# Clinical Data Acquisition Standards Harmonization (CDASH)

# User Guide

**Prepared by:**

## CDISC CDASH Project Team

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# 1.0 Introduction

## 1.1 Purpose

This user guide is an aid to implementers of the Clinical Data Interchange Standards Consortium (CDISC) Clinical Data Acquisition Standards Harmonization (CDASH) standard version 1.1. The aim of the *CDASH Standard Version 1.1* is to describe CDISC-recommended basic standards for the collection of clinical trial data.

This *CDASH User Guide* is intended to be used together with the *CDASH Standard* that is available at www.cdisc.org, and describes how to implement CDASH for the creation of standardized Case Report Forms (CRF) used to collect data in clinical trials. CDISC recommends that *CDASH Standard Version 1.1* be read prior to this user guide (CDASH UG).

This user guide was developed to facilitate those functions involved in the planning, collection, management, and analysis of clinical trials and clinical data, including:

- Clinical Investigators
- Medical Monitors
- Clinical Research Associates (Monitors)
- Clinical Research Study Coordinators
- Clinical Data Managers
- Clinical Data and Statistical Programmers
- Biostatisticians
- Drug Safety
- CRF designers
- Other functions tasked with the responsibility to collect, clean, and ensure the integrity of clinical trial data

As described in *CDASH Standard Version 1.1*, Sponsors need to determine what additional data fields need to be added to address study-specific requirements based on regulatory and applicable business practices. Until therapeutic area (TA) specific data fields have been standardized, sponsors need to add these fields to the CDASH recommendations to fulfill their protocol-specific requirements.

The CDASH standards are part of the CDISC Technical Road Map that is designed to realize the vision of a set of harmonized standards that meet the CDISC Mission and Strategy. The set of standards has been, and will continue to be, developed to support the streamlining of processes within medical research from the production of clinical research protocols through to reporting and/or regulatory submission, warehouse population and/or archive, and post-marketing studies/safety surveillance.

## 1.2 Organization of this Document

This document has been organized into the following sections:

- **Section 1: Introduction**—Provides an overall introduction to the purpose and goals of the CDASH UG project as well as describes the organization of *CDASH UG version 1.0*.
- **Section 2: General Information**—Provides information on conformance rules for CDASH implementations, the order of variables in domain tables, terms used in this document, as well as sections on CDASH Core Designations, Normalized vs. De-normalized Data Structures, recommendations on screen failures, mapping from CDASH to the SDTM, and a section on CDASH-ODM.
- **Section 3: Domain Implementation References**—Provides specific implementation on mapping between CDASH data collection fields and SDTM Required and Expected variables, CRF form level instructions, and CRF paper and EDC examples for the following domains:

  - Common identifying and timing variables
  - Adverse Events (AE)
  - Comments (CO)
  - Prior and Concomitant Medications (CM)
  - Demographics (DM)
  - Disposition (DS)
  - Drug Accountability (DA)
  - ECG Test Results (EG)
  - Exposure (EX)
  - Inclusion and Exclusion Criteria (IE)
  - Laboratory Test Results (LB)
  - Medical History (MH)
  - Physical Examination (PE)
  - Protocol Deviations (DV)
  - Subject Characteristics (SC)
  - Substance Use (SU)
  - Vital Signs (VS)

  This section also includes tables that contain "Variables/Fields Considered Not Necessary on to Collect on CRFs." These tables describe data collection fields that were reviewed by the team during the initial development of the CDASH standard and designated as not necessary to collect on the majority of case report forms.
- **Section 4: Appendices**—Includes a list of team members, acknowledgments, and supplemental information relevant to use of CDISC standards.
- **CRF Examples**: In addition to the CRF examples that are included in each domain section of the User Guide, there are two other sets of CRF examples that are available with the User Guide:

  1. **ODM examples -** the CDASH ODM team has produced a set of ODM files from which CDASH-conformant CRFs can be produced. See Section 2.10 for more information. These ODM files will be maintained with the User Guide on the CDISC member website.
  2. **Library of example CRFs** - the CDASH User Guide team has produced some CDASH-conformant example CRFs in various EDC systems and in paper. The library of example CRFs are maintained in a folder on the CDISC member website along with the CDASH User Guide. The CDASH User Guide team will continue to add example CRFs to this folder, and we invite EDC vendors and other implementers to submit example CRFs to the User Guide team for review and possible inclusion in this library.

## 1.3 Explanation of Table Headers

- Question Text—Descriptive text for the collection field; this text may be included in the CRF completion guidelines to provide additional information about the field or it may be included with the prompt on the CRF to provide further instructions to the site.
- Prompt—The concise label, or shortened version of the Question Text, that displays for the collection field on the CRF.
- CDASH Core—The CDASH category for the collection field, including:
    - HR—Highly recommended; the field should be included on the CRF.
    - R—Recommended/Conditional; the field should be collected on the CRF if certain conditions are met.
    - O—Optional; the field may be included on the CRF if it is needed to satisfy study requirements or for the sponsor's operational database.
    - *Not Specified* – Not applicable in CDASH; not collected on a CRF.
- SDTM Variable Name—The 8 character or less SDTM data element that is part of and describes an observation in the domain.
- SDTM Variable Label—The 40 character or less descriptive label for the SDTM variable.
- SDTM Core—The SDTM category for the domain variable, including:
    - Req—Variables that are required in the SDTM domain and cannot have a null value.
    - Exp—Variables that are required in the SDTM domain but which may have a null value.
    - Perm—Variables that are included in the SDTM domain if they have been collected or derived; permissible variables may have a null value.
    - *Not Specified*—If the variable is not submitted in SDTM or there is no corresponding SDTMIG variable, the *Not Specified* notation will appear in lieu of the SDTM Variable and Core Designation. In some cases there will still be mapping information for SDTM for these CDASH Variable Names. In addition, Sponsors always have the option to map data collected in these fields using supplemental qualifiers in SDTM.
- Mapping Instructions—Supplemental information about the CDASH Variable Name as it relates to the SDTM domain, e.g., implementation guidelines, SDTM mapping instructions, usage examples, etc.

## 1.4 Information for End Users

This user guide has been developed to serve three distinct user groups in the execution of a clinical trial as it relates to the collection and the compilation of the study data. In the appendices, the organization of the user guide is shown with each section relating to its target audience and then also by listing the different target audiences followed by the sections of the user guide that will be most beneficial to that group. Certainly, some of the sections, such as the conformance rules, pertain to all three user groups. The three user groups targeted by this guide are:

- CRF Designers
- Database Builders or Administrators

- SDTM Programmers

See Appendix A for hyperlinks to the relevant sections for each End User.

### 1.4.1 CRF Designers (or Developers)

CRF Designers are those charged with using the CDASH data collection fields as "building blocks" in order to design a case report form that meets the objectives of the protocol and that facilitates proper and correct data entry. They also would be the group most likely to write CRF completion instructions and to utilize the section of the user guide that provides the detail for each of the covered domains. They would also be charged with the creation of CRF fields that do not currently exist in CDASH but are needed to address the objectives of the protocol.

### 1.4.2 Database Builders or Administrators

Database Builders (Administrators) are those that will build the study's underlying database, either in a dedicated CDMS or in an EDC environment. They would ensure that the CRF is in tune with the CDASH core designations and that any variable that is "Highly Recommended" is included on the CRF. They would also be charged with the creation of variables that do not currently exist in CDASH but are needed to address the objectives of the protocol.

### 1.4.3 SDTM Programmers

SDTM Programmers would utilize those sections of the user guide that (perhaps along with database builders) address CRF and database "structure" and would have the most understanding of the implications of what it means to collect data in a de-normalized or normalized orientation. In addition, SDTM programmers would be the group most concerned with the mapping of CDASH variables to SDTM compliant datasets.

# 2.0 General Information

## 2.1 Review the CDISC Standards Documents

Review the *CDASH Standard* in addition to this User Guide before attempting to use any of the individual domain models for data collection.

For information on preparing collected data for submissions, refer to the Study Data Tabulation Model Implementation Guide (SDTMIG), and the *Case Report Tabulation Data Definition Specification* (define.xml), available on the CDISC website, for information about an xml representation of the *Define Data Definition* document.

## 2.2 Conformance Rules for CDASH

### 2.2.1 2-Tier Conformance

Conformance to the CDASH standard is described at two levels. Tier 1 conformance, which is found in the *CDASH Standards V1.1* document, describes the minimum implementation that is required for an individual CRF to be considered "conformant" to the CDASH standard. Tier 2 conformance, which is described in this User Guide, is focused on the operational implementation of CDASH standards as described in this document.

Conformance assumes that the implementer may use a subset of the defined domains as appropriate for the study. So, for example, if an individual study does not include the collection of Inclusion/Exclusion exceptions because none were allowed, that CRF does not have to be created for the study. Implementers should bear in mind that all decisions about protocol, CRF and submission data should be in line with the expectations of the Review Division that will be receiving the submission.

Conformance also assumes that a sponsor's implementation of CDASH is done in a way that makes sense for the study being conducted, and data collection fields from one domain may be mixed with fields from another domain. So, for example, if it makes sense to ask a disposition question such as "was the subject randomized?" on the dosing CRF, or if an informed consent date is recorded on the Demographics form, these will not violate the Conformance rules, provided the conformance rules are followed.

As described in the *CDASH Standard*, Tier 1 Conformance is evaluated at the CRF level (See *CDASH Standard V1.1*, Section 1.3).

Tier 2 Conformance is evaluated at the operational level and means that:

- All Level 1 conformances are met.
- All data collection fields are defined using CDASH naming conventions in the operational database unless an equivalent SDTMIG variable can be used for data collection in a user-friendly manner (e.g., using a recommended input format for data collection)
- All non-CDASH Variable Names in CRFs follow CDASH recommendations for Creating Fields That Do Not Exist in CDASH (Section 2.4.3).
- All Best Practice recommendations in Section 3 of CDASH V1.1 are followed.

## 2.3 Terms Used in this Document

Paper CRFs vs. Electronic CRFs—the term "CRF" used throughout this document refers to both paper and electronic formats, unless otherwise specified.

Fields vs. Variables—the term data collection:

- "Fields" refers to data entry points as shown in an electronic or paper CRF.
- "Variables" refers to how the values entered into the CRF "fields" are stored in a clinical database.
- "Value set" refers to a list of valid responses that are provided to the data entry user for entering responses into a field.

Study Treatment vs. Investigational (Medicinal) Product:—the phrase "study treatment" has been used instead of "investigational (medicinal) product" to include all types of study designs and products.

Mechanisms for Data Collection—different data collection mechanisms can be used to control how data are collected (e.g., tick boxes, check boxes, radio buttons, drop-down lists, and so on). For the purposes of this document, these terms are used interchangeably.

## 2.4 Variables and How to Use Them

### 2.4.1 CDASH Core Designations

#### 2.4.1.1 Definitions

The concept of core designations is used as both a measure of compliance and a general guidance for sponsors. The CDASH core variables are categorized in the "Core" column in the domain tables as outlined in the CDASH standard. To facilitate classification of the different types of data collection fields, the following three categories were used:

- Highly Recommended
- Recommended/Conditional
- Optional

CDISC assumes that sponsors will determine which data collection fields will be collected based on TA- specific data requirements, protocol, and other considerations.

CDASH initially considered utilizing the SDTM Core Designations of Required, Expected, and Permissible to capitalize on prior understanding of these descriptive designations as well as enable a consistent categorization across CDASH and SDTM standards. Yet, when the CDASH domain tables were constructed, it quickly became apparent that CDASH core designations would often differ from SDTM core designations due to the inherent differences between the manner in which data is collected (to ensure most accurate data) and the structure in which it is reported and

submitted. For example, a variable categorized as Required in the SDTM may not be required in CDASH if it can be a derived for SDTM rather than a field captured explicitly on a CRF.

#### 2.4.1.2 Highly Recommended

The following tables provide some specific examples of these differences.

#### 2.4.1.3 Implementation Examples of Highly Recommended Fields

This table gives three examples of Highly Recommended CDASH Variable Names that do not map to Required SDTM variables, and gives the reason for the difference in the core designations between CDASH and SDTM.

| Domain | Prompt | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Reason for CDASH Core Designation | Reason for difference with SDTM Core |
|---|---|---|---|---|---|---|---|
| AE | Start Date | AESTDAT | HR | AESTDTC See additional Information for Sponsors column | Exp | The start date of an adverse event would always need to be collected. | An AE Start Date would nearly always be collected so the Sponsor can determine whether the AE occurred prior to or following exposure to the study article. The CDASH core designation of HR indicates that this field should always be present in the AE CRF. However, if it is not collected in an unusual case, the AE start date column would still appear in a SDTM AE dataset, but simply contain a NULL (or blank) value. Thus, the SDTM core designation of Exp is appropriate for the submission standard. |
| EG | ECG Performed | EGPERF | HR | EGSTAT | Perm | This is needed as a data management tool to verify that missing results are confirmed missing. | Since this "flag" field is primarily used for reconciliation of collected data not "Required" for submission. |
| IE | Met criteria | IEYN | HR | *Not Specified* | *Not Specified* | This is a Yes/No question that is intended to be used primarily as a monitoring or data management tool to verify that the investigator/site reported any entry criteria that were not met for this subject. | This field is not submitted and therefore has no SDTM Core designation. |

#### 2.4.1.4 Recommended/Conditional

A CDASH Recommended/Conditional field is a data collection field that should be collected on the CRF for specific cases or to address TA requirements (although it may be recorded elsewhere in the CRF or from other data collection sources). This is approximately equal to an Expected variable in the SDTM, which is a variable that must be in the dataset, but which may or may not be populated.

#### 2.4.1.5 Implementation Examples of Recommended/Conditional fields

| Domain | Prompt | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Reason for CDASH Core Designation | Reason for difference with SDTM Core |
|---|---|---|---|---|---|---|---|
| AE | Start Time | AESTTIM | R/C | *Not Specified* | *Not Specified* | Collecting the time an AE was started is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail. An example would be in an early phase study where the subject is under the direct care of the site at the time the event started and the study design is such that it is important to know the AE start time with respect to dosing. | No SDTM Core designation since there is no direct one-to-one mapping to a variable for time AE started within the SDTM.<br><br>If collected, AESTTIM would be derived into the AESTDTC variable in SDTM. |
| DA | Date Dispensed | DADDAT | R/C | DADTC | Exp | The date study treatment dispensed should be recorded for each dispensation for a study with multiple periods or multiple products dispensed. | DADTC must always be included in the dataset, but may be null. |
| EX | End Date | EXENDAT | R/C | EXENDTC | Perm | The "condition" under which EXENDAT would be needed in a CRF is when a start date and end date are not expected to be on the same date.<br>If the trial design indicates that the start and end date are on the same day, the end date is not required since it can be assigned to be equal to the start date. | SDTM states that this may not be relevant for injections and has set the Core designation for this variable as Permissible (similar to optional) rather than Expected. |

#### 2.4.1.6 Optional

A CDASH Optional data collection field is one that is available for use if needed. This is roughly equivalent to a Permissible variable in the SDTM and should be used in a domain as appropriate when the data need to be collected or derived in the CRF.

### 2.4.1.7 Implementation Examples of Optional fields

| Domain | Prompt | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Reason for CDASH Core Designation | Reason for difference with SDTM Core |
|---|---|---|---|---|---|---|---|
| AE | Ongoing? | AEONGO | O | *Not Specified* | *Not Specified* | This field will be completed to indicate that the AE has not resolved at the time of data collection. Upon study completion, it is expected that every reported AE should have either an End Date or the Ongoing field will be completed, but not both.<br>The purpose of collecting this field is to help with data cleaning and monitoring, since this field provides further confirmation that the End Date was deliberately left blank. | This is not a direct mapping to the SDTMIG variable AEENRF. The date of data collection in conjunction with End Date and the Ongoing CDASH Variable Names would determine how the SDTMIG variable AEENRF would be populated.<br>In some cases, this information may be determined from AE Outcome. |
| ECG | Subject Position | EGPOS | O | EGPOS | Perm | Results may be affected by whether conditions for ECG as specified in the protocol were properly met. One common condition is the subject's position (e.g., Supine, Standing).<br>If the protocol requires this type of information, then this question may be included to confirm that the subject's position matches the protocol.<br>The following are examples of when it is not necessary to collect these data on the CRF:<br>• Position of the Subject is provided as part of the electronic data<br>• Position of the Subject is not pertinent to the protocol<br>• The protocol specifies only one possible position and the sponsor does not feel there is significant risk of the sites performing the ECG with the subject in the wrong position | No significant difference in Core designation. |
| IE | Criterion Description | IETEST | O | IETEST | Req | This information would either be populated on the eCRF when the site | The SDTM IETEST value is Required for submission but can be derived from |

| Domain | Prompt | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Reason for CDASH Core Designation | Reason for difference with SDTM Core |
|---|---|---|---|---|---|---|---|
| | | | | | | entered the IETESTCD and would not necessarily have to be a separate data collection field; or it would appear in the protocol entry criteria list, or on an eligibility worksheet for the subject.<br>The corresponding IETESTCD is Highly Recommended and would need to be recorded in the CRF/eCRF for each criterion that was not met by the subject.<br>The underlying database would then use the IETESTCD to populate IETEST for the submission dataset. | the IETESTCD that is collected in the database. This allows IETEST to be Optional within CDASH. |

### 2.4.2 Using Fields That Do Exist in CDASH

In order to meet Tier 2 conformance, implementers should use CDASH naming conventions for all CDASH defined fields in the operational database. The CDASH naming conventions may be used as either the full variable name or the root (or core) name of the variables in the operational database as needed. The goal is to have end-to-end traceability of the variable name from the data capture system to the SDTM datasets.

It is recognized that particularly in an EDC system, the variable name of a data collection field, as well as the name in the underlying database, may have various "system" components that become part of the item's identifier. EDC systems, prior to exporting data in a defined format, may require the variable name to include such database "references" as the EDC page name, the item "group" name, or perhaps a combination.

Examples could include:
<refname> CONMED_IG_CM.IT_CMINDC
<refname> STDYDRUG_IG_EX.IT_EXSTDAT (mapped as part of EXSTDTC)
<refname> STDYDRUG_IG_EX.IT_EXSTTIM (mapped as part of EXSTDTC)

As stated above, as long as the CDASH Variable Name name is contained within the system variable name, the eCRF page/item would be considered CDASH conformant.

### 2.4.3 Creating Fields That Do Not Exist in CDASH

Adding new collection variables is often constrained by business rules and systems. The naming conventions and other variable creation recommendations in CDASH are designed to aid implementers and facilitate traceable mapping to submission datasets. See Appendix B for more detailed implementation information and examples.

