row 2: Shows the record selected as Baseline.

Row 3: Shows a date/time in ISO 8601 representation where both the date and time were collected.

Rows 4-5: Show where EGGRPID is used to group related results.

Row	STUDYID	DOMAIN	USUBJID	EGSEQ	EGGRPID	EGTESTCD	EGTEST	EGPOS	EGORRES	EGSTRESC	EGSTRESN
1	ABC	EG	ABC-99-CA-456	1	1	INTP	Interpretation	SUPINE	NORMAL	NORMAL	
2	ABC	EG	ABC-99-CA-456	2	2	INTP	Interpretation	SUPINE	ABNORMAL	ABNORMAL	
3	ABC	EG	ABC-99-CA-456	3	3	INTP	Interpretation	SUPINE	ABNORMAL	ABNORMAL	
4	ABC	EG	ABC-99-CA-456	4	4	INTP	Interpretation	SUPINE	ABNORMAL	ABNORMAL	
5	ABC	EG	ABC-99-CA-456	5	4	INTP	Interpretation	SUPINE	ABNORMAL	ABNORMAL	

Row	EGBLFL	EGEVAL	VISITNUM	VISIT	VISITDY	EGDTC	EGDY
1 (cont)		PRINCIPAL INVESTIGATOR	1	SCREEN I	-2	2003-11-26	-2
2 (cont)	Y	PRINCIPAL INVESTIGATOR	2	SCREEN II	-1	2003-11-27	-1
3 (cont)		PRINCIPAL INVESTIGATOR	3	DAY 10	10	2003-12-07T09:02	10
4 (cont)		PRINCIPAL INVESTIGATOR	4	DAY 15	15	2003-12-12	15
5 (cont)		CARDIOLOGIST	4	DAY 15	15	2003-12-12	15

6 Domain Models Based on the General Observation Classes

6.3 Findings

Inclusion/Exclusion Criteria Not Met (IE)

IE - Description/Overview for Inclusion/Exclusion Criteria Not Met Domain Model

The intent of the domain model is to only collect those criteria that cause the subject to be in violation of the inclusion/exclusion criteria not a response to each criterion.

IE - Specification for Inclusion/Exclusion Criteria Not Met Domain Model

ie.xpt, Inclusion/Exclusion Criteria Not Met — Findings, Version 3.2. One record per inclusion/exclusion criterion not met per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	IE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
IESEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
IESPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Inclusion or Exclusion criteria number from CRF.	Perm
IETESTCD	Inclusion/Exclusion Criterion Short Name	Char	*	Topic	Short name of the criterion described in IETEST. The value in IETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g."1TEST"). IETESTCD cannot contain characters other than letters, numbers, or underscores. Examples: IN01, EX01.	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
IETEST	Inclusion/Exclusion Criterion	Char		Synonym Qualifier	Verbatim description of the inclusion or exclusion criterion that was the exception for the subject within the study. IETEST cannot be longer than 200 characters.	Req
IECAT	Inclusion/Exclusion Category	Char	(IECAT)	Grouping Qualifier	Used to define a category of related records across subjects.	Req
IESCAT	Inclusion/Exclusion Subcategory	Char	*	Grouping Qualifier	A further categorization of the exception criterion. Can be used to distinguish criteria for a sub-study or for to categorize as a major or minor exceptions. Examples: MAJOR, MINOR.	Perm
IEORRES	I/E Criterion Original Result	Char	(NY)	Result Qualifier	Original response to Inclusion/Exclusion Criterion question. Inclusion or Exclusion criterion met?	Req
IESTRESC	I/E Criterion Result in Std Format	Char	(NY)	Result Qualifier	Response to Inclusion/Exclusion criterion result in standard format.	Req
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Perm
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
IEDTC	Date/Time of Collection	Char	ISO 8601	Timing		Perm
IEDY	Study Day of Collection	Num		Timing	1. Study day of collection of the inclusion/exclusion exceptions, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics. This formula should be consistent across the submission.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

IE - Assumptions for Inclusion/Exclusion Criteria Not Met Domain Model

1. IE Definition:
CRF data that captures inclusion and exclusion criteria exceptions per subject. All inclusion or exclusion criteria that are violated, should be stored here, even if a sponsor has granted a waiver or if the subject was admitted by mistake. In cases where a CRF may allow a response of “Not Applicable” and this is checked, no criteria were violated, so these records would not be in IE.
2. The intent of the domain model is to collect responses to only those criteria that the subject did not meet, and not the responses to all criteria. The complete list of Inclusion/Exclusion criteria can be found in the TI trial inclusion/exclusion criteria dataset described in **Section 7.4 - Trial Summary and Eligibility: Trial Inclusion/Exclusion Criteria (TI)**.
3. This domain should be used to document the exceptions to inclusion or exclusion criteria at the time that eligibility for study entry is determined (e.g., at the end of a run-in period or immediately before randomization). This domain should not be used to collect protocol deviations/violations incurred during the course of the study, typically after randomization or start of study medication. See **Section 6.2 - DV Domain** for the DV events domain model that is used to submit protocol deviations/violations.
4. IETEST is to be used only for the verbatim description of the inclusion or exclusion criteria. If the text is ≤ 200 characters, it goes in IETEST; if the text is > 200 characters, put meaningful text in IETEST and describe the full text in the study metadata. See **Section 4: 4.1.5.3.2, Text Strings > 200 Characters in Other Variables** for further information.
5. The following Qualifiers would not generally be used in IE: --MODIFY, --POS, --BODSYS, --ORRESU, --ORNRLO, --ORNRHI, --STRESN, --STRESU, --STNRLO, --STNRHI, --STNRC, --NRIND, --RESCAT, --XFN, --NAM, --LOINC, --SPEC, --SPCCND, --LOC, --METHOD, --BLFL, --FAST, --DRVFL, --TOX, --TOXGR, --SEV, --STAT.

IE - Examples for Inclusion/Exclusion Criteria Not Met Domain Model

This example shows records for three subjects; one with 2 inclusion/exclusion exceptions, and the others with one exception each. Subject XYZ-0007 failed exclusion criterion number 17 and inclusion criterion 3, but was included in the trial. The other two subjects each failed inclusion criterion number 3, but were also included in the trial.

Row	STUDYID	DOMAIN	USUBJID	IESEQ	IESPID	IETESTCD	IETEST	IECAT	IEORRES
1	XYZ	IE	XYZ-0007	1	17	EXCL17	Ventricular Rate	EXCLUSION	Y
2	XYZ	IE	XYZ-0007	2	3	INCL03	Acceptable mammogram from local radiologist?	INCLUSION	N
3	XYZ	IE	XYZ-0047	1	3	INCL03	Acceptable mammogram from local radiologist?	INCLUSION	N
4	XYZ	IE	XYZ-0096	1	3	INCL03	Acceptable mammogram from local radiologist?	INCLUSION	N

Row	IESTRESC	VISITNUM	VISIT	VISITDY	IEDTC	IEDY
1 (cont)	Y	1	WEEK -8	-56	1999-01-10	-58
2 (cont)	N	1	WEEK -8	-56	1999-01-10	-58
3 (cont)	N	1	WEEK -8	-56	1999-01-12	-56
4 (cont)	N	1	WEEK -8	-56	1999-01-13	-55

6 Domain Models Based on the General Observation Classes

6.3 Findings

Immunogenicity Specimen Assessment (IS)

IS – Description/Overview for the Immunogenicity Specimen Assessment Domain Model

The IS domain is intended to be used only for data collected regarding the immunogenic potential of materials under study.

IS – Specification for the Immunogenicity Specimen Assessment Domain Model

IS.xpt, Immunogenicity Specimen Assessments — Findings, Version 3.2. One record per test per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique Identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	IS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across a submission.	Req
ISSEQ	Sequence Number	Char		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
ISGRPID	Group ID	Num		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
ISREFID	Reference ID	Char		Identifier	Internal or external specimen identifier. Example: 458975-01.	Perm
ISSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier.	Perm
ISTESTCD	Immunogenicity Test/Exam Short Name	Char	*	Identifier	Short name of the measurement, test, or examination described in ISTEEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in ISTESTCD cannot be longer than 8 characters, nor can it start with a number. ISTESTCD cannot contain characters other than letters, numbers, or underscores. Sponsor should first check the lab terminology for the LBTEST/LBTESTCD values until CDISC attaches published controlled terminology.	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
ISTEST	Immunogenicity Test or Examination Name	Char	*	Topic	Verbatim name of the test or examination used to obtain the measurement or finding. The value in ISTEST cannot be longer than 40 characters. (Example: Immunoglobulin E). Sponsor should first check the lab terminology for the LBTEST/LBTESTCD values until CDISC attaches published controlled terminology.	Req
ISCAT	Category for Immunogenicity Test	Char	*	Synonym Qualifier	Used to define a category of Topic-variable values across subjects. Example: SEROLOGY	Perm
ISSCAT	Subcategory for Immunogenicity Test	Char	*	Grouping Qualifier	A further categorization of ISCAT.	Perm
ISORRES	Results or Findings in Original Units	Char		Result Qualifier	Results of measurement or finding as originally received or collected.	Exp
ISORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for ISORRES. Examples: Index Value, gpELISA, unit/mL.	Exp
ISSTRESC	Character Results/Findings in Std. Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from ISORRES, in a standard format or in standard units. ISSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in ISSTRESN.	Exp
ISSTRESN	Numeric Results/Findings in Std. Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from ISSTRESC. ISSTRESN should store all numeric test results or findings.	Exp
ISSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized units used for ISSTRESC and ISSTRESN. Examples: Index Value, gpELISA, unit/mL.	Exp
ISSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a test was not done. Should be null if a result exists in ISORRES.	Perm
ISREASND	Reason Not Done	Char		Record Qualifier	Describes why a measurement or test was not performed. Used in conjunction with ISSTAT when value is NOT DONE.	Perm
ISNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor who provided the test results	Perm
ISSPEC	Specimen Type	Char	(SPECTYPE)	Record Qualifier	Defines the types of specimen used for a measurement. Example: SERUM.	Perm
ISMETHOD	Method of Test or Examination	Char		Record Qualifier	Method of test or examination. Examples: ELISA, ELISPOT.	Perm
ISBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. Should be Y or null.	Perm
ISLLOQ	Lower Limit of Quantitation	Num		Variable Qualifier	Indicates the lower limit of quantitation for an assay. Units will be those used for ISSTRESU.	Exp
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
ISDTC	Date/Time of Collection	Char	ISO 8601	Timing	Collection date and time of an observation represented in ISO 8601.	Exp
ISDY	Study Day of Visit/Collection/Exam	Num		Timing	Actual study day of visit/collection/exam expressed in integer days relative to sponsor- defined RFSTDTC in Demographics.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

IS – Assumptions for the Immunogenicity Specimen Assessment Domain Model

1. The Immunogenicity Specimen Assessments (IS) domain model holds assessments which describe whether a therapy provoked/caused/induced an immune response. The response can be either positive or negative. For example, a vaccine is expected to induce a beneficial immune response, while a cellular therapy such as erythropoiesis stimulating agents may cause an adverse immune response.
2. The following Qualifiers would not generally be used in IS: --POS, --BODSYS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STRNC, --NRIND, --RESCAT, --XFN, --LOINC, --SPCCND, --FAST, --TOX, --TOXGR, --SEV.

IS – Examples for the Immunogenicity Specimen Assessment Domain Model

Example 1

In this example, subjects were dosed with a Hepatitis C vaccine. Note that information about administration of the vaccine is found in the Exposure domain, not the Immunogenicity domain, so it is not included here.

Rows 1, 2, 4, & 5: Show the measurement of antibody to the vaccine.

Rows 3 & 6: Show the detection of viral DNA.

Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISTESTCD	ISTEST	ISCAT	ISORRES	ISORRESU	ISSTRESC	ISSTRESN	ISSTRESU
1	ABC-123	IS	123457	1	HCAB	Hepatitis C Virus Antibody	SEROLOGY	3115.016	gpELISA unit/mL	3115.016	3115.016	gpELISA unit/mL
2	ABC-123	IS	123457	2	HCAB	Hepatitis C Virus Antibody	SEROLOGY	1772.78	gpELISA unit/mL	1772.78	1772.78	gpELISA unit/mL
3	ABC-123	IS	123457	3	IGDNA	Hepatitis C DNA	SEROLOGY	POSITIVE		POSITIVE		
4	ABC-123	IS	123460	1	HCAB	Hepatitis C Virus Antibody	SEROLOGY	217.218	gpELISA unit/mL	217.218	217.218	gpELISA unit/mL
5	ABC-123	IS	123460	2	HCAB	Hepatitis C Virus Antibody	SEROLOGY	203.88	gpELISA unit/mL	203.88	203.88	gpELISA unit/mL
6	ABC-123	IS	123460	3	IGDNA	Hepatitis C DNA	SEROLOGY	NEGATIVE		NEGATIVE		

Row	ISSPEC	ISMETHOD	ISBLFL	ISLLOQ	VISITNUM	VISIT	ISDTC	ISDY
1 (cont)	SERUM	ENZYME IMMUNOASSAY	Y	100	1	VISIT 1	2008-10-10	1
2 (cont)	SERUM	ENZYME IMMUNOASSAY		100	2	VISIT 2	2008-11-21	43
3 (cont)	LIVER	POLYMERASE CHAIN REACTION			4	VISIT 4	2009-09-17	343
4 (cont)	SERUM	ENZYME IMMUNOASSAY	Y	100	1	VISIT 1	2008-09-01	1
5 (cont)	SERUM	ENZYME IMMUNOASSAY		100	2	VISIT 2	2008-10-02	31
6 (cont)	LIVER	POLYMERASE CHAIN REACTION			4	VISIT 4	2009-03-01	188

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Example 2

In this example, subject was dosed with the study product consisting of 0.5mL of varicella vaccine. The immunogenic response of the study product as well as the pneumococcal vaccine that was given concomitantly was measured to ensure that immunogenicity of both vaccines was sufficient to provide protection.

Rows 1-4: Show the measurement of antibody to the vaccines.

Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISTESTCD	ISTEST	ISCAT	ISORRES	ISORRESU	ISSTRESC	ISSTRESN
1	GHJ-456	IS	6017	1	PNPSAB14	Pneumococcal Polysacch AB Serotype 14	SEROLOGY	9.715	ug/mL	9.715	9.715
2	GHJ-456	IS	6017	2	VZVAB	Varicella-Zoster Virus Antibody	SEROLOGY	141.616	gpELISA unit/mL	141.616	141.616
3	GHJ-456	IS	6017	3	PNPSAB14	Pneumococcal Polysacch AB Serotype 14	SEROLOGY	13.244	ug/mL	13.244	13.244
4	GHJ-456	IS	6017	4	VZVAB	Varicella-Zoster Virus Antibody	SEROLOGY	870.871	gpELISA unit/mL	870.871	870.871

Row	ISSTRESU	ISSPEC	ISMETHOD	ISBLFL	ISLLOQ	VISITNUM	VISIT	ISDY	ISDTC
1 (cont)	ug/mL	SERUM	ENZYME IMMUNOASSAY	Y	2.5	1	VISIT 1	1	2010-02-06
2 (cont)	gpELISA unit/mL	SERUM	ENZYME IMMUNOASSAY	Y	2.5	1	VISIT 1	1	2010-02-06
3 (cont)	ug/mL	SERUM	ENZYME IMMUNOASSAY		2.5	2	VISIT 2	31	2010-03-09
4 (cont)	gpELISA unit/mL	SERUM	ENZYME IMMUNOASSAY		2.5	2	VISIT 2	31	2010-03-09

6 Domain Models Based on the General Observation Classes

6.3 Findings

Laboratory Test Results (LB)

LB - Description/Overview for Laboratory Test Results Domain Model

Laboratory test findings including, but is not limited to hematology, clinical chemistry and urinalysis data. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.

LB - Specification for Laboratory Test Results Domain Model

lb.xpt, Labs — Findings, Version 3.2. One record per lab test per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	LB	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
LBSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
LBGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
LBREFID	Specimen ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID.	Perm
LBSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on the Lab page.	Perm
LBTESTCD	Lab Test or Examination Short Name	Char	(LBTESTCD)	Topic	Short name of the measurement, test, or examination described in LBTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in LBTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g. "1TEST"). LBTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: ALT, LDH.	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
LBTEST	Lab Test or Examination Name	Char	(LBTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. Note any test normally performed by a clinical laboratory is considered a lab test. The value in LBTEST cannot be longer than 40 characters. Examples: Alanine Aminotransferase, Lactate Dehydrogenase.	Req
LBCAT	Category for Lab Test	Char	*	Grouping Qualifier	Used to define a category of related records across subjects. Examples: such as HEMATOLOGY, URINALYSIS, CHEMISTRY.	Exp
LBSCAT	Subcategory for Lab Test	Char	*	Grouping Qualifier	A further categorization of a test category such as DIFFERENTIAL, COAGULATON, LIVER FUNCTION, ELECTROLYTES.	Perm
LBORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
LBORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for LBORRES. Example: g/L.	Exp
LBORNRL0	Reference Range Lower Limit in Orig Unit	Char		Variable Qualifier	Lower end of reference range for continuous measurements in original units. Should be populated only for continuous results.	Exp
LBORNRI	Reference Range Upper Limit in Orig Unit	Char		Variable Qualifier	Upper end of reference range for continuous measurements in original units. Should be populated only for continuous results.	Exp
LBSTRESC	Character Result/Finding in Std Format	Char	(LBSTRESC)	Result Qualifier	Contains the result value for all findings, copied or derived from LBORRES in a standard format or standard units. LBSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in LBSTRESN. For example, if a test has results “NONE”, “NEG”, and “NEGATIVE” in LBORRES and these results effectively have the same meaning, they could be represented in standard format in LBSTRESC as “NEGATIVE”. For other examples, see general assumptions.	Exp
LBSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from LBSTRESC. LBSTRESN should store all numeric test results or findings.	Exp
LBSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for LBSTRESC or LBSTRESN.	Exp
LBSTNRLO	Reference Range Lower Limit-Std Units	Num		Variable Qualifier	Lower end of reference range for continuous measurements for LBSTRESC/LBSTRESN in standardized units. Should be populated only for continuous results.	Exp
LBSTNRHI	Reference Range Upper Limit-Std Units	Num		Variable Qualifier	Upper end of reference range for continuous measurements in standardized units. Should be populated only for continuous results.	Exp
LBSTNRC	Reference Range for Char Rslt-Std Units	Char		Variable Qualifier	For normal range values that are character in ordinal scale or if categorical ranges were supplied (e.g., “-1 to +1”, “NEGATIVE TO TRACE”).	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
LBNRIND	Reference Range Indicator	Char	(NRIND)	Variable Qualifier	1. Indicates where the value falls with respect to reference range defined by LBORNRL0 and LBORNRI, LBSTNRLO and LBSTNRHI, or by LBSTNRC. Examples: NORMAL, ABNORMAL, HIGH, LOW. 2. Sponsors should specify in the study metadata (Comments column in the define.xml) whether LBNRIND refers to the original or standard reference ranges and results. 3. Should not be used to indicate clinical significance.	Exp
LBSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate exam not done. Should be null if a result exists in LBORRES.	Perm
LBREASND	Reason Test Not Done	Char		Record Qualifier	Describes why a measurement or test was not performed such as BROKEN EQUIPMENT, SUBJECT REFUSED, or SPECIMEN LOST. Used in conjunction with LBSTAT when value is NOT DONE.	Perm
LBNAM	Vendor Name	Char		Record Qualifier	The name or identifier of the laboratory that performed the test.	Perm
LBLOINC	LOINC Code	Char	*	Synonym Qualifier	1. Dictionary-derived LOINC Code for LBTEST. 2. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes	Perm
LBSPEC	Specimen Type	Char	(SPECTYPE)	Record Qualifier	Defines the type of specimen used for a measurement. Examples: SERUM, PLASMA, URINE.	Perm
LBSPCCND	Specimen Condition	Char	(SPECCOND)	Record Qualifier	Free or standardized text describing the condition of the specimen e.g. HEMOLYZED, ICTERIC, LIPEMIC etc.	Perm
LBMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Examples: EIA (Enzyme Immunoassay), ELECTROPHORESIS, DIPSTICK	Perm
LBBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Exp
LBFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status such as Y, N, U, or null if not relevant.	Perm
LBDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records that represent the average of other records, or do not come from the CRF, or are not as originally received or collected are examples of records that might be derived for the submission datasets. If LBDRVFL=Y, then LBORRES may be null, with LBSTRESC, and (if numeric) LBSTRESN having the derived value.	Perm
LBTOX	Toxicity	Char	*	Variable Qualifier	Description of toxicity quantified by LBTOXGR. The sponsor is expected to provide the name of the scale and version used to map the terms, utilizing the define.xml external codelist attributes.	Perm
LBTOXGR	Standard Toxicity Grade	Char	*	Variable Qualifier	Records toxicity grade value using a standard toxicity scale (such as the NCI CTCAE). If value is from a numeric scale, represent only the number (e.g., "2" and not "Grade 2"). The sponsor is expected to provide the name of the scale and version used to map the terms, utilizing the define.xml external codelist attributes.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter 2. May be used in addition to VISITNUM and/or VISITDY	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
LBDTC	Date/Time of Specimen Collection	Char	ISO 8601	Timing		Exp
LBENDTC	End Date/Time of Specimen Collection	Char	ISO 8601	Timing		Perm
LBDY	Study Day of Specimen Collection	Num		Timing	1. Study day of specimen collection, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics. This formula should be consistent across the submission.	Perm
LBTPPT	Planned Time Point Name	Char		Timing	1. Text Description of time when specimen should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See LBTPPTNUM and LBTPPTREF. Examples: Start, 5 min post.	Perm
LBTPPTNUM	Planned Time Point Number	Num		Timing	Numerical version of LBTPPT to aid in sorting.	Perm
LBELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned Elapsed time (in ISO 8601) relative to a planned fixed reference (LBTPPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: “-PT15M” to represent the period of 15 minutes prior to the reference point indicated by LBTPPTREF, or “PT8H” to represent the period of 8 hours after the reference point indicated by LBTPPTREF.	Perm
LBTPPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by LBELTM, LBTPPTNUM, and LBTPPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
LBRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, LBTPPTREF.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

LB - Assumptions for Laboratory Test Results Domain Model

1. LB Definition: This domain captures laboratory data collected on the CRF or received from a central provider or vendor
2. For lab tests that do not have continuous numeric results (e.g., urine protein as measured by dipstick, descriptive tests such as urine color), LBSTNRC could be populated either with normal range values that are character in an ordinal scale (e.g., “NEGATIVE to TRACE”) or a delimited set of values that are considered to be normal (e.g., “YELLOW”, “AMBER”). LBORNRL0, LBORNRLHI, LBSTNRL0, and LBSTNRLHI should be null for these types of tests.

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3. LBNRIND can be added to indicate where a result falls with respect to reference range defined by LBORNRL0 and LBORNRLHI. Examples: HIGH, LOW. Clinical significance would be represented as described in *Section 4: 4.1.5.5, Clinical Significance for Findings Observation Class Data* as a record in SUPPLB with a QNAM of LBCLSIG (see also LB Example 1 below).
4. For lab tests where the specimen is collected over time, i.e., 24-hour urine collection, the start date/time of the collection goes into LBDTC and the end date/time of collection goes into LBENDTC. See *Section 4: 4.1.4.8, Date and Time Reported in a Domain Based on Findings*.
5. The following Qualifiers would not generally be used in LB: --BODSYS, --SEV.
6. A value derived by a central lab according to their procedures is considered collected rather than derived. See *Section 4: 4.1.1.8.1, Origin Metadata For Variables*.
7. The variable, LBORRESU uses the UNIT codelist. This means that sponsors should be submitting a term from the column, “CDISC Submission Value,” in the published Controlled Terminology List that is maintained for CDISC by [NCL EVS](#). When sponsors have units that are not in this column, they should first check to see if their unit is a synonym of an existing unit and submit their lab values using that unit. If this is not the case, then a New-Term Request From should be submitted.

LB - Examples for Laboratory Test Results Domain Model

Example 1

- Row 1:** Shows a value collected in one unit, but converted to selected standard unit. See *Section 4: 4.1.5.1, Original and Standardized Results of Findings and Test Not Done* for additional examples for the population of Result Qualifiers.
- Rows 2-4:** Show two records (rows 2 and 3) for Alkaline Phosphatase done at the same visit, one day apart. Row 4 shows how to create a derived record (average of the records 2 and 3) and flagged derived (LBDRVFL = “Y”) and as the record to use as baseline (LBBFL = “Y”).
- Rows 6 and 7:** Show a suggested use of the LBSCAT variable. It could be used to further classify types of tests within a laboratory panel (i.e., “DIFFERENTIAL”).
- Row 9:** Shows the proper use of the LBSTAT variable to indicate "NOT DONE", where a reason was collected when a test was not done.
- Row 10:** The subject had cholesterol measured. The normal range for this test is <200 mg/dL. Note that the sponsor has decided to make LBSTNRHI =199 however another sponsor may have chosen a different value.
- Row 12:** Shows use of LBSTNRC for Urine Protein that is not reported as a continuous numeric result.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSCAT	LBORRES	LBORRESU	LBORNRL0	LBORNRLHI	LBSTRESC
1	ABC	LB	ABC-001-001	1	ALB	Albumin	CHEMISTRY		30	g/L	35	50	3.0
2	ABC	LB	ABC-001-001	2	ALP	Alkaline Phosphatase	CHEMISTRY		398	IU/L	40	160	398
3	ABC	LB	ABC-001-001	3	ALP	Alkaline Phosphatase	CHEMISTRY		350	IU/L	40	160	350
4	ABC	LB	ABC-001-001	4	ALP	Alkaline Phosphatase	CHEMISTRY						374
5	ABC	LB	ABC-001-001	5	WBC	Leukocytes	HEMATOLOGY		5.9	10 ⁹ /L	4	11	5.9
6	ABC	LB	ABC-001-001	6	LYMLE	Lymphocytes	HEMATOLOGY	DIFFERENTIAL	6.7	%	25	40	6.7
7	ABC	LB	ABC-001-001	7	NEUT	Neutrophils	HEMATOLOGY	DIFFERENTIAL	5.1	10 ⁹ /L	2	8	5.1
8	ABC	LB	ABC-001-001	8	PH	pH	URINALYSIS		7.5		5.0	9.0	7.5

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Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSCAT	LBORRES	LBORRESU	LBORNRL0	LBORNRH1	LBSTRESC
9	ABC	LB	ABC-001-001	9	ALB	Albumin	CHEMISTRY						
10	ABC	LB	ABC-001-001	10	CHOL	Cholesterol	CHEMISTRY		229	mg/dL	0	<200	229
11	ABC	LB	ABC-001-001	11	WBC	Leukocytes	HEMATOLOGY		5.9	10 ⁹ /L	4	11	5.9
12	ABC	LB	ABC-001-001	12	PROT	Protein	URINALYSIS		MODERATE				MODERATE

Note that the use of 10⁹ as a unit is not a standard representation.

Row	LBSTRESN	LBSTRESU	LBSTNRLO	LBSTNRHI	LBSTRNRC	LBNRIND	LBSTAT	LBREASND	LBBLFL	LBFAST	LBDRVFL	VISITNUM	VISIT	LBDMTC
1 (cont)	3.0	g/dL	3.5	5		LOW			Y	Y		1	Week 1	1999-06-19
2 (cont)	398	IU/L	40	160						Y		1	Week 1	1999-06-19
3 (cont)	350	IU/L	40	160						Y		1	Week 1	1999-06-20
4 (cont)	374	IU/L	40	160					Y	Y	Y	1	Week 1	1999-06-19
5 (cont)	5.9	10 ⁹ /L	4	11					Y	Y		1	Week 1	1999-06-19
6 (cont)	6.7	%	25	40		LOW			Y	Y		1	Week 1	1999-06-19
7 (cont)	5.1	10 ⁹ /L	2	8					Y	Y		1	Week 1	1999-06-19
8 (cont)			5.00	9.00					Y	Y		1	Week 1	1999-06-19
9 (cont)							NOT DONE	INSUFFICIENT SAMPLE				2	Week 2	1999-07-21
10 (cont)	229	mg/dL	0	199								2	Week 2	1999-07-21
11 (cont)	5.9	10 ⁹ /L	4	11						Y		2	Week 2	1999-07-21
12 (cont)					NEGATIVE to TRACE	ABNORMAL						2	Week 2	1999-07-21

Row 1, 6: The SUPPLB dataset example shows clinical significance assigned by the investigator for test results where LBNRIND (reference range indicator) is populated.

supplb.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	LB	ABC-001-001	LBSEQ	1	LBCLSIG	Clinical Significance	N	CRF	INVESTIGATOR
2	ABC	LB	ABC-001-001	LBSEQ	6	LBCLSIG	Clinical Significance	N	CRF	INVESTIGATOR

Example 2

Rows 1: Shows an example of a pre-dose urine collection interval (from 4 hours prior to dosing until 15 minutes prior to dosing) with a negative value for LBELTM that reflects the end of the interval in reference to the fixed reference LBTPTREF, the date of which is recorded in LBRFTDTC.

Rows 2-3: Show an example of post-dose urine collection intervals with values for LBELTM that reflect the end of the intervals in reference to the fixed reference LBTPTREF, the date of which is recorded in LBRFTDTC.

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRL0	LBORNRH1	LBSTRESC	LBSTRESN
1	ABC	LB	ABC-001-001	1	GLUC	Glucose	URINALYSIS	7	mg/dL	1	15	0.38	0.38
2	ABC	LB	ABC-001-001	2	GLUC	Glucose	URINALYSIS	11	mg/dL	1	15	0.61	0.61
3	ABC	LB	ABC-001-001	3	GLUC	Glucose	URINALYSIS	9	mg/dL	1	15	0.5	0.5

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Row	LBSTRESU	LBSTNRLO	LBSTNRHI	LBNRIND	VISITNUM	VISIT	LBDMTC	LBENDTC	LBTPT	LBTPPTNUM	LBELTM	LBTPTREF	LBRFTDTC
1 (cont)	mmol/L	0.1	0.8	NORMAL	2	INITIAL DOSING	1999-06-19 T04:00	1999-06-19 T07:45	Pre-dose	1	-PT15M	Dosing	1999-06-19 T08:00
2 (cont)	mmol/L	0.1	0.8	NORMAL	2	INITIAL DOSING	1999-06-19 T08:00	1999-06-19 T16:00	0-8 hours after dosing	2	PT8H	Dosing	1999-06-19 T08:00
3 (cont)	mmol/L	0.1	0.8	NORMAL	2	INITIAL DOSING	1999-06-19 T16:00	1999-06-20 T00:00	8-16 hours after dosing	3	PT16H	Dosing	1999-06-19 T08:00

Example 3

This is an example of pregnancy test records, one with a result and one with no result because the test was not performed due to the subject being male.

Row 1: Shows an example of a pregnancy test record that returns a result of “-” (negative sign) in LBORRES and is standardized to the text value “NEGATIVE” in LBSTRESC

Row 2: Show an example of a pregnancy test that was not performed because the subject was male, and the sponsor felt it was necessary to report a record documenting the reason why the test was not performed, rather than simply excluding the record.

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRLLO	LBORNRIHI	LBSTRESC
1	ABC	LB	ABC-001-001	1	HCG	Choriogonadotropin Beta	CHEMISTRY	-				NEGATIVE
2	ABC	LB	ABC-001-002	1	HCG	Choriogonadotropin Beta	CHEMISTRY					

Row	LBSTRESN	LBSTRESU	LBSTNRLO	LBSTRNHI	LBNRIND	LBSTAT	LBREASND	VISITNUM	VISIT	LBDMTC
1 (cont)								1	BASELINE	1999-06-19T04:00
2 (cont)						NOT DONE	NOT APPLICABLE (SUBJECT MALE)	1	BASELINE	1999-06-24T08:00

6 Domain Models Based on the General Observation Classes

6.3 Findings

Microbiology Domains: MB and MS

Microbiology Specimen (MB)

MB - Description/Overview for Microbiology Specimen Domain Model

Microbiology specimen findings, including gram stain results, and organisms found.

MB - Specifications for Microbiology Specimen Domain Model

mb.xpt, Microbiology Specimen — Findings, Version 3.2. One record per microbiology specimen finding per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	MB	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
MBSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MBGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain to support relationships within the domain and between domains. In MB, used to link to findings about organisms which are stored in MS.	Exp
MBREFID	Reference ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID	Perm
MBSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: ORGANISM IDENTIFIER. For organism identification, MBSPID would remain the same each time the same organism is identified in a new specimen.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MBTESTCD	Microbiology Test or Finding Short Name	Char	*	Topic	Short name of the measurement, test, or finding described in MBTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in MBTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). MBTESTCD cannot contain characters other than letters, numbers, or underscores. Examples for GRAM STAIN findings: GMNROD, GMNCOC, GMSQEPCE, GMPMNLOW. Examples for CULTURE PLATE findings: ORGANISM.	Req
MBTEST	Microbiology Test or Finding Name	Char	*	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in MBTEST cannot be longer than 40 characters. Examples: GRAM NEGATIVE RODS, GRAM NEGATIVE COCCI, SQUAMOUS EPITHELIAL CELLS, PMN PER FIELD LOW, ORGANISM PRESENT	Req
MBCAT	Category for Microbiology Finding	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm
MBSCAT	Subcategory for Microbiology Finding	Char	*	Grouping Qualifier	Used to define a further categorization of MBCAT.	Perm
MBORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the Microbiology measurement or finding as originally received or collected. Examples for GRAM STAIN findings: +3 MODERATE, +2 FEW, <10. Examples for CULTURE PLATE (ORGANISM) findings: KLEBSIELLA PNEUMONIAE, STREPTOCOCCUS PNEUMONIAE.	Exp
MBORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original unit for MBORRES. Example: mcg/mL	Perm
MBSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from MBORRES in a standard format or standard units. MBSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in MBSTRESN. For example, if a test has results "+3 MODERATE", "MOD", and "MODERATE" in MBORRES and these results effectively have the same meaning, they could be represented in standard format in MBSTRESC as "MODERATE".	Exp
MBSTRESN	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 MBSTRESC. MBSTRESN should store all numeric test results or findings.	Perm
MBSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for MBSTRESC and MBSTRESN.	Perm
MBRESCAT	Result Category	Char	*	Variable Qualifier	Used to categorize the result of a finding in a standard format. Example for ORGANISM finding: INFECTING, COLONIZER, CONTAMINANT, or NORMAL FLORA.	Exp
MBSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate Microbiology was not done, or a test was not done. Should be null or have a value of NOT DONE.	Perm
MBREASND	Reason Microbiology Not Performed	Char		Record Qualifier	Reason not done. Used in conjunction with MBSTAT when value is NOT DONE. Examples: BROKEN EQUIPMENT or SUBJECT REFUSED.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MBNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor who provides the test results.	Perm
MBLOINC	LOINC Code	Char	*	Synonym Qualifier	1. Dictionary-derived LOINC Code for MBTEST. 2. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes	Perm
MBSPEC	Specimen Type	Char	(SPECTYPE)	Record Qualifier	Defines the type of specimen used for a measurement. Examples: SPUTUM, BLOOD, PUS.	Perm
MBSPCCND	Specimen Condition	Char	(SPECCOND)	Record Qualifier	Free or standardized text describing the condition of the specimen. Example: CONTAMINATED.	Perm
MBLOC	Specimen Collection Location	Char	(LOC)	Record Qualifier	Location relevant to the collection of the measurement. Examples: LUNG, VEIN, ARM, FOOT	Perm
MBMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Example: GRAM STAIN, MACRO BROTH DILUTION, AGAR DILUTION	Exp
MBBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Perm
MBDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records that represent the average of other records or some other derivation, and those that do not come from the CRF, are examples of records that would be derived for the submission datasets. If MBDRVFL=Y, then MBORRES may be null with MBSTRESC and (if numeric) MBSTRESN having the derived value.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
MBDTC	Date/Time of Specimen Collection	Char	ISO 8601	Timing		Exp
MBDY	Study Day of MB Specimen Collection	Num		Timing	1. Study day of the specimen collection, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics. This formula should be consistent across the submission.	Perm
MBTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when specimen should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See MBTPTNUM and MBTPTREF. Examples: Start, 5 min post.	Perm
MBTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of MBTPT to aid in sorting.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MBELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a planned fixed reference (MBTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: “-PT15M” to represent the period of 15 minutes prior to the reference point indicated by MBTPTREF, or “PT8H” to represent the period of 8 hours after the reference point indicated by MBTPTREF.	Perm
MBTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by MBELTM, MBTPTNUM, and MBTPT. Example: PREVIOUS DOSE.	Perm
MBRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, MBTPTREF.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

MB - Assumptions for Microbiology Specimen Domain Model

1. Definition: The MB domain is designed to store microbiology findings that include organisms found, gram stain results and organism growth status.
2. MBSPID is used to uniquely identify an organism. MBSPID would remain the same each time the same organism is identified in a new specimen. Often the original line number used to record the first occurrence of the organism is used again as an organism identifier when it is found in another specimen. For example, MBSPID is 01 at visit 10 for organism “STAPHYLOCOCCUS AUREUS”. For the same organism at visit 30, MBSPID is again 01.
3. MBTESTCD value for organisms present in a specimen is "ORGANISM".
4. MBDTC can be used to record the date/time that an organism started to grow in the culture, or the date/time that the culture became positive for the organism.
5. MBGRPID is used to link to findings related to that organism in the MS domain. For example, if in Specimen 1, organism STREPTOCOCCUS PNEUMONIAE is found with MBGRPID=1, then findings such as susceptibility tests, colony count, etc. for that organism in Specimen 1, would all have the same value of MSGRPID=1 in the MS domain. The use of GRPID to relate MS to MB greatly simplifies RELREC because only two records are needed in RELREC to describe the relationship of MB to the many related records in MS. With this method there is no need to create detailed relationships at the subject level.
6. MBRESCAT is expected in all records where a microorganism has been identified to differentiate between colonizing organisms and the one(s) that are causing the infection. It is not expected when there is “No growth” or when the results are from a gram stain.
7. The following Qualifiers would not generally be used in MB: --MODIFY, --BODSYS, --FAST, --TOX, --TOXGR --SEV.

Microbiology Susceptibility (MS)

MS - Description/Overview for Microbiology Susceptibility Domain Model

This includes microbiology susceptibility test results, plus results of any other organism-related tests.

MS - Specifications for Microbiology Susceptibility Domain Model

ms.xpt, Microbiology Susceptibility Test — Findings, Version 3.2. One record per microbiology susceptibility test (or other organism-related finding) per organism found in MB, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	MS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
MSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain to support relationships within the domain and between domains. In MS, used to link to organism in MB.	Req
MSREFID	Reference ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID.	Perm
MSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm
MSTESTCD	Microbiology Organism Finding Short Name	Char	*	Topic	Short name of the measurement, test, or finding described in MSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in MSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g. "1TEST). MSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples for GROWTH findings: EXTGROW, COLCOUNT. For SUSCEPTIBILITY findings, the test is the drug the organism was tested with, i.e. PENICLLN, AMOXCLLN.	Req
MSTEST	Organism Test or Finding Name	Char	*	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. Examples for GROWTH findings: Extent of Growth, Colony Count. Examples for SUSCEPTIBILITY findings: Amoxicillin Susceptibility, Penicillin Susceptibility	Req
MSCAT	Category for Organism Findings	Char	*	Grouping Qualifier	Used to define a category of related records. Examples: GROWTH, SUSCEPTIBILITY.	Req
MSSCAT	Subcategory for Organism Findings	Char	*	Grouping Qualifier	A further categorization of a test category. Examples: CULTURE, ISOLATE	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MSORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the Microbiology Organism measurement or finding as originally received or collected. Examples for GROWTH findings: GROWTH INTO 3RD QUADRANT. Examples for SUSCEPTIBILITY findings:.0080,.0023	Exp
MSORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for MSORRES. Example: mcg/mL	Exp
MSSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from MSORRES in a standard format or standard units. MSSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in MSSTRESN. For example, if a test has results “+3 MODERATE”, “MOD”, and “MODERATE”, and in MSORRES and these results effectively have the same meaning, they could be represented in standard format in MSSTRESC as “MODERATE”.	Exp
MSSTRESN	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 MSSTRESC. MSSTRESN should store all numeric test results or findings.	Exp
MSSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for MSSTRESC and MSSTRESN.	Exp
MSRESCAT	Result Category	Char	(MSRESCAT)	Variable Qualifier	Used to categorize the result of a finding in a standard format. Example for SUSCEPTIBILITY finding: SUSCEPTIBLE, INTERMEDIATE, RESISTANT, or UNKNOWN.	Exp
MSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a test on an organism was not done, or a test was not performed. Should be null if a result exists in MSORRES or have a value of NOT DONE.	Perm
MSREASND	Reason Test Not Done	Char		Record Qualifier	Reason not done. Describes why a measurement or test was not performed. Used in conjunction with MSSTAT when value is NOT DONE. Example: SAMPLE LOST	Perm
MSNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor that provided the test results.	Perm
MSLOINC	LOINC Code	Char	*	Synonym Qualifier	1. Dictionary-derived LOINC Code for MSTEST. 2. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes	Perm
MSMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Example: GRAM STAIN, MACRO BROTH DILUTION, AGAR DILUTION	Exp
MSBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be “Y” or null.	Perm
MSDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records that represent the average of other records or some other derivation, and those that do not come from the CRF, are examples of records that would be derived for the submission datasets. If MSDRVFL=Y, then MSORRES may be null, with MSSTRESC and (if numeric) MSSTRESN having the derived value.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
MSDTC	Date/Time of Test	Char	ISO 8601	Timing		Perm
MSDY	Study Day of Test	Num		Timing	1. Study day of the test, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics. This formula should be consistent across the submission.	Perm
MSTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when test should be done. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See MSTPTNUM and MSTPTREF. Examples: Start, 5 min post.	Perm
MSTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of MSTPT to aid in sorting.	Perm
MSELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Elapsed time (in ISO 8601) relative to a planned fixed reference (MSTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by MSTPTREF, or "P8H" to represent the period of 8 hours after the reference point indicated by MSTPTREF.	Perm
MSTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by MSELTM, MSTPTNUM, and MSTPT. Example: PREVIOUS DOSE.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

MS - Assumptions for Microbiology Susceptibility Domain Model

1. Definition: The MS domain is designed to store any findings related to the organisms found and submitted in MB. This will usually consist of susceptibility testing results, but can also be other organism-related findings such as extent of growth of an organism. This domain is intended to be used in conjunction with the MB domain described above.
2. The following Qualifiers would not generally be used in MB: --MODIFY, --BODSYS, --SPEC, --SPCCND, --FAST, --TOX, --TOXGR --SEV.

MB-MS - Examples for Microbiology Specimen and Microbiology Susceptibility Domain Models

Example 1: MB specimen findings

- Rows 1, 2:** Show gram stain results for Specimen 1 (MBREFID=SP01).
Rows 3, 4: Show organisms found in specimen 1 at visit 1. The MBGRPID is used to link these organisms to findings about these organisms in MS, by MSGRPID.
Row 5: Shows the organism assigned as ORG02 is still present in Specimen 2 at Visit 2.
Row 6: Shows no organisms have grown at Visit 3. Therefore the organism recorded is "NO GROWTH".
Rows 1-6: Show MBMETHOD being used for reporting the method of testing the sample, e.g. GRAM STAIN or MICROBIAL CULTURE, SOLID.

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Row	STUDYID	DOMAIN	USUBJID	MBSEQ	MBGRPID	MBREFID	MBSPID	MBTESTCD	MBTEST	MBORRES
1	ABC	MB	ABC-001-001	1		SP01		GMNCOC	Gram Negative Cocci	2+ FEW
2	ABC	MB	ABC-001-001	2		SP01		GMNROD	Gram Negative Rods	2+ FEW
3	ABC	MB	ABC-001-001	3	1	SP01	ORG01	ORGANISM	Organism Present	STREPTOCOCCUS PNEUMONIAE
4	ABC	MB	ABC-001-001	4	2	SP01	ORG02	ORGANISM	Organism Present	KLEBSIELLA PNEUMONIAE
5	ABC	MB	ABC-001-001	5	3	SP02	ORG02	ORGANISM	Organism Present	KLEBSIELLA PNEUMONIAE
6	ABC	MB	ABC-001-001	6		SP03	ORG03	ORGANISM	Organism Present	NO GROWTH

Row	MBSTRESC	MBRESCAT	MBLOC	MBSPEC	MBSPCND	MBMETHOD	VISITNUM	MBDTC
1 (cont)	FEW		LUNG	SPUTUM	MUCOID	GRAM STAIN	1	2005-06-19T08:00
2 (cont)	FEW		LUNG	SPUTUM	MUCOID	GRAM STAIN	1	2005-06-19T08:00
3 (cont)	STREPTOCOCCUS PNEUMONIAE	INFECTING	LUNG	SPUTUM	MUCOID	MICROBIAL CULTURE, SOLID	1	2005-06-19T08:00
4 (cont)	KLEBSIELLA PNEUMONIAE	COLONIZER	LUNG	SPUTUM	MUCOID	MICROBIAL CULTURE, SOLID	1	2005-06-19T08:00
5 (cont)	KLEBSIELLA PNEUMONIAE	COLONIZER	LUNG	SPUTUM		MICROBIAL CULTURE, SOLID	2	2005-06-26T08:00
6 (cont)	NO GROWTH		LUNG	SPUTUM		MICROBIAL CULTURE, SOLID	3	2005-07-06T08:00

If the method of the collection of the sputum is reported (e.g., EXPECTORATION or BIOPSY), this information would go into SUPPMB, since MBMETHOD refers to the method used to obtain the results.

suppmb.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	MB	ABC-001-001	MBSEQ	1	COLMETH	Collection Method	EXPECTORATION	CRF	

Example 2: MS – Findings about organisms from Example 1, related within USUBJID, by MBGRPID=MSGRPID

- Row 1:** Shows extent of growth of Organism 1 found at Visit 1 in specimen 1 (MBGRPID=1, Row 3 in MB example above).
Rows 2, 3: Show results of susceptibility testing on Organism 1 found at Visit 1 in specimen 1 (MBGRPID=1, Row 3 in MB example above).
Row 4: Shows extent of growth of Organism 2 found at Visit 1 in specimen 1 (MBGRPID=2, Row 4 in MB example above).

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- Rows 5, 6:** Show results of susceptibility testing on Organism 2 found at Visit 1 in specimen 1 (MBGRPID=2, Row 4 in MB example above).
Row 7: Shows results of susceptibility testing on Organism 2 found at Visit 1 in specimen 2 (MBGRPID=3, Row 5 in MB example above).

Row	STUDYID	DOMAIN	USUBJID	MSSEQ	MSGRPID	MSTESTCD	MSTEST	MSCAT	MSORRES	MSORRESU
1	ABC	MS	ABC-001-001	1	1	EXTGROW	Extent of Growth	GROWTH	IN 2ND QUADRANT	
2	ABC	MS	ABC-001-001	2	1	DRUGA	Sponsor Drug	SUSCEPTIBILITY	0.004	mg/L
3	ABC	MS	ABC-001-001	3	1	PENICLLN	Penicillin	SUSCEPTIBILITY	0.023	mg/L
4	ABC	MS	ABC-001-001	4	2	EXTGROW	Extent of Growth	GROWTH	>=30 COLONIES IN 2ND QUADRANT	
5	ABC	MS	ABC-001-001	5	2	DRUGA	Sponsor Drug	SUSCEPTIBILITY	0.125	mg/L
6	ABC	MS	ABC-001-001	6	2	PENICLLN	Penicillin	SUSCEPTIBILITY	0.023	mg/L
7	ABC	MS	ABC-001-001	7	3	PENICLLN	Penicillin	SUSCEPTIBILITY	0.026	mg/L

Row	MSSTRESC	MSSTRESN	MSSTRESU	MSRESCAT	MSMETHOD	VISITNUM
1 (cont)	IN 2ND QUADRANT					1
2 (cont)	0.004	0.004	mg/L	SUSCEPTIBLE	E-TEST	1
3 (cont)	0.023	0.023	mg/L	RESISTANT	E-TEST	1
4 (cont)	>=30 COLONIES IN 2ND QUADRANT					1
5 (cont)	0.125	0.125	mg/L	SUSCEPTIBLE	E-TEST	1
6 (cont)	0.023	0.023	mg/L	INTERMEDIATE	E-TEST	1
7 (cont)	0.026	0.026	mg/L	INTERMEDIATE	E-TEST	2

Example 3: MB with multiple labs

- Row 1, 2:** Show the same organism identified by a central and a local lab. Note that MBSPID is different for each lab, and also MBGRPID is different for each lab. This is because the organism is found and tracked separately for each lab although it came from the same specimen.

Row	STUDYID	DOMAIN	USUBJID	MBSEQ	MBGRPID	MBREFID	MBSPID	MBTESTCD	MBTEST	MBORRES	MBSTRESC
1	ABC	MB	ABC-001-002	1	1	SPEC01	ORG01	ORGANISM	Organism Present	ENTEROCOCCUS FAECALIS	ENTEROCOCCUS FAECALIS
2	ABC	MB	ABC-001-002	2	2	SPEC01	ORG02	ORGANISM	Organism Present	ENTEROCOCCUS FAECALIS	ENTEROCOCCUS FAECALIS

Row	MBRESCAT	MBNAM	MBLOC	MBSPEC	MBMETHOD	VISITNUM	MBDTC
1 (cont)	INFECTING	CENTRAL	SKIN SITE 1	FLUID	MICROBIAL CULTURE, SOLID	1	2005-07-21T08:00
2 (cont)	INFECTING	LOCAL	SKIN SITE 1	FLUID	MICROBIAL CULTURE, SOLID	1	2005-07-21T08:00

Example 4: MS – findings about organisms from Example 3, multiple labs

- Rows 1, 2:** Show susceptibility test results done by the central lab, for the organism identified by the central lab where MBGRPID=1 in Row 1 of Example 3 above. Note that the central lab performed only one method of susceptibility testing (the E-TEST) for the two drugs, Sponsor and Amoxicillin.
Rows 3-8: Show susceptibility test results done by the local lab, for the organism identified by the local lab where MBGRPID=2 in Row 2 of Example 3 above. Note that the local lab has performed three different methods of susceptibility testing (Broth Dilution, Zone Size, and E-TEST) for two drugs, thus providing six records for MSGRPID=2.

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Row	STUDYID	DOMAIN	USUBJID	MSSEQ	MSGRPID	MSREFID	MSTESTCD	MSTEST	MSCAT	MSORRES	MSORRESU
1	ABC	MS	ABC-001-002	1	1	CENTABC	DRUGA	Sponsor Drug	SUSCEPTIBILITY	0.25	ug/dL
2	ABC	MS	ABC-001-002	2	1	CENTABC	AMOXCLAV	Amoxicillin / Clavulanate	SUSCEPTIBILITY	1	ug/dL
3	ABC	MS	ABC-001-002	3	2	LOCXYZ	DRUGA	Sponsor Drug	SUSCEPTIBILITY	0.5	ug/dL
4	ABC	MS	ABC-001-002	4	2	LOCXYZ	AMOXCLAV	Amoxicillin / Clavulanate	SUSCEPTIBILITY	0.5	ug/dL
5	ABC	MS	ABC-001-002	5	2	LOCXYZ	DRUGA	Sponsor Drug	SUSCEPTIBILITY	23	mm
6	ABC	MS	ABC-001-002	6	2	LOCXYZ	AMOXCLAV	Amoxicillin / Clavulanate	SUSCEPTIBILITY	25	mm
7	ABC	MS	ABC-001-002	7	2	LOCXYZ	DRUGA	Sponsor Drug	SUSCEPTIBILITY	0.25	ug/dL
8	ABC	MS	ABC-001-002	8	2	LOCXYZ	AMOXCLAV	Amoxicillin / Clavulanate	SUSCEPTIBILITY	1	ug/dL

Row	MSSTRESC	MSSTRESN	MSSTRESU	MSRESCAT	MSMETHOD	VISITNUM
1 (cont)	0.25	0.25	ug/dL	SUSCEPTIBLE	E-TEST	1
2 (cont)	1	1	ug/dL	RESISTANT	E-TEST	1
3 (cont)	0.5	0.5	ug/dL	SUSCEPTIBLE	MACRO BROTH DILUTION	1
4 (cont)	0.5	0.5	ug/dL	RESISTANT	MACRO BROTH DILUTION	1
5 (cont)	23	23	mm	SUSCEPTIBLE	ZONE SIZE	1
6 (cont)	25	25	mm	RESISTANT	ZONE SIZE	1
7 (cont)	0.25	0.25	ug/dL	SUSCEPTIBLE	E-TEST	1
8 (cont)	1	1	ug/dL	RESISTANT	E-TEST	1

Example 5: RELREC to relate MB and MS

Rows 1, 2: Show the one-to-many relationship between MB and MS. For any organism found in a microbiology specimen and recorded in MB, there may be multiple findings about that organism recorded in MS. The organism in MB can be linked to its findings in MS because the value assigned to MBGRPID = the value assigned to MSGRPID for any organism within a subject.

Row	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	MB		MBGRPID		ONE	A
2	MS		MSGRPID		MANY	A

6 Domain Models Based on the General Observation Classes

6.3 Findings

Microscopic Findings (MI)

MI - Description/Overview for Microscopic Findings Domain Model

The Microscopic Findings dataset provides a record for each microscopic finding observed. There may be multiple microscopic tests on a subject or specimen.

MI - Specification for Microscopic Findings Domain Model

mi.xpt, Microscopic Findings — Findings, Version 3.2. One record per finding per specimen per subject, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	MI	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
MISEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MIGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject. This is not the treatment group number.	Perm
MIREFID	Reference ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen barcode number.	Perm
MISPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number from the MI Findings page.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
MITESTCD	Microscopic Examination Short Name	Char	(MITESTCD)	Topic	Short name of the measurement, test, or examination described in MITEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in MITESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). MITESTCD cannot contain characters other than letters, numbers, or underscores. Examples: HER2, BRCA1, TTF1.	Req
MITEST	Microscopic Examination Name	Char	(MITEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in MITEST cannot be longer than 40 characters. Examples: Human Epidermal Growth Factor Receptor 2, Breast Cancer Susceptibility Gene 1, Thyroid Transcription Factor 1.	Req
MITSTDTL	Microscopic Examination Detail	Char		Record Qualifier	Further description of the test performed in producing the MI result. This would be used to represent specific attributes, such as intensity score or percentage of cells displaying presence of the biomarker or compound	Perm
MICAT	Category for Microscopic Finding	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm
MISCAT	Subcategory for Microscopic Finding	Char	*	Grouping Qualifier	Used to define a further categorization of MICAT.	Perm
MIORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the histopathology measurement or finding as originally received or collected.	Exp
MIORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original unit for MIORRES.	Perm
MISTRESC	Character Result/Finding in Standard Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from MIORRES in a standard format or standard units. MISTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in MISTRESN.	Exp
MISTRESN	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 MISTRESC. MISTRESN should store all numeric test results or findings.	Perm
MISTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for MISTRESC and MISTRESN.	Perm
MIRESCAT	Result Category	Char	*	Result Qualifier	Used to categorize the result of a finding. Examples: MALIGNANT or BENIGN for tumor findings.	Perm
MISTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate examination not done or result is missing. Should be null if a result exists in MIORRES or have a value of NOT DONE when MIORRES=NULL.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
MIREASND	Reason Not Done	Char		Record Qualifier	Reason not done. Used in conjunction with MISTAT when value is NOT DONE. Examples: SAMPLE AUTOLYZED, SPECIMEN LOST.	Perm
MINAM	Laboratory/Vendor Name	Char		Record Qualifier	Name or identifier of the vendor (e.g., laboratory) that provided the test results.	Perm
MISPEC	Specimen Material Type	Char	(SPECTYPE)	Record Qualifier	Subject of the observation. Defines the type of specimen used for a measurement. Examples: TISSUE, BLOOD, BONE MARROW.	Req
MISPCOND	Specimen Condition	Char	(SPECCOND)	Variable Qualifier	Free or standardized text describing the condition of the specimen. Example: AUTOLYZED.	Exp
MILOC	Specimen Collection Location	Char	(LOC)	Record Qualifier	Location relevant to the collection of the specimen. Examples: LUNG, KNEE JOINT, ARM, THIGH.	Perm
MILAT	Specimen Laterality within Subject	Char	(LAT)	Variable Qualifier	Qualifier for laterality of the location of the specimen in MILOC. Examples: LEFT, RIGHT, BILATERAL.	Perm
MIDIR	Specimen Directionality within Subject	Char	(DIR)	Variable Qualifier	Qualifier for directionality of the location of the specimen in MILOC. Examples: DORSAL, PROXIMAL.	Perm
MIMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. This could include the technique or type of staining used for the slides. Examples: IHC, Crystal Violet, Safranin, Trypan Blue, or Propidium Iodide.	Perm
MIBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Exp
MIEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Example: PATHOLOGIST, PEER REVIEW, SPONSOR PATHOLOGIST.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
MIDTC	Date/Time of Specimen Collection	Char	ISO 8601	Timing	Date/time of specimen collection, in ISO 8601 format.	Exp
MIDY	Study Day of Specimen Collection	Num		Timing	Study day of specimen collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

MI - Assumptions for Microscopic Findings Domain Model

1. MI Definition: The Microscopic Findings dataset provides a record for each microscopic finding observed in a specimen.
2. This domain holds findings resulting from the microscopic examination of tissue samples. These examinations are performed on a specimen, which has been prepared with some type of stain. Some examinations of cells in fluid specimens such as blood or urine are classified as lab tests and should be stored in the LB domain. The LOINC coding system may be used to resolve questions about where a particular test should be stored. Tests classified as "PATH" or "CYTO" in LOINC should be stored in the MI domain. Biomarkers assessed by histologic or histopathological examination (by employing cytochemical / immunocytochemical stains) will be stored in the MI domain.
3. The variable MITSTDTL is proposed to be used when biomarker tests are represented in the MI domain. It represents test parameter details descriptive of slide stain results (e.g., cells at 1+ intensity cytoplasm stain, H-Score, nuclear reaction score). Note: MITESTCD reflects the biomarker of interest (e.g., BRCA1, HER2, TTF1), and MITSTDTL further qualifies the record.
4. These variables are generally not used for this domain: --POS, --MODIFY, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STNRC, --NRIND, --LEAD, --CSTATE, --BLFL, --FAST, --DRVFL, --DTHREL, --LLOQ, --ULOQ, --EXCLFL, --REASEX.

MI - Examples for Microscopic Findings Domain Model

Example 1

Immunohistochemistry (IHC) is a method that involves treating tissue with a stain that adheres to very specific substances. IHC is the method most commonly used to assess the amount of HER2 receptor protein on the surface of the cancer cells. A cell with too many receptors receives too many growth signals. In this study, IHC assessment of HER2 in samples of breast cancer tissue yielded reaction scores on a scale of 0 to 3+. Reaction scores of 0 to 1+, are categorized as "HER2 negative." while scores 2+ or 3+ are categorized as "HER2 positive." Results between 1+ and 2+ are considered borderline. For further information on this test see <http://www.breastcancer.org/symptoms/testing/types/ihc.jsp>

Row 1: Shows an example where subject ABC-1001 is HER2 negative with a receptor protein stain reaction score of 0.

Row 2: Shows an example where subject ABC-2002 is HER2 positive with a receptor protein stain reaction score of 2+.

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Row	STUDYID	DOMAIN	USUBJID	MISEQ	MITESTCD	MITEST	MITSTDTL	MIORRES	MISTRESC	MIRESCAT	MISPEC	MILOC	MIMETHOD	VISIT
1	ABC	MI	ABC-1001	1	HER2	Human Epidermal Growth Factor Receptor 2	Reaction Score	0	0	NEGATIVE	TISSUE	BREAST	IHC	SCREENING
2	ABC	MI	ABC-2002	1	HER2	Human Epidermal Growth Factor Receptor 2	Reaction Score	2+	2+	POSITIVE	TISSUE	BREAST	IHC	SCREENING

Example 2

In this study, immunohistochemistry (IHC) for BRCA1 protein expression in a tissue was reported using a reaction score, a stain intensity score, and a composite score. The reaction score was assessed as the percentage of tumor cells that stained positive on a scale from 0 to 3. Stain intensity was assessed as absent, mild, moderate, or strong, and scored from 0 to 3. The product of the two scores was the composite score. For details of the scoring method see:

<http://annonc.oxfordjournals.org/content/early/2011/03/02/annonc.mdq770.full>

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Rows 1-3: A reaction score of '2' (Row 1) is multiplied by stain intensity score of '3' (Row 2) to yield the derived composite score of '6' (Row 3).

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Row	STUDYID	DOMAIN	USUBJID	MISEQ	MITESTCD	MITEST	MITSTDTL	MIORRES	MISTRESC	MISTRESN	MISPEC	MILOC	MIMETHOD	MIDRVFL	VISIT
1	ABC	MI	ABC-1001	1	BRCA1	Breast Cancer Susceptibility Gene 1	Reaction Score	2	2	2	TISSUE	BREAST	IHC		SCREENING
2	ABC	MI	ABC-1001	2	BRCA1	Breast Cancer Susceptibility Gene 1	Stain Intensity Score	strong	3	3	TISSUE	BREAST	IHC		SCREENING
3	ABC	MI	ABC-1001	3	BRCA1	Breast Cancer Susceptibility Gene 1	Composite Score	6	6	6	TISSUE	BREAST	IHC	Y	SCREENING

A variable that is included in the MI domain (since it's not in the Findings general observation class), but of importance to the BRCA1 results is stored in SUPPMI. In this example, the fact that the reaction score assessed staining in the nucleus (rather than another subcellular location) is represented by the Supplemental Qualifier QNAM for Subcellular Location.

suppmi.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	MI	ABC-1001	MISEQ	1	SUBCELOC	Subcellular Location	NUCLEUS	CRF	

Example 3

In this study, IHC staining for Thyroid Transcription Factor 1 was reported at a detailed level. Staining intensity of cytoplasm was assessed on a semi-quantitative scale ranging from 0 to 3+, and the percentage of tumor cells at each intensity level was reported. These results were used to calculate the H-Score, which ranges from 0 to 300. The H-Score algorithm is as follows: (% cells with 0 intensity) * 0 + (% cells with 1+ intensity) * 1 + (% of cells with 2+ intensity) * 2 + (% of cells with 3+ intensity) * 3.

Rows 1-4: Show an example where the Thyroid Transcription Factor 1 staining intensity was assessed as a percent of cells stained.

Row 5: Shows the subjects Thyroid Transcription Factor 1 H-Score.

mi.xpt

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MITESTCD	MITEST	MITSTDTL	MIORRES	MIORRESU	MISTRESC	MISTRESN	MISTRESU
1	ABC	MI	ABC-1001	1	TTF1	Thyroid Transcription Factor 1	The percentage of cells with 0 intensity of staining	25	%	25	25	%
2	ABC	MI	ABC-1001	2	TTF1	Thyroid Transcription Factor 1	The percentage of cells with 1+ intensity of staining	40	%	40	40	%
3	ABC	MI	ABC-1001	3	TTF1	Thyroid Transcription Factor 1	The percentage of cells with 2+ intensity of staining	35	%	35	35	%
4	ABC	MI	ABC-1001	4	TTF1	Thyroid Transcription Factor 1	The percentage of cells with 3+ intensity of staining	0	%	0	0	%
5	ABC	MI	ABC-1001	5	TTF1	Thyroid Transcription Factor 1	H-Score of staining	110		110	110	

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Row	MISPEC	MILOC	MIMETHOD	MIDRVFL	VISIT
1 (cont)	TISSUE	LUNG	IHC		SCREENING
2 (cont)	TISSUE	LUNG	IHC		SCREENING
3 (cont)	TISSUE	LUNG	IHC		SCREENING
4 (cont)	TISSUE	LUNG	IHC		SCREENING
5 (cont)	TISSUE	LUNG	IHC	Y	SCREENING

A variable that is included in the MI domain (since it's not in the Findings general observation class), but of importance to the TTF1 results is stored in SUPPMI. In this example, the fact that the reaction score assessed cell cytoplasm (rather than another subcellular location) is represented by the Supplemental Qualifier QNAM for Subcellular Location.

suppmi.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	MI	ABC-1001	MISEQ	1	SUBCELOC	Subcellular Location	CYTOPLASM	CRF	
2	ABC	MI	ABC-1001	MISEQ	2	SUBCELOC	Subcellular Location	CYTOPLASM	CRF	
3	ABC	MI	ABC-1001	MISEQ	3	SUBCELOC	Subcellular Location	CYTOPLASM	CRF	
4	ABC	MI	ABC-1001	MISEQ	4	SUBCELOC	Subcellular Location	CYTOPLASM	CRF	
5	ABC	MI	ABC-1001	MISEQ	5	SUBCELOC	Subcellular Location	CYTOPLASM	CRF	

6 Domain Models Based on the General Observation Classes

6.3 Findings

Morphology (MO)

MO - Description/Overview for Morphology Domain Model

Macroscopic results (e.g. size, shape, color, and abnormalities of body parts or specimens) that are seen by the naked eye or observed via procedures such as imaging modalities, endoscopy, or other technologies. Many morphology results are obtained from a procedure, although information about the procedure may or may not be collected.

MO - Specification for Morphology Domain Model

mo.xpt, Morphology — Findings, Version 3.2. One record per Morphology finding per location per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	MO	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
MOSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MOGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
MOREFID	Reference ID	Char		Identifier	Internal or external procedure identifier.	Perm
MOSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number from the procedure or test page.	Perm
MOLNKID	Link ID	Char		Identifier	Identifier used to link results of a procedure to the procedure performed.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MOTESTCD	Test or Examination Short Name	Char	(MOTESTCD)	Topic	Short name of the measurement, test, or examination described in MOTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in MOTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). MOTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: VOLUME, INTP	Req
MOTEST	Test or Examination Name	Char	(MOTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in MOTEST cannot be longer than 40 characters. Examples: Volume, Interpretation	Req
MOCAT	Category for Test	Char	*	Grouping Qualifier	Used to categorize observations across subjects.	Perm
MOSCAT	Subcategory for Test	Char	*	Grouping Qualifier	A further categorization.	Perm
MOPOS	Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.	Perm
MOORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the procedure measurement or finding as originally received or collected.	Exp
MOORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for MOORRES.	Perm
MOSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from MOORRES in a standard format or standard units. MOSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in MOSTRESN.	Exp
MOSTRESN	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 MOSTRESC. MOSTRESN should store all numeric test results or findings.	Perm
MOSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for MOSTRESC or MOSTRESN.	Perm
MOSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a test was not done, or a measurement was not taken. Should be null if a result exists in MOORRES.	Perm
MOREASND	Reason Test Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: BROKEN EQUIPMENT or SUBJECT REFUSED. Used in conjunction with MOSTAT when value is NOT DONE.	Perm
MOXFN	External File Path	Char		Record Qualifier	File path to the external file.	Perm
MONAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor who provided the test results.	Perm
MOLOC	Location Used for Measurement	Char	(LOC)	Record Qualifier	Location relevant to the collection of the measurement. Examples: BRAIN, KIDNEY, LIVER. etc.	Perm
MOLAT	Specimen Laterality within Subject	Char	(LAT)	Variable Qualifier	Qualifier for laterality of the specimen within the subject for paired specimens. Examples: LEFT, RIGHT, BILATERAL.	Perm
MODIR	Specimen Directionality within Subject	Char	(DIR)	Variable Qualifier	Qualifier for directionality of the specimen within the subject. Examples: DORSAL, PROXIMAL.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
MOPORTOT	Portion or Totality	Char	(PORTOT)	Variable Qualifier	Qualifier for anatomical location or specimen further detailing the portion of totality which means arrangement of, or apportioning of. Examples: ENTIRE, PARTIAL	Perm
MOMETHOD	Method of Procedure Test	Char	(METHOD)	Record Qualifier	Method of the test or examination result.	Perm
MOANMETH	Analysis Method	Char	*	Record Qualifier	Analysis method applied to obtain a summarized result. Examples: STEREOLOGY	Perm
MOBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be “Y” or null.	Exp
MODRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records that represent the average of other records, or that do not come from the CRF, or are not as originally collected or received are examples of records that would be derived for the submission datasets. If MODRVFL=Y, then MOORRES could be null, and (if numeric) MOSTRESN having the derived value.	Perm
MOEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain collected or derived data. Examples: INVESTIGATOR, ADJUDICATION COMMITTEE, VENDOR.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
MODTC	Date/Time of Test	Char	ISO 8601	Timing	Date of test.	Exp
MODY	Study Day of Test	Num		Timing	1. Study day of the procedure or test, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm
MOTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when measurement should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See MOTPTNUM and MOTPTREF. Examples: Start, 5 min post.	Perm
MOTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of MOTPT to aid in sorting.	Perm
MOELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a fixed time point reference (MOTPTREF). Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: “-PT15M” to represent the period of 15 minutes prior to the reference point indicated by MOTPTREF, or “PT8H” to represent the period of 8 hours after the reference point indicated by MOTPTREF.	Perm
MOTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by MOELTM, MOTPTNUM, and MOTPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
MORFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, MOTPTREF.	Perm

** Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)*

MO - Assumptions for Morphology Domain Model

1. MO Definition: CRF or eDT Findings Data received as a result of tests or procedures.
 - a. Macroscopic results (e.g. size, shape, color, and abnormalities of body parts or specimens) that are seen by the naked eye or observed via procedures such as imaging modalities, endoscopy, or other technologies. Many morphology results are obtained from a procedure, although information about the procedure may or may not be collected. The protocol design and/or CRFs will usually specify whether PR information would be collected. When additional data about a procedure that produced morphology findings is collected, the data about the procedure is stored in the PR domain and the link between the morphology findings and the procedure should be recording using RELREC. If only morphology information was collected, without any procedure information, then a PR domain would not be needed.
 - b. The MO domain is intended for use when morphological findings are noted in the course of a study such as via a physical exam or imaging technology. It is not intended for use in studies in which lesions or tumors are of primary interest and are identified and tracked throughout the study.
 - c. While the CDISC SEND Implementation Guide (SENDIG) has separate domains for Macroscopic Findings (MA) and Organ Measurements (OM) for pre-clinical data, the MO domain for clinical studies is intended for the representation of data on both of these topics.
 - d. In prior SDTMIG versions, morphology test examples, such as “Eye Color” were aligned to the Subject Characteristics (SC) domain and should now be mapped as a Morphology test (MOTEST).
2. The following Qualifiers would not generally be used in MO: --MODIFY, --BODSYS, --FAST, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, -- and --LOINC.

MO - Examples for Morphology Domain Model

Example 1

This example shows Morphology tests related to cardiovascular assessments. Other tests of cardiovascular function would be submitted in another appropriate and associated physiology domain.

Rows 1-3: Display three cardiovascular morphology measurements for one subject.

mo.xpt

Row	STUDYID	DOMAIN	USUBJID	MOSEQ	MOTESTCD	MOTEST	MOORRES	MOORRESU	MOSTRESC	MOSTRESN	MOSTRESU	MOLOC	MOLAT
1	XYZ	MO	XYZ-AB-333-009	1	AREA	Area	20	cm2	20	20	cm2	HEART, ATRIUM	LEFT
2	XYZ	MO	XYZ-AB-333-009	2	VOLUME	Volume	22	ml	22	22	ml	HEART, ATRIUM	LEFT
3	XYZ	MO	XYZ-AB-333-009	3	NUMDVSL	Number of Diseased Vessels	2		2	2		CORONARY ARTERY	

Example 2

This example shows imaging data results from an Alzheimer's disease study.

This example represents seven MRI imaging tests done on the brain at the screening visit and at first treatment, Visit 1, for one subject. It also shows the controlled terminology for MOTESTCD and MOTEST. MOREFID is used in RELREC to link the data with the MRI information reported in the Device-in-Use domain. MOREFID contains the identifier of the image used to determine the MO results.

The Device Identifier and Device-in-Use domains are used in this example from the SDTM Implementation Guide for Medical Devices (SDTMIG-MD).

Row 1: Displays the overall MRI image interpretation result at the screening visit.

Row 2-7: Display the volume results at various anatomical locations and lateralities within the brain at the screening visit.

Rows 8-14: Display the same seven imaging tests at Visit 1.

mo.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MOSEQ	MOREFID	MOTESTCD	MOTEST	MOORRES	MOORRESU	MOSTRESC	MOSTRESN	MOSTRESU
1	STUDYX	MO	P0001	ABC174	1	1234-5678	INTP	Interpretation	NORMAL		NORMAL		
2	STUDYX	MO	P0001	ABC174	2	1234-5678	VOLUME	Volume	1200	mL	1200	1200	mL
3	STUDYX	MO	P0001	ABC174	3	1234-5678	VOLUME	Volume	2725	mL	2725	2725	mL
4	STUDYX	MO	P0001	ABC174	4	1234-5678	VOLUME	Volume	2685	mL	2685	2685	mL
5	STUDYX	MO	P0001	ABC174	5	1234-5678	VOLUME	Volume	15635	mL	15635	15635	mL
6	STUDYX	MO	P0001	ABC174	6	1234-5678	VOLUME	Volume	15650	mL	15650	15650	mL
7	STUDYX	MO	P0001	ABC174	7	1234-5678	VOLUME	Volume	7505	mL	7505	7505	mL
8	STUDYX	MO	P0001	ABC174	8	1234-6666	INTP	Interpretation	NORMAL		NORMAL		
9	STUDYX	MO	P0001	ABC174	9	1234-6666	VOLUME	Volume	1200	mL	1200	1200	mL
10	STUDYX	MO	P0001	ABC174	10	1234-6666	VOLUME	Volume	2725	mL	2725	2725	mL
11	STUDYX	MO	P0001	ABC174	11	1234-6666	VOLUME	Volume	2685	mL	2685	2685	mL

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Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MOSEQ	MOREFID	MOTESTCD	MOTEST	MOORRES	MOORRESU	MOSTRESC	MOSTRESN	MOSTRESU
12	STUDYX	MO	P0001	ABC174	12	1234-6666	VOLUME	Volume	15635	mL	15635	15635	mL
13	STUDYX	MO	P0001	ABC174	13	1234-6666	VOLUME	Volume	15650	mL	15650	15650	mL
14	STUDYX	MO	P0001	ABC174	14	1234-6666	VOLUME	Volume	7505	mL	7505	7505	mL

Row	MOLOC	MOLAT	MOMETHOD	MOEVAL	VISITNUM	VISIT	VISITDY	MODTC	MODY
1 (cont)	BRAIN		MRI	INVESTIGATOR	1	SCREENING	-14	2011-03-20	-10
2 (cont)	BRAIN		MRI		1	SCREENING	-14	2011-03-20	-10
3 (cont)	HIPPOCAMPUS	LEFT	MRI		1	SCREENING	-14	2011-03-20	-10
4 (cont)	HIPPOCAMPUS	RIGHT	MRI		1	SCREENING	-14	2011-03-20	-10
5 (cont)	TEMPORAL LOBE	LEFT	MRI		1	SCREENING	-14	2011-03-20	-10
6 (cont)	TEMPORAL LOBE	RIGHT	MRI		1	SCREENING	-14	2011-03-20	-10
7 (cont)	BRAIN VENTRICLE		MRI		1	SCREENING	-14	2011-03-20	-10
8 (cont)	BRAIN		MRI	INVESTIGATOR	2	VISIT 1	1	2011-04-03	1
9 (cont)	BRAIN		MRI		2	VISIT 1	1	2011-04-03	1
10 (cont)	HIPPOCAMPUS	LEFT	MRI		2	VISIT 1	1	2011-04-03	1
11 (cont)	HIPPOCAMPUS	RIGHT	MRI		2	VISIT 1	1	2011-04-03	1
12 (cont)	TEMPORAL LOBE	LEFT	MRI		2	VISIT 1	1	2011-04-03	1
13 (cont)	TEMPORAL LOBE	RIGHT	MRI		2	VISIT 1	1	2011-04-03	1
14 (cont)	BRAIN VENTRICLE		MRI		2	VISIT 1	1	2011-04-03	1

DI Domain

The example below shows a Device Identifiers (DI) domain record based on the MRI device used for the brain measurement. A prerequisite for any Device domain is that there will be at least one record in DI. The standard controlled terminology for DIPARMCD, DIPARM, and DIVAL is represented in the table.

Row 1: Displays the record for the MRI device.

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	STUDYX	DI	ABC174	1	TYPE	Device Type	MRI

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Device-in-Use (DU) data example related to MO results for the MRI device

This example shows data from one subject collected at two visits regarding parameters from an MRI imaging protocol. DUGRPID is used to facilitate the creation of a RELREC relationship to the morphological result(s) (see table below).

Rows 1-6: Represent six Device In-Use records collected at the screening visit for the subject.

Rows 7-12: Represent six Device In-Use records collected at the first treatment visit for the same subject.

du.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUGRPID	DUREFID	DUTESTCD	DUTEST	DUORRES	DUORRESU
1	STUDYX	DU	2324-P0001	ABC174	1	DUMO1	222333-444555	COILSTR	Coil Strength	1.5	Tesla
2	STUDYX	DU	2324-P0001	ABC174	2	DUMO1	222333-444555	ANTPLANE	Anatomical Plane	CORONAL	
3	STUDYX	DU	2324-P0001	ABC174	3	DUMO1	222333-444555	STHICK	Slice Thickness	1	mm
4	STUDYX	DU	2324-P0001	ABC174	4	DUMO1	222333-444555	MATRIX	Matrix	256X256	
5	STUDYX	DU	2324-P0001	ABC174	5	DUMO1	222333-444555	FLDVIEW	Field of View	24	cm
6	STUDYX	DU	2324-P0001	ABC174	6	DUMO1	222333-444555	RCBDWTH	Receiver Bandwidth	16	kHz
7	STUDYX	DU	2324-P0001	ABC174	7	DUMO2	444555-666777	COILSTR	Coil Strength	1.0	Tesla
8	STUDYX	DU	2324-P0001	ABC174	8	DUMO2	444555-666777	ANTPLANE	Anatomical Plane	CORONAL	
9	STUDYX	DU	2324-P0001	ABC174	9	DUMO2	444555-666777	STHICK	Slice Thickness	2	mm
10	STUDYX	DU	2324-P0001	ABC174	10	DUMO2	444555-666777	MATRIX	Matrix	256X256	
11	STUDYX	DU	2324-P0001	ABC174	11	DUMO2	444555-666777	FLDVIEW	Field of View	25	cm
12	STUDYX	DU	2324-P0001	ABC174	12	DUMO2	444555-666777	RCBDWTH	Receiver Bandwidth	16	kHz

Row	DUSTRESC	DUSTRESN	DUSTRESU	VISITNUM	VISIT	VISITDY	DUDTC	DUDY
1 (cont)	1.5	1.5	Tesla	1	SCREENING	-7	2011-04-19	-7
2 (cont)	CORONAL			1	SCREENING	-7	2011-04-19	-7
3 (cont)	1	1	mm	1	SCREENING	-7	2011-04-19	-7
4 (cont)	256X256			1	SCREENING	-7	2011-04-19	-7
5 (cont)	24	24	cm	1	SCREENING	-7	2011-04-19	-7
6 (cont)	16	1	kHz	1	SCREENING	-7	2011-04-19	-7
7 (cont)	1.0	1.0	Tesla	2	VISIT 1	1	2011-04-25	1
8 (cont)	CORONAL			2	VISIT 1	1	2011-04-25	1
9 (cont)	2	2	mm	2	VISIT 1	1	2011-04-25	1
10 (cont)	256X256			2	VISIT 1	1	2011-04-25	1
11 (cont)	25	25	cm	2	VISIT 1	1	2011-04-25	1
12 (cont)	16	16	kHz	2	VISIT 1	1	2011-04-25	1

Example on the use of RELREC to relate MO and DU

Rows 1- 2: Show the relationship between the MO and DU records for the screening visit. MOREFID was used to link the records in DU by DUGRPID. DUGRPID was assigned to all of the records for this visit for the device.

Rows 3-4: Show the relationship between the MO and DU records for Visit 1. MOREFID was used to link the records in DU by DUGRPID. DUGRPID was assigned to all of the records for this visit for the device.

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relrec.xpt

Row	STUDYID	USUBJID	RDOMAIN	IDVAR	IDVARVAL	RELTYPE	RELID
1	STUDYX	2324-P0001	MO	MOREFID	1234-5678		MODU1
2	STUDYX	2324-P0001	DU	DUGRPID	DUMO1		MODU1
3	STUDYX	2324-P0001	MO	MOREFID	1234-6666		MODU2
4	STUDYX	2324-P0001	DU	DUGRPID	DUMO2		MODU2

Example 3

This example is from a Polycystic Kidney Disease study where kidney, liver and heart (left ventricle) measurements were recorded. The example below shows one subject (USUBJID=2324-P0001) who had MO results based on a CT-SCAN image at the Baseline visit.

Row 1-6: Display right and left kidney measurements of width, length, and depth.

Row 7: Displays the liver volume measurements.

Rows 8-10: Display kidney volume measurements (left, right, and both) at the baseline visit.

Rows 7-10: Display (in MOANMETH) the analytical method used to obtain volume measurements from the CT SCAN

Row 11: Displays mass measurement.

mo.xpt

Row	STUDYID	DOMAIN	USUBJID	MOSEQ	MOTESTCD	MOTEST	MOORRES	MOORRESU	MOSTRESC	MOSTRESN	MOSTRESU	MOLOC
1	STUDY01	MO	2324-P0001	1	WIDTH	Width	5	mm	5	5	mm	KIDNEY
2	STUDY01	MO	2324-P0001	2	WIDTH	Width	5	mm	5	5	mm	KIDNEY
3	STUDY01	MO	2324-P0001	3	LENGTH	Length	11	mm	11	11	mm	KIDNEY
4	STUDY01	MO	2324-P0001	4	LENGTH	Length	11	mm	11	11	mm	KIDNEY
5	STUDY01	MO	2324-P0001	5	DEPTH	Depth	2	mm	2	2	mm	KIDNEY
6	STUDY01	MO	2324-P0001	6	DEPTH	Depth	2	mm	2	2	mm	KIDNEY
7	STUDY01	MO	2324-P0001	7	VOLUME	Volume	25	mL	25	25	mL	LIVER
8	STUDY01	MO	2324-P0001	8	VOLUME	Volume	50	mL	50	50	mL	KIDNEY
9	STUDY01	MO	2324-P0001	9	VOLUME	Volume	50	mL	50	50	mL	KIDNEY
10	STUDY01	MO	2324-P0001	10	VOLUME	Volume	100	mL	100	100	mL	KIDNEY
11	STUDY01	MO	2324-P0001	11	MASS	Mass	225	g	225	225	g	HEART, LEFT VENTRICLE

Row	MOLAT	MOMETHOD	MOANMETH	VISITNUM	VISIT	MODTC
1 (cont)	LEFT	CT SCAN		1	BASELINE	2010-06-19
2 (cont)	RIGHT	CT SCAN		1	BASELINE	2010-06-19
3 (cont)	LEFT	CT SCAN		1	BASELINE	2010-06-19
4 (cont)	RIGHT	CT SCAN		1	BASELINE	2010-06-19
5 (cont)	LEFT	CT SCAN		1	BASELINE	2010-06-19
6 (cont)	RIGHT	CT SCAN		1	BASELINE	2010-06-19
7 (cont)		CT SCAN	STEREOLOGY	1	BASELINE	2010-06-19
8 (cont)	LEFT	CT SCAN	STEREOLOGY	1	BASELINE	2010-06-19
9 (cont)	RIGHT	CT SCAN	STEREOLOGY	1	BASELINE	2010-06-19
10 (cont)	BILATERAL	CT SCAN	STEREOLOGY	1	BASELINE	2010-06-19
11 (cont)		CT SCAN		1	BASELINE	2010-06-19

6 Domain Models Based on the General Observation Classes

6.3 Findings

Pharmacokinetic Domains: PC and PP

Pharmacokinetics Concentrations (PC)

PC – Description/Overview for Pharmacokinetics Concentrations Domain Model

Concentrations of drugs/metabolites in fluids or tissues as a function of time.

PC – Specification for Pharmacokinetics Concentrations Domain Model

pc.xpt, Pharmacokinetic Concentrations — Findings, Version 3.2. One record per sample characteristic or time-point concentration per reference time point or per analyte per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	PC	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Unique subject identifier within the submission.	Req
PCSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
PCGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain to support relationships within the domain and between domains.	Perm
PCREFID	Reference ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID.	Perm
PCSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number.	Perm
PCTESTCD	Pharmacokinetic Test Short Name	Char		Topic	Short name of the analyte or specimen characteristic. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PCTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). PCTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: ASA, VOL, SPG.	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
PCTEST	Pharmacokinetic Test Name	Char		Synonym Qualifier	Name of the analyte or specimen characteristic. Note any test normally performed by a clinical laboratory is considered a lab test. The value in PCTEST cannot be longer than 40 characters. Examples: Acetylsalicylic Acid, Volume, Specific Gravity.	Req
PCCAT	Test Category	Char	*	Grouping Qualifier	Used to define a category of related records. Examples: ANALYTE, SPECIMEN PROPERTY.	Perm
PCSCAT	Test Subcategory	Char	*	Grouping Qualifier	A further categorization of a test category.	Perm
PCORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
PCORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for PCORRES. Example: mg/L.	Exp
PCSTRESC	Character Result/Finding in Standard Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from PCORRES in a standard format or standard units. PCSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in PCSTRESN. For example, if a test has results “NONE”, “NEG”, and “NEGATIVE” in PCORRES and these results effectively have the same meaning, they could be represented in standard format in PCSTRESC as “NEGATIVE”. For other examples, see general assumptions.	Exp
PCSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from PCSTRESC. PCSTRESN should store all numeric test results or findings.	Exp
PCSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for PCSTRESC and PCSTRESN.	Exp
PCSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a result was not obtained. Should be null if a result exists in PCORRES.	Perm
PCREASND	Reason Test Not Done	Char		Record Qualifier	Describes why a result was not obtained such as SPECIMEN LOST. Used in conjunction with PCSTAT when value is NOT DONE.	Perm
PCNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor who provides the test results.	Exp
PCSPEC	Specimen Material Type	Char	(SPECTYPE)	Record Qualifier	Defines the type of specimen used for a measurement. Examples: SERUM, PLASMA, URINE.	Exp
PCSPCCND	Specimen Condition	Char	(SPECCOND)	Record Qualifier	Free or standardized text describing the condition of the specimen e.g. HEMOLYZED, ICTERIC, LIPEMIC etc.	Perm
PCMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Examples include HPLC/MS, ELISA. This should contain sufficient information and granularity to allow differentiation of various methods that might have been used within a study.	Perm
PCFAST	Fasting Status	Char	(NY)	Record Qualifier	Indicator used to identify fasting status.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
PCDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records that represent the average of other records, which do not come from the CRF, are examples of records that would be derived for the submission datasets. If PCDRVFL=Y, then PCORRES may be null with PCSTRESC, and (if numeric) PCSTRESN having the derived value.	Perm
PCLLOQ	Lower Limit of Quantitation	Num		Variable Qualifier	Indicates the lower limit of quantitation for an assay. Units should be those used in PCSTRESU.	Exp
PCULOQ	Upper Limit of Quantitation	Num		Variable Qualifier	Indicates the upper limit of quantitation for an assay. Units should be those used in PCSTRESU.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter 2. May be used in addition to VISITNUM and/or VISITDY	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
PCDTC	Date/Time of Specimen Collection	Char	ISO 8601	Timing	Date/time of specimen collection represented in ISO 8601 character format. If there is no end time, then this will be the collection time.	Exp
PCENDTC	End Date/Time of Specimen Collection	Char	ISO 8601	Timing	End date/time of specimen collection represented in ISO 8601 character format. If there is no end time, the collection time should be stored in PCDTC, and PCENDTC should be null.	Perm
PCDY	Actual Study Day of Specimen Collection	Num		Timing	1. Study day of specimen collection, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm
PCTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when specimen should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See PCTPTNUM and PCTPTREF. Examples: Start, 5 min post.	Perm
PCTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of PCTPT to aid in sorting.	Perm
PCELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a planned fixed reference (PCTPTREF) 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.	Perm
PCTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point used as a basis for PCTPT, PCTPTNUM, and PCELTM. Example: Most Recent Dose.	Perm
PCRFTDTC	Date/Time of Reference Point	Char	ISO 8601	Timing	Date/time of the reference time point described by PCTPTREF.	Perm
PCEVLINT	Evaluation Interval	Char	ISO 8601	Timing	Evaluation Interval associated with a PCTEST record represented in ISO 8601 character format. Example: "-P2H" to represent an interval of 2 hours prior to a PCTPT.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

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PC – Assumptions for Pharmacokinetics Concentrations Domain Model

1. PC Definition: Data collected about tissue (e.g., serum or plasma) concentrations of analytes (usually study drugs and/or their metabolites) as a function of time after dosing the study drug.
2. The structure is one record per concentration or sample characteristic per analyte. In addition to one record for each concentration measurement, specimen properties (e.g., volume and pH) are handled via separate records in this dataset.
3. Due to space limitations, not all expected or permissible Findings variables are included in the example.
4. The following Qualifiers would not generally be used in PC: --BODSYS, --SEV.

PC – Examples for Pharmacokinetics Concentrations Domain Model

Example 1

This example shows concentration data for Drug A and metabolite of Drug A from plasma and from urine (shaded rows) samples collected pre-dose and after dosing on two different study days, Days 1 and 11.

All Rows:

PCTPTREF is a text value of the description of a “zero” time (e.g. time of dosing). It should be meaningful. If there are multiple PK profiles being generated, the zero time for each will be different (e.g., a different dose such as "first dose", "second dose") and, as a result, values for PCTPTREF must be different. In this example such values for PCTPTREF are required to make values of PCTPTNUM and PCTPT unique [see Section 4: 4.1.4.10, Representing Time Points].

Rows 5, 6, 19, 20, 25, 26, 29, 30:

Specimen properties (VOLUME and PH) are submitted as values of PCTESTCD in separate rows. These have a PCCAT value of SPECIMEN PROPERTY.

The elapsed times for urine samples are based upon the elapsed time (from the reference time point, PCTPTREF) for the end of the specimen collection period. Elapsed time values that are the same for urine and plasma samples have been assigned the same value for PCTPT. For the urine samples, the value in PCEVLINT describes the planned evaluation (or collection) interval relative to the time point. The actual evaluation interval can be determined by subtracting PCDDTC from PCENDTC.

Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCGRPID	PCREFID	PCTESTCD	PCTEST	PCCAT	PCSPEC	PCORRES	PCORRESU	PCSTRESC	PCSTRESN	PCSTRESU	PCSTAT
1	ABC-123	PC	123-0001	1	Day 1	A554134-10	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	<0.1	ng/mL	<0.1		ng/mL	
2	ABC-123	PC	123-0001	2	Day 1	A554134-10	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	<0.1	ng/mL	<0.1		ng/mL	
3	ABC-123	PC	123-0001	3	Day 1	A554134-11	DRGA_MET	Drug A Metabolite	ANALYTE	URINE	<2	ng/mL	<2		ng/mL	
4	ABC-123	PC	123-0001	4	Day 1	A554134-11	DRGA_PAR	Drug A Parent	ANALYTE	URINE	<2	ng/mL	<2		ng/mL	
5	ABC-123	PC	123-0001	5	Day 1	A554134-11	VOLUME	Volume	SPECIMEN PROPERTY	URINE	3500	mL	100	100	mL	
6	ABC-123	PC	123-0001	6	Day 1	A554134-11	PH	PH	SPECIMEN PROPERTY	URINE	5.5		5.5	5.5		
7	ABC-123	PC	123-0001	7	Day 1	A554134-12	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	5.4	ng/mL	5.4	5.4	ng/mL	
8	ABC-123	PC	123-0001	8	Day 1	A554134-12	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	4.74	ng/mL	4.74	4.74	ng/mL	
9	ABC-123	PC	123-0001	9	Day 1	A554134-13	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	5.44	ng/mL	5.44	5.44	ng/mL	

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Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCGRPID	PCREFID	PCTESTCD	PCTEST	PCCAT	PCSPEC	PCORRES	PCORRESU	PCSTRESC	PCSTRESN	PCSTRESU	PCSTAT
10	ABC-123	PC	123-0001	10	Day 1	A554134-13	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	1.09	ng/mL	1.09	1.09	ng/mL	
11	ABC-123	PC	123-0001	11	Day 1	A554134-14	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA						NOT DONE
12	ABC-123	PC	123-0001	12	Day 1	A554134-14	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	<0.1	ng/mL	<0.1		ng/mL	
13	ABC-123	PC	123-0001	13	Day 11	A554134-15	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	3.41	ng/mL	3.41	3.41	ng/mL	
14	ABC-123	PC	123-0001	14	Day 11	A554134-15	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	<0.1	ng/mL	<0.1		ng/mL	
15	ABC-123	PC	123-0001	15	Day 11	A554134-16	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	8.74	ng/mL	8.74	8.74	ng/mL	
16	ABC-123	PC	123-0001	16	Day 11	A554134-16	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	4.2	ng/mL	4.2	4.2	ng/mL	
17	ABC-123	PC	123-0001	17	Day 11	A554134-17	DRGA_MET	Drug A Metabolite	ANALYTE	URINE	245	ng/mL	245	245	ng/mL	
18	ABC-123	PC	123-0001	18	Day 11	A554134-17	DRGA_PAR	Drug A Parent	ANALYTE	URINE	13.1	ng/mL	13.1	13.1	ng/mL	
19	ABC-123	PC	123-0001	19	Day 11	A554134-17	VOLUME	Volume	SPECIMEN PROPERTY	URINE	574	mL	574	574	mL	
20	ABC-123	PC	123-0001	20	Day 11	A554134-17	PH	PH	SPECIMEN PROPERTY	URINE	5.5		5.5	5.5		
21	ABC-123	PC	123-0001	21	Day 11	A554134-18	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	9.02	ng/mL	9.02	9.02	ng/mL	
22	ABC-123	PC	123-0001	22	Day 11	A554134-18	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	1.18	ng/mL	1.18	1.18	ng/mL	
23	ABC-123	PC	123-0001	23	Day 11	A554134-19	DRGA_MET	Drug A Metabolite	ANALYTE	URINE	293	ng/mL	293	293	ng/mL	
24	ABC-123	PC	123-0001	24	Day 11	A554134-19	DRGA_PAR	Drug A Parent	ANALYTE	URINE	7.1	ng/mL	7.1	7.1	ng/mL	
25	ABC-123	PC	123-0001	25	Day 11	A554134-19	VOLUME	Volume	SPECIMEN PROPERTY	URINE	363	mL	363	363	mL	
26	ABC-123	PC	123-0001	26	Day 11	A554134-19	PH	PH	SPECIMEN PROPERTY	URINE	5.5		5.5	5.5		
27	ABC-123	PC	123-0001	27	Day 11	A554134-20	DRGA_MET	Drug A Metabolite	ANALYTE	URINE	280	ng/mL	280	280	ng/mL	
28	ABC-123	PC	123-0001	28	Day 11	A554134-20	DRGA_PAR	Drug A Parent	ANALYTE	URINE	2.4	ng/mL	2.4	2.4	ng/mL	
29	ABC-123	PC	123-0001	29	Day 11	A554134-20	VOLUME	Volume	SPECIMEN PROPERTY	URINE	606	mL	606	606	mL	
30	ABC-123	PC	123-0001	30	Day 11	A554134-20	PH	PH	SPECIMEN PROPERTY	URINE	5.5		5.5	5.5		
31	ABC-123	PC	123-0001	31	Day 11	A554134-21	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	3.73	ng/mL	3.73	3.73	ng/mL	
32	ABC-123	PC	123-0001	32	Day 11	A554134-21	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	<0.1	ng/mL	<0.1		ng/mL	

Row	PCLLOQ	PCULOQ	VISITNUM	VISIT	VISITDY	PCDTC	PCENDTC	PCDY	PCTPT	PCTPTNUM	PCTPTREF	PCRFTDTC	PCELTMT	PCEVLINT
1 (cont)	0.10	20	1	DAY 1	1	2001-02-01T07:45		1	PREDOSE	0	Day 1 Dose	2001-02-01T08:00	-PT15M	
2 (cont)	0.10	20	1	DAY 1	1	2001-02-01T07:45		1	PREDOSE	0	Day 1 Dose	2001-02-01T08:00	-PT15M	
3 (cont)	2.00	500	1	DAY 1	1	2001-02-01T07:45	2001-02-01T07:45	1	PREDOSE	0	Day 1 Dose	2001-02-01T08:00	-PT15M	
4 (cont)	2.00	500	1	DAY 1	1	2001-02-01T07:45	2001-02-01T07:45	1	PREDOSE	0	Day 1 Dose	2001-02-01T08:00	-PT15M	
5 (cont)			1	DAY 1	1	2001-02-01T07:45	2001-02-01T07:45	1	PREDOSE	0	Day 1 Dose	2001-02-01T08:00	-PT15M	
6 (cont)			1	DAY 1	1	2001-02-01T07:45	2001-02-01T07:45	1	PREDOSE	0	Day 1 Dose	2001-02-01T08:00	-PT15M	
7 (cont)	0.10	20	1	DAY 1	1	2001-02-01T09:30		1	1H30MIN	1.5	Day 1 Dose	2001-02-01T08:00	PT1H30M	
8 (cont)	0.10	20	1	DAY 1	1	2001-02-01T09:30		1	1H30MIN	1.5	Day 1 Dose	2001-02-01T08:00	PT1H30M	
9 (cont)	0.10	20	1	DAY 1	1	2001-02-01T14:00		1	6H	6	Day 1 Dose	2001-02-01T08:00	PT6H00M	
10 (cont)	0.10	20	1	DAY 1	1	2001-02-01T14:00		1	6H	6	Day 1 Dose	2001-02-01T08:00	PT6H	

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Row	PCLLOQ	PCULOQ	VISITNUM	VISIT	VISITDY	PCDTC	PCENDTC	PCDY	PCTPT	PCTPTNUM	PCTPTREF	PCRFDTDC	PCELTM	PCEVLINT
11 (cont)		20	2	DAY 2	2	2001-02-02T08:00		2	24H	24	Day 1 Dose	2001-02-01T08:00	PT24H	
12 (cont)	0.10	20	2	DAY 2	2	2001-02-02T08:00		2	24H	24	Day 1 Dose	2001-02-01T08:00	PT24H	
13 (cont)	0.10	20	3	DAY 11	11	2001-02-11T07:45		11	PREDOSE	0	Day 11 Dose	2001-02-11T08:00	-PT15M	
14 (cont)	0.10	20	3	DAY 11	11	2001-02-11T07:45		11	PREDOSE	0	Day 11 Dose	2001-02-11T08:00	-PT15M	
15 (cont)	0.10	20	3	DAY 11	11	2001-02-11T09:30		11	1H30MIN	1.5	Day 11 Dose	2001-02-11T08:00	PT1H30M	
16 (cont)	0.10	20	3	DAY 11	11	2001-02-11T09:30		11	1H30MIN	1.5	Day 11 Dose	2001-02-11T08:00	PT1H30M	
17 (cont)	2.00	500	3	DAY 11	11	2001-02-11T08:00	2001-02-11T14:03	11	6H	6	Day 11 Dose	2001-02-11T08:00	PT6H	-PT6H
18 (cont)	2.00	500	3	DAY 11	11	2001-02-11T08:00	2001-02-11T14:03	11	6H	6	Day 11 Dose	2001-02-11T08:00	PT6H	-PT6H
19 (cont)			3	DAY 11	11	2001-02-11T08:00	2001-02-11T14:03	11	6H	6	Day 11 Dose	2001-02-11T08:00	PT6H	-PT6H
20 (cont)			3	DAY 11	11	2001-02-11T08:00	2001-02-11T14:03	11	6H	6	Day 11 Dose	2001-02-11T08:00	PT6H	-PT6H
21 (cont)	0.10	20	3	DAY 11	11	2001-02-11T14:00		11	6H	6	Day 11 Dose	2001-02-11T08:00	PT6H	
22 (cont)	0.10	20	3	DAY 11	11	2001-02-11T14:00		11	6H	6	Day 11 Dose	2001-02-11T08:00	PT6H	
23 (cont)	2.00		3	DAY 11	11	2001-02-11T14:03	2001-02-11T20:10	11	12H	12	Day 11 Dose	2001-02-11T08:00	PT12H	-PT6H
24 (cont)	2.00		3	DAY 11	11	2001-02-11T14:03	2001-02-11T20:10	11	12H	12	Day 11 Dose	2001-02-11T08:00	PT12H	-PT6H
25 (cont)			3	DAY 11	11	2001-02-11T14:03	2001-02-11T20:10	11	12H	12	Day 11 Dose	2001-02-11T08:00	PT12H	-PT6H
26 (cont)			3	DAY 11	11	2001-02-11T14:03	2001-02-11T20:10	11	12H	12	Day 11 Dose	2001-02-11T08:00	PT12H	-PT6H
27 (cont)	2.00		4	DAY 12	12	2001-02-11T20:03	2001-02-12T08:10	12	24H	24	Day 11 Dose	2001-02-11T08:00	PT24H	-P12H
28 (cont)	2.00		4	DAY 12	12	2001-02-11T20:03	2001-02-12T08:10	12	24H	24	Day 11 Dose	2001-02-11T08:00	PT24H	-P12H
29 (cont)			4	DAY 12	12	2001-02-11T20:03	2001-02-12T08:10	12	24H	24	Day 11 Dose	2001-02-11T08:00	PT24H	-P12H
30 (cont)			4	DAY 12	12	2001-02-11T20:03	2001-02-12T08:10	12	24H	24	Day 11 Dose	2001-02-11T08:00	PT24H	-P12H
31 (cont)	0.10	20	4	DAY 12	12	2001-02-12T08:00		12	24H	24	Day 11 Dose	2001-02-11T08:00	PT24H	
32 (cont)	0.10	20	4	DAY 12	12	2001-02-12T08:00		12	24H	24	Day 11 Dose	2001-02-11T08:00	PT24H	

Pharmacokinetics Parameters (PP)

PP – Description/Overview for Pharmacokinetics Parameters Domain Model

Pharmacokinetic parameters derived from pharmacokinetic concentration-time (PC) data.

PP – Specification for Pharmacokinetics Parameters Domain Model

pp.xpt, Pharmacokinetic Parameters — Findings, Version 3.2. One record per PK parameter per time-concentration profile per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	PP	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Unique subject identifier within the submission.	Req
PPSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
PPGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain to support relationships within the domain and between domains.	Perm
PPTTESTCD	Parameter Short Name	Char	(PKPARAMCD)	Topic	Short name of the pharmacokinetic parameter. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PPTTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). PPTTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: AUCALL, TMAX, CMAX.	Req
PPTTEST	Parameter Name	Char	(PKPARAM)	Synonym Qualifier	Name of the pharmacokinetic parameter. The value in PPTTEST cannot be longer than 40 characters. Examples: AUC All, Time of CMAX, Max Conc.	Req
PPCAT	Parameter Category	Char	*	Grouping Qualifier	Used to define a category of related records. For PP, this should be the name of the analyte in PCTEST whose profile the parameter is associated with.	Exp
PPSCAT	Parameter Subcategory	Char	*	Grouping Qualifier	Categorization of the model type used to calculate the PK parameters. Examples include COMPARTMENTAL, NON-COMPARTMENTAL.	Perm
PPORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
PPORRESU	Original Units	Char	(PKUNIT)	Variable Qualifier	Original units in which the data were collected. The unit for PPORRES. Example: ng/L.	Exp
PPSTRESC	Character Result/Finding in Standard Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from PPORRES in a standard format or standard units. PPSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in PPSTRESN.	Exp
PPSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from PPSTRESC. PPSTRESN should store all numeric test results or findings.	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
PPSTRESU	Standard Units	Char	(PKUNIT)	Variable Qualifier	Standardized unit used for PPSTRESC and PPSTRESN.	Exp
PPSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a parameter was not calculated. Should be null if a result exists in PPORRES.	Perm
PPREASND	Reason Parameter Not Calculated	Char		Record Qualifier	Describes why a parameter was not calculated, such as INSUFFICIENT DATA. Used in conjunction with PPSTAT when value is NOT DONE.	Perm
PPSPEC	Specimen Material Type	Char	(SPECTYPE)	Record Qualifier	Defines the type of specimen used for a measurement. If multiple specimen types are used for a calculation (e.g., serum and urine for renal clearance), then this field should be left blank. Examples: SERUM, PLASMA, URINE.	Exp
PPDTC	Date/Time of Parameter Calculations	Char	ISO 8601	Timing	Nominal date/time of parameter calculations.	Perm
PPRFTDTC	Date/Time of Reference Point	Char	ISO 8601	Timing	Date/time of the reference time point from the PC records used to calculate a parameter record. The values in PPRFTDTC should be the same as that in PCRFTDTC for related records.	Exp
PPSTINT	Planned Start of Assessment Interval	Char	ISO 8601	Timing	The start of a planned evaluation or assessment interval relative to the Time Point Reference.	Perm
PPENINT	Planned End of Assessment Interval	Char	ISO 8601	Timing	The end of a planned evaluation or assessment interval relative to the Time Point Reference.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

PP – Assumptions for Pharmacokinetics Parameters Domain Model

1. PP Definition: Data describing the parameters of the time-concentration curve for PC data (e.g., area under the curve all, maximum concentration, time of maximum observed concentration sampled during a dosing interval).
2. It is recognized that PP is a derived dataset, and may be produced from an analysis dataset that might have a different structure. As a result, some sponsors may need to normalize their analysis dataset in order for it to fit into the SDTM-based PP domain.
3. The structure is one record per PK parameter per time-concentration profile per subject
4. Information pertaining to all parameters (e.g., number of exponents, model weighting) should be submitted in the SUPPPP dataset.
5. The following Qualifiers would not generally be used in PP: --BODSYS, --SEV.

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PP – Examples for Pharmacokinetics Parameters Domain Model

Example 1

This example shows PK parameters calculated from time-concentration profiles for parent drug and one metabolite in plasma and urine for one subject on Days 1 (Rows 1-12) and 8 (Rows 13-24). Note that PPRFTDTC is populated in order to link the PP records to the respective PC records. Note that PPSPEC is null for Clearance (PPTESTCD = CLO) records since it is calculated from multiple specimen sources (plasma and urine).

Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPGRPID	PPTESTCD	PPTEST	PPCAT	PPORRES	PPORRESU
1	ABC-123	PP	ABC-123-0001	1	DAY1_PAR	TMAX	Time of CMAX	DRUG A PARENT	1.87	h
2	ABC-123	PP	ABC-123-0001	2	DAY1_PAR	CMAX	Max Conc	DRUG A PARENT	44.5	ug/L
3	ABC-123	PP	ABC-123-0001	3	DAY1_PAR	AUCALL	AUC All	DRUG A PARENT	294.7	h*mg/L
4	ABC-123	PP	ABC-123-0001	4	DAY1_PAR	LAMZHL	Half-Life Lambda z	DRUG A PARENT	0.75	h
5	ABC-123	PP	ABC-123-0001	5	DAY1_PAR	VZO	Vz Obs	DRUG A PARENT	10.9	L
6	ABC-123	PP	ABC-123-0001	6	DAY1_PAR	CLO	Total CL Obs	DRUG A PARENT	1.68	L/h
7	ABC-123	PP	ABC-123-0001	7	DAY1_MET	TMAX	Time of CMAX	DRUG A METABOLITE	0.94	h
8	ABC-123	PP	ABC-123-0001	8	DAY1_MET	CMAX	Max Conc	DRUG A METABOLITE	22.27	ug/L
9	ABC-123	PP	ABC-123-0001	9	DAY1_MET	AUCALL	AUC All	DRUG A METABOLITE	147.35	h*mg/L
10	ABC-123	PP	ABC-123-0001	10	DAY1_MET	LAMZHL	Half-Life Lambda z	DRUG A METABOLITE	0.38	h
11	ABC-123	PP	ABC-123-0001	11	DAY1_MET	VZO	Vz Obs	DRUG A METABOLITE	5.45	L
12	ABC-123	PP	ABC-123-0001	12	DAY1_MET	CLO	Total CL Obs	DRUG A METABOLITE	0.84	L/h
13	ABC-123	PP	ABC-123-0001	13	DAY11_PAR	TMAX	Time of CMAX	DRUG A PARENT	1.91	h
14	ABC-123	PP	ABC-123-0001	14	DAY11_PAR	CMAX	Max Conc	DRUG A PARENT	46.0	ug/L
15	ABC-123	PP	ABC-123-0001	15	DAY11_PAR	AUCALL	AUC All	DRUG A PARENT	289.0	h*mg/L
16	ABC-123	PP	ABC-123-0001	16	DAY11_PAR	LAMZHL	Half-Life Lambda z	DRUG A PARENT	0.77	h
17	ABC-123	PP	ABC-123-0001	17	DAY11_PAR	VZO	Vz Obs	DRUG A PARENT	10.7	L
18	ABC-123	PP	ABC-123-0001	18	DAY11_PAR	CLO	Total CL Obs	DRUG A PARENT	1.75	L/h
19	ABC-123	PP	ABC-123-0001	19	DAY11_MET	TMAX	Time of CMAX	DRUG A METABOLITE	0.96	h
20	ABC-123	PP	ABC-123-0001	20	DAY11_MET	CMAX	Max Conc	DRUG A METABOLITE	23.00	ug/L
21	ABC-123	PP	ABC-123-0001	21	DAY11_MET	AUCALL	AUC All	DRUG A METABOLITE	144.50	h*mg/L
22	ABC-123	PP	ABC-123-0001	22	DAY11_MET	LAMZHL	Half-Life Lambda z	DRUG A METABOLITE	0.39	h
23	ABC-123	PP	ABC-123-0001	23	DAY8_MET	VD	Vol of Distribution	DRUG A METABOLITE	5.35	L
24	ABC-123	PP	ABC-123-0001	24	DAY8_MET	CL	Clearance	DRUG A METABOLITE	0.88	L/h

Row	PPSTRESC	PPSTRESN	PPSTRESU	PPSPEC	VISITNUM	VISIT	PPDTC	PPRFTDTC
1 (cont)	1.87	1.87	H	PLASMA	1	DAY 1	2001-03-01	2001-02-01T08:00
2 (cont)	44.5	44.5	ug/L	PLASMA	1	DAY 1	2001-03-01	2001-02-01T08:00
3 (cont)	294.7	294.7	h.mg/L	PLASMA	1	DAY 1	2001-03-01	2001-02-01T08:00
4 (cont)	0.75	0.75	H	PLASMA	1	DAY 1	2001-03-01	2001-02-01T08:00
5 (cont)	10.9	10.9	L	PLASMA	1	DAY 1	2001-03-01	2001-02-01T08:00
6 (cont)	1.68	1.68	L/h		1	DAY 1	2001-03-01	2001-02-01T08:00
7 (cont)	0.94	0.94	h	PLASMA	1	DAY 1	2001-03-01	2001-02-01T08:00
8 (cont)	22.27	22.27	ug/L	PLASMA	1	DAY 1	2001-03-01	2001-02-01T08:00
9 (cont)	147.35	147.35	h.mg/L	PLASMA	1	DAY 1	2001-03-01	2001-02-01T08:00
10 (cont)	0.38	0.38	h	PLASMA	1	DAY 1	2001-03-01	2001-02-01T08:00
11 (cont)	5.45	5.45	L	PLASMA	1	DAY 1	2001-03-01	2001-02-01T08:00

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Row	PPSTRESC	PPSTRESN	PPSTRESU	PPSPEC	VISITNUM	VISIT	PPDTC	PPRFTDTC
12 (cont)	0.84	0.84	L/h		1	DAY 1	2001-03-01	2001-02-01T08:00
13 (cont)	1.91	1.91	h	PLASMA	2	DAY 11	2001-03-01	2001-02-11T08:00
14 (cont)	46.0	46.0	ug/L	PLASMA	2	DAY 11	2001-03-01	2001-02-11T08:00
15 (cont)	289.0	289.0	h.mg/L	PLASMA	2	DAY 11	2001-03-01	2001-02-11T08:00
16 (cont)	0.77	0.77	h	PLASMA	2	DAY 11	2001-03-01	2001-02-11T08:00
17 (cont)	10.7	10.7	L	PLASMA	2	DAY 11	2001-03-01	2001-02-11T08:00
18 (cont)	1.75	1.75	L/h		2	DAY 11	2001-03-01	2001-02-11T08:00
19 (cont)	0.96	0.96	h	PLASMA	2	DAY 11	2001-03-01	2001-02-11T08:00
20 (cont)	23.00	23.00	ug/L	PLASMA	2	DAY 11	2001-03-01	2001-02-11T08:00
21 (cont)	144.50	144.50	h.mg/L	PLASMA	2	DAY 11	2001-03-01	2001-02-11T08:00
22 (cont)	0.39	0.39	h	PLASMA	2	DAY 11	2001-03-01	2001-02-11T08:00
23 (cont)	5.35	5.35	L	PLASMA	2	DAY 11	2001-03-01	2001-02-11T08:00
24 (cont)	0.88	0.88	L/h		2	DAY 11	2001-03-01	2001-02-11T08:00

Example 2

This example shows PK parameters calculated from time-concentration profiles for parent drug (Drug A) from one subject on Days 1 (Rows 1-7) and 14 (Rows 8-14). This example shows the use of PPSTINT and PPENINT to describe the AUC segments referred to in AUCINT.

Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPGRPID	PPTSTCD	PPTST	PPCAT	PPORRES	PPORRESU
1	ABC-123	PP	ABC-123-001	1	DRUGA_DAY1	TMAX	Time of CMAX	DRUG A PARENT	0.65	h
2	ABC-123	PP	ABC-123-001	2	DRUGA_DAY1	CMAX	Max Conc	DRUG A PARENT	6.92	ng/mL
3	ABC-123	PP	ABC-123-001	3	DRUGA_DAY1	AUCALL	AUC All	DRUG A PARENT	45.5	h*ng/mL
4	ABC-123	PP	ABC-123-001	4	DRUGA_DAY1	AUCINT	AUC from T1 to T2	DRUG A PARENT	43.6	h*ng/mL
5	ABC-123	PP	ABC-123-001	5	DRUGA_DAY1	LAMZHL	Half-Life Lambda z	DRUG A PARENT	7.74	h
6	ABC-123	PP	ABC-123-001	6	DRUGA_DAY1	VZFO	Vz Obs by F	DRUG A PARENT	256	L
7	ABC-123	PP	ABC-123-001	7	DRUGA_DAY1	CLFO	Total CL Obs by F	DRUG A PARENT	20.2	L/hr
8	ABC-123	PP	ABC-123-001	15	DRUGA_DAY14	TMAX	Time of CMAX	DRUG A PARENT	0.65	h
9	ABC-123	PP	ABC-123-001	16	DRUGA_DAY14	CMAX	Max Conc	DRUG A PARENT	6.51	ng/mL
10	ABC-123	PP	ABC-123-001	17	DRUGA_DAY14	AUCALL	AUC All	DRUG A PARENT	34.2	h*ng/mL
11	ABC-123	PP	ABC-123-001	18	DRUGA_DAY14	AUCINT	AUC from T1 to T2	DRUG A PARENT	35.6	h*ng/mL
12	ABC-123	PP	ABC-123-001	19	DRUGA_DAY14	AUCINT	AUC from T1 to T2	DRUG A PARENT	38.4	h*ng/mL
13	ABC-123	PP	ABC-123-001	20	DRUGA_DAY14	AUCINT	AUC from T1 to T2	DRUG A PARENT	2.78	h*ng/mL
14	ABC-123	PP	ABC-123-001	21	DRUGA_DAY14	LAMZHL	Half-Life Lambda z	DRUG A PARENT	7.6	h
15	ABC-123	PP	ABC-123-001	22	DRUGA_DAY14	VZFO	Vz Obs by F	DRUG A PARENT	283	L
16	ABC-123	PP	ABC-123-001	23	DRUGA_DAY14	CLFO	Total CL Obs by F	DRUG A PARENT	28.1	L/h

Row	PPSTRESC	PPSTRESN	PPSTRESU	PPSPEC	VISITNUM	VISIT	PPDTC	PPRFTDTC	PPSTINT	PPENINT
1 (cont)	0.65	0.65	h	PLASMA	1	DAY 1	2001-02-25	2001-02-01T08:00		
2 (cont)	6.92	6.92	ng/mL	PLASMA	1	DAY 1	2001-02-25	2001-02-01T08:00		
3 (cont)	45.5	45.5	h*ng/mL	PLASMA	1	DAY 1	2001-02-25	2001-02-01T08:00		
4 (cont)	43.6	43.6	h*ng/mL	PLASMA	1	DAY 1	2001-02-25	2001-02-01T08:00	PT0M	PT24H
5 (cont)	7.74	7.74	h	PLASMA	1	DAY 1	2001-02-25	2001-02-01T08:00		
6 (cont)	256000	256	L	PLASMA	1	DAY 1	2001-02-25	2001-02-01T08:00		

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7 (cont)	20200	20.2	L/h	PLASMA	1	DAY 1	2001-02-25	2001-02-01T08:00		
8 (cont)	0.65	0.65	h	PLASMA	2	DAY 14	2001-02-25	2001-02-15T08:00		
9 (cont)	6.51	6.51	ng/mL	PLASMA	2	DAY 14	2001-02-25	2001-02-15T08:00		
10 (cont)	34.2	34.2	h*ng/mL	PLASMA	2	DAY 14	2001-02-25	2001-02-15T08:00		
11 (cont)	35.6	35.6	h*ng/mL	PLASMA	2	DAY 14	2001-02-25	2001-02-15T08:00	PT0M	PT24H
12 (cont)	38.4	38.4	h*ng/mL	PLASMA	2	DAY 14	2001-02-25	2001-02-15T08:00	PT0M	PT48H
13 (cont)	2.78	2.78	h*ng/mL	PLASMA	2	DAY 14	2001-02-25	2001-02-15T08:00	PT24H	PT48H
14 (cont)	7.6	7.6	h	PLASMA	2	DAY 14	2001-02-25	2001-02-15T08:00		
15 (cont)	283	283	L	PLASMA	2	DAY 14	2001-02-25	2001-02-15T08:00		
16 (cont)	28.1	28.1	L/h	PLASMA	2	DAY 14	2001-02-25	2001-02-15T08:00		

PC-PP – Relating PP Records to PC Records

It is a requirement that sponsors document the concentrations used to calculate each parameter. For many sponsors, this need is currently met via the analysis metadata. As a result of feedback received from many sponsors on the draft version of this document, sponsors may continue to document the concentrations used to calculate each parameter via the analysis datasets.

This section serves as a reference for sponsors who wish to document relationships between PK parameter records in a Pharmacokinetic Parameter (PP) dataset and specific time-point concentration records in a Pharmacokinetic Concentration (PC) dataset according to the SDTM using the RELREC table [*Section 8: 8.2, Relating Peer Records* and *Section 8: 8.3, Relating Datasets*].

PC-PP – Relating Datasets

If all time-point concentrations in PC are used to calculate all parameters for all subjects, then the relationship between the two datasets can be documented as shown in the table below.

RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
PC		PCGRPID		MANY	A
PP		PPGRPID		MANY	A

Note that incorporating the name of the analyte and the day of the collection into the value of --GRPID (or some equivalent method for assigning different values of --GRPID for all the combinations of analytes and reference time points) is necessary when there is more than one reference time point (PCRFTDTC and PPRFTDTC, which are the same for related records), and more than one analyte (PCTESTCD, copied into PPCAT to indicate the analyte with which the parameters are associated), since these variables are part of the natural key [*see Section 3: 3.2.1.1, Primary Keys*] for both datasets. In this case, --GRPID is a surrogate key [*see Section 3: 3.2.1.1, Primary Keys*] used for the relationship.

PC-PP – Relating Records

Four possible examples of different types of relationships between PC and PP records for one drug (DRUG X in this case) are described. For all of these, the actual PC and PP data are the same. The only variables whose values change across the examples are the sponsor-defined PCGRPID and PPGRPID. As in the case for relating datasets above, --GRPID values must take into account all the combinations of analytes and reference time points, since both are part of the natural key [*see Section 3: 3.2.1.1, Primary Keys*] for both datasets. To conserve space, the PC and PP domains appear only once, but with four --GRPID columns, one for each of the examples. Note that a submission dataset would contain only one --GRPID column with a set of values such as those shown in one of the four columns in the PC and PP datasets, or values defined by the sponsor. Note that --GRPID values in PC and PP do not need to be the same (e.g., examples show PC with underscores and PP without underscores). The example specifics are as follows:

Example 1: All PK time-point-concentration values in the PC dataset are used to calculate all the PK parameters in the PP dataset for both Days 1 and 8 for one subject.

Pharmacokinetic Concentrations (PC) Dataset For All Examples

Pharmacokinetic Parameters (PP) Dataset For All Examples

RELREC Example 1. All PC records used to calculate all PK parameters

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

Example 2: Two PC values were excluded from the calculation of all PK parameters for the Day 1 data. Day 8 values are related as per Example 1.

RELREC Example 2: Only some records in PC used to calculate all PK parameters

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

Example 3: Two PC values were excluded from the calculation of two PK parameters, but used in the others for Day 1. Day 8 values are related as per Example 1.

RELREC Example 3. Only some records in PC used to calculate some parameters

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

Example 4: Only Some PC records for Day 1 were used to calculate parameters: Time Point 5 was excluded from Tmax, Time Point 6 from Cmax, and Time Points 11 and 12 were excluded from AUC. Day 8 values are related as per Example 1.

RELREC Example 4: Only Some records in PC used to calculate parameters

- Method A (Many to many, using PCGRPID and PPGRPID)
- Method B (One to many omitted - see note below)
- Method C (Many to one omitted - see note below)
- Method D (One to one, using PCSEQ and PPSEQ)

For each example, PCGRPID and PPGRPID were used to group related records within each respective dataset. The values for these, as well as the values for PCSEQ and PPSEQ, were then used to populate combinations of IDVAR and IDVARVAL in the RELREC table using four methods (A-D) for Examples 1-3. Only two methods (A and D) are shown for Example 4, due to its complexity. Since the relationship between PC records and PP records for Day 8 data does not change across the examples, it is shown only for Example 1, and not repeated.

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Data For All Examples

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Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCGRPID	PCGRPID	PCGRPID	PCGRPID	PCREFID	PCTESTCD	PCTEST	PCCAT	PCSPEC	PCORRES	PCORRESU
					Example 1	Example 2	Example 3	Example 4							
1	ABC-123	PC	ABC-123-0001	1	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-01	DRUG X	Study Drug	ANALYTE	PLASMA	9	ug/mL
2	ABC-123	PC	ABC-123-0001	2	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-02	DRUG X	Study Drug	ANALYTE	PLASMA	20	ug/mL
3	ABC-123	PC	ABC-123-0001	3	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-03	DRUG X	Study Drug	ANALYTE	PLASMA	31	ug/mL
4	ABC-123	PC	ABC-123-0001	4	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-04	DRUG X	Study Drug	ANALYTE	PLASMA	38	ug/mL
5	ABC-123	PC	ABC-123-0001	5	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_B	123-0001-05	DRUG X	Study Drug	ANALYTE	PLASMA	45	ug/mL
6	ABC-123	PC	ABC-123-0001	6	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_C	123-0001-06	DRUG X	Study Drug	ANALYTE	PLASMA	47.5	ug/mL
7	ABC-123	PC	ABC-123-0001	7	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-07	DRUG X	Study Drug	ANALYTE	PLASMA	41	ug/mL
8	ABC-123	PC	ABC-123-0001	8	DY1_DRGX	EXCLUDE	DY1_DRGX_B	DY1_DRGX_A	123-0001-08	DRUG X	Study Drug	ANALYTE	PLASMA	35	ug/mL
9	ABC-123	PC	ABC-123-0001	9	DY1_DRGX	EXCLUDE	DY1_DRGX_B	DY1_DRGX_A	123-0001-09	DRUG X	Study Drug	ANALYTE	PLASMA	31	ug/mL
10	ABC-123	PC	ABC-123-0001	10	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_A	123-0001-10	DRUG X	Study Drug	ANALYTE	PLASMA	25	ug/mL
11	ABC-123	PC	ABC-123-0001	11	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_D	123-0001-11	DRUG X	Study Drug	ANALYTE	PLASMA	18	ug/mL
12	ABC-123	PC	ABC-123-0001	12	DY1_DRGX	DY1_DRGX	DY1_DRGX_A	DY1_DRGX_D	123-0001-12	DRUG X	Study Drug	ANALYTE	PLASMA	12	ug/mL
13	ABC-123	PC	ABC-123-0001	13			DY11_DRGX		123-0002-13	DRUG X	Study Drug	ANALYTE	PLASMA	10.0	ug/mL
14	ABC-123	PC	ABC-123-0001	14			DY11_DRGX		123-0002-14	DRUG X	Study Drug	ANALYTE	PLASMA	21.0	ug/mL
15	ABC-123	PC	ABC-123-0001	15			DY11_DRGX		123-0002-15	DRUG X	Study Drug	ANALYTE	PLASMA	32.0	ug/mL
16	ABC-123	PC	ABC-123-0001	16			DY11_DRGX		123-0002-16	DRUG X	Study Drug	ANALYTE	PLASMA	39.0	ug/mL
17	ABC-123	PC	ABC-123-0001	17			DY11_DRGX		123-0002-17	DRUG X	Study Drug	ANALYTE	PLASMA	46.0	ug/mL
18	ABC-123	PC	ABC-123-0001	18			DY11_DRGX		123-0002-18	DRUG X	Study Drug	ANALYTE	PLASMA	48.0	ug/mL
19	ABC-123	PC	ABC-123-0001	19			DY11_DRGX		123-0002-19	DRUG X	Study Drug	ANALYTE	PLASMA	40.0	ug/mL
20	ABC-123	PC	ABC-123-0001	20			DY11_DRGX		123-0002-20	DRUG X	Study Drug	ANALYTE	PLASMA	35.0	ug/mL
21	ABC-123	PC	ABC-123-0001	21			DY11_DRGX		123-0002-21	DRUG X	Study Drug	ANALYTE	PLASMA	30.0	ug/mL
22	ABC-123	PC	ABC-123-0001	22			DY11_DRGX		123-0002-22	DRUG X	Study Drug	ANALYTE	PLASMA	24.0	ug/mL
23	ABC-123	PC	ABC-123-0001	23			DY11_DRGX		123-0002-23	DRUG X	Study Drug	ANALYTE	PLASMA	17.0	ug/mL
24	ABC-123	PC	ABC-123-0001	24			DY11_DRGX		123-0002-24	DRUG X	Study Drug	ANALYTE	PLASMA	11.0	ug/mL

Row	PCSTRESC	PCSTRESN	PCSTRESU	PCCLLOQ	VISITNUM	VISIT	VISITDY	PCDTC	PCDY	PCTPT	PCTPTNUM	PCTPTREF	PCRFTDTC	PCELTM
1 (cont)	9	9	ug/mL	1.00	1	DAY 1	1	2001-02-01T08:35	1	5 min	1	Day 1 Dose	2001-02-01T08:30	PT5M
2 (cont)	20	20	ug/mL	1.00	1	DAY 1	1	2001-02-01T08:55	1	25 min	2	Day 1 Dose	2001-02-01T08:30	PT25M
3 (cont)	31	31	ug/mL	1.00	1	DAY 1	1	2001-02-01T09:20	1	50 min	3	Day 1 Dose	2001-02-01T08:30	PT50M
4 (cont)	38	38	ug/mL	1.00	1	DAY 1	1	2001-02-01T09:45	1	75 min	4	Day 1 Dose	2001-02-01T08:30	PT1H15M
5 (cont)	45	45	ug/mL	1.00	1	DAY 1	1	2001-02-01T10:10	1	100 min	5	Day 1 Dose	2001-02-01T08:30	PT1H40M
6 (cont)	47.5	47.5	ug/mL	1.00	1	DAY 1	1	2001-02-01T10:35	1	125 min	6	Day 1 Dose	2001-02-01T08:30	PT2H5M
7 (cont)	41	41	ug/mL	1.00	1	DAY 1	1	2001-02-01T11:00	1	150 min	7	Day 1 Dose	2001-02-01T08:30	PT2H30M
8 (cont)	35	35	ug/mL	1.00	1	DAY 1	1	2001-02-01T11:50	1	200 min	8	Day 1 Dose	2001-02-01T08:30	PT3H20M
9 (cont)	31	31	ug/mL	1.00	1	DAY 1	1	2001-02-01T12:40	1	250 min	9	Day 1 Dose	2001-02-01T08:30	PT4H10M
10 (cont)	25	25	ug/mL	1.00	1	DAY 1	1	2001-02-01T14:45	1	375 min	10	Day 1 Dose	2001-02-01T08:30	PT6H15M
11 (cont)	18	18	ug/mL	1.00	1	DAY 1	1	2001-02-01T16:50	1	500 min	11	Day 1 Dose	2001-02-01T08:30	PT8H20M
12 (cont)	12	12	ug/mL	1.00	1	DAY 1	1	2001-02-01T18:30	1	600 min	12	Day 1 Dose	2001-02-01T08:30	PT10H
13 (cont)	10.0	10.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T08:35	8	5 min	1	Day 8 Dose	2001-02-08T08:30	PT5M
14 (cont)	21.0	21.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T08:55	8	25 min	2	Day 8 Dose	2001-02-08T08:30	PT25M
15 (cont)	32.0	32.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T09:20	8	50 min	3	Day 8 Dose	2001-02-08T08:30	PT50M

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Row	PCSTRESC	PCSTRESN	PCSTRESU	PCLLOQ	VISITNUM	VISIT	VISITDY	PCDTC	PCDY	PCTPT	PCTPTNUM	PCTPTREF	PCRFTDTC	PCELTM
16 (cont)	39.0	39.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T09:45	8	75 min	4	Day 8 Dose	2001-02-08T08:30	PT1H15M
17 (cont)	46.0	46.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T10:10	8	100 min	5	Day 8 Dose	2001-02-08T08:30	PT1H40M
18 (cont)	48.0	48.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T10:35	8	125 min	6	Day 8 Dose	2001-02-08T08:30	PT2H5M
19 (cont)	40.0	40.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T11:00	8	150 min	7	Day 8 Dose	2001-02-08T08:30	PT2H30M
20 (cont)	35.0	35.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T11:50	8	200 min	8	Day 8 Dose	2001-02-08T08:30	PT3H20M
21 (cont)	30.0	30.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T12:40	8	250 min	9	Day 8 Dose	2001-02-08T08:30	PT4H10M
22 (cont)	24.0	24.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T14:45	8	375 min	10	Day 8 Dose	2001-02-08T08:30	PT6H15M
23 (cont)	17.0	17.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T16:50	8	500 min	11	Day 8 Dose	2001-02-08T08:30	PT8H20M
24 (cont)	11.0	11.0	ug/mL	1.00	2	DAY 8	8	2001-02-08T18:30	8	600 min	12	Day 8 Dose	2001-02-08T08:30	PT10H

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Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPDTC	PPGRPID	PPGRPID	PPGRPID	PPGRPID	PPTESTCD	PPTEST
						Example 1	Example 2	Example 3	Example 4		
1	ABC-123	PP	ABC-123-0001	1	2001-02-01T08:35	DY1DRGX	DY1DRGX	DY1DRGX_A	TMAX	TMAX	Time to Max Effect
2	ABC-123	PP	ABC-123-0001	2	2001-02-01T08:35	DY1DRGX	DY1DRGX	DY1DRGX_A	CMAX	CMAX	Max Effect Concentration
3	ABC-123	PP	ABC-123-0001	3	2001-02-01T08:35	DY1DRGX	DY1DRGX	DY1DRGX_A	AUC	AUC	Area Under Curve
4	ABC-123	PP	ABC-123-0001	4	2001-02-01T08:35	DY1DRGX	DY1DRGX	DY1DRGX_HALF	OTHER	T1/2, 1	Half-life of 1st exp phase
5	ABC-123	PP	ABC-123-0001	5	2001-02-01T08:35	DY1DRGX	DY1DRGX	DY1DRGX_HALF	OTHER	T1/2, 2	Half-life of 2nd exp phase
6	ABC-123	PP	ABC-123-0001	6	2001-02-01T08:35	DY1DRGX	DY1DRGX	DY1DRGX_A	OTHER	VD	Volume of Distribution
7	ABC-123	PP	ABC-123-0001	7	2001-02-01T08:35	DY1DRGX	DY1DRGX	DY1DRGX_A	OTHER	CL	Clearance
8	ABC-123	PP	ABC-123-0001	8	2001-02-08T08:35	DY11DRGX			TMAX	Time to Max Effect	
9	ABC-123	PP	ABC-123-0001	9	2001-02-08T08:35	DY11DRGX			CMAX	Max Effect Concentration	
10	ABC-123	PP	ABC-123-0001	10	2001-02-08T08:35	DY11DRGX			AUC	Area Under Curve	
11	ABC-123	PP	ABC-123-0001	11	2001-02-08T08:35	DY11DRGX			T1/2, 1	Half-life of 1st exp phase	
12	ABC-123	PP	ABC-123-0001	12	2001-02-08T08:35	DY11DRGX			T1/2, 2	Half-life of 2nd exp phase	
13	ABC-123	PP	ABC-123-0001	13	2001-02-08T08:35	DY11DRGX			VD	Volume of Distribution	
14	ABC-123	PP	ABC-123-0001	14	2001-02-08T08:35	DY11DRGX			CL	Clearance	

Row	PPCAT	PPORRES	PPORRESU	PPSTRESC	PPSTRESN	PPSTRESU
1 (cont)	DRUG X	1.87	h	1.87	1.87	h
2 (cont)	DRUG X	44.5	ng/mL	44.5	44.5	ng/mL
3 (cont)	DRUG X	294.7	h*ug/mL	294.7	294.7	h*ug/mL
4 (cont)	DRUG X	0.75	h	0.75	0.75	h
5 (cont)	DRUG X	4.69	h	4.69	4.69	h
6 (cont)	DRUG X	10.9	L	10.9	10.9	L
7 (cont)	DRUG X	1.68	L/h	1.68	1.68	L/h
8 (cont)	DRUG X	1.91	h	1.91	1.91	h
9 (cont)	DRUG X	46.0	ng/mL	46.0	46.0	ng/mL
10 (cont)	DRUG X	289.0	h*ug/mL	289.0	289.0	h*ug/mL
11 (cont)	DRUG X	0.77	h	0.77	0.77	h
12 (cont)	DRUG X	4.50	h	4.50	4.50	h
13 (cont)	DRUG X	10.7	L	10.7	10.7	L
14 (cont)	DRUG X	1.75	L/h	1.75	1.75	L/h

RELREC Example 1. All PC records used to calculate all PK parameters.