Prior to adding any new variables to current domain models, review the CDASH model as well as this User Guide. When adding variables not already defined in a CDASH domain, they will fall under one of these categories:

- A variable that is used for data cleaning purposes only, and is not submitted in SDTM (e.g., were any concomitant medications taken?).
- A variable with a response that can be mapped directly into SDTM with no change from how it was collected (e.g., Adverse Event reported term).
- A variable that will eventually be mapped into SDTM, but is collected in such a way that it requires some sort of change from the way it was collected (e.g., collected dates and times that are reported in ISO 8601 format).

In general, when an implementer is creating new data collection fields and the corresponding database variables, the process should follow, within the boundaries of your data management system, the general guidelines that are used for CDASH Variable Names and variables. These guidelines are:

- For fields:
  - With a direct mapping to an SDTM variable: If a value can be collected exactly as it will be reported in SDTM, the SDTM variable should be used in the operational database to streamline the mapping process. In other words, any collection variable whose meaning is the same as an SDTM variable should be a copy of the SDTM variable, and its label and meaning should not be modified for data collection. Implementers should follow CDISC variable fragment naming conventions. See SDTMIG V3.1.2 Appendices C1, C5, and D.
  - Without a direct one-to-one mapping to SDTM: If a study requires a field that is not identical to an SDTM field, for example the data type in which it is collected is different from the SDTM data type, or the SDTM variable is derived from collected data, the operational database should use a different name from the SDTM variable into which it will be mapped. An example would be if a study collects Findings data in a de-normalized format and then maps the data to the normalized SDTM format. Implementers should follow CDISC variable fragment naming conventions, and CDASH naming conventions where they exist (e.g., --DAT for dates, --TIM for times, --YN for prompts, etc).
- Use of Controlled Terminology for data collection:
  - In general, if controlled terminology can be used for a data collection field, it should be used. The use of free text fields should be limited.
  - If a CDISC Controlled Terminology list exists for the field, it should be used, or a subset of it should be used as appropriate for the study.
    - Extensible Code Lists may have sponsor/study—specific terms added to them. Make sure a synonymous terms does not already exist in the code list
    - Non-extensible code lists should be used as they are, or a subset of them should be used as appropriate for the study. See CDISC Controlled Terminology for information on requesting new terms for Code Lists.
    - If the study requires a different set of terms for any code list that exists in CDISC Controlled Terminology, ensure that the collected data can be mapped to the CDISC code list for submission.
- When creating new data collection fields, and to facilitate mapping of collected data into SDTM data sets Implementers should refer to the:
  - List of reserved domain codes in the current SDTMIG and use those that are applicable for creating new variables.

- Variable naming fragments in the current SDTMIG and use those that are applicable for creating new variables.

### 2.4.4 Mapping from CDASH to SDTM Datasets

The CDASH project identifies the basic data collection fields needed from a clinical, scientific, and regulatory perspective to enable more efficient data collection at the investigative sites. The SDTM and the SDTMIG provide a standard for the submission of data based on collected data. CDASH moves upstream in the data-flow and identifies a basic set of highly recommended and recommended/conditional data collection fields that are expected to be present on the majority of CRFs. When applicable the CDASH data collection fields can be mapped to the SDTM structure. When the data are identical between the two standards, the SDTMIG variable names are presented in the CDASH domain tables. In cases where the data are not identical, CDASH has suggested new variable names. As part of this mapping, *SDTMIG* variable names have been provided under the "Additional Information for Sponsors" column where applicable as an aid.

SDTM and CDASH are clearly related. All *SDTMIG* Required variables have been discussed and included in the CDASH standard, determined to be derivable, or can be obtained from data sources other than the CRF. Therefore, there are instances where the variables do not exactly match due to their different purposes (i.e., data submission vs. data collection).

#### 2.4.4.1 SDTM Variables Not Included in CDASH

CDASH has attempted to approach data collection with efficiency and consistency, and has always kept the SDTM mapping as an ultimate goal. Therefore, when an SDTM variable is Required or Expected, CDASH has addressed this either by directly collecting the variable, or providing implementation guidance on how to obtain that variable from derivations of collected data, or mappings from the operational databases.

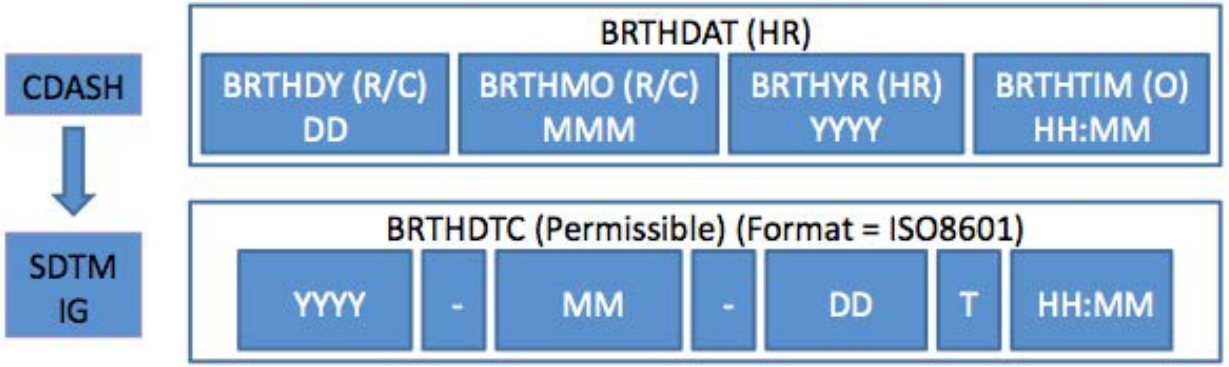
#### 2.4.4.2 CDASH Fields With No Mapping to SDTM

The CDASH recommendation also includes some data collection fields that are not included in the SDTMIG (e.g., "Were there any adverse events?" or "Were any concomitant medications taken?"). These "operational" fields are intended to assist in the cleaning of data and in confirming that no data are missing. To facilitate the use of these types of fields, suggested variable names are provided (e.g., AEYN, CMYN, CMONGO) in the "Variable Name" column and are shaded to denote that they are CDASH-suggested data collection variable names and not SDTMIG variable names.

### 2.4.5 Mapping collected dates and times to SDTM

CDASH recommends an unambiguous format for collecting dates. Examples include using a format of DD-MMM-YYYY where "DD" is the day as a 2-digit numeric value, "MMM" is the month as a 3- character letter abbreviation in the local language, and "YYYY" is the year as a 4-digit numeric value; or using a pop-up calendar in an EDC system.

Any date can be composed of one or more of the elements of year, month, day and time. These components can be stored in a single variable or as a separate variable for each of the components. BRTHDAT is used in the example below.




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

**YYYY-MM-DDThh:mm:ss**

where:

[YYYY] = four-digit year

[MM] = two-digit representation of the month (01-12, 01=January, etc.)

[DD] = two-digit day of the month (01 through 31)

[T] = (time designator) indicates time information follows

[hh] = two digits of hour (00 through 23) (am/pm is NOT allowed)

[mm] = two digits of minute (00 through 59)

[ss] = two digits of second (00 through 59)

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

[-] (hyphen): to separate the time Elements "year" from "month" and "month" from "day" and to represent missing date components.

[:] (colon): to separate the time Elements "hour" from "minute" and "minute" from "second"

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.

(Source: SDTMIG V.3.1.2, section 4.1.4.1 – 4.1.4.2)

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 (CDASH format) | Precision | ISO 8601 Date/Time (SDTM format) |
|---|---|---|
| 15 Dec 2003 13:14 | Complete date and time – unknown seconds | 2003-12-15T13:14 |
| 15 Dec 2003 | Complete date – unknown time | 2003-12-15 |
| Dec 2003 | Unknown day – unknown time | 2003-12 |
| 2003 | Unknown month, day and time | 2003 |

In any process where a date is being captured in an electronic system, the entry field should be displayed to the user in a format that is consistent with the CDASH standard. As long as the displayed field is CDASH conformant (i.e., unambiguous), the date(/time) may be stored in the data capture system and/or underlying database in any format, and this will not violate CDASH conformance.

### 2.4.6 RELREC: Creating Relationships between Collected Case Report Form Data

Data collected on Case Report Forms can have traceable relationships that can be represented in SDTM. Capturing these relationships on the CRF supports the creation of Related Records (RELREC) in SDTM. In order to be able to establish RELREC, the relationship must be collected on the CRF. For example, in some companies it can be common practice to collect Adverse Events (AE), and document if those AEs had a Concomitant Medication (CM) as an action taken. Similarly, CM CRFs can solicit if the reason the subject took the medication was due to an AE. If these relationships are documented on the CRF as questions, and the AE and CM relationship is collected, RELREC can be populated in SDTM from these collected data.

There are many ways to establish a RELREC relationship, the most common being between 2 records in separate datasets (or domains) such as AE and CM, LB and AE, and AE and DS. See the SDTMIG v3.1.2 section 8.0 for a discussion on this topic. For the purpose of this section, collecting information for relationships between AE and CM, and AE and DS records will be described.

Note the use of variables CMSPID, CMAENO, AESPID, AEDIS, and DSSPID in the following examples. These variables are used to create the needed RELREC relationships in SDTM.

### 2.4.6.1 RELREC Example 1—AE/CM

In Example 1 below, subject 001 had an Adverse Event (AESPID=3) of Hypercholesterolemia on 17-Sep-2007. It was categorized as ongoing with a mild severity and an action taken of "Other Medication." The other medication which was given for the AE is Mevacor, shown in the CM record with a CMSPID of 6. Similarly, in the CM file a con med of Mevacor (CMSPID=6) was taken on 14-Oct-2007. The dose was 40 mg once a day, and it was recorded to have been taken for AESPID 3. This recorded information is sufficient enough to produce a RELREC, shown in the last table. The RELREC is related by AESPID and CMSPID. IN SDTM, RELREC relationships are at the record level within datasets; however the relationship needs to be created at the variable level within CDASH.

**AE record:**

| AESPID | STUDYID | SUBJID | AETERM | AESTDAT | AEENDAT | AEONGO | AESEV | AESER | AEREL | AEACN | AEACNOTH | AEOUT | AEDIS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 3 | ABC-123 | 001-001 | Hypercholesterolemia | 17-Sep-07 | | Y | MILD | N | N | NONE | OTHER MEDICATION | NOT RECOVERED/ NOT RESOLVED | N |

**CM record:**

| CMSPID | STUDYID | SUBJID | CMTRT | CMINDC | CMDSTXT | CMDOSU | CMDOSFRQ | CMSTDAT | CMPRIOR | CMENDAT | CMONGO | CMAENO |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 6 | ABC-123 | 001-001 | Mevacor | Hypercholesterolemia | 40 | mg | QD | 14-Oct-07 | Y | | Y | 3 |

**RELREC record:**

| Row | STUDYID | RDOMAIN | USUBJID | IDVAR | IDVARVAL | RELTYPE | RELID |
|---|---|---|---|---|---|---|---|
| 1 | ABC-123 | AE | ABC-123-001-001 | AESPID | 3 | | 1 |
| 2 | ABC-123 | CM | ABC-123-001-001 | CMSPID | 6 | | 1 |

### 2.4.6.2 RELREC Example 2—AE/DS

In Example 2 below, subject 001 was involved in a cholesterol lowering trial. An Adverse Event (AESPID=3) of Hypercholesterolemia was recorded on 17-Sep-2007. It was categorized as ongoing, with a severity of severe and an action taken of "Other Medication." AEDIS "Did the adverse event cause the subject to be discontinued from the study?" has been checked "Yes."

The subject also discontinued the study on 30-Sep-2007 because of Hypercholesterolemia, as "Lack of Efficacy". The AEDIS variable creates the relationship between the AE form and the End of Study form.

This recorded information is sufficient enough to produce a RELREC, shown in the table below. The RELREC is related by AESPID and DSSPID. IN SDTM, RELREC relationships are at the record level within datasets; however the relationship needs to be created at the variable level within CDASH.

**AE record:**

| AESPID | STUDYID | SUBJID | AETERM | AESTDAT | AEENDAT | AEONGO | AESEV | AESER | AEREL | AEACN | AEACNOTH | AEOUT | AEDIS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 3 | ABC-123 | 001-001 | Hypercholesterolemia | 17-Sep-07 | | Y | SEVERE | N | N | DRUG WITHDRAWN | OTHER MEDICATION | NOT RECOVERED/ NOT RESOLVED | Y |

**DS record:**

| DSSPID | STUDYID | SUBJID | DSCAT | DSTERM | DSDECOD | DSSTDAT |
|---|---|---|---|---|---|---|
| 1 | ABC-123 | 001-001 | DISPOSITION EVENT | HYPERCHOLESTEROLEMIA | LACK OF EFFICACY | 30-SEP-2007 |

**RELREC record:**

| Row | STUDYID | RDOMAIN | USUBJID | IDVAR | IDVARVAL | RELTYPE | RELID |
|---|---|---|---|---|---|---|---|
| 1 | ABC-123 | AE | ABC-123-001-001 | AESPID | 3 | | 1 |
| 2 | ABC-123 | DS | ABC-123-001-001 | DSSPID | 1 | | 1 |

## 2.5 General Recommendations on Screen Failures

Screen failure data are data collected for those who fail screening and who are not subsequently enrolled in the study. Section 10.1 of *ICH E3* describes the reporting of subject disposition in the clinical study report. This section states that it may be "relevant to provide the number of patients screened for inclusion and a breakdown of the reasons for excluding patients during screening, if this could help clarify the appropriate patient population for eventual drug use." Although screen failure data may not be relevant for all studies, it is recommended that screen failure data be proactively collected in all studies to avoid issues associated with retroactive collection of screen failure data, such as inaccuracies and workflow management. Proactive and timely collection of screen failure data may also be used to identify eligibility criteria that contribute to enrollment challenges.

Using CDASH, the minimum data to be collected should include a subject identifier and reason for screen failure. The subject identifier is needed to avoid double counting subjects who repeat the screening procedure. The possible reasons for screen failure should optimally include refusal to participate and the individual ineligibility criteria. Typically, there is a reason on the End of Study form indicating "Screen Failure". This information allows overall summarization of all subjects screened/enrolled and when captured, provides easy subject accountability for the Clinical Study Report. Other data may be considered for collection, such as date of informed consent, sex, race, date of birth or age, or other data to further describe the reason for ineligibility (e.g., the lab value that was out of range).

SDTM does not provide a separate domain specifically for screen failure data and does not require that the screen failure data be included in SDTM. Data for screen failure subjects, if submitted, should be included in the appropriate SDTM domains. Reference the SDTMIG V3.1.2 for further guidance on submitting Screen Failure data.

## 2.6 Data Collection to Facilitate Coding

### 2.6.1 General Considerations

Adverse events, Medical History and prior and concomitant medications are often coded to standard dictionaries (thesauri). There are many coding dictionaries, but this section will use the Medical Dictionary for Regulatory Activities (MedDRA®) and the World Health Organization Drug Dictionary (WHO-DD) as examples.

The SDTMIG variable AEDECOD is the dictionary-derived text description of AETERM (the reported term for the adverse event) or AEMODIFY (the modified reported term). In MedDRA® the AEDECOD is the Preferred Term and is a required variable. Corresponding SDTMIG variables CMDECOD (for medications) and MHDECOD (for medical history items) are permissible. It is the equivalent of the preferred term in the dictionary used for coding, and is a required variable. Corresponding SDTMIG variables CMDECOD (for medications) and MHDECOD (for medical history items) are permissible.

Although these --DECOD variables are typically not collected on (e)CRFs, and are therefore outside the scope of CDASH, they are each derived from variables that **are** collected (AETERM, CMTRT, and MHTERM, respectively). Hence, conventions adopted in the collection of these reported terms can have an impact on the resulting --DECOD variables. For this reason, CDASH recommends (Section 3.4, Ref. #11 of the Standard, Version 1.1) that guidance be provided to the sites to ensure clear reporting of adverse events, prior and concomitant medications and medical history items.

It is recommended that implementers consult with medical coders, review relevant documentation and ensure that all elements needed to facilitate the coding process are collected.

### 2.6.2 Adverse Events and Medical History Items

With regard to adverse events and medical history items, the CDASH standard (Section 3.4, Ref #11, Section 5.3, Item #3, and Section 5.13, Item #5) offers some guidance on the recording of reported terms. Additional guidance may be derived from the document *MedDRA® Term Selection: Points to Consider*, which is released with every update of the MedDRA® Dictionary. Although this document is intended to promote accurate and consistent term selection during the coding activity, many of the issues and problems of term selection discussed in the document may be prevented if sites are offered guidance and training in order to avoid their occurrence. Data managers are encouraged to enter into discussion with coding specialists and medical staff to develop guidance to sites in accordance with applicable coding conventions and other company/project agreements and requirements.

The examples in the following paragraphs consider some of the more common or significant issues. These examples have been derived from the MedDRA® *Points to Consider* document, which is designed specifically for use with the MedDRA® Dictionary. However, the Guidance that can be derived from this document may be valuable when other dictionaries are being used.

- Most sponsors employ "out of context" coding, i.e. the coder is supplied with a reported term, without any further information for that subject (not even other reported terms – coding is typically done without subject identifiers). Full out-of-context coding would mean that the coder is also not coding with regard to any characteristics of the study (e.g., study drug, indication, etc.) Sites should be advised that "nothing can be assumed", and that the reported term should include all information relevant to the event being reported. For example, if "Congestion" is reported as an adverse event for a particular subject together with several other pulmonary events, the coder cannot assume that the congestion is "Lung congestion", rather than congestion of some other organ (e.g. nose, ear, etc.). The reported term "Congestion" will need to be queried before it can be coded.

- The MedDRA® Dictionary permits the coding of some terms reported without complete specificity, and this may not always be desirable. For example, the reported term "Chest Pain" has a direct match in the MedDRA® thesaurus; its preferred term is "Chest Pain", and the Primary SOC (System Organ Class) is "General disorders and administration site conditions". However, the reported term "Chest Pain – Cardiac" is associated with the preferred term "Angina pectoris" and the Primary SOC "Cardiac disorders". In some drug development programs, this distinction may be important. In the absence of guidance to sites, the sponsor has little alternative but to query the reported term "Chest Pain" in order to discover whether or not it is cardiac in origin. Guidance and training would remove the need for most of these queries.

- Certain abbreviations are ambiguous, and should be avoided. For example, "GU Pain" could refer to genito-urinary pain or gastric ulcer pain. Sites should be advised to avoid potentially ambiguous abbreviations, and may even be supplied with a list of acceptable and/or unacceptable abbreviations. If ambiguous abbreviations are presented for coding, the sponsor has little choice but to query the site or to use a generic code such as "Pain".

- If a diagnosis is reported together with one or more of its characteristic signs or symptoms, it is recommended to code the diagnosis; for example, "chest pain due to myocardial infarction" would be coded to "myocardial infarction" unless myocardial infarction is already reported as a separate AE. However, if the diagnosis could represent a pre-existing condition, the situation is not so simple. Consider the example "Shortness of breath due to cancer". If the cancer is a pre-existing condition that has not worsened, then it belongs in the subject's medical history (where it might be coded separately), and "shortness of breath" is the event that should be coded. If the cancer is worsening, or is a new event, then the cancer should be coded. Sites should be offered guidance on how to report such occurrences. In this case, if the site reports "Shortness of breath due to pre-existing cancer", the situation is clear.