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

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID *
1	ABC-123	PC	ABC-123-0001	PCGRPID	DY1_DRGX		1
2	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX		1
3	ABC-123	PC	ABC-123-0001	PCGRPID	DY11_DRGX		2
4	ABC-123	PP	ABC-123-0001	PPGRPID	DY11DRGX		2

* RELID 1 indicates all PC records with PCGRPID = DY1_DRGX are related to all PP records with PPGRPID = DY1DRGX.

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

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

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID *
1	ABC-123	PC	ABC-123-0001	PCSEQ	1		1
2	ABC-123	PC	ABC-123-0001	PCSEQ	2		1
3	ABC-123	PC	ABC-123-0001	PCSEQ	3		1
4	ABC-123	PC	ABC-123-0001	PCSEQ	4		1
5	ABC-123	PC	ABC-123-0001	PCSEQ	5		1
6	ABC-123	PC	ABC-123-0001	PCSEQ	6		1
7	ABC-123	PC	ABC-123-0001	PCSEQ	7		1
8	ABC-123	PC	ABC-123-0001	PCSEQ	8		1
9	ABC-123	PC	ABC-123-0001	PCSEQ	9		1
10	ABC-123	PC	ABC-123-0001	PCSEQ	10		1
11	ABC-123	PC	ABC-123-0001	PCSEQ	11		1
12	ABC-123	PC	ABC-123-0001	PCSEQ	12		1
13	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX		1
14	ABC-123	PC	ABC-123-0001	PCSEQ	13		2
15	ABC-123	PC	ABC-123-0001	PCSEQ	14		2
16	ABC-123	PC	ABC-123-0001	PCSEQ	15		2
17	ABC-123	PC	ABC-123-0001	PCSEQ	16		2
18	ABC-123	PC	ABC-123-0001	PCSEQ	17		2
19	ABC-123	PC	ABC-123-0001	PCSEQ	18		2
20	ABC-123	PC	ABC-123-0001	PCSEQ	19		2
21	ABC-123	PC	ABC-123-0001	PCSEQ	20		2
22	ABC-123	PC	ABC-123-0001	PCSEQ	21		2
23	ABC-123	PC	ABC-123-0001	PCSEQ	22		2
24	ABC-123	PC	ABC-123-0001	PCSEQ	23		2
25	ABC-123	PC	ABC-123-0001	PCSEQ	24		2
26	ABC-123	PP	ABC-123-0001	PPGRPID	DY8DRGX		2

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

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

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

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

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

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

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

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

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

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

RELREC Example 2: Only some records in PC used to calculate all PK parameters: Time Points 8 and 9 on Day 1 not used for any PK parameters.

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

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

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

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

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

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

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

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID *
8	ABC-123	PC	ABC-123-0001	PCSEQ	10		1
9	ABC-123	PC	ABC-123-0001	PCSEQ	11		1
10	ABC-123	PC	ABC-123-0001	PCSEQ	12		1
11	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX		1

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

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

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

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

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

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

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

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

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

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

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

RELREC Example 3. Only some records in PC used to calculate some parameters: Time Points 8 and 9 on Day 1 not used for half-life calculations, but used for other parameters.

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

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

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

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

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

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

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

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID *
5	ABC-123	PC	ABC-123-0001	PCSEQ	5		1
6	ABC-123	PC	ABC-123-0001	PCSEQ	6		1
7	ABC-123	PC	ABC-123-0001	PCSEQ	7		1
8	ABC-123	PC	ABC-123-0001	PCSEQ	8		1
9	ABC-123	PC	ABC-123-0001	PCSEQ	9		1
10	ABC-123	PC	ABC-123-0001	PCSEQ	10		1
11	ABC-123	PC	ABC-123-0001	PCSEQ	11		1
12	ABC-123	PC	ABC-123-0001	PCSEQ	12		1
13	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX_A		1
14	ABC-123	PC	ABC-123-0001	PCSEQ	1		2
15	ABC-123	PC	ABC-123-0001	PCSEQ	2		2
16	ABC-123	PC	ABC-123-0001	PCSEQ	3		2
17	ABC-123	PC	ABC-123-0001	PCSEQ	4		2
18	ABC-123	PC	ABC-123-0001	PCSEQ	5		2
19	ABC-123	PC	ABC-123-0001	PCSEQ	6		2
20	ABC-123	PC	ABC-123-0001	PCSEQ	7		2
21	ABC-123	PC	ABC-123-0001	PCSEQ	10		2
22	ABC-123	PC	ABC-123-0001	PCSEQ	11		2
23	ABC-123	PC	ABC-123-0001	PCSEQ	12		2
24	ABC-123	PP	ABC-123-0001	PPGRPID	DY1DRGX_HALF		2

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

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

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

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

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

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

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

* RELID 2 indicates records with a PCGRPID value of DAYDY1DRGX_A are related to records with PPSEQ values of 4 and 5.

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

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

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20	ABC-123	PC	ABC-123-0001	PCSEQ	3		2
21	ABC-123	PC	ABC-123-0001	PCSEQ	4		2
22	ABC-123	PC	ABC-123-0001	PCSEQ	5		2
23	ABC-123	PC	ABC-123-0001	PCSEQ	6		2
24	ABC-123	PC	ABC-123-0001	PCSEQ	7		2
25	ABC-123	PC	ABC-123-0001	PCSEQ	10		2
26	ABC-123	PC	ABC-123-0001	PCSEQ	11		2
27	ABC-123	PC	ABC-123-0001	PCSEQ	12		2
28	ABC-123	PP	ABC-123-0001	PPSEQ	4		2
29	ABC-123	PP	ABC-123-0001	PPSEQ	5		2

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

* RELID 1 indicates records with PCSEQ values of 1-12 are related to records with PPSEQ values of 1-3 and 6-7.

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

RELREC Example 4: Only Some records in PC used to calculate parameters: Time Point 5 excluded from Tmax, 6 from Cmax, and Time Points 11 and 12 from AUC

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

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

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

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

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

* Same RELID of "3" Indicates that AUC used PCGRPID values DY1DRGX_A, DY1DRGX_B, and DY1DRGX_C.

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

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

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

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

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

- * RELID 1 indicates records with PCSEQ values of 1-4 and 6-12 are related to the record with a PPSEQ value of 1.
- * RELID 2 indicates records with PCSEQ values of 1-5 and 7-12 are related to the record with a PPSEQ value of 2.
- * RELID 3 indicates records with PCSEQ values of 1-10 are related to the record with a PPSEQ value of 3.
- * RELID 4 indicates records with PCSEQ values of 1-12 are related to the records with PPSEQ values of 4-7.

PC-PP – Conclusions

Relating the datasets [*Section 8: 8.3, Relating Datasets*] is the simplest method; however, all time-point concentrations in PC must be used to calculate all parameters for all subjects. If datasets cannot be related, then individual subject records must be related [*Section 8: 8.2, Relating Peer Records*]. In either case, the values of PCGRPID and PPGRPID must take into account multiple analytes and multiple reference time points, if they exist.

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

Please note that an attempt has been made to approximate real PK data; however, the example values are not intended to reflect data used for actual analysis. When certain time-point concentrations have been omitted from PP calculations in Examples 2-4, the actual parameter values in the PP dataset have not been recalculated from those in Example 1 to reflect those omissions.

PC-PP – Suggestions for Implementing RELREC in the Submission of PK Data

Determine which of the scenarios best reflects how PP data are related to PC data. Questions that should be considered:

1. Do all parameters for each PK profile use all concentrations for all subjects? If so, create a PPGRPID value for all PP records and a PCGRPID value for all PC records for each profile for each subject, analyte, and reference time point. Decide whether to relate datasets or records. If choosing the latter, create records in RELREC for each PCGRPID value and each PPGRPID value (Method A). Use RELID to show which PCGRPID and PPGRPID records are related. Consider RELREC Methods B, C, and D as applicable.
2. Do all parameters use the same concentrations, although maybe not all of them (Example 2)? If so, create a single PPGRPID value for all PP records, and two PCGRPID values for the PC records: a PCGRPID value for ones that were used and a PCGRPID value for those that were not used. Create records in RELREC for each PCGRPID value and each PPGRPID value (Method A). Use RELID to show which PCGRPID and PPGRPID records are related. Consider RELREC Methods B, C, and D as applicable.
3. Do any parameters use the same concentrations, but not as consistently as what is shown in Examples 1 and 2? If so, refer to Example 3. Assign a GRPID value to the PP records that use the same concentrations. More than one PPGRPID value may be necessary. Assign as many PCGRPID values in the PC domain as needed to group these records. Create records in RELREC for each PCGRPID value and each PPGRPID value (Method A). Use RELID to show which PCGRPID and PPGRPID records are related. Consider RELREC Methods B, C, and D as applicable.
4. If none of the above applies, or the data become difficult to group, then start with Example 4, and decide which RELREC method would be easiest to implement and represent.

6 Domain Models Based on the General Observation Classes

6.3 Findings

Physical Examination (PE)

PE – Description/Overview for Physical Examination Domain Model

Findings collected during a physical examination of the subject. It has findings that are discovered that are related to body systems. Does not include vital signs measurements, which are stored in the vital signs domain.

PE – Specification for Physical Examination Domain Model

pe.xpt, Physical Examination — Findings, Version 3.2. One record per body system or abnormality per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	PE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
PESEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
PEGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
PESPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a CRF.	Perm
PETESTCD	Body System Examined Short Name	Char	*	Topic	Short name of the measurement, test, or examination described in PETEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g. "1TEST"). PETESTCD cannot contain characters other than letters, numbers, or underscores.	Req
PETEST	Body System Examined	Char	*	Synonym Qualifier	Verbatim term part of the body examined. The value in PETEST cannot be longer than 40 characters. Examples: Cardiovascular and Respiratory. For subject-level exam, value should be "Physical Examination".	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
PEMODIFY	Modified Reported Term	Char		Synonym Qualifier	If PEORRES is modified as part of a defined procedure, then PEMODIFY will contain the modified text.	Perm
PECAT	Category for Examination	Char	*	Grouping Qualifier	Used to define a category of examination. Examples: GENERAL, NEUROLOGICAL.	Perm
PESCAT	Subcategory for Examination	Char	*	Grouping Qualifier	A further categorization of the examination. Used if needed to add further detail to PECAT.	Perm
PEBODSYS	Body System or Organ Class	Char		Result Qualifier	Body system or organ class (MedDRA SOC) that is involved in a measurement from the standard hierarchy (e.g., MedDRA).	Perm
PEORRES	Verbatim Examination Finding	Char		Result Qualifier	Text description of any abnormal findings. If the examination was completed and there were no abnormal findings, the value should be NORMAL. If the examination was not performed on a particular body system, or at the subject level, then the value should be null, and NOT DONE should appear in PESTAT.	Exp
PEORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for PEORRES.	Perm
PESTRESC	Character Result/Finding in Standard Format	Char		Result Qualifier	If there are findings for a body system, then either the dictionary preferred term (if findings are coded using a dictionary) or PEORRES (if findings are not coded) should appear here. If PEORRES is null, PESTRESC should be null	Exp
PESTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate exam not done. Should be null if a result exists in PEORRES.	Perm
PEREASND	Reason Not Examined	Char		Record Qualifier	Describes why an examination was not performed or why a body system was not examined. Example: SUBJECT REFUSED. Used in conjunction with STAT when value is NOT DONE.	Perm
PELOC	Location of Physical Exam Finding	Char	(LOC)	Record Qualifier	Can be used to specify where a physical exam finding occurred. Example: ARM for skin rash.	Perm
PEMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Examples: XRAY, MRI.	Perm
PEEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain collected or derived data. Examples: INVESTIGATOR, ADJUDICATION COMMITTEE.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
PEDTC	Date/Time of Examination	Char	ISO 8601	Timing		Exp
PEDY	Study Day of Examination	Num		Timing	1. Study day of physical exam, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

PE – Assumptions for Physical Examination Domain Model

1. PE Definition: Data that captures findings about physical exams. This could be information about which body systems that were examined and specific abnormalities were collected.
2. The PE domain provides an example where the result, PEORRES, is coded. This is in contrast to Events and Interventions domains (e.g., AE, CM, and MH), in which the topic variable (AETERM, CMTRT, and EXTRT, respectively) is the one coded.
3. The following Qualifiers would not generally be used in PE: --FXN, --NAM, --LOINC, --FAST, --TOX, --TOXGR.

PE – Examples for Physical Examination Domain Model

Example 1

The example shows data for one subject collected at two different visits. In all of the records except 8 and 13 the data comes from the general physical examination. In this case PECAT is "GENERAL". Additional data collected about an ophthalmologic examination is also added to this domain.

Row 1: Shows how PESTRESC is populated if result is “NORMAL”.

Row 2: Shows the proper use of the --STAT variable to indicate "NOT DONE", and when PEREASND is used to indicate why a body system (PETEST) was not examined.

Rows 4-6: Show how PESPID is used to show the sponsor-defined identifier, which in this case is a CRF sequence number used for identifying abnormalities within a body system.

Rows 4-7: Show how PESTRESC is populated if abnormality is dictionary coded.

Rows 8, 13: Show how the PECAT variable can be used to indicate a different type of physical examination. In this case, the ophthalmologic examination may have been collected in a separate dataset in the operational database.

Row	STUDYID	DOMAIN	USUBJID	PESEQ	PESPID	PETESTCD	PETEST	PECAT	PELOC	PEBODSYS	PEORRES
1	ABC	PE	ABC-001-001	1	1	HEAD	Head	GENERAL			NORMAL
2	ABC	PE	ABC-001-001	2	1	RESP	Respiratory	GENERAL			
3	ABC	PE	ABC-001-001	3	1	ENT	Ear/nose/throat	GENERAL			NORMAL
4	ABC	PE	ABC-001-001	4	1	SKIN	Skin	GENERAL	FACE	SKIN	ACNE
5	ABC	PE	ABC-001-001	5	2	SKIN	Skin	GENERAL	HANDS	SKIN	ALLERGIC REACTION
6	ABC	PE	ABC-001-001	6	3	SKIN	Skin	GENERAL	ARM	SKIN	SKINRASH
7	ABC	PE	ABC-001-001	7	1	CV	Cardiovascular	GENERAL		CARDIOVASCULAR	HEART MURMUR
8	ABC	PE	ABC-001-001	8	1	FUNDOSCP	Fundoscopy	OPHTHAMOLOGIC			NORMAL
9	ABC	PE	ABC-001-001	9	1	RESP	Respiratory	GENERAL			NORMAL
10	ABC	PE	ABC-001-001	10	1	ENT	Ear/nose/throat	GENERAL			NORMAL
11	ABC	PE	ABC-001-001	11	1	NECK	Neck	GENERAL			NORMAL
12	ABC	PE	ABC-001-001	12	1	CARDIO	Cardiovascular	GENERAL			NORMAL
13	ABC	PE	ABC-001-001	13	1	FUNDOSCP	Fundoscopy	OPHTHAMOLOGIC			NORMAL

Row	PESTRESC	PESTAT	PEREASND	VISITNUM	VISIT	VISITDY	PEDTC	PEDY
1 (cont)	NORMAL			1	BASELINE	1	1999-06-06	-3
2 (cont)		NOT DONE	INVESTIGATOR ERROR	1	BASELINE	1	1999-06-06	-3
3 (cont)	NORMAL			1	BASELINE	1	1999-06-06	-3

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Row	PESTRESC	PESTAT	PEREASND	VISITNUM	VISIT	VISITDY	PEDTC	PEDY
4 (cont)	ACNE NOS			1	BASELINE	1	1999-06-06	-3
5 (cont)	DERMATITIS			1	BASELINE	1	1999-06-06	-3
6 (cont)	RASH			1	BASELINE	1	1999-06-06	-3
7 (cont)	CARDIAC MURMUR			1	BASELINE	1	1999-06-06	-3
8 (cont)	NORMAL			1	BASELINE	1	1999-06-06	-3
9 (cont)	NORMAL			2	VISIT 1	45	1999-07-21	45
10 (cont)	NORMAL			2	VISIT 1	45	1999-07-21	45
11 (cont)	NORMAL			2	VISIT 1	45	1999-07-21	45
12 (cont)	NORMAL			2	VISIT 1	45	1999-07-21	45
13 (cont)	NORMAL			2	VISIT 1	45	1999-07-21	45

6 Domain Models Based on the General Observation Classes

6.3 Findings

Questionnaires (QS)

QS – Description/Overview for Questionnaires Domain Model

Questionnaires are named, stand-alone instruments designed to provide an assessment of a concept. Questionnaires have a defined standard structure, format, and content; consist of conceptually related items that are typically scored; and have documented methods for administration and analysis. Most often, questionnaires have as their primary purpose the generation of a quantitative statistic to assess a qualitative concept.

QS – Specification for Questionnaires Domain Model

qs.xpt, Questionnaires — Findings, Version 3.2. One record per questionnaire per question per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	QS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
QSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
QSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
QSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Question number on a questionnaire.	Perm
QSTESTCD	Question Short Name	Char	(QSTESTCD)	Topic	Topic variable for QS. Short name for the value in QSTEST, which can be used as a column name when converting the dataset from a vertical format to a horizontal format. The value in QSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g. "1TEST"). QSTESTCD cannot contain characters other than letters, numbers, or underscores. See QS Terminology Spreadsheet for specific text for QSTESTCD. Examples: ADCCMD01, BPR0103	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
QSTEST	Question Name	Char	(QSTEST)	Synonym Qualifier	Verbatim name of the question or group of questions used to obtain the measurement or finding. The value in QSTEST cannot be longer than 40 characters. See QS Terminology Spreadsheet for specific text for QSTEST. Example: Fist, BPR01 - Emotional Withdrawal	Req
QSCAT	Category of Question	Char	(QSCAT)	Grouping Qualifier	Used to define a category of related records that will be meaningful to the Reviewer. See QS Terminology Spreadsheet for specific text for QSCAT. Examples: ADAS-COG, MDS-UPDRS.	Req
QSSCAT	Subcategory for Question	Char	*	Grouping Qualifier	A further categorization of the questions within the category. Examples: MENTAL HEALTH DOMAIN, DEPRESSION DOMAIN, WORD RECALL.	Perm
QSORRES	Finding in Original Units	Char		Result Qualifier	Finding as originally received or collected (e.g. RARELY, SOMETIMES). When sponsors apply codelist to indicate the code values are statistically meaningful standardized scores, which are defined by sponsors or by valid methodologies such as SF36 questionnaires, QSORRES will contain the decode format, and QSSTRESC and QSSTRESN may contain the standardized code values or scores.	Exp
QSORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for QSORRES, such as minutes or seconds or the units associated with a visual analog scale.	Perm
QSSTRESC	Character Result/Finding in Standard Format	Char		Result Qualifier	Contains the finding for all questions or sub-scores, copied or derived from QSORRES in a standard format or standard units. QSSTRESC should store all findings in character format; if findings are numeric, they should also be stored in numeric format in QSSTRESN. If question scores are derived from the original finding, then the standard format is the score. Examples: 0, 1. When sponsors apply codelist to indicate the code values are statistically meaningful standardized scores, which are defined by sponsors or by valid methodologies such as SF36 questionnaires, QSORRES will contain the decode format, and QSSTRESC and QSSTRESN may contain the standardized code values or scores.	Exp
QSSTRESN	Numeric Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric findings in standard format; copied in numeric format from QSSTRESC. QSSTRESN should store all numeric results or findings.	Perm
QSSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for QSSTRESC or QSSTRESN.	Perm
QSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a questionnaire or response to a questionnaire was not done. Should be null if a result exists in QSORRES.	Perm
QSREASND	Reason Not Performed	Char		Record Qualifier	Describes why a question was not answered. Used in conjunction with QSSTAT when value is NOT DONE. Example: SUBJECT REFUSED.	Perm
QSBFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
QSDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records that represent the average of other records or questionnaire sub-scores that do not come from the CRF are examples of records that would be derived for the submission datasets. If QSDRVFL=Y, then QSORRES may be null with QSSTRESC and (if numeric) QSSTRESN having the derived value.	Perm
QSEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Examples: STUDY SUBJECT, CAREGIVER, INVESTIGATOR.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTTC in Demographics.	Perm
QSDTC	Date/Time of Finding	Char	ISO 8601	Timing	Date of questionnaire.	Exp
QSDY	Study Day of Finding	Num		Timing	1. Study day of finding collection, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTTC variable in Demographics.	Perm
QSTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when questionnaire should be administered. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See QSTPTNUM and QSTPTREF.	Perm
QSTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of QSTPT to aid in sorting.	Perm
QSELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned Elapsed time (in ISO 8601) relative to a planned fixed reference (QSTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by QSTPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by QSTPTREF.	Perm
QSTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by QSELTM, QSTPTNUM, and QSTPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
QSRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, LBTPPTREF.	Perm
QSEVLINT	Evaluation Interval	Char	ISO 8601	Timing	Evaluation Interval associated with a QSTEST question represented in ISO 8601 character format. Example: "-P2Y" to represent an interval of 2 years in the question "Have you experienced any episodes in the past 2 years?"	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

QS – Assumptions for Questionnaires Domain Model

1. QS Definition: Questionnaires are named, stand-alone instruments designed to provide an assessment of a concept. Questionnaires have a defined standard structure, format, and content; consist of conceptually related items that are typically scored; and have documented methods for administration and analysis. Most often, questionnaires have as their primary purpose the generation of a quantitative statistic to assess a qualitative concept.
2. CDISC publishes standard Questionnaire Supplements to the SDTMIG along with controlled terminology. All standard supplement development is coordinated with the CDISC SDTM QS Sub-Team as the governing body. The process involves drafting the controlled terminology and defining questionnaire-specific standardized values for Qualifier, Timing, and Result variables to populate the SDTM QS Domain. All controlled terminology is governed by the Controlled Terminology QS Sub-Team. The Questionnaire Supplements are developed based on user demand and therapeutic area standards development needs. Sponsors should always consult the CDISC website to review the terminology and supplements prior to modeling any questionnaire data in the QS Domain. Sponsors may participate and/or request the development of additional supplements and terminology through the CDISC SDTM QS Sub-Team and the Controlled Terminology QS Sub-Team. CDISC COP-017 describes this process (http://www.cdisc.org/stuff/contentmgr/files/0/4c011269a1cb48cb0c8eab2c3e172694/misc/cdisc_cop_017_cdisc_sdtmig_questionnaire_supplements_v1_2013_06_28.pdf). Once generated, the QS Supplement is posted on the CDISC website (<http://www.cdisc.org/content2909>).
3. The names of the questionnaires should be described under the variable QSCAT in the questionnaire domain. These could be either abbreviations or longer names. For example, ADAS-COG, BPI SHORT FORM, C-SSRS BASELINE. Sponsors should always consult CDISC Controlled Terminology. Names of subcategories for groups of items/questions could be described under QSSCAT. Refer to the QS Terminology Naming Rules document within the QS Documentation Folder of the CDISC Portal Home for the rules.
4. Sponsors should always consult the published Questionnaire Supplements for guidance on submitting derived information in SDTM. Derived records that are submitted in the QS domain should be flagged by QSDRVFL and identified with appropriate category/subcategory names (QSSCAT), item names (QSTEST), and results (QSSTRESC, QSSTRESN).
5. The following Qualifiers would not generally be used in QS: --POS, --BODSYS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STRNC, --NRIND, --XFN, --LOINC, --SPEC, --SPCCND, --LOC, --FAST, --TOX, --TOXGR, --SEV.
6. The sponsor is expected to provide information about the version used for each validated questionnaire in the metadata (using the Comments column in the define.xml). This could be provided as value-level metadata for QSCAT. If more than one version of a questionnaire is used in a study, the version used for each record should be specified in the Supplemental Qualifiers datasets, as described in **Section 8: 8.4, Relating Non-Standard Variables Values to a Parent Domain**. The sponsor is expected to provide information about the scoring rules in the metadata.
7. If the verbatim question text is > 40 characters, put meaningful text in QSTEST and describe the full text in the study metadata. See **Section 4: 4.1.5.3.1, Test Name (--TEST) Greater Than 40 Characters** for further information.

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QS – Examples for Questionnaires Domain Model

Example 1

This example shows data from one subject collected at one visit for the HAMD 17 questionnaire. The example uses standard controlled terminology for QSTESTCD, QSTEST, QSCAT and QSSORRES for the HAMD 17 measure. HAMD17 is usually captured multiple times in a study.

Rows 1-18: Represent the 17 questions from the HAMD 17 Form. Note that Question 16 has two parts, A and B. All original results are represented with the standard terminology in QSORRES. This result is then transformed into a Standard Numeric score in QSSTRESN [see *Section 4: 4.1.5.1, Original and Standardized Results of Findings and Test Not Done*].

Row 19: Represents the total score derived from the individual questions on the HAMD 17 Form. QSDRVFL is set to “Y”.

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES
1	STUDYX	QS	P0001	1	HAMD101	HAMD1-Depressed Mood	HAMD 17	Absent
2	STUDYX	QS	P0001	2	HAMD102	HAMD1-Feelings of Guilt	HAMD 17	Self reproach, feels he/she has let people down
3	STUDYX	QS	P0001	3	HAMD103	HAMD1-Suicide	HAMD 17	Ideas or gestures suicide
4	STUDYX	QS	P0001	4	HAMD104	HAMD1-Insomnia Early - Early Night	HAMD 17	No difficulty falling asleep
5	STUDYX	QS	P0001	5	HAMD105	HAMD1-Insomnia Middle - Middle Night	HAMD 17	No difficulty
6	STUDYX	QS	P0001	6	HAMD106	HAMD1-Insomnia Early Hours -Morning	HAMD 17	No difficulty
7	STUDYX	QS	P0001	7	HAMD107	HAMD1-Work and Activities	HAMD 17	No difficulty
8	STUDYX	QS	P0001	8	HAMD108	HAMD1-Retardation	HAMD 17	Complete stupor
9	STUDYX	QS	P0001	9	HAMD109	HAMD1-Agitation	HAMD 17	Fidgetiness
10	STUDYX	QS	P0001	10	HAMD110	HAMD1-Anxiety Psychic	HAMD 17	No difficulty
11	STUDYX	QS	P0001	11	HAMD111	HAMD1-Anxiety Somatic	HAMD 17	Moderate
12	STUDYX	QS	P0001	12	HAMD112	HAMD1-Somatic Symptoms GI	HAMD 17	None
13	STUDYX	QS	P0001	13	HAMD113	HAMD1-General Somatic Symptoms	HAMD 17	None
14	STUDYX	QS	P0001	14	HAMD114	HAMD1-Genital Symptoms	HAMD 17	Mild
15	STUDYX	QS	P0001	15	HAMD115	HAMD1-Hypochondriasis	HAMD 17	Not present
16	STUDYX	QS	P0001	16	HAMD116A	HAMD1-Loss of WT According to Patient	HAMD 17	Definite (according to patient) weight loss
17	STUDYX	QS	P0001	17	HAMD116B	HAMD1-Loss of WT According to WK Meas	HAMD 17	Greater than 2 lb weight loss in week
18	STUDYX	QS	P0001	18	HAMD117	HAMD1-Insight	HAMD 17	Denies being ill at all
19	STUDYX	QS	P0001	19	HAMD118	HAMD1-Total Score	HAMD 17	18

Row	QSSTRESC	QSSTRESN	QSBLFL	QSDRVFL	VISITNUM	QSDTC	QSEVAL	QSEVLINT
1 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-PIW
2 (cont)	1	1	Y		1	2012-08-11	INVESTIGATOR	-PIW
3 (cont)	3	3	Y		1	2012-08-11	INVESTIGATOR	-PIW
4 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-PIW
5 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-PIW
6 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-PIW
7 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-PIW
8 (cont)	4	4	Y		1	2012-08-11	INVESTIGATOR	-PIW
9 (cont)	1	1	Y		1	2012-08-11	INVESTIGATOR	-PIW
10 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-PIW

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Row	QSSTRESC	QSSTRESN	QSBFL	QSDRVFL	VISITNUM	QSDTC	QSEVAL	QSEVLINT
11 (cont)	2	2	Y		1	2012-08-11	INVESTIGATOR	-P1W
12 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W
13 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W
14 (cont)	1	1	Y		1	2012-08-11	INVESTIGATOR	-P1W
15 (cont)	0	0	Y		1	2012-08-11	INVESTIGATOR	-P1W
16 (cont)	2	2	Y		1	2012-08-11	INVESTIGATOR	-P1W
17 (cont)	2	2	Y		1	2012-08-11	INVESTIGATOR	-P1W
18 (cont)	2	2	Y		1	2012-08-11	INVESTIGATOR	-P1W
19 (cont)	18	18	Y	Y	1	2012-08-11	INVESTIGATOR	-P1W

Example 2

This example shows data from one subject collected at two visits for a CGI questionnaire. The example uses standard controlled terminology for QSTESTCD, QSTEST, QSCAT and QSORRES for the CGI measure.

Rows 1-6: Represent the 3 detail questions from the CGI Form. All original results are represented with the standard terminology in QSORRES. This result is then transformed into a Standard Numeric score in QSSTRESN [see *Section 4: 4.1.5.1, Original and Standardized Results of Findings and Test Not Done*].

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES
1	STUDYX	QS	2324-P0001	1	CGI0101	CGI01-Severity of illness	CGI	Severely ill
2	STUDYX	QS	2324-P0001	2	CGI0102	CGI01-Global improvement	CGI	Much worse
3	STUDYX	QS	2324-P0001	3	CGI0103	CGI01-Efficacy index	CGI	Unchanged or worse - None
4	STUDYX	QS	2324-P0001	4	CGI0101	CGI01-Severity of illness	CGI	Markedly ill
5	STUDYX	QS	2324-P0001	5	CGI0102	CGI01-Global improvement	CGI	Minimally worse
6	STUDYX	QS	2324-P0001	6	CGI0103	CGI01-Efficacy index	CGI	Minimal - Do not significantly interfere with patient's functioning

Row	QSSTRESC	QSSTRESN	QSBFL	QSEVAL	VISITNUM	QSDTC
1 (cont)	6	6		INVESTIGATOR	2	2012-10-21
2 (cont)	6	6		INVESTIGATOR	2	2012-10-21
3 (cont)	13	13		INVESTIGATOR	2	2012-10-21
4 (cont)	5	5		INVESTIGATOR	3	2012-11-20
5 (cont)	5	5		INVESTIGATOR	3	2012-11-20
6 (cont)	10	10		INVESTIGATOR	3	2012-11-20

6 Domain Models Based on the General Observation Classes

6.3 Findings

Reproductive System Findings (RP)

RP – Description/Overview for Reproductive System Findings Domain Model

The Reproductive System Findings domain captures all Reproductive information related to a subject.

RP – Specification for Reproductive System Findings Domain Model

rp.xpt, Reproductive System Findings — Findings, Version 3.2. One record per Reproductive System Finding per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	RP	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
RPSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
RPGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
RPREFID	Reference ID	Char		Identifier	Internal or external Reproductive System Findings record identifier.	Perm
RPSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm
RPTESTCD	Repro System Findings Test Short Name	Char	(RPTESTCD)	Topic	Short name of the measurement, test, or examination described in RPTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in RPTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g. "1TEST"). RPTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: NUMLIV, NUMPREG, BCMETHOD, etc.	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
RPTEST	Reproductive System Findings Test Name	Char	(RPTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in RPTEST cannot be longer than 40 characters. Examples: Number of Live Births, Number of Pregnancies, Birth Control Method, etc.	Req
RPCAT	Category for Repro System Findings	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm
RPSCAT	Subcategory for Repro System Findings	Char	*	Grouping Qualifier	A further categorization of RP records.	Perm
RPORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the Reproductive System Findings test as originally received or collected.	Exp
RPORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for RPORRES. Examples: YEARS.	Exp
RPSTRESC	Character Result/Finding in Std. Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from RPORRES in a standard format or standard units. RPSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in RPSTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in RPORRES and these results effectively have the same meaning; they could be represented in standard format in RPSTRESC as "NEGATIVE".	Exp
RPSTRESN	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 RPSTRESC. RPSTRESN should store all numeric test results or findings.	Exp
RPSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for RPSTRESC and RPSTRESN.	Exp
RPSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a Reproductive System Findings test was not done. Should be null if a result exists in RPORRES.	Perm
RPREASND	Reason Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: BROKEN EQUIPMENT or SUBJECT REFUSED. Used in conjunction with RPSTAT when value is NOT DONE.	Perm
RPBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Perm
RPDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records which represent the average of other records or which do not come from the CRF are examples of records that would be derived for the submission datasets. If RPDRVFL=Y, then RPORRES may be null, with RPSTRESC and (if numeric) RPSTRESN having the derived value.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Perm
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
RPDTC	Date/Time of Measurements	Char	ISO 8601	Timing	Date of Reproductive System Finding.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
RPDY	Study Day of Repro System Findings	Num		Timing	1. Study day of Reproductive System Findings observation, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

RP – Assumptions for Reproductive System Findings Domain Model

1. RP Definition: The Reproductive System Findings domain captures all Reproductive information related to a subject. Up to this point, organizations have been aligning reproductive information to various SDTM domains such as Subject Characteristics and Events. The development of this domain specifies that all reproductive detail information for a subject will now be consolidated in the Reproductive System Findings domain. This domain will contain information regarding, for example, the subject’s reproductive ability, reproductive history such as number of previous pregnancies and number of births, pregnant during the study, etc.”
2. Information on medications related to reproduction, such as contraceptives or fertility treatments, need to be included in the CM domain, not RP.
3. The following Qualifiers would not generally be used in RP: --MODIFY, --BODSYS, --LOINC, --SPCCND, --FAST, --TOX, --TOXGR, --SEV.
4. Terminology: Controlled terminology is under development for the RP domain, thus some values in the examples are not CDISC controlled terms. Verify demonstrated terminology against current standards before adopting it.

RP – Examples for Reproductive System Findings Domain Model

Example 1

This shows data reported in the original result and units in RPORRES and RPORRESU and standardized in RPSTRESC, RPSTRESN and RPSTRESU. It also shows the standard terminology for RPTESTCD and RPTEST.

Rows 1-11: Represent Reproductive System Findings at the screening visit, visit 1 and visit 2 for USUBJID=2324-P0001. Childbearing Potential and Pregnant During the Study are captured at multiple visits during the study (see rows 7-11), while the other findings are only captured at the screening visit.

Rows 12-21: Represent Reproductive System Findings at the screening visit, visit 1 and visit 2 for USUBJID=2324-P0002. Childbearing Potential is captured at multiple visits during the study (see rows 19-21), while the other findings are only captured at the screening visit.

Row	STUDYID	DOMAIN	USUBJID	RPSEQ	RPTESTCD	RPTEST	RPORRES	RPORRESU	RPSTRESC	RPSTRESN
1	STUDYX	RP	2324-P0001	1	NUMSPAB	Number of Elective/Spontaneous Abortions	1		1	1
2	STUDYX	RP	2324-P0001	2	NUMLIV	Number of Live Births	2		2	2
3	STUDYX	RP	2324-P0001	3	NUMPREG	Number of Pregnancies	3		3	3
4	STUDYX	RP	2324-P0001	4	MENOSTAT	Menopause Status	Pre-Menopause		Pre-Menopause	
5	STUDYX	RP	2324-P0001	5	MENARAGE	Menarche Age	10	YEARS	10	10
6	STUDYX	RP	2324-P0001	6	BCMETHOD	Birth Control Method	FOAM OR OTHER SPERMICIDES		FOAM OR OTHER SPERMICIDES	
7	STUDYX	RP	2324-P0001	7	CHILDPOT	Childbearing Potential	Y		Y	
8	STUDYX	RP	2324-P0001	8	CHILDPOT	Childbearing Potential	Y		Y	
9	STUDYX	RP	2324-P0001	9	PREGNT	Pregnant During the Study	N		N	
10	STUDYX	RP	2324-P0001	10	CHILDPOT	Childbearing Potential	Y		Y	
11	STUDYX	RP	2324-P0001	11	PREGNT	Pregnant During the Study	N		N	
12	STUDYX	RP	2324-P0002	1	NUMSPAB	Number of Elective/Spontaneous Abortions	0		0	0
13	STUDYX	RP	2324-P0002	2	NUMLIV	Number of Live Births	1		1	1
14	STUDYX	RP	2324-P0002	3	NUMPREG	Number of Pregnancies	1		1	1
15	STUDYX	RP	2324-P0002	4	MENOSTAT	Menopause Status	MENOPAUSE		MENOPAUSE	
16	STUDYX	RP	2324-P0002	5	MENOPAGE	Menopause Age	55	YEARS	55	55
17	STUDYX	RP	2324-P0002	6	MENARAGE	Menarche Age	11	YEARS	11	11

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Row	STUDYID	DOMAIN	USUBJID	RPSEQ	RPTESTCD	RPTEST	RPORRES	RPORRESU	RPSTRESC	RPSTRESN
18	STUDYX	RP	2324-P0002	7	BCMETHOD	Birth Control Method	DIAPHRAGM		DIAPHRAGM	
19	STUDYX	RP	2324-P0002	8	CHILDPOT	Childbearing Potential	N		N	
20	STUDYX	RP	2324-P0002	9	CHILDPOT	Childbearing Potential	N		N	
21	STUDYX	RP	2324-P0002	10	CHILDPOT	Childbearing Potential	N		N	

Row	RPSTRESU	RPDUR	RPBLFL	VISITNUM	VISIT	VISITDY	RPDTC	RPDY
1 (cont)			Y	1	SCREENING	1	2008-03-09	-10
2 (cont)			Y	1	SCREENING	1	2008-03-09	-10
3 (cont)			Y	1	SCREENING	1	2008-03-09	-10
4 (cont)			Y	1	SCREENING	1	2008-03-09	-10
5 (cont)	YEARS		Y	1	SCREENING	1	2008-03-09	-10
6 (cont)		P3Y	Y	1	SCREENING	1	2008-03-09	-10
7 (cont)			Y	1	SCREENING	1	2008-03-09	-10
8 (cont)				2	Day 1	1	2008-03-19	1
9 (cont)				2	Day 1	1	2008-03-19	1
10 (cont)				3	Day 29	29	2008-04-16	29
11 (cont)				3	Day 29	29	2008-04-16	29
12 (cont)			Y	1	SCREENING	1	2009-03-09	-10
13 (cont)			Y	1	SCREENING	1	2009-03-09	-10
14 (cont)			Y	1	SCREENING	1	2009-03-09	-10
15 (cont)			Y	1	SCREENING	1	2009-03-09	-10
16 (cont)	YEARS		Y	1	SCREENING	1	2009-03-09	-10
17 (cont)	YEARS		Y	1	SCREENING	1	2009-03-09	-10
18 (cont)		P3Y	Y	1	SCREENING	1	2009-03-09	-10
19(cont)			Y	1	SCREENING	1	2009-03-09	-10
20 (cont)				2	Day 1	1	2009-03-19	1
21 (cont)				3	Day 29	29	2009-04-16	29

6 Domain Models Based on the General Observation Classes

6.3 Findings

Subject Characteristics (SC)

SC – Description/Overview for Subject Characteristics Domain Model

The subject characteristics domain is for data not collected in other domains that is subject-related.

SC – Specification for Subject Characteristics Domain Model

sc.xpt, Subject Characteristics — Findings, Version 3.2. One record per characteristic per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SC	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SCSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
SCGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
SCSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm
SCTESTCD	Subject Characteristic Short Name	Char	(SCTESTCD)	Topic	Short name of the measurement, test, or examination described in SCTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in SCTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g. "1TEST"). SCTESTCD cannot contain characters other than letters, numbers, or underscores. Example: MARISTAT, NATORIG.	Req
SCTEST	Subject Characteristic	Char	(SCTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in SCTEST cannot be longer than 40 characters. Examples: Marital Status, National Origin.	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
SCCAT	Category for Subject Characteristic	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm
SCSCAT	Subcategory for Subject Characteristic	Char	*	Grouping Qualifier	A further categorization of the subject characteristic.	Perm
SCORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the subject characteristic as originally received or collected.	Exp
SCORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original Unit in which the data were collected. The unit for SCORRES.	Perm
SCSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from SCORRES in a standard format or standard units. SCSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in SCSTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in SCORRES and these results effectively have the same meaning, they could be represented in standard format in SCSTRESC as "NEGATIVE".	Exp
SCSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from SCSTRESC. SCSTRESN should store all numeric test results or findings.	Perm
SCSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for SCSTRESC or SCSTRESN.	Perm
SCSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that the measurement was not done. Should be null if a result exists in SCORRES.	Perm
SCREASND	Reason Not Performed	Char		Record Qualifier	Describes why the observation has no result. Example: subject refused. Used in conjunction with SCSTAT when value is NOT DONE.	Perm
SCDTC	Date/Time of Collection	Char	ISO 8601	Timing		Perm
SCDY	Study Day of Examination	Num		Timing	1. Study day of collection, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFDSTDC variable in Demographics.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

SC – Assumptions for Subject Characteristics Domain Model

1. SC Definition: Subject Characteristics is for data not collected in other domains that are subject-related. Examples: education level, marital status, national origin, etc.
2. The structure for demographic data is fixed and includes date of birth, age, sex, race, ethnicity and country. The structure of subject characteristics is based on the Findings general observation class and is an extension of the demographics data. Subject Characteristics consists of data that is collected once per subject (per test). SC contains data that is either not normally expected to change during the trial or whose change is not of interest after the initial collection. Sponsor should ensure that data considered for submission in SC do not actually belong in another domain.

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3. The following Qualifiers would not generally be used in SC: --MODIFY, --POS, --BODSYS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STNRC, --NRIND, --RESCAT, --XFN, --NAM, --LOINC, --SPEC, --SPCCND, --METHOD, --BLFL, --FAST, --DRVRL, --TOX, --TOXGR, --SEV.

SC – Examples for Subject Characteristics Domain Model

The example below shows data that is collected once per subject and does not fit into the Demographics domain. For this example the national origin and marital status were collected.

Row	STUDYID	DOMAIN	USUBJID	SCSEQ	SCTESTCD	SCTEST	SCORRES	SCSTRESC	SCDTC
1	ABC	SC	ABC-001-001	1	NATORIG	National Origin	UNITED STATES	USA	1999-06-19
2	ABC	SC	ABC-001-001	2	MARISTAT	Marital Status	DIVORCED	DIVORCED	1999-06-19
3	ABC	SC	ABC-001-002	1	NATORIG	National Origin	CANADA	CAN	1999-03-19
4	ABC	SC	ABC-001-002	2	MARISTAT	Marital Status	MARRIED	MARRIED	1999-03-19
5	ABC	SC	ABC-001-003	1	NATORIG	National Origin	USA	USA	1999-05-03
6	ABC	SC	ABC-001-003	2	MARISTAT	Marital Status	NEVER MARRIED	NEVER MARRIED	1999-05-03
7	ABC	SC	ABC-002-001	1	NATORIG	National Origin	JAPAN	JPN	1999-06-14
8	ABC	SC	ABC-002-001	2	MARISTAT	Marital Status	WIDOWED	WIDOWED	1999-06-14

6 Domain Models Based on the General Observation Classes

6.3 Findings

Subject Status (SS)

SS – Description/Overview for Subject Status Domain Model

Subject Status is for data relating to general subject characteristics that are evaluated periodically to determine if they have changed.

SS – Specification for Subject Status Domain Model

SS.xpt, Subject Status — Findings, Version 3.2. One record per finding per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
SSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
SSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number from the procedure or test page.	Perm
SSTESTCD	Status Short Name	Char	(SSTESTCD)	Topic	Short name of the status assessment described in SSTEEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in SSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). SSTESTCD cannot contain characters other than letters, numbers, or underscores. Example: SURVSTAT	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
SSTEST	Status Name	Char	(SSTEST)	Synonym Qualifier	Verbatim name of the status assessment used to obtain the finding. The value in SSTEST cannot be longer than 40 characters. Example: Survival Status	Req
SSCAT	Category for Assessment	Char	*	Grouping Qualifier	Used to categorize observations across subjects.	Perm
SSSCAT	Subcategory for Assessment	Char	*	Grouping Qualifier	A further categorization.	Perm
SSORRES	Result or Finding Original Result	Char		Result Qualifier	Result of the status assessment finding as originally received or collected.	Exp
SSSTRESC	Character Result/Finding in Std Format	Char	(SSSTRESC)	Result Qualifier	Contains the result value for all findings, copied or derived from SSORRES in a standard format.	Exp
SSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a status assessment was not done. Should be null if a result exists in SSORRES.	Perm
SSREASND	Reason Assessment Not Performed	Char		Record Qualifier	Describes why an assessment was not performed. Example: SUBJECT REFUSED. Used in conjunction with SSSTAT when value is NOT DONE.	Perm
SSEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain collected or derived data. Examples: CAREGIVER, ADJUDICATION COMMITTEE, FRIEND.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
SSDTC	Date/Time of Assessment	Char	ISO 8601	Timing		Exp
SSDY	Study Day of Assessment	Num		Timing	1. Study day of the test, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

SS – Assumptions for Subject Status Domain Model

1. SS Definition: Subject Status is for data relating to general subject characteristics that are evaluated periodically to determine if they have changed.
2. Subject Status does not contain details about the circumstances of a subject’s status. The response to the status assessment may trigger collection of additional details but those details are to be stored in appropriate separate domains. For example, if a subject’s Survival Status is “DEAD”, the date of death must be stored in DM and within a final disposition record in DS. Only the status collection date, the status question and the status response are stored in SS.
3. Subject Status must not contain data that belong in another domain. Periodic data collection is not the sole criteria for storing data in SS. The criterion is whether the test reflects the subject’s status at a point in time. It is not for recording clinical test results, event terms, treatment names or other data which belong elsewhere.
4. RELREC may be used to link assessments in SS with data in other domains that were collected as a result of the subject status assessment.

SS – Examples for Subject Status Domain Model

Example 1

In this example, subjects complete a ten-week treatment regimen and are then contacted by phone every month for three months. The phone contact assesses the subject’s survival status. If the survival status is “DEAD”, additional information is collected in order to complete the subject’s final disposition record in DS and to record the date of death in DM (DS and DM records are not shown here).

ss.xpt

Row	STUDYID	DOMAIN	USUBJID	SSSEQ	SSTESTCD	SSTEST	SSORRES	SSSTRESC	VISITNUM	VISIT	SSDTC
1	XYZ	SS	XYZ-333-009	1	SURVSTAT	Survival Status	ALIVE	ALIVE	10	MONTH 1	2010-04-15
2	XYZ	SS	XYZ-333-009	2	SURVSTAT	Survival Status	ALIVE	ALIVE	20	MONTH 2	2010-05-12
3	XYZ	SS	XYZ-333-009	3	SURVSTAT	Survival Status	ALIVE	ALIVE	30	MONTH 3	2010-06-15
4	XYZ	SS	XYZ-428-021	1	SURVSTAT	Survival Status	ALIVE	ALIVE	10	MONTH 1	2010-08-03
5	XYZ	SS	XYZ-428-021	2	SURVSTAT	Survival Status	DEAD	DEAD	20	MONTH 2	2010-09-06

6 Domain Models Based on the General Observation Classes

6.3 Findings

Oncology Domains: TU, TR and RS

Assessment of the change in tumor burden is an important feature of the clinical evaluation of cancer therapeutics: both tumor shrinkage (objective response) and disease progression are useful endpoints in cancer clinical trials¹. The domains presented here are intended to represent data collected in clinical trials where sites of disease (e.g. tumors or lymph nodes) are identified and then repeatedly measured/assessed at subsequent time points and used in an evaluation of response(s). As such these domains would be applicable for representing data to support assessment criteria such as RECIST (solid tumors), Cheson² (e.g. lymphoma), or, Hallek³⁽³⁾ (chronic lymphocytic leukemia). Note these are examples only and this is not an exhaustive list. Some response criteria may require additional data for an assessment of response and that data should reside in the appropriate SDTM domain (e.g. LB for lab test results). The SDTM domain examples provided in the documentation package reference RECIST criteria primarily but examples have been provided that use Cheson criteria (for Lymphoma) and Hallek (for chronic lymphocytic leukemia).

The tumor package consists of three SDTM domains based on the SDTM Findings Observation Class. The three domains are related but each has a distinct purpose. An alternative approach using a single domain was considered but was ultimately rejected in favor of this relational approach to representing data. This approach is consistent with current SDTM philosophy. When creating an analysis dataset, data from the three SDTM domains can be combined. The three domains are introduced below.

References:

¹ RECIST Criteria - Eisenhauer E.A., Therasse, P., Bogaerts, J., Schwartz, L.H., Sargent, D., Ford, R., Dancey, J., Arbuck, S., Gwyther, S., Mooney, M., Rubinstein, L., Shankar, L., Dodd, L., Kaplan, R., Lacombe, D., Verwij, J. New Response Evaluation Criteria in Solid Tumours: Revised RECIST Guideline (Version 1.1). *European Journal of Cancer*. 2009;45:228-247 (<http://www.eortc.be/recist/>)

² Cheson BD, , Pfistner B, Juweid ME, Gascoyne RD, Specht L, et al. Revised Response Criteria for Malignant Lymphoma. *Journal of Clinical Oncology*. 2007;25:579-586 . *Journal of Clinical Oncology*. Vol 25 Number 5 Feb 10 2007

³ Hallek M, Cheson BD, Catovsky D, Caligaris-Cappio F, Dighiero G, Dohner H, Hillmen P, Keating MJ, Montserrat E, Rai KR, Kipps TJ. Guidelines for the diagnosis and treatment of chronic lymphocytic leukemia: a report from the International Workshop on Chronic Lymphocytic Leukemia (IWCLL) updating the National Cancer Institute-Working Group (NCI-WG) 1996 guidelines. *Blood*. 2008;111:5446-5456.

Tumor Identification (TU)

TU – Description/Overview for Tumor Identification Domain Model

The TU domain represents data that uniquely identifies tumors (i.e. malignant tumors and other sites of disease, e.g. lymph nodes). The tumors are identified by an investigator and/or independent assessor and classified according to the disease assessment criteria. In RECIST terms this equates to the identification of Target, Non-Target or New tumors. A record in the TU domain contains the following information: a unique tumor ID value; anatomical location of the tumor; method used to identify the tumor; role of the individual identifying the tumor; and timing information.

TU – Specification for Tumor Identification Domain Model

tu.xpt, Tumor Identification - Findings, Version 3.2 - One record per identified tumor per subject per assessor, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TU	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
TUSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a dataset for a subject. May be any valid number.	Req
TUGRPID	Group ID	Char		Identifier	Used to link together a block of related records within a subject in a domain. Can be used to group split or merged tumors which have been identified.	Perm
TUREFID	Reference ID	Char		Identifier	Internal or external identifier. Example: Medical image ID number.	Perm
TUSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier.	Perm
TULNKID	Link ID	Char		Identifier	Identifier used to link identified tumors to the assessment results (in TR domain) over the course of the study.	Exp
TUTESTCD	Tumor Identification Short Name	Char	(TUTESTCD)	Topic	Short name of the TEST in TUTEST. TUTESTCD cannot be longer than 8 characters nor can start with a number. TUTESTCD contain characters other than letters, numbers, or underscores. Example: TUMIDENT (Tumor Identification). See Assumption 2.	Req
TUTEST	Tumor Identification Test Name	Char	(TUTEST)	Synonym Qualifier	Verbatim name of the test for the tumor identification. The value in TUTEST cannot be longer than 40 characters. Example: Tumor Identification. See Assumption 2.	Req
TUORRES	Tumor Identification Result	Char		Result Qualifier	Result of the Tumor identification. The result of tumor identification is a classification of identified tumor. Examples: When TUTESTCD=TUMIDENT (Tumor Identification), values of TUORRES might be: TARGET, NON-TARGET, or NEW. or BENIGN ABNORMALITY	Exp
TUSTRESC	Tumor Identification Result Std. Format	Char	(TUMIDENT)	Record Qualifier	Contains the result value for all findings copied from TUORRES.	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
TUNAM	Vendor Name	Char		Record Qualifier	The name or identifier of the vendor that performed the Tumor Identification. This column can be left Null when the Investigator provides the complete set of data in the domain.	Perm
TULOC	Location of the Tumor	Char	(LOC)	Record Qualifier	Used to specify the anatomical location of the identified tumor. Example: LIVER Note: When anatomical location is broken down and collected as distinct pieces of data that when combined provide the overall location information (e.g. laterality /directionality / distribution) then the additional anatomical location qualifiers should be used. See Assumption 3.	Exp
TULAT	Laterality	Char	(LAT)	Record Qualifier	Qualifier for anatomical location or specimen further detailing laterality, for example, LEFT, RIGHT, BILATERAL.	Perm
TUDIR	Directionality	Char	(DIR)	Record Qualifier	Qualifier for anatomical location or specimen further detailing directionality, for example, UPPER, INTERIOR.	Perm
TUPORTOT	Portion or Totality	Char	(PORTOT)	Record Qualifier	Qualifier for anatomical location or specimen further detailing the distribution which means arrangement of, or apportioning of, for example, ENTIRE, SINGLE, SEGMENT, MULTIPLE.	Perm
TUMETHOD	Method of Identification	Char	(METHOD)	Record Qualifier	Method used to identify the tumor. Examples: MRI, CT SCAN.	Exp
TUEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Examples: INVESTIGATOR, INDEPENDNT ASSESSOR This column can be left Null when the Investigator provides the complete set of data in the domain. However the column should contain no Null values when data from one or more independent assessors is included meaning that the rows attributed to the Investigator should contain a value of INVESTIGATOR.	Exp
TUEVALID	Evaluator Identifier	Char	(MEDEVAL)	Variable Qualifier	The Evaluator Specified variable is used in conjunction with TUEVAL to provide an additional level of detail. When multiple assessors play the role identified in TUEVAL, values of TUEVALID will attribute a row of data to a particular assessor. TUEVALID should not contain the names of the assessors, or a code identifier for a specific assessor, but should contain values such as RADIOLOGIST, RADIOLOGIST 1 or RADIOLOGIST 2. The TUEVALID variable is subject to CDISC Controlled Terminology. See Assumption 7.	Perm
TUACPTFL	Accepted Record Flag	Char	(NY)	Record Qualifier	In cases where more than one independent assessor (e.g. RADIOLOGIST 1, RADIOLOGIST 2, ADJUDICATOR) provide independent assessments at the same time point this flag identifies the record that is considered to be the accepted assessment.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
					2. May be used in addition to VISITNUM and/or VISITDY.	
VISITDY	Planned Study Day of Visit	Num		Timing		Perm
EPOCH	Epoch	Char		Timing	Epoch associated with the Element in the planned sequence of Elements for the ARM to which the subject was assigned.	Perm
TUDTC	Date/Time of Tumor Identification	Char	ISO 8601	Timing	TUDTC variable represents the date of the scan/image/physical exam not the date that the image was read to identify tumors. TUDTC variable does not represent the VISIT date.	Exp
TUDY	Study Day of Tumor Identification	Num		Timing	1. Study day of the scan/image/physical exam, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

TU – Assumptions for Tumor Identification Domain Model

TU Definition: The TU domain represents data that uniquely identifies tumors (i.e. malignant tumors and other sites of disease, e.g. lymph nodes). The tumors are usually tracked during the course of a study and will contribute to an assessment of response to therapy. The TU domain should contain only one record for each unique tumor identified by an assessor (e.g. Investigator or Radiologist). The initial identification of a tumor is done once, usually at baseline (e.g. the identification of Target and Non-Target tumors). The identification information, including the location description, must not be repeated for every visit. The following are examples of when post-baseline records might be included in the TU domain:

- A new tumor may emerge at any time during a study therefore a new post-baseline record would represent the identification of the new tumor.
 - If a tumor identified at baseline subsequently splits into separate distinct tumors then additional post-baseline records can be included to distinctly identify the split tumors.
 - If one or more tumors identified at baseline subsequently merge together then an additional post-baseline record can be included to distinctly identify the merged tumor.
 - In situations where a re-baseline of Targets and Non-Targets is required (e.g. a cross-over study) then a separate set of Target and Non-Target tumors might be identified and those identification records would be represented.
1. TRLNKID is used to relate an identification record in TU domain to assessment records in the TR domain. The organization of data across the TU and TR domains requires a linking mechanism. The TULNKID variable is used to provide a unique code for each identified tumor. The values of TULNKID are compound values that may carry the following information: an indication of the role (or assessor) providing the data record when it is someone other than the principle investigator; an indication of whether the data record is for a target or non-target tumor; a tracking identifier or number; and, an indication of whether the tumor has split or merged (see assumption below for details on splitting and merging). A RELREC relationship record can be created to describe link, probably as a dataset to dataset link.
 2. During the course of a trial a tumor might split, into one or more distinct tumors, or, two or more tumors might merge to form a single tumor. The following example shows the preferred approach for representing this information. However, the approach depends on how the data for split and merged tumors are captured. To follow the preferred approach, measurements of each distinct tumor must be captured individually. In the example target tumor T04, identified at the SCREEN visit, splits into two at WEEK 16. Two new records are created with TUTEST="Tumor Split" and the TULNKID reflects the split by adding

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0.1 & 0.2 to the original TULNKID value. At WEEK 24, in the example below, target tumors T02 & T03, identified at screening, merge together. A single new record is created this TUTESET="Tumor Merged" and the TULNKID reflects the original TULNKID values assigned at the SCREEN visit.

TULNKID	TUTESETCD	TUTESET	TUORRES	VISIT
T01	TUMIDENT	Tumor Identification	TARGET	SCREEN
T02	TUMIDENT	Tumor Identification	TARGET	SCREEN
T03	TUMIDENT	Tumor Identification	TARGET	SCREEN
T04	TUMIDENT	Tumor Identification	TARGET	SCREEN
NT01	TUMIDENT	Tumor Identification	NON-TARGET	SCREEN
NT02	TUMIDENT	Tumor Identification	NON-TARGET	SCREEN
T04.1	TUSPLIT	Tumor Split	TARGET	WEEK 16
T04.2	TUSPLIT	Tumor Split	TARGET	WEEK 16
T02/T03	TUMERGE	Tumor Merged	TARGET	WEEK 24
NEW01	TUMIDENT	Tumor Identification	NEW	WEEK 32

If the data collection does not support this approach (i.e., measurements of split tumors are reported as a summary under the 'parent' tumor), then it may not be possible to include a record in the TU domain. In this situation, the assessments of split and merge tumors would be represented only in the TR domain.

- During the course of a trial when a New Tumor is identified, information about that new tumor may be collected to different levels of detail. For example, if anatomical location of a new tumor is not collected, then TULOC will be blank. All new tumors are to be represented in TU and TR domains.
- Additional anatomical location variables (--LAT, --DIR, --PORTOT) have been added to the SDTM model. These extra variables allow for more detailed information to be collected that further clarifies the value of the TULOC variable.
- When a new Tumor is identified a record must be included in both the TU and TR domains. At a minimum, the TR record would contain TRLNKID='NEW01' and TRTESTCD='TUMSTATE' and TRORRES='PRESENT' for unequivocal new tumors. The TU record may contain different levels of detail depending upon the data collection methods employed. The following three scenarios represent the most commonly seen scenarios (it is possible that a sponsor's chosen method is not reflected below):
 - The occurrence of a New Tumor is the sole piece of information that a sponsor collects because this is a sign of disease progression and no further details are required. In such cases a record would be created where TUTESET="Tumor Identification" and TUORRES="NEW", and the identifier, TULNKID, would be populated in order to link to the associated information in the TR domain.
 - The occurrence of a New Tumor and the anatomical location of that newly identified Tumor are the only collected pieces of information. In this case it is expected that a record would be created where TUTESET="Tumor Identification" and TUORRES="NEW", the TULOC variable would be populated with the anatomical location information (the additional location variables may be populated depending on the level of detail collected), and the identifier, TULNKID, would be populated in order to link to the associated information in the TR domain.
 - A sponsor might record the occurrence of a New Tumor to the same level of detail as Target Tumors. In this case the occurrence of the new tumor and the anatomical location information, and also measure the New Tumor. In this case it is expected that a record would be created where TUTESET="Tumor Identification" and TUORRES="NEW", the TULOC variable would be populated with the anatomical location information (the additional location variables may be populated depending on the level of detail collected), and the identifier, TULNKID, would be populated in order to link to the associated information in the TR domain. In this scenario measurements/assessments would also be recorded in the TR domain.
- The Acceptance Flag variable (TUACPTFL) identifies those records that have been determined to be the accepted assessments/measurements by an independent assessor. This flag would be provided by an independent assessor and when multiple assessors (e.g. RADIOLOGIST 1, RADIOLOGIST 2, ADJUDICATOR) provide assessments or evaluations at the same time point or an overall evaluation. This flag should not be used by a sponsor for any other

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purpose i.e. it is not expected that the TUACPTFL flag would be populated by the sponsor. Instead that type of record selection should be handled in the analysis dataset.

7. The Evaluator Specified variable (TUEVALID) is used in conjunction with TUEVAL to provide additional detail of who is providing tumor identification information. For example TUEVAL="INDEPENDENT ASSESSOR" and TUEVALID="RADIOLOGIST 1". The TUEVALID variable is subject to Controlled Terminology. TUEVAL must also be populated when TUEVALID is populated.
8. The following proposed supplemental Qualifiers would be used to represent information regarding previous irradiation of a tumor when that information is captured in association with a specific tumor.

QNAM	QLABEL	Definition
PREVIR	Previously Irradiated	Indication of previous irradiation to a tumor.
PREVIRP	Irradiated then Subsequent Progression	Indication of documented progression subsequent to irradiation.

TU – Examples for Tumor Identification Domain Model

TU Example 1

Row	STUDYID	DOMAIN	USUBJID	TUSEQ	TUGRPID	TULNKID	TUTESTCD	TUTEST	TUORRES	TUSTRESC	TULOC	TULAT
1	ABC	TU	44444	1		T01	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	
2	ABC	TU	44444	2		T02	TUMIDENT	Tumor Identification	TARGET	TARGET	KIDNEY	RIGHT
3	ABC	TU	44444	3		T03	TUMIDENT	Tumor Identification	TARGET	TARGET	CERVICAL LYMPH NODE	LEFT
4	ABC	TU	44444	4		T04	TUMIDENT	Tumor Identification	TARGET	TARGET	SKIN OF THE TRUNK	
5	ABC	TU	44444	5		NT01	TUMIDENT	Tumor Identification	NON-TARGET	NON-TARGET	THYROID GLAND	RIGHT
6	ABC	TU	44444	6		NT02	TUMIDENT	Tumor Identification	NON-TARGET	NON-TARGET	CEREBELLUM	RIGHT
7	ABC	TU	44444	7	T04	T04.1	TUSPLIT	Tumor Split	TARGET	TARGET	SKIN OF THE TRUNK	
8	ABC	TU	44444	8	T04	T04.2	TUSPLIT	Tumor Split	TARGET	TARGET	SKIN OF THE TRUNK	

Row	TUMETHOD	TUEVAL	VISITNUM	VISIT	TUDTC	TUDY
1 (cont)	CT SCAN	INVESTIGATOR	10	SCREEN	2010-01-01	-3
2 (cont)	CT SCAN	INVESTIGATOR	10	SCREEN	2010-01-01	-3
3 (cont)	MRI	INVESTIGATOR	10	SCREEN	2010-01-02	-2
4 (cont)	PHOTOGRAPHY	INVESTIGATOR	10	SCREEN	2010-01-03	-1
5 (cont)	CT SCAN	INVESTIGATOR	10	SCREEN	2010-01-01	-3
6 (cont)	MRI	INVESTIGATOR	10	SCREEN	2010-01-02	-2
7 (cont)	PHOTOGRAPHY	INVESTIGATOR	40	WEEK 6	2010-02-20	48
8 (cont)	PHOTOGRAPHY	INVESTIGATOR	40	WEEK 6	2010-02-20	48

SUPPTU for Example 1:

Row	STUDYID	RDOMAIN	USUBJID	IDVAL	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	ABC	TU	44444	TUSEQ	1	PREVIR	Previously Irradiated	N	CRF
2	ABC	TU	44444	TUSEQ	2	PREVIR	Previously Irradiated	N	CRF
3	ABC	TU	44444	TUSEQ	3	PREVIR	Previously Irradiated	Y	CRF
4	ABC	TU	44444	TUSEQ	3	PREVIRP	Irradiated then Subsequent Progression	Y	CRF

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5	ABC	TU	44444	TUSEQ	4	PREVIR	Previously Irradiated	N	CRF
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TU Example 2

Row	STUDYID	DOMAIN	USUBJID	TUSEQ	TUGRPID	TULNKID	TUTESTCD	TUTEST	TUORRES	TUSTRESC	TULOC	TULAT
1	ABC	TU	55555	1		T01	TUMIDENT	Tumor Identification	TARGET	TARGET	CERVICAL LYMPH NODE	LEFT
2	ABC	TU	55555	2		T02	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	
3	ABC	TU	55555	3		T03	TUMIDENT	Tumor Identification	TARGET	TARGET	THYROID GLAND	RIGHT
4	ABC	TU	55555	4		NT01	TUMIDENT	Tumor Identification	NON-TARGET	NON-TARGET	KIDNEY	RIGHT
5	ABC	TU	55555	5		NT02	TUMIDENT	Tumor Identification	NON-TARGET	NON-TARGET	CEREBELLUM	RIGHT
6	ABC	TU	55555	6		NEW01	TUMIDENT	Tumor Identification	NEW	NEW	LUNG	
7	ABC	TU	55555	7		NEW02	TUMIDENT	Tumor Identification	NEW	NEW	CEREBELLUM	LEFT

Row	TUMETHOD	TUNAM	TUEVAL	TUEVALID	VISITNUM	VISIT	TUDTC	TUDY
1 (cont)	MRI	ACE IMAGING	INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN	2010-01-02	-2
2 (cont)	CT SCAN	ACE IMAGING	INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN	2010-01-01	-3
3 (cont)	CT SCAN	ACE IMAGING	INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN	2010-01-01	-3
4 (cont)	CT SCAN	ACE IMAGING	INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN	2010-01-01	-3
5 (cont)	MRI	ACE IMAGING	INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN	2010-01-02	-2
6 (cont)	CT SCAN	ACE IMAGING	INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6	2010-02-20	48
7 (cont)	MRI	ACE IMAGING	INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12	2010-04-02	88

Note: Additional extended examples of the oncology domains, including TU, are presented together in a spreadsheet attached to this document. The oncology domains are very closely related and presenting the examples in a single workbook provides a better way for viewing the relationships between the domains.

Tumor Results (TR)

TR – Description/Overview for Tumor Results Domain Model

The TR domain represents quantitative measurements and/or qualitative assessments of the tumors i.e. malignant tumors and other sites of disease, e.g. lymph nodes) identified in the TU domain. These measurements are usually taken at baseline and then at each subsequent assessment to support response evaluations. A record in the TR domain contains the following information: a unique tumor ID value; test and result; method used; role of the individual assessing the tumor; and timing information.

Clinically accepted evaluation criteria expect that a tumor identified by the tumor ID is the same tumor at each subsequent assessment. The TR domain does not include anatomical location information on each measurement record because this would be a duplication of information already represented in TU. This duplication of data was a deciding factor in multi-domain approach to representing this data.

TR – Specification for Tumor Results Domain Model

tr.xpt, Tumor Results - Findings, Version 3.2 - One record per tumor measurement/assessment per visit per subject per assessor, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TR	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
TRSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a dataset for a subject. May be any valid number.	Req
TRGRPID	Group ID	Char		Identifier	Used to link together a block of related records within a subject in a domain.	Perm
TRREFID	Reference ID	Char		Identifier	Internal or external identifier.	Perm
TRSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier.	Perm
TRLNKID	Link ID	Char		Identifier	Identifier used to link the assessment result records to the individual tumor identification record in TU domain.	Exp
TRLNKGRP	Link Group	Char		Identifier	Used to group and link all of the measurement/assessment records used in the assessment of the response record in the RS domain.	Perm
TRTESTCD	Tumor Assessment Short Name	Char	(TRTESTCD)	Topic	Short name of the TEST in TRTEST. TRTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: TUMSTATE, DIAMETER. See Assumption 2.	Req
TRTEST	Tumor Assessment Test Name	Char	(TRTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in TRTEST cannot be longer than 40 characters. Examples: Tumor State, Diameter, Longest Perpendicular diameter, Volume, Area. See Assumption 2.	Req
TRORES	Result or Finding in Original Units	Char		Result Qualifier	Result of the Tumor measurement/assessment as originally received or collected.	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
TRORESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for TRORES. Example: mm	Exp
TRSTRESC	Character Result/Finding in Std Format	Char		Record Qualifier	Contains the result value for all findings, copied or derived from TRORES in a standard format or standard units. TRSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in TRSTRESN	Exp
TRSTRESN	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 TRSTRESC. TRSTRESN should store all numeric test results or findings.	Exp
TRSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for TRSTRESN.	Exp
TRSTAT	Completion Status	Char	(ND)	Result Qualifier	Used to indicate a scan/image/physical exam was not performed or a tumor measurement was not taken. Should be Null if a result exists in TRORES.	Perm
TRREASND	Reason Tumor Measurement Not Performed	Char		Record Qualifier	Describes why a scan/image/physical exam was not performed or a tumor measurement was not taken. Examples: SCAN NOT PERFORMED, NOT ASSESSABLE: Image obscured, TUMOR. Used in conjunction with TRSTAT when value is NOT DONE.	Perm
TRNAM	Vendor Name	Char		Record Qualifier	The name or identifier of the vendor that performed the Tumor measurement or assessment. This column can be left Null when the Investigator provides the complete set of data in the domain.	Perm
TRMETHOD	Method used to Identify the Tumor		(METHOD)	Record Qualifier	Method used to measure the tumor. Examples: MRI, CT SCAN.	Exp
TREVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Examples: INVESTIGATOR, INDEPENDENT ASSESSOR. This column can be left Null when the Investigator provides the complete set of data in the domain. However the column should contain no Null values when data from one or more independent assessors is included meaning that the rows attributed to the Investigator should contain a value of INVESTIGATOR.	Exp
TREVALID	Evaluator Identifier	Char	(MEDEVAL)	Variable Qualifier	The Evaluator Specified variable is used in conjunction with TREVAL to provide an additional level of detail. When multiple assessors play the role identified in TREVAL, values of TREVALID will attribute a row of data to a particular assessor. TREVALID should not contain the names of the assessors, or a code identifier for a specific assessor, but should contain values such as RADIOLOGIST, RADIOLOGIST 1 or RADIOLOGIST 2. The TREVALID variable is subject to CDISC Controlled Terminology. Note TREVAL must also be populated when TREVALID is populated. See Assumption 7.	Perm
TRACPTFL	Accepted Record Flag	Char	(NY)	Record Qualifier	In cases where more than one independent assessor (e.g. RADIOLOGIST 1, RADIOLOGIST 2, ADJUDICATOR) provide independent assessments at	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
					the same timepoint this flag identifies the record that is considered to be the accepted assessment.	
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing		Perm
EPOCH	Epoch	Char		Timing	Epoch associated with the Element in the planned sequence of Elements for the ARM to which the subject was assigned	Perm
TRDTC	Date/Time of Tumor Measurement	Char	ISO 8601	Timing	TRDTC variable represents the date of the scan/image/physical exam not the date that the image was read to identify tumors. TRDTC variable does not represent the VISIT date.	Exp
TRDY	Study Day of Tumor Measurement	Num		Timing	1. Study day of the scan/image/physical exam, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm

TR – Assumptions for Tumor Results Domain Model

The TR domain represents quantitative measurements and/or qualitative assessments of the tumors (i.e. malignant tumors and other sites of disease, e.g. lymph nodes) identified in the TU domain. These measurements are usually taken at baseline and then at each subsequent assessment to support response evaluations.

1. TRLNKID is used to relate records in the TR domain to an identification record in TU domain. The organization of data across the TU and TR domains requires a RELREC relationship to link the related data rows. A dataset to dataset link would be the most appropriate linking mechanism. Utilizing one of the existing ID variables is not possible because all three (GRPID, REFID & SPID) may be used for other purposes per SDTM. The --LNKID variable is used for values that support a RELREC dataset to dataset relationship and to provide a unique code for each identified tumor.
2. TRLNKGRP is used to relate records in the TR domain to a response assessment record in RS domain. The organization of data across the TR and RS domains requires a RELREC relationship to link the related data rows. A dataset to dataset link would be the most appropriate linking mechanism. Utilizing one of the existing ID variables is not possible because all three (GRPID, REFID & SPID) may be used for other purposes per SDTM. The --LNKGRP variable is used for values that support a RELREC dataset to dataset relationship and to provide a unique code for each response and associated tumor measurements/assessments.
3. TRTESTCD / TRTEST values for this domain are published as Controlled Terminology. The sponsor should not derive results for any test (e.g. “Percent Change From Nadir in Sum of Diameter”) if the result was not collected. Tests would be included in the domain only if those data points have been collected on a CRF or have been supplied by an external assessor as part of an electronic data transfer. It is not intended that the sponsor would create derived records to supply those values in the TR domain. Derived records/results should be provided in the analysis dataset.
4. When a tumor has split or merged, assessments will be recorded for the new records created in the TU domain. If split and merge tumors are not represented in the TU domain due to the approach used in data collection (e.g. if measurements of split tumors are reported as a summary under the ‘parent’ tumor), the TRTEST=‘Tumor State’ and TRORES can be used to indicate that the tumor has split or merged.

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5. When a tumor is too small to measure per assessment criteria and a default value can be recorded for that assessment (e.g. in RECIST, a value of 5mm is used, in the calculation when determining response, for too small to measure tumors. This default value is expected in TRSTERSC & TRSTRESN for studies using RECIST.) the information should be represented on a single row of data showing the standardization between the original result, TRORES, and the standard results, TRSTRESC/TRSTRESN, as follows:

TRLNKID	TRTESTCD	TRTEST	TRORES	TRORESU	TRSTRESC	TRSTRESN	TRSTRESU
T01	DIAMETER	Diameter	TOO SMALL TO MEASURE	mm	5	5	mm

Note: This is an exception to SDTM-IG general variable rule 4.1.5.1.1

6. The Acceptance Flag variable (TRACPTFL) identifies those records that have been determined to be the accepted assessments/measurements by an independent assessor. This flag would be provided by an independent assessor and when multiple assessors (e.g. RADIOLOGIST 1, RADIOLOGIST 2, ADJUDICATOR) provide assessments or evaluations at the same time point or an overall evaluation. This flag should not be used by a sponsor for any other purpose i.e. it is not expected that the TRACPTFL flag would be populated by the sponsor. Instead that type of record selection should be handled in the analysis dataset.
7. The Evaluator Specified variable (TREVALID) is used in conjunction with TREVAL to provide additional detail of who is providing measurements or assessments. For example TREVAL="INDEPENDENT ASSESSOR" and TREVALID="RADIOLOGIST 1". The TREVALID variable is to Controlled Terminology. TREVAL must also be populated when TREVALID is populated.

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TR – Examples for Tumor Results Domain Model

TR Example 1

Row	STUDYID	DOMAIN	USUBJID	TRSEQ	TRGRPID	TRLNKGRP	TRLNKID	TRTESTCD	TRTEST	TORRES	TORRESU
1	ABC	TR	44444	1	TARGET	A1	T01	DIAMETER	Diameter	17	mm
2	ABC	TR	44444	2	TARGET	A1	T02	DIAMETER	Diameter	16	mm
3	ABC	TR	44444	3	TARGET	A1	T03	DIAMETER	Diameter	15	mm
4	ABC	TR	44444	4	TARGET	A1	T04	DIAMETER	Diameter	14	mm
5	ABC	TR	44444	5	TARGET	A1		SUMDIAM	Sum of Diameter	62	mm
6	ABC	TR	44444	6	TARGET	A1		SUMNLNLD	Sum Diameters of Non Lymph Node Tumors	47	mm
7	ABC	TR	44444	7	NON-TARGET	A1	NT01	TUMSTATE	Tumor State	PRESENT	
8	ABC	TR	44444	8	NON-TARGET	A1	NT02	TUMSTATE	Tumor State	PRESENT	
9	ABC	TR	44444	9	TARGET	A2	T01	DIAMETER	Diameter	0	mm
10	ABC	TR	44444	10	TARGET	A2	T02	DIAMETER	Diameter	TOO SMALL TO MEASURE	mm
11	ABC	TR	44444	11	TARGET	A2	T03	DIAMETER	Diameter	12	mm
12	ABC	TR	44444	12	TARGET	A2	T04	DIAMETER	Diameter		
13	ABC	TR	44444	13	TARGET	A2	T04.1	DIAMETER	Diameter	6	mm
14	ABC	TR	44444	14	TARGET	A2	T04.2	DIAMETER	Diameter	7	mm
15	ABC	TR	44444	15	TARGET	A2		SUMDIAM	Sum of Diameter	30	mm
16	ABC	TR	44444	16	TARGET	A2		SUMNLNLD	Sum Diameters of Non Lymph Node Tumors	18	mm
17	ABC	TR	44444	17	TARGET	A2		LNSTATE	Lymph Nodes State	PATHOLOGICAL	
18	ABC	TR	44444	18	TARGET	A2		ACNSD	Absolute Change From Nadir in Sum of Diameter	-32	mm
19	ABC	TR	44444	19	TARGET	A2		PCBSD	Percent Change From Baseline in Sum of Diameter	-52	%
20	ABC	TR	44444	20	TARGET	A2		PCNSD	Percent Change From Nadir in Sum of Diameter	-52	%
21	ABC	TR	44444	21	NON-TARGET	A2	NT01	TUMSTATE	Tumor State	PRESENT	
22	ABC	TR	44444	22	NON-TARGET	A2	NT02	TUMSTATE	Tumor State	PRESENT	
23	ABC	TR	44444	23	TARGET	A3	T01	DIAMETER	Diameter	0	mm
24	ABC	TR	44444	24	TARGET	A3	T02	DIAMETER	Diameter	6	mm
25	ABC	TR	44444	25	TARGET	A3	T03	DIAMETER	Diameter		
26	ABC	TR	44444	26	TARGET	A3	T04	DIAMETER	Diameter		
27	ABC	TR	44444	27	NON-TARGET	A3	NT01	TUMSTATE	Tumor State		
28	ABC	TR	44444	28	NON-TARGET	A3	NT02	TUMSTATE	Tumor State		

Row	TRSTRESC	TRSTRESN	TRSTRESU	TRSTAT	TRREASND	TRMETHOD	TREVAL	VISITNUM	VISIT	TRDTC	TRDY
1 (cont)	17	17	mm			CT SCAN	INVESTIGATOR	10	SCREEN	2010-01-01	-3
2 (cont)	16	16	mm			CT SCAN	INVESTIGATOR	10	SCREEN	2010-01-01	-3
3 (cont)	15	15	mm			MRI	INVESTIGATOR	10	SCREEN	2010-01-02	-2
4 (cont)	14	14	mm			PHOTOGRAPHY	INVESTIGATOR	10	SCREEN	2010-01-03	-1
5 (cont)	62	62	mm				INVESTIGATOR	10	SCREEN		
6 (cont)	47	47	mm				INVESTIGATOR	10	SCREEN		
7 (cont)	PRESENT					CT SCAN	INVESTIGATOR	10	SCREEN	2010-01-01	-3

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Row	TRSTRESC	TRSTRESN	TRSTRESU	TRSTAT	TRREASND	TRMETHOD	TREVAL	VISITNUM	VISIT	TRDTC	TRDY
8 (cont)	PRESENT					MRI	INVESTIGATOR	10	SCREEN	2010-01-02	-2
9 (cont)	0	0	mm			CT SCAN	INVESTIGATOR	40	WEEK 6	2010-02-18	46
10 (cont)	5	5	mm			CT SCAN	INVESTIGATOR	40	WEEK 6	2010-02-18	46
11 (cont)	12	12	mm			MRI	INVESTIGATOR	40	WEEK 6	2010-02-19	47
12 (cont)				NOT DONE	TUMOR SPLIT OR DIVIDED	PHOTOGRAPHY	INVESTIGATOR	40	WEEK 6		
13 (cont)	6	6	mm			PHOTOGRAPHY	INVESTIGATOR	40	WEEK 6	2010-02-20	48
14 (cont)	7	7	mm			PHOTOGRAPHY	INVESTIGATOR	40	WEEK 6	2010-02-20	48
15 (cont)	30	30	mm				INVESTIGATOR	40	WEEK 6		
16 (cont)	18	18	mm				INVESTIGATOR	40	WEEK 6		
17 (cont)	PATHOLOGICAL						INVESTIGATOR	40	WEEK 6		
18 (cont)	-32	-32	mm				INVESTIGATOR	40	WEEK 6		
19 (cont)	-52	-52	%				INVESTIGATOR	40	WEEK 6		
20 (cont)	-52	-52	%				INVESTIGATOR	40	WEEK 6		
21 (cont)	PRESENT					CT SCAN	INVESTIGATOR	40	WEEK 6	2010-02-18	46
22 (cont)	PRESENT					MRI	INVESTIGATOR	40	WEEK 6	2010-02-19	47
23 (cont)	0	0	mm			CT SCAN	INVESTIGATOR	60	WEEK 12	2010-04-02	88
24 (cont)	6	6	mm			CT SCAN	INVESTIGATOR	60	WEEK 12	2010-04-02	88
25 (cont)				NOT DONE	SCAN NOT PERFORMED	MRI	INVESTIGATOR	60	WEEK 12		
26 (cont)				NOT DONE	NOT ASSESSABLE: POOR IMAGE QUALITY	PHOTOGRAPHY	INVESTIGATOR	60	WEEK 12		
27 (cont)						CT SCAN	INVESTIGATOR	60	WEEK 12	2010-04-02	88
28 (cont)				NOT DONE	SCAN NOT PERFORMED	MRI	INVESTIGATOR	60	WEEK 12		

TR Example 2

Row	STUDYID	DOMAIN	USUBJID	TRSEQ	TRGRPID	TRLNKGRP	TRLNKID	TRTESTCD	TRTEST	TORRES	TORRESU
1	ABC	TR	55555	1	TARGET	A1	R1-T01	DIAMETER	Diameter	20	mm
2	ABC	TR	55555	2	TARGET	A1	R1-T02	DIAMETER	Diameter	15	mm
3	ABC	TR	55555	3	TARGET	A1	R1-T03	DIAMETER	Diameter	15	mm
4	ABC	TR	55555	4	TARGET	A1		SUMDIAM	Sum of Diameter	50	mm
5	ABC	TR	55555	5	TARGET	A1		SUMNLNLD	Sum Diameters of Non Lymph Node Tumors	30	mm
6	ABC	TR	55555	6	NON-TARGET	A1	R1-NT01	TUMSTATE	Tumor State	PRESENT	
7	ABC	TR	55555	7	NON-TARGET	A1	R1-NT02	TUMSTATE	Tumor State	PRESENT	
8	ABC	TR	55555	8	TARGET	A2	R1-T01	DIAMETER	Diameter	12	mm
9	ABC	TR	55555	9	TARGET	A2	R1-T02	DIAMETER	Diameter	0	mm
10	ABC	TR	55555	10	TARGET	A2	R1-T03	DIAMETER	Diameter	13	mm
11	ABC	TR	55555	11	TARGET	A2		SUMDIAM	Sum of Diameter	25	mm
12	ABC	TR	55555	12	TARGET	A2		SUMNLNLD	Sum Diameters of Non Lymph Node Tumors	13	mm
13	ABC	TR	55555	13	TARGET	A2		LNSTATE	Lymph Nodes State	PATHOLOGICAL	
14	ABC	TR	55555	14	TARGET	A2		ACNSD	Absolute Change From Nadir in Sum of Diameters	-25	mm
15	ABC	TR	55555	15	TARGET	A2		PCBSD	Percent Change From Baseline in Sum of Diameters	-50	%
16	ABC	TR	55555	16	TARGET	A2		PCNSD	Percent Change From Nadir in Sum of Diameters	-50	%

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Row	STUDYID	DOMAIN	USUBJID	TRSEQ	TRGRPID	TRLNKGRP	TRLNKID	TRTESTCD	TRTEST	TORRES	TORRESU
17	ABC	TR	55555	17	NON-TARGET	A2	R1-NT01	TUMSTATE	Tumor State	ABSENT	
18	ABC	TR	55555	18	NON-TARGET	A2	R1-NT02	TUMSTATE	Tumor State	ABSENT	
19	ABC	TR	55555	19	NEW	A2	R1-NEW01	TUMSTATE	Tumor State	EQUIVOCAL	
20	ABC	TR	55555	20	TARGET	A3	R1-T01	DIAMETER	Diameter	7	mm
21	ABC	TR	55555	21	TARGET	A3	R1-T02	DIAMETER	Diameter	20	mm
22	ABC	TR	55555	22	TARGET	A3	R1-T03	DIAMETER	Diameter	10	mm
23	ABC	TR	55555	23	TARGET	A3		SUMDIAM	Sum of Diameter	37	mm
24	ABC	TR	55555	24	TARGET	A3		SUMNLD	Sum Diameters of Non Lymph Node Tumors	30	mm
25	ABC	TR	55555	25	TARGET	A3		LNSTATE	Lymph Nodes State	NONPATHOLOGICAL	
26	ABC	TR	55555	26	TARGET	A3		ACNSD	Absolute Change From Nadir in Sum of Diameters	17	mm
27	ABC	TR	55555	27	TARGET	A3		PCBSD	Percent Change From Baseline in Sum of Diameters	-26	%
28	ABC	TR	55555	28	TARGET	A3		PCNSD	Percent Change From Nadir in Sum of Diameters	48	%
29	ABC	TR	55555	29	NON-TARGET	A3	NT01	TUMSTATE	Tumor State	ABSENT	
30	ABC	TR	55555	30	NON-TARGET	A3	NT02	TUMSTATE	Tumor State	ABSENT	
31	ABC	TR	55555	31	NEW	A3	R1-NEW01	TUMSTATE	Tumor State	EQUIVOCAL	
32	ABC	TR	55555	32	NEW	A3	R1-NEW02	TUMSTATE	Tumor State	UNEQUIVOCAL	

Row	TRSTRESC	TRSTRESN	TRSTRESU	TRNAM	TRMETHOD	TREVAL	TREVALID	VISITNUM	VISIT	TRDTC	TRDY
1 (cont)	20	20	mm	ACE IMAGING	MRI	INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN	2010-01-02	-2
2 (cont)	15	15	mm	ACE IMAGING	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN	2010-01-01	-3
3 (cont)	15	15	mm	ACE IMAGING	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN	2010-01-01	-3
4 (cont)	50	50	mm	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN		
5 (cont)	30	30	mm	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN		
6 (cont)	PRESENT			ACE IMAGING	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN	2010-01-02	-2
7 (cont)	PRESENT			ACE IMAGING	MRI	INDEPENDENT ASSESSOR	RADIOLOGIST 1	10	SCREEN	2010-01-04	1
8 (cont)	12	12	mm	ACE IMAGING	MRI	INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6	2010-02-18	46
9 (cont)	0	0	mm	ACE IMAGING	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6	2010-02-19	47
10 (cont)	13	13	mm	ACE IMAGING	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6	2010-02-19	47
11 (cont)	25	25	mm	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6		
12 (cont)	13	13	mm	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6		
13 (cont)	PATHOLOGICAL			ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6		
14 (cont)	-25	-25	mm	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6		
15 (cont)	-60	-50	%	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6		
16 (cont)	-50	-50	%	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6		
17 (cont)	ABSENT			ACE IMAGING	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6	2010-02-19	47
18 (cont)	ABSENT			ACE IMAGING	MRI	INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6	2010-02-18	46
19 (cont)	EQUIVOCAL			ACE IMAGING	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST 1	40	WEEK 6	2010-02-18	46
20 (cont)	7	7	mm	ACE IMAGING	MRI	INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12	2010-04-02	88
21 (cont)	20	20	mm	ACE IMAGING	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12	2010-04-02	88
22 (cont)	10	10	mm	ACE IMAGING	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12	2010-04-02	88
23 (cont)	37	37	mm	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12		
24 (cont)	30	30	mm	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12		
25 (cont)	NONPATHOLOGICAL			ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12		
26 (cont)	17	17	mm	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12		
27 (cont)	-26	-26	%	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12		

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Row	TRSTRESC	TRSTRESN	TRSTRESU	TRNAM	TRMETHOD	TREVAL	TREVALID	VISITNUM	VISIT	TRDTC	TRDY
28 (cont)	48	48	%	ACE IMAGING		INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12		
29 (cont)	ABSENT			ACE IMAGING	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12	2010-04-02	88
30 (cont)	ABSENT			ACE IMAGING	MRI	INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12	2010-04-02	88
31 (cont)	EQUIVOCAL			ACE IMAGING	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12	2010-04-02	88
32 (cont)	UNEQUIVOCAL			ACE IMAGING	MRI	INDEPENDENT ASSESSOR	RADIOLOGIST 1	60	WEEK 12	2010-04-02	88

Note: Additional extended examples of the oncology domains, including TR, are presented together in a spreadsheet attached to this document. The oncology domains are very closely related and presenting the examples in a single workbook provides a better way for viewing the relationships between the domains.

Disease Response (RS)

RS – Description/Overview for Disease Response Domain Model

RS (Disease Response): The RS domain represents the response evaluation(s) determined from the data in TR. Data from other sources (in other SDTM domains) might also be used in an assessment of response.

RS – Specification for Disease Response Domain Model

rs.xpt, Disease Response - Findings, Version 3.2 - One record per response assessment per visit per subject per assessor, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	RS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
RSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a dataset for a subject. May be any valid number.	Req
RSGRPID	Group ID	Char		Identifier	Used to link together a block of related records within a subject in a domain.	Perm
RSREFID	Reference ID	Char		Identifier	Internal or external identifier.	Perm
RSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier.	Perm
RSLNKID	Link ID	Char		Identifier	Used to link the response assessment to the appropriate measurement records (in TR) for same tumor that was used to determine the response result.	Perm
RSLNKGRP	Link Group	Char		Identifier	Used to link the response assessment to the all of the measurement/assessment records in the TR domain which were used in the assessment of the response.	Perm
RSTESTCD	Response Assessment Short Name	Char	(RSTESTCD)	Topic	Short name of the TEST in RSTEST. RSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: TRGRES, NTRGRES, OVRRESP, BESTRESP, NRADPROG	Req
RSTEST	Response Assessment Name	Char	(RSTEST)	Synonym Qualifier	Verbatim name of the response assessment. The value in RSTEST cannot be longer than 40 characters. Examples: Target Response, Non-target Response, Overall Response, Best Overall Response, Non-radiological progression (i.e. Symptomatic deterioration)	Req
RSCAT	Category for Response Assessment	Char		Grouping Qualifier	RSCAT is used to identify the criteria used in the assessment of response and a version number if appropriate	Exp
RSORRES	Response Assessment Original Result	Char		Result Qualifier	Result of the Response assessment as originally received, collected, or calculated.	Exp
RSSTRESC	Response Assessment Result in Std Format	Char		Record Qualifier	Contains the result value for the response assessment, copied or derived from RSORRES in a standard format or standard units. RSSTRESC should store all results or findings in character format;	Exp
RSSTAT	Completion Status	Char	(ND)	Result	Used to indicate the response assessment was not performed. Should be Null if	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
				Qualifier	a result exists in RSORRES.	
RSREASND	Reason Response Assessment Not Performed	Char		Record Qualifier	Describes why a response assessment was not performed. Examples: All target tumors not evaluated, Subject does not have non-target tumors. Used in conjunction with TRSTAT when value is NOT DONE.	Perm
RSNAM	Vendor Name	Char		Record Qualifier	The name or identifier of the vendor that performed the response assessment. This column can be left Null when the Investigator provides the complete set of data in the domain.	Perm
RSEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Examples: INVESTIGATOR, INDEPENDENT ASSESSOR. This column can be left Null when the Investigator provides the complete set of data in the domain. However the column should contain no Null values when data from one or more independent assessors is included meaning that the rows attributed to the Investigator should contain a value of INVESTIGATOR.	Exp
RSEVALID	Evaluator Identifier	Char	(MEDEVAL)	Variable Qualifier	The Evaluator Specified variable is used in conjunction with RSEVAL to provide an additional level of detail. When multiple assessors play the role identified in RSEVAL, values of RSEVALID will attribute a row of data to a particular assessor. RSEVALID should not contain the names of the assessors, or a code identifier for a specific assessor. The RSEVALID variable is subject to CDISC Controlled Terminology. Examples: RADIOLOGIST, RADIOLOGIST 1 or RADIOLOGIST 2. See Assumption 4	Perm
RSACPTFL	Accepted Record Flag	Char	(NY)	Record Qualifier	In cases where more than one independent assessor (e.g. RADIOLOGIST 1, RADIOLOGIST 2, ADJUDICATOR) provides an evaluation of response this flag identifies the record that is considered to be the accepted evaluation.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing		Perm
EPOCH	Epoch	Char		Timing	Epoch associated with the Element in the planned sequence of Elements for the ARM to which the subject was assigned	Perm
RSDTC	Date/Time of Response Assessment	Char	ISO 8601	Timing	RSDTC may be derived from the dates of scans/images/physical exams which may be performed on different dates. However, if all assessments are performed on the same date, RSDTC may be consistent with the TUDTC and TRDTC. Note the physical exam date may correspond to the visit date.	Exp
RSDY	Study Day of Response Assessment	Num		Timing	1. Study day of the response assessment, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm

RS – Assumptions for Disease Response Domain Model

RS Definition: The RS domain represents the response evaluation determined from the data in TR. Data from other sources (in other SDTM domains) might also be used in an assessment of response for example, lab test results (LB) or assessments of symptoms. The RSLNKGRP variable is used to provide a link between the records in the TR domain that contribute to a response assessment record in the RS domain and records should exist in the RELREC dataset to support this relationship. A RELREC relationship could also be defined using RSLNKID when a response evaluation relates back to an individual tumor. Any data that contributes to an assessment of response should be linked to the RS record through a RELREC relationship regardless of the domain that data resides in (e.g. a response criteria might require lab results that would reside in the LB domain).

1. RSTESTCD / RSTEST values for this domain are published as Controlled Terminology. It is not intended that the sponsor would create derived records to supply those values in the RS domain example. Derived records/results should be provided in the analysis dataset. For example BEST Response assessment records must only be included when provided by an assessor and should not be derived by the sponsor.
2. RSCAT is used to identify the criteria used in the assessment of response and a version number if appropriate. “CLINICAL ASSESSMENT” is used to represent the situation when the assessment of response was based on other evidence that was not defined as objective evidence in the criteria being used to evaluate response per protocol.
3. When an evaluation of symptomatic deterioration is collected (which in RECIST terms is symptomatic of progressive disease) the information would be recorded as follows:

RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC
NRADPROG	Non-Radiological Progression	CLINICAL ASSESSMENT	Pleural Effusion	PD

The actual symptomatic deterioration is recorded as the RSORRES when RSTEST=“Non-Radiological Progression”. The standard result variable RSSTRESC records the standardized response (e.g. RSSTRESC=“PD”).

Note: This is an exception to SDTM-IG general variable rule 4.1.5.1.1

4. The Evaluator Specified variable (RSEVALID) is used in conjunction with RSEVAL to provide additional detail of who is providing the response assessments. For example RSEVAL=“INDEPENDENT ASSESSOR” and RSEVALID=“RADIOLOGIST 1”. The RSEVALID variable is to Controlled Terminology. RSEVAL must also be populated when RSEVALID is populated.
5. The Acceptance Flag variable (RSACPTFL) identifies those records that have been determined to be the accepted assessments/measurements by an independent assessor. This flag would be provided by an independent assessor and when multiple assessors (e.g. RADIOLOGIST 1, RADIOLOGIST 2, ADJUDICATOR) provide assessments or evaluations at the same time point or an overall evaluation. This flag should not be used by a sponsor for any other purpose i.e. it is not expected that the RSACPTFL flag would be populated by the sponsor. Instead that type of record selection should be handled in the analysis dataset.

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RS – Examples for Disease Response Domain Model

RS Example 1

Row	STUDYID	DOMAIN	USUBJID	RSSEQ	RSLNKGPR	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	RSSTAT
1	ABC	RS	44444	1		TRGRES	Target Response	RECIST 1.1	PR	PR	
2	ABC	RS	44444	2		NTRGRES	Non-target Response	RECIST 1.1	SD	SD	
3	ABC	RS	44444	3	A2	OVRLRESP	Overall Response	RECIST 1.1	PR	PR	
4	ABC	RS	44444	4		TRGRES	Target Response	RECIST 1.1			NOT DONE
5	ABC	RS	44444	5		NTRGRES	Non-target Response	RECIST 1.1			NOT DONE
6	ABC	RS	44444	6		NRADPROG	Non-Radiological Progression	CLINICAL ASSESSMENT	Pleural Effusion	PD	
7	ABC	RS	44444	7	A3	OVRLRESP	Overall Response	CLINICAL ASSESSMENT	PD	PD	

Row	RSREASND	RSEVAL	VISITNUM	VISIT	RSDTC	RSDY
1 (cont)		INVESTIGATOR	40	WEEK 6	2010-02-18	46
2 (cont)		INVESTIGATOR	40	WEEK 6	2010-02-18	46
3 (cont)		INVESTIGATOR	40	WEEK 6	2010-02-18	46
4 (cont)	All targets not assessed	INVESTIGATOR	60	WEEK 12	2010-04-02	88
5 (cont)	Non-targets not assessed	INVESTIGATOR	60	WEEK 12	2010-04-02	88
6 (cont)		INVESTIGATOR	60	WEEK 12	2010-04-02	88
7 (cont)		INVESTIGATOR	60	WEEK 12	2010-04-02	88

RS Example 2

Row	STUDYID	DOMAIN	USUBJID	RSSEQ	RSLNKGPR	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	RSNAM
1	ABC	RS	55555	1		TRGRES	Target Response	RECIST 1.1	PR	PR	ACE IMAGING
2	ABC	RS	55555	2		NTRGRES	Non-target Response	RECIST 1.1	CR	CR	ACE IMAGING
3	ABC	RS	55555	3		NEWLPROG	New Lesion Progression	RECIST 1.1	Equivocal	Equivocal	ACE IMAGING
4	ABC	RS	55555	4	A2	OVRLRESP	Overall Response	RECIST 1.1	PR	PR	ACE IMAGING
5	ABC	RS	55555	5		TRGRES	Target Response	RECIST 1.1	PD	PD	ACE IMAGING
6	ABC	RS	55555	6		NTRGRES	Non-target Response	RECIST 1.1	CR	CR	ACE IMAGING
7	ABC	RS	55555	7		NEWLPROG	New Lesion Progression	RECIST 1.1	Unequivocal	Unequivocal	ACE IMAGING
8	ABC	RS	55555	8	A3	OVRLRESP	Overall Response	RECIST 1.1	PD	PD	ACE IMAGING

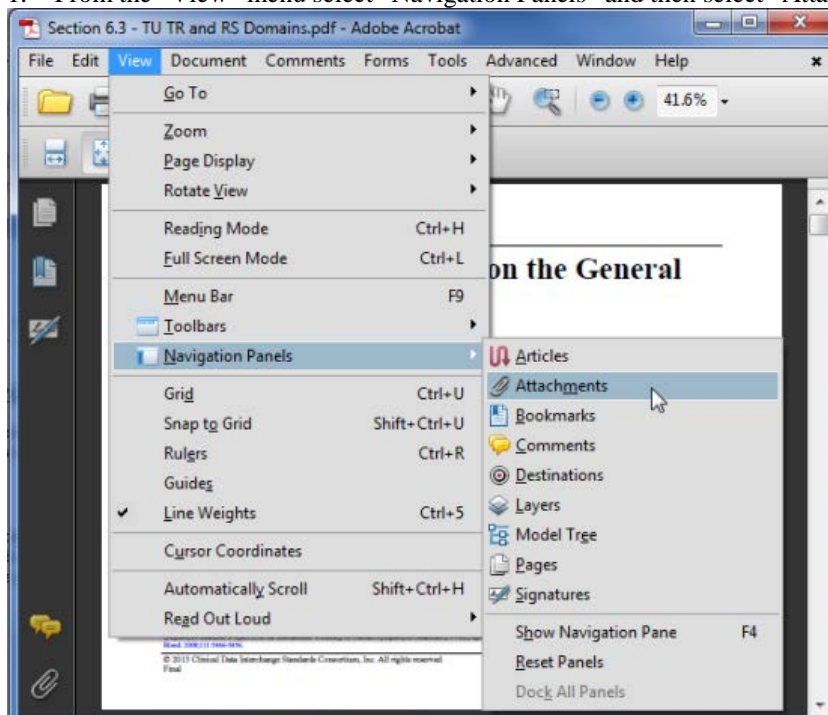
Row	RSEVAL	RSEVALID	RSACPTFL	VISITNUM	VISIT	RSDTC	RSDY
1 (cont)	INDEPENDENT ASSESSOR	RADIOLOGIST 1	Y	40	WEEK 6	2010-02-18	46
2 (cont)	INDEPENDENT ASSESSOR	RADIOLOGIST 1	Y	40	WEEK 6	2010-02-18	46
3 (cont)	INDEPENDENT ASSESSOR	RADIOLOGIST 1	Y	40	WEEK 6	2010-02-18	46
4 (cont)	INDEPENDENT ASSESSOR	RADIOLOGIST 1	Y	40	WEEK 6	2010-02-18	46
5 (cont)	INDEPENDENT ASSESSOR	RADIOLOGIST 1	Y	60	WEEK 12	2010-04-02	88
6 (cont)	INDEPENDENT ASSESSOR	RADIOLOGIST 1	Y	60	WEEK 12	2010-04-02	88
7 (cont)	INDEPENDENT ASSESSOR	RADIOLOGIST 1	Y	60	WEEK 12	2010-04-02	88
8 (cont)	INDEPENDENT ASSESSOR	RADIOLOGIST 1	Y	60	WEEK 12	2010-04-02	88

Additional extended examples of the oncology domains, including RS, are presented together in a spreadsheet attached to this document. The oncology domains are very closely related and presenting the examples in a single workbook provides a better way for viewing the relationships between the domains.

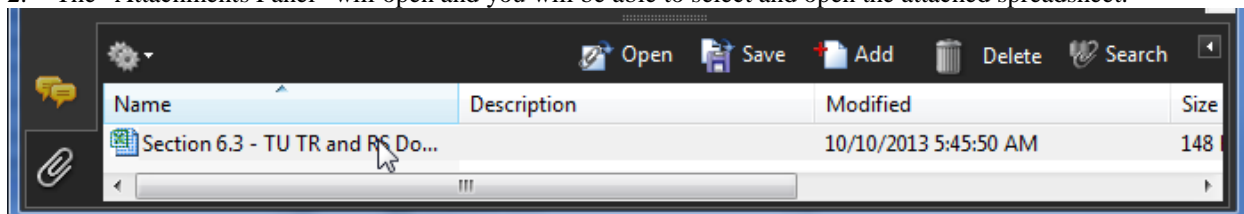
TU, TR and RS Domain Examples

Detailed examples of the oncology domains are presented in the spreadsheet attached to this PDF document. To access the example spreadsheet follow the instructions below.

1. From the “View” menu select “Navigation Panels” and then select “Attachments”, or [click here](#).



2. The “Attachments Panel” will open and you will be able to select and open the attached spreadsheet.



Notes on the spreadsheet:

- The first tab (Introduction) contains an introduction and description of each of the examples. Several examples appear in each sheet but the examples numbered the same are related and present a consistent scenario.
- The second tab (TU Domain) contains examples of TU data
- The third tab (TR Domain) contains examples of TR data
- The fourth tab (RS Domain) contains examples of RS data.
- The fifth tab (RelRec) contains an example of RELREC representing the relationship between TU, TR and RS.
- The sixth tab (TD Domain) contains examples of TD data.

6 Domain Models Based on the General Observation Classes

6.3 Findings

Vital Signs (VS)

VS – Description/Overview for Vital Signs Domain Model

Measurements including but not limited to blood pressure, temperature, respiration, body surface area, BMI, height and weight.

VS – Specification for Vital Signs Domain Model

vs.xpt, Vital Signs — Findings, Version 3.2. One record per vital sign measurement per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	VS	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VSSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
VSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
VSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm
VSTESTCD	Vital Signs Test Short Name	Char	(VSTESTCD)	Topic	Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g. "1TEST"). VSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: SYSBP, DIABP, BMI.	Req

CDISC SDTM Implementation Guide (Version 3.2)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
VSTEST	Vital Signs Test Name	Char	(VSTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in VSTEST cannot be longer than 40 characters. Examples: Systolic Blood Pressure, Diastolic Blood Pressure, Body Mass Index.	Req
VSCAT	Category for Vital Signs	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm
VSSCAT	Subcategory for Vital Signs	Char	*	Grouping Qualifier	A further categorization of a measurement or examination.	Perm
VSP0S	Vital Signs Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.	Perm
VSORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the vital signs measurement as originally received or collected.	Exp
VSORRESU	Original Units	Char	(VSRESU)	Variable Qualifier	Original units in which the data were collected. The unit for VSORRES. Examples: IN, LB, BEATS/MIN.	Exp
VSSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from VSORRES in a standard format or standard units. VSSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in VSSTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in VSORRES and these results effectively have the same meaning, they could be represented in standard format in VSSTRESC as "NEGATIVE".	Exp
VSSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from VSSTRESC. VSSTRESN should store all numeric test results or findings.	Exp
VSSTRESU	Standard Units	Char	(VSRESU)	Variable Qualifier	Standardized unit used for VSSTRESC and VSSTRESN.	Exp
VSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a vital sign measurement was not done. Should be null if a result exists in VSORRES.	Perm
VSREASND	Reason Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: BROKEN EQUIPMENT or SUBJECT REFUSED. Used in conjunction with VSSTAT when value is NOT DONE.	Perm
VSLOC	Location of Vital Signs Measurement	Char	(LOC)	Record Qualifier	Location relevant to the collection of Vital Signs measurement. Example: ARM for blood pressure.	Perm
VSLAT	Laterality	Char	(LAT)	Result Qualifier	Qualifier for anatomical location or specimen further detailing laterality. Examples: RIGHT, LEFT, BILATERAL	Perm
VSBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Exp
VSDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records which represent the average of other records or which do not come from the CRF are examples of records that would be derived for the submission datasets. If VSDRVFL=Y, then VSORRES may be null, with VSSTRESC and (if numeric) VSSTRESN having the derived value.	Perm

CDISC SDTM Implementation Guide (Version 3.2)

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
VSDTC	Date/Time of Measurements	Char	ISO 8601	Timing		Exp
VSDY	Study Day of Vital Signs	Num		Timing	1. Study day of vital signs measurements, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm
VSTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when measurement should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See VSTPTNUM and VSTPTREF. Examples: Start, 5 min post.	Perm
VSTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of VSTPT to aid in sorting.	Perm
VSELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned Elapsed time (in ISO 8601) relative to a planned fixed reference (VSTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date time variable. Represented as an ISO 8601 Duration. Examples: “-PT15M” to represent the period of 15 minutes prior to the reference point indicated by VSTPTREF, or “PT8H” to represent the period of 8 hours after the reference point indicated by VSTPTREF.	Perm
VSTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by VSELTM, VSTPTNUM, and VSTPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
VSRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, LBTPREF.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

VS – Assumptions for Vital Signs Domain Model

- VS Definition: CRF data that captures measurements such as blood pressure, height, weight, pulse, and body temperature, or derived data such as body mass index.
- In cases where the LOINC dictionary is used for Vital Sign tests, the permissible variable VSLOINC could be used. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external codelist attributes
- If a reference range is available for a vital signs test, the variables VSORNRLO, VSORNRHI, VSNRIND from the Findings observation class may be added to the domain. VSORNRLO and VSORNRHI would represent the reference range, and VSNRIND would be used to indicate where a result falls in respect to the reference range (examples: HIGH, LOW). Clinical significance would be represented as described in **Section 4: 4.1.5.5, Clinical Significance for Findings Observation Class Data** as a record in SUPPVS with a QNAM of VSCLSIG.
- The following Qualifiers would not generally be used in VS: --BODSYS, --XFN, --SPEC, --SPCCND, --FAST, --TOX, --TOXGR.

VS – Examples for Vital Signs Domain Model

The example below shows one subject with two visits, Baseline and Visit 2, including examples of both collected and derived baseline measurements.

Rows 1, 2, 4, 5, 8, 9: VSTPT and VSTPTNUM are populated since more than one measurement was taken at this visit.

Rows 3, 6: Show an example of a derived value that was not considered to be an original result. In this case the sponsor derived the value in a different variable in the operational database. VSTPT and VSTPTNUM are not populated for these derived records.

Rows 8, 9: Show two temperatures taken at the baseline visit. Row 9 has a "Y" in the VSBLFL to indicate it was used as the baseline measurement.

Row 14: Shows a value collected in one unit, but converted to selected standard unit.

Row 15: Shows the proper use of the --STAT variable to indicate "NOT DONE" where a reason was collected when a test was not done.

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU
1	ABC	VS	ABC-001-001	1	SYSBP	Systolic Blood Pressure	SITTING	154	mmHg	154	154	mmHg
2	ABC	VS	ABC-001-001	2	SYSBP	Systolic Blood Pressure	SITTING	152	mmHg	152	152	mmHg
3	ABC	VS	ABC-001-001	3	SYSBP	Systolic Blood Pressure	SITTING			153	153	mmHg
4	ABC	VS	ABC-001-001	4	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg
5	ABC	VS	ABC-001-001	5	DIABP	Diastolic Blood Pressure	SITTING	48	mmHg	48	48	mmHg
6	ABC	VS	ABC-001-001	6	DIABP	Diastolic Blood Pressure	SITTING			46	46	mmHg
7	ABC	VS	ABC-001-001	7	PULSE	Pulse Rate	SITTING	72	BEATS/MIN	72	72	BEATS/MIN
8	ABC	VS	ABC-001-001	8	TEMP	Temperature		34.7	C	34.7	34.7	C
9	ABC	VS	ABC-001-001	9	TEMP	Temperature		36.2	C	36.2	36.2	C
10	ABC	VS	ABC-001-001	10	WEIGHT	Weight	STANDING	90.5	kg	90.5	90.5	kg
11	ABC	VS	ABC-001-001	11	HEIGHT	Height	STANDING	157	cm	157	157	cm
12	ABC	VS	ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	95	mmHg	95	95	mmHg
13	ABC	VS	ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	44	mmHg	44	44	mmHg
14	ABC	VS	ABC-001-001	14	TEMP	Temperature		97.16	F	36.2	36.2	C
15	ABC	VS	ABC-001-001	15	WEIGHT	Weight						

Row	VSSTAT	VSREASND	VSLOC	VSLAT	VSBLFL	VSDRVFL	VISITNUM	VISIT	VISITDY	VSDTC	VSDY	VSTPT	VSTPTNUM
1 (cont)			ARM	LEFT			1	BASELINE	1	1999-06-19T08:45	1	BASELINE 1	1
2 (cont)			ARM	LEFT			1	BASELINE	1	1999-06-19T09:00	1	BASELINE 2	2
3 (cont)			ARM	LEFT	Y	Y	1	BASELINE	1	1999-06-19	1		
4 (cont)			ARM	LEFT			1	BASELINE	1	1999-06-19T08:45	1	BASELINE 1	1
5 (cont)			ARM	LEFT			1	BASELINE	1	1999-06-19T09:00	1	BASELINE 2	2
6 (cont)			ARM	LEFT	Y	Y	1	BASELINE	1	1999-06-19	1		
7 (cont)			ARM	LEFT	Y		1	BASELINE	1	1999-06-19	1		
8 (cont)			MOUTH				1	BASELINE	1	1999-06-19T08:45	1	BASELINE 1	1
9 (cont)			MOUTH		Y		1	BASELINE	1	1999-06-19T09:00	1	BASELINE 2	2
10 (cont)					Y		1	BASELINE	1	1999-06-19	1		
11 (cont)					Y		1	BASELINE	1	1999-06-19	1		
12 (cont)			ARM	LEFT			2	VISIT 2	35	1999-07-21	33		
13 (cont)			ARM	LEFT			2	VISIT 2	35	1999-07-21	33		
14 (cont)			MOUTH				2	VISIT 2	35	1999-07-21	33		
15 (cont)	NOT DONE	Subject refused					2	VISIT 2	35	1999-07-21	33		

6 Domain Models Based on the General Observation Classes

6.4 Findings About Events or Interventions

Findings About Events or Interventions is a specialization of the Findings General Observation Class. As such, it shares all qualities and conventions of Findings observations but is specialized by the addition of the --OBJ variable.

6.4.1 When to Use Findings About

It is intended, as its name implies, to be used when collected data represent "findings about" an Event or Intervention that cannot be represented within an Event or Intervention record or as a Supplemental Qualifier to such a record. Examples include the following:

- Data or observations that have different timing from an associated Event or Intervention as a whole:
For example, if severity of an AE is collected at scheduled time points (e.g., per visit) throughout the duration of the AE, the severities have timing that are different from that of the AE as a whole. Instead, the collected severities represent "snapshots" of the AE over time.
- Data or observations about an Event or Intervention which have Qualifiers of their own that can be represented in Findings variables (e.g., units, method):
These Qualifiers can be grouped together in the same record to more accurately describe their context and meaning (rather than being represented by multiple Supplemental Qualifier records). For example, if the size of a rash is measured, then the result and measurement unit (e.g., centimeters or inches) can be represented in the Findings About domain in a single record, while other information regarding the rash (e.g., start and end times), if collected would appear in an Event record.
- Data or observations about an Event or Intervention for which no Event or Intervention record has been collected or created:
For example, if details about a condition (e.g., primary diagnosis) are collected, but the condition was not collected as Medical History because it was a prerequisite for study participation, then the data can be represented as results in the Findings About domain, and the condition as the Object of the Observation (see [Section 6.4.3, Variables Unique To Findings About](#)).
- Data or information about an Event or Intervention that indicate the occurrence of related symptoms or therapies:
Depending on the Sponsor's definitions of reportable events or interventions and regulatory agreements, representing occurrence observations in either the Findings About domain or the appropriate Event or Intervention domain(s) is at the Sponsor's discretion. For example, in a migraine study, when symptoms related to a migraine event are queried and their occurrence is not considered either an AE or a record to be represented in another Events domain, then the symptoms can be represented in the Findings About domain.
- Data or information that indicate the occurrence of pre-specified AEs:
Since there is a requirement that every record in the AE domain represent an event that actually occurred, AE probing questions that are answered in the negative (e.g., did not occur, unknown, not done) cannot be stored in the AE domain. Therefore, answers to probing questions about the occurrence of pre-specified adverse events can be stored in the Findings About domain, and for each positive response (i.e., where occurrence indicates yes) there should be a record reflected in the AE domain. The Findings About record and the AE record may be linked via RELREC.

6.4.2 Naming Findings About Domains

Findings About domains are defined to store Findings About Events or Interventions. Sponsors may choose to represent Findings About data collected in the study in a single FA dataset (potentially splitting the FA domain into physically separate datasets following the guidance described in *Section 4: 4.1.1.7, Splitting Domains*), or separate datasets assigning unique custom 2-character domain codes following the SR (Skin Response) domain example.

For example, if Findings About clinical events and Findings About medical history are collected in a study, they could be represented as either:

- 1) A single FA domain, perhaps separated with different FACAT and/or FASCAT values
- 2) A split FA domain following the guidance in Section 4.1.1.7 where:
 - The DOMAIN value would be “FA”
 - Variables that require a prefix would use “FA”
 - The dataset names would be the domain name plus up to two additional characters indicating the parent domain (e.g., FACE for the Findings About clinical events and FAMH for findings about medical history).
 - FASEQ must be unique within USUBJID for all records across the split datasets.
 - Supplemental Qualifier datasets would need to be managed at the split-file level, for example, suppfac.xpt and suppfamh.xpt and RDOMAIN would be defined as “FA”.
 - If a dataset-level RELREC is defined (e.g., between the CE and FACE datasets), then RDOMAIN may contain up to four characters to effectively describe the relationship between the CE parent records with the FACE child records.
- 3) Separate domains where:
 - The DOMAIN value is sponsor defined and does not begin with FA. This is an additional application of Findings About that is new to this version of the SDTMIG. An example is the Skin Response domain, with a domain code of SR.
 - All published Findings About guidance applies, specifically:
 - The --OBJ variable cannot be added to any standard domain. A domain is either a Findings domain or Findings About domain, not one or the other depending on situations.
 - When the --OBJ variable is included in a domain, this identifies it as a Findings About domain, and the --OBJ variable must be populated for all records.
 - All published domain guidance applies, specifically:
 - Variables that require a prefix would use the 2-character domain code chosen.

6.4.3 Variables Unique to Findings About

The variable, --OBJ, is unique to Findings About. In conjunction with FATESTCD, it describes what the topic of the observation is; therefore both are required to be populated for every record. FATESTCD describes the measurement/evaluation and FAOBJ describes the Event or Intervention that the measurement/evaluation is about.

When collected data fit a Qualifier variable listed in *SDTM: Sections 2.2.1, 2.2.2, or 2.2.3*, and are represented in the Findings About domain, then the name of the variable should be used as the value of FATESTCD. For example,

FATESTCD	FATEST
OCCUR	Occurrence
SEV	Severity/Intensity
TOXGR	Toxicity Grade

The use of the same names (e.g., SEV, OCCUR) for both Qualifier variables in the observation classes and FATESTCD is deliberate, but should not lead users to conclude that the collection of such data (e.g., severity/intensity, occurrence) must be stored in the Findings About domain. In fact, data should only be stored in the Findings About domain if they do not fit in the general-observation-class domain. If the data describe the underlying Event or Intervention as a whole and share it's timing, then the data should be stored as a qualifier of the general-observation-class record.

In general, the value in FAOBJ should match the value in --TERM or --TRT, unless the parent domain is dictionary coded or subject to controlled terminology, in which case FAOBJ should then match the value in --DECOD.

Representing collected relationships supporting Findings About data are described in ***Section 8: 8.6, How to Determine Where Data Belong in SDTM-compliant Data Tabulations*** and are demonstrated in ***Section 6.4 - FA Domain: Examples for Findings About Domain Model***.

6 Domain Models Based on the General Observation Classes

6.4 Findings About Events or Interventions

Findings About (FA)

FA – Description/Overview for Findings About Domain Model

A dataset used to capture the findings about an event or intervention that cannot be represented within an event or intervention record or as a supplemental qualifier.

FA – Specification for Findings About Domain Model

fa.xpt, Findings About Events or Interventions — Findings Sub-Class, Version 3.1.2. One record per finding, per object, per time point, per visit per subject Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	FA	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
FASEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
FAGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
FASPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor’s operational database. Example: Line number on a CRF.	Perm
FATESTCD	Findings About Test Short Name	Char	(FATESTCD)	Topic	Short name of the measurement, test, or examination described in FATEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in FATESTCD cannot be longer than 8 characters, nor can it start with a number (e.g. “1TEST”). FATESTCD cannot contain characters other than letters, numbers, or underscores. Example: SEV, OCCUR.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
FATEST	Findings About Test Name	Char	(FATEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in FATEST cannot be longer than 40 characters. Examples: Severity/Intensity, Occurrence	Req
FAOBJ	Object of the Observation	Char		Record Qualifier	Used to describe the object or focal point of the findings observation that is represented by --TEST. Examples: the term (such as Acne) describing a clinical sign or symptom that is being measured by a Severity test, or an event such as VOMIT where the volume of Vomit is being measured by a VOLUME test.	Req
FACAT	Category for Findings About	Char	*	Grouping Qualifier	Used to define a category of related records. Examples: GERD, PRE-SPECIFIED AE.	Perm
FASCAT	Subcategory for Findings About	Char	*	Grouping Qualifier	A further categorization of FACAT.	Perm
FAORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the test as originally received or collected.	Exp
FAORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for FAORRES.	Perm
FASTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from FAORRES in a standard format or standard units. FASTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in FASTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in FAORRES and these results effectively have the same meaning; they could be represented in standard format in FASTRESC as "NEGATIVE".	Exp
FASTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from FASTRESC. FASTRESN should store all numeric test results or findings.	Perm
FASTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for FASTRESC and FASTRESN.	Perm
FASTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that the measurement was not done. Should be null if a result exists in FAORRES.	Perm
FAREASND	Reason Not Performed	Char		Record Qualifier	Describes why a question was not answered. Example: subject refused. Used in conjunction with FASTAT when value is NOT DONE.	Perm
FALOC	Location of the Finding About	Char	(LOC)	Record Qualifier	Used to specify the location of the clinical evaluation. Example: ARM	Perm
FALAT	Laterality of Location of the Finding About	Char	(LAT)	Result Qualifier	Qualifier for anatomical location or specimen further detailing laterality. Examples: RIGHT, LEFT, BILATERAL	
FABLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
FAEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain collected or derived data. Examples: INVESTIGATOR, ADJUDICATION COMMITTEE, VENDOR.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
FADTC	Date/Time of Collection	Char	ISO 8601	Timing		Perm
FADY	Study Day of Collection	Num		Timing	1. Study day of collection, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics. This formula should be consistent across the submission.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

FA - Assumptions for Findings About Domain Model

- The following qualifiers should generally not be used in FA: --BODSYS, --MODIFY, --SEV, --TOXGR.

FA - Examples for Findings About Domain Model

Example 1: Migraine Symptoms Diary

The form shown below collects severity and symptoms data at multiple time points about a migraine event.

Migraine Symptoms Diary	
Migraine Reference Number	xx
When did the migraine start?	DD-MMM-YYYY HH:MM
Answer the following 5 Minutes BEFORE Dosing	
Severity of Migraine	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
Associated Symptoms:	
Sensitivity to light	<input type="radio"/> No <input type="radio"/> Yes
Sensitivity to sound	<input type="radio"/> No <input type="radio"/> Yes
Nausea	<input type="radio"/> No <input type="radio"/> Yes
Aura	<input type="radio"/> No <input type="radio"/> Yes
Answer the following 30 Minutes AFTER Dosing	
Severity of Migraine	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe

Migraine Symptoms Diary	
<i>Associated Symptoms:</i>	
Sensitivity to light	<input type="radio"/> No <input type="radio"/> Yes
Sensitivity to sound	<input type="radio"/> No <input type="radio"/> Yes
Nausea	<input type="radio"/> No <input type="radio"/> Yes
Aura	<input type="radio"/> No <input type="radio"/> Yes
Answer the following 90 Minutes AFTER Dosing	
Severity of Migraine	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
<i>Associated Symptoms:</i>	
Sensitivity to light	<input type="radio"/> No <input type="radio"/> Yes
Sensitivity to sound	<input type="radio"/> No <input type="radio"/> Yes
Nausea	<input type="radio"/> No <input type="radio"/> Yes
Aura	<input type="radio"/> No <input type="radio"/> Yes

The collected data below the migraine start date on the CRF meet the following Findings About criteria: 1) Data that do not describe an Event or Intervention as a whole and 2) Data that indicate the occurrence of related symptoms.

In this mock scenario, the Sponsor's conventions and/or reporting agreements consider migraine as a clinical event (as opposed to a reportable AE) and consider the pre-specified symptom responses as findings about the migraine, therefore the data are represented in the Findings About domain with FATESTCD = "OCCUR" and FAOBJ defined as the symptom description. Therefore, the mock datasets represent (1) The migraine event record in the CE domain, (2) The severity and symptoms data, per time point, in the Findings About domain, and (3) A dataset-level relationship in RELREC based on the sponsor ID (--SPID) value which was populated with a system generated identifier unique to each iteration of this form.

ce.xpt

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CESPID	CETERM	CEDECOD	CESTDTC
1	ABC	CE	ABC-123	1	90567	Migraine	Migraine	2007-05-16T10:30

fa.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FASPID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC
1	ABC	FA	ABC-123	1	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS	SEVERE	SEVERE
2	ABC	FA	ABC-123	2	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS	Y	Y
3	ABC	FA	ABC-123	3	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS	N	N
4	ABC	FA	ABC-123	4	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS	Y	Y
5	ABC	FA	ABC-123	6	90567	OCCUR	Occurrence	Aura	MIGRAINE SYMPTOMS	Y	Y
6	ABC	FA	ABC-123	7	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS	MODERATE	MODERATE
7	ABC	FA	ABC-123	8	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS	Y	Y
8	ABC	FA	ABC-123	9	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS	N	N
9	ABC	FA	ABC-123	10	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS	N	N
10	ABC	FA	ABC-123	12	90567	OCCUR	Occurrence	Aura	MIGRAINE SYMPTOMS	Y	Y
11	ABC	FA	ABC-123	13	90567	SEV	Severity/Intensity	Migraine	MIGRAINE SYMPTOMS	MILD	MILD
12	ABC	FA	ABC-123	14	90567	OCCUR	Occurrence	Sensitivity To Light	MIGRAINE SYMPTOMS	N	N
13	ABC	FA	ABC-123	15	90567	OCCUR	Occurrence	Sensitivity To Sound	MIGRAINE SYMPTOMS	N	N
14	ABC	FA	ABC-123	16	90567	OCCUR	Occurrence	Nausea	MIGRAINE SYMPTOMS	N	N
15	ABC	FA	ABC-123	18	90567	OCCUR	Occurrence	Aura	MIGRAINE SYMPTOMS	N	N

Row	FADTC	FATPT	FAELTM	FATPTREF
1 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
2 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
3 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
4 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
5 (cont)	2007-05-16	5M PRE-DOSE	-PT5M	DOSING
6 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
7 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
8 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
9 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
10 (cont)	2007-05-16	30M POST-DOSE	PT30M	DOSING
11 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
12 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
13 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
14 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING
15 (cont)	2007-05-16	90M POST-DOSE	PT90M	DOSING

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	CE		CESPID		ONE	1
2	ABC	FA		FASPID		MANY	1

Example 2: Rash Assessment

This CRF collects details about rash events at each visit, until resolved.

Rash Assessment	
Date of Assessment	DD-MMM-YYYY
Associated AE reference number	xx
Rash Diameter	<input type="radio"/> cm <input type="radio"/> in
Lesion Type & Count	
Macules	<input type="radio"/> 0 <input type="radio"/> 1 to 25 <input type="radio"/> 26 to 100 <input type="radio"/> 101 to 200 <input type="radio"/> 201 to 300 <input type="radio"/> >300
Papules	<input type="radio"/> 0 <input type="radio"/> 1 to 25 <input type="radio"/> 26 to 100 <input type="radio"/> 101 to 200 <input type="radio"/> 201 to 300 <input type="radio"/> >300
Vesicles	<input type="radio"/> 0 <input type="radio"/> 1 to 25 <input type="radio"/> 26 to 100 <input type="radio"/> 101 to 200 <input type="radio"/> 201 to 300 <input type="radio"/> >300
Pustules	<input type="radio"/> 0 <input type="radio"/> 1 to 25 <input type="radio"/> 26 to 100 <input type="radio"/> 101 to 200 <input type="radio"/> 201 to 300 <input type="radio"/> >300
Scabs	<input type="radio"/> 0 <input type="radio"/> 1 to 25 <input type="radio"/> 26 to 100 <input type="radio"/> 101 to 200 <input type="radio"/> 201 to 300 <input type="radio"/> >300
Scars	<input type="radio"/> 0 <input type="radio"/> 1 to 25 <input type="radio"/> 26 to 100 <input type="radio"/> 101 to 200 <input type="radio"/> 201 to 300 <input type="radio"/> >300

The collected data meet the following Findings About criteria: 1) Data that do not describe an Event or Intervention as a whole and 2) Data (“about” an Event or Intervention) which have Qualifiers of their own that can be represented in Findings variables (e.g., units, method)

In this mock scenario, the rash event is considered a reportable AE; therefore the form design collects a reference number to the AE form where the event is captured. Data points collected on the Rash Assessment form can be represented in the Findings About domain and related to the AE via RELREC. Note, in the mock datasets below, the AE started on May 10, 2007 and the rash assessment was conducted on May 12 and May 19, 2007.

Certain Required or Expected variables have been omitted in consideration of space and clarity.

ae.xpt

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AESPID	AETERM	...	AEBODSYS	...	AELOC	AELAT	AESEV	AESER	AEACN	AESTDTC	...
1	XYZ	AE	XYZ-789	47869	5	Injection site rash	...	General disorders and administration site conditions	...	ARM	LEFT	MILD	N	NOT APPLICABLE	2007-05-10	...

fa.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FASPID	FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	FASTRESC	FASTRESU	VISITNUM	FADTC
1	XYZ	FA	XYZ-789	123451	5	DIAM	Diameter	Injection Site Rash	2.5	IN	2.5	IN	3	2007-05-12
2	XYZ	FA	XYZ-789	123452	5	COUNT	Count	Macules	26 to 100		26 to 100		3	2007-05-12
3	XYZ	FA	XYZ-789	123453	5	COUNT	Count	Papules	1 to 25		1 to 25		3	2007-05-12
4	XYZ	FA	XYZ-789	123454	5	COUNT	Count	Vesicles	0		0		3	2007-05-12
5	XYZ	FA	XYZ-789	123455	5	COUNT	Count	Pustules	0		0		3	2007-05-12
6	XYZ	FA	XYZ-789	123456	5	COUNT	Count	Scabs	0		0		3	2007-05-12
7	XYZ	FA	XYZ-789	123457	5	COUNT	Count	Scars	0		0		3	2007-05-12
8	XYZ	FA	XYZ-789	123459	5	DIAM	Diameter	Injection Site Rash	1	IN	1	IN	4	2007-05-19
9	XYZ	FA	XYZ-789	123460	5	COUNT	Count	Macules	1 to 25		1 to 25		4	2007-05-19
10	XYZ	FA	XYZ-789	123461	5	COUNT	Count	Papules	1 to 25		1 to 25		4	2007-05-19
11	XYZ	FA	XYZ-789	123462	5	COUNT	Count	Vesicles	0		0		4	2007-05-19
12	XYZ	FA	XYZ-789	123463	5	COUNT	Count	Pustules	0		0		4	2007-05-19
13	XYZ	FA	XYZ-789	123464	5	COUNT	Count	Scabs	0		0		4	2007-05-19
14	XYZ	FA	XYZ-789	123465	5	COUNT	Count	Scars	0		0		4	2007-05-19

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	XYZ	AE		AESPID		ONE	23
2	XYZ	FA		FASPID		MANY	23

Example 3: Rheumatoid Arthritis History

The form below collects information about rheumatoid arthritis. In this mock scenario, rheumatoid arthritis is a prerequisite for participation in an osteoporosis trial and was not collected as a Medical History event.

Rheumatoid Arthritis History	
Date of Assessment	DD-MMM-YYYY
During the past 6 months, how would you rate the following:	
Joint stiffness	<input type="radio"/> MILD <input type="radio"/> MODERATE <input type="radio"/> SEVERE
Inflammation	<input type="radio"/> MILD <input type="radio"/> MODERATE <input type="radio"/> SEVERE
Joint swelling	<input type="radio"/> MILD <input type="radio"/> MODERATE <input type="radio"/> SEVERE
Joint pain (arthralgia)	<input type="radio"/> MILD <input type="radio"/> MODERATE <input type="radio"/> SEVERE
Malaise	<input type="radio"/> MILD <input type="radio"/> MODERATE <input type="radio"/> SEVERE
Duration of early morning stiffness (hours and minutes)	_____ Hours _____ Minutes

The collected data meet the following Findings About criteria: Data (“about” an Event or Intervention) for which no Event or Intervention record has been collected or created. In this mock scenario, the rheumatoid arthritis history was assessed on August 13, 2006.

fa.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC	FADTC	FAEVLINT
1	ABC	FA	ABC-123	1	SEV	Severity/Intensity	Joint Stiffness	RHEUMATOID ARTHRITIS HISTORY	SEVERE	SEVERE	2006-08-13	-P6M
2	ABC	FA	ABC-123	2	SEV	Severity/Intensity	Inflammation	RHEUMATOID ARTHRITIS HISTORY	MODERATE	MODERATE	2006-08-13	-P6M
3	ABC	FA	ABC-123	3	SEV	Severity/Intensity	Joint Swelling	RHEUMATOID ARTHRITIS HISTORY	MODERATE	MODERATE	2006-08-13	-P6M
4	ABC	FA	ABC-123	4	SEV	Severity/Intensity	Arthralgia	RHEUMATOID ARTHRITIS HISTORY	MODERATE	MODERATE	2006-08-13	-P6M
5	ABC	FA	ABC-123	5	SEV	Severity/Intensity	Malaise	RHEUMATOID ARTHRITIS HISTORY	MILD	MILD	2006-08-13	-P6M
6	ABC	FA	ABC-123	6	DUR	Duration	Early Morning Stiffness	RHEUMATOID ARTHRITIS HISTORY	PT1H30M	PT1H30M	2006-08-13	-P6M

Example 4: Findings About Fracture Events

In this example, details about bone-fracture events are collected. This form is designed to collect multiple entries of fracture information including an initial entry for the most recent fracture prior to study participation, as well as entry of information for fractures that occur during the study.