- The MedDRA® Points to Consider document advises coders to make a clear distinction between definitive and provisional diagnoses. The preferred option for a provisional diagnosis is to select a term for the diagnosis and terms for signs and symptoms. A provisional diagnosis may change (or a definitive diagnosis may not become available before the end of the trial), whereas signs and symptoms do not. For example, the preferred coding option for "myocardial infarction with chest pain, diaphoresis and dyspnea" is "myocardial infarction. The preferred coding option for "possible myocardial infarction with chest pain, diaphoresis and dyspnea" is to code both the diagnosis and the symptoms. Sponsors are free to select a coding option other than the preferred, but it is important that sites are given clear guidance so that the option selected for coding can be applied consistently.

### 2.6.3 Medications

With regard to medications, the CDASH standard (Section 3.4, Ref #11, and Section 5.5, Item #3) offers some guidance on the recording of medication names, and on the use of additional Recommended/Conditional data collection fields (e.g., CMROUTE, CMINDC) to facilitate coding. The following paragraphs describe the potential implications on the coding of medications of choices and conventions around what is collected on the (e)CRF.

The purpose of coding medications is usually to provide a "Standardized Medication Name" (CMDECOD) and a "Medication Class" (CMCLAS). Most dictionaries facilitate the derivation of the Standardized Medication Name on identification of the medication that was taken. However, identifying a medication completely and precisely is not always easy, for various reasons.

Some drugs with very similar names have different ingredients, for example:

- ProAir® and Pro-Air™ are both medications for treatment of asthma and COPD, but the former contains albuterol sulfate or fluticasone proprionate, whereas the latter contains procaterol hydrochloride
- "Children's Tylenol® plus cold", "Children's Tylenol® plus cold & allergy", "Children's Tylenol® plus cold & cough", and "Children's Tylenol® plus multi-symptom cold" are not the same. Paracetamol and phenylephrine hydrochloride are common ingredients to all four, but additional ingredients differ

- "Drazepam" could be a mis-spelling of diazepam or prazepam, similar types of drug, but different nonetheless. For misspellings, where the appropriate medication is not immediately apparent, the medication name should be queried for confirmation.

In an ideal world, it would be preferable to collect all the ingredients of a particular medication. However, in a clinical trials setting, the best we can probably hope for is to obtain the exact, complete, correctly spelled brand name. Experience has shown that requesting the generic name of a drug results in inconsistencies with regard to the inclusion or exclusion of the salt/ester. For example, betamethasone dipropionate is used topically; however, if the site records only betamethasone, which can be administered orally, as drops, or inhaled, the topical route of the drug will be lost. In this case collecting route of administration (CMROUTE) or the indication (CMINDC) would provide the additional information needed to code this medication.

In the WHO Drug Dictionaries medicinal products are classified according to the main therapeutic use of the main active ingredient, on the basic principle of only one medication class (ATC – Anatomic, Therapeutic, Chemical code) for each pharmaceutical formulation. However, a product can have two or more possible ATC codes if it is available in two or more strengths or formulations with clearly different therapeutic uses. In addition, a product may be used for two or more equally important indications, and the main therapeutic use of a drug may differ from one country to another. This will often give several classification alternatives.

Where multiple medication classes are available, selecting the "preferred" class may require additional information. Some sponsors classify medications according to their usage, in which case it is important to collect the indication (CMINDC) for which the medication was used. For example, aspirin used as prophylaxis for cardiovascular problems is typically classified within the Blood and Blood Forming Organs anatomic class, whereas its use for pain relief is typically classed within the Nervous System anatomic class. With some drugs, route (CMROUTE) can help accurately determine the correct usage class.

Regardless of the sponsor's coding philosophy, the country of manufacture of the drug can be important in a small number of cases. For example, tamsulosin is marketed in the US under the name Flomax®, and is used to treat BPH (benign prostatic hyperplasia). However, in Italy, tamsulosin is marketed under the name Omnic®, because Flomax® in that country is a brand name for morniflumate, a non-steroidal anti-inflammatory agent.

In summary, when medications are to be coded, it is recommended that the indication (CMINDC) and route (CMROUTE) or anatomical location (CMLOC) be collected along with the medication name. As stated earlier, it is also recommended that implementers consult with medical coders before finalizing the choices of variable to be collected on the CRF to ensure that the coders have sufficient information to be able to accurately complete the coding.

## 2.7 Order of Fields in Each Domain

CDISC has ordered the fields in the CDASH domain tables using the order that was typically observed in the CRF samples that were reviewed. Although the layout of CRFs is out of scope for CDASH V1.0 and V1.1, as an aid to implementers, CDASH tables present the CRF fields in the order they would typically be found on a CRF.

When deciding on the order of fields in a CRF, implementers should consider how the CRF is being used. When designing a CRF consider the following:

- Headings – Place fields that are routinely collected on multiple forms at the top or beginning of the form. Providing the clinical site with a consistent order of these fields will result in more reliable data. For example, if the collection date and time are both collected, they should appear first and second respectively on each form where they are both collected.

- Clinical flow – Fields should be placed on the form in the order that they are expected to be collected during the clinical assessment. It is acceptable to include fields from different domains on the same form. Some datasets have a more predictive clinical flow than others. For example if the clinician asks for a concomitant medication dose, they will most likely ask in this order: dose, unit, frequency and route.
- Group related fields for a single clinical encounter together, although multiple clinical encounters (ex. visits or time points) may appear together on one form. For example, if heart rate and temperature are taken every hour for four hours on study day 1, the form can collect the data for Hour 1 (heart rate result and unit, temperature result and unit), followed by the data for hour 2, and followed by hour 3 and 4. In this scenario, there would be labels indicating each time point within the Day 1.
- Group related fields together. Test results and their associated units should always appear next to each other. For example, the results of the ECG test PR should be followed by units.
- Data that are dependent on other data should be placed in such as way that this dependence is obvious. For example, if there is a question where Other, specify is an option, the text box used to specify the other item should be placed immediately after the initial item, and should be indented or otherwise formatted to show it is a subpart of the original question.
- If the source data are collected on a separate source document and the data are transcribed to the CRF, the ideal CRF field order would follow the source data field order.

## 2.8 Data Structures: Normalized vs. De-normalized

The CDASH Findings domain tables (e.g., DA, EG, IE, LB, SU, and VS) are presented in a structure that is similar to the SDTM submission model, which is to list the variable names and some examples of the tests in a normalized structure, even though many Data Management systems collect the data in a de-normalized structure. Listed below are representations of data in their de-normalized and normalized structures.

It is expected that implementers will need to modify to include protocol specific tests in a CRF presentation layout. Sponsors should use the CDASH recommendations to identify the types of data to collect while referring to the SDTM and CDISC Controlled Terminology for additional metadata, (e.g., labels, data type, controlled terminology, and so on).

The format for data being exported from many DM systems is de-normalized. A de-normalized dataset is a dataset structured as a “short and wide” file. In this case (see 2.8.1.1), the tests are all listed horizontally (de-normalized) across the page for each subject record. The file shows one record per subject visit, with all tests and results displayed horizontally across the page. This format is sometimes optimal and simplest for entering data. Simplicity during data entry is important because it facilitates cleaner data collection. However, this format is not optimal for data analysis and reporting as it is difficult to do accurate counts of data because all tests are on one line.

Conversely, a normalized dataset is structured as “long and narrow.” The file shows one test per record or one test per row. In this case, (see 2.8.1.2), the tests are all listed vertically (normalized) down the page for each test for each subject. The tests become standalone records as compared with one record per visit. This format is optimal for data mining as it allows a user to easily count tests and results. This format is also the format that was adopted by the CDISC SDS team. However, it can complicate entry of data in some cases.

Both normalized and de-normalized data capture are conformant to CDASH provided that naming convention rules are followed and controlled terminology are used where available. Implementers need to evaluate their needs and their data entry system to determine which method will provide optimal data collection.

Other sections of the SDTM standard are intentionally not reproduced in this document. Implementers should refer to the SDTM and SDTMIG on the CDISC website for additional information (http://www.cdisc.org/standards ).

### 2.8.1 Comparison of Normalized vs. De-normalized Data Structures

| Data Structure | Variable Name | Advantages | Disadvantages |
|---|---|---|---|
| Normalized | Variable names are, for example, –TEST, --TESTCD, --ORRES, --ORRESU | There is no additional mapping required for data analysis or submission.<br><br>***Example:*** LBTEST is already normalized to collect all verbatim test names performed by a clinical laboratory (e.g., Sodium, Potassium, and so on).<br>***Example:*** VSTESTCD is normalized to collect all short names for vital signs (e.g., DIABP, RESP, and so on).<br>***Example:*** QSORRES is normalized to collect all findings as originally received or collected (e.g., 'No change', 'Very much improved', and so on).<br>***Example:*** a single variable DATEST is used to collect the accountability assessment (i.e., 'DISPAMT' and 'RETAMT'). | The value-level metadata must be provided. The individual test names have to be collected on the CRFs and captured in the database, or derived in the dataset.<br>Normalized data collection is much simpler, with one result variable and one unit variable.<br><br>In QS there can be different numbers of responses for different questions and they can use different code lists, which adds complexity to a normalized data collection. |
| De-normalized | Variables names are derived from the controlled terminology, where available or the test code values to be defined by the sponsor. | Variables are de-normalized and there is no need to populate the value-level metadata.<br><br>***Example:*** Variable 'SODIUM' is used to collect Sodium level.<br>***Example:*** Variable 'PULSE' is used to collect Pulse rate data.<br>***Example:*** Variable 'VMIMPROV' shows the finding of 'Very much improved'.<br>***Example:*** Variable 'DISPAMT' represents the "What is the amount dispensed?' and 'RETAMT' represents 'What is the amount returned?' for the accountability assessment. | Additional programming is needed to restructure data into the for data analysis/submission.<br>A separate units variable is needed for each test. |

## 2.8.2 LB Domain

### 2.8.2.1 De-normalized Example—LB

| Subject | Timepoint | Draw_date | Sodium | Potassium | Chloride | Glucose | Calcium | Urea Nitrogen | Creatinine | Bilirubin | AST | ALT | Protein | Cholesterol | Triglycerides | Platelet Count |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Screening | 7-Aug-03 | 143 | 4.8 | 98 | 4.8 | 2.48 | 5.4 | 72 | 7.1 | 26 | 18 | 80 | 6.36 | 1.62 | 228 |
| 1 | Visit 1 | 14-Aug-03 | . | . | . | 5.1 | . | . | . | . | . | . | . | . | . | . |
| 1 | Visit 2 | 21-Aug-03 | . | . | . | 5.5 | . | . | . | . | . | . | . | . | . | . |

### 2.8.2.2 Normalized Example—LB

| SUBJID | LBSPID | LBTESTCD | LBTEST | LBCAT | LBORRES | LBORRESU | LBORNRLO | LBORNRHI | VISIT | VISITNUM | LBDTC |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ABC-123-01-01-001 | 1 | ALT | ALANINE AMINOTRANSFERASE | CHEMISTRY | 18 | U/L | 0 | 40 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 2 | AST | ASPARTATE AMINOTRANSFERASE | CHEMISTRY | 26 | U/L | 3 | 44 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 3 | BILI | BILIRUBIN | CHEMISTRY | 7.1 | µmol/L | 0 | 17 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 4 | BUN | BLOOD UREA NITROGEN | CHEMISTRY | 5.4 | mmol/L | 2.9 | 8.9 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 5 | CA | CALCIUM | CHEMISTRY | 2.48 | mmol/L | 2.1 | 2.6 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 6 | CL | CHLORIDE | CHEMISTRY | 98 | mmol/L | 99 | 108 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 7 | CHOL | CHOLESTEROL | CHEMISTRY | 6.36 | mmol/L | 3.3 | 6.18 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 8 | CREAT | CREATININE | CHEMISTRY | 72 | µmol/L | 68 | 118 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 9 | GLUC | GLUCOSE | CHEMISTRY | 4.8 | mmol/L | 3.9 | 6.1 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 10 | PLAT | PLATELET | HEMATOLOGY | 228 | 10^9/L | 130 | 400 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 11 | K | POTASSIUM | CHEMISTRY | 4.8 | mmol/L | 3.9 | 5.3 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 12 | PROT | PROTEIN | CHEMISTRY | 80 | g/L | 6.2 | 7.8 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 13 | SODIUM | SODIUM | CHEMISTRY | 143 | mmol/L | 136 | 142 | SCREENING | 0 | 2003-08-07 |

| SUBJID | LBSPID | LBTESTCD | LBTEST | LBCAT | LBORRES | LBORRESU | LBORNRLO | LBORNRHI | VISIT | VISITNUM | LBDTC |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ABC-123-01-01-001 | 14 | TRIG | TRIGLYCERIDES | CHEMISTRY | 1.62 | mmol/L | 0.45 | 1.69 | SCREENING | 0 | 2003-08-07 |
| ABC-123-01-01-001 | 15 | GLUC | GLUCOSE | CHEMISTRY | 5.1 | mmol/L | 3.9 | 6.1 | Visit 1 | 1 | 2003-08-14 |
| ABC-123-01-01-001 | 15 | GLUC | GLUCOSE | CHEMISTRY | 5.5 | mmol/L | 3.9 | 6.1 | Visit 2 | 2 | 2003-08-21 |

## 2.8.3 VS Domain

### 2.8.3.1 De-normalized Example—VS

| CASE_ID | VISITNUM | SITEID | SUBJID | VISDAT | PAGE | FORMNAME | STUDYID | PTINIT | PULSE | SYSBP | DIABP | TEMP | RESP | HEIGHT | WEIGHT |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 001-001 | 0 | 1 | 1 | 24-Mar-98 | 4 | VITALS_1 | ABC-124 | TNK | 102 | 130 | 85 | 97.7 | 18 | 63 | 143.9 |
| 001-001 | 1 | 1 | 1 | 17-Apr-98 | 7 | VITALS_2 | ABC-124 | TNK | 64 | 120 | 76 | 98.2 | 18 | . | . |

### 2.8.3.2 Normalized Example—VS

| STUDYID | SUBJID | VSSPID | VSTEST | VSORRES | VSORRESU | VISIT | VISITNUM | VSDAT |
|---|---|---|---|---|---|---|---|---|
| ABC-124 | ABC-124-001-001 | 1 | DIASTOLIC BLOOD PRESSURE | 85 | mmHg | SCREENING | 0 | 1998-03-24 |
| ABC-124 | ABC-124-001-001 | 2 | HEIGHT | 63 | in | SCREENING | 0 | 1998-03-24 |
| ABC-124 | ABC-124-001-001 | 3 | PULSE RATE | 102 | beats/min | SCREENING | 0 | 1998-03-24 |
| ABC-124 | ABC-124-001-001 | 4 | RESPIRATORY RATE | 18 | per min | SCREENING | 0 | 1998-03-24 |
| ABC-124 | ABC-124-001-001 | 5 | SYSTOLIC BLOOD PRESSURE | 130 | mmHg | SCREENING | 0 | 1998-03-24 |
| ABC-124 | ABC-124-001-001 | 6 | TEMPERATURE | 97.7 | °F | SCREENING | 0 | 1998-03-24 |
| ABC-124 | ABC-124-001-001 | 7 | WEIGHT | 143.9 | lb | SCREENING | 0 | 1998-03-24 |
| ABC-124 | ABC-124-001-001 | 8 | DIASTOLIC BLOOD PRESSURE | 76 | mmHg | Visit 1 | 1 | 1998-04-17 |
| ABC-124 | ABC-124-001-001 | 9 | PULSE RATE | 64 | beats/min | Visit 1 | 1 | 1998-04-17 |
| ABC-124 | ABC-124-001-001 | 10 | RESPIRATORY RATE | 18 | per min | Visit 1 | 1 | 1998-04-17 |
| ABC-124 | ABC-124-001-001 | 11 | SYSTOLIC BLOOD PRESSURE | 120 | mmHg | Visit 1 | 1 | 1998-04-17 |
| ABC-124 | ABC-124-001-001 | 12 | TEMPERATURE | 98.2 | °F | Visit 1 | 1 | 1998-04-17 |

### 2.8.4 QS Domain

#### 2.8.4.1 De-normalized Example—QS

| SUBJID | VISDAT | PAGE | FORMNAME | STUDYID | PTINIT | VMIMPROV | M_IMPROV | MINPROV | NOCHNG |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 10-May-08 | 4 | GLOBLCGI | ABC-124 | FMS | 2 | 2 | 2 | 1 |
| 1 | 11-Jun-08 | 15 | GLOBLCGI | ABC-124 | FMS | 2 | 1 | 2 | 2 |
| 1 | 9-Jul-08 | 27 | GLOBLCGI | ABC-124 | FMS | 1 | 2 | 2 | 2 |
| 2 | 18-Nov-08 | 4 | GLOBLCGI | ABC-124 | LHH | 2 | 2 | 1 | 2 |
| 2 | 18-Dec-08 | 15 | GLOBLCGI | ABC-124 | LHH | 2 | 1 | 2 | 2 |
| 2 | 18-Jan-09 | 27 | GLOBLCGI | ABC-124 | LHH | 1 | 2 | 2 | 2 |

#### 2.8.4.2 Normalized Example—QS

| STUDYID | SUBJID | QSSPID | QSCAT | QSTEST | QSORRES | QSSCORE | VISITNUM | VISIT | QSDAT |
|---|---|---|---|---|---|---|---|---|---|
| ABC-124 | ABC-124-001-001 | 1 | Investigator Assessment | Global Improvement | No change | 4 | 1 | Day 1 | 2008-05-10 |
| ABC-124 | ABC-124-001-001 | 2 | Investigator Assessment | Global Improvement | Much Improved | 2 | 2 | WEEK 4 | 2008-06-11 |
| ABC-124 | ABC-124-001-001 | 3 | Investigator Assessment | Global Improvement | Very much improved | 1 | 3 | WEEK 8 | 2008-07-09 |
| ABC-124 | ABC-124-001-002 | 1 | Investigator Assessment | Global Improvement | Minimally Improved | 3 | 1 | Day 1 | 2008-11-18 |
| ABC-124 | ABC-124-001-002 | 2 | Investigator Assessment | Global Improvement | Much Improved | 2 | 2 | WEEK 4 | 2008-12-18 |
| ABC-124 | ABC-124-001-002 | 3 | Investigator Assessment | Global Improvement | Very much improved | 1 | 3 | WEEK 8 | 2009-01-18 |

## 2.9 Form Level CRF Instructions

### 2.9.1 General Design Considerations for Completion Instructions

Whenever possible, details related to the completion of a single field should be placed with the field itself on the CRF. If this is not possible due to the medium and/or system being used to create the CRFs, then it is permissible to include the field level instructions at the top of the form in what is generally considered the form level instruction area. In some cases, such as when the form level instructions are very lengthy or include graphics or flowcharts, a separate CRF completion instruction guideline may be required.