Bone Fracture Assessment	
<i>Complete form for most recent fracture prior to study participation.</i>	
Enter Fracture Event Reference Number for all fractures occurring during study participation:	_____
How did fracture occur	<input type="radio"/> Pathologic <input type="radio"/> Fall <input type="radio"/> Other trauma <input type="radio"/> Unknown
What was the outcome	<input type="radio"/> Normal Healing <input type="radio"/> Complications Select all that apply: <input type="checkbox"/> <i>Complication x</i> <input type="checkbox"/> <i>Complication y</i> <input type="checkbox"/> <i>Complication z</i>

Bone Fracture Assessment	
Additional therapeutic measures required	<input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> Yes Select all that apply <input type="checkbox"/> Therapeutic measure a <input type="checkbox"/> Therapeutic measure b <input type="checkbox"/> Therapeutic measure c

The collected data meet the following Findings About criteria: (1) Data (“about” an Event or Intervention) that indicate the occurrence of related symptoms or therapies and (2) Data (“about” an event/intervention) for which no Event or Intervention record has been collected or created

Determining when data further describe the parent event record either as Variable Qualifiers or Supplemental Qualifiers may be dependent on data collection design. In the above form, responses are provided for the most recent fracture but an event record reference number was not collected. But for in-study fracture events, a reference number is collected which would allow representing the responses as part of the Event record either as Supplemental Qualifiers and/or variables like --OUT and --CONTRT.

The below domains reflect responses to each Bone Fracture Assessment question. The historical-fracture responses that are without a parent record are represented in the FA domain, while the current-fracture responses are represented as Event records with Supplemental Qualifiers.

Historical Fractures Having No Event Records

fa.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FASPID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FADTC
1	ABC	FA	ABC-US-701-002	1	798654	REAS	Reason	Bone Fracture	BONE FRACTURE ASSESSMENT - HISTORY	FALL	2006-04-10
2	ABC	FA	ABC-US-701-002	2	798654	OUT	Outcome	Bone Fracture	BONE FRACTURE ASSESSMENT - HISTORY	COMPLICATIONS	2006-04-10
3	ABC	FA	ABC-US-701-002	3	798654	OCCUR	Occurrence	Complications	BONE FRACTURE ASSESSMENT	Y	2006-04-10
4	ABC	FA	ABC-US-701-002	4	798654	OCCUR	Occurrence	Therapeutic Measure	BONE FRACTURE ASSESSMENT	Y	2006-04-10

suppfa.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	FA	ABC-US-701-002	FASEQ	1	FATYP	FA Type	MOST RECENT	CRF	
2	ABC	FA	ABC-US-701-002	FASEQ	2	FATYP	FA Type	MOST RECENT	CRF	
3	ABC	FA	ABC-US-701-002	FASEQ	3	FATYP	FA Type	MOST RECENT	CRF	
4	ABC	FA	ABC-US-701-002	FASEQ	4	FATYP	FA Type	MOST RECENT	CRF	

Current Fractures Having Event Records

ce.xpt

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CESPID	CETERM	CELOC	CEOUT	CECONTRT	CESTDTC
1	ABC	CE	ABC-US-701-002	1	1	Fracture	ARM	NORMAL HEALING	Y	2006-07-03
2	ABC	CE	ABC-US-701-002	2	2	Fracture	LEG	COMPLICATIONS	N	2006-10-15

suppce.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC	CE	ABC-US-701-002	CESPID	1	REAS	Reason	FALL	CRF	
2	ABC	CE	ABC-US-701-002	CESPID	2	REAS	Reason	OTHER TRAUMA	CRF	
3	ABC	CE	ABC-US-701-002	CESPID	2	OUT	Outcome	COMPLICATIONS	CRF	

Example 5: Pre-Specified Adverse Events

In this example, three AEs are pre-specified and are scheduled to be asked at each visit. If the occurrence is yes, then a complete AE record is collected on the AE form.

Pre-Specified Adverse Events of Clinical Interest	
Date of Assessment	DD-MMM-YYYY
Did the following occur? <i>If Yes, then enter a complete record in the AE CRF</i>	
Headache	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Done
Respiratory infection	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Done
Nausea	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Done

The collected data meet the following Findings About criteria: Data that indicate the occurrence of pre-specified adverse events.

In this mock scenario, each response to the pre-specified terms is represented in the Findings About domain. For the Y responses, an AE record is represented in the AE domain with its respective Qualifiers and timing details. In the example below, the AE of “Headache” encompasses multiple pre-specified Y responses and the AE of “Nausea” asked about on October 10, reported that it occurred and started on October 8 and ended on October 9. Note, in the example below, no relationship was collected to link the yes responses with the AE entries, therefore no RELREC was created.

fa.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FAORRES	FASTRESC	FASTAT	VISITNUM	VISIT	FADTC
1	QRS	FA	1234	1	OCCUR	Occurrence	Headache	Y	Y		2	VISIT 2	2005-10-01
2	QRS	FA	1234	2	OCCUR	Occurrence	Respiratory Infection	N	N		2	VISIT 2	2005-10-01
3	QRS	FA	1234	3	OCCUR	Occurrence	Nausea			NOT DONE	2	VISIT 2	2005-10-01
4	QRS	FA	1234	4	OCCUR	Occurrence	Headache	Y	Y		3	VISIT 3	2005-10-10
5	QRS	FA	1234	5	OCCUR	Occurrence	Respiratory Infection	N	N		3	VISIT 3	2005-10-10
6	QRS	FA	1234	6	OCCUR	Occurrence	Nausea	Y	Y		3	VISIT 3	2005-10-10

ae.xpt

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AEPRESP	AEBODSYS	AESEV	AEACN	AESTDTC	AEENDTC
1	QRS	AE	1234	1	Headache	Headache	Y	Nervous system disorders	MILD	NONE	2005-09-30	
2	QRS	AE	1234	2	Nausea	Nausea	Y	Gastrointestinal disorders	MODERATE	NONE	2005-10-08	2005-10-09

Example 6: Findings About GERD

In this example, the following CRF is used to capture data about pre-specified symptoms of the disease under study on a daily basis. The date of the assessment is captured, but start and end timing of the events are not.

SYMPTOMS	INVESTIGATOR GERD SYMPTOM MEASUREMENT
----------	---------------------------------------

	VOLUME (mL)	NUMBER OF EPISODES	MAXIMUM SEVERITY <i>None, Mild, Moderate, Severe</i>
Vomiting			
Diarrhea			
Nausea			

The collected data meet the following Findings About criteria: 1) data that do not describe an Event or Intervention as a whole, and 2) data (“about” an Event or Intervention) having Qualifiers that can be represented in Findings variables (e.g., units, method).

The data below represent data from two visits for one subject. Records occur in blocks of three for Vomit, and in blocks of two for Diarrhea and Nausea.

Rows 1-3: Show the results for the Vomiting tests at Visit 1.

Rows 4-5: Show the results for the Diarrhea tests at Visit 1.

Rows 6-7: Show the results for the Nausea tests at Visit 1.

Rows 8-10: Show the results for the Vomiting tests at Visit 2. These indicate that Vomiting was absent at Visit 2.

Rows 11-12: Show the results for the Diarrhea tests at Visit 2.

Rows 13-14: Indicate that Nausea was not assessed at Visit 2.

fa.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESU	FASTRESC	FASTRESU	FASTAT
1	XYZ	FA	XYZ-701-002	1	VOL	Volume	Vomit	GERD	250	mL	250	mL	
2	XYZ	FA	XYZ-701-002	2	NUMEPISD	Number of Episodes	Vomit	GERD	>10		>10		
3	XYZ	FA	XYZ-701-002	3	SEV	Severity/Intensity	Vomit	GERD	SEVERE		SEVERE		
4	XYZ	FA	XYZ-701-002	4	NUMEPISD	Number of Episodes	Diarrhea	GERD	2		2		
5	XYZ	FA	XYZ-701-002	5	SEV	Severity/Intensity	Diarrhea	GERD	SEVERE		SEVERE		
6	XYZ	FA	XYZ-701-002	6	NUMEPISD	Number of Episodes	Nausea	GERD	1		1		
7	XYZ	FA	XYZ-701-002	7	SEV	Severity/Intensity	Nausea	GERD	MODERATE		MODERATE		
8	XYZ	FA	XYZ-701-002	8	VOL	Volume	Vomit	GERD	0	mL	0	mL	
9	XYZ	FA	XYZ-701-002	9	NUMEPISD	Number of Episodes	Vomit	GERD	0		0		
10	XYZ	FA	XYZ-701-002	10	SEV	Severity/Intensity	Vomit	GERD	NONE		NONE		
11	XYZ	FA	XYZ-701-002	11	NUMEPISD	Number of Episodes	Diarrhea	GERD	1		1		
12	XYZ	FA	XYZ-701-002	12	SEV	Severity/Intensity	Diarrhea	GERD	SEVERE		SEVERE		
13	XYZ	FA	XYZ-701-002	13	NUMEPISD	Number of Episodes	Nausea	GERD					NOT DONE
14	XYZ	FA	XYZ-701-002	14	SEV	Severity/Intensity	Nausea	GERD					NOT DONE

Row	VISITNUM	VISIT	FADTC
1 (cont)	1	VISIT 1	2006-02-02
2 (cont)	1	VISIT 1	2006-02-02
3 (cont)	1	VISIT 1	2006-02-02
4 (cont)	1	VISIT 1	2006-02-02
5 (cont)	1	VISIT 1	2006-02-02
6 (cont)	1	VISIT 1	2006-02-02
7 (cont)	1	VISIT 1	2006-02-02
8 (cont)	2	VISIT 2	2006-02-03

9 (cont)	2	VISIT 2	2006-02-03
10 (cont)	2	VISIT 2	2006-02-03
11 (cont)	2	VISIT 2	2006-02-03
12 (cont)	2	VISIT 2	2006-02-03
13 (cont)	2	VISIT 2	2006-02-03
14 (cont)	2	VISIT 2	2006-02-03

Example 7: Findings About GERD

This example is similar to the one above except that with the following CRF, which includes a separate column to collect the occurrence of symptoms, measurements are collected only for symptoms that occurred. There is a record for the occurrence test for each symptom. If Vomiting occurs, there are 3 additional records, and for each occurrence of Diarrhea or Nausea there are two additional records.

Whether there are adverse event records related to these symptoms depends on agreements in place for the study about whether these symptoms are considered reportable adverse events.

SYMPTOMS	INVESTIGATOR GERD SYMPTOM MEASUREMENT (IF SYMPTOM OCCURRED)			
	OCCURRED? <i>Yes/No</i>	VOLUME (mL)	NUMBER OF EPISODES	MAXIMUM SEVERITY <i>Mild, Moderate, Severe</i>
Vomiting				
Diarrhea				
Nausea				

The collected data meet the following Findings About criteria: 1) data that do not describe an Event or Intervention as a whole, 2) data (“about” an Event or Intervention) having Qualifiers that can be represented in Findings variables (e.g., units, method), and 3) data (“about” an Event or Intervention) that indicate the occurrence of related symptoms or therapies.

The data below represent two visits for one subject.

- Rows 1-4:** Show the results for the Vomiting tests at Visit 1.
- Rows 5-7:** Show the results for the Diarrhea tests at Visit 1.
- Rows 8-10:** Show the results for the Nausea tests at Visit 1.
- Row 11:** Show that Vomiting was absent at Visit 2.
- Rows 12-14:** Show the results for the Diarrhea tests at Visit 2.
- Row 15:** Show that Nausea was not assessed at Visit 2.

fa.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESU	FASTRESC	FASTRESU	FASTAT
1	XYZ	FA	XYZ-701-002	1	OCCUR	Occurrence	Vomit	GERD	Y		Y		
2	XYZ	FA	XYZ-701-002	2	VOL	Volume	Vomit	GERD	250	mL	250	mL	
3	XYZ	FA	XYZ-701-002	3	NUMEPISD	Number of Episodes	Vomit	GERD	>10		>10		
4	XYZ	FA	XYZ-701-002	4	SEV	Severity/Intensity	Vomit	GERD	SEVERE		SEVERE		
5	XYZ	FA	XYZ-701-002	5	OCCUR	Occurrence	Diarrhea	GERD	Y		Y		

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESU	FASTRESC	FASTRESU	FASTAT
6	XYZ	FA	XYZ-701-002	6	NUMEPISD	Number of Episodes	Diarrhea	GERD	2		2		
7	XYZ	FA	XYZ-701-002	7	SEV	Severity/Intensity	Diarrhea	GERD	SEVERE		SEVERE		
8	XYZ	FA	XYZ-701-002	8	OCCUR	Occurrence	Nausea	GERD	Y		Y		
9	XYZ	FA	XYZ-701-002	9	NUMEPISD	Number of Episodes	Nausea	GERD	1		1		
10	XYZ	FA	XYZ-701-002	10	SEV	Severity/Intensity	Nausea	GERD	MODERATE		MODERATE		
11	XYZ	FA	XYZ-701-002	11	OCCUR	Occurrence	Vomit	GERD	N		N		
12	XYZ	FA	XYZ-701-002	12	OCCUR	Occurrence	Diarrhea	GERD	Y		Y		
13	XYZ	FA	XYZ-701-002	13	NUMEPISD	Number of Episodes	Diarrhea	GERD	1		1		
14	XYZ	FA	XYZ-701-002	14	SEV	Severity/Intensity	Diarrhea	GERD	SEVERE		SEVERE		
15	XYZ	FA	XYZ-701-002	15	OCCUR	Occurrence	Nausea	GERD					NOT DONE

Row	VISITNUM	FADTC
1 (cont)	1	2006-02-02
2 (cont)	1	2006-02-02
3 (cont)	1	2006-02-02
4 (cont)	1	2006-02-02
5 (cont)	1	2006-02-02
6 (cont)	1	2006-02-02
7 (cont)	1	2006-02-02
8 (cont)	1	2006-02-02
9 (cont)	1	2006-02-02
10 (cont)	1	2006-02-02
11 (cont)	2	2006-02-03
12 (cont)	2	2006-02-03
13 (cont)	2	2006-02-03
14 (cont)	2	2006-02-03
15 (cont)	2	2006-02-03

Example 8: Severity Assessments per Visit of Adverse Events

The adverse event module collects, instead of a single assessment of severity, assessments of severity at each visit, as follows:

<i>At each visit, record severity of the Adverse Event.</i>						
Visit	1	2	3	4	5	6
Severity						

The collected data meet the following Findings About criteria: data that do not describe an Event or Intervention as a whole.

AE Domain (For clarity, only selected variables are shown.)

Row 1: Shows the record for a verbatim term of "Morning queasiness", for which the maximum severity over the course of the event was "Moderate."

Row 2: Shows the record for a verbatim term of "Watery stools", for which "Mild" severity was collected at Visits 2 and 3 before the event ended.

ae.xpt

Row	DOMAIN	USUBJID	AESEQ	AETERM	...	AEDECOD	...	AESEV	...	AESTDTC	AEENDTC
-----	--------	---------	-------	--------	-----	---------	-----	-------	-----	---------	---------

1	AE	123	1	Morning queasiness	...	Nausea	...	MODERATE	...	2006-02-01	2006-02-23
2	AE	123	2	Watery stools	...	Diarrhea	...	MILD	...	2006-02-01	2006-02-15

FA domain

Rows 1-4: Show severity data collected at the four visits that occurred between the start and end of the AE, “Morning queasiness”. FAOBJ = NAUSEA, which is the value of AEDECOD in the associated AE record.

Rows 5-6: Show severity data collected at the two visits that occurred between the start and end of the AE, “Watery stools.” FAOBJ = DIARRHEA, which is the value of AEDECOD in the associated AE record.

fa.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FAORRES	VISITNUM	VISIT	FADTC
1	XYZ	FA	XYZ-US-701-002	1	SEV	Severity/Intensity	Nausea	MILD	2	VISIT 2	2006-02-02
2	XYZ	FA	XYZ-US-701-002	2	SEV	Severity/Intensity	Nausea	MODERATE	3	VISIT 3	2006-02-09
3	XYZ	FA	XYZ-US-701-002	3	SEV	Severity/Intensity	Nausea	MODERATE	4	VISIT 4	2006-02-16
4	XYZ	FA	XYZ-US-701-002	4	SEV	Severity/Intensity	Nausea	MILD	5	VISIT 5	2006-02-23
5	XYZ	FA	XYZ-US-701-002	5	SEV	Severity/Intensity	Diarrhea	MILD	2	VISIT 2	2006-02-02
6	XYZ	FA	XYZ-US-701-002	6	SEV	Severity/Intensity	Diarrhea	MILD	3	VISIT 3	2006-02-09

RELREC dataset

Depending on how the relationships were collected, in this example, RELREC could be created with either 2 or 6 RELIDs. With 2 RELIDs, the Sponsor is describing that the severity ratings are related to the AE as well as being related to each other. With 6 RELIDs, the Sponsor is describing that the severity ratings are related to the AE only (and not to each other).

Example with two RELIDs:

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	AE	XYZ-US-701-002	AESEQ	1		1
2	ABC	FA	XYZ-US-701-002	FASEQ	1		1
3	ABC	FA	XYZ-US-701-002	FASEQ	2		1
4	ABC	FA	XYZ-US-701-002	FASEQ	3		1
5	ABC	FA	XYZ-US-701-002	FASEQ	4		1
6	ABC	AE	XYZ-US-701-002	AESEQ	2		2
7	ABC	FA	XYZ-US-701-002	FASEQ	5		2
8	ABC	FA	XYZ-US-701-002	FASEQ	6		2

Example with six RELIDs:

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	AE	XYZ-US-701-002	AESEQ	1		1
2	ABC	FA	XYZ-US-701-002	FASEQ	1		1
3	ABC	AE	XYZ-US-701-002	AESEQ	1		2
4	ABC	FA	XYZ-US-701-002	FASEQ	2		2
5	ABC	AE	XYZ-US-701-002	AESEQ	1		3
6	ABC	FA	XYZ-US-701-002	FASEQ	3		3

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
7	ABC	AE	XYZ-US-701-002	AESEQ	1		4
8	ABC	FA	XYZ-US-701-002	FASEQ	4		4
9	ABC	AE	XYZ-US-701-002	AESEQ	2		5
10	ABC	FA	XYZ-US-701-002	FASEQ	5		5
11	ABC	AE	XYZ-US-701-002	AESEQ	2		6
12	ABC	FA	XYZ-US-701-002	FASEQ	6		6

6 Domain Models Based on the General Observation Classes

6.4 Findings About Events or Interventions

Skin Response (SR)

SR – Description/Overview for Skin Response Domain Model

The Skin Response (SR) is the first implementation of the Findings About concept that is Findings About an Intervention and uses a different domain code instead of FA.

SR – Specification for Skin Response Domain Model

SR.xpt, Skin Response — Findings, Version 3.2. One record per test per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique Identifier for a Study.	Req
DOMAIN	Domain Abbreviation	Char	SR	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across submission.	Req
SRSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
SRGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
SRREFID	Reference ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID.	Perm
SRSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor defined identifier.	Perm
SRTESTCD	Skin Response Test or Exam Short Name	Char	*	Topic	Short name of the measurement, test, or examination described in SRTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in SRTESTCD cannot be longer than 8 characters, nor can it start with a number. SRTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
SRTEST	Skin Response Test or Examination Name	Char	*	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in SRTEST cannot be longer than 40 characters. (E.g., Wheal Diameter).	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
SROBJ	Object of the Observation	Char		Record Qualifier	Used to describe the object or focal point of the findings observation that is represented by --TEST. Examples: the dose of the immunogenic material or the allergen associated with the response. (e.g., Johnson Grass IgE 0.15 BAU mL).	Req
SRCAT	Category for Test	Char		Grouping Qualifier	Used to define a category of Topic-variable values across subjects.	Perm
SRSCAT	Subcategory for Test	Char		Grouping Qualifier	A further categorization of SRCAT values.	Perm
SRORRES	Results or Findings in Original Units	Char		Result Qualifier	Results of measurement or finding as originally received or collected.	Exp
SRORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for SRORRES. Example: mm.	Exp
SRSTRESC	Character Results/Findings in Std. Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from SRORRES in a standard format or in standard units. SRSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in SRSTRESN.	Exp
SRSTRESN	Numeric Results/Findings in Std. Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from SRSTRESC. SRSTRESN should store all numeric test results or findings.	Exp
SRSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized units used for SRSTRESC and SRSTRESN, Example: mm.	Exp
SRSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate exam not done. Should be null if a result exists in SRORRES.	Perm
SRREASND	Reason Not Done	Char		Record Qualifier	Describes why a measurement or test was not performed. Used in conjunction with SRSTAT when value is NOT DONE.	Perm
SRNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor who provided the test results	Perm
SRSPEC	Specimen Type	Char	(SPECTYPE)	Record Qualifier	Defines the types of specimen used for a measurement. E.g., SKIN.	Perm
SRLOC	Location used for Measurement	Char	(LOC)	Record Qualifier	Location relevant to the collection of the measurement.	Perm
SRLAT	Laterality	Char	(LAT)	Result Qualifier	Qualifier for anatomical location further detailing laterality of intervention administration. Examples: RIGHT, LEFT, BILATERAL	Perm
SRMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of test or examination (ELISA, EIA Microneutralization, PRNT (Plaque Reduction Neutralization Tests)	Perm
SREVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of person who provided evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Should be null for records that contain collected or derived data. Examples: INVESTIGATOR, ADJUDICATION COMMITTEE, VENDOR	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter 2. May be used in addition to VISITNUM and/or VISITDY	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
SRDTC	Date/Time of Collection	Char	ISO 8601	Timing	Collection date and time of an observation represented in ISO 8601	Exp
SRDY	Study Day of Visit/Collection/Exam	Num		Timing	Actual study day of visit/collection/exam expressed in integer days relative to sponsor- defined RFSTDTC in Demographics	Perm
SRTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when measurement should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See SRTPTNUM and SRTPTREF. Examples: Start, 5 min post.	Perm
SRTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of SRTPT to aid in sorting.	Perm
SRELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a fixed time point reference (SRTPTREF). Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: “-PT15M” to represent the period of 15 minutes prior to the reference point indicated by EGTPTREF, or “PT8H” to represent the period of 8 hours after the reference point indicated by SRTPTREF.	Perm
SRTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by SRELTM, SRTPTNUM, and SRTPT. Example: INTRADERMAL INJECTION.	Perm
SRRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, SRTPTREF.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

SR - Assumptions for Skin Response Domain Model

1. The SR domain is a Findings About domain used to submit dermal responses to antigens. The method of assessment is typically a skin-prick test.
2. Because a subject is typically exposed to many test materials at the same time, SROBJ is needed to represent the test material for each response record.
3. The following Qualifiers would not generally be used in SR: --POS, --BODSYS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STRNC, --NRIND, --RESCAT, --XFN, --LOINC, --SPCCND, --FAST, --TOX, --TOXGR, --SEV.

SR - Examples for Skin Response Domain Model

Example 1

In this example, the subject is dosed with increasing concentrations of Johnson Grass IgE.

Rows 1-4: Show responses associated with the administration of a Histamine Control.

Rows 5-8: Show responses associated with the administration of Johnson Grass IgE. These records describe the dose response to different concentrations of Johnson Grass IgE antigen, as reflected in SROBJ.

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All rows show a specific location on the BACK (e.g., QUADRANT1). Since Quadrant1, Quadrant2, etc., are not currently part of the SDTM terminology, the sponsor has decided to include this information in the SRSUBLOC suppqal variable.

sr.xpt

Row	STUDYID	DOMAIN	USUBJID	SRSEQ	SRTESTCD	SRTEST	SROBJ	SRORRES	SRORRESU	SRSTRESC	SRSTRESN	SRSTRESU
1	SPI-001	SR	SPI-001-11035	1	WHEALDIA	Wheal Diameter	Histamine Control 10 mg/mL	5	mm	5	5	mm
2	SPI-001	SR	SPI-001-11035	2	WHEALDIA	Wheal Diameter	Histamine Control 10 mg/mL	4	mm	4	4	mm
3	SPI-001	SR	SPI-001-11035	3	WHEALDIA	Wheal Diameter	Histamine Control 10 mg/mL	5	mm	5	5	mm
4	SPI-001	SR	SPI-001-11035	4	WHEALDIA	Wheal Diameter	Histamine Control 10 mg/mL	5	mm	5	5	mm
5	SPI-001	SR	SPI-001-11035	5	WHEALDIA	Wheal Diameter	Johnson Grass IgE 0.05 BAU/mL	10	mm	10	10	mm
6	SPI-001	SR	SPI-001-11035	6	WHEALDIA	Wheal Diameter	Johnson Grass IgE 0.10 BAU/mL	11	mm	11	11	mm
7	SPI-001	SR	SPI-001-11035	7	WHEALDIA	Wheal Diameter	Johnson Grass IgE 0.15 BAU/mL	20	mm	20	20	mm
8	SPI-001	SR	SPI-001-11035	8	WHEALDIA	Wheal Diameter	Johnson Grass IgE 0.20 BAU/mL	30	mm	30	30	mm

Row	SRLOC	VISITNUM	VISIT
1 (cont)	BACK	1	VISIT 1
2 (cont)	BACK	1	VISIT 1
3 (cont)	BACK	1	VISIT 1
4 (cont)	BACK	1	VISIT 1
5 (cont)	BACK	1	VISIT 1
6 (cont)	BACK	1	VISIT 1
7 (cont)	BACK	1	VISIT 1
8 (cont)	BACK	1	VISIT 1

suppsr.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	SPI-001	SR	SPI-001-11035	SRSEQ	1	SRSUBLOC	Anatomical Sub-Location	QUADRANT1	CRF
2	SPI-001	SR	SPI-001-11035	SRSEQ	2	SRSUBLOC	Anatomical Sub-Location	QUADRANT2	CRF
3	SPI-001	SR	SPI-001-11035	SRSEQ	3	SRSUBLOC	Anatomical Sub-Location	QUADRANT3	CRF
4	SPI-001	SR	SPI-001-11035	SRSEQ	4	SRSUBLOC	Anatomical Sub-Location	QUADRANT4	CRF
5	SPI-001	SR	SPI-001-11035	SRSEQ	5	SRSUBLOC	Anatomical Sub-Location	QUADRANT1	CRF
6	SPI-001	SR	SPI-001-11035	SRSEQ	6	SRSUBLOC	Anatomical Sub-Location	QUADRANT2	CRF
7	SPI-001	SR	SPI-001-11035	SRSEQ	7	SRSUBLOC	Anatomical Sub-Location	QUADRANT3	CRF
8	SPI-001	SR	SPI-001-11035	SRSEQ	8	SRSUBLOC	Anatomical Sub-Location	QUADRANT4	CRF

Example 2

In this example, the study product dose is 0.05 BAU/mL of Dog Epi IgG at increasing concentrations. The size of the wheal is being measured (reaction to Dog Epi IgG) to evaluate the efficacy of the Dog Epi IgG extract versus Negative Control (NC)/Positive Control (PC) in the testing of allergenic extracts.

Rows 1-6: Show the response (description and reaction grade) to the study product at a series of different dose levels, the latter reflected in SROBJ. The descriptions of SRORRES values are correlated to a grade and the grade values are stored in SRSTRESC.

Rows 7-12: Show the results of wheal diameter measurements in response to the study product at a series of different dose levels.

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While SROBJ is populated for all rows, the more detailed information regarding the study product would be submitted in the EX dataset. The relationship between the SR records and the EX records would be represented using RELREC.

sr.xpt

Row	STUDYID	DOMAIN	USUBJID	SRSPID	SRTESTCD	SRTEST	SROBJ	SRORRES
1	CC-001	SR	CC-001-101	1	RCTGRDE	Reaction Grade	Dog Epi IgG 0 mg	NEGATIVE
2	CC-001	SR	CC-001-101	2	RCTGRDE	Reaction Grade	Dog Epi IgG 0.1 mg	NEGATIVE
3	CC-001	SR	CC-001-101	3	RCTGRDE	Reaction Grade	Dog Epi IgG 0.5 mg	ERYTHEMA, INFILTRATION, POSSIBLY DISCRETE PAPULES
4	CC-001	SR	CC-001-101	4	RCTGRDE	Reaction Grade	Dog Epi IgG 1 mg	ERYTHEMA, INFILTRATION, PAPULES, VESICLES
5	CC-001	SR	CC-001-101	5	RCTGRDE	Reaction Grade	Dog Epi IgG 1.5 mg	ERYTHEMA, INFILTRATION, PAPULES, VESICLES
6	CC-001	SR	CC-001-101	6	RCTGRDE	Reaction Grade	Dog Epi IgG 2 mg	ERYTHEMA, INFILTRATION, PAPULES, COALESCING VESICLES
7	CC-001	SR	CC-001-101	7	WHEALDIA	Wheal Diameter	Dog Epi IgG 0 mg	5
8	CC-001	SR	CC-001-101	8	WHEALDIA	Wheal Diameter	Dog Epi IgG 0.1 mg	10
9	CC-001	SR	CC-001-101	9	WHEALDIA	Wheal Diameter	Dog Epi IgG 0.5 mg	22
10	CC-001	SR	CC-001-101	10	WHEALDIA	Wheal Diameter	Dog Epi IgG 1 mg	100
11	CC-001	SR	CC-001-101	11	WHEALDIA	Wheal Diameter	Dog Epi IgG 1.5 mg	1
12	CC-001	SR	CC-001-101	12	WHEALDIA	Wheal Diameter	Dog Epi IgG 2 mg	8

Row	SRORRESU	SRSTRESC	SRSTRESN	SRSTRESU	SRLOC	VISITNUM	VISIT
1 (cont)		NEGATIVE			FOREARM	1	WEEK 1
2 (cont)		NEGATIVE			FOREARM	1	WEEK 1
3 (cont)		1+			FOREARM	1	WEEK 1
4 (cont)		2+			FOREARM	1	WEEK 1
5 (cont)		2+			FOREARM	1	WEEK 1
6 (cont)		3+			FOREARM	1	WEEK 1
7 (cont)	mm	5	5	mm	FOREARM	1	WEEK 1
8 (cont)	mm	10	10	mm	FOREARM	1	WEEK 1
9 (cont)	mm	22	22	mm	FOREARM	1	WEEK 1
10 (cont)	mm	100	100	mm	FOREARM	1	WEEK 1
11 (cont)	mm	1	1	mm	FOREARM	1	WEEK 1
12 (cont)	mm	8	8	mm	FOREARM	1	WEEK 1

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSPID	EXTRT	EXDOSE	EXDOSEU	EXROUTE	EXLOC
1	CC-001	EX	101	1	Dog Epi IgG	0	mg	CUTANEOUS	FOREARM
2	CC-001	EX	101	2	Dog Epi IgG	0.1	mg	CUTANEOUS	FOREARM
3	CC-001	EX	101	3	Dog Epi IgG	0.5	mg	CUTANEOUS	FOREARM
4	CC-001	EX	101	4	Dog Epi IgG	1	mg	CUTANEOUS	FOREARM
5	CC-001	EX	101	5	Dog Epi IgG	1.5	mg	CUTANEOUS	FOREARM
6	CC-001	EX	101	6	Dog Epi IgG	2	mg	CUTANEOUS	FOREARM

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RELREC below shows record level relationships.

relrec.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
CC-001	SR	CC-001-101	SRSPID	1		R1
CC-001	SR	CC-001-101	SRSPID	7		R1
CC-001	EX	CC-001-101	EXSPID	1		R1
CC-001	SR	CC-001-101	SRSPID	2		R2
CC-001	SR	CC-001-101	SRSPID	8		R2
CC-001	EX	CC-001-101	EXSPID	2		R2
CC-001	SR	CC-001-101	SRSPID	3		R3
CC-001	SR	CC-001-101	SRSPID	9		R3
CC-001	EX	CC-001-101	EXSPID	3		R3
CC-001	SR	CC-001-101	SRSPID	4		R4
CC-001	SR	CC-001-101	SRSPID	10		R4
CC-001	EX	CC-001-101	EXSPID	4		R4
CC-001	SR	CC-001-101	SRSPID	5		R5
CC-001	SR	CC-001-101	SRSPID	11		R5
CC-001	EX	CC-001-101	EXSPID	5		R5
CC-001	SR	CC-001-101	SRSPID	6		R6
CC-001	SR	CC-001-101	SRSPID	12		R6
CC-001	EX	CC-001-101	EXSPID	6		R6

Example 3

This example shows the results from a tuberculin PPD skin tests administered using the Mantoux technique. The subject was given an intradermal injection of standard tuberculin purified protein derivative (PPD-S) in their left forearm at Visit 1 (See Exposure record below). At Visit 2, the induration diameter and presence of blistering were recorded. Because the tuberculin PPD skin test cannot be interpreted using the induration diameter and blistering alone (e.g. risk for being infected with TB must also be considered), the interpretation of the skin test resides in its own row.

- Row 1:** Shows the diameter in millimeters of the induration after receiving an intradermal injection of 0.1 mL containing 5TU of PPD-S in the left forearm.
- Row 2:** Shows the presence of blistering at the tuberculin PPD skin test site.
- Row 3:** Shows the interpretation of the tuberculin PPD skin test. SRGRPID is used to tie together the results to the interpretation.

All rows show how to use the timing variables to record that a skin test was given via the Mantoux technique and that the planned time for reading the test was 48 hours later. However, a comparison of datetime values in SRDTC and SRRFTDTC shows that the test was read after the 48 hour planned interval.

sr.xpt

Row	STUDYID	DOMAIN	USUBJID	SRSEQ	SRGRPID	SRTESTCD	SRTEST	SROBJ	SRORRES	SRORRESU	SRSTRESC	SRSTRESN	SRSTRESU
1	ABC	SR	ABC-001	1	1	INDURDIA	Induration Diameter	Tuberculin PPD-S	16	mm	16	16	mm
2	ABC	SR	ABC-001	2	1	BLISTER	Blistering	Tuberculin PPD-S	Y		Y		
3	ABC	SR	ABC-001	3	1	INTP	Interpretation	Tuberculin PPD-S	POSITIVE		POSITIVE		

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Row	SRLOC	SRLAT	SRMETHOD	VISITNUM	VISIT	SRDTC	SRTPT	SRELTM	SRTPTREF	SRRFTDTC
1 (cont)	FOREARM	LEFT	RULER	2	VISIT 2	2011-01-19T14:08:24	48 H	PT48H	MANTOUX ADMINISTRATION	2011-01-17T08:30:00
2 (cont)	FOREARM	LEFT		2	VISIT 2	2011-01-19T14:08:24	48 H	PT48H	MANTOUX ADMINISTRATION	2011-01-17T08:30:00
3 (cont)				2	VISIT 2	2011-01-19T14:08:24	48 H	PT48H	MANTOUX ADMINISTRATION	2011-01-17T08:30:00

Row 1: Shows how to record Tuberculin PPD skin test administration technique.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXVAMT	EXVAMTU	VISITNUM	VISIT	EXSTDTC
1	ABC	EX	ABC-001	1	Tuberculin PPD-S	5	TU	0.1	mL	1	VISIT 1	2011-01-17T08:30:00

RELREC below shows record level relationships.

relrec.xpt

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC	SR	ABC-001	SRGRPID	1		R1
ABC	EX	ABC-001	EXSEQ	1		R1

7 Section Overview

SDTMIG 3.2 has re-designed Section 7. In the same way that Sections 5 & 6 have been turned into a collection of more granular documents, each describing a single domain, or a collection of related ones, Section 7 is now a set of smaller documents that better organizes the Trial Design datasets.

This new approach will allow the Submission Data Standards (SDS) Team to both simplify the maintenance of these dataset specifications as well as enable the easy addition of new datasets in the future (as has been the case in this release for the Trial Disease Assessment (TD) dataset) without having to design a complex numbering schema.

The below table describes the new Trial Design datasets groupings by document, and it provides a clear alignment of old and new Trial Design datasets. Please beware that all references to Section 7 in the entire SDTMIG have been updated to reflect the new organization.

The Table of Contents for the entire SDTMIG should reflect all domains and datasets (old and new) that make up this new release.

Section 7 Organization (SDTMIG 3.2)	Content	Section 7 Organization (pre-SDTMIG 3.2)
7.1 Introduction	An overview of the Trial Design purpose, concepts, and content.	Section 7.1 – Introduction
7.2 Experimental Design	Trial Design datasets that describe the planned design of the study, and provide the representation of study treatment in its most granular components [<i>see Trial Elements (TE)</i>] as well as the representation of all sequences of these components [<i>see Trial Arms (TA)</i>] as specified by the study protocol.	Section 7.2 Trial Arm Section 7.3 Trial Elements
7.3 Schedule For Assessments	Trial Design datasets that describe the protocol-defined planned schedule of subject encounters at the healthcare facility where the study is being conducted [<i>see Trial Visits (TV)</i>], as well as planned schedule of efficacy assessments related to the disease under study [<i>see new Trial Disease Assessments (TD)</i>].	Section 7.4 Trial Visits
7.4 Trial Summary And Eligibility	Trial Design datasets that describe the characteristics of the trial [<i>see Trial Summary Information (TS)</i>], as well as subject eligibility criteria for trial participation [<i>see Trial Inclusion/Exclusion Criteria (TI)</i>].	Section 7.5 Trial Inclusion/Exclusion Criteria Section 7.6 Trial Summary Information
Section 7.5 - How To Model The Design Of a Clinical Trial	A short guidance for how to develop the Trial Design datasets for any study.	Section 7.7 - How To Model The Design Of a Clinical Trial

7 Trial Design Datasets

7.1 Introduction

7.1.1 Purpose of Trial Design Model

ICH E3, Guidance for Industry, Structure and Content of Clinical Study Reports, Section 9.1, calls for a brief, clear description of the overall plan and design of the study, and supplies examples of charts and diagrams for this purpose in Annex IIIa and Annex IIIb. Each Annex corresponds to an example trial, and each shows a diagram describing the study design and a table showing the schedule of assessments. The *SDTM: Section 3, Trial Design Model* provides a standardized way to describe those aspects of the planned conduct of a clinical trial shown in the study design diagrams of these examples. The standard Trial Design Datasets will allow reviewers to:

- clearly and quickly grasp the design of a clinical trial
- compare the designs of different trials
- search a data warehouse for clinical trials with certain features
- compare planned and actual treatments and visits for subjects in a clinical trial.

Modeling a clinical trial in this standardized way requires the explicit statement of certain decision rules that may not be addressed or may be vague or ambiguous in the usual prose protocol document. Prospective modeling of the design of a clinical trial should lead to a clearer, better protocol. Retrospective modeling of the design of a clinical trial should ensure a clear description of how the trial protocol was interpreted by the sponsor.

7.1.2 Definitions of Trial Design Concepts

A clinical trial is a scientific experiment involving human subjects, which is intended to address certain scientific questions (the objectives of the trial). [See CDISC glossary for more complete definitions of clinical trial and objective.]

Trial Design: The design of a clinical trial is a plan for what will be done to subjects, and what data will be collected about them, in the course of the trial, to address the trial's objectives.

Epoch: As part of the design of a trial, the planned period of subjects' participation in the trial is divided into Epochs. Each Epoch is a period of time that serves a purpose in the trial as a whole. That purpose will be at the level of the primary objectives of the trial. Typically, the purpose of an Epoch will be to expose subjects to a treatment, or to prepare for such a treatment period (e.g., determine subject eligibility, wash out previous treatments) or to gather data on subjects after a treatment has ended. Note that at this high level a “treatment” is a treatment strategy, which may be simple (e.g., exposure to a single drug at a single dose) or complex. Complex treatment strategies could involve tapering through several doses, titrating dose according to clinical criteria, complex regimens involving multiple drugs, or strategies that involve adding or dropping drugs according to clinical criteria.

Arm: An Arm is a planned path through the trial. This path covers the entire time of the trial. The group of subjects assigned to a planned path is also often colloquially called an Arm. The group of subjects assigned to an Arm is also often called a treatment group, and in this sense, an Arm is equivalent to a treatment group.

Study Cell: Since the trial as a whole is divided into Epochs, each planned path through the trial (i.e., each Arm) is divided into pieces, one for each Epoch. Each of these pieces is called a Study Cell. Thus, there is a study cell for each combination of Arm and Epoch. Each Study Cell represents an implementation of the purpose of its associated Epoch. For an Epoch whose purpose is to expose subjects to treatment, each Study Cell associated with the Epoch has an associated treatment strategy. For example, a three-Arm parallel trial might have a Treatment Epoch whose purpose is to expose subjects to one of three study treatments: placebo, investigational product, or active control. There would be three Study Cells associated with the Treatment Epoch, one for each Arm. Each of these Study Cells exposes the subject to one of the three study treatments. Another example involving more complex treatment

strategies: a trial compares the effects of cycles of chemotherapy drug A given alone or in combination with drug B, where drug B is given as a pre-treatment to each cycle of drug A.

Element: An Element is a basic building block in the trial design. It involves administering a planned intervention, which may be treatment or no treatment, during a period of time. Elements for which the planned intervention is "no treatment" would include Elements for screening, washout, and follow-up.

Study Cells and Elements: Many, perhaps most, clinical trials, involve a single, simple administration of a planned intervention within a Study Cell, but for some trials, the treatment strategy associated with a Study Cell may involve a complex series of administrations of treatment. It may be important to track the component steps in a treatment strategy both operationally and because secondary objectives and safety analyses require that data be grouped by the treatment step during which it was collected. The steps within a treatment strategy may involve different doses of drug, different drugs, or different kinds of care, as in pre-operative, operative, and post-operative periods surrounding surgery. When the treatment strategy for a Study Cell is simple, the Study Cell will contain a single Element, and for many purposes there is little value in distinguishing between the Study Cell and the Element. However, when the treatment strategy for a Study Cell consists of a complex series of treatments, a Study Cell can contain multiple Elements. There may be a fixed sequence of Elements, or a repeating cycle of Elements, or some other complex pattern. In these cases, the distinction between a Study Cell and an Element is very useful.

Branch: In a trial with multiple Arms, the protocol plans for each subject to be assigned to one Arm. The time within the trial at which this assignment takes place is the point at which the Arm paths of the trial diverge, and so is called a branch point. For many trials, the assignment to an Arm happens all at one time, so the trial has one branch point. For other trials, there may be two or more branches that collectively assign a subject to an Arm. The process that makes this assignment may be a randomization, but it need not be.

Treatments: The word "treatment" may be used in connection with Epochs, Study Cells, or Elements, but has somewhat different meanings in each context:

- Since Epochs cut across Arms, an "Epoch treatment" is at a high level that does not specify anything that differs between Arms. For example, in a three-period crossover study of three doses of Drug X, each treatment Epoch is associated with Drug X, but not with a specific dose.
- A "Study Cell treatment" is specific to a particular Arm. For example, a parallel trial might have Study Cell treatments Placebo and Drug X, without any additional detail (e.g., dose, frequency, route of administration) being specified. A Study Cell treatment is at a relatively high level, the level at which treatments might be planned in an early conceptual draft of the trial, or in the title or objectives of the trial.
- An "Element treatment" may be fairly detailed. For example, for an Element representing a cycle of chemotherapy, Element treatment might specify 5 daily 100 mg doses of Drug X.

The distinctions between these levels are not rigid, and depend on the objectives of the trial. For example, route is generally a detail of dosing, but in a bioequivalence trial that compared IV and oral administration of Drug X, route is clearly part of Study Cell treatment.

Visit: A clinical encounter. The notion of a Visit derives from trials with outpatients, where subjects interact with the investigator during Visits to the investigator's clinical site. However, the term is used in other trials, where a trial Visit may not correspond to a physical Visit. For example, in a trial with inpatients, time may be subdivided into Visits, even though subjects are in hospital throughout the trial. For example, data for a screening Visit may be collected over the course of more than one physical visit. One of the main purposes of Visits is the performance of assessments, but not all assessments need take place at clinic Visits; some assessments may be performed by means of telephone contacts, electronic devices or call-in systems. The protocol should specify what contacts are considered Visits and how they are defined.

7.1.3 Current and Future Contents of the Trial Design Model

The datasets currently included in the Trial Design Model:

- Trial Arms: describes the sequences of Elements in each Epoch for each Arm, and thus describes the complete sequence of Elements in each Arm.
- Trial Elements: describes the Elements used in the trial.
- Trial Visits: describes the planned schedule of Visits.
- Trial Inclusion/Exclusion: describes the inclusion/exclusion criteria used to screen subjects.
- Trial Summary: lists key facts (parameters) about the trial that are likely to appear in a registry of clinical trials.
- Trial Disease Assessment: provides information on the protocol-specified disease assessment schedule, and will be used for comparison with the actual occurrence of the efficacy assessments in order to determine whether there was good compliance with the schedule

The Trial Inclusion/Exclusion (TI) is discussed in *Section 7.4 - Trial Summary And Eligibility: Trial Inclusion/Exclusion Criteria (TI)*. The IE domain (subject specific inclusion/exclusion criteria not met) described in *Section 6.3 - IE Domain* contains the actual exceptions to those criteria for enrolled subjects. The Trial Inclusion/Exclusion dataset was developed before the define.xml standard for metadata. Because the text of all inclusion/exclusion criteria can now be included in define.xml, this dataset may be deprecated in future versions of the SDTM.

Future versions of the Trial Design Model are expected to include additional aspects of clinical trials; some of these additional aspects will be used in submissions, while others are needed for accurate representation of protocols for the planning stage, but will have limited effects on the SDTM.

Work is underway on representing the schedule of assessments and planned interventions. When this work is completed, it is expected that the information on planned assessments and interventions will be submitted along with SDTM datasets containing actual subject data, to allow the comparison of planned and actual assessments and interventions.

The current Trial Design Model has limitations in representing protocols, which include the following:

- plans for indefinite numbers of repeating Elements (e.g., indefinite numbers of chemotherapy cycles)
- indefinite numbers of Visits (e.g., periodic follow-up Visits for survival)
- indefinite numbers of Epochs
- indefinite numbers of Arms.

The last two situations arise in dose-escalation studies where increasing doses are given until stopping criteria are met. Some dose-escalation studies enroll a new cohort of subjects for each new dose, and so, at the planning stage, have an indefinite number of Arms. Other dose-escalation studies give new doses to a continuing group of subjects, and so are planned with an indefinite number of Epochs.

There may also be limitations in representing other patterns of Elements within a Study Cell that are more complex than a simple sequence. For the purpose of submissions about trials that have already completed, these limitations are not critical, so it is expected that development of the Trial Design Model to address these limitations will have a minimal impact on SDTM.

7 Trial Design Datasets

7.2 Experimental Design: TA and TE

This subsection contains the Trial Design datasets that describe the planned design of the study, and provide the representation of study treatment in its most granular components [see [Section 7.2, Trial Elements \(TE\)](#)] as well as the representation of all sequences of these components [see [Section 7.2, Trial Arms \(TA\)](#)] as specified by the study protocol.

The TA and TE datasets are interrelated, and they provide the building block for the development of the subject-level treatment information [see [Section 5 - DM Domain](#) and [Section 5 - SE Domain](#) for the subject's actual study treatment information]

Trial Arms (TA)

This section contains:

- The Trial Arms dataset and assumptions
- A series of example trials, which illustrate the development of the Trial Arms dataset
- Advice on various issues in the development of the Trial Arms dataset
- A recap of the Trial Arms dataset, and the function of its variables.

TA – Description/Overview for Trial Arms Dataset

The trial arms table describes each planned arm in the trial. An arm is described as an ordered sequence of elements.

TA – Specification for Trial Arms Dataset

ta.xpt, Trial Arms — Trial Design, Version 3.2. One record per planned Element per Arm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TA	Identifier	Two-character abbreviation for the domain.	Req
ARMCD	Planned Arm Code	Char	*	Topic	ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than that for other “short” variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20.	Req
ARM	Description of Planned Arm	Char	*	Synonym Qualifier	Name given to an Arm or treatment group.	Req
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the order of the Element within the Arm.	Req
ETCD	Element Code	Char	*	Record Qualifier	ETCD (the companion to ELEMENT) is limited to 8 characters and does not have special character restrictions. These values should be	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
					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	*	Synonym Qualifier	The name of the Element. The same Element may occur more than once within an Arm.	Perm
TABRANCH	Branch	Char		Rule	Condition subject met, at a "branch" in the trial design at the end of this Element, to be included in this Arm; (e.g., randomization to DRUG X).	Exp
TATRANS	Transition Rule	Char		Rule	If the trial design allows a subject to transition to an Element other than the next Element in sequence, then the conditions for transitioning to those other Elements, and the alternative Element sequences, are specified in this rule (e.g., Responders go to washout).	Exp
EPOCH	Epoch	Char	(EPOCH)	Timing	Name of the Trial Epoch with which this Element of the Arm is associated.	Req

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

TA – Assumptions for Trial Arms Dataset

1. TAETORD is an integer. In general the value of TAETORD is 1 for the first Element in each Arm, 2 for the second Element in each Arm, etc. Occasionally, it may be convenient to skip some values (see [Example Trial 6](#) for an example). Although the values of TAETORD need not always be sequential, their order must always be the correct order for the Elements in the Arm path.
2. Elements in different Arms with the same value of TAETORD may or may not be at the same time, depending on the design of the trial. The example trials illustrate a variety of possible situations. The same Element may occur more than once within an Arm.
3. TABRANCH describes the outcome of a branch decision point in the trial design for subjects in the Arm. A branch decision point takes place between Epochs, and is associated with the Element that ends at the decision point. For instance, if subjects are assigned to an Arm where they receive treatment A through a randomization at the end of Element X, the value of TABRANCH for Element X would be "Randomized to A."
4. Branch decision points may be based on decision processes other than randomizations, such as clinical evaluations of disease response or subject choice.
5. There is usually some gap in time between the performance of a randomization and the start of randomized treatment. However, in many trials this gap in time is small and it is highly unlikely that subjects will leave the trial between randomization and treatment. In these circumstances, the trial does not need to be modeled with this time period between randomization and start of treatment as a separate Element.
6. Some trials include multiple paths that are closely enough related so that they are all considered to belong to one Arm. In general, this set of paths will include a "complete" path along with shorter paths that skip some Elements. The sequence of Elements represented in the Trial Arms should be the complete, longest path. TATRANS describes the decision points that may lead to a shortened path within the Arm.
7. If an Element does not end with a decision that could lead to a shortened path within the Arm, then TATRANS will be blank. If there is such a decision, TATRANS will be in a form like, "If condition X is true, then go to Epoch Y" or "If condition X is true, then go to Element with TAETORD=Z."
8. EPOCH is not strictly necessary for describing the sequence of Elements in an Arm path, but it is the conceptual basis for comparisons between Arms, and also provides a useful way to talk about what is happening in a blinded trial while it is blinded. During periods of blinded treatment, blinded participants will not know which Arm and Element a subject is in, but EPOCH should provide a description of the time period that does not depend on knowing Arm.
9. EPOCH should be assigned in such a way that Elements from different Arms with the same value of EPOCH are "comparable" in some sense. The degree of similarity across Arms varies considerably in different trials, as illustrated in the examples.

10. Note that Study Cells are not explicitly defined in the Trial Arms dataset. A set of records with a common value of both ARMCD and EPOCH constitute the description of a Study Cell. Transition rules within this set of records are also part of the description of the Study Cell.
11. EPOCH may be used as a timing variable in other datasets, such as EX and DS, and values of EPOCH must be different for different epochs. For instance, in a crossover trial with three treatment epochs, each must be given a distinct name; all three cannot be called "TREATMENT".

TA – Examples for Trial Arms Dataset

The core of the Trial Design Model is the Trial Arms (TA) dataset. For each Arm of the trial, it contains one record for each occurrence of an Element in the path of the Arm.

Although the Trial Arms dataset has one record for each trial Element traversed by subjects assigned to the Arm, it is generally more useful to work out the overall design of the trial at the Study Cell level, then to work out the Elements within each Study Cell, and finally to develop the definitions of the Elements that are contained in the Trial Elements table.

It is generally useful to draw diagrams, like those mentioned in ICH E3, when working out the design of a trial. The protocol may include a diagram that can serve as a starting point. Such a diagram can then be converted into a Trial Design Matrix, which displays the Study Cells and which can be, in turn, converted into the Trial Arms dataset.

This section uses example trials of increasing complexity, numbered 1 to 7, to illustrate the concepts of trial design. For each example trial, the process of working out the Trial Arms table is illustrated by means of a series of diagrams and tables, including the following:

- A diagram showing the branching structure of the trial in a "study schema" format such as might appear in a protocol.
- A diagram that shows the "prospective" view of the trial, the view of those participating in the trial. It is similar to the "study schema" view in that it usually shows a single pool of subjects at the beginning of the trial, with the pool of subjects being split into separate treatment groups at randomizations and other branches. They show the epochs of the trial, and, for each group of subjects and each epoch, the sequence of elements within each epoch for that treatment group. The arms are also indicated on these diagrams.
- A diagram that shows the "retrospective" view of the trial, the view of the analyst reporting on the trial. The style of diagram looks more like a matrix; it is also more like the structure of the Trial Arms dataset. It is an arm-centered view, which shows, for each study cell (epoch/arm combination) the sequence of elements within that study cell. It can be thought of as showing, for each arm the elements traversed by a subject who completed that arm as intended.
- If the trial is blinded, a diagram that shows the trial as it appears to a blinded participant.
- A Trial Design Matrix, an alternative format for representing most of the information in the diagram that shows Arms and Epochs, and emphasizes the Study Cells.
- The Trial Arms dataset.

Readers are advised to read the following section with Example 1 before reading other examples, since Example 1 explains the conventions used for the diagrams and tables.

Example Trial 1, a Parallel Trial

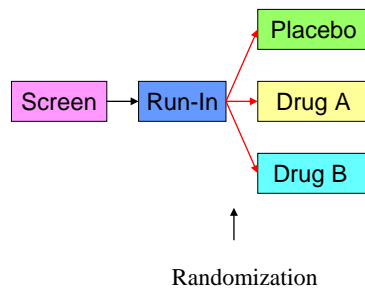
Diagrams that represent study schemas generally conceive of time as moving from left to right, use horizontal lines to represent periods of time, and slanting lines to represent branches into separate treatments, convergence into a common follow-up, or cross-over to a different treatment.

In this document, diagrams are drawn using "blocks" corresponding to trial Elements rather than horizontal lines. Trial Elements are the various treatment and non-treatment time periods of the trial, and we want to emphasize the separate trial Elements that might otherwise be "hidden" in a single horizontal line. See [Section 7.2: Trial Elements \(TE\)](#) for more information about defining trial Elements. In general, the Elements of a trial will be fairly clear. However, in the process of working out a trial design, alternative definitions of trial Elements may be considered, in which case diagrams for each alternative may be constructed.

In the study schema diagrams in this document, the only slanting lines used are those that represent branches, the decision points where subjects are divided into separate treatment groups. One advantage of this style of diagram, which does not show convergence of separate paths into a single block, is that the number of Arms in the trial can be determined by counting the number of parallel paths at the right end of the diagram.

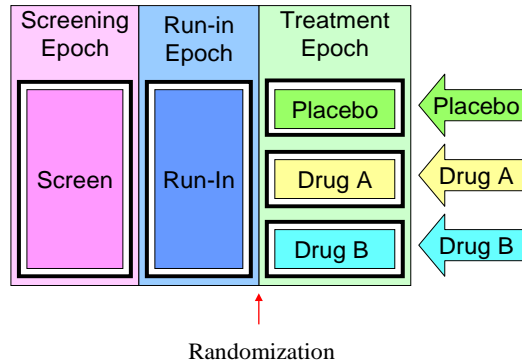
Below is the study schema diagram for Example Trial 1, a simple parallel trial. This trial has three Arms, corresponding to the three possible left-to-right "paths" through the trial. Each path corresponds to one of the three treatment Elements at the right end of the diagram. Note that the randomization is represented by the three red arrows leading from the Run-in block.

Example Trial 1: Parallel Design Study schema



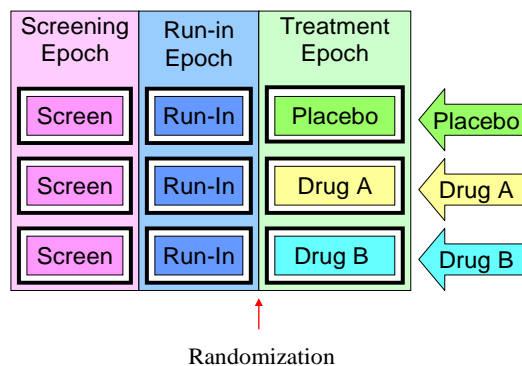
The next diagram for this trial shows the epochs of the trial, indicates the three Arms, and shows the sequence of elements for each group of subjects in each epoch. The arrows are at the right hand side of the diagram because it is at the end of the trial that all the separate paths through the trial can be seen. Note that, in this diagram, the randomization, which was shown using three red arrows connecting the Run-in block with the three treatment blocks in the first diagram, is now indicated by a note with an arrow pointing to the line between two epochs.

Example Trial 1: Parallel Design Prospective view



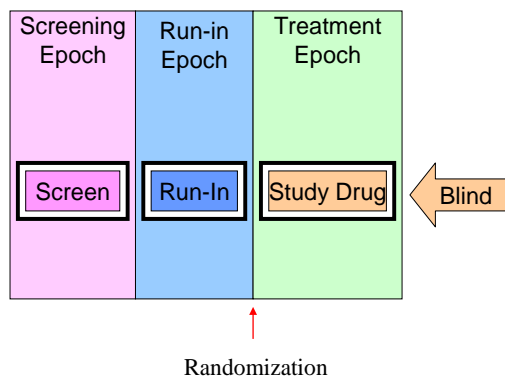
The next diagram can be thought of as the “retrospective” view of a trial, the view back from a point in time when a subject’s assignment to an arm is known. In this view, the trial appears as a grid, with an arm represented by a series of study cells, one for each epoch, and a sequence of elements within each study cell. In this trial, as in many trials, there is exactly one element in each study cell, but later examples will illustrate that this is not always the case.

Example Trial 1: Parallel Design Retrospective view



The next diagram shows the trial from the viewpoint of blinded participants. To blinded participants in this trial, all Arms look alike. They know when a subject is in the Screen Element, or the Run-in Element, but when a subject is in the Treatment Epoch, they know only that the subject is in an Element which involves receiving study drug, not which study drug, and therefore not which Element.

Example Trial 1: Parallel Trial Blinded View



A trial design matrix is a table with a row for each Arm in the trial and a column for each Epoch in the trial. It is closely related to the retrospective view of the trial, and many users may find it easier to construct a table than to draw a diagram. The cells in the matrix represent the Study Cells, which are populated with trial Elements. In this trial, each Study Cell contains exactly one Element.

The columns of a Trial Design Matrix are the Epochs of the trial, the rows are the Arms of the trial, and the cells of the matrix (the Study Cells) contain Elements. Note that the randomization is not represented in the Trial Design Matrix. All the diagrams above and the trial design matrix below are alternative representations of the trial design. None of them contains all the information that will be in the finished Trial Arms dataset, but users may find it useful to draw some or all of them when working out the dataset.

Trial Design Matrix for Example Trial 1

	Screen	Run-in	Treatment
Placebo	Screen	Run-in	PLACEBO
A	Screen	Run-in	DRUG A
B	Screen	Run-in	DRUG B

For Example Trial 1, the conversion of the Trial Design Matrix into the Trial Arms dataset is straightforward. For each cell of the matrix, there is a record in the Trial Arms dataset. ARM, EPOCH, and ELEMENT can be populated directly from the matrix. TAETORD acts as a sequence number for the Elements within an Arm, so it can be populated by counting across the cells in the matrix. The randomization information, which is not represented in the Trial Design Matrix, is held in TABRANCH in the Trial Arms dataset. TABRANCH is populated only if there is a branch at the end of an Element for the Arm. When TABRANCH is populated, it describes how the decision at the branch point would result in a subject being in this Arm.

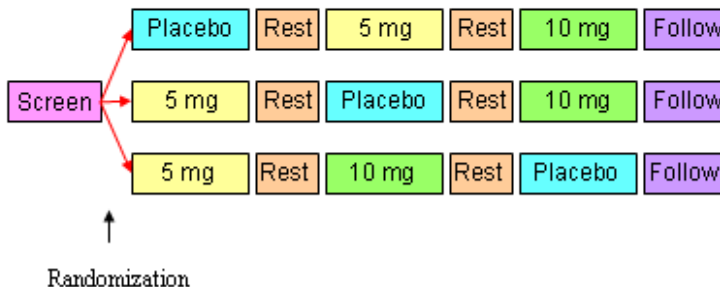
Trial Arms Dataset for Example Trial 1

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
1	EX1	TA	P	Placebo	1	SCRN	Screen			Screen
2	EX1	TA	P	Placebo	2	RI	Run-In	Randomized to Placebo		Run-In
3	EX1	TA	P	Placebo	3	P	Placebo			Treatment
4	EX1	TA	A	A	1	SCRN	Screen			Screen
5	EX1	TA	A	A	2	RI	Run-In	Randomized to Drug A		Run-In
6	EX1	TA	A	A	3	A	Drug A			Treatment
7	EX1	TA	B	B	1	SCRN	Screen			Screen
8	EX1	TA	B	B	2	RI	Run-In	Randomized to Drug B		Run-In
9	EX1	TA	B	B	3	B	Drug B			Treatment

Example Trial 2, a Crossover Trial

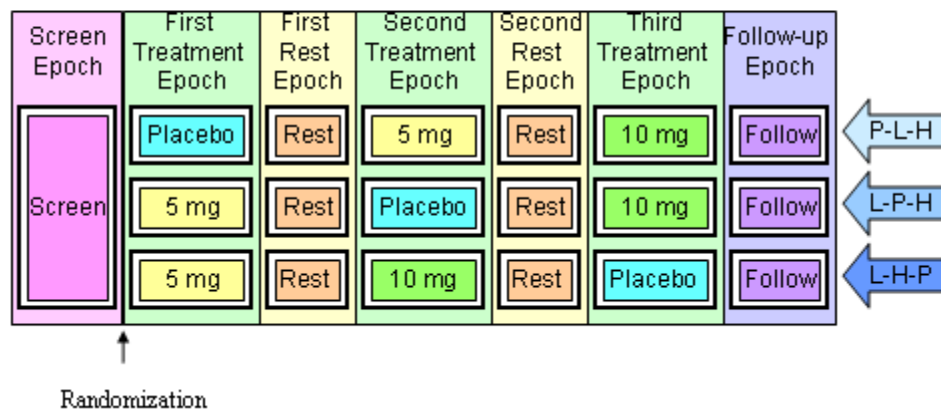
The diagram below is for a crossover trial. However, the diagram does not use the crossing slanted lines sometimes used to represent crossover trials, since the order of the blocks is sufficient to represent the design of the trial. Slanted lines are used only to represent the branch point at randomization, when a subject is assigned to a sequence of treatments. As in most crossover trials, the Arms are distinguished by the order of treatments, with the same treatments present in each Arm. Note that even though all three Arms of this trial end with the same block, the block for the follow-up Element, the diagram does not show the Arms converging into one block. Also note that the same block (the "Rest" Element) occurs twice within each Arm. Elements are conceived of as "reusable" and can appear in more than one Arm, in more than one Epoch, and more than once in an Arm.

Example Trial 2: Crossover Trial Study Schema



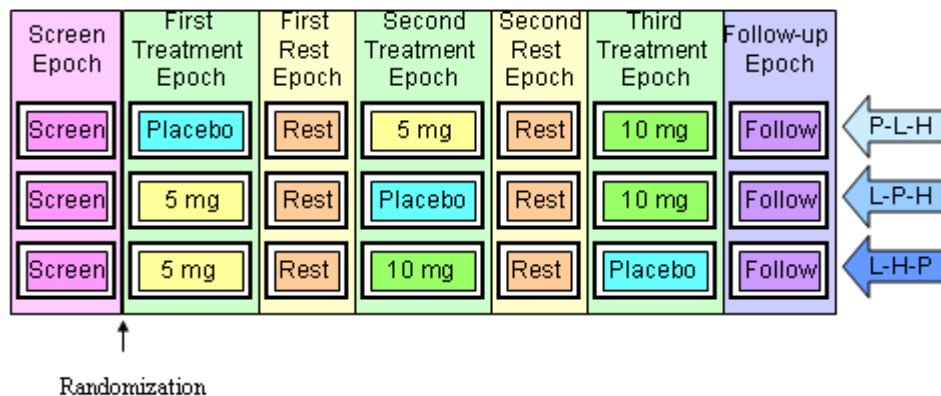
The next diagram for this crossover trial shows the prospective view of the trial, identifies the epoch and arms of the trial, and gives each a name. As for most crossover studies, the objectives of the trial will be addressed by comparisons between the arms and by within-subject comparisons between treatments. The design thus depends on differentiating the periods during which the subject receives the three different treatments and so there are three different treatment epochs. The fact that the rest periods are identified as separate Epochs suggests that these also play an important part in the design of the trial; they are probably designed to allow subjects to return to “baseline” with data collected to show that this occurred. Note that Epochs are not considered “reusable”, so each Epoch has a different name, even though all the Treatment Epochs are similar and both the Rest Epochs are similar. As with the first example trial, there is a one to one relationship between the Epochs of the trial and the Elements in each Arm.

Example Trial 2: Crossover Trial Prospective View



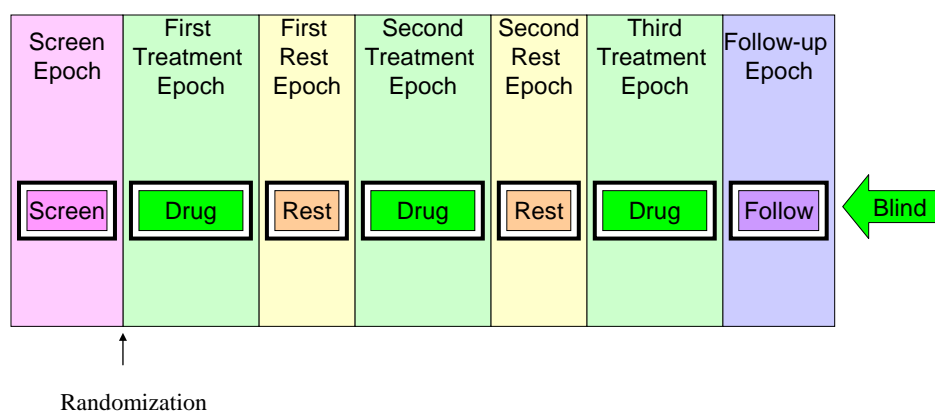
The next diagram shows the retrospective view of the trial.

Example Trial 2: Crossover Trial Retrospective View



The last diagram for this trial shows the trial from the viewpoint of blinded participants. As in the simple parallel trial above, blinded participants see only one sequence of Elements, since during the treatment Epochs they do not know which of the treatment Elements a subject is in.

Example Trial 2: Crossover Trial Blinded View



The trial design matrix for the crossover example trial is shown below. It corresponds closely to the retrospective diagram above.

Trial Design Matrix for Example Trial 2

	Screen	First Treatment	First Rest	Second Treatment	Second Rest	Third Treatment	Follow-up
P-5-10	Screen	Placebo	Rest	5 mg	Rest	10 mg	Follow-up
5-P-10	Screen	5 mg	Rest	Placebo	Rest	10 mg	Follow-up
5-10-P	Screen	5 mg	Rest	10 mg	Rest	Placebo	Follow-up

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It is straightforward to produce the Trial Arms dataset for this crossover trial from the diagram showing Arms and Epochs, or from the Trial Design Matrix. To avoid confusion between the “Screen” Epoch, and the “Screen” Element, the word “Epoch” has been included in all the Epoch names.

Trial Arms Dataset for Example Trial 2

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
1	EX2	TA	P-5-10	Placebo-5mg-10mg	1	SCRN	Screen	Randomized to Placebo - 5 mg - 10 mg		Screen Epoch
2	EX2	TA	P-5-10	Placebo-5mg-10mg	2	P	Placebo			First Treatment Epoch
3	EX2	TA	P-5-10	Placebo-5mg-10mg	3	REST	Rest			First Rest Epoch
4	EX2	TA	P-5-10	Placebo-5mg-10mg	4	5	5 mg			Second Treatment Epoch
5	EX2	TA	P-5-10	Placebo-5mg-10mg	5	REST	Rest			Second Rest Epoch
6	EX2	TA	P-5-10	Placebo-5mg-10mg	6	10	10 mg			Third Treatment Epoch
7	EX2	TA	P-5-10	Placebo-5mg-10mg	7	FU	Follow-up			Follow-up Epoch
8	EX2	TA	5-P-10	5mg-Placebo-10mg	1	SCRN	Screen	Randomized to 5 mg - Placebo - 10 mg		Screen Epoch
9	EX2	TA	5-P-10	5mg-Placebo-10mg	2	5	5 mg			First Treatment Epoch
10	EX2	TA	5-P-10	5mg-Placebo-10mg	3	REST	Rest			First Rest Epoch
11	EX2	TA	5-P-10	5mg-Placebo-10mg	4	P	Placebo			Second Treatment Epoch
12	EX2	TA	5-P-10	5mg-Placebo-10mg	5	REST	Rest			Second Rest Epoch
13	EX2	TA	5-P-10	5mg-Placebo-10mg	6	10	10 mg			Third Treatment Epoch
14	EX2	TA	5-P-10	5mg-Placebo-10mg	7	FU	Follow-up			Follow-up Epoch
15	EX2	TA	5-10-P	5mg-10mg-Placebo	1	SCRN	Screen	Randomized to 5 mg - 10 mg – Placebo		Screen Epoch
16	EX2	TA	5-10-P	5mg-10mg-Placebo	2	5	5 mg			First Treatment Epoch
17	EX2	TA	5-10-P	5mg-10mg-Placebo	3	REST	Rest			First Rest Epoch
18	EX2	TA	5-10-P	5mg-10mg-Placebo	4	10	10 mg			Second Treatment Epoch
19	EX2	TA	5-10-P	5mg-10mg-Placebo	5	REST	Rest			Second Rest Epoch

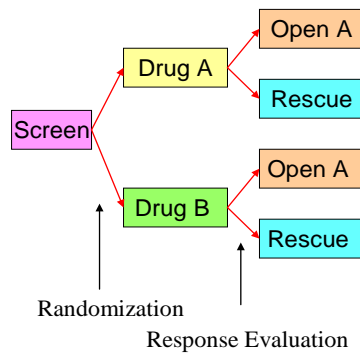
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Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
20	EX2	TA	5-10-P	5mg-10mg-Placebo	6	P	Placebo			Third Treatment Epoch
21	EX2	TA	5-10-P	5mg-10mg-Placebo	7	FU	Follow-up			Follow-up Epoch

Example Trial 3, a Trial with Multiple Branch Points

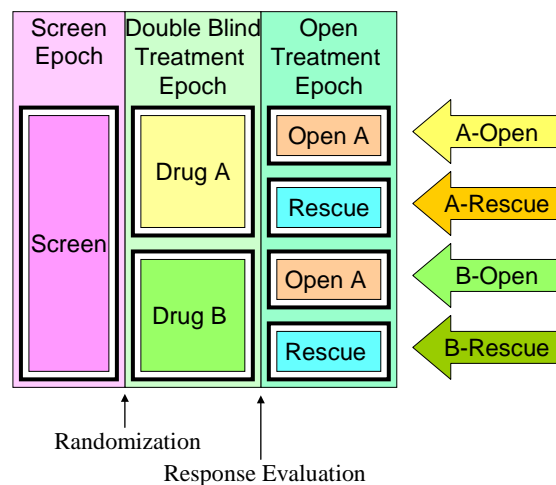
Each of the paths for the trial shown in the diagram below goes through one branch point at randomization, and then through another branch point when response is evaluated. This results in four Arms, corresponding to the number of possible paths through the trial, and also to the number of blocks at the right end of the diagram. The fact that there are only two kinds of block at the right end ("Open DRUG X" and "Rescue") does not affect the fact that there are four "paths" and thus four Arms.

Example Trial 3: Multiple Branches Study Schema



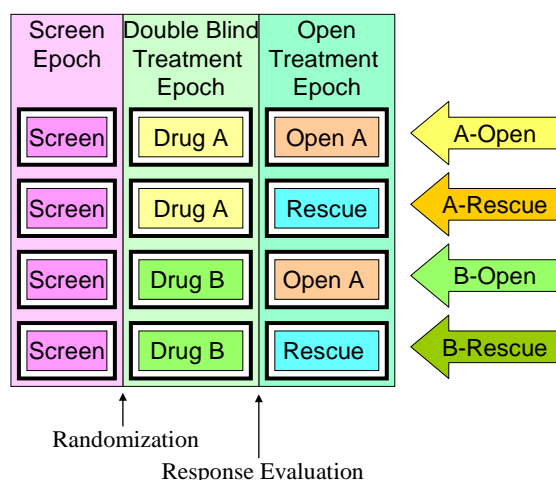
The next diagram for this trial is the prospective view. It shows the epochs of the trial and how the initial group of subjects is split into two treatment groups for the double blind treatment epoch, and how each of those initial treatment groups is split in two at the response evaluation, resulting in the four Arms of this trial. The names of the Arms have been chosen to represent the outcomes of the successive branches that, together, assign subjects to Arms. These compound names were chosen to facilitate description of subjects who may drop out of the trial after the first branch and before the second branch. See *Section 5 - DM Domain: Example 7, DM - Examples for the DEMOGRAPHICS Domain Model*, which illustrates DM and SE data for such subjects.

Example Trial 3 : Multiple Branches Prospective View



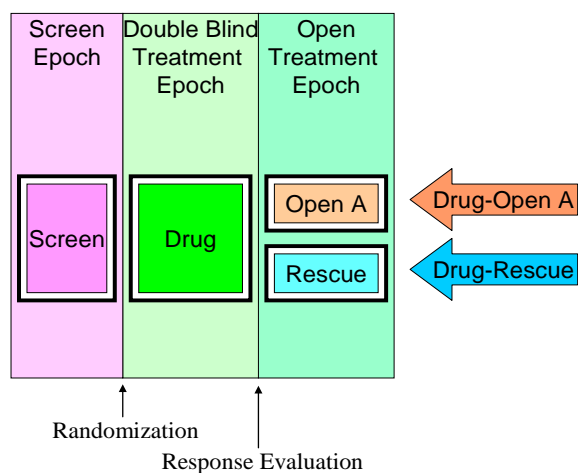
The next diagram shows the retrospective view. As with the first two example trials, there is one element in each study cell.

Example Trial 3 : Multiple Branches Retrospective View



The last diagram for this trial shows the trial from the viewpoint of blinded participants. Since the prospective view is the view most relevant to study participants, the blinded view shown here is a prospective view. Since blinded participants can tell which treatment a subject receives in the Open Label Epoch, they see two possible element sequences.

Example Trial 3 : Multiple Branches Blinded Prospective View



The trial design matrix for this trial can be constructed easily from the diagram showing Arms and Epochs.

Trial Design Matrix for Example Trial 3

	Screen	Double Blind	Open Label
A-Open A	Screen	Treatment A	Open Drug A
A-Rescue	Screen	Treatment A	Rescue
B-Open A	Screen	Treatment B	Open Drug A
B-Rescue	Screen	Treatment B	Rescue

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Creating the Trial Arms dataset for Example Trial 3 is similarly straightforward. Note that because there are two branch points in this trial, TABRANCH is populated for two records in each Arm. Note also that the values of ARMCD, like the values of ARM, reflect the two separate processes that result in a subject's assignment to an Arm.

Trial Arms Dataset for Example Trial 3

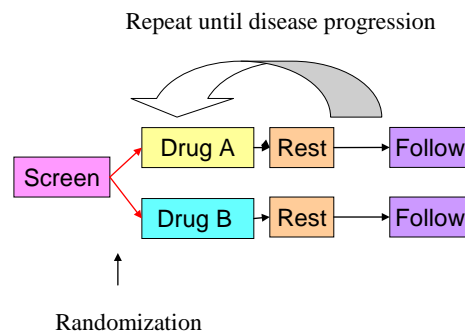
Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	CATRANS	EPOCH
1	EX3	TA	AA	A-Open A	1	SCRN	Screen	Randomized to Treatment A		Screen
2	EX3	TA	AA	A-Open A	2	DBA	Treatment A	Assigned to Open Drug A on basis of response evaluation		Double Blind
3	EX3	TA	AA	A-Open A	3	OA	Open DRUG A			Open Label
4	EX3	TA	AR	A-Rescue	1	SCRN	Screen	Randomized to Treatment A		Screen
5	EX3	TA	AR	A-Rescue	2	DBA	Treatment A	Assigned to Rescue on basis of response evaluation		Double Blind
6	EX3	TA	AR	A-Rescue	3	RSC	Rescue			Open Label
7	EX3	TA	BA	B-Open A	1	SCRN	Screen	Randomized to Treatment B		Screen
8	EX3	TA	BA	B-Open A	2	DBB	Treatment B	Assigned to Open Drug A on basis of response evaluation		Double Blind
9	EX3	TA	BA	B-Open A	3	OA	Open DRUG A			Open Label
10	EX3	TA	BR	B-Rescue	1	SCRN	Screen	Randomized to Treatment B		Screen
11	EX3	TA	BR	B-Rescue	2	DBB	Treatment B	Assigned to Rescue on basis of response evaluation		Double Blind
12	EX3	TA	BR	B-Rescue	3	RSC	Rescue			Open Label

See [Issue 1, Distinguishing Between Branches and Transitions](#) for additional discussion of when a decision point in a trial design should be considered to give rise to a new Arm.

Example Trial 4, Cycles of Chemotherapy

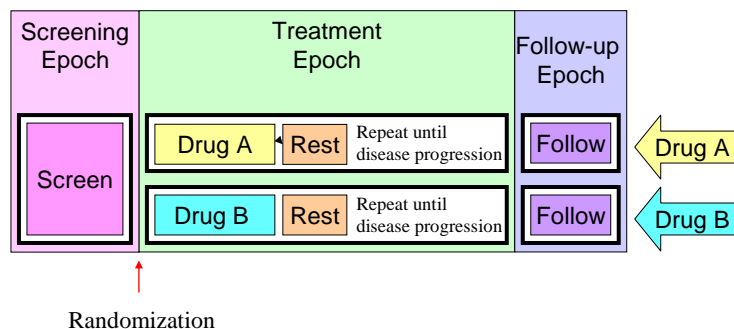
The diagram below uses a new symbol, a large curved arrow representing the fact that the chemotherapy treatment (A or B) and the rest period that follows it are to be repeated. In this trial, the chemotherapy "cycles" are to be repeated until disease progression. Some chemotherapy trials specify a maximum number of cycles, but protocols that allow an indefinite number of repeats are not uncommon.

Example Trial 4: Cyclical Chemotherapy Study Schema



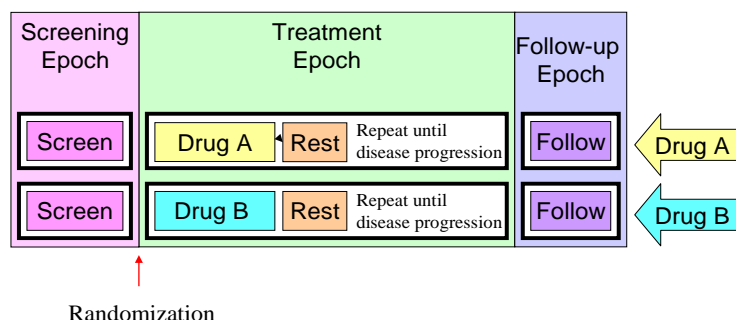
The next diagram shows the prospective view of this trial. Note that, in spite of the repeating element structure, this is, at its core, a two-arm parallel study, and thus has two arms. In SDTMIG 3.1.1, there was an implicit assumption that each element must be in a separate epoch, and trials with cyclical chemotherapy were difficult to handle. The introduction of the concept of study cells, and the dropping of the assumption that elements and epochs have a one to one relationship resolves these difficulties. This trial is best treated as having just three epochs, since the main objectives of the trial involve comparisons between the two treatments, and do not require data to be considered cycle by cycle.

Example Trial 4: Cyclical Chemotherapy Prospective View



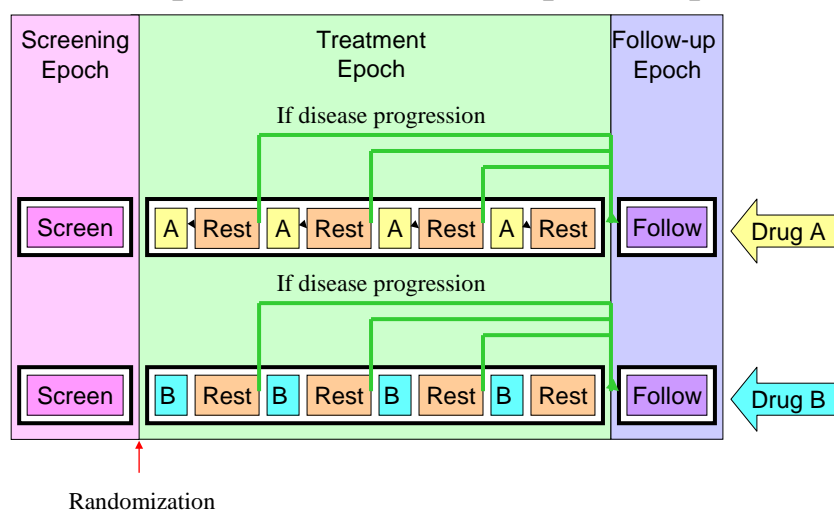
The next diagram shows the retrospective view of this trial.

Example Trial 4: Cyclical Chemotherapy Retrospective View



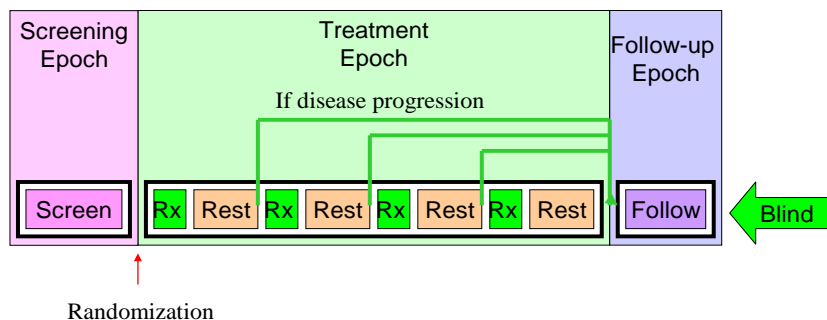
For the purpose of developing a Trial Arms dataset for this oncology trial, the diagram must be redrawn to explicitly represent multiple treatment and rest elements. If a maximum number of cycles is not given by the protocol, then, for the purposes of constructing an SDTM Trial Arms dataset for submission, which can only take place after the trial is complete, the number of repeats included in the Trial Arms dataset should be the maximum number of repeats that occurred in the trial. The next diagram assumes that the maximum number of cycles that occurred in this trial was four. Some subjects will not have received all four cycles, because their disease progressed. The rule that directed that they receive no further cycles of chemotherapy is represented by a set of green arrows, one at the end of each Rest epoch, that shows that a subject “skips forward” if their disease progresses. In the Trial Arms dataset, each “skip forward” instruction is a transition rule, recorded in the TATRANS variable; when TATRANS is not populated, the rule is to transition to the next element in sequence.

Example Trial 4: Cyclical Chemotherapy Retrospective View with Explicit Repeats



The logistics of dosing mean that few oncology trials are blinded, if this trial is blinded, then the next diagram shows the trial from the viewpoint of blinded participants.

Example Trial 4: Cyclical Chemotherapy Blinded View



The Trial Design Matrix for Example Trial 4 corresponds to the diagram showing the retrospective view with explicit repeats of the treatment and rest elements. As noted above, the Trial Design Matrix does not include information on when randomization occurs; similarly, information corresponding to the “skip forward” rules is not represented in the Trial Design Matrix.

Trial Design Matrix for Example Trial 4

	Screen	Treatment								Follow-up
A	Screen	Trt A	Rest	Trt A	Rest	Trt A	Rest	Trt A	Rest	Follow-up
B	Screen	Trt B	Rest	Trt B	Rest	Trt B	Rest	Trt B	Rest	Follow-up

The Trial Arms dataset for Example Trial 4 requires the use of the TATRANS variable in the Trial Arms dataset to represent the "repeat until disease progression" feature. In order to represent this rule in the diagrams that explicitly represent repeated elements, a green "skip forward" arrow was included at the end of each element where disease progression is assessed. In the Trial Arms dataset, TATRANS is populated for each element with a green arrow in the diagram. In other words, if there is a possibility that a subject will, at the end of this Element, "skip forward" to a later part of the Arm, then TATRANS is populated with the rule describing the conditions under which a subject will go to a later element. If the subject always goes to the next Element in the Arm (as was the case for the first three example trials presented here) then TATRANS is null.

The Trial Arms datasets presented below corresponds to the Trial Design Matrix above.

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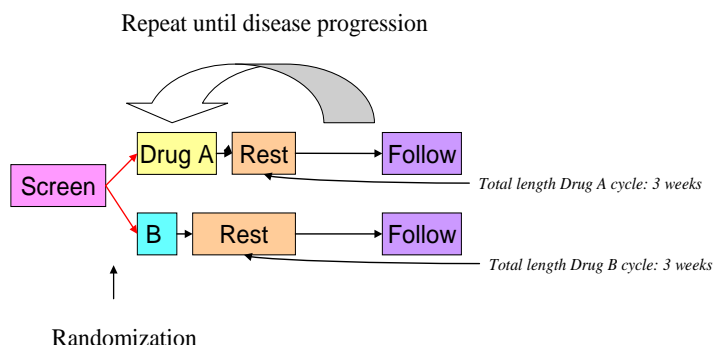
Trial Arms Dataset for Example Trial 4

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
1	EX4	TA	A	A	1	SCRN	Screen	Randomized to A		Screen
2	EX4	TA	A	A	2	A	Trt A			Treatment
3	EX4	TA	A	A	3	REST	Rest		If disease progression, go to Follow-up Epoch	Treatment
4	EX4	TA	A	A	4	A	Trt A			Treatment
5	EX4	TA	A	A	5	REST	Rest		If disease progression, go to Follow-up Epoch	Treatment
6	EX4	TA	A	A	6	A	Trt A			Treatment
7	EX4	TA	A	A	7	REST	Rest		If disease progression, go to Follow-up Epoch	Treatment
8	EX4	TA	A	A	8	A	Trt A			Treatment
9	EX4	TA	A	A	9	REST	Rest			Treatment
10	EX4	TA	A	A	10	FU	Follow-up			Follow-up
11	EX4	TA	B	B	1	SCRN	Screen	Randomized to B		Screen
12	EX4	TA	B	B	2	B	Trt B			Treatment
13	EX4	TA	B	B	3	REST	Rest		If disease progression, go to Follow-up Epoch	Treatment
14	EX4	TA	B	B	4	B	Trt B			Treatment
15	EX4	TA	B	B	5	REST	Rest		If disease progression, go to Follow-up Epoch	Treatment
16	EX4	TA	B	B	6	B	Trt B			Treatment
17	EX4	TA	B	B	7	REST	Rest		If disease progression, go to Follow-up Epoch	Treatment
18	EX4	TA	B	B	8	B	Trt B			Treatment
19	EX4	TA	B	B	9	REST	Rest			Treatment
20	EX4	TA	B	B	10	FU	Follow-up			Follow-up

Example Trial 5, Cycles with Different Treatment Durations

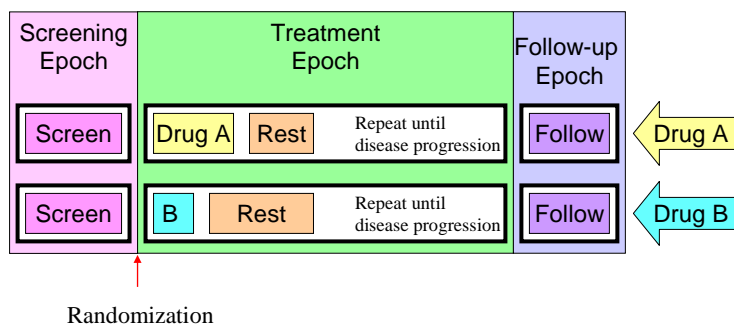
Example Trial 5 is much like the last oncology trial in that the two treatments being compared are given in cycles, and the total length of the cycle is the same for both treatments. However, in this trial Treatment A is given over longer duration than Treatment B. Because of this difference in treatment patterns, this trial cannot be blinded.

Example Trial 5: Different Chemo Durations Study Schema



In SDTMIG 3.1.1, the assumption of a one to one relationship between elements and epochs made this example difficult to handle. However, without that assumption, this trial is essentially the same as Trial 4. The next diagram shows the retrospective view of this trial.

Example Trial 5: Cyclical Chemotherapy Retrospective View



The Trial Design Matrix for this trial is almost the same as for Example Trial 4; the only difference is that the maximum number of cycles for this trial was assumed to be three.

Trial Design Matrix for Example Trial 5

	Screen	Treatment						Follow-up
A	Screen	Trt A	Rest A	Trt A	Rest A	Trt A	Rest A	Follow-up
B	Screen	Trt B	Rest B	Trt B	Rest B	Trt B	Rest B	Follow-up

The Trial Arms dataset for this trial shown below corresponds to the Trial Design Matrix above.

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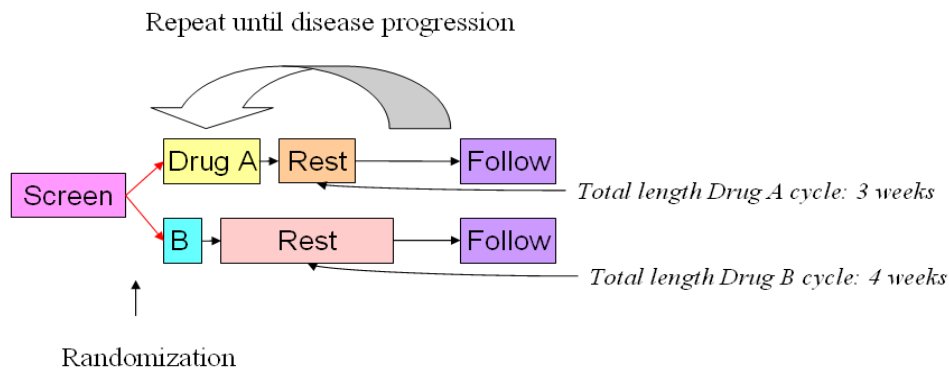
Trial Arms Dataset for Example Trial 5, with one Epoch per Cycle

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
1	EX5	TA	A	A	1	SCRN	Screen	Randomized to A		Screen
2	EX5	TA	A	A	2	A	Trt A			Treatment
3	EX5	TA	A	A	3	RESTA	Rest A		If disease progression, go to Follow-up Epoch	Treatment
4	EX5	TA	A	A	4	A	Trt A			Treatment
5	EX5	TA	A	A	5	RESTA	Rest A		If disease progression, go to Follow-up Epoch	Treatment
6	EX5	TA	A	A	6	A	Trt A			Treatment
7	EX5	TA	A	A	7	RESTA	Rest A			Treatment
8	EX5	TA	A	A	8	FU	Follow-up			Follow-up
9	EX5	TA	B	B	1	SCRN	Screen	Randomized to B		Screen
10	EX5	TA	B	B	2	B	Trt B			Treatment
11	EX5	TA	B	B	3	RESTB	Rest B		If disease progression, go to Follow-up Epoch	Treatment
12	EX5	TA	B	B	4	B	Trt B			Treatment
13	EX5	TA	B	B	5	RESTB	Rest B		If disease progression, go to Follow-up Epoch	Treatment
14	EX5	TA	B	B	6	B	Trt B			Treatment
15	EX5	TA	B	B	7	RESTB	Rest B			Treatment
16	EX5	TA	B	B	8	FU	Follow-up			Follow-up

Example Trial 6, Chemotherapy Trial with Cycles of Different Lengths

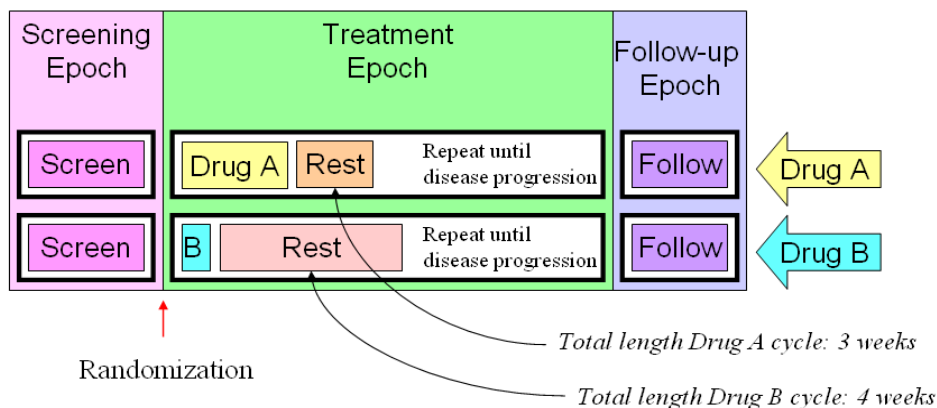
Example Trial 6 is an oncology trial comparing two types of chemotherapy that are given using cycles of different lengths with different internal patterns. Treatment A is given in 3-week cycles with a longer duration of treatment and a short rest, while Treatment B is given in 4-week cycles with a short duration of treatment and a long rest.

Example Trial 6: Different Cycle Durations Study Schema



The design of this trial is very similar to that for Example Trials 4 and 5. The main difference is that there are two different rest elements, the short one used with Drug A and the long one used with Drug B. The next diagram shows the retrospective view of this trial.

Example Trial 6: Cyclical Chemotherapy Retrospective View



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The Trial Design Matrix for this trial assumes that there were a maximum of four cycles of Drug A and a maximum of three cycles of Drug B.

Trial Design Matrix for Example Trial 6

	Screen	Treatment								Follow-up
A	Screen	Trt A	Rest A	Trt A	Rest A	Trt A	Rest A	Trt A	Rest A	Follow-up
B	Screen	Trt B	Rest B		Trt B	Rest B		Trt B	Rest B	Follow-up

In the following Trial Arms dataset, because the Treatment Epoch for Arm A has more Elements than the Treatment Epoch for Arm B, TAETORD is 10 for the Follow-up Element in Arm A, but 8 for the Follow-up Element in Arm B. It would also be possible to assign a TAETORD value of 10 to the Follow-up Element in Arm B. The primary purpose of TAETORD is to order Elements within an Arm; leaving gaps in the series of TAETORD values does not interfere with this purpose.

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Trial Arms Dataset for Example Trial 6

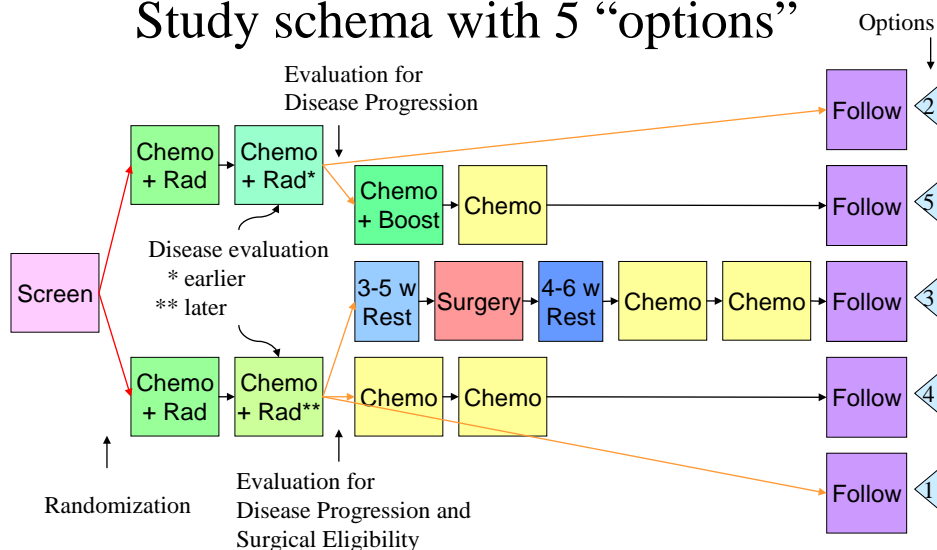
Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
1	EX6	TA	A	A	1	SCRN	Screen	Randomized to A		Screen
2	EX6	TA	A	A	2	A	Trt A			Treatment
3	EX6	TA	A	A	3	RESTA	Rest A		If disease progression, go to Follow-up Epoch	Treatment
4	EX6	TA	A	A	4	A	Trt A			Treatment
5	EX6	TA	A	A	5	RESTA	Rest A		If disease progression, go to Follow-up Epoch	Treatment
6	EX6	TA	A	A	6	A	Trt A			Treatment
7	EX6	TA	A	A	7	RESTA	Rest A		If disease progression, go to Follow-up Epoch	Treatment
8	EX6	TA	A	A	8	A	Trt A			Treatment
9	EX6	TA	A	A	9	RESTA	Rest A			Treatment
10	EX6	TA	A	A	10	FU	Follow-up			Follow-up
11	EX6	TA	B	B	1	SCRN	Screen	Randomized to B		Screen
12	EX6	TA	B	B	2	B	Trt B			Treatment
13	EX6	TA	B	B	3	RESTB	Rest B		If disease progression, go to Follow-up Epoch	Treatment
14	EX6	TA	B	B	4	B	Trt B			Treatment
15	EX6	TA	B	B	5	RESTB	Rest B		If disease progression, go to Follow-up Epoch	Treatment
16	EX6	TA	B	B	6	B	Trt B			Treatment
17	EX6	TA	B	B	7	RESTB	Rest B			Treatment
18	EX6	TA	B	B	8	FU	Follow-up			Follow-up

Example Trial 7, Trial with Disparate Arms

In open trials, there is no requirement to maintain a blind, and the Arms of a trial may be quite different from each other. In such a case, changes in treatment in one Arm may differ in number and timing from changes in treatment in another Arm, so that there is nothing like a one-to-one match between the Elements in the different Arms. In such a case, Epochs are likely to be defined as broad intervals of time, spanning several Elements, and be chosen to correspond to periods of time that will be compared in analyses of the trial.

Example Trial 7, RTOG 93-09, involves treatment of lung cancer with chemotherapy and radiotherapy, with or without surgery. The protocol (RTOG-93-09), which is available online at the Radiation Oncology Therapy Group (RTOG) website <http://www.rtog.org/members/numericactive.html>, does not include a study schema diagram, but does include a text-based representation of diverging “options” to which a subject may be assigned. All subjects go through the branch point at randomization, when subjects are assigned to either Chemotherapy + Radiotherapy (CR) or Chemotherapy + Radiotherapy + Surgery (CRS). All subjects receive induction chemotherapy and radiation, with a slight difference between those randomized to the two arms during the second cycle of chemotherapy. Those randomized to the non-surgery arm are evaluated for disease somewhat earlier, to avoid delays in administering the radiation boost to those whose disease has not progressed. After induction chemotherapy and radiation, subjects are evaluated for disease progression, and those whose disease has progressed stop treatment, but enter follow-up. Not all subjects randomized to receive surgery who do not have disease progression will necessarily receive surgery. If they are poor candidates for surgery or do not wish to receive surgery, they will not receive surgery, but will receive further chemotherapy. The diagram below is based on the text “schema” in the protocol, with the five “options” it names. The diagram in this form might suggest that the trial has five arms.

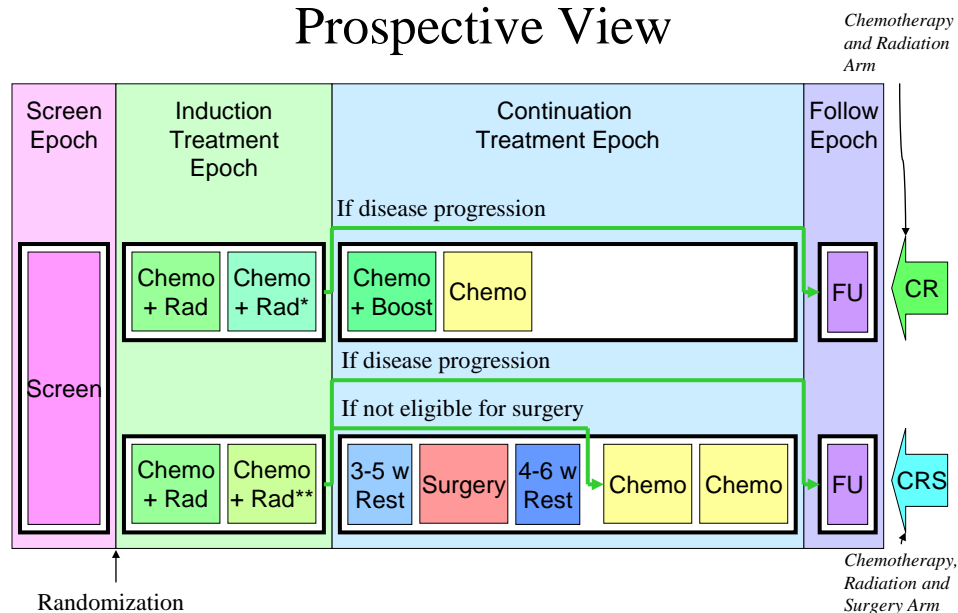
Example Trial 7: RTOG 93-09 Study schema with 5 “options”



However, the objectives of the trial make it clear that this trial is designed to compare two treatment strategies, chemotherapy and radiation with and without surgery, so this study is better modeled as a two-Arm trial, but with major "skip forward" arrows for some subjects, as illustrated in the following diagram. This diagram also shows more detail within the blocks labeled “Induction Chemo + RT” and “Additional Chemo” than the diagram above. Both the “induction” and “additional” chemotherapy are given in two cycles. Also, the second induction cycle is different for the two arms, since radiation therapy for those assigned to the non-surgery arm includes a “boost” which those assigned to surgery arm do not receive.

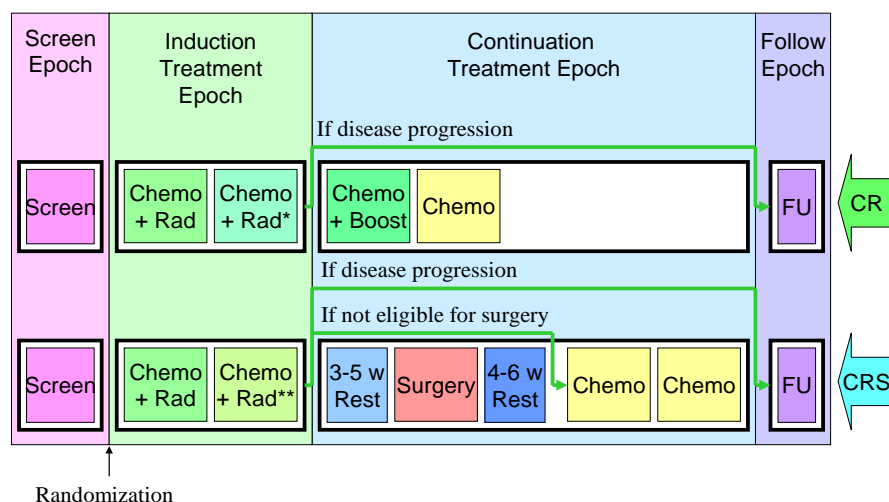
The next diagram shows the prospective view of this trial. The protocol conceives of treatment as being divided into two parts, Induction and Continuation, so these have been treated as two different epochs. This is also an important point in the trial operationally, the point when subjects are “registered” a second time, and when subjects are identified who will “skip forward” because of disease progression or ineligibility for surgery.

Example Trial 7: RTOG 93-09 Prospective View



The next diagram shows the retrospective view of this trial. The fact that the elements in the study cell for the CR arm in the Continuation Treatment Epoch do not fill the space in the diagram is an artifact of the diagram conventions. Those subjects who do receive surgery will in fact spend a longer time completing treatment and moving into follow-up. Although it is tempting to think of the horizontal axis of these diagrams as a timeline, this can sometimes be misleading. The diagrams are not necessarily “to scale” in the sense that the length of the block representing an element represents its duration, and elements that line up on the same vertical line in the diagram may not occur at the same relative time within the study.

Example Trial 7: RTOG 93-09 Retrospective View



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The Trial Design Matrix for Example Trial 7, RTOG 93-09, a Two-Arm Trial is shown in the following table.

	Screen	Induction		Continuation				Follow-up	
CR	Screen	Initial Chemo + RT	Chemo + RT (non-Surgery)	Chemo		Chemo		Off Treatment Follow-up	
CRS	Screen	Initial Chemo + RT	Chemo + RT (Surgery)	3-5 w Rest	Surgery	4-6 w Rest	Chemo	Chemo	Off Treatment Follow- up

The Trial Arms dataset for the trial is shown below for Example Trial 7, as a two-Arm trial

Row	STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
1	EX7	TA	1	CR	1	SCRN	Screen	Randomized to CR		Screen
2	EX7	TA	1	CR	2	ICR	Initial Chemo + RT			Induction
3	EX7	TA	1	CR	3	CRNS	Chemo+RT (non-Surgery)		If progression, skip to Follow-up.	Induction
4	EX7	TA	1	CR	4	C	Chemo			Continuation
5	EX7	TA	1	CR	5	C	Chemo			Continuation
6	EX7	TA	1	CR	6	FU	Off Treatment Follow-up			Follow-up
7	EX7	TA	2	CRS	1	SCRN	Screen	Randomized to CRS		Screen
8	EX7	TA	2	CRS	2	ICR	Initial Chemo + RT			Induction
9	EX7	TA	2	CRS	3	CRS	Chemo+RT (Surgery)		If progression, skip to Follow-up. If no progression, but subject is ineligible for or does not consent to surgery, skip to Addl Chemo.	Induction
10	EX7	TA	2	CRS	4	R3	3-5 week rest			Continuation
11	EX7	TA	2	CRS	5	SURG	Surgery			Continuation
12	EX7	TA	2	CRS	6	R4	4-6 week rest			Continuation
13	EX7	TA	2	CRS	7	C	Chemo			Continuation
14	EX7	TA	2	CRS	8	C	Chemo			Continuation
15	EX7	TA	2	CRS	9	FU	Off Treatment Follow-up			Follow-up

TA – Issues In Trial Arms Dataset

1. Distinguishing Between Branches and Transitions

Both the Branch and Transition columns contain rules, but the two columns represent two different types of rules. Branch rules represent forks in the trial flowchart, giving rise to separate Arms. The rule underlying a branch in the trial design appears in multiple records, once for each "fork" of the branch. Within any one record, there is no choice (no "if" clause) in the value of the Branch condition. For example, the value of TABRANCH for a record in Arm A is "Randomized to Arm A" because a subject in Arm A must have been randomized to Arm A. Transition rules are used for choices within an Arm. The value for TATRANS does contain a choice (an "if" clause). In Example Trial 4, subjects who receive 1, 2, 3, or 4 cycles of Treatment A are all considered to belong to Arm A.

In modeling a trial, decisions may have to be made about whether a decision point in the flow chart represents the separation of paths that represent different Arms, or paths that represent variations within the same Arm, as illustrated in the discussion of Example Trial 7. This decision will depend on the comparisons of interest in the trial.

Some trials refer to groups of subjects who follow a particular path through the trial as "cohorts", particularly if the groups are formed successively over time. The term "cohort" is used with different meanings in different protocols and does not always correspond to an Arm.

2. Subjects Not Assigned to an Arm

Some trial subjects may drop out of the study before they reach all of the branch points in the trial design. In the Demographics domain, values of ARM and ARMCD must be supplied for such subjects, but the special values used for these subjects should not be included in the Trial Arms dataset; only complete Arm paths should be described in the Trial Arms dataset. Demographics Assumption 4 [*Section 5 - DM Domain: DM - Assumptions for the DEMOGRAPHICS Domain Model*] describes special ARM and ARMCD values used for subjects who do not reach the first branch point in a trial. When a trial design includes two or more branches, special values of ARM and ARMCD may be needed for subjects who pass through the first branch point, but drop out before the final branch point. See *Section 5 - DM Domain: Example 7, DM - Examples for the DEMOGRAPHICS Domain Model* for an example of how to construct values of ARM and ARMCD for such trials.

3. Defining Epochs

The series of examples in [Section 7.2: TA - Examples for Trial Arms Dataset](#) provides a variety of scenarios and guidance about how to assign Epoch in those scenarios. In general, assigning Epochs for blinded trials is easier than for unblinded trials. The blinded view of the trial will generally make the possible choices clear. For unblinded trials, the comparisons that will be made between Arms can guide the definition of Epochs. For trials that include many variant paths within an Arm, comparisons of Arms will mean that subjects on a variety of paths will be included in the comparison, and this is likely to lead to definition of broader Epochs.

4. Rule Variables

The Branch and Transition columns shown in the example tables are variables with a Role of "Rule." The values of a Rule variable describe conditions under which something is planned to happen. At the moment, values of Rule variables are text. At some point in the future, it is expected that these will become executable code. Other Rule variables are present in the Trial Elements and Trial Visits datasets.

Trial Elements (TE)

TE – Description/Overview for Trial Elements Dataset

The Trial Elements (TE) dataset contains the definitions of the elements that appear in the Trial Arms (TA) dataset. An Element may appear multiple times in the Trial Arms table because it appears either 1) in multiple Arms, 2) multiple times within an Arm, or 3) both. However, an Element will appear only once in the Trial Elements table.

Each row in the TE dataset may be thought of as representing a "unique Element" in the sense of "unique" used when a case report form template page for a collecting certain type of data is often referred to as "unique page." For instance, a case report form might be described as containing 87 pages, but only 23 unique pages. By analogy, the trial design matrix for [Example Trial 1](#) has 9 Study Cells, each of which contains one Element, but the same trial design matrix contains only 5 unique Elements, so the trial Elements dataset for that trial has only 5 records.

An Element is a building block for creating Study Cells and an Arm is composed of Study Cells. Or, from another point of view, an Arm is composed of Elements, i.e., the trial design assigns subjects to Arms, which are comprised of a sequence of steps called Elements.

Trial Elements represent an interval of time that serves a purpose in the trial and are associated with certain activities affecting the subject. "Week 2 to Week 4" is not a valid Element. A valid Element has a name that describes the purpose of the Element and includes a description of the activity or event that marks the subject's transition into the Element as well as the conditions for leaving the Element.

TE – Specification for Trial Elements Dataset

te.xpt, Trial Elements — Trial Design, Version 3.2 One record per planned Element

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

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

TE – Assumptions for Trial Elements Dataset

1. There are no gaps between Elements. The instant one Element ends, the next Element begins. A subject spends no time "between" Elements.
2. ELEMENT, the Description of the Element, usually indicates the treatment being administered during an Element, or, if no treatment is being administered, the other activities that are the purpose of this period of time, such as Screening, Follow-up, Washout. In some cases, this may be quite passive, such as Rest, or Wait (for disease episode).
3. TESTRL, the Rule for Start of Element, identifies the event that marks the transition into this Element. For Elements that involve treatment, this is the start of treatment.
4. For Elements that do not involve treatment, TESTRL can be more difficult to define. For washout and follow-up Elements, which always follow treatment Elements, the start of the Element may be defined relative to the end of a preceding treatment. For example, a washout period might be defined as starting 24 or 48 hours after the last dose of drug for the preceding treatment Element or Epoch. This definition is not totally independent of the Trial Arms dataset, since it relies on knowing where in the trial design the Element is used, and that it always follows a treatment Element. Defining a clear starting point for the start of a non-treatment Element that always follows another non-treatment Element can be particularly difficult. The transition may be defined by a decision-making activity such as enrollment or randomization. For example, every Arm of a trial which

involves treating disease episodes might start with a screening Element followed by an Element which consists of waiting until a disease episode occurs. The activity that marks the beginning of the wait Element might be randomization.

5. TESTRL for a treatment Element may be thought of as “active” while the start rule for a non-treatment Element, particularly a follow-up or washout Element, may be “passive.” The start of a treatment Element will not occur until a dose is given, no matter how long that dose is delayed. Once the last dose is given, the start of a subsequent non-treatment Element is inevitable, as long as another dose is not given.
6. Note that the date/time of the event described in TESTRL will be used to populate the date/times in the Subject Elements dataset, so the date/time of the event should be one that will be captured in the CRF.
7. Specifying TESTRL for an Element that serves the first Element of an Arm in the Trial Arms dataset involves defining the start of the trial. In the examples in this document, obtaining informed consent has been used as “Trial Entry.”
8. TESTRL should be expressed without referring to Arm. If the Element appears in more than one Arm in the Trial Arms dataset, then the Element description (ELEMENT) must not refer to any Arms.
9. TESTRL should be expressed without referring to Epoch. If the Element appears in more than one Epoch in the Trial Arms dataset, then the Element description (ELEMENT) must not refer to any Epochs.
10. For a blinded trial, it is useful to describe TESTRL in terms that separate the properties of the event that are visible to blinded participants from the properties that are visible only to those who are unblinded. For treatment Elements in blinded trials, wording such as the following is suitable, “First dose of study drug for a treatment Epoch, where study drug is X.”
11. Element end rules are rather different from Element start rules. The actual end of one Element is the beginning of the next Element. Thus the Element end rule does not give the conditions under which an Element does end, but the conditions under which it should end or is planned to end.
12. At least one of TEENRL and TEDUR must be populated. Both may be populated.
13. TEENRL describes the circumstances under which a subject should leave this Element. Element end rules may depend on a variety of conditions. For instance, a typical criterion for ending a rest Element between oncology chemotherapy-treatment Elements would be, “15 days after start of Element and after WBC values have recovered.” The Trial Arms dataset, not the Trial Elements dataset, describes where the subject moves next, so TEENRL must be expressed without referring to Arm.
14. TEDUR serves the same purpose as TEENRL for the special (but very common) case of an Element with a fixed duration. TEDUR is expressed in ISO 8601. For example, a TEDUR value of P6W is equivalent to a TEENRL of “6 weeks after the start of the Element.”
15. Note that Elements that have different start and end rules are different Elements and must have different values of ELEMENT and ETCD. For instance, Elements that involve the same treatment but have different durations are different Elements. The same applies to non-treatment Elements. For instance, a washout with a fixed duration of 14 days is different from a washout that is to end after 7 days if drug cannot be detected in a blood sample, or after 14 days otherwise.

TE – Examples for Trial Elements Dataset

Below are Trial Elements datasets for Example Trials 1 and 2 described in [Section 7.2, Example Trial 1, A Parallel Trial, TA – Examples For Trial Arms](#) and [Section 7.2, Example Trial 2, A Crossover Trial, TA – Examples For Trial Arms Dataset](#). Both these trials are assumed to have fixed-duration Elements. The wording in TESTRL is intended to separate the description of the event that starts the Element into the part that would be visible to a blinded participant in the trial (e.g., “First dose of a treatment Epoch”) from the part that is revealed when the study is unblinded (e.g., “where dose is 5 mg”). Care must be taken in choosing these descriptions to be sure that they are “Arm and Epoch neutral.” For instance, in a crossover trial such as Example Trial 3 described in [Section 7.2, Example Trial 3, A Trial With Multiple Branch Points, TA - Examples for Trial Arms Dataset](#), where an Element may appear in one of multiple Epochs, the wording must be appropriate for all the possible Epochs. The wording for Example Trial 2 uses the wording “a treatment Epoch.” The SDS Team is considering adding a separate variable to the Trial Elements dataset that would hold information on the treatment that is associated with an Element. This would make it clearer which Elements are “treatment Elements”, and therefore, which Epochs contain treatment Elements, and thus are “treatment Epochs”.

Trial Elements Dataset for Example Trial 1

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Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	EX1	TE	SCRN	Screen	Informed consent	1 week after start of Element	P7D
2	EX1	TE	RI	Run-In	Eligibility confirmed	2 weeks after start of Element	P14D
3	EX1	TE	P	Placebo	First dose of study drug, where drug is placebo	2 weeks after start of Element	P14D
4	EX1	TE	A	Drug A	First dose of study drug, where drug is Drug A	2 weeks after start of Element	P14D
5	EX1	TE	B	Drug B	First dose of study drug, where drug is Drug B	2 weeks after start of Element	P14D

Trial Elements Dataset for Example Trial 2

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	EX2	TE	SCRN	Screen	Informed consent	2 weeks after start of Element	P14D
2	EX2	TE	P	Placebo	First dose of a treatment Epoch, where dose is placebo	2 weeks after start of Element	P14D
3	EX2	TE	5	5 mg	First dose of a treatment Epoch, where dose is 5 mg drug	2 weeks after start of Element	P14D
4	EX2	TE	10	10 mg	First dose of a treatment Epoch, where dose is 10 mg drug	2 weeks after start of Element	P14D
5	EX2	TE	REST	Rest	48 hrs after last dose of preceding treatment Epoch	1 week after start of Element	P7D
6	EX2	TE	FU	Follow-up	48 hrs after last dose of third treatment Epoch	3 weeks after start of Element	P21D

The Trial Elements dataset for Example Trial 4 illustrates Element end rules for Elements that are not of fixed duration. The Screen Element in this study can be up to 2 weeks long, but may end earlier, so is not of fixed duration. The Rest Element has a variable length, depending on how quickly WBC recovers. Note that the start rules for the A and B Elements have been written to be suitable for a blinded study.

Trial Elements Dataset for Example Trial 4

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	EX4	TA	SCRN	Screen	Informed Consent	Screening assessments are complete, up to 2 weeks after start of Element	
2	EX4	TA	A	Trt A	First dose of treatment Element, where drug is Treatment A	5 days after start of Element	P5D
3	EX4	TA	B	Trt B	First dose of treatment Element, where drug is Treatment B	5 days after start of Element	P5D
4	EX4	TA	REST	Rest	Last dose of previous treatment cycle + 24 hrs	At least 16 days after start of Element and WBC recovered	
5	EX4	TA	FU	Follow-up	Decision not to treat further	4 weeks	P28D

TE – Trial Elements Issues

1. Granularity of Trial Elements

Deciding how finely to divide trial time when identifying trial Elements is a matter of judgment, as illustrated by the following examples:

1. Example Trial 2 (described in [Example Trial 2](#), and with Elements described in [Section 7.2: TE - Examples for Trial Elements Dataset](#)) was represented using three treatment Epochs separated by two washout Epochs and followed by a follow-up Epoch. It might have been modeled using three treatment Epochs that included both the 2-week treatment period and the 1-week rest period. Since the first week after the third treatment period would be included in the third treatment Epoch, the Follow-up Epoch would then have a duration of 2 weeks.
2. In Example Trials 4, 5, and 6 in [Example Trial 4](#), [Example Trial 5](#) and [Example Trial 6](#) separate Treatment and Rest Elements were identified. However, the combination of treatment and rest could be represented as a single Element.
3. A trial might include a dose titration, with subjects receiving increasing doses on a weekly basis until certain conditions are met. The trial design could be modeled in any of the following ways:
 - using several one-week Elements at specific doses, followed by an Element of variable length at the chosen dose,
 - as a titration Element of variable length followed by a constant dosing Element of variable length
 - one Element with dosing determined by titration

The choice of Elements used to represent this dose titration will depend on the objectives of the trial and how the data will be analyzed and reported. If it is important to examine side effects or lab values at each individual dose, the first model is appropriate. If it is important only to identify the time to completion of titration, the second model might be appropriate. If the titration process is routine and is of little interest, the third model might be adequate for the purposes of the trial.

2. Distinguishing Elements, Study Cells, and Epochs

It is easy to confuse Elements, which are reusable trial building blocks, with Study Cells, which contain the Elements for a particular Epoch and Arm, and with Epochs, which are time periods for the trial as a whole. In part, this is because many trials have Epochs for which the same Element appears in all Arms. In other words, in the trial design matrix for many trials, there are columns (Epochs) in which all the Study Cells have the same contents. Furthermore, it is natural to use the same name (e.g., Screen or Follow-up) for both such an Epoch and the single Element that appears within it.

Confusion can also arise from the fact that, in the blinded treatment portions of blinded trials, blinded participants do not know which Element a subject is in, but do know what Epoch the subject is in.

In describing a trial, one way to avoid confusion between Elements and Epochs is to include "Element" or "Epoch" in the values of ELEMENT or EPOCH when these values (such as Screening or Follow-up) would otherwise be the same. It becomes tedious to do this in every case, but can be useful to resolve confusion when it arises or is likely to arise.

The difference between Epoch and Element is perhaps clearest in crossover trials. In Example Trial 2, as for most crossover trials, the analysis of PK results would include both treatment and period effects in the model. "Treatment effect" derives from Element (Placebo, 5 mg, or 10 mg), while "Period effect" derives from the Epoch (1st, 2nd, or 3rd Treatment Epoch).

3. Transitions Between Elements

The transition between one Element and the next can be thought of as a three-step process:

Step Number	Step Question	How step question is answered by information in the Trial Design datasets
1	Should the subject leave the current Element?	Criteria for ending the current Element are in TEENRL in the TE dataset.
2	Which Element should the subject enter next?	<ul style="list-style-type: none"> • If there is a branch point at this point in the trial, evaluate criteria described in TABRANCH (e.g., randomization results) in the TA dataset • otherwise, if TATRANS in the TA dataset is populated in this Arm at this point, follow those instructions • otherwise, move to the next Element in this Arm as specified by TAETORD in the TA dataset.
3	What does the subject do to enter the next Element?	The action or event that marks the start of the next Element is specified in TESTRL in the TE dataset

Note that the subject is not "in limbo" during this process. The subject remains in the current Element until Step 3, at which point the subject transitions to the new Element. There are no gaps between Elements.

From this table, it is clear that executing a transition depends on information that is split between the Trial Elements and the Trial Arms datasets.

It can be useful, in the process of working out the Trial Design datasets, to create a dataset that supplements the Trial Arms dataset with the TESTRL, TEENRL, and TEDUR variables, so that full information on the transitions is easily accessible. However, such a working dataset is not an SDTM dataset, and should not be submitted.

The following table shows a fragment of such a table for Example Trial 4. Note that for all records that contain a particular Element, all the TE variable values are exactly the same. Also, note that when both TABRANCH and TATRANS are blank, the implicit decision in Step 2 is that the subject moves to the next Element in sequence for the Arm.

ARM	EPOCH	TAETORD	ELEMENT	TESTRL	TEENRL	TEDUR	TABRANCH	TATRANS
A	Screen	1	Screen	Informed Consent	Screening assessments are complete, up to 2 weeks after start of Element		Randomized to A	
A	Treatment	2	Trt A	First dose of treatment in Element, where drug is Treatment A	5 days after start of Element	P5D		
A	Treatment	3	Rest	Last dose of previous treatment cycle + 24 hrs	16 days after start of Element and WBC recovers			If disease progression, go to Follow-up Epoch
A	Treatment	4	Trt A	First dose of treatment in Element, where drug is Treatment A	5 days after start of Element	P5D		

Note that both the second and fourth rows of this dataset involve the same Element, Trt A, and so TESTRL is the same for both. The activity that marks a subject's entry into the fourth Element in Arm A is "First dose of treatment Element, where drug is Treatment A." This is not the subject's very first dose of Treatment A, but it is their first dose in this Element.

7 Trial Design Datasets

Scheduling of Assessments: TV and TD

This subsection contains the Trial Design datasets that describe the protocol-defined planned schedule of subject encounters at the healthcare facility where the study is being conducted [see [Section 7.3, Trial Visits \(TV\)](#)], as well as planned schedule of efficacy assessments related to the disease under study [see [Section 7.3, Trial Disease Assessments \(TD\)](#)].

The TV and TD datasets are complementary of each other, and they provide the standard measure of time against which the subject's actual schedule can be compared to ensure compliance with the study schedule.

Trial Visits (TV)

TV – Description/Overview for Trial Visits Dataset

The Trial Visits (TV) dataset describes the planned Visits in a trial. Visits are defined as "clinical encounters" and are described using the timing variables VISIT, VISITNUM, and VISITDY.

Protocols define Visits in order to describe assessments and procedures that are to be performed at the Visits.

TV – Specification for Trial Visits Dataset

tv.xpt, Trial Visits — Trial Design, Version 3.2. One record per planned Visit per Arm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TV	Identifier	Two-character abbreviation for the domain	Req
VISITNUM	Visit Number	Num		Topic	1. Clinical encounter number 2. Numeric version of VISIT, used for sorting.	Req
VISIT	Visit Name	Char		Synonym Qualifier	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY as a text description of the clinical encounter.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	1. Planned study day of VISIT. 2. Due to its sequential nature, used for sorting.	Perm
ARMCD	Planned Arm Code	Char	*	Record Qualifier	1.ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
					2. 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	*	Synonym Qualifier	1. Name given to an Arm or Treatment Group. 2. If the timing of Visits for a trial does not depend on which Arm a subject is in, then Arm should be left blank.	Perm
TVSTRL	Visit Start Rule	Char		Rule	Rule describing when the Visit starts, in relation to the sequence of Elements.	Req
TVENRL	Visit End Rule	Char		Rule	Rule describing when the Visit ends, in relation to the sequence of Elements.	Perm

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

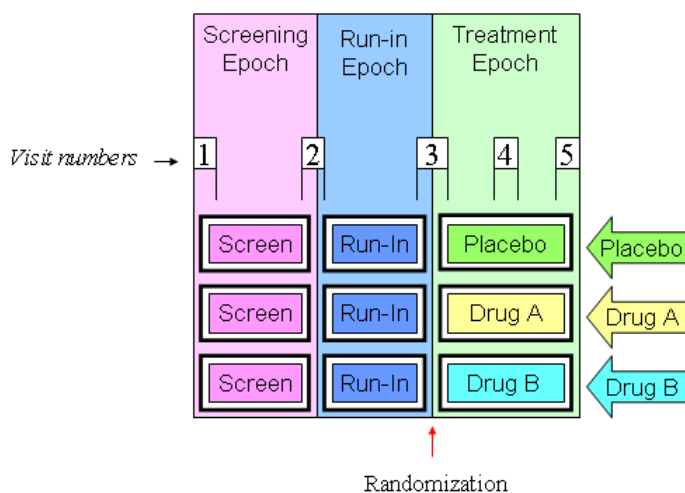
TV – Assumptions for Trial Visits Dataset

- Although the general structure of the Trial Visits dataset is "One Record per Planned Visit per Arm", for many clinical trials, particularly blinded clinical trials, the schedule of Visits is the same for all Arms, and the structure of the Trial Visits dataset will be "One Record per Planned Visit". If the schedule of Visits is the same for all Arms, ARMCD should be left blank for all records in the TV dataset. For trials with trial Visits that are different for different Arms, such as Example Trial 7 in *Section 7.2 - Experimental Design: Example Trial 7, Trial With Disparate Arms, TA - Examples for Trial Arms Dataset*, ARMCD and ARM should be populated for all records. If some Visits are the same for all Arms, and some Visits differ by Arm, then ARMCD and ARM should be populated for all records, to assure clarity, even though this will mean creating near-duplicate records for Visits that are the same for all Arms.
- A Visit may start in one Element and end in another. This means that a Visit may start in one Epoch and end in another. For example, if one of the activities planned for a Visit is the administration of the first dose of study drug, the Visit might start in the screen Epoch, in the screen Element, and end in a treatment Epoch, in a treatment Element.
- TVSTRL describes the scheduling of the Visit and should reflect the wording in the protocol. In many trials, all Visits are scheduled relative to the study's Day 1, RFSTDTC. In such trials, it is useful to include VISITDY, which is, in effect, a special case representation of TVSTRL.
- Note that there is a subtle difference between the following two examples. In the first case, if Visit 3 were delayed for some reason, Visit 4 would be unaffected. In the second case, a delay to Visit 3 would result in Visit 4 being delayed as well.
 - Case 1: Visit 3 starts 2 weeks after RFSTDTC. Visit 4 starts 4 weeks after RFSTDTC.
 - Case 2: Visit 3 starts 2 weeks after RFSTDTC. Visit 4 starts 2 weeks after Visit 3.
- Many protocols do not give any information about Visit ends because Visits are assumed to end on the same day they start. In such a case, TVENRL may be left blank to indicate that the Visit ends on the same day it starts. Care should be taken to assure that this is appropriate, since common practice may be to record data collected over more than one day as occurring within a single Visit. Screening Visits may be particularly prone to collection of data over multiple days. See [Section 7.3, TV - Examples for Trial Visits Dataset](#) for examples showing how TVENRL could be populated.
- The values of VISITNUM in the TV dataset are the valid values of VISITNUM for planned Visits. Any values of VISITNUM that appear in subject-level datasets that are not in the TV dataset are assumed to correspond to unplanned Visits. This applies, in particular, to the subject-level Subject Visits (SV) dataset; see *Section 5 - SV Domain* on the SV dataset for additional information about handling unplanned Visits. If a subject-level dataset includes both VISITNUM and VISIT, then records that include values of VISITNUM that appear in the TV dataset should also include the corresponding values of VISIT from the TV dataset.

TV – Examples for Trial Visits Dataset

The diagram below shows Visits by means of numbered "flags" with Visit Numbers. Each "flag" has two supports, one at the beginning of the Visit, the other at the end of the Visit. Note that Visits 2 and 3 span Epoch transitions. In other words, the transition event that marks the beginning of the Run-in Epoch (confirmation of eligibility) occurs during Visit 2, and the transition event that marks the beginning of the Treatment Epoch (the first dose of study drug) occurs during Visit 3.

Example Trial 1: Parallel Design Planned Visits



Two Trial Visits datasets are shown for this trial. The first shows a somewhat idealized situation, where the protocol has given specific timings for the Visits. The second shows a more usual situation, where the timings have been described only loosely.

Trial Visits Dataset for Example Trial 1 with explicitly scheduled starts and ends of Visits

Row	STUDYID	DOMAIN	VISITNUM	TVSTRL	TVENRL
1	EX1	TV	1	Start of Screen Epoch	1 hour after start of Visit
2	EX1	TV	2	30 minutes before end of Screen Epoch	30 minutes after start of Run-in Epoch
3	EX1	TV	3	30 minutes before end of Run-in Epoch	1 hour after start of Treatment Epoch
4	EX1	TV	4	1 week after start of Treatment Epoch	1 hour after start of Visit
5	EX1	TV	5	2 weeks after start of Treatment Epoch	1 hour after start of Visit

Trial Visits Dataset for Example Trial 1 with loosely described starts and ends of Visits

Row	STUDYID	DOMAIN	VISITNUM	TVSTRL	TVENRL
1	EX1	TV	1	Start of Screen Epoch	
2	EX1	TV	2	On the same day as, but before, the end of the Screen Epoch	On the same day as, but after, the start of the Run-in Epoch
3	EX1	TV	3	On the same day as, but before, the end of the Run-in Epoch	On the same day as, but after, the start of the Treatment Epoch
4	EX1	TV	4	1 week after start of Treatment Epoch	
5	EX1	TV	5	2 weeks after start of Treatment Epoch	At Trial Exit

Although the start and end rules in this example reference the starts and ends of Epochs, the start and end rules of some Visits for trials with Epochs that span multiple Elements will need to reference Elements rather than Epochs. When an Arm includes repetitions of the same Element, it may be necessary to use TAETORD as well as an Element name to specify when a Visit is to occur.

TV – Trial Visits Issues

1. Identifying Trial Visits

In general, a trial's Visits are defined in its protocol. The term “Visit” reflects the fact that data in outpatient studies is usually collected during a physical Visit by the subject to a clinic. Sometimes a Trial Visit defined by the protocol may not correspond to a physical Visit. It may span multiple physical Visits, as when screening data may be collected over several clinic Visits but recorded under one Visit name (VISIT) and number (VISITNUM). A Trial Visit may also represent only a portion of an extended physical Visit, as when a trial of in-patients collects data under multiple Trial Visits for a single hospital admission.

Diary data and other data collected outside a clinic may not fit the usual concept of a Trial Visit, but the planned times of collection of such data may be described as “Visits” in the Trial Visits dataset if desired.

2. Trial Visit Rules

Visit start rules are different from Element start rules because they usually describe when a Visit should occur, while Element start rules describe the moment at which an Element is considered to start. There are usually gaps between Visits, periods of time that do not belong to any Visit, so it is usually not necessary to identify the moment when one Visit stops and another starts. However, some trials of hospitalized subjects may divide time into Visits in a manner more like that used for Elements, and a transition event may need to be defined in such cases.

Visit start rules are usually expressed relative to the start or end of an Element or Epoch, e.g., “1-2 hours before end of First Wash-out” or “8 weeks after end of 2nd Treatment Epoch.” Note that the Visit may or may not occur during the Element used as the reference for Visit start rule. For example, a trial with Elements based on treatment of disease episodes might plan a Visit 6 months after the start of the first treatment period, regardless of how many disease episodes have occurred.

Visit end rules are similar to Element end rules, describing when a Visit should end. They may be expressed relative to the start or end of an Element or Epoch, or relative to the start of the Visit.

The timings of Visits relative to Elements may be expressed in terms that cannot be easily quantified. For instance, a protocol might instruct that at a baseline Visit the subject be randomized, given study drug, and instructed to take the first dose of study Drug X at bedtime that night. This baseline Visit is thus started and ended before the start of the treatment Epoch, but we don't know how long before the start of the treatment Epoch the Visit will occur. The trial start rule might contain the value, “On the day of, but before, the start of the Treatment Epoch.”