### 2.9.2 General Content Considerations for Completion Instructions

When creating form level instructions for a CRF, the following points should be considered:

- The instructions should include clear references to the time period for which data are to be reported for the study, or to specific time windows that are allowed.
- The instructions should provide references to protocol sections for the specifics of and/or limitations on the data to be reported.
- The instructions should include any special instructions for additional reporting or actions required beyond what is collected on the CRF.
- The instructions should include considerations on how data collected on one CRF might have an impact on data that are reported on a different CRF.
- The instructions should refer to any special forms for reporting of protocol data of interest which is related to the CRF being completed but which might not be reported on that specific CRF.

## 2.10 CDASH ODM

### 2.10.1 Introduction

The Operational Data Model (ODM) is a vendor neutral, platform-independent format for interchange and archive of research data. The model includes the research data along with its associated metadata, administrative data, reference data and audit information. All of the information that needs to be shared among different software systems during the setup, operation, analysis, and submission or for long term retention is included in the model.

ODM has been designed to be compliant with guidance and regulations published by the FDA for computer systems used in research trials. The ODM standard is intended to be both the formal specification and a user guide for transferring or archiving of research data. Please refer to the CDISC ODM standard located at www.cdisc.org for more information.

The CDASH-ODM metadata described here is an implementation of ODM that provides examples of basic case report form content. It may require modification to be applicable for a particular study or to be implementable in a particular database system. There are also other possible implementations that will conform to CDASH. For example, not all CDASH optional data fields are included in these examples. Also in some cases, such as Medical History, examples of how to collect data related to a specific condition (e.g., high blood pressure) or procedure (e.g., appendectomy) will be study specific. The primary purpose of these examples is to provide a starting point for creation of CDASH based CRFs.

Some of the potential advantages of using CDASH-ODM are that it can be used in various systems to expedite the creation of CDASH conformant CRFs, it can create reusable mappings to SDTM, and it can be used as a foundation to create a metadata repository.

CDASH to SDTM mappings are included in Section 3 as an aid to implementers. The intended purpose of the mapping tables is to relate or link the collection on the CRF in CDASH to the SDTM variables. These tables, and the associated ODM.xml, ODM CRF examples with Data Definitions, and Example CRF Library provide a starting point for creation of CDASH based paper and EDC (Electronic Data Capture) CRFs. The EDC ODM examples are intentionally different in order to present as much variety as possible to assist the implementer. For example:

1) Character fields are defaulted at 999 characters with exceptions for those fields that would never need as many as 999 characters such as
   - Coded fields like AEYN which uses the 1 character YN code list and the code list is not extensible
   - Fields associated with units such as CMDOSU

Even though the SAS Transport Version 5 limit is 200 characters, SDTM submissions can accommodate text strings that exceed 200 characters by the use of Supplemental Qualifiers datasets. Please see the SDTMIG for further information regarding text strings greater than 200 characters.

2) Some forms, such as AE and CM, use items with ODM DataType "date" or "partialDate," which only allows for a date component and not a time component. Other forms, such as DS, DV, EG and EX, use items with ODM DataType "datetime" or "partialDatetime" which include both date and time components. The date display used is DD-MMM-YYYY where MMM is the 3 character value for the month (e.g., MAR for MARCH). ODM prescribes the use of ISO8601 based date, time and datetime formats for electronic data transfer, irrespective of the manner in which these values are displayed.

3) Some items, such as SU "Duration" and EX "Interruption Duration", have the ODM DataType "durationDatetime." These examples show a range of duration components (year, months, days, hours and minutes). It is expected that a sponsor would restrict the available components as required. ODM prescribes the use of ISO8601 base duration formats for electronic data transfer, irrespective of the manner in which these values are displayed.

4) There are examples of both a pre-specified unit and a selection box to choose a unit. The EG form has Mean Ventricular Rate variable with a pre-specified unit of "BEATS/MIN"). The VS form for the Height variable has a selection box to choose the unit of "CM" or "IN."

5) MH shows two pre-printed terms "High Blood Pressure" and "Appendectomy," each using a different subset of items from the MH Domain. The last ItemGroup of the form shows the entry of a verbatim MH term using a different selection of items.

6) SC shows the entry of a variety of results through the repeated use of the SCORRES CDASH variable, including: a) decimal value for "Gestational Age at Birth" b) free text result for Education Level and c) coded result for Skin Type and Marital Status.

7) Three Vital Signs forms are included. The first form is an example of singular collection for all of the tests. The second form divides the tests into groups, with each test/group also containing an item for "Not Done" and an item for "Clinically Significant" for that test. Additionally, in the second form the "Blood Pressure" test ItemGroup is repeating and contains an additional "Time of measurement" Item. This allows for multiple blood pressure recordings at different times to be entered into the form. The third form is almost identical to the second form, with the addition of a field for Vital Signs Date (maps to VSDTC) for scenarios in which Visit Date is not collected on the CRF.

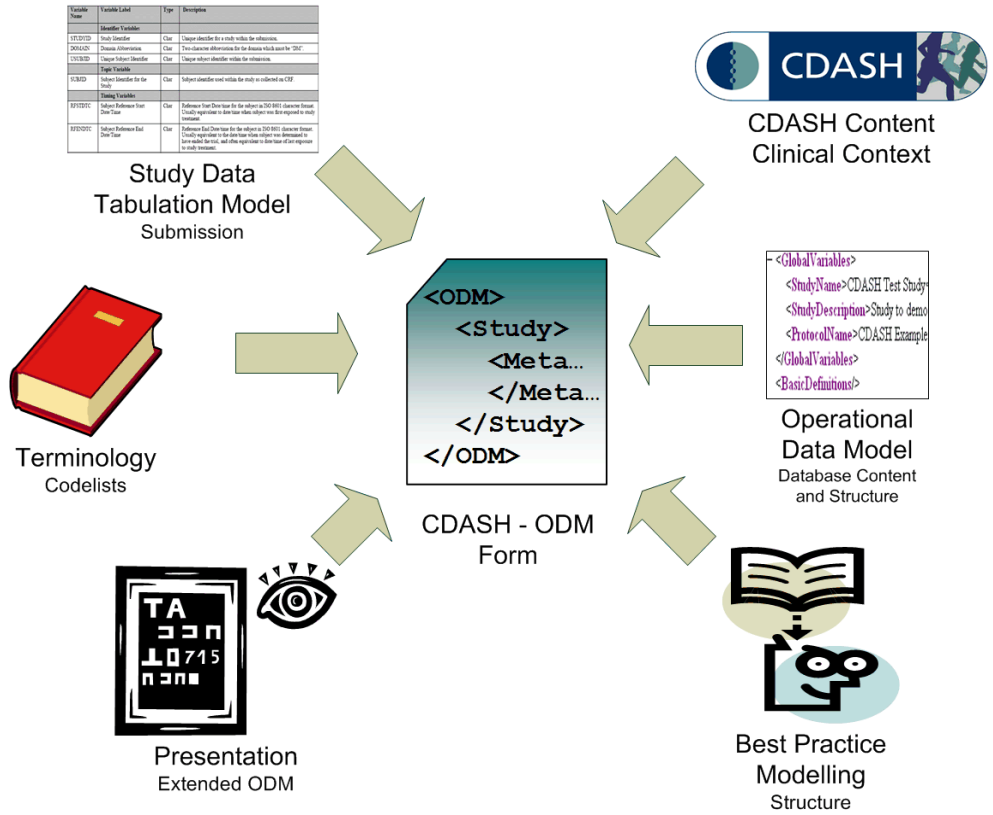
8) It is also recognized that ODM does not currently include attributes to accommodate "Item Prompt" and "Select-all-that-apply" responses. To illustrate how to apply CDASH where native ODM cannot, several different vendor-specific CRF examples are included. CDISC does not endorse any specific clinical data management software. The vendor-specific examples were developed and provided as a courtesy of the volunteer authors of this document and their sponsoring companies, with permission of the respective software vendors.

### 2.10.2 Description

The CDASH-ODM project was started in 2008 with the goal of developing the machine-readable metadata to accompany the domains and common variables addressed in the CDASH standard:

| | |
|---|---|
| Common Identification Variables | Exposure (EX) |
| Common Timing Variables | Inclusion and Exclusion Criteria (IE) |
| Adverse Events (AE) | Laboratory Test Results (LB) |
| Comments (CO) | Medical History (MH) |
| Prior and Concomitant Medications (CM) | Physical Examination (PE) |
| Demographics (DM) | Protocol Deviations (DV) |
| Disposition (DS) | Subject Characteristics (SC) |
| Drug Accountability (DA) | Substance Use (SU) |
| ECG Test Results (EG) | Vital Signs (VS) |

CDASH-ODM comprises elements from the SDTM, CDISC Controlled Terminology, CDASH data collection fields, extended ODM, operational ODM and best practice modelling structures:




The ODM XML and an HTML representation of it along with mapping instructions will be available to CDISC members at www.cdisc.org. Annotated CRFs (paper renditions) and EDC forms are included in this User Guide for each domain.

While CDASH-ODM does provide the common fields needed to create a basic CRF, implementers will need to augment them with therapeutic area specific data collection fields and other fields as needed due to any specific regulatory or local requirements.

When creating the CDASH-ODM, particularly for findings domains such as Vital Signs, Labs, ECGs, etc., the CDASH standard does not identify individual tests that are conducted. The CDASH-ODM representations contain some examples of tests, using tests and test codes from the CDISC Controlled Terminology code lists.

### 2.10.3 Use of Object Identifiers in CDASH file

Object Identifiers (OIDs) are employed in the CDASH ODM file in accordance with the CDISC ODM specification in order to reference definition elements, such as Forms, ItemGroups, Items and so on. Each definition element is given an OID, which represents a unique name for that element. When a reference must be made to an element, the reference is made using the element's OID.

An OID does not provide any meaning beyond a "unique identifier" (from a database perspective, it is comparable to a primary key). More specifically, the CDISC ODM does not define OIDs as having any business meaning - i.e. the OID alone does not provide any means of determining the purpose of an object, or its source such as any given section of the CDASH specification. In accordance with this usage, and in order to help avoid misinterpretation of the CDASH ODM, all OIDs are generated using a date pattern, which changes each a new version of the CDASH ODM file is created. References from the CDASH ODM file to the appropriate section of the CDASH Specification or SDTM are provided by the ODM Alias mechanism alone.

More information can be found in the CDISC ODM Specification version 1.3.1:

- OIDs - Section 2.11 "Element Identifiers and References"
- Alias - Section 3.1.1.3.6.6 "Alias"

**Considerations for Implementation:**

1) In the example ODM CRFs, the set of allowable values for datetime variables is abbreviated to 3 values, e.g., only Jan, Feb, Mar listed for the month date component. These fields would need to be expanded to add complete lists to facilitate entry.

2) Several results fields in Findings are an ODM data type of “float.” All SDTM Findings results variables (--ORRES) are character, irrespective of the test. The ODM Findings results fields that are defined as float are:

- DA (Drug Accountability): Amount Returned, Amount Dispensed
- EG (Electrocardiogram): Summary (Mean) Ventricular Rate, PR, QRS, QT, QTc - Bazett’s
- EX (Exposure): Total Volume, Infusion Rate, and Planned Dose are not SDTM variables. The values will be in SUPPEX with a character data type.
- SC (Subject Characteristics): Gestational Age at Birth
- VS (Vital Signs): Height, Weight, Diastolic, Systolic, Pulse, Temperature

Some data type format changes may need to occur when transforming collected data from CDASH to SDTM.

3) Most example variables used a subset of the controlled terminology except AESEV (Adverse Event Severity), which uses the entire list and is not extensible. Refer to Controlled Terminologies for a complete listing of allowable values.

# 3.0 Domain Implementation Reference

Section 3 CDASH to SDTM Mapping tables include all of the CDASH variables and all of the Required and Expected SDTMIG V3.1.2 variables, and show how to populate the SDTM variables from data collection based on CDASH. Some, but not all, SDTMIG Permissible variables have also been included in the Section 3 tables.

## 3.1 CDASH to SDTM Mapping - Common Identifier and Timing Variables

The table below compares common (e.g., "Header") variables that are found in both CDASH and SDTM. Some common variables such as DOMAIN are derived (not collected) and only used in SDTM. An explanation as to why some variables are not used in CDASH has also been provided.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Variable Label | SDTM Core | SDTM Type | CDASH Explanation | SDTM Description |
|---|---|---|---|---|---|---|---|---|---|
| | What is the sponsor identifier? | SPONSOR | O | *Not Specified* | *Not Specified* | *Not Specified* | *Not Specified* | An identifier for the entity with the overall regulatory responsibility for the Protocol. Since Study IDs and subsequent identifiers within the study (e.g., SITEID) are unique to a Sponsor, the Sponsor ID may be needed to uniquely identify records to external partners and regulatory agencies. | |
| | What is the study identifier? | STUDYID | HR | STUDYID | Study Identifier | Req | Char | Unique Identifier for a study that is assigned by the clinical researcher or research-sponsoring organization and is unique for the researcher or research-sponsoring organization. While this field is not typically captured on a CRF, it should be displayed clearly on the CRF and/or the EDC system. This field can be derived into the database or created and populated during SDTM dataset creation before submission. | Unique identifier for a study. |
| | What is the site identifier? | SITEID | HR | SITEID | Study Site Identifier | Req | Char | Study site identifier (alias) that is assigned by the clinical researcher or research sponsoring organization and is unique within the study. (Might not be unique across studies.) | Unique identifier for a study site within a submission. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Variable Label | SDTM Core | SDTM Type | CDASH Explanation | SDTM Description |
|---|---|---|---|---|---|---|---|---|---|
| | What is the subject identifier? | SUBJID | HR | SUBJID | Subject Identifier for the Study | Req | Char | Unique subject identifier within a site and a study. | Subject identifier used within the study. Often the ID of the subject as recorded on a CRF. |
| | For this multi-study subject, what is the unique subject identifier? | Unique Subject ID | O | USUBJID | Unique Subject Identifier | Req | Char | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This is a useful identifier for combining research results data for a study subject when the subject is known to have participated in more than one trial for a given treatment (e.g., for analyses such as "overall exposure to study drug"). Generally, this identifier is assigned retrospectively, but might be assigned during the second trial when the subjects are known to have been in an earlier trial (e.g., follow-on trials). | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. |
| | What is the investigator identifier? | INVID | O | INVID | Investigator Identifier | Perm | Char | Unique Investigator Identifier (alias) code for a researcher at a study site who oversees all aspects of the study at a site, including protocol submission for IRB/EC approval, participant recruitment, informed consent, data collection, and analysis. | An identifier to describe the Investigator for the study. May be used in addition to the SITEID. Not needed if SITEID is equivalent to INVID. |
| | *What is the visit name?* | VISIT | *O* | VISIT | Visit Name | Perm | Char | Textual representation of the visit number. Identifier (alias) for a clinical study encounter that encompasses planned and unplanned trial interventions, procedures, and assessments that may be performed on a subject. A visit has a start and an end, each described with a rule. | Protocol-defined description of a clinical encounter. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Variable Label | SDTM Core | SDTM Type | CDASH Explanation | SDTM Description |
|---|---|---|---|---|---|---|---|---|---|
| | *What is the visit number?* | VISITNUM | *O* | VISITNUM | Visit Number | Exp | Num | Numerical representation of the visit. Identifier (alias) for a clinical study encounter that encompasses planned and unplanned trial interventions, procedures, and assessments that may be performed on a subject. | Clinical encounter number. Numeric version of VISIT, used for sorting. |
| | (Date of collection)<br><br>(Time of Collection) | --DAT<br><br>--TIM | See individual Domain table for Core Designation<br><br>See individual Domain table for Core Designation | --DTC | Date/Time of Collection | Exp | Char | Test Date<br><br>Time test was performed (if applicable) | Collection date and time of an observation represented in IS0 8601 character format. |
| | *Not Specified* | *Not Specified* | *Not Specified* | DOMAIN | Domain Abbreviation | Req | Char | Two-character abbreviation for the domain. This field is typically not captured on a CRF as it is not meaningful to personnel at the investigative sites. This field can be derived into the database or created and populated during SDTM dataset creation before submission. | Two-character abbreviation for the domain most relevant to the observation. The Domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged. |
| | *Not Specified* | *Not Specified* | *Not Specified* | --SEQ | Sequence Number | Req | Num | Sequence Number given to ensure uniqueness of subject records within a domain. This field is not collected on the CRFs. Sponsors will need to derive an appropriate sequence number during SDTM dataset creation before submission. | Sequence number to ensure uniqueness of records within a dataset for a subject (or within a parameter, in the case of the Trial Summary domain). May be any valid number (including decimals) and does not have to start at 1. Should be assigned to be in a consistent chronological order. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Variable Label | SDTM Core | SDTM Type | CDASH Explanation | SDTM Description |
|---|---|---|---|---|---|---|---|---|---|
| | *Not Specified* | *Not Specified* | *Not Specified* | --GRPID | Group ID | Perm | Char | Used to tie together a block of related records in a single domain for a subject. | Optional group identifier, used to link together a block of related records within a subject in a domain. Also used to link together a block of related records in the Trial Summary dataset (Section 3.4). |
| | *Not Specified* | *Not Specified* | *Not Specified* | --REFID | Reference ID | Perm | Char | Internal or external identifier such as a serial number on an SAE reporting form. | Optional internal or external identifier such as lab specimen ID, or UUID for an ECG waveform or a medical image. |
| | *Various* | *--SPID* | *O* | --SPID | Sponsor ID | Perm | Char | Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database (derived) (e.g., line number on an Adverse Event page).<br>For AE CRFs, it can be beneficial to use a sequence number in a data query to clearly communicate to the site the specific record in question. | Sponsor-defined identifier. Example: pre-printed line identifier on a Concomitant Medications page. |

## 3.2 Adverse Events (AE)

These recommendations are for *non-solicited* or *pre-specified* adverse events. As with all the data collection variables recommended in CDASH V1.1, it is assumed that sponsors will add other data variables as needed to meet protocol-specific and other data collection requirements (e.g., TA-specific data elements and others as required per protocol, business practice and operating procedures). Sponsors should define the appropriate collection period for adverse events. All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