3. Visit Schedules Expressed with Ranges

Ranges may be used to describe the planned timing of Visits (e.g., 12-16 days after the start of 2nd Element), but this is different from the “windows” that may be used in selecting data points to be included in an analysis associated with that Visit. For example, although Visit 2 was planned for 12-16 days after the start of treatment, data collected 10-18 days after the start of treatment might be included in a “Visit 1” analysis. The two ranges serve different purposes.

4. Contingent Visits

Section 5 - SV Domain, which describes the Subject Visits dataset, describes how records for unplanned Visits are incorporated. It is sometimes difficult to decide exactly what constitutes an “unplanned Visit” versus a “contingent Visit,” a Visit that is contingent on a “trigger” event, such as a certain adverse event, a finding above a certain threshold value, or a decision to discontinue a subject’s participation in the trial. Contingent Visits may be included in the Trial Visits table, with start rules that describe the circumstances under which they will take place. Since values of VISITNUM must be assigned to all records in the Trial Visits dataset, a contingent Visit included in the Trial Visits dataset must have a VISITNUM, but the VISITNUM value may not be a “chronological” value, due to the uncertain timing of the Visit.

Trial Disease Assessments (TD)

TD – Description/Overview for Trial Disease Assessments Dataset

The TD domain provides information on the protocol-specified disease assessment schedule, and will be used for comparison with the actual occurrence of the efficacy assessments in order to determine whether there was good compliance with the schedule.

TD – Specification for Trial Disease Assessments Dataset

td.xpt, Trial Disease Assessments - Trial Design, Version 3.2. One record per planned constant assessment period

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

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
					by any subject across the trial at that point in time.	

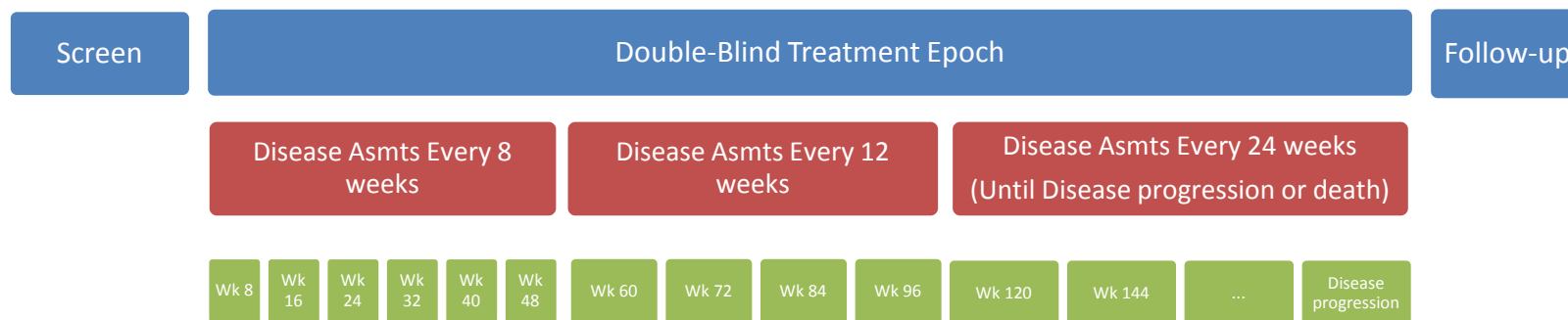
* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

TD – Assumptions for Trial Disease Assessments Dataset

1. TD Definition: The TD domain provides information on the protocol-specified disease assessment schedule, and will be used for comparison with the actual occurrence of the efficacy assessments in order to determine whether there was good compliance with the 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, in particular, for studies with progression-free survival (PFS) endpoints. TD has limited utility within oncology and was developed specifically with RECIST in mind and where an assessment time bias analysis is appropriate. It is understood that extending this approach to Cheson and other criteria may not be appropriate or may pose difficulties.
2. A planned schedule of assessments will have a defined start point and the TDANCVAR variable is used to identify the variable in ADSL that holds the “anchor” date. By default, the anchor variable for the first pattern is ANCH1DT. An anchor date must be provided for each pattern of assessments and each anchor variable must exist in ADSL. TDANCVAR is therefore a Required variable. Anchor date variable names should adhere to ADaM variable naming conventions (e.g. ANCH1DT, ANCH2DT, etc). One anchor date may be used to anchor more than one pattern of disease assessments. When that is the case, the appropriate offset for the start of a subsequent pattern, represented as an ISO 8601 duration value, should be provided in the TDSTOFF variable.
3. The TDSTOFF variable is used in conjunction with the anchor date value (from the anchor date variable identified in TDANCVAR). If the pattern of disease assessments does not start exactly on a date collected on the CRF, this variable will represent the offset between the anchor date value and the start date of the pattern of disease assessments. This may be a positive or negative interval value represent in an ISO 8601 format.
4. This domain should not be created when the disease assessment schedule may vary for individual subjects, for example when completion of the first phase of a study is event driven. .

TD – Examples for Trial Disease Assessments Dataset

Example 1:

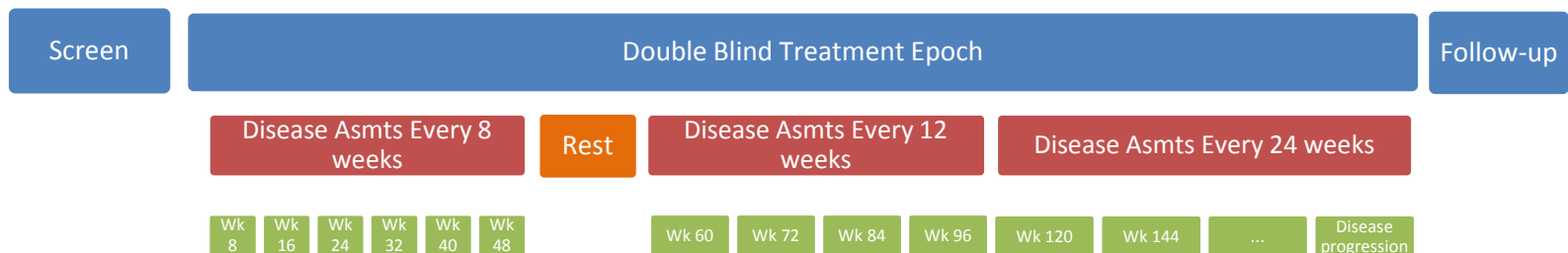


This example shows a study where the disease assessment schedule changes over the course of the study. In this example, there are three distinct disease-assessment schedule patterns. A single anchor date variable (TDANCVAR) provides the anchor date for each pattern. The offset variable (TDSTOFF) used in conjunction with the anchor date variable provides the start point of each pattern of assessments..

- The first disease-assessment schedule pattern starts at the reference start date (identified in the ADSL ANCH1DT variable) and repeats every 8 weeks for a total of six repeats (i.e., Week 8, Week 16, Week 24, Week 32, Week 40, and Week 48). Note that there is an upper and lower limit around the planned disease assessment target where the first assessment (8 Weeks) could occur as early as Day 53 and as late as Week 9. This upper and lower limit (-3 days, +1 week) would be applied to all assessments during that pattern.
- The second disease assessment schedule starts from Week 48 and repeats every 12 weeks for a total of 4 repeats (i.e., Week 60, Week 72, Week 84, Week 96), with respective upper and lower limits of -1 week and + 1 week.
- The third disease assessment schedule starts from Week 96 and repeats every 24 weeks (i.e. Week 120, Week 144, etc.) ,with respective upper and lower limits of -1 week and + 1 week, for an indefinite length of time. The schematic above shows that, for the third pattern, assessments will occur until disease progression, and this therefore leaves the pattern open ended. However, when data is included in an analysis, the total number of repeats can be identified and the highest number of repeat assessments for any subject in that pattern must be recorded in the TDNUMRPT variable on the final pattern record.

Row	STUDYID	DOMAIN	TDORDER	TDANCVAR	TDSTOFF	TDTGTPAI	TDMINPAI	TDMAXPAI	TDNUMRPT
1	ABC123	TD	1	ANCH1DT	P0D	P8W	P53D	P9W	6
2	ABC123	TD	2	ANCH1DT	P60W	P12W	P11W	P13W	4
3	ABC123	TD	3	ANCH1DT	P120W	P24W	P23W	P25W	12

Example 2:

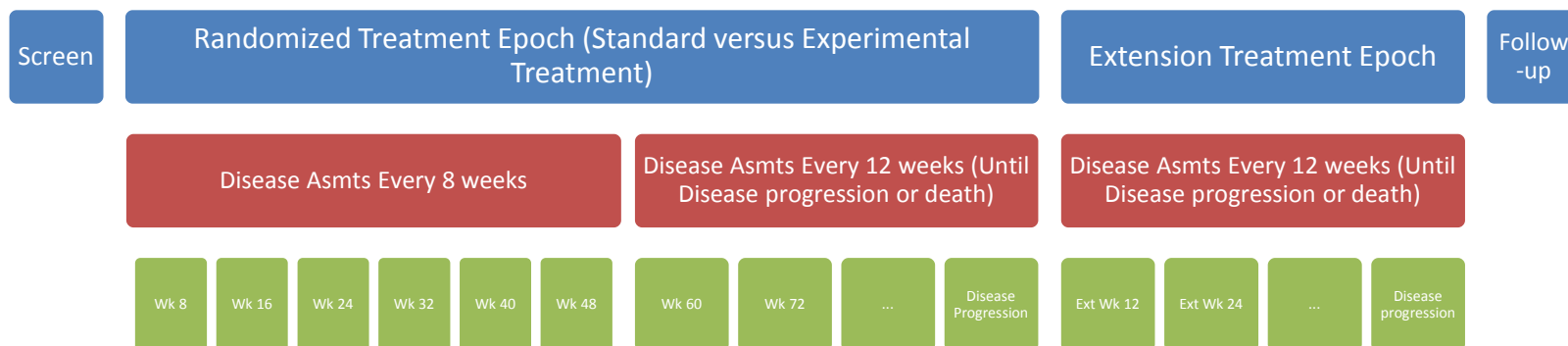


This example is the same as Example 1, except that there is a rest period of 14 days prior to the start of the second disease-assessment schedule. This example also shows how three different reference/anchor dates can be used.

- The Rest is not represented as a row in this domain since no disease assessments occur during the Rest. Note: Although, Rest is not important in TD, it is important that it is represented in other trial design datasets.
- The second pattern of assessments starts on the date identified in the ADSL variable ANCH2DT and repeats every 12 weeks for a total of 4 repeats with respective upper and lower limits of -1 week and + 1 week,.
- The third disease assessment schedule pattern follows on from the second pattern starting on the date identified in the ADSL variable ANCH3DT and repeats every 24 weeks with respective upper and lower limits of -1 week and + 1 week. The schematic above for the final disease-assessment pattern indicates that assessments will occur until disease progression, and this therefore leaves the pattern open ended. However, when data is included in an analysis, the total number of repeats can be identified and the highest number of repeat assessments for any subject in that pattern must be recorded in the TDNUMRPT variable on the final pattern record. In this instance, the maximum number of observed assessments was 17.

Row	STUDYID	DOMAIN	TDORDER	TDANCVAR	TDSTOFF	TDTGTPAI	TDMINPAI	TDMAXPAI	TDNUMRPT
1	ABC123	TD	1	ANCH1DT	P0D	P8W	P53D	P9W	6
2	ABC123	TD	2	ANCH2DT	P0D	P12W	P11W	P13W	4
3	ABC123	TD	3	ANCH3DT	P0D	P24W	P23W	P25W	17

Example 3:



This example shows a study where subjects are randomized to standard treatment or an experimental treatment. The subjects who are randomized to standard treatment are given the option to receive experimental treatment after the end of the standard treatment (e.g. disease progression on standard treatment). In the randomized treatment epoch, the disease assessment schedule changes over the course of the study. At the start of the extension treatment epoch, subjects are re-baselined, e.g. a extension baseline disease assessments is performed and the disease assessment schedule is restarted.

In this example, there are three distinct disease-assessment schedule patterns.

- The first disease-assessment schedule pattern starts at the reference start date (identified in the ADSL ANCH1DT variable) and repeats every 8 weeks for a total of six repeats (i.e., Week 8, Week 16, Week 24, Week 32, Week 40, and Week 48), with respective upper and lower limits of -3 days and + 1 week.
- The second disease assessment schedule starts from Week 48 and repeats every 12 weeks (i.e., Week 60, Week 72, etc.), with respective upper and lower limits of -1 week and + 1 week, for an indefinite length of time. The schematic above shows that, for the second pattern, assessments will occur until disease progression, and this therefore leaves the pattern open ended.
- The third disease assessment schedule starts at the extension reference start date (identified in the ADSL ANCH2DT variable) from Week 96 and repeats every 24 weeks (i.e. Week 120, Week 144, etc.) ,with respective upper and lower limits of -1 week and + 1 week, for an indefinite length of time. The schematic above shows that, for the third pattern, assessments will occur until disease progression, and this therefore leaves the pattern open ended.

For open ended patterns, the total number of repeats can be identified when the data analysis is performed and the highest number of repeat assessments for any subject in that pattern must be recorded in the TDNUMRPT variable on the final pattern record.

Row	STUDYID	DOMAIN	TDORDER	TDANCVAR	TDSTOFF	TDTGTPAI	TDMINPAI	TDMAXPAI	TDNUMRPT
1	ABC123	TD	1	ANCH1DT	P0D	P8W	P53D	P9W	6
2	ABC123	TD	2	ANCH1DT	P60W	P12W	P11W	P13W	17
3	ABC123	TD	3	ANCH2DT	P0D	P12W	P11W	P23W	17

Trial Design Datasets

Trial Summary and Eligibility: TI and TS

This subsection contains the Trial Design datasets that describe the characteristics of the trial [see [Section 7.4, Trial Summary Information \(TS\)](#)], as well as subject eligibility criteria for trial participation [see [Section 7.4, Trial Inclusion/Exclusion Criteria \(TI\)](#)].

The TI and TS datasets are a tabular synopsis for the study protocol.

Trial Inclusion/Exclusion Criteria (TI)

TI – Description/Overview for Trial Inclusion/Exclusion Criteria Dataset

The Trial Inclusion Exclusion (TI) dataset is not subject oriented. It contains all the inclusion and exclusion criteria for the trial, and thus provides information that may not be present in the subject-level data on inclusion and exclusion criteria. The IE domain (described in [Section 6.3 - IE Domain](#)) contains records only for inclusion and exclusion criteria that subjects did not meet.

Ti – Specification for Trial Inclusion/Exclusion Criteria Dataset

ti.xpt, Trial Inclusion/Exclusion Criteria — Trial Design, Version 3.2. One record per I/E criterion

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TI	Identifier	Two-character abbreviation for the domain.	Req
IETESTCD	Incl/Excl Criterion Short Name e	Char	*	Topic	Short name IETEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in IETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., “1TEST”). IETESTCD cannot contain characters other than letters, numbers, or underscores. The prefix “IE” is used to ensure consistency with the IE domain.	Req
IETEST	Inclusion/Exclusion Criterion	Char	*	Synonym Qualifier	Full text of the inclusion or exclusion criterion. The prefix “IE” is used to ensure consistency with the IE domain.	Req
IECAT	Inclusion/Exclusion Category	Char	(IECAT)	Grouping Qualifier	Used for categorization of the inclusion or exclusion criteria.	Req
IESCAT	Inclusion/Exclusion Subcategory	Char	*	Grouping Qualifier	A further categorization of the exception criteria for a sub-study or for to categorize as a major or minor exceptions. Examples: MAJOR, MINOR.	Perm
TIRL	Inclusion/Exclusion Criterion Rule	Char		Rule	Rule that expresses the criterion in computer-executable form (see assumption 4 below).	Perm
TIVERS	Protocol Criteria	Char		Record	The number of this version of the	Perm

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
	Versions			Qualifier	Inclusion/Exclusion criteria. May be omitted if there is only one version.	

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

TI – Assumptions for Trial Inclusion/Exclusion Criteria Dataset

1. If inclusion/exclusion criteria were amended during the trial, then each complete set of criteria must be included in the TI domain. TIVERS is used to distinguish between the versions.
2. Protocol version numbers should be used to identify criteria versions, though there may be more versions of the protocol than versions of the inclusion/exclusion criteria. For example, a protocol might have versions 1, 2, 3, and 4, but if the inclusion/exclusion criteria in version 1 were unchanged through versions 2 and 3, and only changed in version 4, then there would be two sets of inclusion/exclusion criteria in TI, one for version 1 and one for version 4.
3. Individual criteria do not have versions. If a criterion changes, it should be treated as a new criterion, with a new value for IETESTCD. If criteria have been numbered and values of IETESTCD are generally of the form INCL00n or EXCL00n, and new versions of a criterion have not been given new numbers, separate values of IETESTCD might be created by appending letters, e.g. INCL003A, INCL003B.
4. IETEST contains the text of the inclusion/exclusion criterion. However, since entry criteria are rules, the variable TIRL has been included in anticipation of the development of computer executable rules.
5. If a criterion text is <200 characters, it goes in IETEST; if the text is >200 characters, put meaningful text in IETEST and describe the full text in the study metadata. See [Section 4: 4.1.5.3.1, Test Name \(--TEST\) Greater Than 40 Characters](#) for further information.

TI – Examples for Trial Inclusion/Exclusion Criteria Dataset

This example shows records for a trial that had two versions of inclusion/exclusion criteria.

Rows 1-3 show the two inclusion criteria and one exclusion criterion for version 1 of the protocol.

Rows 4-6 show the inclusion/exclusion criteria for version 2.2 of the protocol, which changed the minimum age for entry from 21 to 18.

Row	STUDYID	DOMAIN	IETESTCD	IETEST	IECAT	TIVERS
1	XYZ	TI	INCL01	Has disease under study	INCLUSION	1
2	XYZ	TI	INCL02	Age 21 or greater	INCLUSION	1
3	XYZ	TI	EXCL01	Pregnant or lactating	EXCLUSION	1
4	XYZ	TI	INCL01	Has disease under study	INCLUSION	2.2
5	XYZ	TI	INCL02A	Age 18 or greater	INCLUSION	2.2
6	XYZ	TI	EXCL01	Pregnant or lactating	EXCLUSION	2.2

Trial Summary Information (TS)

TS – Description/Overview for Trial Summary Information Dataset

The Trial Summary (TS) dataset allows the sponsor to submit a summary of the trial in a structured format. Each record in the Trial Summary dataset contains the value of a parameter, a characteristic of the trial. For example, Trial Summary is used to record basic information about the study such as trial phase, protocol title, and trial objectives. The Trial Summary dataset contains information about the planned and actual trial characteristics.

TS – Specification for Trial Summary Information Dataset

ts.xpt, Trial Summary — Trial Design, Version 3.2. One record per trial summary parameter value

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	TS	Identifier	Two-character abbreviation for the domain.	Req
TSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a dataset. Allows inclusion of multiple records for the same TSPARMCD, and can be used to join related records.	Req
TSGRPID	Group ID	Char		Identifier	Used to tie together a group of related records	Perm
TSPARMCD	Trial Summary Parameter Short Name	Char	TSPARMCD	Topic	TSPARMCD (the companion to TSPARM) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that TSPARMCD will need to serve as variable names. Examples: AGEMIN, AGEMAX	Req
TSPARM	Trial Summary Parameter	Char	TSPARM	Synonym Qualifier	Term for the Trial Summary Parameter. The value in TSPARM cannot be longer than 40 characters. Examples Planned Minimum Age of Subjects, Planned Maximum Age of Subjects	Req
TSVAL	Parameter Value	Char	*	Result Qualifier	Value of TSPARM. Example: “ASTHMA” when TSPARM value is “Trial Indication”. TSVAL can only be null when TSVALNF is populated. Text over 200 characters can be added to additional columns TSVAL1-TSVALn.	Exp
TSVALNF	Parameter Null Flavor	Char	NULLFLAVOR	Result Qualifier	Null flavor for the value of TSPARM, to be populated if and only if TSVAL is null.	Perm
TSVALCD	Parameter Value Code	Char	*	Result Qualifier	This is the code of the term in TSVAL. For example; 6CW7F3G59X is the code for Gabapentin, C49488 is the code for Y. The length of this variable can be longer than 8 to accommodate the length of the external terminology.	Exp
TSVCDREF	Name of the Reference Terminology	Char		Result Qualifier	The name of the Reference Terminology from which TSVALCD is taken. For example; CDISC, SNOMED, ISO 8601.	Exp
TSVCDVER	Version of the Reference Terminology	Char		Result Qualifier	The version number of the Reference Terminology, if applicable.	Exp

* Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

TS – Assumptions for Trial Summary Information Dataset

1. The intent of this dataset is to provide a summary of trial information. This is not subject-level data.
2. A list of values for TSPARM and TSPARMCD can be found on the CDISC website using this link: [CDISC Controlled Terminology](#)
3. Further information about the parameters is included below in Table 1. TSVAL may have controlled terminology depending on the value of TSPARMCD.
Conditions for including parameters are included in Table 1.
4. Controlled terminology for TSPARM is extensible. The meaning of any added parameters should be explained in the metadata for the TS dataset.
5. For some trials, there will be multiple records in the Trial Summary dataset for a single parameter. For example, a trial that addresses both Safety and Efficacy could have two records with TSPARMCD = TTYPE, one with the TSVAL = "SAFETY" and the other with TSVAL = "EFFICACY."
TSSEQ has a different value for each record for the same parameter. Note that this is different from datasets that contain subject data, where the --SEQ variable has a different value for each record for the same subject.
6. The method for treating text > 200 characters in Trial Summary is similar to that used for the Comments special-purpose domain ([Section 5 - CO Domain](#)). If TSVAL is > 200 characters, then it should be split into multiple variables, TSVAL-TSVALn.
7. Since TS does not contain subject-level data, there is no restriction analogous to the requirement in subject-level datasets that the blocks bound by TSGRPID are within a subject. TSGRPID can be used to tie together any block of records in the dataset. TSGRPID is most likely to be used when the TS dataset includes multiple records for the same parameter. For example, if a trial compared a dose of 50 mg twice a day with a dose of 100 mg once a day, a record with TSPARMCD = DOSE and TSVAL=50 and a record with TSPARMCD = DOSFREQ and TSVAL = BID could be assigned one GRPID, while a record with TSPARMCD = DOSE and TSVAL=100 and a record with TSPARMCD = DOSFREQ and TSVAL = Q24H could be assigned a different GRPID.
8. The order of parameters in the examples of TD datasets in [Section 7.4: TS – Examples](#) should not be taken as a requirement. There are no requirements or expectations about the order of parameters within the TS dataset.
11. Not all protocols describe objectives in a way that specifically designates each objective as “primary” or “secondary.” If the protocol does not provide information about which objectives meet the definition of TSPARM=OBJPRIM (i.e., “The principle purpose of the trial”), then all objectives should be given as values of TSPARM=OBJPRIM. The Trial Summary Parameter “Trial Secondary Objective” is defined as “The auxiliary purpose of the trial.” A protocol may use multiple designations for objectives that are not primary (e.g., Secondary, Tertiary, and Exploratory), but all these non-primary objectives should be given as values of TSPARM=OBJSEC.
12. As per the definitions, the Primary Outcome Measure is associated with the Primary Objective and the Secondary Outcome Measure is associated with the Secondary Objective. It is possible for the same Outcome measure to be associated with more than one objective. For example two objectives could use the same outcome measure at different time points, or using different analysis methods.
13. If a primary objective is assessed by means of multiple outcome measures, then all of these outcome measures should be provided as values of TSPARM=OUTMSPR. Similarly, all outcome measures used to assess secondary objectives should be provided as values of TSPARM=OUTMSSEC.
14. There is a code value for TSVALCD only when there is controlled terminology for TSVAL. For example; when TSPARMCD = PLANSUB or TSPARMCD = TITLE then TSVALCD will be null.
15. Trial Indication: A clinical pharmacology study on healthy volunteers, whose sole purpose is to collect pharmacokinetic data would have no trial indication, so TSVAL would be null and TSVALNF would be NA. A vaccine study on healthy subjects, whose intended purpose is to prevent influenza infection, would have INDIC=Influenza. If the trial is to treat, diagnosis, or prevent a disease, then INDIC is “If Applicable”
16. TSVALNF contains a “null flavor,” a value that provides additional coded information when TSVAL is null. For example, for TSPARM = MAXAGE, there is no value if a study does not specify a maximum age. In this case, the appropriate null flavor is PINF, which stands for positive infinity. In a clinical pharmacology study conducted in healthy volunteers for a drug which indications are not yet established, the appropriate null flavor for TINDC would be NA, which stands for not applicable. TSVALNF can also be used in a case where the value of a particular parameter is unknown.
17. Dun and Bradstreet (D&B) maintains its "data universal numbering system," known as DUNS. It issues unique 9-digit numbers to businesses. Each sponsor organization has a DUNS number. A UNII (Unique

Ingredient Identifier) is an identifier for a single defined substance. The UNII is a non-proprietary, free, unique, unambiguous, non semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information.

TS – Examples for Trial Summary Information Dataset

Example 1:

This example shows all of the parameters that are required or expected in the Trial Summary dataset. Use controlled terminology for TSVAl (see [NCI EVS Terminology Resources](#)).

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
1	XYZ	TS	1		ADDON	Added on to Existing Treatments	Y		C49488	CDISC	2011-06-10
2	XYZ	TS	1		AGEMAX	Planned Maximum Age of Subjects	P70Y			ISO 8601	
3	XYZ	TS	1		AGEMIN	Planned Minimum Age of Subjects	P18M			ISO 8601	
4	XYZ	TS	1		LENGTH	Planned Trial Length	P3M			ISO 8601	
5	XYZ	TS	1		PLANSUB	Planned Number of Subjects	300				
6	XYZ	TS	1		RANDOM	Trial is Randomized	Y		C49488	CDISC	2011-06-10
7	XYZ	TS	1		SEXPOP	Sex of Participants	BOTH		C49636	CDISC	2011-06-10
8	XYZ	TS	1		STOPRULE	Study Stop Rules	INTERIM ANALYSIS FOR FUTILITY				
9	XYZ	TS	1		TBLIND	Trial Blinding Schema	DOUBLE BLIND		C15228	CDISC	2011-06-10
10	XYZ	TS	1		TCNTRL	Control Type	PLACEBO		C49648	CDISC	2011-06-10
11	XYZ	TS	1		TDIGRP	Diagnosis Group	Neurofibromatosis Syndrome (Disorder)		19133005	SNOMED	
12	XYZ	TS	1		TINDTP	Trial Indication Type	TREATMENT		C49656	CDISC	2011-06-10

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Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
13	XYZ	TS	1		TITLE	Trial Title	A 24 Week Study of Oral Gabapentin vs. Placebo as add-on Treatment to Phenytoin in Subjects with Epilepsy due to Neurofibromatosis				
14	XYZ	TS	1		TPHASE	Trial Phase Classification	Phase II Trial		C15601	CDISC	2011-06-10
15	XYZ	TS	1		TTYPE	Trial Type	EFFICACY		C49666	CDISC	2011-06-10
16	XYZ	TS	2		TTYPE	Trial Type	SAFETY		C49667	CDISC	2011-06-10
17	XYZ	TS	1		CURTRT	Current Therapy or Treatment	Phenytoin		6158TKWOC5	UNII	
18	XYZ	TS	1		OBJPRIM	Trial Primary Objective	Reduction in the 3-month seizure frequency from baseline				
19	XYZ	TS	1		OBJSEC	Trial Secondary Objective	Percent reduction in the 3-month seizure frequency from baseline				
20	XYZ	TS	2		OBJSEC	Trial Secondary Objective	Reduction in the 3-month tonic-clonic seizure frequency from baseline				
21	XYZ	TS	1		SPONSOR	Clinical Study Sponsor	Pharmaco		1234567	DUNS	
22	XYZ	TS	1		INDIC	Trial Indication	Tonic-Clonic Epilepsy (Disorder)		352818000	SNOMED	
23	XYZ	TS	1		TRT	Investigational Therapy or Treatment	Gabapentin		6CW7F3G59X	UNII	
24	XYZ	TS	1		RANDQT	Randomization Quotient	0.67				
25	XYZ	TS	1		STRATFCT	Stratification Factor	SEX				
26	XYZ	TS	1		REGID	Registry Identifier	NCT123456789		NCT123456789	ClinicalTrials.GOV	
27	XYZ	TS	2		REGID	Registry Identifier	XXYYZZ456		XXYYZZ456	EUDRAC	
28	XYZ	TS	1		OUTMSPRI	Primary	SEIZURE				

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Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
						Outcome Measure	FREQUENCY				
29	XYZ	TS	1		OUTMSSEC	Secondary Outcome Measure	SEIZURE FREQUENCY				
30	XYZ	TS	2		OUTMSSEC	Secondary Outcome Measure	SEIZURE DURATION				
31	XYZ	TS	1		OUTMSEXP	Exploratory Outcome Measure	SEIZURE INTENSITY				
32	XYZ	TS	1		PCLAS	Pharmacological Class of Investigational Therapy	Anti-epileptic Agent		N0000175753	NDF-RT	
33	XYZ	TS	1		FCNTRY	Planned Country of Investigational Site(s)	USA		USA	ISO 3166	
34	XYZ	TS	2		FCNTRY	Planned Country of Investigational Site(s)	CAN		CAN	ISO 3166	
35	XYZ	TS	3		FCNTRY	Planned Country of Investigational Site(s)	MEX		MEX	ISO 3166	
36	XYZ	TS	1		ADAPT	Adaptive Design	N		C49487	CDISC	2011-06-10
37	XYZ	TS	1	DateDesc1	DCUTDTC	Data Cutoff Date	2011-04-01			ISO 8601	
38	XYZ	TS	1	DateDesc1	DCUTDESC	Data Cutoff Description	DATABASE LOCK				
39	XYZ	TS	1		INTMODEL	Intervention Model	PARALLEL		C82639	CDISC	
40	XYZ	TS	1		NARMS	Planned Number of Arms	3				
41	XYZ	TS	1		STYPE	Study Type	INTERVENTIONAL		C98388	CDISC	
42	XYZ	TS	1		INTTYPE	Intervention Type	DRUG		C1909	CDISC	
43	XYZ	TS	1		SSTDTC	Study Start Date	2009-03-11			ISO 8601	
44	XYZ	TS	1		SENDTC	Study End Date	2011-04-01			ISO 8601	
45	XYZ	TS	1		ACTSUB	Actual Number of Subjects	304				
46	XYZ	TS	1		HLTSUBJI	Healthy Subject	N		C49487	CDISC	2011-06-10

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Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
						Indicator					
47	XYZ	TS	1		SDMDUR	Stable Disease Minimum Duration	P3W			ISO 8601	
48	XYZ	TS	1		CRMDUR	Confirmed Response Minimum Duration	P28D			ISO 8601	

Example 2:

This example shows an example of how to implement the null flavor in TSVAlNF when the value in TSVAl is missing.

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
1	XYZ	TS	1		AGEMAX	Planned Maximum Age of Subjects		PINF		ISO 21090	
2	XYZ	TS	1		TPHASE	Trial Phase Classification		NA		ISO 21090	
3	XYZ	TS	1		INTTYPE	Intervention Type		OTH		ISO 21090	

TS – Use of Null Flavor Enumeration

The variable TSVALNF is based on the idea of a “null flavor” as embodied in the ISO 21090 standard, “Health Informatics – Harmonized data types for information exchange.” A null flavor is an ancillary piece of data that provides additional information when its primary piece of data is null (has a missing value). There is controlled terminology for the null flavor data item which includes such familiar values as Unknown, Other, and Not Applicable among its fourteen terms.

The proposal to include a null flavor variable to supplement the TSVAl variable in the Trial Summary dataset arose when it was realized that the Trial Summary model did not have a good way to represent the fact that a protocol placed no upper limit on the age of study subjects. When the trial summary parameter is AGEMAX, then TSVAl should have a value expressed as an ISO8601 time duration (e.g., P43Y for 43 years old or P6M for 6 months old). While it would be possible to allow a value such as NONE or UNBOUNDED to be entered in TSVAl, validation programs would then have to recognize this special term as an exception to the expected data format. Therefore, it was decided that a separate null flavor variable that uses the ISO 21090 null flavor terminology would be a better solution.

It was also decided to specify the use of a null flavor variable with this updated release of trial summary as a way of testing the use of such a variable in a limited setting. As its title suggests, the ISO 21090 standard was developed for use with healthcare data, and it is expected that it will eventually see wide use in the clinical data from which clinical trial data is derived. CDISC already uses this data type standard in the BRIDG model and the CDISC SHARE project. The null flavor, in particular, is a solution to the widespread problem of needing or wanting to convey information that will help in the interpretation of a missing value. Although null flavors could certainly be eventually used for this purpose in other cases, such as with subject data, doing so at this time would be extremely disruptive and premature. The use of null flavors for the one variable TSVAl should provide an opportunity for sponsors and reviewers to learn about the null flavors and to evaluate their usefulness in one concrete setting.

The controlled terminology for null flavor, which supersedes use of [Appendix C1 – Trial Summary Codes](#), is included below

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

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

The numbers in the first column of the table above describe the hierarchy of these values, i.e.,

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

The one value at level 1, No information, is the least informative. It merely confirms that the primary piece of data is null.

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

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

7 Trial Design Datasets

7.5 How to Model the Design of a Clinical Trial

The following steps allow the modeler to move from more-familiar concepts, such as Arms, to less-familiar concepts, such as Elements and Epochs. The actual process of modeling a trial may depart from these numbered steps. Some steps will overlap, there may be several iterations, and not all steps are relevant for all studies.

1. Start from the flow chart or schema diagram usually included in the trial protocol. This diagram will show how many Arms the trial has, and the branch points, or decision points, where the Arms diverge.
2. Write down the decision rule for each branching point in the diagram. Does the assignment of a subject to an Arm depend on a randomization? On whether the subject responded to treatment? On some other criterion?
3. If the trial has multiple branching points, check whether all the branches that have been identified really lead to different Arms. The Arms will relate to the major comparisons the trial is designed to address. For some trials, there may be a group of somewhat different paths through the trial that are all considered to belong to a single Arm.
4. For each Arm, identify the major time periods of treatment and non-treatment a subject assigned to that Arm will go through. These are the Elements, or building blocks, of which the Arm is composed.
5. Define the starting point of each Element. Define the rule for how long the Element should last. Determine whether the Element is of fixed duration.
6. Re-examine the sequences of Elements that make up the various Arms and consider alternative Element definitions. Would it be better to “split” some Elements into smaller pieces or “lump” some Elements into larger pieces? Such decisions will depend on the aims of the trial and plans for analysis.
7. Compare the various Arms. In most clinical trials, especially blinded trials, the pattern of Elements will be similar for all Arms, and it will make sense to define Trial Epochs. Assign names to these Epochs. During the conduct of a blinded trial, it will not be known which Arm a subject has been assigned to, or which treatment Elements they are experiencing, but the Epochs they are passing through will be known.
8. Identify the Visits planned for the trial. Define the planned start timings for each Visit, expressed relative to the ordered sequences of Elements that make up the Arms. Define the rules for when each Visit should end.
9. Identify the inclusion and exclusion criteria to be able to populate the TI dataset. If inclusion and exclusion criteria were amended so that subjects entered under different versions, populate TIVERS to represent the different versions.
10. Populate the TS dataset with summary information.

8 Representing Relationships and Data

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

- [Section 8.1, Relating Groups of Records within a Domain Using the --GRPID Variable](#) describes a relationship between a group of records for a given subject within the same dataset.
- [Section 8.2, Relating Peer Records](#) describes a relationship between independent records (usually in separate datasets) for a subject, such as a concomitant medication taken to treat an adverse event.
- [Section 8.3, Relating Datasets](#) describes 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).
- [Section 8.4, Relating Non-Standard Variables Values to a Parent Domain](#) describes a method for representing the 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.
- [Section 8.5, Relating Comments to a Parent Domain](#) describes a dependent relationship between a comment in the Comments domain (see *Section 5 – CO Domain*) and a parent record (or records) in other datasets, such as a comment recorded in association with an adverse event.
- [Section 8.6, How to Determine Where Data Belong In SDTM-Compliant Data Tabulations](#) discusses the concept of related datasets and whether to place additional data in a separate dataset or a Supplemental Qualifier special-purpose dataset, and the concept of modeling Findings data that refers to data in another general-observation-class dataset.

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

- The Sequence Number (--SEQ) variable uniquely identifies a record for a given USUBJID within a domain. The variable --SEQ is required in all domains except DM. For example, if subject 1234-2003 has 25 adverse event records in the adverse event (AE) domain, then 25 unique AESEQ values should be established for this subject. Conventions for establishing and maintaining --SEQ values are sponsor-defined. Values may or may not be sequential depending on data processes and sources.
- The Reference Identifier (--REFID) variable can be used to capture a sponsor-defined or external identifier, such as an identifier provided in an electronic data transfer. Some examples are lab-specimen identifiers and ECG identifiers. --REFID is permissible in all domains, but never required. Values for --REFID are sponsor -defined and can be any alphanumeric strings the sponsor chooses, consistent with their internal practices.
- The Grouping Identifier (--GRPID) variable, used to link related records for a subject within a dataset, is explained below in [Section 8.1](#).

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

The optional grouping identifier variable --GRPID is permissible in all domains that are based on the general observation classes. It is used to identify relationships between records within a USUBJID within a single domain. An example would be Intervention records for a combination therapy where the treatments in the combination varies from subject to subject. In such a case, the relationship is defined by assigning the same unique character value to the --GRPID variable. The values used for --GRPID can be any values the sponsor chooses; however, if the sponsor uses values with some embedded meaning (rather than arbitrary numbers), those values should be consistent across the submission to avoid confusion. It is important to note that --GRPID has no inherent meaning across subjects or across domains.

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

8.1.1 --GRPID Example

The following table illustrates how to use --GRPID in the Concomitant Medications (CM) domain to identify a combination therapy. In this example, both subjects 1234 and 5678 have reported two combination therapies, each consisting of three separate medications. Each component of a combination is given the same value for CMGRPID.

Note that for USUBJID 1234, the medications for CMGRPID = “COMBO THPY 1” (Rows 1-3) are different from the medications for CMGRPID = “COMBO THPY 2” (Rows 4-6). Likewise, for USUBJID 5678, the medications for CMGRPID = “COMBO THPY 1” (Rows 7-9) are different from the medications for CMGRPID = “COMBO THPY 2” (Rows 10-12). Additionally, the medications for Subject 1234 CMGRPID = “COMBO THPY 1” and CMGRPID = “COMBO THPY 2” (Rows 1-6) are different from the medications for Subject 5678 CMGRPID = “COMBO THPY 1” and CMGRPID = “COMBO THPY 2” (Rows 7-12). This example illustrates how CMGRPID groups information only within a subject within a domain.

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMGRPID	CMTRT	CMDECOD	CMDOSE	CMDOSU	CMSTDT	CMENDTC
1	1234	CM	1234	1	COMBO THPY 1	Verbatim Med A	Generic Med A	100	mg	2004-01-17	2004-01-19
2	1234	CM	1234	2	COMBO THPY 1	Verbatim Med B	Generic Med B	50	mg	2004-01-17	2004-01-19
3	1234	CM	1234	3	COMBO THPY 1	Verbatim Med C	Generic Med C	200	mg	2004-01-17	2004-01-19
4	1234	CM	1234	4	COMBO THPY 2	Verbatim Med D	Generic Med D	150	mg	2004-01-21	2004-01-22
5	1234	CM	1234	5	COMBO THPY 2	Verbatim Med E	Generic Med E	100	mg	2004-01-21	2004-01-22
6	1234	CM	1234	6	COMBO THPY 2	Verbatim Med F	Generic Med F	75	mg	2004-01-21	2004-01-22
7	1234	CM	5678	1	COMBO THPY 1	Verbatim Med G	Generic Med G	37.5	mg	2004-03-17	2004-03-25
8	1234	CM	5678	2	COMBO THPY 1	Verbatim Med H	Generic Med H	60	mg	2004-03-17	2004-03-25
9	1234	CM	5678	3	COMBO THPY 1	Verbatim Med I	Generic Med I	20	mg	2004-03-17	2004-03-25
10	1234	CM	5678	4	COMBO THPY 2	Verbatim Med J	Generic Med J	100	mg	2004-03-21	2004-03-22
11	1234	CM	5678	5	COMBO THPY 2	Verbatim Med K	Generic Med K	50	mg	2004-03-21	2004-03-22
12	1234	CM	5678	6	COMBO THPY 2	Verbatim Med L	Generic Med L	10	mg	2004-03-21	2004-03-22

8.2 Relating Peer Records

The Related Records (RELREC) special-purpose dataset is used to describe relationships between records for a subject (as described in this section), and relationships between datasets (as described in [Section 8.3, Relating Datasets](#)). In both cases, relationships represented in RELREC are collected relationships, either by explicit references or check boxes on the CRF, or by design of the CRF, such as vital signs captured during an exercise stress test.

A relationship is defined by adding a record to RELREC for each record to be related and by assigning a unique character identifier value for the relationship. Each record in the RELREC special-purpose dataset contains keys that identify a record (or group of records) and the relationship identifier, which is stored in the RELID variable. The value of RELID is chosen by the sponsor, but must be identical for all related records within USUBJID. It is recommended that the sponsor use a standard system or naming convention for RELID (e.g., all letters, all numbers, capitalized).

Records expressing a relationship are specified using the key variables STUDYID, RDOMAIN (the two-letter domain code of the record in the relationship), and USUBJID, along with IDVAR and IDVARVAL. Single records can be related by using a unique-record-identifier variable such as --SEQ in IDVAR. Groups of records can be related by using grouping variables such as --GRPID in IDVAR. IDVARVAL would contain the value of the variable described in IDVAR. Using --GRPID can be a more efficient method of representing relationships in RELREC, such as when relating an adverse event (or events) to a group of concomitant medications taken to treat the adverse event(s).

The RELREC dataset should be used to represent either:

- Explicit relationships, such as concomitant medications taken as a result of an adverse event.
- Information of a nature that necessitates using multiple datasets, as described in [Section 8.3](#).

8.2.1 RELREC Dataset

relrec.xpt, Related Records, Version 3.1.2. One record per related record, group of records or dataset

Variable	Variable Label	Type	Controlled Terms, Codelist or Format	CDISC Notes	Core
STUDYID	Study Identifier	Char		Unique identifier for a study	Req
RDOMAIN	Related Domain Abbreviation	Char	DOMAIN	Two-character abbreviation for the domain of the parent record(s)	Req
USUBJID	Unique Subject Identifier	Char		Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Exp
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.	Req
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.	Exp
RELTYPE	Relationship Type	Char	ONE, MANY	Identifies the hierarchical level of the records in the relationship. Values should be either ONE or MANY. Used only when identifying a relationship between datasets (as described in Section 8.3).	Exp
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.	Req

**indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)*

8.2.2 RELREC Dataset Examples

Example 1

This example shows how to use the RELREC dataset to relate records stored in separate domains for USUBJID 123456 who had two lab tests performed (Rows 5 and 6) and took two concomitant medications (Rows 2 and 3) as the result of an adverse event (Rows 1 and 4). This example represents a situation in which the adverse event is related to both the concomitant medications and the lab tests, but there is no relationship between the lab values and the concomitant medications

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	EFC1234	AE	123456	AESEQ	5		1
2	EFC1234	CM	123456	CMSEQ	11		1
3	EFC1234	CM	123456	CMSEQ	12		1
4	EFC1234	AE	123456	AESEQ	5		2
5	EFC1234	LB	123456	LBSEQ	47		2
6	EFC1234	LB	123456	LBSEQ	48		2

Example 2

Example 2 is the same scenario as Example 1; however, the relationship between concomitant medications (Rows 2 and 3) and lab values (Rows 4 and 5) and their relationship with the adverse event (Row 1) was collected.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	EFC1234	AE	123456	AESEQ	5		1
2	EFC1234	CM	123456	CMSEQ	11		1
3	EFC1234	CM	123456	CMSEQ	12		1
4	EFC1234	LB	123456	LBSEQ	47		1
5	EFC1234	LB	123456	LBSEQ	48		1

Example 3

Example 3 is the same scenario as Example 2. However, the two concomitant medications have been grouped by the sponsor in the CM dataset by assigning a CMGRPID of "COMBO 1", allowing the elimination of a record in the RELREC dataset.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	EFC1234	AE	123456	AESEQ	5		1
2	EFC1234	CM	123456	CMGRPID	COMBO1		1
3	EFC1234	LB	123456	LBSEQ	47		1
4	EFC1234	LB	123456	LBSEQ	48		1

Additional examples may be found in the domain examples such as the examples for Disposition/Adverse Event found in *Section 6.2 - DS Domain: DS - Examples for DISPOSITION Domain Model*, Example 4, and all of the Pharmacokinetics examples in *Section 6.3 - PC and PP Domains: 6.3.10.5, Relating PP Records to PC Records*.

8.3 Relating Datasets

The Related Records (RELREC) special-purpose dataset can also be used to identify relationships between datasets (e.g., a one-to-many or parent-child relationship). The relationship is defined by including a single record for each related dataset that identifies the key(s) of the dataset that can be used to relate the respective records.

Relationships between datasets should only be recorded in the RELREC dataset when the sponsor has found it necessary to split information between datasets that are related, and that may need to be examined together for analysis or proper interpretation. Note that it is not necessary to use the RELREC dataset to identify associations from data in the SUPP-- datasets or the CO dataset to their parent general-observation-class dataset records or special-purpose domain records, as both these datasets include the key variable identifiers of the parent record(s) that are necessary to make the association.

8.3.1 RELREC Dataset Relationship Example

This example shows how to use the RELREC dataset to represent related information that is submitted as two datasets that have a one-to-many relationship. In the example below all the records in one domain are being related to all of the records in the other, so both USUBJID and IDVARVAL are null.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	EFC1234	MB		MBGRPID		ONE	A
2	EFC1234	MS		MSGRPID		MANY	A

In the sponsor's operational database, these datasets may have existed as either separate datasets that were merged for analysis, or one dataset that may have included observations from more than one general observation class (e.g., Events and Findings). The value in IDVAR must be the name of the key used to merge/join the two datasets. In the above example, the --GRPID variable is used as the key to identify the related observations. The values for the --GRPID variable in the two datasets are sponsor defined. Although other variables may also serve as a single merge key when the corresponding values for IDVAR are equal, --GRPID, --SPID, or --REFID are typically used for this purpose.

The variable RELTYPE identifies the type of relationship between the datasets. The allowable values are ONE and MANY (controlled terminology is expected). This information defines how a merge/join would be written, and what would be the result of the merge/join. The possible combinations are the following:

1. ONE and ONE. This combination indicates that there is **NO** hierarchical relationship between the datasets and the records in the datasets. Only one record from each dataset will potentially have the same value of the IDVAR within USUBJID.
2. ONE and MANY. This combination indicates that there **IS** a hierarchical (parent/child) relationship between the datasets. One record within USUBJID in the dataset identified by RELTYPE=ONE will potentially have the same value of the IDVAR with many (one or more) records in the dataset identified by RELTYPE=MANY.
3. MANY and MANY. This combination is unusual and challenging to manage in a merge/join, and may represent a relationship that was never intended to convey a usable merge/join (such as in described for PC and PP in [Section 6.3 - PC and PP Domains: Relating PP Records to PC Records](#)).

Since IDVAR identifies the keys that can be used to merge/join records between the datasets, the root values (e.g., --GRPID in the above example) for IDVAR must be the same for both records with the same RELID. --SEQ cannot be used because --SEQ only has meaning within a subject within a dataset, not across datasets.

8.4 Relating Non-Standard Variables Values to a Parent Domain

The SDTM does not allow the addition of new variables. Therefore, the Supplemental Qualifiers special purpose dataset model is used to capture non-standard variables and their association to parent records in general-observation-class datasets (Events, Findings, Interventions) and Demographics. Supplemental Qualifiers may be represented as separate SUPP-- datasets for each dataset containing sponsor-defined variables (see [Section 8.4.2, Submitting Supplemental Qualifiers in Separate Datasets](#) for more on this topic).

SUPP-- represents the metadata and data for each non-standard variable/value combination. As the name "Supplemental Qualifiers" suggests, this dataset is intended to capture additional Qualifiers for an observation. Data that represent separate observations should be treated as separate observations. The Supplemental Qualifiers dataset is structured similarly to the RELREC dataset, in that it uses the same set of keys to identify parent records. Each SUPP-- record also includes the name of the Qualifier variable being added (QNAM), the label for the variable (QLABEL), the actual value for each instance or record (QVAL), the origin (QORIG) of the value [see [Section 4: 4.1.1.8, Origin Metadata](#)], and the Evaluator (QEQVAL) to specify the role of the individual who assigned the value (such as ADJUDICATION COMMITTEE or SPONSOR). Controlled terminology for certain expected values for QNAM and QLABEL are included in [Appendix C2 - Supplemental Qualifier Name Codes](#).

SUPP-- datasets are also used to capture attributions. An attribution is typically an interpretation or subjective classification of one or more observations by a specific evaluator, such as a population flag that classifies a subject or their data according to their evaluability for efficacy analysis, or whether an observation is considered to be clinically significant. Since it is possible that different attributions may be necessary in some cases, SUPP-- provides a mechanism for incorporating as many attributions as are necessary. A SUPP-- dataset can contain both objective data (where values are collected or derived algorithmically) and subjective data (attributions where values are assigned by a person or committee). For objective data, the value in QEVAL will be null. For subjective data (when QORIG="ASSIGNED"), the value in QEVAL should reflect the role of the person or institution assigning the value (e.g., SPONSOR or ADJUDICATION COMMITTEE).

The combined set of values for the first six columns (STUDYID...QNAM) should be unique for every record. That is, there should not be multiple records in a SUPP-- dataset for the same QNAM value, as it relates to IDVAR/IDVARVAL for a USUBJID in a domain. For example, if two individuals provide a determination on whether an Adverse Event is Treatment Emergent (e.g., the investigator and an independent adjudicator) then separate QNAM values should be used for each set of information, perhaps AETRTEMI and AETRTEMA. This is necessary to ensure that reviewers can join/merge/transpose the information back with the records in the original domain without risk of losing information.

When populating a SUPPDM dataset with population flags related to the Demographics domain (subject-level evaluability), there should be one record for each population flag for each subject. QVAL values for population flags should be Y or N, with no null values. In the event that evaluability is based upon individual visits or CRF pages, additional population flags attached to other domains may be included in SUPP-- datasets.

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

8.4.1 Supplemental Qualifiers: SUPP-- Datasets

supp--.xpt, Supplemental Qualifiers [DOMAIN NAME], Version 3.1.2. One record per IDVAR, IDVARVAL, and QNAM value per subject

Variable	Variable Label	Type	Controlled Terms, Codelist or Format	CDISC Notes	Core
STUDYID	Study Identifier	Char		Study Identifier of the Parent record(s).	Req
RDOMAIN	Related Domain Abbreviation	Char	DOMAIN	Two-character abbreviation for the domain of the parent record(s).	Req
USUBJID	Unique Subject Identifier	Char		Unique Subject Identifier of the Parent record(s).	Req
IDVAR	Identifying Variable	Char	*	Identifying variable in the dataset that identifies the related record(s). Examples: --SEQ, --GRPID.	Exp
IDVARVAL	Identifying Variable Value	Char		Value of identifying variable of the parent record(s).	Exp
QNAM	Qualifier Variable Name	Char	*	The short name of the Qualifier variable, which is used as a column name in a domain view with data from the parent domain. The value in QNAM cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). QNAM cannot contain characters other than letters, numbers, or underscores. This will often be the column name in the sponsor's operational dataset.	Req

Variable	Variable Label	Type	Controlled Terms, Codelist or Format	CDISC Notes	Core
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.	Req
QVAL	Data Value	Char		Result of, response to, or value associated with QNAM. A value for this column is required; no records can be in SUPP-- with a null value for QVAL.	Req
QORIG	Origin	Char		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. See Section 4: 4.1.1.8, Origin Metadata .	Req
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.	Exp

*indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)

A record in a SUPP-- dataset relates back to its parent record(s) via the key identified by the STUDYID, RDOMAIN, USUBJID and IDVAR/IDVARVAL variables. An exception is SUPP-- dataset records that are related to Demographics (DM) records, such as the Intent To Treat (ITT) and Safety (SAFETY) subject-level population flags, where both IDVAR and IDVARVAL will be null because the key variables STUDYID, RDOMAIN, and USUBJID are sufficient to identify the unique parent record in DM (DM has one record per USUBJID).

All records in the SUPP-- datasets must have a value for QVAL. Transposing source variables with missing/null values may generate SUPP-- records with null values for QVAL, causing the SUPP-- datasets to be extremely large. When this happens, the sponsor must delete the records where QVAL is null prior to submission.

See **Section 4: 4.1.5.3, Text Strings That Exceed the Maximum Length for General-Observation-Class Domain Variables** for information on representing information greater than 200 characters in length.

See **Appendix C2 - Supplemental Qualifier Name Codes** for controlled terminology for QNAM and QLABEL for some of the most common Supplemental Qualifiers. Additional QNAM values may be created as needed, following the guidelines provided in the CDISC Notes for QVAL.

8.4.2 Submitting Supplemental Qualifiers in Separate Datasets

There is a one-to-one correspondence between a domain dataset and its Supplemental Qualifier dataset by creating one SUPPQUAL for each domain dataset. **The single SUPPQUAL dataset option that was introduced in SDTMIG v3.1.1 is now deprecated.** The set of Supplemental Qualifiers for each domain is included in a separate dataset with the name SUPP-- where "--" denotes the source domain which the Supplemental Qualifiers relate back to. For example, population flags and other Demographics Qualifiers would be submitted in suppdm.xpt. When data have been split into multiple datasets (see **Section 4: 4.1.1.7, Splitting Domains**), longer names such as SUPPFAMH may be needed. In cases where data about Associated Persons (see Associated Persons Implementation Guide) have been collected, an associated person with Supplemental Qualifiers for Findings About their medical history, the resulting dataset name SUPPAPFAMH) would be too long so that, in this case only, the "SUPP" portion should be shortened to "SQ". resulting in a dataset name of SQAPFAMH.

8.4.3 SUPP-- Examples

The examples below demonstrate how a set of SUPP-- datasets could be used to relate non-standard information to a parent domain.

Example 1

In the two rows of suppdm.xpt, population flags are defined as supplemental information to a subject’s demographic data. IDVAR and IDVARVAL are null because the key variables STUDYID, RDOMAIN, and USUBJID are sufficient to identify a unique parent record in DM.

suppdm.xpt: Supplemental Qualifiers for DM

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	1996001	DM	99-401			ITT	Intent to Treat	Y	DERIVED	SPONSOR
2	1996001	DM	99-401			PPROT	Per Protocol Set	N	DERIVED	SPONSOR

Example 2

The two rows of suppae.xpt add qualifying information to adverse event data (RDOMAIN=AE). IDVAR defines the key variable used to link this information to the AE data (AESEQ). IDVARVAL specifies the value of the key variable within the parent AE record that the SUPPAE record applies to. The remaining columns specify the supplemental variables’ names (AESOSP and AETRTEM), labels, values, origin, and who made the evaluation.

suppae.xpt: Supplemental Qualifiers for AE

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	1996001	AE	99-401	AESEQ	1	AESOSP	Other Medically Important SAE	Spontaneous Abortion	CRF	
2	1996001	AE	99-401	AESEQ	1	AETRTEM	Treatment Emergent Flag	N	DERIVED	SPONSOR

Example 3

This is an example of how the language used for a questionnaire might be represented. The parent domain (RDOMAIN) is QS, and IDVAR is QSCAT. QNAM holds the name of the Supplemental Qualifier variable being defined (QSLANG). The language recorded in QVAL applies to all of the subject’s records where IDVAR (QSCAT) equals the value specified in IDVARVAL. In this case, IDVARVAL has values for two questionnaires (SF36 and ADAS) for two separate subjects. QVAL identifies the questionnaire language version (French or German) for each subject.

suppqs.xpt: Supplemental Qualifiers for QS

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	1996001	QS	99-401	QSCAT	SF36	QSLANG	Questionnaire Language	FRENCH	CRF	
2	1996001	QS	99-401	QSCAT	ADAS	QSLANG	Questionnaire Language	FRENCH	CRF	
3	1996001	QS	99-802	QSCAT	SF36	QSLANG	Questionnaire Language	GERMAN	CRF	
4	1996001	QS	99-802	QSCAT	ADAS	QSLANG	Questionnaire Language	GERMAN	CRF	

Additional examples may be found in the domain examples such as for Demographics in Examples 3, 4, and 5 under **Section 5 - DM Domain: DM - Examples for the DEMOGRAPHICS Domain Model**, for ECGs in Example 1 under **Section 6.3 - EG Domain: EG - Examples for the ECG TEST RESULTS Domain Model**, and for Labs in Example 1 under **Section 6.3 - LB Domain: LB - Examples for the LABORATORY TEST RESULTS Domain Model**

8.4.4 When Not to Use Supplemental Qualifiers

Examples of data that should not be submitted as Supplemental Qualifiers are the following:

- Subject-level objective data that fit in Subject Characteristics (SC). Examples include Subject Initials, Eye Color.
- Findings interpretations that should be added as an additional test code and result. An example of this would be a record for ECG interpretation where EGTESTCD = “INTP”, and the same EGGRPID or EGREFID value would be assigned for all records associated with that ECG [**Section 4: 4.1.5.5, Clinical Significance For Findings Observation Class Data**].

- Comments related to a record or records contained within a parent dataset. Although they may have been collected in the same record by the sponsor, comments should instead be captured in the CO special-purpose domain.
- Data not directly related to records in a parent domain. Such records should instead be captured in either a separate general observation class or special purpose domain.

8.5 Relating Comments to a Parent Domain

The Comments special-purpose domain, which is also described in *Section 5 - CO Domain*, is used to capture unstructured free text comments. It allows for the submission of comments related to a particular domain (e.g., adverse events) or those collected on separate general-comment log-style pages not associated with a domain. Comments may be related to a Subject, a domain for a Subject, or to specific parent records in any domain. The Comments special-purpose domain is structured similarly to the Supplemental Qualifiers (SUPP--) dataset, in that it uses the same set of keys (STUDYID, RDOMAIN, USUBJID, IDVAR, and IDVARVAL) to identify related records.

All comments except those collected on log-style pages not associated with a domain are considered child records of subject data captured in domains. STUDYID, USUBJID, and DOMAIN (with the value CO) must always be populated. RDOMAIN, IDVAR, and IDVARVAL should be populated as follows:

1. Comments related only to a subject in general (likely collected on a log-style CRF page/screen) would have RDOMAIN, IDVAR, IDVARVAL null, as the only key needed to identify the relationship/association to that subject is USUBJID.
2. Comments related only to a specific domain (and not to any specific record(s)) for a subject would populate RDOMAIN with the domain code for the domain with which they are associated. IDVAR and IDVARVAL would be null.
3. Comments related to specific domain record(s) for a subject would populate the RDOMAIN, IDVAR, and IDVARVAL variables with values that identify the specific parent record(s).

If additional information is collected further describing the comment relationship to a parent record(s), and it cannot be represented using the relationship variables, RDOMAIN, IDVAR and IDVARVAL, this can be done by two methods:

1. Values may be placed in COREF, such as the CRF page number or name
2. Timing variables may be added to the CO special-purpose domain, such as VISITNUM and/or VISIT. See CO special-purpose *Section 5 - CO Domain: CO - Assumptions for the COMMENTS Domain Model*, Assumption 6 for a complete list of Identifier and Timing variables that can be added to the CO special-purpose domain.

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

Examples for Comments data can be found in *Section 5 - CO Domain: CO - Examples for the COMMENTS Domain Model*.

8.6 How to Determine Where Data Belong in SDTM-Compliant Data Tabulations

8.6.1 Guidelines for Determining the General Observation Class

Section 2: 2.6, Creating a New Domain discusses when to place data in an existing domain and how to create a new domain. A key part of the process of creating a new domain is determining whether an observation represents an Event, Intervention, or Finding. Begin by considering the content of the information in the light of the definitions of the three general observation classes [*SDTM: Section 2.2, The General Observation Classes*] rather than by trying to deduce the class from the information's physical structure; physical structure can sometimes be misleading. For example, from a structural standpoint, one might expect Events observations to include a start and stop date. However, Medical History data (data about previous conditions or events) is Events data regardless of whether dates were collected.

An Intervention is something that is done to a subject (possibly by the subject) that is expected to have a physiological effect. This concept of an intended effect makes Interventions relatively easy to recognize, although there are grey areas around some testing procedures. For example, exercise stress tests are designed to produce and then measure certain physiological effects. The measurements from such a testing procedure are Findings, but some aspects of the procedure might be modeled as Interventions.

An Event is something that happens to a subject spontaneously. Most, although not all, Events data captured in clinical trials is about medical events. Since many medical events must, by regulation, be treated as adverse events, new Events domain will be created only for events that are clearly not adverse events; the existing Medical History and Clinical Events domain are the appropriate places to store most medical events that are not adverse events. Many aspects of medical events, including tests performed to evaluate them, interventions that may have caused them, and interventions given to treat them, may be collected in clinical trials. Where to place data on assessments of events can be particularly challenging, and is discussed further in [Section 8.6.3, Guidelines for Differentiating between Events, Findings, and Findings About Events](#).

Findings general-observation-class data are measurements, tests, assessments, or examinations performed on a subject in the clinical trial. They may be performed on the subject as a whole (e.g., height, heart rate), or on a "specimen" taken from a subject (e.g., a blood sample, an ECG tracing, a tissue sample). Sometimes the relationship between a subject and a finding is less direct; a finding may be about an event that happened to the subject or an intervention they received. Findings about Events and Interventions are discussed further in [Section 8.6.3, Guidelines for Differentiating between Events, Findings, and Findings About Events](#).

8.6.2 Guidelines for Forming New Domains

It may not always be clear whether a set of data represents one topic or more than one topic, and thus whether it should be combined into one dataset (domain) or split into two or more datasets (domains). This implementation guide shows examples of both.

In some cases, a single data structure works well for a variety of types of data. For example, all questionnaire data is placed in the QS domain, with particular questionnaires identified by QSCAT [*Section 6.3 - QS Domain*]. Although some operational databases may store urinalysis data in a separate dataset, SDTM places all lab data in the LB domain [*Section 6.3 - LB Domain*] with urinalysis tests identified using LBSPEC.

In other cases, a particular topic may be very broad and/or require more than one data structure (and therefore require more than one dataset). Two examples in this implementation guide are the topics of microbiology and pharmacokinetics. Both have been modeled using two domain datasets (see *Section 6.3 - MB and MS Domains* for Microbiology) and *Section 6.3 - PC and PP Domains* for Pharmacokinetics). This is because, within these scientific areas, there is more than one topic, and each topic results in a different data structure. For example, the topic for PC is plasma (or other specimen) drug concentration as a function of time, and the structure is one record per analyte per time point per reference time point (e.g., dosing event) subject. PP contains characteristics of the time-

concentration curve such as AUC, Cmax, Tmax, half-life, and elimination rate constant; the structure is one record per parameter per analyte per reference time point per subject.

8.6.3 Guidelines for Differentiating between Events, Findings, and Findings about Events

This section discusses Events, Findings, and Findings about Events. The relationship between Interventions, Findings, and Findings about Interventions would be handled similarly.

The Findings About domain was specially created to store findings about events. This section discusses Events and Findings generally, but it is particularly useful for understanding the distinction between the CE and FA domains.

There may be several sources of confusion about whether a particular piece of data belongs in an Event record or a Findings record. One generally thinks of an event as something that happens spontaneously, and has a beginning and end; however, one should consider the following:

- Events of interest in a particular trial may be pre-specified, rather than collected as free text.
- Some events may be so long lasting in that they are perceived as "conditions" rather than "events", and their beginning and end dates are not of interest.
- Some variables or data items one generally expects to see in an Events record may not be present. For example, a post-marketing study might collect the occurrence of certain adverse events, but no dates.
- Properties of an Event may be measured or assessed, and these are then treated as Findings About Events, rather than as Events.
- Some assessments of events (e.g., severity, relationship to study treatment) have been built into the SDTM Events model as Qualifiers, rather than being treated as Findings About Events.
- Sponsors may choose how they define an Event. For example, adverse event data may be submitted using one record that summarizes an event from beginning to end, or using one record for each change in severity.

The structure of the data being considered, although not definitive, will often help determine whether the data represent an Event or a Finding. The questions below may assist sponsors in deciding where data should be placed in SDTM.

Question	Interpretation of Answers
Is this a measurement, with units, etc.?	<ul style="list-style-type: none"> • “Yes” answer indicates a Finding. • “No” answer is inconclusive.
Is this data collected in a CRF for each visit, or an overall CRF log-form?	<ul style="list-style-type: none"> • Collection forms that are independent of visits suggest Event or Intervention general observation class data • Data collected at visits is usually for items that can be controlled by the study schedule, namely planned Findings or planned (study) Interventions or Events. • Data collected at an initial visit may fall into any of the three general observation classes.
What date/times are collected?	<ul style="list-style-type: none"> • If the dates collected are start and/or end dates, then data are probably about an Event or Intervention. • If the dates collected are dates of assessments, then data probably represents a Finding. • If dates of collection are different from other dates collected, it suggests that data are historical, or that it is about an Event or Intervention that happened independently of the study schedule for data collection.

Question	Interpretation of Answers
Is verbatim text collected, and then coded?	<ul style="list-style-type: none"> • “Yes” answer suggests that this is Events or Interventions general-observation-class data. However, Findings general-observation-class data from an examination that identifies abnormalities may also be coded. Note that for Events and Interventions general-observation-class data, the topic variable is coded, while for Findings general-observation-class data, it is the result that is coded. • A “No” answer is inconclusive. It does not rule out Events or Interventions general-observation-class data, particularly if Events or Interventions are pre-specified; it also does not rule out Findings general observation class data.
If this is data about an event, does it apply to the event as a whole?	<ul style="list-style-type: none"> • “Yes” answer suggests this is traditional Events general-observation-class data, and should have a record in an Events domain. • “No” answer suggests that there are multiple time-based findings about an event, and that this data should be treated as Findings About data.

The Events general observation class is intended for observations about a clinical event as a whole. Such observations typically include what the condition was, captured in --TERM (the topic variable), and when it happened (captured in its start and/or end dates). Other qualifier values collected (severity, seriousness, etc.) apply to the totality of the event. Note that sponsors may choose how they define the "event as a whole."

Data that does not describe the event as a whole should not be stored in the record for that event or in a --SUPP record tied to that event. If there are multiple assessments of an event, then each should be stored in a separate FA record.

When data related to an event does not fit into one of the existing Event general observation class Qualifiers, the first question to consider is whether the data represents information about the event itself, or whether it represents data about something (a Finding or Intervention) that is associated with the event.