### 3.2.1 CDASH to SDTM Mapping—AE

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Were any adverse events experienced? | AEYN | O | *Not Specified* | *Not Specified* | Does not map to SDTM.<br>The CRF should be annotated to indicate that this field is NOT SUBMITTED. |
| 2. | AE Identifier | AESPID | O | AESPID | Perm | Maps directly to SDTM.<br>May be used to create RELREC to link this record with a record in another domain. |
| 3. | What is the adverse event term? | AETERM | HR | AETERM | Req | Maps directly to SDTM.<br>Can be represented either as an open entry field to capture verbatim terms reported by subjects or could be pre-printed in the situation where solicited AEs of interest are captured. 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.<br>In most cases, the verbatim term (i.e. investigator-reported term) will be classified based on a standard medical dictionary such as MedDRA, after the data have been collected on the CRF. The dictionary-related data will be stored in fields not defined by CDASH. |
| 4. | *Not Specified* | *Not Specified* | *Not Specified* | AEDECOD | Req | This REQUIRED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 5. | *Not Specified* | *Not Specified* | *Not Specified* | AEBODSYS | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Mapping Instructions |
|---|---|---|---|---|---|---|
| 6. | *Not Specified* | *Not Specified* | *Not Specified* | AELLT | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 7. | *Not Specified* | *Not Specified* | *Not Specified* | AELLTCD | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 8. | *Not Specified* | *Not Specified* | *Not Specified* | AEPTCD | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 9. | *Not Specified* | *Not Specified* | *Not Specified* | AEHLT | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 10. | *Not Specified* | *Not Specified* | *Not Specified* | AEHLTCD | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 11. | *Not Specified* | *Not Specified* | *Not Specified* | AEHLGT | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Mapping Instructions |
|---|---|---|---|---|---|---|
| 12. | *Not Specified* | *Not Specified* | *Not Specified* | AEHLGTCD | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 13. | *Not Specified* | *Not Specified* | *Not Specified* | AEBDSYCD | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 14. | *Not Specified* | *Not Specified* | *Not Specified* | AESOC | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 15. | *Not Specified* | *Not Specified* | *Not Specified* | AESOCCD | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 16. | Does the subject have <specific adverse event>? | AEOCCUR | O | CEOCCUR<br>or<br>FAORRES | *Exp* | Since the SDTM AE domain is intended to hold only Adverse Events that actually happen, the values collected in AEOCCUR for pre-specified AEs should be submitted in either a Clinical Events domain, or in a Findings About Adverse Events data set (FAAE).<br>In Clinical Events, the pre-specified AE is submitted as the CETERM, CEPRESP would be populated with a value of "Y" to indicate this was a pre-specified AE, and CEOCCUR would be populated with the value collected in AEOCCUR.<br>In Findings About, FATESTCD= OCCUR, FATEST=Occurrence, FAOBJ=[the pre-specified AE], and FAORRES=[the value collected in AEOCCUR]. |
| 17. | What is the date the adverse event started? | AESTDAT | HR | AESTDTC | Exp | **For the SDTM dataset,** the SDTM variable --STDTC is derived by concatenating CDASH Start Date and Time (if time is applicable) into --STDTC using the ISO 8601 format. See SDTMIG 4.1.4.1. |
| 18. | At what time did the adverse event start? | AESTTIM | R/C | | | |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Mapping Instructions |
|---|---|---|---|---|---|---|
| 19. | What date did the adverse event end? | AEENDAT | HR | AEENDTC | Exp | **For the SDTM dataset,** the SDTM variable --ENDTC is derived by concatenating CDASH End Date and Time (if time is applicable) into --ENDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 20. | At what time did the adverse event end? | AEENTIM | R/C | | | |
| 21. | Is the adverse event ongoing? | AEONGO | O | AEENRF<br>or<br>AEENRTPT and AEENTPT | Perm | May be used to derive a value into an SDTM relative timing variable such as AEENRF or AEENRTPT.<br>When populating AEENRF, if the value of AEONGO is "Y", the value of "DURING", "AFTER" or "DURING/AFTER" may be derived.<br>When populating AEENRTPT, if the value of AEONGO is "Y", the value of "ONGOING" may be derived. Note: AEENRTPT must refer to a "time point anchor" described in AEENTPT.<br>See SDTMIG section 4.1.4.7 for more information. |
| 22. | What was the severity of the adverse event? | AESEV | R/C | AESEV | Perm | Maps directly to SDTM.<br>The sponsor is expected to provide the toxicity scale name and version used to map the terms utilizing the define.xml external code list attributes. |
| 23. | What is the toxicity grade of the adverse event? | AETOXGR | R/C | AETOXGR | Perm | Maps directly to SDTM.<br>The sponsor is expected to provide the toxicity scale name and version used to map the terms utilizing the define.xml external code list attributes. |
| 24. | Is the adverse event serious? | AESER | R/C | AESER | Exp | Maps directly to SDTM. |
| 25. | Is the adverse event associated with a congenital anomaly or birth defect? | AESCONG | R/C | AESCONG | Perm | Maps directly to SDTM. |
| 26. | Did the adverse event result in persistent or significant disability or incapacity? | AESDISAB | R/C | AESDISAB | Perm | Maps directly to SDTM. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Mapping Instructions |
|---|---|---|---|---|---|---|
| 27. | Did the adverse event result in death? | AESDTH | R/C | AESDTH | Perm | Maps directly to SDTM. |
| 28. | Did the adverse event result in initial or prolonged hospitalization for the subject? | AESHOSP | R/C | AESHOSP | Perm | Maps directly to SDTM. |
| 29. | Is the adverse event life threatening? | AESLIFE | R/C | AESLIFE | Perm | Maps directly to SDTM. |
| 30. | Is the adverse event a medically important event not covered by other "serious" criteria? | AESMIE | R/C | AESMIE | Perm | Maps directly to SDTM. |
| 31. | Is this event related to study treatment? | AEREL | HR | AEREL | Exp | Maps directly to SDTM.<br>Controlled Terminology may be defined in the future. It is recommended that you check with the appropriate regulatory authority for population of this variable so that it meets their expectations for your submission. |
| 32. | What action was taken with study treatment? | AEACN | HR | AEACN | Exp | Maps directly to SDTM. |
| 33. | What other action was taken in response to this adverse event? | AEACNOTH | O | AEACNOTH | Perm | Maps directly to SDTM.<br>If possible/desired, create sponsor-controlled terminology. |
| 34. | What was the outcome of this adverse event? | AEOUT | HR | AEOUT | Perm | Maps directly to SDTM. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Mapping Instructions |
|---|---|---|---|---|---|---|
| 35. | Did the adverse event cause the subject to be discontinued from the study? | AEDIS | O | *Not Specified* | *Not Specified* | May be used to create a RELREC to link the Adverse Event to the Disposition record.<br>May also be submitted in a SUPPAE dataset. The value of AEDIS may be used to populate SUPPAE.QVAL where SUPPAE.QNAM = AEDIS. |
| 36. | *Not Specified* | *Not Specified* | *Not Specified* | AETRTFL | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |

## 3.2.2 Implementation Examples—AE

### 3.2.2.1 Example 1

This is an example of an AE dataset using AEYN. This is a log style collection of AEs with pre-printed line numbers. In this example AESER is collected in addition to the seriousness criteria.

- Row 1 shows an example of a subject that does not have any AEs to report. There will be no records for the subject in the AE SDTM submission dataset.
- Rows 2 and 3 show examples of a subject that has AEs to report.

| Row | AEYN | AESPID | AETERM | AESTDAT | AESTTIM | AEENDAT | AEENTIM | AEONGO | AESEV |
|---|---|---|---|---|---|---|---|---|---|
| 1 | N | | | | | | | | |
| 2 | Y | 1 | HEADACHE | 02-JAN-2004 | 12:12 | 02-JAN-2004 | 17:34 | | MODERATE |
| 3 | Y | 2 | DIZZINESS | 04-FEB-2004 | | | | Y | SEVERE |

| Row | AESER | AESCONG | AESDISAB | AESDTH | AESHOSP | AESLIFE | AESMIE | AEREL | AEACN |
|---|---|---|---|---|---|---|---|---|---|
| 1 (cont) | | | | | | | | | |
| 2 (cont) | N | | | | | | | Y | DOSE NOT CHANGED |
| 3 (cont) | Y | N | Y | N | Y | N | N | Y | DOSE REDUCED |

| Row | AEACNOTH | AEOUT | AEDIS |
|---|---|---|---|
| 1 (cont) | | | |
| 2 (cont) | | RECOVERED/RESOLVED | N |
| 3 (cont) | Concomitant Treatment Given | NOT RECOVERED/NOT RESOLVED | N |

#### 3.2.2.2 Example 2

This is an example of an AE dataset using AEYN. This is a visit-based collection of AEs with line numbers. In this example, AESER is not collected; only the serious criteria responses are collected.

- Row 1 shows an example of a subject that does not have any AEs to report.
- Rows 2, 3, and 4 show examples of a subject that has AEs to report.

| Row | AEYN | AESPID | AETERM | AESTDAT | AESTTIM | AEENDAT | AEENTIM | AEONGO | AESEV |
|---|---|---|---|---|---|---|---|---|---|
| 1 | N | | | | | | | | |
| 2 | Y | 1 | HEADACHE | 02-JAN-2004 | 12:12 | 02-JAN-2004 | 17:34 | | MODERATE |
| 3 | Y | 2 | DIZZINESS | 04-FEB-2004 | | | | Y | SEVERE |
| 4 | Y | 3 | DIZZINESS | 04-FEB-2004 | | | | Y | SEVERE |

| Row | AESCONG | AESDISAB | AESDTH | AESHOSP | AESLIFE | AESMIE | AEREL | AEACN | AEACNOTH | AEDIS |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 (cont) | | | | | | | | | | |
| 2 (cont) | N | N | N | N | N | N | Y | DOSE NOT CHANGED | None | N |
| 3 (cont) | N | Y | N | Y | N | N | Y | DOSE NOT CHANGED | Subject rested | N |
| 4 (cont) | N | Y | N | Y | N | N | Y | DOSE REDUCED | Medication given to reduce dizziness | N |

### 3.2.2.3 Example 3

This is an example of an AE dataset where neither AEYN nor line numbers were used. Collection is log style. In this example, only AESER is collected; Headache and Dizziness are solicited AEs

- Rows 1 and 2 show an example of solicited / pre-specified Adverse Events.
- Row 3 shows an example of a spontaneously reported Adverse Event.

| Row | AEOCCUR | AETERM | AESTDAT | AESTTIM | AEENDAT | AEENTIM | AEONGO | AETOXGR |
|---|---|---|---|---|---|---|---|---|
| 1 | Y | HEADACHE | 02-JAN-2004 | 12:12 | 02-JAN-2004 | 17:34 | | GRADE 1 |
| 2 | Y | DIZZINESS | 04-FEB-2004 | | | | Y | GRADE 2 |
| 3 | | STIFF NECK | 02-MAR-2004 | 06:02 | 03-MAR-2004 | 12:30 | | GRADE 2 |

| Row | AESER | AEREL | AEACN |
|---|---|---|---|
| 1 (cont) | N | Y | None |
| 2 (cont) | Y | Y | Dose Reduced |
| 3 (cont) | N | N | None |

### 3.2.3 Completion Instructions—Adverse Events (AE)

- All Serious Adverse Events (SAEs), regardless of relationship to study drug, must be reported via telephone or fax within 24 hours of discovery
- Record the AEs and corresponding information on the AE Record CRF through the <protocol-specified period>.
- Record all AEs except <list of protocol-defined exceptions> on the AE CRF after informed consent is obtained.
- Safety information (e.g., AE, SAE) identified for all subjects must be recorded on source documents from the <protocol-defined timepoint>.

## 3.3 Comments (CO)

There are no mandatory data elements for inclusion in a separate Comments CRF. This is consistent with currently evolving common practices and the *ICH Guidelines.* This does not pertain to solicited free-text comment data collection fields that may appear within another established domain, and is not meant to discourage investigators from providing unsolicited comments where they are appropriate. CDASH recommends that implementers avoid the creation of a separate General Comments CRF and provide free text fields that are associated with other data collection fields on existing CRFs when additional information related to those fields is needed.

It is responsibility of study conduct teams to design and utilize the data collection tools capable of capturing data that is useful for analysis purposes. Therefore, code lists should be developed for data collection fields as much as possible, and free text fields should be limited to those that are required for the study.

Individual sponsor companies must determine their own path in collecting unsolicited comments on CRFs, and this should be done with input from the Review Division that will receive the submission.

### 3.3.1 CDASH to SDTM Mapping—CO

Examples are only those present on other domains where comments are used. See the SDTMIG for instructions on mapping comments.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | *<protocol-specified question>* | *Not Specified* | *Not Specified* | *COVAL* | *Req* | Maps directly to SDTM.<br>For "targeted" comments, the implementer should link the comment to the appropriate record(s) or domain. |

### 3.3.2 Implementation Examples—CO

N/A

### 3.3.3 Form Level Completion Instructions—CO

- CDASH does not recommend the use of a separate Comments CRF, so no form level instructions are provided for a Comments page.
- For comments related to a specific field on another CRF, provide instructions on what is expected for each comment field in that CRF's field-level completion instructions.

## 3.4 Prior and Concomitant Medications (CM)

### 3.4.1 ATC Classifications

The Anatomical Therapeutic Chemical (ATC) is a classification system in which drugs are divided into different groups according to the organ or system on which they act, and their chemical, pharmacological and therapeutic properties.

See http://www.who-umc.org/DynPage.aspx?id=30537#FAQwhatistheatc for more information about ATC coding.

### 3.4.2 CDASH to SDTM Mapping—CM

The core designations specified in the CDASH CM domain are representative of the fields required for general medication reporting and do not address the core designation requirements of specific CDASH implementations. In the case of medications of interest, the core designations for fields in the CM domain may vary for a specific implementation of the CDASH standard and/or data analysis requirements. All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Were any medications taken? | CMYN | O | *Not Specified* | *Not Specified* | Does not map to SDTM.<br>The CRF should be annotated to indicate that this field is NOT SUBMITTED. |
| 2. | What is the medication / treatment identifier? | CMSPID | O | CMSPID | Perm | Maps directly to SDTM.<br>May be used to create RELREC to link this record with a record in another domain. |
| 3. | What was the term for the medication/therapy taken?<br><br>Or<br><br>What was the term for the medication taken? | CMTRT | HR | CMTRT | Req | Maps directly to SDTM. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| | Did the subject take < *specific medication/ treatment* >?<br>or<br>Has the subject taken < *specific medication/ treatment* >? | CMOCCUR | O | CMOCCUR | Perm | Maps directly to SDTM. |
| 4. | What were the active ingredient(s)? | CMINGRD | O | *Not Specified* | *Not Specified* | Does not map to SDTM.<br>The CRF should be annotated to indicate that this field is NOT SUBMITTED. |
| 5. | For what indication was the medication/ therapy taken? | CMINDC | R/C | CMINDC | Perm | Maps directly to SDTM. |
| 6. | What was the ID of the adverse event(s) for which the medication was taken? | CMAENO | O | *Not Specified* | *Not Specified* | May be used to create RELREC to link this record with a record in another domain. |
| 7. | What was the ID of the medical history condition(s) for which the medication was taken? | CMMHNO | O | *Not Specified* | *Not Specified* | May be used to create RELREC to link this record with a record in another domain. |
| 8. | What was the individual dose of the medication/ therapy? | CMDSTXT | O | CMDOSE or CMDOSTXT | Perm<br><br>Perm | Numeric values map to CMDOSE in SDTM.<br>Non-numeric values (e.g., 200-400) map to CMDOSTXT in SDTM. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 9. | What was the total daily dose of the medication/ therapy? | CMDOSTOT | O | CMDOSTOT | Perm | Maps directly to SDTM. |
| 10. | What was the unit of the medication/therapy? | CMDOSU | O | CMDOSU | Perm | Maps directly to SDTM. |
| 11. | What was the dose form of the medication/therapy? | CMDOSFRM | O | CMDOSFRM | Perm | Maps directly to SDTM. |
| 12. | What was the frequency of the medication/therapy? | CMDOSFRQ | O | CMDOSFRQ | Perm | Maps directly to SDTM. |
| 13. | What was the route of administration of the medication/therapy? | CMROUTE | R/C | CMROUTE | Perm | Maps directly to SDTM. |
| 14. | What was the start date of the medication/therapy? | CMSTDAT | HR | CMSTDTC | Perm | **For the SDTM dataset,** the SDTM variable --STDTC is derived by concatenating CDASH Start Date and Time (if time is applicable) into --STDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 15. | What was the start time of the medication/therapy? | CMSTTIM | R/C | | | |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 16. | Was the medication/therapy taken prior to the study? | CMPRIOR | R/C | CMSTRF or CMSTRTPT and CMSTTPT | Perm | May be used to derive a value into an SDTM relative timing variable such as CMSTRF or CMSTRTPT.<br>When populating CMSTRF, if the value of CMPRIOR is "Y", the value of "BEFORE" may be derived.<br>When populating CMSTRTPT, if the value of CMPRIOR is "Y", the value of "BEFORE" may be derived. Note: CMSTRTPT must refer to a "time point anchor" described in CMSTTPT.<br>See SDTMIG section 4.1.4.7 for more information. |
| 17. | What was the end date of the medication/therapy? | CMENDAT | R/C | CMENDTC | Perm | **For the SDTM-based dataset**, the SDTM variable CMENDTC is derived by concatenating CDASH End Date and Time (if time is collected) into CMENDTC using the ISO 8601 format. |
| 18. | What was the end time of the medication/therapy? | CMENTIM | R/C | | | |
| 19. | Is the medication / therapy still ongoing? | CMONGO | R/C | CMENRF or CMENRTPT and CMENTPT | Perm | May be used to derive a value into an SDTM relative timing variable such as CMENRF or CMENRTPT.<br>When populating CMENRF, if the value of CMONGO is "Y", the value of "DURING", "AFTER" or "DURING/AFTER" may be derived.<br>When populating CMENRTPT, if the value of CMONGO is "Y", the value of "ONGOING" may be derived. Note: CMENRTPT must refer to a "time point anchor" described in CMENTPT.<br>See SDTMIG section 4.1.4.7 for more information. |

## 3.4.3 Implementation Examples—CM

### 3.4.3.1 Example 1— Spontaneous concomitant medications with dosing information and ingredients to help in coding

- Row 1 shows an example where the subject did not take any concomitant medications. There will be no record for the subject in the CM dataset.
- Rows 2 through 5 show an example of a subject that took several concomitant medications. Note that Row 2 contains only the response to the form-level question "Did the subject take any medications?" and Rows 3 through 5 contain the actual medications that were reported.
- Row 3 shows an example where the ingredients are listed to assist in coding the medication. The start and end dates are partial dates, and the medication is ongoing. One record for the subject will appear in the CM dataset, and the two ingredients listed in row 3 will appear as two records in the supplemental qualifiers domain for CM (SUPPCM).