- If the data consist of a finding or intervention that is associated with the event, it is likely that it can be stored in a relevant Findings or Intervention general observation class dataset, with the connection to the Event record being captured using RELREC. For example, if a subject had a fever of 102 that was treated with aspirin, the fever would be stored in an adverse event record, the temperature could be stored in a vital signs record, and the aspirin could be stored in a concomitant medication record, and RELREC might be used to link those records.
- If the data item contains information about the event, then consider storing it as a Supplemental Qualifier. However, a number of circumstances may rule out the use of a Supplemental Qualifier:
 - The data are measurements that need units, normal ranges, etc.
 - The data are about the non-occurrence or non-evaluation of a pre-specified Adverse Event, data that may not be stored in the AE domain, since each record in the AE domain must represent a reportable event that occurred.

If a Supplemental Qualifier is not appropriate, the data may be stored in Findings About. **Section 6.4 - FA Domain** provides additional information and examples.

Appendices

Appendix A: CDISC SDS Team *

Leadership Team		
Name	Company	
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Emily Hartley	Critical Path Institute
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Naveed Khaja	Independent
Shannon Labout	Statistics & Data Corporation
Sandy Lei	Johnson & Johnson
Bess Leroy	Critical Path Institute
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* Individuals having met membership criteria as of publication date.

Appendices

Appendix B: Glossary And Abbreviations

The following abbreviations and terms are used in this document. Additional definitions can be found in the CDISC Glossary available at <http://www.cdisc.org/glossary/index.html>.

ADaM	CDISC Analysis Dataset Model
ATC code	Anatomic Therapeutic Chemical code from WHO Drug
CDISC	Clinical Data Interchange Standards Consortium
CRF	Case report form (sometimes case record form)
CRT	Case report tabulation
CTCAE	Common Terminology Criteria for Adverse Events
Dataset	A collection of structured data in a single file
Domain	A collection of observations with a topic-specific commonality
eDT	Electronic Data Transfer
FDA	Food and drug Administration
HL7	Health Level 7
ICD9	International Classification of Diseases, 9th revision.
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICH E2A	ICH guidelines on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
ICH E2B	ICH guidelines on Clinical Safety Data Management: Data Elements for Transmission of Individual Cases Safety Reports
ICH E3	ICH guidelines on Structure and Content of Clinical Study Reports
ICH E9	ICH guidelines on Statistical Principles for Clinical Trials
ISO	International Organization for Standardization
ISO 8601	ISO character representation of dates, date/times, intervals, and durations of time. The SDTM uses the extended format.
LOINC	Logical Observation, Identifiers, Names, and Codes
MedDRA	Medical Dictionary for Regulatory Activities
NCI	National Cancer Institute (NIH)
SDS	Submission Data Standards. Also the name of the Team that created the SDTM and SDTMIG.
SDTM	Study Data Tabulation Model
SDTMIG	Submission Data Standards Study Data Tabulation Model Implementation Guide: Human Clinical Trials [this document]
SEND	Standard for Exchange of Non-Clinical Data
SF-36	A multi-purpose, short-form health survey with 36 questions
SNOMED	Systematized Nomenclature of Medicine (a dictionary)
SOC	System Organ Class (from MedDRA)
TDM	Trial Design Model
UUID	Universally Unique Identifier
V3.x	Version 3.1 of the SDTMIG and all subsequent versions of the SDTMIG
WHODRUG	World Health Organization Drug Dictionary
XML	eXtensible Markup Language

Appendices

Appendix C: Controlled Terminology

CDISC Terminology is centrally managed by the CDISC Controlled Terminology Team, supporting the terminology needs of all CDISC foundational standards (SDTM, CDASH, ADaM, SEND) and all disease/therapeutic area standards.

New/modified terms have a 3-month development period during which the Controlled Terminology Team evaluates the requests received, incorporates as much as possible for each quarterly release, and has a quarterly public review comment period followed by a publication release.

Visit the [CDISC Controlled Terminology](#) page to find the most recently published terminology packages (final or under review), or visit the [NCI Enterprise Vocabulary Services](#) website for access to the full list of CDISC terminology.

Note that the [NCI Enterprise Vocabulary Services](#) website does provide SDTM terminology in two forms:

- Terminology for all standard SDTM domains
- Terminology for commonly used questionnaires in biomedical and therapeutic area research (modeled using the QS Domain Model)

Please be sure to explore the [NCI Enterprise Vocabulary Services](#) website carefully to ensure access to the full SDTM Terminology package.

SDTM Implementation Guides (v3.1.3 or earlier) have traditionally included several appendices regarding to Controlled Terminology. As terminology is revised/updated on a quarterly basis, starting with SDTMIG 3.2, all current Controlled Terminology can be found directly on the above websites. This Appendix C has been simplified to only contain a couple of important Terminology Code Lists that are specific to this Implementation Guide

Appendix C1: Trial Summary Codes

The Parameter table includes text to indicate if the parameter should be included in the dataset.

To make this domain useful, a minimum number of trial summary parameters should be provided as shown below. The column titled “Record with this Parameter” indicates whether the parameter should be included in the dataset. If a record is included, either TSVAL or TSVLNF must be populated.

Most of the new parameters are coming from www.clinicaltrials.gov and the controlled terminology shown below is aligned with that source. All definitions of the parameters are maintained in NCI EVS.

The Notes column provides some additional information about the specific parameter or its values.

TSPARMCD	TSPARM	TSVAL (Codelist Name or Format)	Record with this Parameter	Notes
ADDON	Added on to Existing Treatments	No Yes Response	Required	
AGEMAX	Planned Maximum Age of Subjects	ISO 8601	Required	If there is no maximum age, TSVLNF = PINF
AGEMIN	Planned Minimum Age of Subjects	ISO 8601	Required	If there is no minimum age, populate TSVAL with P0Y
LENGTH	Planned Trial Length	ISO 8601	Required	
PLANSUB	Planned Number of Subjects	number	Required	
RANDOM	Trial is Randomized	No Yes Response	Required	
SEXPOP	Sex of Participants	Sex of Participants	Required	
STOPRULE	Study Stop Rules	text	Required	Protocol-specified stopping rule. If there is no stopping rule record “NONE” in this field.
TBLIND	Trial Blinding Schema	Trial Blinding Schema	Required	
TCNTRL	Control Type	Control Type	Required	
TDIGRP	Diagnosis Group	SNOMED CT	Conditionally Required	If the study population is healthy subjects (i.e., healthy subjects flag is Y), this parameter is not expected. If the healthy subject flag is N, then this parameter would contain the diagnosis/medical problem of the study population. [Validation rule; IF healthy volunteers = N then TDIGRP must be present and not null]
TINDTP	Trial Indication Type	Trial Indication Type	Conditionally Required	If study type is “INTERVENTIONAL” this parameter is required. A study in healthy volunteers may have TSVAL null and TSVLNF = NA.
TITLE	Trial Title	text	Required	Use as many rows as needed.
TPHASE	Trial Phase Classification	Trial Phase	Required	
TTYPER	Trial Type	Trial Type	Required	Use as many rows as needed.

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TSPARMCD	TSPARM	TSVAL (Codelist Name or Format)	Record with this Parameter	Notes
CURTRT	Current Therapy or Treatment	SRS Preferred Substance Name (or Device Name)	Conditionally Required	Required when ADDON equals "Y". Use as many rows as needed for combination or multiple therapies.
OBJPRIM	Trial Primary Objective	text	Required	
OBJSEC	Trial Secondary Objective	text	If Applicable	If applicable. Use as many rows as needed.
SPONSOR	Clinical Study Sponsor	DUNS	Required	
COMPTRT	Comparative Treatment Name	SRS Preferred Substance Name	If Applicable	If applicable. Don't include if there are no active comparators. Use as many rows as needed.
INDIC	Trial Indication	SNOMED CT	If Applicable	If applicable. Don't include if the sole purpose is to collect PK data. See Assumption 16 above. Use as many rows as needed.
TRT	Investigational Therapy or Treatment	UNII	Conditionally Required	If study type is "INTERVENTIONAL" this parameter is required.
RANDQT	Randomization Quotient	number	Conditionally Required	Required only when there is only one investigational treatment. The value is always a number between 0 and 1. There are cases where the ratio is 1 (e.g., crossover study or open label study where all subjects are exposed to investigational therapy).
STRATFCT	Stratification Factor	Any allowable variable name	If Applicable	If applicable. Use as many rows as needed, one for each factor.
REGID	Registry Identifier	CLINICALTRIALS.GOV / EUDRAC	Required	Use as many rows as needed, one for each registry ID
OUTMSPRI	Primary Outcome Measure	text	Required	Use as many rows as needed.
OUTMSSEC	Secondary Outcome Measure	text	If Applicable	If applicable (i.e, if the trial has a secondary outcome measure). Use as many rows as needed.
OUTMSEXP	Exploratory Outcome Measure	text	If Applicable	If applicable (i.e, if the trial has exploratory outcome). measure. Use as many rows as needed.
PCLAS	Pharmacological Class of Inv Therapy	NDF-RT	Conditionally Required	If study type is "INTERVENTIONAL" and if Intervention Type is one for which pharmacological class is applicable this parameter is required.
FCNTRY	Planned Country of Investigational Sites	ISO 3166-1 alpha-3	Required	Use as many rows as needed, one for each country.
ADAPT	Adaptive Design	No Yes Response	Required	Does the protocol include any adaptive design features?
DCUTDTC	Data Cutoff Date	ISO 8601	Required	Use GRPID to associate the Data Cutoff Date to Data Cutoff Description.

TSPARMCD	TSPARM	TSVAL (Codelist Name or Format)	Record with this Parameter	Notes
DCUTDESC	Data Cutoff Description	text	Required	Use GRPID to associate the Data Cutoff Date to Data Cutoff Description.
INTMODEL	Intervention Model	Intervention Model	Conditionally Required	If study type is "INTERVENTIONAL" this parameter is required.
NARMS	Planned Number of Arms	number	Required	
STYPE	Study Type	Study Type	Required	
INTTYPE	Intervention Type	Intervention Type	Conditionally Required	If study type is "INTERVENTIONAL" this parameter is required.
SSTDTC	Study Start Date	ISO 8601	Required	
SENDTC	Study End Date	ISO 8601	Required	
ACTSUB	Actual Number of Subjects	number	Required	
HLTSUBJI	Healthy Subject Indicator	No Yes Response	Required	If the healthy subject indicator is N, then TDIGRP value should be provided.
SDMDUR	Stable Disease Minimum Duration	ISO 8601	If Applicable	If applicable.
CRMDUR	Confirmed Response Minimum Duration	ISO 8601	If Applicable	If applicable.

Appendix C2: Supplemental Qualifiers Name Codes

The following table contains an initial set of standard name codes for use in the Supplemental Qualifiers (SUPP--) special-purpose datasets. There are no specific conventions for naming QNAM and some sponsors may choose to include the 2-character domain in the QNAM variable name. Note that the 2-character domain code is not required in QNAM since it is present in the variable RDOMAIN in the SUPP-- datasets.

QNAM	QLABEL	Applicable Domains
AESOSP	Other Medically Important SAE	AE
AETRTEM	Treatment Emergent Flag	AE
--CLSIG	Clinically Significant	Findings
COMPLT	Completers Population Flag	DM
FULLSET	Full Analysis Set Flag	DM
ITT	Intent to Treat Population Flag	DM
PPROT	Per Protocol Set Flag	DM
SAFETY	Safety Population Flag	DM
--REAS	Reason	All general observation classes

Appendices

Appendix D: CDISC Variable-Naming Fragments

The CDISC SDS group has defined a standard list of fragments to use as a guide when naming variables in SUPP-- datasets (as QNAM) or assigning --TESTCD values that could conceivably be treated as variables in a horizontal listing derived from a V3.x dataset. In some cases, more than one fragment is used for a given keyword. This is necessary when a shorter fragment must be used for a --TESTCD or QNAM that incorporates several keywords that must be combined while still meeting the 8-character variable naming limit of SAS transport files. When using fragments, the general rule is to use the fragment(s) that best conveys the meaning of the variable within the 8-character limit; thus, the longer fragment should be used when space allows. If the combination of fragments still exceeds 8 characters, a character should be dropped where most appropriate (while avoiding naming conflicts if possible) to fit within the 8-character limit.

In other cases the same fragment may be used for more than one meaning, but these would not normally overlap for the same variable.

Keyword(s)	Fragment
ACTION	ACN
ADJUSTMENT	ADJ
ANALYSIS DATASET	AD
ASSAY	AS
BASELINE	BL
BIRTH	BRTH
BODY	BOD
CANCER	CAN
CATEGORY	CAT
CHARACTER	C
CLASS	CLAS
CLINICAL	CL
CODE	CD
COMMENT	COM
CONCOMITANT	CON
CONDITION	CND
CONGENITAL	CONG
DATE TIME - CHARACTER	DTC
DAY	DY
DEATH	DTH
DECODE	DECOD
DERIVED	DRV
DESCRIPTION	DESC
DISABILITY	DISAB
DOSE, DOSAGE	DOS, DOSE
DURATION	DUR
ELAPSED	EL
ELEMENT	ET
EMERGENT	EM
END	END, EN
ETHNICITY	ETHNIC

Keyword(s)	Fragment
EVALUATION	EVL
EVALUATOR	EVAL
EXTERNAL	X
FASTING	FAST
FILENAME	FN
FLAG	FL
FORMULATION, FORM	FRM
FREQUENCY	FRQ
GRADE	GR
GROUP	GRP
HOSPITALIZATION	HOSP
IDENTIFIER	ID
INDICATION	INDC
INDICATOR	IND
INTERPRETATION	INTP
INTERVAL	INT
INVESTIGATOR	INV
LIFE-THREATENING	LIFE
LOCATION	LOC
LOINC CODE	LOINC
LOWER LIMIT	LO
MEDICALLY-IMPORTANT EVENT	MIE
NAME	NAM
NON-STUDY THERAPY	NST
NORMAL RANGE	NR
NOT DONE	ND
NUMBER	NUM
NUMERIC	N
OBJECT	OBJ
ONGOING	ONGO
ORDER	ORD

Keyword(s)	Fragment
ORIGIN	ORIG
ORIGINAL	OR
OTHER	OTH, O
OUTCOME	OUT
OVERDOSE	OD
PARAMETER	PARM
PATTERN	PATT
POPULATION	POP
POSITION	POS
QUALIFIER	QUAL
REASON	REAS
REFERENCE	REF, RF
REGIMEN	RGM
RELATED	REL, R
RELATIONSHIP	REL
RESULT	RES
RULE	RL
SEQUENCE	SEQ
SERIOUS	S, SER
SEVERITY	SEV
SIGNIFICANT	SIG
SPECIMEN	SPEC, SPC

Keyword(s)	Fragment
SPONSOR	SP
STANDARD	ST, STD
START	ST
STATUS	STAT
SUBCATEGORY	SCAT
SUBJECT	SUBJ
SUPPLEMENTAL	SUPP
SYSTEM	SYS
TEXT	TXT
TIME	TM
TIME POINT	TPT
TOTAL	TOT
TOXICITY	TOX
TRANSITION	TRANS
TREATMENT	TRT
UNIQUE	U
UNIT	U
UNPLANNED	UP
UPPER LIMIT	HI
VALUE	VAL
VARIABLE	VAR
VEHICLE	V

Appendices

Appendix E: Revision History

Changes from CDISC SDTMIG V3.1.3 to V3.2

Category, Document, or Section	Classification	Type	Description of change
General	Major	Format	Conversion of SDTMIG from a single document to a PDF Portfolio, or a collection of multiple files assembled into an integrated PDF unit. Not all PDF viewers can display a PDF portfolio, but any PDF viewer which supports Flash should display the PDF portfolio as intended. The "About " file offers a few options
	Major	Format	Organized new SDTMIG by the basic sections of previous SDTMIG releases (Sections 1-8), with the following new structure: <ul style="list-style-type: none"> - Section 1: a single document - Section 2: a single document - Section 3: a single document - Section 4: a single document - Section 5: a collection of smaller documents, one per domain - Section 6: a collection of 3 sub-folders (one for each Observation Class), each containing individual documents (one per domain or sets of related domains) - Section 7: a collection of smaller documents - Section 8: a single document - Appendices: a folder containing smaller documents, one per appendix (A through F)
	Major	Format	For the individual Domain, the numbering schema has been replaced by a clear and consistent organization with smaller sub-sections such as "Description/Overview", "Specification", "Assumptions", and "Examples"
	Major	Update	Updated Controlled Terminology for applicable variables across all domains, if available.
	Major	Removal	Removed the References column from all domain models specifications
	Major	Update	Updated all Controlled Terminology links, in each Domain/Dataset Specification table, to point to the NCI Enterprise Vocabulary Service website: corrected the hyperlinks to point to " http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc "
	Minor	Format	Cross-referencing of Sections, sub-sections, assumptions, examples, appendices have all been harmonized with the following format: <ul style="list-style-type: none"> - Section/Appendix-number: sub-section-number, [segment header], title <p>where <i>[segment header]</i> may be a named example or assumption <i>title</i> is the actual title of the document, section or sub-section being referenced</p>
	Section 1 - Introduction	Minor	Format
	Minor	Format	"Appendix E" reference changed to "Appendix E - Revision History".
	Minor	Format	"Section 1, Introduction" reference changed to "Section 1 - Introduction".
	Minor	Format	"Section 2, Fundamentals of the SDTM" reference changed to "Section 2 - Fundamentals of the SDTM".
	Minor	Format	"Section 3, Submitting Data in Standard Format Section" reference changed to "Section 3 - Submitting Data in Standard Format Section".
	Minor	Format	"Section 4, Assumptions for Domain Models" reference changed to "Section 4 - Assumptions For Domain Models".
	Minor	Format	"Section 4.1.3" reference changed to "Section 4: 4.1.3, Coding And Controlled Terminology Assumptions".
	Minor	Format	"Section 5, Models For Special-Purpose Domains" reference changed to "Section 5 – Models For Special-Purpose Domains".
	Minor	Format	"Section 6, Domain Models Based on the General Observation Classes" reference

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Category, Document, or Section	Classification	Type	Description of change
			changed to "Section 6 – Domain Models Based On The General Observation Classes".
	Minor	Format	"Section 7, Trial Design Datasets" reference changed to "Section 7 - Trial Design Datasets".
	Minor	Format	"Section 8, Representing Relationships and Data " reference changed to "Section 8 - Representing Relationships and Data " .
Section 2 - Fundamentals of the SDTM	Minor	Format	"Appendix C1" reference changed to "Appendix C - Controlled Terminology".
	Minor	Format	"Appendix C2 or Appendix C2A" reference changed to "Appendix C - Controlled Terminology".
	Minor	Format	"Figure 2.6" reference changed to "Figure 2.6, Creating A New Domain".
	Minor	Format	"Section 2.6" reference changed to "Section 2.6, Creating A New Domain".
	Minor	Format	"Section 3.2" reference changed to "Section 3: 3.2, Using The CDISC Domain Models In Regulatory Submissions - Dataset Metadata".
	Minor	Format	"Section 4" reference changed to "Section 4 - Assumptions For Domain Models".
	Minor	Format	"Section 4.1.1.8" reference changed to "Section 4: 4.1.1.8, Origin Metadata".
	Minor	Format	"Section 5, Models For Special-Purpose Domains" reference changed to "Section 5 – Models For Special-Purpose Domains".
	Minor	Format	"Section 6, Domain Models Based on the General Observation Classes" reference changed to "Section 6 – Domain Models Based On The General Observation Classes".
	Minor	Format	"Section 6.1" reference changed to "Section 6.1 - Interventions".
	Minor	Format	"Section 6.2" reference changed to "Section 6.2 - Events".
	Minor	Format	"Section 6.3" reference changed to "Section 6.3 - Findings".
	Minor	Format	"Section 7" reference changed to "Section 7 - Trial Design Datasets".
	Minor	Format	"Section 8" reference changed to "Section 8 - Representing Relationships and Data " .
	Minor	Format	"Section 8, Representing Relationships and Data " reference changed to "Section 8 - Representing Relationships and Data " .
	Minor	Format	"Section 8.4" reference changed to "Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain".
	Minor	Format	"Section 8.6.1" reference changed to "Section 8: 8.6.1, Guidelines For Determining The General Observation Class".
	Minor	Format	"Table 2.2.5" reference changed to "SDTM: Table 2.2.5".
	Minor	Format	"Tables 2.2.1, 2.2.2, or 2.2.3" reference changed to "SDTM: Tables 2.2.1, 2.2.2, or 2.2.3".
	Minor	Update	In section 2.2, 3rd paragraph, 4th & 5th 1st statements reference to specification changed from "define.xml" to "DEFINE-XML".
Minor	Update	In section 2.5, last bullet reference to specification changed from "define.xml" to "DEFINE-XML".	
Section 3 - Submitting Data in Standard Format	Minor	Format	"assumption 4.1.1.9" reference changed to "Section 4: 4.1.1.9, Assigning Natural Keys In The Metadata".
	Minor	Format	"Section 4.1.1.5" reference changed to "Section 4: 4.1.1.5, CDISC Core Variables".
	Minor	Format	"Section 4.1.1.8" reference changed to "Section 4: 4.1.1.8, Origin Metadata".
	Minor	Format	"Section 8.4" reference changed to "Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain".
	Minor	Format	"Table 3.2.1" reference changed to "Table 3.2.1, SDTM Submission Dataset-Definition Metadata Example".
	Minor	Update	In section 3.2.1.2, 3rd paragraph, 1st statement reference to specification changed from "CRT-DDS" to "DEFINE-XML".
Section 4 - Assumptions For Domain Models	Major	Addition	New "4.1.5.8 ACCOUNTING FOR LONG-TERM FOLLOW-UP" section added, related to new Subject Status (SS) Domain
	Minor	Format	"Appendix C" reference changed to "Appendix C - Controlled Terminology".
	Minor	Format	"Appendix C2 for a list of standard and reserved domain codes" reference changed to "Appendix C regarding Controlled Terminology information that includes a list of standard domain codes".
	Minor	Format	"Appendix C5" reference changed to "Appendix C2 - Supplemental Qualifier Name Codes".

Category, Document, or Section	Classification	Type	Description of change
	Minor	Format	"Appendix D" reference changed to "Appendix D - CDISC Variable-Naming Fragments".
	Minor	Format	"Assumption 4.1.4.8" reference changed to "Assumption 4.1.4.8, Date And Time Reported In A Domain Based On Findings".
	Minor	Format	"Section 3.2" reference changed to "Section 3: 3.2, Using The CDISC Domain Models In Regulatory Submissions - Dataset Metadata".
	Minor	Format	"Section 4.1.1.5" reference changed to "Section 4.1.1.5, CDISC Core Variables".
	Minor	Format	"Section 4.1.1.7" reference changed to "Section 4.1.1.7, Splitting Domains".
	Minor	Format	"Section 4.1.2.8.1" reference changed to "Section 4.1.2.8.1, Multiple Values For An Intervention Or Event Topic Variable".
	Minor	Format	"Section 4.1.2.8.3" reference changed to "Section 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable".
	Minor	Format	"Section 4.1.3.2" reference changed to "Section 4.1.3.2, Controlled Terminology Text Case".
	Minor	Format	"Section 4.1.4.3" reference changed to "Section 4.1.4.3, Intervals Of Time And Use Of Duration For --DUR Variables".
	Minor	Format	"Section 4.1.4.4" reference changed to "Section 4.1.4.4, Use Of The "Study Day" Variables".
	Minor	Format	"Section 4.1.5.1.2" reference changed to "Section 4.1.5.1.2, Tests Not Done".
	Minor	Format	"Section 4.1.5.1.3" reference changed to "Section 4.1.5.1.3, Examples Of Original And Standard Units And Test Not Done".
	Minor	Format	"Section 5" reference changed to "Section 5 – Models For Special-Purpose Domains".
	Minor	Format	"Section 5.2" reference changed to "Section 5 - CO Domain".
	Minor	Format	"Section 5.2.1.1" reference changed to "Section 5 - CO Domain: CO - Assumptions for the COMMENTS Domain Model".
	Minor	Format	"Section 5.3.1" reference changed to "Section 5 - SE Domain".
	Minor	Format	"Section 6" reference changed to "Section 6 – Domain Models Based On The General Observation Classes".
	Minor	Format	"Section 6.2.2.1" reference changed to "Section 6.2 - DS Domain: Assumption 5, DS - Assumptions for DISPOSITION Domain Model".
	Minor	Format	"Section 6.3.2.1 assumption 4" reference changed to "Section 6.3 - IE Domain: Assumption 4, IE - Assumptions for INCLUSION/EXCLUSION CRITERIA NOT MET Domain Model".
	Minor	Format	"Section 6.4" reference changed to "Section 6.4 - FA Domain".
	Minor	Format	"Section 6.4.2" reference changed to "Section 6.4: 6.4.2, Naming FINDINGS ABOUT Domains".
	Minor	Format	"Section 6.4.3" reference changed to "Section 6.4: 6.4.3, Variables Unique To FINDINGS ABOUT".
	Minor	Format	"Section 7" reference changed to "Section 7 - Trial Design Datasets".
	Minor	Format	"Section 7.4" reference changed to "Section 7.3 - Schedule for Assessments: Trial Visits (TV)".
	Minor	Format	"Section 7.5.2 assumption 5" reference changed to "Section 7.4 - Trial Summary And Eligibility: Assumption 5, TI - Assumptions for Trial Inclusion/Exclusion Criteria Dataset".
	Minor	Format	"Section 7.6.1" reference changed to "Section 7.4 - Trial Summary And Eligibility: Trial Summary Dataset (TS)".
	Minor	Format	"Section 8" reference changed to "Section 8 - Representing Relationships and Data".
	Minor	Format	"Section 8.4" reference changed to "Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain".
	Minor	Format	"Section 8.4.1" reference changed to "Section 8: 8.4.1, Supplemental Qualifiers: SUPP-- Datasets".
	Minor	Format	"Table 2.2.5" reference changed to "SDTM: Table 2.2.5".
	Minor	Format	"Tables 2.2.1, 2.2.2, 2.2.3, 2.2.3.1, 2.2.4, and 2.2.5 of the SDTM" reference changed to "SDTM: Tables 2.2.1, 2.2.2, 2.2.3, 2.2.3.1, 2.2.4, and 2.2.5".
	Minor	Removal	Deleted former bullet # 5 in Section 4.1.1.7 that read "5) Variables of the same

Category, Document, or Section	Classification	Type	Description of change
			name in separate datasets should have the same SAS Length attribute to avoid any difficulties if the sponsor or FDA should decide to append datasets together."
	Minor	Update	Section 4.1.3.1, 1st paragraph, 3rd statement modified from "For V3.1.2, controlled terminology is now represented one of three ways:" to "Controlled terminology is now represented one of three ways:".
	Minor	Update	Section 4.1.4.7, 3rd paragraph, 1st statement modified from "Allowable values for --STRF and --ENRF are "BEFORE", "DURING", "DURING/AFTER", "AFTER", and "U" (for unknown)." to "Allowable values for --STRF and --ENRF are "BEFORE", "DURING", "DURING/AFTER", "AFTER", "COINCIDENT", "ONGOING", and "U" (for unknown).".
	Minor	Update	Section 4.1.4.7, 5th paragraph, 2nd statement modified from "Sponsors are cautioned that doing so in conjunction with directly collecting or mapping data such as "BEFORE", "PRIOR", etc. to --STRF and --ENRF ..." to "Sponsors are cautioned that doing so in conjunction with directly collecting or mapping data such as "BEFORE", "PRIOR", "ONGOING", etc. to --STRF and --ENRF ...".
	Minor	Update	Section 4.1.4.7, 4th paragraph, 1st statement modified from "As an example, a CRF checkbox that identifies concomitant medication use that began prior to the study treatment period would translate into CMSTRF = "BEFORE" if selected." to "As an example, a CRF checkbox that identifies concomitant medication use that began prior to the study treatment period would translate into CMSTRF = "BEFORE" if selected; similarly, . a CRF checkbox that identifies concomitant medication use that continues after the study treatment period would translate into CMENRF = "ONGOING" if selected. ".
	Minor	Format	In section 4.1.5.1.3, the style of describing examples on pages 30-31 was updated so that it is consistent with the way they're introduced in domains "Rows 1-2 show ..." instead of (Rows 1,2 at end)
	Minor	Addition	Updated last statement on 2nd from bottom paragraph on page 6 to read "The natural key is then defined as follows (this example is for displaying natural keys only actual data modeling should follow the SDTMIG-MD):" This update was made to reflect that this example actually uses data that would be modeled differently now that there is a Devices IG; the example will be better updated in the next release.
	Minor	Addition	Reference to "(Define-XML)" in Section 4.1.1.1 was updated to read "(see <i>Define-XML V2.0 Specification</i>)"
	Minor	Addition	In Section 4.1.1.8.1, added "(note that other values may be defined by other standards)" to last statement in first paragraph.
	Minor	Update	Section 4.1.2.6, sub-section 2.C.5, 2nd statement changed from "As such these variables are often used in IDVAR in a RELREC relationship often in a dataset to dataset relationship" to "As such these variables are often used in IDVAR in a RELREC relationship when there is a dataset to dataset relationship".
	Minor	Format	In section 4.1.5.1.3, deleted paragraph right after lab example.
	Minor	Update	In section 4.1.5.1.1, last paragraph, 4th statement updated from "The rules for modifying the value for analysis purposes should be defined in the analysis plan and only changed in the ADaM datasets" to "The rules for imputing a numeric value for analysis purposes should be defined in the analysis plan, and a numeric value should be only be imputed in the ADaM datasets"
	Minor	Update	In Section 4.1.2.3, 3rd paragraph, 1st statement was re-written from "Sample Rows from individual study dm.xpt files for a same subject that participates first in ACME01 study, then ACME14 study" to "The below dm.xpt sample rows illustrate a single subject who participates in two studies, first in ACME01 and later in ACME14"
	Minor	Update	In Section 4.1.2.4, last statement changed from "The Sponsor's define.xml may indicate as a general note or assumption whether case sensitivity applies to text data for any or all variables in the dataset" to "The case used in the text data must match the case used in the Controlled Terminology provided in the Define-XML".
	Minor	Update	Updated section 4.1.3.1, first paragraph, from "For V3.1.2 ..." to "As of V3.1.2", and "...is now ..." to "...is...".
	Minor	Update	In section 4.1.4.4, 2nd paragraph, 3rd statement, replaced "decremented" with

Category, Document, or Section	Classification	Type	Description of change
			"decreased".
	Minor	Update	In section 4.1.1.9, inserted the following text after the 1st statement: "In a case where a dataset includes a mix of records with different natural keys, the natural key that provides the most granularity is the one that should be provided."
	Minor	Update	Section 4.1.2.6.3.A, changed last statement from "Groups of medications taken to treat an SAE, recorded in/on the SAE collection, and could be part of a different grouping of medications for each subject would more appropriately use --GRPID" to "Groups of medications recorded on an SAE form as treatments for the SAE would more appropriately use --GRPID as the groupings are likely to differ across subjects."
	Minor	Update	Section 4.1.2.1, 2nd paragraph, 3rd statement. Changed "(such as XML)" to "(such as SDS-XML)".
	Minor	Update	In section 4.1.3.2, deleted last statement from first paragraph that read "Deviations to this rule should be described in the define.xml", and inserted last paragraph as "The text case used in the definition of the controlled terminology in the Define-XML should match the text case used in the data."
	Minor	Update	In Section 4.1.2.3, inserted "in the DEFINE-XML" before the word comments at end of 1st paragraph, 2nd statement.
Section 5 - CO Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Format	"Section 8.5" reference changed to "Section 8: 8.5, Relating Comments To A Parent Domain".
Section 5 - DM Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Format	"Appendix C5" reference changed to "Appendix C2 - Supplemental Qualifier Name Codes".
	Minor	Format	"Section 1.2" reference changed to "Section 4: 1.2, Organization Of This Document".
	Minor	Format	"Section 4.1.1.4" reference changed to "Section 4: 4.1.1.4, Order Of The Variables".
	Minor	Format	"Section 4.1.2.7.1" reference changed to "Section 4: 4.1.2.7.1, "Specify" Values For Non-Result Qualifier Variables".
	Minor	Format	"Section 4.1.2.8.3" reference changed to "Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable".
	Minor	Format	"Section 5.1.1.2" reference changed to "Section 5 - DM Domain: DM - Examples for the DEMOGRAPHICS Domain Model".
	Minor	Format	"Section 5.3.1.2" reference changed to "Section 5 - SE Domain: SE - Examples for the SUBJECT ELEMENTS Domain Model".
	Minor	Format	"Section 7.2.3.1" reference changed to "Section 7.2 - Experimental Design: Example Trial 1, A Parallel Trial, TA – Examples For Trial Arms Dataset".
	Minor	Format	"Section 7.2.3.3" reference changed to "Section 7.2 - Experimental Design: Example Trial 3, A Trial With Multiple Branch Points, TA - Examples for Trial Arms Dataset".
	Minor	Format	"Section 7.2.4.2" reference changed to "Section 7.2 - Experimental Design: Issue 2, Subjects Not Assigned To An Arm, TA – Issues In Trial Arms Dataset".
	Minor	Format	"Section 8.4" reference changed to "Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain".
	Section 5 - SE Domain	Major	Removal
Minor		Format	"Section 4.1.4.4" reference changed to "Section 4: 4.1.4.4, Use Of The "Study Day" Variables".
Minor		Format	"Section 5.1.1.2" reference changed to "Section 5 - DM Domain: DM - Examples for the DEMOGRAPHICS Domain Model".
Minor		Format	"Section 7.1.2" reference changed to "Section 7 - Introduction: 7.1.2, Definitions Of Trial Design Concepts".
Minor		Format	"Section 7.2" reference changed to "Section 7.2 - Experimental Design: Trial Arms (TA)".
Minor		Format	"Section 7.2.3.3" reference changed to "Section 7.2 - Experimental Design: Example Trial 3, A Trial With Multiple Branch Points, TA - Examples for Trial Arms Dataset".
	Minor	Format	"Section 7.3" reference changed to "Section 7.2 - Experimental Design: Trial

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Category, Document, or Section	Classification	Type	Description of change
			Elements (TE)".
	Minor	Format	"Section 7.4" reference changed to "Section 7.3 - Schedule for Assessments: Trial Visits (TV)".
	Minor	Format	"Table 5.3.1" reference changed to "Section 5 - DM Domain".
	Minor	Format	"Table 5.3.2" reference changed to "Section 5 - SV Domain".
Section 5 - SV Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Format	"Section 4.1.4.5" reference changed to "Section 4: 4.1.4.5, Clinical Encounters And Visits".
	Minor	Format	"Section 7.2" reference changed to "Section 7.2 - Experimental Design: Trial Arms (TA)".
	Minor	Format	"Section 7.3" reference changed to "Section 7.2 - Experimental Design: Trial Elements (TE)".
	Minor	Format	"Section 7.4" reference changed to "Section 7.3 - Schedule for Assessments: Trial Visits (TV)".
	Minor	Format	"Table 5.3.1" reference changed to "Section 5 - DM Domain".
	Minor	Format	"Table 5.3.2" reference changed to "Section 5 - SV Domain".
Section 6.1 - CM Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Format	"Assumption 4.1.2.8.3" reference changed to "Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable".
Section 6.1 - EX and EC Domains	Major	Addition	New domain: Exposure as Collected (EC)
	Major	Removal	Deleted "References" column from EX Domain specification table.
	Minor	Addition	Added the following variables to the EX domain model: EXREFID, EXLNKID, EXLNKGRP, EXLAT, EXDIR, EXFAST, EXRFTDTC
	Minor	Removal	Removed the following permissible variables from the EX domain model: EXDOSTOT, EXTRTV, EXVAMT, EXVAMTU, TAETORD
	Minor	Addition	Added point in time rule to EXENDTC; EXSTDTC should be copied to EXENDTC for point in time administrations.
	Minor	Update	Assumption 1, clarified EX definition by acknowledging the domain as a derived dataset where EXDOSU is in the protocol-specified unit.
	Minor	Addition	Added reference in Assumptions section to the Exposure as Collected (EC) domain.
	Minor	Addition	Added note to the Additional Interventions Qualifiers assumption that 1) the inclusion of administrations not taken, not given or missed is under evaluation and 2) --DOSTOT is under evaluation for potential deprecation and replacement with a mechanism to describe total dose over any interval of time (e.g., day, week, month).
Minor	Addition	Added additional examples and revised existing examples to align with the additions/deletions/changes in the EX domain model.	
Section 6.1 - PR Domain	Major	Addition	New domain.
Section 6.1 - SU Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Format	"Assumption 4.1.2.8.3" reference changed to "Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable".
	Minor	Format	"Section 4.1.2.6" reference changed to "Section 4: 4.1.2.6, Grouping Variables And Categorization".
	Minor	Format	"Section 4.1.4.7" reference changed to "Section 4: 4.1.4.7, Use Of Relative Timing Variables".
	Minor	Update	Added (FRM) as controlled terminology for SUDOSFRM in Specification table.
	Minor	Update	Update CDISC Notes for SUDOSFRM to read "Dose form for SUTRT. Examples: INJECTION, LIQUID, or POWDER."
	Minor	Update	Updated CDISC Notes for SUDOSU to read "Units for SUDOSE, SUDOSTXT, and SUDOSTOT. Examples: OZ (OUNCES), PACK (CIGARETTE EQUIVALENTS), or G (GRAMS)."
Section 6.2 - AE Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Format	"Appendix C5 (standard Supplemental Qualifier name codes)" reference changed to "Appendix C2 - Supplemental Qualifier Name Codes".
	Minor	Format	"FA, Section 6.4" reference changed to "Section 6.4 - FA Domain".
	Minor	Format	"Section 1.1" reference changed to "Section 1: 1.1, Purpose".
	Minor	Format	"Section 3.2" reference changed to "Section 3: 3.2, Using The CDISC Domain

Category, Document, or Section	Classification	Type	Description of change
			Models In Regulatory Submissions - Dataset Metadata".
	Minor	Format	"Section 4.1.1.4" reference changed to "Section 4: 4.1.1.4, Order Of The Variables".
	Minor	Format	"Section 4.1.2.6" reference changed to "Section 4: 4.1.2.6, Grouping Variables And Categorization".
	Minor	Format	"Section 4.1.4.7" reference changed to "Section 4: 4.1.4.7, Use Of Relative Timing Variables".
	Minor	Format	"Section 6.4" reference changed to "Section 6.4 - FA Domain".
	Minor	Format	"Section 8.4" reference changed to "Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain".
	Minor	Update	Updated CDISC Notes for AELOC to read "Location of Event Char (LOC) Record Qualifier Describes anatomical location relevant for the event (e.g., ARM for skin rash)."
	Minor	Update	Added (TOXGRV3) as controlled terminology for AETOXGR in Specification table.
Section 6.2 - CE Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Format	"Section 4.1.2.7" reference changed to "Section 4: 4.1.2.7, Submitting Free Text From The CRF".
	Minor	Format	"Section 4.1.4.7" reference changed to "Section 4: 4.1.4.7, Use Of Relative Timing Variables".
Section 6.2 - DS Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Format	"Section 7.2" reference changed to "Section 7.2 - Experimental Design: Trial Arms (TA)".
	Minor	Update	Added (EPOCH) as controlled terminology for EPOCH in Specification table.
	Minor	Update	Updated CDISC Notes for EPOCH so that it reads "EPOCH may be used when DSCAT = "DISPOSITION EVENT". Examples: SCREENING, TREATMENT, FOLLOW-UP"
	Minor	Update	Updated column EPOCH in Example 1 so that it reads "TREATMENT" instead of "TREATMENT PHASE"
	Minor	Update	Updated column EPOCH in Example 3 so that it reads "TREATMENT" instead of "TREATMENT PHASE"
Section 6.2 - DV Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Update	Added (EPOCH) as controlled terminology for EPOCH in Specification table.
Section 6.2 - HO Domain	Major	Addition	New domain.
Section 6.2 - MH Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Format	"Section 4.1.4.7" reference changed to "Section 4: 4.1.4.7, Use Of Relative Timing Variables".
	Minor	Update	Corrected font for header and sub-headers
	Minor	Update	Updated CDISC Note for MHDECOD: added period at end of sentence.
	Minor	Update	Updated CDISC Note for MHSTAT to read "Used to indicate that a question about a pre-specified condition was not answered. Should be null or have a value of NOT DONE."
	Minor	Update	Updated CDISC Note for MHSTAT to read "Describes the reason why data for a pre-specific condition was not collected. Used in conjunction with MHSTAT when value is NOT DONE.."
	Minor	Update	Deleted assumption 2.e as it is not applicable anymore because the MedDRA variables are in Section 2.2.2 of SDTM v1.4
	Minor	Update	Added "s." to last statement in assumption 2.c.
	Minor	Update	Updated Assumption 1.a to read "The Medical History dataset generally includes the subject's prior and concomitant conditions at the start of the trial. Examples of subject medical history information could include general medical history and gynecological history, and primary diagnosis".
	Minor	Update	Updated label for REASND to read "Reason Medical History Not Done or Not Occurred".

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Category, Document, or Section	Classification	Type	Description of change
	Minor	Update	Updated role for MHPRESP to "Variable Qualifier of --TERM".
	Minor	Update	Updated CDISC Notes for MHREASND to read "Describes the reason why data for a pre-specific condition was not collected. Used in conjunction with MHSTAT when value is NOT DONE."
	Minor	Update	Added "." to last statement in CDISC Notes for MHDECOD.
	Minor	Update	Added "." to last statement in CDISC Notes for MHENRF.
	Minor	Update	Updated CDISC Notes for MHSTAT to read "Used to indicate that a question about a pre-specified condition was not asked/answered. Should be null or have a value of NOT DONE."
Section 6.3 - DA Domain	Major	Removal	Deleted "References" column from Domain specification table.
Section 6.3 - DD Domain	Major	Addition	New domain.
Section 6.3 - EG Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Major	Update	Updated specification table, by replacing EGLOC with EGLEAD variable.
	Minor	Format	"Section 4.1.1.8.1" reference changed to "Section 4: 4.1.1.8.1, Origin Metadata For Variables".
	Minor	Format	"Section 4.1.5.1" reference changed to "Section 4: 4.1.5.1, Original And Standardized Results Of Findings And Test Not Done".
	Minor	Format	"Section 4.1.5.5" reference changed to "Section 4: 4.1.5.5, Clinical Significance For Findings Observation Class Data".
Section 6.3 - IE Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Format	"Section 4.1.5.3.2" reference changed to "Section 4: 4.1.5.3.2, Text Strings > 200 Characters In Other Variables".
	Minor	Format	"Section 6.2.4.1" reference changed to "Section 6.2 - DV Domain".
	Minor	Format	"Section 7.5" reference changed to "Section 7.4 - Trial Summary And Eligibility: Trial Inclusion/Exclusion Criteria (TI)".
Section 6.3 - IS Domain	Major	Addition	New domain.
Section 6.3 - LB Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Major	Addition	Added Assumption # 7.
	Minor	Format	"Assumption 4.1.4.8" reference changed to "Section 4: 4.1.4.8, Date And Time Reported In A Domain Based On Findings".
	Minor	Format	"Section 4.1.1.8.1" reference changed to "Section 4: 4.1.1.8.1, Origin Metadata For Variables".
	Minor	Format	"Section 4.1.5.1" reference changed to "Section 4: 4.1.5.1, Original And Standardized Results Of Findings And Test Not Done".
	Minor	Format	"Section 4.1.5.5" reference changed to "Section 4: 4.1.5.5, Clinical Significance For Findings Observation Class Data".
	Minor	Update	Example 2: Order of columns now: VISITNUM, VISIT
	Minor	Update	Example 3: Order of columns now: VISITNUM, VISIT
	Minor	Update	CDISC Note for LBTOXGR: Records toxicity grade value using a standard toxicity scale (such as the NCI CTCAE). If value is from a numeric scale, represent only the number (e.g., "2" and not "Grade 2"). The sponsor is expected to provide the name of the scale and version used to map the terms, utilizing the define.xml external codelist attributes .
	Minor	Update	LB Example 1, rows 2 & 4 , Changed units for LBSTRESU to "IU/L"
	Minor	Update	LB Example 1, row 5 , Changed units for LBSTRESU to "10^9/L"
	Minor	Update	Added (METHOD) as controlled terminology for LBMETHOD in Specification table.
	Minor	Update	Added (SPECCOND) as controlled terminology for LBSPCCND in Specification table.
	Minor	Update	Added (NRIND) as controlled terminology for LBNRIND in Specification table.
Minor	Update	LB Example 2, rows 1-3, Changed units for LBTESTCD to "GLUC"	
Section 6.3 - MB and MS Domains	Major	Removal	Deleted "References" column from Domain specification table in both MB and MS domains.
	Minor	Update	Assumption 1 in MB domain updated to read "...gram stain".

Category, Document, or Section	Classification	Type	Description of change
	Minor	Update	Updated CDISC Notes for MBORRES, from "STREPTOCOCCUS PNEUMONIAE PENICILLIN RESISTANT" to "STREPTOCOCCUS PNEUMONIAE".
	Minor	Update	Added (SPECTYPE) as controlled terminology for MBSPEC in Specification table.
	Minor	Update	Added (SPECCOND) as controlled terminology for MBSPCCND in Specification table.
	Minor	Update	Added (METHOD) as controlled terminology for MBMETHOD in Specification table.
	Minor	Update	Updated CDISC Notes for MBLOC so that examples read "Examples: LUNG, VEIN, ARM, FOOT"
	Minor	Update	Updated CDISC Notes for MBMETHOD so that examples read "Example: GRAM STAIN, MACRO BROTH DILUTION, AGAR DILUTION"
	Minor	Update	Updated 2nd statement of Assumption #5 for MB so that it reads "For example, if in Specimen 1, organism STREPTOCOCCUS PNEUMONIAE is found with MBGRPID=1, then findings such as susceptibility tests, colony count, etc. for that organism in Specimen 1, would all have the same value of MSGRPID=1 in the MS domain. "
	Minor	Update	Updated value in MBORRES in Example 1, row 3, from "STREPTOCOCCUS PNEUMONIAE PENICILLIN RESISTANT" to "STREPTOCOCCUS PNEUMONIAE".
	Minor	Update	Updated value in MBSTRESC in Example 1, row 3, from "STREPTOCOCCUS PNEUMONIAE PENICILLIN RESISTANT" to "STREPTOCOCCUS PNEUMONIAE".
	Minor	Update	Updated value in MBMETHOD in Example 1, rows 3-6, from "CULTURE PLATE" to "MICROBIAL CULTURE, SOLID".
	Minor	Update	Updated descriptive text for MB Example 1, rows 1-6, so that it reads "Show MBMETHOD being used for reporting the method of testing the sample, e.g. GRAM STAIN or MICROBIAL CULTURE, SOLID."
	Minor	Update	Updated value in MBMETHOD in Example 3, rows 1-2, from "CULTURE PLATE" to "MICROBIAL CULTURE, SOLID".
	Minor	Update	Updated value in MSMETHOD in Example 4, rows 3-4, from "BROTH DILUTION" to "MACRO BROTH DILUTION".
	Minor	Update	Updated value in MSORRESU in Example 4, rows 1-4, 7, 8, from "mcg/dL" to "ug/dL".
	Minor	Update	Updated value in MSSTRESU in Example 4, rows 1-4, 7, 8, from "mcg/dL" to "ug/dL".
	Minor	Update	Added (METHOD) as controlled terminology for MSMETHOD in Specification table.
	Minor	Update	Added (MSRESCAT) as controlled terminology for MSRESCAT in Specification table.
	Minor	Update	Updated value in MSSTRESU in Example 2, rows 2, 3, 5-7, from "mcg/mL" to "mg/L".
	Minor	Update	Updated value in MSORRESU in Example 2, rows 2, 3, 5-7, from "mcg/mL" to "mg/L".
	Minor	Update	Updated CDISC Notes for MSMETHOD so that examples read "Example: GRAM STAIN, MACRO BROTH DILUTION, AGAR DILUTION"
Section 6.3 - MI Domain	Major	Addition	New domain.
Section 6.3 - MO Domain	Major	Addition	New domain.
Section 6.3 - PC and PP Domains	Major	Removal	Deleted "References" column from Domain specification table in both PC and PP domains.
	Major	Update	Order of sub-sections now: PC - SPECIFICATIONS PC - ASSUMPTIONS PC - EXAMPLES PP - SPECIFICATIONS PP - ASSUMPTIONS

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Category, Document, or Section	Classification	Type	Description of change
			PP - EXAMPLES
	Major	Addition	Added PCULOQ to Specification Table for PC.
	Major	Addition	Added PPENINT to Specification Table for PP.
	Major	Addition	Added PPSTINT to Specification Table for PP.
	Major	Addition	Added new Example 2 for PP
	Minor	Format	"Section 3.2.1.1" reference changed to "Section 3: 3.2.1.1, Primary Keys".
	Minor	Format	"Section 4.1.4.10" reference changed to "Section 4: 4.1.4.10, Representing Time Points".
	Minor	Format	"Section 8.2" reference changed to "Section 8: 8.2, Relating Peer Records".
	Minor	Format	"Section 8.3" reference changed to "Section 8: 8.3, Relating Datasets".
	Minor	Update	1st suggestion, 3rd statement in <i>PC-PP – Suggestions For Implementing Relrec in the Submission of PK Data</i> section updated to read "Decide whether to relate datasets or records."
	Minor	Update	Example on page 14, inserted "pc.xpt" prior to example table.
	Minor	Update	Example on page 15, inserted "pp.xpt" prior to example table.
	Minor	Update	1st statement in PC-PP – Conclusions section updated to read "Relating the datasets [Section 8: 8.3, Relating Datasets] is the simplest method;"
	Minor	Removal	Removed "(PC dataset for all example, continued)" subheader from Example on page 14, prior to example table.
	Minor	Update	Updated beginning of 3rd statement in 1st paragraph of "Relating Records" subsection from "As in the case for relating datasets above (Section 6.3.10.5.1), -- GRPID values must ..." to "As in the case for relating datasets above, --GRPID values must ...".
	Minor	Update	PP Example 1, rows 2, 9, 16 & 23 , Changed units for PPORRESU to "ng/mL"
	Minor	Update	PP Example 1, rows 2, 9, 16 & 23, Changed units for PPSTRESU to "ng/mL"
	Minor	Update	PP Example 1, rows 3, 10, 17 & 24, Changed units for PPORRESU to "h*ug/MI"
	Minor	Update	PP Example 1, rows 3, 10, 17 & 24, Changed units for PPSTRESU to "h*ug/mL"
	Minor	Update	Added (SPECTYPE) as controlled terminology for PCSPEC in Specification table.
	Minor	Update	Added (SPECCOND) as controlled terminology for PCSPCCND in Specification table.
	Minor	Update	Added (METHOD) as controlled terminology for PCMETHOD in Specification table.
	Minor	Update	Updated (PKUNIT) as controlled terminology for PPORRESU in Specification table.
	Minor	Update	Updated (PKUNIT) as controlled terminology for PPSTRESU in Specification table.
	Minor	Update	Added (SPECTYPE) as controlled terminology for PPSPEC in Specification table.
	Minor	Update	PC Example 1, rows 5, 6, 19, 20, 25, 26, 29 & 30, Changed value for PCCAT to "SPECIMEN PROPERTY"
	Minor	Update	PC Example 1, added PCULOQ column to example.
	Minor	Update	Changed role of PCSPEC variable from "Req" to "Exp" in Specification table for PC domain.
Section 6.3 - PE Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Update	Updated CDISC Notes for PEEVAL so that the examples provided now read "Examples: INVESTIGATOR, ADJUDICATION COMMITTEE."
	Minor	Update	Added (METHOD) as controlled terminology for PEMETHOD in Specification table.
	Minor	Update	Added (EVAL) as controlled terminology for PEEVAL in Specification table.
	Minor	Update	PE Example 1, row 6, Changed value for PELOC to "ARM"
Section 6.3 - QS Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Major	Update	Updated QSCAT in Example 2 to map to the QS CT. Updated QSTESTCD for to map to the QS CT.
	Minor	Format	"Section 4.1.4.10" reference changed to "Section 4: 4.1.10, Representing Time Points".
	Minor	Format	"Section 4.1.5.1" reference changed to "Section 4: 4.1.5.1, Original And Standardized Results Of Findings And Test Not Done".
	Minor	Format	"Section 4.1.5.3.1" reference changed to "Section 4: 4.1.5.3.1, Test Name (--TEST)"

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Category, Document, or Section	Classification	Type	Description of change
			Greater Than 40 Characters".
	Minor	Format	"Section 8.4" reference changed to "Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain".
	Minor	Update	Added (QSCAT) as controlled terminology for QSCAT in Specification table.
	Minor	Update	Added (QSTESTCD) as controlled terminology for QSTESTCD in Specification table.
	Minor	Update	Added (QSTEST) as controlled terminology for QSTEST in Specification table.
	Minor	Update	Updated CDISC Notes for QSTESTCD so that the examples provided now read "Examples: ADCCMD01, BPR0103.".
	Minor	Update	Updated CDISC Notes for QSTEST so that the examples provided now read "Example: Fist, BPR01 - Emotional Withdrawal.".
	Minor	Update	Updated CDISC Notes for QSCAT so that the examples provided now read "Examples: ADAS-COG, MDS-UPDRS.".
Section 6.3 - RP Domain	Major	Addition	New domain.
Section 6.3 - SC Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Minor	Update	Updated (SCTESTCD) as controlled terminology for SCTESTCD in Specification table.
	Minor	Update	Updated (SCTEST) as controlled terminology for SCTEST in Specification table.
	Minor	Update	Updated CDISC Notes for SCTESTCD so that examples provided are now current with the SCTESTCD controlled terminology and include new values of "MARISTAT, NATORIG"
	Minor	Update	Updated CDISC Notes for SCTEST so that examples provided are now current with the SCTEST controlled terminology and include new values of "Marital Status, National Origin"
	Minor	Update	Updated Assumption 1 so that examples provided are now current with the controlled terminology and include new values of "education level, marital status, national origin"
	Minor	Update	Updated Example 1 for SCTESTCD column so that values are now current with the SCTESTCD controlled terminology and include new values of "MARISTAT, NATORIG"
	Minor	Update	Updated Example 1 for SCTEST so that examples values are now current with the SCTEST controlled terminology and include new values of "Marital Status, National Origin"
	Minor	Update	Updated Example 1 for SCORRES so that examples values are now current with the SCTEST controlled terminology and include new values of "UNITED STATES, DIVORCED, CANADA, MARRIED, USA, NEVER MARRIED, JAPAN, WIDOWED", respectively for each row.
	Minor	Update	Updated Example 1 for SCSTRESC so that examples values are now current with the SCTEST controlled terminology and include new values of "UNITED STATES, DIVORCED, CANADA, MARRIED, USA, NEVER MARRIED, JAPAN, WIDOWED", respectively for each row.
Section 6.3 - SS Domain	Major	Addition	New domain.
Section 6.3 - VS Domain	Major	Removal	Deleted "References" column from Domain specification table.
	Major	Addition	Added VSLAT variable after VSLOC to Specification Table for VS.
	Major	Addition	Added VSLAT column after VSLOC to Example 1.
	Minor	Format	"Section 4.1.5.5" reference changed to "Section 4: 4.1.5.5, Clinical Significance For Findings Observation Class Data".
	Minor	Update	Updated CDISC Notes for VSLOC so that examples provided are now current with the LOC controlled terminology and include new value of "ARM"
	Minor	Update	Updated Example 1, rows 1-7, 12-13, for VSLOC column so that examples provided are now current with the LOC controlled terminology and include new value of "ARM"
	Minor	Update	Updated Example 1, row 7, for VSORRESU and VSSTRESU columns so that value is now "BEATS/MIN"
	Minor	Update	Updated Example 1, rows 1-7, 12-13, for VSLAT column so that examples provided are now current with the LOC controlled terminology and include new

Category, Document, or Section	Classification	Type	Description of change
			value of "LEFT"
Section 6.4 - FA Domain	Major	Addition	Added FASTRESC and FASTRESU column to Example 2.
	Major	Update	Section 6.4.2 re-written to address domain references given new domains available after SDTMIG 3.1.2, and to bring up to date some other
	Minor	Format	"Section 4.1.1.7" reference changed to "Section 4: 4.1.1.7, Splitting Domains".
	Minor	Format	"Section 6.4.3" reference changed to "Section 6.4.3, Variables Unique To FINDINGS ABOUT".
	Minor	Format	"Section 6.4.6" reference changed to "Section 6.4.6, FA - Examples For FINDINGS ABOUT Domain Model".
	Minor	Format	"Section 8.6" reference changed to "Section 8: 8.6, How To Determine Where Data Belong In SDTM-compliant Data Tabulations".
	Minor	Format	"Tables 2.2.1, 2.2.2, or 2.2.3" reference changed to "SDTM: Sections 2.2.1, 2.2.2, or 2.2.3".
	Minor	Update	Added "..." column(s) to Example 5 to represent omitted variables.
	Minor	Update	Added "..." column(s) to Example 7 to represent omitted variables.
	Minor	Update	Updated (FATEST) as controlled terminology for FATEST in Specification table.
	Minor	Update	Updated (FATESTCD) as controlled terminology for FATESTCD in Specification table.
	Minor	Update	Updated (FAEVAL) as controlled terminology for FAEVAL in Specification table.
	Minor	Update	Added "..." column(s) to Example 2 to represent omitted variables.
	Minor	Update	Updated Example 2, rows 1 & 8, for FATESTCD column so that examples provided are now current with the FATESTCD controlled terminology and include new value of "DIAM"
Minor	Update	Updated Example 2, rows 1 & 8, for FATEST column so that examples provided are now current with the FATEST controlled terminology and include new value of "Diameter"	
Section 6.4 - SR Domain	Major	Addition	New domain.
Section 7	Major	Format	A complete re-design of Section 7, where In the same way that Sections 5 & 6 have been turned into a collection of more granular documents (each describing a single domain, or a collection of related ones), Section 7 is now a set of smaller documents that better organizes the Trial Design datasets.
Section 7.1 - Introduction	Minor	Format	"The Trial Design Model of the SDTM" reference changed to "SDTM: Section 3, Trial Design Model".
	Minor	Format	"Section 7.5" reference changed to "Section 7.4 - Trial Summary And Eligibility: Trial Inclusion/Exclusion Criteria (TI)".
Section 7.2 - Experimental Design	Minor	Format	"Section 5.1" reference changed to "Section 5 - DM Domain".
	Minor	Format	"Section 5.1.1.1" reference changed to "Section 5 - DM Domain: DM - Assumptions for the DEMOGRAPHICS Domain Model".
	Minor	Format	"Section 5.1.1.2" reference changed to "Section 5 - DM Domain: Example 7, DM - Examples for the DEMOGRAPHICS Domain Model".
	Minor	Format	"Section 5.3.1" reference changed to "Section 5 - SE Domain".
	Minor	Format	"Section 7.2" reference changed to "Section 7.2, Trial Arms (TA)".
	Minor	Format	"Section 7.2.3" reference changed to "Section 7.2, TA - Examples for Trial Arms (TA) Dataset".
	Minor	Format	"Section 7.2.3.1" reference changed to "Section 7.2, Example Trial 1, A Parallel Trial, TA – Examples For Trial Arms Dataset".
	Minor	Format	"Section 7.2.3.2" reference changed to "Section 7.2, Example Trial 2, A Crossover Trial, TA – Examples For Trial Arms Dataset".
	Minor	Format	"Section 7.2.3.3" reference changed to "Section 7.2, Example Trial 3, A Trial With Multiple Branch Points, TA - Examples for Trial Arms Dataset".
	Minor	Format	"Section 7.2.3.4" reference changed to "Section 7.2, Example Trial 4, Cycles Of Chemotherapy, TA - Examples for Trial Arms Dataset".
	Minor	Format	"Section 7.2.3.5" reference changed to "Section 7.2, Example Trial 5, Cycles With Different Treatment Durations, TA - Examples for Trial Arms Dataset".
	Minor	Format	"Section 7.2.3.6" reference changed to "Section 7.2, Example Trial 6, Chemotherapy Trial With Cycles Of Different Lengths, TA - Examples for Trial

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Category, Document, or Section	Classification	Type	Description of change
			Arms (TA) Dataset".
	Minor	Format	"Section 7.2.3.6" reference changed to "Section 7.2, Example Trial 6, Chemotherapy Trial With Cycles of Different Lengths, TA - Examples for Trial Arms Dataset".
	Minor	Format	"Section 7.2.4.1" reference changed to "Section 7.2, Issue 1, Distinguishing Between Branches And Transitions, TA – Issues In Trial Arms Dataset".
	Minor	Format	"Section 7.3" reference changed to "Section 7.2, Trial Elements (TE)".
	Minor	Format	"Section 7.3.3" reference changed to "Section 7.2, TE - Examples for the Trial Elements Domain Model".
Section 7.3 - Schedule of Assessments	Major	Addition	New domain: Trial Disease Assessment (TD)
	Minor	Format	"N/A" reference changed to "Section 7.3, Trial Disease Assessments (TD)".
	Minor	Format	"Section 5.3.2" reference changed to "Section 5 - SV Domain".
	Minor	Format	"Section 7.2.3.7" reference changed to "Section 7.2 - Experimental Design: Example Trial 7, Trial With Disparate Arms, TA - Examples for Trial Arms Dataset".
	Minor	Format	"Section 7.4" reference changed to "Section 7.3, Trial Visits (TV)".
	Minor	Format	"Section 7.4.3" reference changed to "Section 7.3, TV - Examples for Trial Visits Dataset".
Section 7.4 - Trial Summary And Eligibility	Minor	Format	"Appendix C3" reference changed to "Appendix C1 - Controlled Terminology".
	Minor	Format	"Section 4.1.5.3.1" reference changed to "Section 4: 4.1.5.3.1, Test Name (--TEST) Greater Than 40 Characters".
	Minor	Format	"Section 5.2" reference changed to "Section 5 - CO Domain".
	Minor	Format	"Section 6.3.2" reference changed to "Section 6.3 - IE Domain".
	Minor	Format	"Section 7.6.3" reference changed to "Section 7.4, TS – Examples For Trial Summary Information Dataset".
	Minor	Update	Removed "proposed" from 1st paragraph, 1st statement in section USE OF NULL FLAVOR ENUMERATION .
Section 8 - Relationships	Major	Update	Section 8.4.2 has been rewritten.
	Minor	Format	"Appendix C5" reference changed to "Appendix C2 - Supplemental Qualifier Name Codes".
	Minor	Format	"SDTM Section 2.2" reference changed to "SDTM: Section 2.2, The General Observation Classes".
	Minor	Format	"Section 2.6" reference changed to "Section 2: 2.6, Creating A New Domain".
	Minor	Format	"Section 4.1.1.7" reference changed to "Section 4: 4.1.1.7, Splitting Domains".
	Minor	Format	"Section 4.1.1.8" reference changed to "Section 4: 4.1.1.8, Origin Metadata".
	Minor	Format	"Section 4.1.5.3" reference changed to "Section 4: 4.1.5.3, Text Strings That Exceed The Maximum Length For General-Observation-Class Domain Variables".
	Minor	Format	"Section 4.1.5.5" reference changed to "Section 4: 4.1.5.5, Clinical Significance For Findings Observation Class Data".
	Minor	Format	"Section 5.1.1.2" reference changed to "Section 5 - DM Domain: DM - Examples for the DEMOGRAPHICS Domain Model".
	Minor	Format	"Section 5.2" reference changed to "Section 5 - CO Domain".
	Minor	Format	"Section 5.2.1.1" reference changed to "Section 5 - CO Domain: CO - Assumptions for the COMMENTS Domain Model".
	Minor	Format	"Section 5.2.1.2" reference changed to "Section 5 - CO Domain: CO - Examples for the COMMENTS Domain Model".
	Minor	Format	"Section 6.2.2.2" reference changed to "Section 6.2 - DS Domain: DS - Examples for DISPOSITION Domain Model".
	Minor	Format	"Section 6.3.1.2" reference changed to "Section 6.3 - EG Domain: EG - Examples for the ECG TEST RESULTS Domain Model".
	Minor	Format	"Section 6.3.10.5" reference changed to "Section 6.3 - PC and PP Domains: 6.3.10.5, Relating PP Records to PC Records".
	Minor	Format	"Section 6.3.10.5" reference changed to "Section 6.3 - PC and PP Domains".
	Minor	Format	"Section 6.3.3.2" reference changed to "Section 6.3 - LB Domain: LB - Examples for the LABORATORY TEST RESULTS Domain Model".
	Minor	Format	"Section 6.3.5" reference changed to "Section 6.3 - QS Domain".
	Minor	Format	"Section 6.3.9" reference changed to "Section 6.3 - MB and MS Domains".

Category, Document, or Section	Classification	Type	Description of change
	Minor	Format	"Section 6.4" reference changed to "Section 6.4 - FA Domain".
	Minor	Format	"Section 8.1" reference changed to "Section 8.1, Relating Groups Of Records Within A Domain Using The --GRPID Variable".
	Minor	Format	"Section 8.2" reference changed to "Section 8.2, Relating Peer Records".
	Minor	Format	"Section 8.3" reference changed to "Section 8.3, Relating Datasets".
	Minor	Format	"Section 8.4" reference changed to "Section 8.4, Relating Non-Standard Variables Values To A Parent Domain".
	Minor	Format	"Section 8.4.2" reference changed to "Section 8.4.2, Submitting Supplemental Qualifiers In Separate Datasets".
	Minor	Format	"Section 8.5" reference changed to "Section 8.5, Relating Comments To A Parent Domain".
	Minor	Format	"Section 8.6" reference changed to "Section 8.6, How To Determine Where Data Belong In SDTM-compliant Data Tabulations".
	Minor	Format	"Section 8.6.3" reference changed to "Section 8.6.3, Guidelines For Differentiating Between Events, Findings, and Findings About Events".
	Minor	Removal	Section 8.4.3, deleted example 4 as it is superseded by new HO domain
	Minor	Update	Section 8.4, re-wrote 1st paragraph so that now it reads "Therefore, the Supplemental Qualifiers special purpose dataset model is used to capture non-standard variables and their association to parent records in general-observation-class datasets (Events, Findings, Interventions) and Demographics. Supplemental Qualifiers may be represented as separate SUPP-- datasets for each dataset containing sponsor-defined variables (see Section 8.4.2, Submitting Supplemental Qualifiers In Separate Datasets for more on this topic)".
	Minor	Update	Section 8.4.1 header updated to read "SUPPLEMENTAL QUALIFIERS: SUPP-- DATASETS"
	Minor	Removal	Deleted 3rd statement , in Section 8.4, 1st paragraph that used to read "Most references in this guide will use the designation of SUPP-- rather than SUPPQUAL to serve as a reminder of the preferred submission format for Supplemental Qualifiers.". Statement deleted as the SUPPQUAL option is now deprecated.
Appendix C	Minor	Update	Reduction of Appendix C to contain only Trial Summary Codes and Supplemental Qualifiers Name Codes; this is being done as CDISC Terminology is centrally managed by the CDISC Controlled Terminology Team, and up-to-date CDISC Terminology information is best found at the NCI Enterprise Vocabulary Services website

Appendices

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

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