- Rows 4 and 5 show examples of medications where ingredients are not listed, either because they were not available or because they were not considered necessary for coding purposes, but additional dosing information is available.

| Row | SUBJID | CMYN | CMTRT | CMINGRD | CMINDC | CMDSTXT | CMDOSU | CMDOSFRM | CMDOSFRQ |
|---|---|---|---|---|---|---|---|---|---|
| 1 | XYZ-0001 | N | - | - | - | - | - | - | - |
| 2 | XYZ-0002 | Y | - | - | - | - | - | - | - |
| 3 | XYZ-0002 | - | VIVELLE | ETHINYLESTRADIOL, NORGESTIMATE | ESTROGEN DEFICIENCY | - | - | PATCH | QS |
| 4 | XYZ-0002 | - | COREG | - | HYPERTENSION | 3.125 | mg | TABLET | QD |
| 5 | XYZ-0002 | - | CAPOTEN | - | HYPERTENSION | 25 | mg | TABLET | BID |

| Row | CMSTDAT | CMPRIOR | CMENDAT | CMONGO |
|---|---|---|---|---|
| 1 (cont) | - | - | - | - |
| 2 (cont) | - | - | - | - |
| 3 (cont) | JAN-2004 | - | - | Y |
| 4 (cont) | - | Y | - | Y |
| 5 (cont) | - | Y | 01-MAR-2008 | - |

### 3.4.3.2 Example 2— Spontaneous concomitant medications with links to related records in the medical history

- Row 2 shows an example where the subject's medication is linked to a Medical History record. The line number of the medication is stored in CMSPID, and the corresponding line number on the Medical History CRF is stored in CMMHNO. That relationship can be documented by creating a record in the RELREC dataset.
- Rows 3 and 4 show an example where the dose frequency for the medication was changed during the study treatment period. In Row 2, the medication was started prior to study treatment and ended during study treatment. In Row 3, the medication continued with a new dose frequency and was not ongoing when the study treatment period ended.
- Row 5 shows an example where the medication was started prior to study treatment but only the year was known. The medication is ongoing when the study treatment period ended, so there is no end date.

| Row | SUBJID | CMYN | CMSPID | CMTRT | CMINDC | CMMHNO | CMDSTXT | CMDOSU | CMDOSFRM |
|---|---|---|---|---|---|---|---|---|---|
| 1 | XYZ-0011 | Y | - | - | - | - | - | - | - |
| 2 | XYZ-0011 | - | 1 | MAXALT | MIGRAINE | 3 | 5 | mg | TABLET |
| 3 | XYZ-0011 | - | 2 | ZYLOPRIM | GOUT | - | 100 | mg | TABLET |
| 4 | XYZ-0011 | - | 3 | ZYLOPRIM | GOUT | - | 100 | mg | TABLET |
| 5 | XYZ-0011 | - | 4 | AMBIEN CR | INSOMNIA | - | 12.5 | mg | TABLET |

| Row | CMDOSFRQ | CMSTDAT | CMPRIOR | CMENDAT | CMONGO |
|---|---|---|---|---|---|
| 1 (cont) | - | - | - | - | - |
| 2 (cont) | ONCE | - | Y | 10-APR-2008 | - |
| 3 (cont) | BID | MAR-2007 | - | 13-MAR-2008 | - |
| 4 (cont) | TID | - | Y | 01-JUN-2008 | - |
| 5 (cont) | QD | 1997 | - | - | Y |

#### 3.4.3.3 Example 3— Pre-specified medications of interest

In this example the sponsor only wants to know whether or not the subject takes any of the four pre-printed blood thinners during study treatment.

- For each subject, four rows contain the pre-specified medications of interest. The investigator checks YES only those medications that the subject has taken.
- Rows 1 through 4 show an example where the subject has taken each of the pre-specified medications and all additional information has been completed. The final submission dataset will contain four records for the subject.
- Rows 5 through 8 show an example where the subject has taken only one of the medications, and the investigator has completed the additional information for that medication. The final submission dataset will contain only one record for the subject.

| Row | SUBJID | CMOCCUR | CMSPID | CMTRT | CMPRESP | CMDSTXT | CMDOSU | CMDOSFRM |
|---|---|---|---|---|---|---|---|---|
| 1 | XYZ-0113 | Y | 1 | PREDNISONE | Y | 5 | mg | TABLET |
| 2 | XYZ-0113 | Y | 2 | NSAID | Y | 100 | mg | TABLET |
| 3 | XYZ-0113 | Y | 3 | COUMADIN | Y | 5 | mg | TABLET |
| 4 | XYZ-0113 | Y | 4 | PLAVIX | Y | 12.5 | mg | TABLET |
| 5 | XYZ-0012 | N | 1 | PREDNISONE | Y | - | - | - |
| 6 | XYZ-0012 | Y | 2 | NSAID | Y | 700 | mg | TABLET |
| 7 | XYZ-0012 | N | 3 | COUMADIN | Y | - | - | - |
| 8 | XYZ-0012 | N | 4 | PLAVIX | Y | - | - | - |

| Row | CMDOSFRQ | CMSTDAT | CMPRIOR | CMENDAT | CMONGO |
|---|---|---|---|---|---|
| 1 (cont) | ONCE | - | Y | 10-APR-2008 | - |
| 2 (cont) | BID | MAR-2007 | - | 13-MAR-2008 | - |
| 3 (cont) | TID | - | Y | 01-JUN-2008 | - |
| 4 (cont) | QD | 1997 | - | - | Y |
| 5 (cont) | - | - | - | - | - |
| 6 (cont) | ONCE | JUL-2008 | - | JUL-2008 | - |
| 7 (cont) | - | - | - | - | - |
| 8 (cont) | - | - | - | - | - |

### 3.4.4 Form Level Completion Instructions—CM

- Record all <protocol-specified inclusions> medications taken within <protocol-specified period>.
- Do not record < list of protocol-defined exceptions>.
- <protocol medications “of interest”> must be recorded on the <name of special medication CRF>

## 3.5 Demographics (DM)

### 3.5.1 CDASH to SDTM Mapping—DM

These recommendations are for Demographics data. The Demographics domain is a special purpose domain that collects specific data elements that are mapped to SDTM. Additional data elements may be collected on the same page as Demographics data, but those elements will be mapped to other Domains. All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | What is the subject's date of birth? | BRTHDAT | HR | BRTHDTC | Perm | The sponsor may choose to database the date of birth as a single variable (BRTHDAT), *or* as separate variables for each component of the date/time (BRTHYR, BRTHMO, BRTHDY, BRTHTIM – see below). The sponsor may choose a method based on database considerations, or for regulatory reasons.<br>It is expected that what is collected for BRTHDAT (complete date or whichever components are collected) is reported in the SDTM BRTHDTC in the ISO 8601 format. If data are collected in a manner resulting in a reduced precision level, then the AGE (SDTM expected variable), if not collected on the CRF, should be derived using a documented algorithm that describes how the age was derived and/or imputed for those birth dates collected with reduced precision.<br>**For the SDTM-based dataset**, the SDTM variable BRTHDTC is derived from the collected date and time components (BRTHDAT or BRTHYR, BRTHMO, BRTHDY, and BRTHTIM) concatenating as necessary into the ISO 8601 format. |
| 2. | What is the subject's year of birth? | BRTHYR (Year component of BRTHDAT) | HR | BRTHDTC (year component) | Perm | |
| 3. | What is the subject's month of birth? | BRTHMO (Month component of BRTHDAT) | R/C | BRTHDTC (month component) | Perm | |
| 4. | What is the subject's day of birth? | BRTHDY (Day component of BRTHDAT) | R/C | BRTHDTC (day component) | Perm | |
| 5. | What is the time of the subject's birth? | BRTHTIM (Time component of BRTHDAT) | O | BRTHDTC (time component) | Perm | |
| 6. | What is the subject's age? | AGE | O | AGE | Exp | Maps directly to SDTM. |
| 7. | What is the age unit used? | AGEU | O | AGEU | Exp | Maps directly to SDTM. |
| 8. | What is the date of collection? | DMDAT | R/C | DMDTC | Perm | **For the SDTM dataset**, the SDTM variable --DTC is derived by concatenating CDASH Date and Time (if time is applicable) into --DTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 9. | What is the sex of the subject? | SEX | HR | SEX | Req | Maps directly to SDTM. |
| 10. | What is the ethnicity of the subject? | ETHNIC | R/C | ETHNIC | Perm | Maps directly to SDTM. |
| 11. | What is the race of the subject? | RACE | R/C | RACE | Exp | Maps directly to SDTM. |
| 12. | Specify other race. | RACEOTH | O | SUPPDM.QNAM (value of RACEOTH) | (Non-standard variable) | This information could be submitted in a SUPPDM dataset. The value of RACEOTH may be used to populate SUPPDM.QVAL where SUPPDM.QNAM = RACEOTH. |
| 13. | *Not Specified* | *Not Specified* | *Not Specified* | ARM | Req | This REQUIRED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 14. | *Not Specified* | *Not Specified* | *Not Specified* | ARMCD | Req | This REQUIRED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 15. | *Not Specified* | *Not Specified* | *Not Specified* | COUNTRY | Req | This REQUIRED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 16. | *Not Specified* | *Not Specified* | *Not Specified* | ACTARMCD | Req | This REQUIRED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 17. | *Not Specified* | *Not Specified* | *Not Specified* | ACTARM | Req | This REQUIRED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 18. | *Not Specified* | *Not Specified* | *Not Specified* | RFXSTDTC | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 19. | *Not Specified* | *Not Specified* | *Not Specified* | RFXENDTC | Exp | This EXPECTED field in SDTM is not accounted for in the This REQUIRED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 20. | *Not Specified* | *Not Specified* | *Not Specified* | RFICDTC | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 21. | *Not Specified* | *Not Specified* | *Not Specified* | RFPENDTC | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 22. | *Not Specified* | *Not Specified* | *Not Specified* | DTHDTC | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 23. | *Not Specified* | *Not Specified* | *Not Specified* | DTHFL | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |

## 3.5.2 Implementation Examples—DM

### 3.5.2.1 Example 1

This is an example of a Demographics CRF that collects Race and Ethnicity according to the FDA Guidance Document, with the addition of a sponsor defined field for "Other." For one subject, only the year and month of birth were collected. Below the CRF is a partial SDTM representation of the data.

#### 3.5.2.1.1 Paper Case Report Form (DM)

**Demographics**

**Date of Birth**
(DD/MMM/YYYY)
_ _/_ _ _/_ _ _ _

**Sex**
1 ☐ Male 2 ☐ Female

**Ethnicity**
1 ☐ Hispanic 2 ☐ Non- Hispanic

**Race**
(Select all that apply)
1 ☐ White
2 ☐ Black/African American
3 ☐ Asian
4 ☐ Native Hawaiian/Other Pacific Islander
5 ☐ American Indian/Alaska Native
99 ☐ Other—Specify: _____

| BRTHDTC (Perm) | AGE (Exp) | AGEU (Exp) | SEX (Req) | RACE (Exp) | ETHNIC (Perm) |
|---|---|---|---|---|---|
| 1990-10-20 | 18 | YEARS | FEMALE | NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER | HISPANIC OR LATINO |
| 1965-03-07 | 41 | YEARS | FEMALE | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO |
| 1970-10 | 38 | YEARS | UNKNOWN | AMERICAN INDIAN OR ALASKAN NATIVE | NOT HISPANIC OR LATINO |
| 2008-10-01T19:39 | 2 | MONTHS | MALE | ASIAN | HISPANIC OR LATINO |
| 2008-12-12T00:30 | 4 | DAYS | FEMALE | WHITE | NOT HISPANIC OR LATINO |

#### 3.5.2.2 Example 2

See Subject Characteristics (SC) Section 3.15 for an example of a DM CRF that collects some SC data.

### 3.5.3 Form Level Completion Instructions—DM

Record data for all fields on this page.

## 3.6 Disposition (DS)

The information eventually submitted in the SDTMIG DS domain can be captured on many other CRFs. Most typical are: Demographics, Randomization and End of Study.

### 3.6.1 CDASH to SDTM Mapping—DS

All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

| | Question Text | Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v.3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | To which period of the trial does this disposition refer? | EPOCH | R/C | EPOCH | Perm | Maps directly to SDTM. |
| 2. | What was the subject's status?<br>and /or<br>Specify Status | DSTERM<br>and<br>DSDECOD | HR | DSTERM<br>and DSDECOD | Req | Maps directly to SDTM.<br>Both DSDECOD and DSTERM must be populated in SDTM.<br>If DSTERM was collected as an "Other, Specify" free text, populate DSTERM with the free text and populate DSDECOD with the sponsor-defined standardized text.<br>If DSDECOD was collected with no free text, populate DSTERM and DSDECOD in SDTM with the DSDECOD value that was collected. |
| 3. | What was date the subject completed <protocol milestones/disposition event>? | DSSTDAT | R/C | DSSTDTC | Exp | **For the SDTM dataset**, the SDTM variable --STDTC is derived by concatenating CDASH Start Date and Time (if time is applicable) into --STDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 4. | What was time the subject completed or discontinued? | DSSTTIM | O | | Exp | **For the SDTM dataset**, the SDTM variable --STDTC is derived by concatenating CDASH Start Date and Time (if time is applicable) into --STDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 5. | Was treatment unblinded by the site? | DSUNBLND | O | Not Specified | Not Specified | If DSUNBLIND = 'Y', then DSDECOD = 'TREATMENT UNBLINDED' and 'DSCAT' = "OTHER EVENT". If DSUNBLIND = 'N', then the CRF should be annotated to indicate that this value is NOT SUBMITTED. |
| 6. | Will the subject continue? | DSCONT | O | Not Specified | Not Specified | This information may be submitted in SUPPDS or FADS. |

| | | | | | | |
|---|---|---|---|---|---|---|
| 7. | What is the next period the subject will continue to? | DSNEXT | O | Not Specified | Not Specified | May be used to create RELREC to link this record with a record in another domain. |
| 8. | *Not Specified* | *Not Specified* | *Not Specified* | DSCAT | Req | This REQUIRED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |

## 3.6.2 Implementation Examples—DS

### 3.6.2.1 Disposition Example 1

In this example, a DS CRF collects 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).

***Notes:***

1. Not all variables specified in the CDISC DS domain are present on the CRF (e.g., DSSCAT, DSSTDY). Since they are not used; the variables are not present on the DS dataset. However, all required and expected variables are present and populated.
2. In the Events observation class, the date/time of the Disposition Event is the DSSTDAT variable. The date of collection of the disposition information is the DSDAT variable.
3. EPOCH can be derived from VISITNUM. In the example below, when VISITNUM = 0, then EPOCH = SCREENING. EPOCH is populated when DSCAT is a disposition event and null when DSCAT is a protocol milestone.

There are multiple disposition events for each subject:

- Subject 123101 has 3 records to indicate the completion of 3 stages of the study, which are screening, treatment phase and follow-up. Protocol milestone records for informed consent and randomization are also included.
- Subject 123102 is a screen drop. 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.
- Subject 123103 completed the screening stage but did not complete the treatment stage.
- Subject 123104 died on October 29, 2003 (see DSSTDAT) after the completion of treatment, but prior to the completion of follow-up. Note that the date of collection of the event information was on October 31, 2003 (DSDAT).
- Subject 123105 discontinued study treatment due to an AE, but went on to complete the follow-up phase of the trial.

The following table is sample data that illustrates the above bullet points:

| | STUDYID | DOMAIN | SUBJID | DSSPID | DSTERM | DSDECOD | DSCAT | VISITNUM | EPOCH | DSDAT | DSSTDAT |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Row 1 | ABC123 | DS | 123101 | 1 | INFORMED CONSENT OBTAINED | INFORMED CONSENT OBTAINED | PROTOCOL MILESTONE | 0 | | 21-SEP-2003 | 21-SEP-2003 |
| Row 2 | ABC123 | DS | 123101 | 2 | COMPLETED | COMPLETED | DISPOSITION EVENT | 0 | SCREENING | 29-SEP-2003 | 29-SEP-2003 |
| Row 3 | ABC123 | DS | 123101 | 3 | RANDOMIZED | RANDOMIZED | PROTOCOL MILESTONE | 1 | | 30-SEP-2003 | 30-SEP-2003 |
| Row 4 | ABC123 | DS | 123101 | 4 | COMPLETED | COMPLETED | DISPOSITION EVENT | 2 | TREATMENT PHASE | 31-OCT-2003 | 31-OCT-2003 |
| Row 5 | ABC123 | DS | 123101 | 5 | COMPLETED | COMPLETED | DISPOSITION EVENT | 3 | FOLLOW-UP | 15-NOV-2003 | 15-NOV-2003 |
| Row 6 | ABC123 | DS | 123102 | 1 | INFORMED CONSENT OBTAINED | INFORMED CONSENT OBTAINED | PROTOCOL MILESTONE | 0 | | 21-NOV-2003 | 21-NOV-2003 |
| Row 7 | ABC123 | DS | 123102 | 2 | SUBJECT DENIED MRI PROCEDURE | PROTOCOL VIOLATION | DISPOSITION EVENT | 0 | SCREENING | 22-NOV-2003 | 20-NOV-2003 |
| Row 8 | ABC123 | DS | 123103 | 1 | INFORMED CONSENT OBTAINED | INFORMED CONSENT OBTAINED | PROTOCOL MILESTONE | 0 | | 15-SEP-2003 | 15-SEP-2003 |
| Row 9 | ABC123 | DS | 123103 | 2 | COMPLETED | COMPLETED | DISPOSITION EVENT | 0 | SCREENING | 22-SEP-2003 | 22-SEP-2003 |
| Row 10 | ABC123 | DS | 123103 | 3 | RANDOMIZED | RANDOMIZED | PROTOCOL MILESTONE | 1 | | 30-SEP-2003 | 30-SEP-2003 |
| Row 11 | ABC123 | DS | 123103 | 4 | SUBJECT MOVED | LOST TO FOLLOW-UP | DISPOSITION EVENT | 1 | TREATMENT PHASE | 31-OCT-2003 | 31-OCT-2003 |
| Row 12 | ABC123 | DS | 123104 | 1 | INFORMED CONSENT OBTAINED | INFORMED CONSENT OBTAINED | PROTOCOL MILESTONE | 0 | | 15-SEP-2003 | 15-SEP-2003 |
| Row 13 | ABC123 | DS | 123104 | 2 | COMPLETED | COMPLETED | DISPOSITION EVENT | 0 | SCREENING | 22-SEP-2003 | 22-SEP-2003 |
| Row 14 | ABC123 | DS | 123104 | 3 | RANDOMIZED | RANDOMIZED | PROTOCOL MILESTONE | 1 | | 30-SEP-2003 | 30-SEP-2003 |
| Row 15 | ABC123 | DS | 123104 | 4 | COMPLETED | COMPLETED | DISPOSITION EVENT | 2 | TREATMENT PHASE | 15-OCT-2003 | 15-OCT-2003 |
| Row 16 | ABC123 | DS | 123104 | 5 | SUBJECT DIED | DEATH | DISPOSITION EVENT | 1 | FOLLOW-UP | 31-OCT-2003 | 31-OCT-2003 |
| Row 17 | ABC123 | DS | 123105 | 1 | INFORMED | INFORMED | PROTOCOL | 0 | | 28-SEP-2003 | 28-SEP-2003 |

| | STUDYID | DOMAIN | SUBJID | DSSPID | DSTERM | DSDECOD | DSCAT | VISITNUM | EPOCH | DSDAT | DSSTDAT |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | CONSENT OBTAINED | CONSENT OBTAINED | MILESTONE | | | | |
| Row 18 | ABC123 | DS | 123105 | 2 | COMPLETED | COMPLETED | DISPOSITION EVENT | 0 | SCREENING | 02-OCT-2003 | 02-OCT-2003 |
| Row 19 | ABC123 | DS | 123105 | 3 | RANDOMIZED | RANDOMIZED | PROTOCOL MILESTONE | 1 | | 02-OCT-2003 | 02-OCT-2003 |
| Row 20 | ABC123 | DS | 123105 | 4 | ANEMIA | ADVERSE EVENT | DISPOSITION EVENT | 2 | TREATMENT PHASE | 17-OCT-2003 | 17-OCT-2003 |
| Row 21 | ABC123 | DS | 123105 | 5 | COMPLETED | COMPLETED | DISPOSITION EVENT | 3 | FOLLOW-UP | 02-NOV-2003 | 02-NOV-2003 |

### 3.6.2.2 Disposition Example 2

In this example, the sponsor has chosen to simply submit whether or not the subject completed the study. Examples are shown of one subject who completed the study, and two subjects who discontinued the study prior to completion. In this very straightforward situation, only required and expected variables have been included.

| | STUDYID | DOMAIN | SUBJID | DSSPID | DSTERM | DSDECOD | DSSTDAT |
|---|---|---|---|---|---|---|---|
| Row 1 | ABC456 | DS | 456101 | 1 | COMPLETED | COMPLETED | 21-SEP-2003 |
| Row 2 | ABC456 | DS | 456102 | 1 | SUBJECT TAKING STUDY MED ERRATICALLY | PROTOCOL VIOLATION | 29-SEP-2003 |
| Row 3 | ABC456 | DS | 456103 | 1 | LOST TO FOLLOW-UP | LOST TO FOLLOW-UP | 15-OCT-2003 |

### 3.6.2.3 Disposition Example 3

In this example, the sponsor collects whether or not the subject completes the treatment and follow-up phases as well as whether the subject's treatment assignment was unblinded. The date of the unblinding is represented in DSSTDAT. Note that maintaining the blind as per protocol is not considered to be an event since there is no change in the subject's state.

| | STUDYID | DOMAIN | SUBJID | DSSPID | DSCAT | EPOCH | DSTERM | DSDECOD | DSSTDAT |
|---|---|---|---|---|---|---|---|---|---|
| Row 1 | ABC789 | DS | 789101 | 1 | DISPOSITION EVENT | TREATMENT PHASE | COMPLETED | COMPLETED | 12-SEP-2004 |
| Row 2 | ABC789 | DS | 789101 | 2 | DISPOSITION EVENT | FOLLOW-UP | COMPLETED | COMPLETED | 20-DEC-2004 |
| Row 3 | ABC789 | DS | 789102 | 1 | DISPOSITION EVENT | TREATMENT PHASE | SKIN RASH | ADVERSE EVENT | 30-SEP-2004 |
| Row 4 | ABC789 | DS | 789102 | 2 | OTHER EVENTS | TREATMENT PHASE | SUBJECT HAD SEVERE RASH | TREATMENT UNBLINDED | 01-OCT-2004 |
| Row 5 | ABC789 | DS | 789102 | 3 | DISPOSITION EVENT | FOLLOW-UP | COMPLETED | COMPLETED | 28-DEC-2004 |

### 3.6.3 Form Level Completion Instructions—DS

- Record all relevant protocol milestones, such as Informed Consent Obtained, or Randomized.
- Once the subject has completed or discontinued from the study, record the subject's final disposition on this page.

## 3.7 Drug Accountability (DA)

The CDASH Drug Accountability domain defines the variables needed to collect information about drug dispensed to and returned from clinical trial subjects. The Drug Accountability (DA) variables are sometimes used to calculate the subject's compliance with the study treatment—however, based on the study design, this may not provide the most accurate information, as medication that is not returned may not necessarily have been consumed by the subject, thereby giving a false estimate of compliance. In addition, the *SDTMIG* standard separates DA from compliance and treats each differently.

The name of the study treatment (DATEST values) can be pre-specified on the CRF if the data are collected in a de-normalized format. The *SDTMIG* states "one record per drug accountability finding per subject." The combined use of the *SDTMIG* variables provides the ability to uniquely identify findings.

The term "dispensed" refers to when the test article/study product is given to the subject. This is independent of other dosing conditions specified in the protocol.

### 3.7.1 CDASH to SDTM Mapping—DA

Refer to Section 2.7 for more information about normalized versus de-normalized structures for Findings Domains. This section will provide two options for collection of Drug Accountability data. All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

#### 3.7.1.1 Mapping to SDTM from Normalized DA Collection

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Was drug accountability performed? | DAPERF | O | *Not Specified* | *Not Specified* | May be used to derive a value into the SDTM variable, DASTAT. If DAPERF = "N", the value of DASTAT will be "NOT DONE". If DAPERF = "Y", DASTAT should be null. |
| 2. | What type of treatment was dispensed or returned? | DACAT | O | DACAT | Perm | Maps directly to SDTM.<br>May be used to create RELREC to link this record with a record in EX domain. |
| 3. | What was the name of the study treatment dispensed or returned? | DASCAT | O | DASCAT | Perm | Maps directly to SDTM. |
| 4. | What date was the study treatment (dispensed or returned)? | DADAT | R/C | DADTC | Exp | **For the SDTM-based dataset,** the SDTM variable --DTC is derived by concatenating CDASH Date and Time (if time is applicable) into --DTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 5. | What is the treatment label identifier? | DAREFID | O | DAREFID | Perm | Maps directly to SDTM.<br>May be used to create RELREC to link this record with a record in EX domain. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 6. | Is this the amount dispensed or the amount returned? | DATEST | HR | DATEST<br>and<br>DATESTCD | Req<br><br>Req | Maps directly to SDTM. DATESTCD may be derived from the value collected in DATEST. Both DATESTCD and DATEST are required in SDTM. |
| 7. | What is the amount dispensed or the amount returned? | DAORRES | HR | DAORRES<br>and<br>DASTRESC | Exp<br><br>Exp | The value collected in DAORRES maps directly to the SDTM variable DAORRES.<br>DASTRESC is the standardized value for DAORRES and should be populated for any record where DAORRES has a value.<br>If the value in DASTRESC is a numeric value, it should also be populated into the DASTRESN variable. |
| 8. | What are the units of study treatment dispensed or returned? | DAORRESU | HR | DAORRESU | Perm | Maps directly to SDTM. |

### 3.7.1.2 Mapping to SDTM from De-normalized DA Collection

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Was drug accountability performed for dispensed study treatment? | DISPAMT.DAPERF | O | *Not Specified* | *Not Specified* | May be used to derive a value into the SDTM variable, DASTAT. If DAPERF = "N", the value of DASTAT will be "NOT DONE". If DAPERF = "Y", DASTAT should be null. |
| 2. | What type of treatment was dispensed? | DISPAMT.DACAT | O | DACAT | Perm | Maps directly to SDTM.<br>May be used to create RELREC to link this record with a record in EX domain. |
| 3. | What was the name of the study treatment dispensed? | DISPAMT.DASCAT | O | DASCAT | Perm | Maps directly to SDTM. |
| 4. | What is the dispensed treatment label identifier? | DISPAMT.DAREFID | O | DAREFID | Perm | Maps directly to SDTM. May be used to create RELREC to link this record with a record in EX domain. |
| 5. | What date was the study treatment dispensed? | DISPAMT.DADAT | R/C | DADTC | Exp | **For the SDTM-based dataset**, the SDTM variable --DTC is derived by concatenating CDASH Date and Time (if time is applicable) into --DTC using the ISO 8601 format. See SDTMIG **Section** 4.1.4.1. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 6. | What is the amount dispensed? | DISPAMT.DAORRES | HR | DATESTCD<br>and<br>DATEST<br>and<br>DAORRES<br>and<br>DASTRESC<br>and<br>DASTRESN | Req<br><br>Req<br><br>Exp<br><br>Exp<br><br>Exp | DISPAMT.DAORRES would be mapped to SDTMIG variables:<br>DATESTCD with the value of 'DISPAMT'<br><br>DATEST with the value of 'Dispensed Amount'<br><br>DAORRES with the collected result value<br><br>DASTRESC with the collected result value, standardized (if needed)<br><br>DASTRESN with the standardized result value if numeric |
| 7. | What are the units of study treatment dispensed? | DISPAMT.DAORRESU | HR | DAORRESU | Exp | The value collected in DAORRESU maps directly to the SDTM variable DAORRESU where DATESTCD=DISPAMT |
| 8. | Was drug accountability performed for returned study treatment? | RETAMT.DAPERF | O | *Not Specified* | *Not Specified* | May be used to derive a value into the SDTM variable DASTAT. If DAPERF = "N", the value of DASTAT will be "NOT DONE". If DAPERF = "Y", DASTAT should be null. |
| 9. | What type of treatment was returned? | RETAMT.DACAT | O | DACAT | Perm | Maps directly to SDTM.<br>May be used to create RELREC to link this record with a record in EX domain. |
| 10. | What was the name of the study treatment returned? | RETAMT.DASCAT | O | DASCAT | Perm | Maps directly to SDTM. |
| 11. | What is the returned treatment label identifier? | RETAMT.DAREFID | O | DAREFID | Perm | Maps directly to SDTM.<br>May be used to create RELREC to link this record with a record in EX domain. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 12. | What was the date the study treatment was returned? | RETAMT.DADAT | R/C | DADTC | Exp | **For the SDTM-based dataset**, the SDTM variable --DTC is derived by concatenating CDASH Date and Time (if time is applicable) into --DTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 13. | What is the amount returned? | RETAMT.DAORRES | HR | DATESTCD<br>and<br>DATEST<br>and<br>DAORRES<br>and<br>DASTRESC<br>and<br>DASTRESN | Req<br><br>Req<br><br>Exp<br><br>Exp<br><br>Exp | RETAMT.DAORRES would be mapped to SDTMIG variables:<br>DATESTCD with the value of 'RETAMT'<br><br>DATEST with the value of 'Returned Amount'<br><br>DAORRES with the collected result value<br><br>DASTRESC with the collected result value, standardized (if needed)<br><br>DASTRESN with the standardized result value if numeric |
| 14. | What are the units of study treatment returned? | RETAMT.ORRESU | HR | DAORRESU | Exp | The value collected in DAORRESU maps directly to the SDTM variable DAORRESU where DATESTCD=RETAMT |

### 3.7.2 Implementation Examples—DA

- Rows 1 and 2 show subject 12345 was dispensed 8 tablets of study medication on 02 Jan 2009 and returned 0 tablets on 09 Jan 2009.
- Row 3 shows 8 tablets of placebo dispensed to subject 98761 on 03 Jan 2008. This subject either dropped out or the Drug Accountability CRF was not completed for the return of the Placebo tablets for this subject because there is no RETAMT record.
-
-
-

- Rows 4 and 5 shows subject 56785 was dispensed 8 tablets of study medication on 04 Jan 2009, returned 2 of them on 09 Jan 2009.

| | SUBJID | DADAT | DATESTCD | DATEST | DAORRES | DAORRESU | DACAT | DASCAT |
|---|---|---|---|---|---|---|---|---|
| 1 | 12345 | 02-JAN-2009 | DISPAMT | Dispensed Amount | 8 | Tablets | Study Medication | Bottle A |
| 2 | 12345 | 09-JAN-2009 | RETAMT | Returned Amount | 0 | Tablets | Study Medication | Bottle A |
| 3 | 98761 | 03-JAN-2009 | DISPAMT | Dispensed Amount | 8 | Tablets | Placebo | Bottle B |
| 4 | 56785 | 04-JAN-2009 | DISPAMT | Dispensed Amount | 8 | Tablets | Study Medication | Bottle A |
| 5 | 56785 | 09-JAN-2009 | RETAMT | Returned Amount | 2 | Tablets | Study Medication | Bottle A |

### 3.7.3 Form Level Completion Instructions—DA

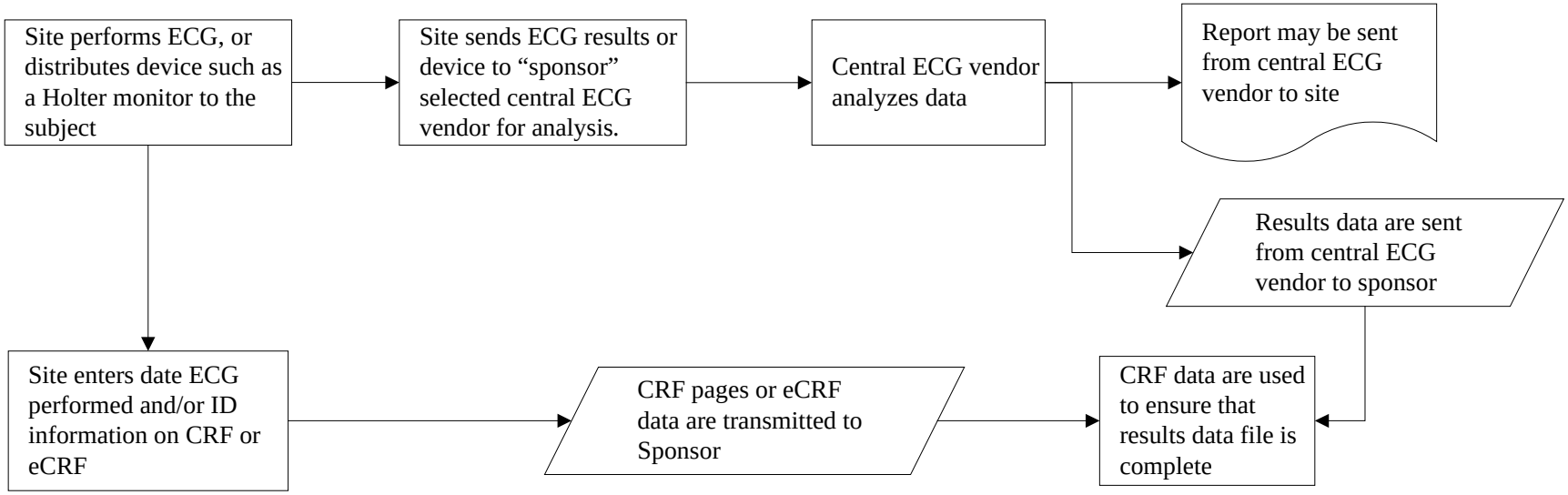
All investigational product dispensed to and returned by the subject should be recorded on this page.

# 3.8 ECG (ECG)

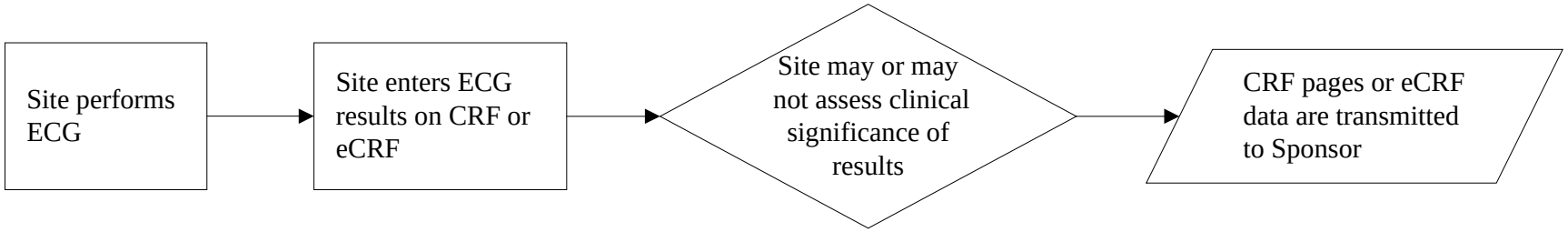
## 3.8.1 ECG Scenario Flowcharts (EG)

CDASH provides guidance on collection of ECG data under three different scenarios represented in the following process flow diagrams.

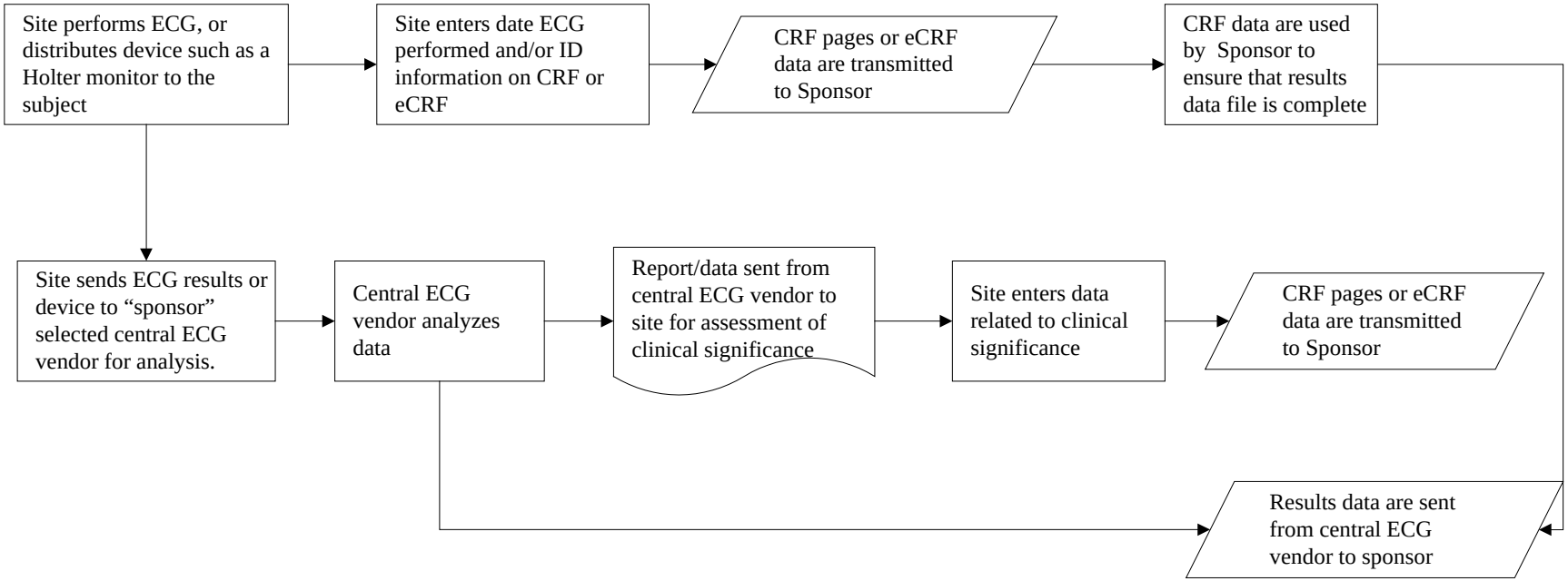
**Scenario 1: Central Processing**



**Scenario 2: Local Processing**




**Scenario 3: Central Processing with Secondary Site Assessment of Clinical Significance**



### 3.8.2 CDASH to SDTM Mapping—EG

Although ECGs have three scenarios, this does not affect the variables to be submitted, therefore, there is just one mapping table included in the User Guide.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Was the ECG performed? | EGPERF | Scenario 1: HR<br>Scenario 2: HR<br>Scenario 3: HR | *Not Specified* | *Not Specified* | May be used to derive a value into the SDTM variable EGSTAT. If EGPERF = "N", the value of EGSTAT will be "NOT DONE". If EGPERF = "Y", EGSTAT should be null. |
| 2. | What was the ECG reference identifier? | EGREFID | Scenario 1: O<br>Scenario 2: *Not Specified*<br>Scenario 3: O | EGREFID | Perm | Maps directly to SDTM.<br>May be used to create RELREC to link this record with a record in another domain. |
| 3. | What was the method used to measure ECG? | EGMETHOD | Scenario 1: O<br>Scenario 2: O<br>Scenario 3: O | EGMETHOD | Perm | Maps directly to SDTM. |
| 4. | What was the position of the subject during ECG measurement? | EGPOS | Scenario 1: O<br>Scenario 2: O<br>Scenario 3: O | EGPOS | Perm | Maps directly to SDTM. |
| 5. | What was the ECG date? | EGDAT | Scenario 1: HR<br>Scenario 2: HR<br>Scenario 3: HR | EGDTC | Exp | **For the SDTM dataset**, the SDTM variable --DTC is derived by concatenating CDASH Date and Time (if time is applicable) into --DTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 6. | What was the ECG time? | EGTIM | Scenario 1:R/C<br>Scenario 2:R/C<br>Scenario 3:R/C | EGDTC | Exp | **For the SDTM dataset**, the SDTM variable --DTC is derived by concatenating CDASH Date and Time (if time is applicable) into --DTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 7. | What was the planned time point of the measurement? | EGTPT | Scenario 1:R/C<br>Scenario 2:R/C<br>Scenario 3:R/C | EGTPT | Perm | Maps directly to SDTM. |
| 8. | What was the ECG test name? | EGTEST | Scenario 1: *Not Specified*<br>Scenario 2: HR<br>Scenario 3: HR | EGTEST<br>and<br>EGTESTCD | Req | Maps directly to SDTM.<br>EGTESTCD may be derived from the value collected in EGTEST. Both EGTESTCD and EGTEST are required in SDTM. |
| 9. | What was the result of the ECG? | EGORRES | Scenario 1: *Not Specified*<br>Scenario 2: HR<br>Scenario 3:R/C | EGORRES<br>and<br>EGSTRESC | Exp | The value collected in EGORRES maps directly to the SDTM variable EGORRES.<br>EGSTRESC is the standardized value for EGORRES and should be populated for any record where EGORRES has a value.<br>If the value in EGSTRESC is a numeric value, it should also be copied into the EGSTRESN variable. |
| 10. | What were the ECG result units? | EGORRESU | Scenario 1: *Not Specified*<br>Scenario 2: HR<br>Scenario 3: O | EGORRESU | Exp | Maps directly to SDTM. |
| 11. | Was the ECG clinically significant? | EGCLSIG | Scenario 1: *Not Specified*<br>Scenario 2: O<br>Scenario 3: HR | SUPPEG. QNAM (value of EGCLSIG) | (Non-standard variable) | This information could be submitted in a SUPPEG dataset. The value of EGCLSIG may be used to populate SUPPEG.QVAL where SUPPEG.QNAM = EGCLSIG. . |

All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

## 3.8.3 Implementation Examples—EG

### 3.8.3.1 Example 1

The site performs the ECG on equipment that electronically transfers the measurements to a central ECG vendor, who provides the measurements and an overall assessment of the results directly to the Sponsor. The Sponsor would like to use the CRF data to ensure that the electronic data files are complete. This falls under Scenario 1.

### 3.8.3.2 Example 2

The site performs the ECG measurements and reports them along with an overall assessment on the CRF. This is Scenario 2.

### 3.8.3.3 Example 3

The site distributes a Holter monitor to the subjects at Visit 1. The subject wears the monitor for 24 hours and returns it to the site. The site then sends the measurements from the Holter monitor to a central ECG vendor who provides the data electronically to the sponsor and sends a report to the site. The investigator provides their assessment of clinical significance to any abnormal measurements. This is Scenario 3.

### 3.8.3.4 Example 4

The site performs the ECG on equipment that electronically transfers the measurements to a central ECG vendor. The Sponsor does not require any reconciliation of the electronic data received by the ECG vendor. In this situation, no CRF for ECG data is required. It is not necessary for the site to provide any additional information to that which the Sponsor is already receiving electronically from the ECG vendor.

### 3.8.3.5 Example 5

The site performs the ECG measurements, and the study design only requires a simple assessment of the clinician's overall impression of whether the results are normal or abnormal as well as the clinical significance of the interpretation.

It is extremely common for sponsors to combine the interpretation and clinical significance into a single response as illustrated below.

Some of the rationale for this design was to ensure clinical significance was only associated with an abnormal result and thereby reduce the need for queries, and to reduce the number of items the clinician was required to mark. This design is not CDASH-conformant because clinical significance should be collected as a separate field.

For EDC studies, the features of the EDC system can be used to only permit clinical significance to be entered if the interpretation was given as "abnormal".

**Non-conformant example:**

**ECG Interpretation**

□ Normal □ Abnormal, not clinical significant □ Abnormal, clinically significant

If abnormal, please describe: _____

_____

The CDASH-conformant version of this CRF is given below. Note that the order of the questions and layout may be changed without affecting the conformance.

**CDASH-conformant example:**

ECG Interpretation □ Normal □ Abnormal

Clinically significant? □ Yes □ No

Abnormality _____

_____

### 3.8.4 Form Level Completion Instructions—EG

- ECG tracings should <protocol-specified process for tracing retention or forwarding>.
- Please remember that an abnormality on an ECG may represent a new adverse event. Record all Adverse Events on the Adverse Events CRF.

## 3.9 Exposure (EX)

This proposal includes the SDTMIG-based variables that appear in the *SDTMIG* 3.1.1. The *SDTMIG* defines the EX domain model as follows:

"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. Examples include but are not limited to placebo, active comparator, and study treatment. Treatments that are not protocol-specified should be recorded in the Concomitant Medications (CM) domain."

The dose variables in this proposal refer to the collection of the "actual dose" rather than the "planned dose."

### 3.9.1 CDASH to SDTM Mapping—EX

All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Is treatment data available? | EXYN | O | *Not Specified* | *Not Specified* | Does not map to SDTM.<br>The CRF should be annotated to indicate that this field is NOT SUBMITTED. |
| 2. | What was the treatment start date? | EXSTDAT | HR | EXSTDTC | EXP | **For the SDTM dataset**, the SDTM variable --STDTC is derived by concatenating CDASH Start Date and Time (if time is applicable) into --STDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 3. | What was the treatment start time? | EXSTTIM | R/C | EXSTDTC | EXP | **For the SDTM dataset**, the SDTM variable --STDTC is derived by concatenating CDASH Start Date and Time (if time is applicable) into --STDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 4. | What is the treatment label identifier? | EXREFID | R/C | EXREFID | Perm | Maps directly to SDTM. |
| 5. | What was the treatment end date? | EXENDAT | R/C | EXENDTC | Perm | **For the SDTM dataset**, the SDTM variable --ENDTC is derived by concatenating CDASH End Date and Time (if time is applicable) into --ENDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 6. | What was the treatment end time? | EXENTIM | R/C | EXENDTC | Perm | **For the SDTM dataset**, the SDTM variable --ENDTC is derived by concatenating CDASH End Date and Time (if time is applicable) into --ENDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 7. | What was the dose per administration? | EXDSTXT | R/C | EXDOSE<br>or<br>EXDOSTXT | EXP | Numeric values map to EXDOSE in SDTM.<br>Non-numeric values (e.g., 200-400) map to EXDOSTXT in SDTM. |
| 8. | What were the units for the dose? | EXDOSU | R/C | EXDOSU | EXP | Maps directly to SDTM. |
| 9. | What was the lot number of the study treatment used? | EXLOT | O | EXLOT | Perm | Maps directly to SDTM. |
| 10. | What was the study treatment? | EXTRT | R/C | EXTRT | REQ | Maps directly to SDTM. |
| 11. | Was the dose adjusted from planned? | EXDOSADJ | O | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPEX dataset. The value of EXDOSADJ may be used to populate SUPPEX.QVAL where SUPPEX.QNAM = EXDOSADJ |
| 12. | What was the reason the dose was adjusted? | EXADJ | O | EXADJ | Perm | Maps directly to SDTM. |
| 13. | What was the frequency of study treatment dosing? | EXDOSFRQ | R/C | EXDOSFRQ | Perm | Maps directly to SDTM. |
| 14. | What was the route of administration for the study treatment? | EXROUTE | R/C | EXROUTE | Perm | Maps directly to SDTM. |
| 15. | What was the formulation of the study treatment? | EXDOSFRM | R/C | EXDOSFRM | Perm | Maps directly to SDTM. |
| 16. | If the dose was interrupted, how long was the interruption? | EXINTRP | O | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPEX dataset. The value of EXINTRP may be used to populate SUPPEX.QVAL where SUPPEX.QNAM = EXINTRP |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 17. | If the dose was interrupted, what were the units for the duration? | EXINTRPU | O | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPEX dataset. The value of EXINTRPU may be used to populate SUPPEX.QVAL where SUPPEX.QNAM = EXINTRPU |
| 18. | What was the anatomical location of the administration? | EXLOC | O | EXLOC | Perm | Maps directly to SDTM. |
| 19. | What was the total volume of study treatment administered? | EXVAMT | O | EXVAMT | Perm | Maps directly to SDTM. |
| 20. | What were the units for the volume of study treatment administered? | EXVAMTU | O | EXVAMTU | Perm | Maps directly to SDTM |
| 21. | What was the study treatment infusion rate? | EXFLRT | O | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPEX dataset. The value of EXFLRT may be used to populate SUPPEX.QVAL where SUPPEX.QNAM = EXFLRT. |
| 22. | What were the units for the infusion rate? | EXFLRTU | O | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPEX dataset. The value of EXFLRT may be used to populate SUPPEX.QVAL where SUPPEX.QNAM = EXFLRTU. |
| 23. | What was the planned time point for study treatment? | EXTPT | O | EXTPT | Perm | Maps directly to SDTM. |
| 24. | Did subject complete the full course of study treatment? | EXTRTCMP | O | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPEX dataset. The value of EXTRTCMP may be used to populate SUPPEX.QVAL where SUPPEX.QNAM = EXTRTCMP. |
| 25. | What was the planned dose per administration? | EXPDOSE | O | *Not Specified* | | This information could be submitted in a SUPPEX dataset. The value of EXPDOSE may be used to populate SUPPEX.QVAL where SUPPEX.QNAM = EXPDOSE. |
| 26. | What were the units for the planned dose? | EXPDOSU | O | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPEX dataset. The value of EXPDOSU may be used to populate SUPPEX.QVAL where SUPPEX.QNAM = EXPDOSU. . |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 27. | Was the planned dose administered? | EXPOCCUR | O | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPEX dataset. The value of EXPOCCUR be used to populate SUPPEX.QVAL where SUPPEX.QNAM = EXPOCCUR.<br>***The SDS EX Sub-team is currently working on a convention for this. |

## 3.9.2 Implementation Examples—EX

### 3.9.2.1 Example 1

This section provides an example of how exposure data could be collected via a CRF using CDASH standards.

- Subject 12335 takes a 30 mg tablet of Drug A three times a day starting on 05 January 2009, and ends on 10 January 2009.
- Subject 98761 takes a 50 mg capsule of Drug B twice a day starting on 06 January 2009, and ends of 15 January 2009.
- Subject 56785 takes a 40 mg capsule of Drug C twice a day starting on 10 January 2009, and is ongoing.

| SUBJID | EXTRT | EXSTDAT | EXENDAT | EXDOSE | EXDOSU | EXDOSFRM | EXDOSFRQ |
|---|---|---|---|---|---|---|---|
| 12335 | Drug A | 05 Jan 2009 | 10 Jan 2009 | 30 | mg | Tablet | TID |
| 98761 | Drug B | 06 Jan 2009 | 15 Jan 2009 | 50 | mg | Capsule | BID |
| 56785 | Drug C | 10 Jan 2009 | - | 40 | mg | Capsule | BID |

## 3.9.3 Form Level Completion Instructions—EX

- This page is used to record <include protocol-specified information to be reported> for all investigational product taken by the subject as per the protocol.
- Investigational product dispensed to a subject but not actually taken must not be recorded on this page but must be reflected in the Drug Accountability CRF(s).
- The exposure CRF page must be consistent with the Drug Accountability CRFs.

## 3.10 Inclusion and Exclusion Criteria (IE)

These recommendations are for the inclusion or exclusion criteria that are identified during the eligibility process as "not met" for subjects who are subsequently enrolled in the study. It is not intended to collect protocol deviations or violations that occur after enrollment. As with all the data collection variables recommended in the *CDASH V1.1*, it is assumed that sponsors will add other data variables as needed to meet protocol-specific and other data collection requirements (e.g., TA-specific data elements and others as required per protocol, business practice, and operating procedures). The following table includes the CDASH recommendations for collecting IE data and mapping it to the Required variables in an SDTMIG IE dataset.

### 3.10.1 CDASH to SDTM Mapping—IE

All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

| 1. | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Mapping Instructions |
|---|---|---|---|---|---|---|
| 2. | Did the subject meet all eligibility criteria? | IEYN | HR | *Not Specified* | *Not Specified* | May be used to derive a value into the SDTM variable IEORRES. Only negative responses will be included in the IEORRES, i.e. “No” for Inclusion Criteria and “Yes” for Exclusion Criteria. |
| 3. | What was the category of the criterion? | IECAT | O | IECAT | Req | Maps directly to SDTM. |
| 4. | What is the identifier of the criterion the subject did not meet? | IETESTCD | HR | IETESTCD | Req | Maps directly to SDTM. |
| 5. | What is the description of the criterion the subject did not meet? | IETEST | O | IETEST | Req | Maps directly to SDTM. |

| 1. | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Mapping Instructions |
|---|---|---|---|---|---|---|
| 6. | *Not Specified* | *Not Specified* | *Not Specified* | IEORRES | Req | This REQUIRED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 7. | *Not Specified* | *Not Specified* | *Not Specified* | IESTRESC | Req | This REQUIRED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |

## 3.10.2 Implementation Examples—IE

### 3.10.2.1 Example 1

This is an example of an IE paper CRF that collects IEYN (did the subject meet all eligibility criteria) and IETESTCD (the identifier for the criteria that are not met).

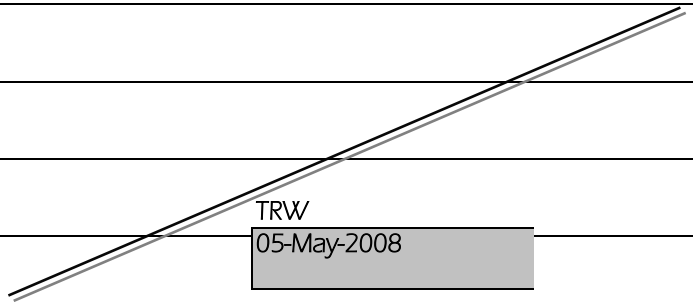
In this example, a worksheet would be used per subject by the site to record all the responses to the inclusion and exclusion criteria. This worksheet would be a source document for that subject.

The following is an example of a worksheet used during screening for subject 1003:

| **Subject: 1003** | | **Protocol: 123XYZ** |
|---|---|---|
| **Criterion Identifier (record this identifier on the CRF for any criterion that is not met by this subject)** | **Criterion** | **Yes or No** |
| **Inclusion Criteria** | | |
| IN001 | Subject between the ages of 18 and 45 | Yes |
| IN002 | Male; or Female with no child-bearing potential | Yes |
| IN003 | History of elevated intra-ocular pressure between 20 and 25 for less than six months | Yes |
| **Exclusion Criteria** | | |
| EX001 | History of cancer | No |
| EX002 | History of drug abuse | No |
| EX003 | History of diabetes | No |
| EX004 | Elevated liver enzymes at screening | No |
| EX005 | History of cardiovascular disease | Yes |

This worksheet would be considered a source document for this subject and maintained in the Investigator's study files for that subject.

The data would then be filled in for this subject on the paper CRF:

| Protocol — 123XYZ | Site: | Subject: |
|---|---|---|
| | E45 | 1003 |
| | | |
| Did the Subject meet all eligibility criteria? | Yes ☐ | No X |
| | | |
| What is identifier of the criterion the subject did not meet? | | |
| EX005 | | |
| | | |
| | | |
| | | |
|   | | |

Finally the data entered from the CRF would be entered in the Sponsor's database and the resulting SDTM+/- output would result:

- Rows 1, 4, and 5 show an example of subjects that met all the eligibility criteria.
- Rows 2 and 3 show examples of subjects that did not meet all eligibility criteria, including subject 1003 from the CRF example.

| Row | SubjectID | IEYN | IETESTCD |
|---|---|---|---|
| 1 | 1001 | Y | |
| 2 | 1002 | N | IN001 |
| 3 | 1003 | N | EX005 |
| 4 | 1004 | Y | |
| 5 | 1005 | Y | |

The table is "SDTM +/-" because no data is submitted for subjects who meet all eligibility criteria. The records for subjects 1001, 1004 and 1005 would be removed during the preparation of the SDTM datasets. The IETESTCDs would be used for subjects 1003 and 1004 to map in the IETEST and other variables required in the SDTMIG dataset.

#### 3.10.2.2 Example 2

This is an example dataset from an EDC IE CRF that collects IEYN for each subject, and IETEST for any criteria that are not met by a subject. IEYN and IETEST fields use drop-down lists. When IETEST is recorded for a subject, IETESTCD and IECAT are displayed for the site to verify.

- Rows 1, 4, and 5 show an example of subjects that met all the eligibility criteria.
- Rows 2 and 3 show examples of subjects that did not meet all eligibility criteria.

| Row* | SUBJID* | IEYN** | IETESTCD* | IETEST** | IECAT* |
|---|---|---|---|---|---|
| 1 | 1001 | Y | | | |
| 2 | 1002 | N | IN001 | Subject between the ages of 18 and 45 | INCLUSION |
| 3 | 1003 | N | EX005 | History of cardiovascular disease | EXCLUSION |
| 4 | 1004 | Y | | | |
| 5 | 1005 | Y | | | |

*Columns highlighted in red are displayed (only) in EDC. **Columns in black are entered by the site using a list of values from the system.

### 3.10.3 Form Level Completion Instructions—IE

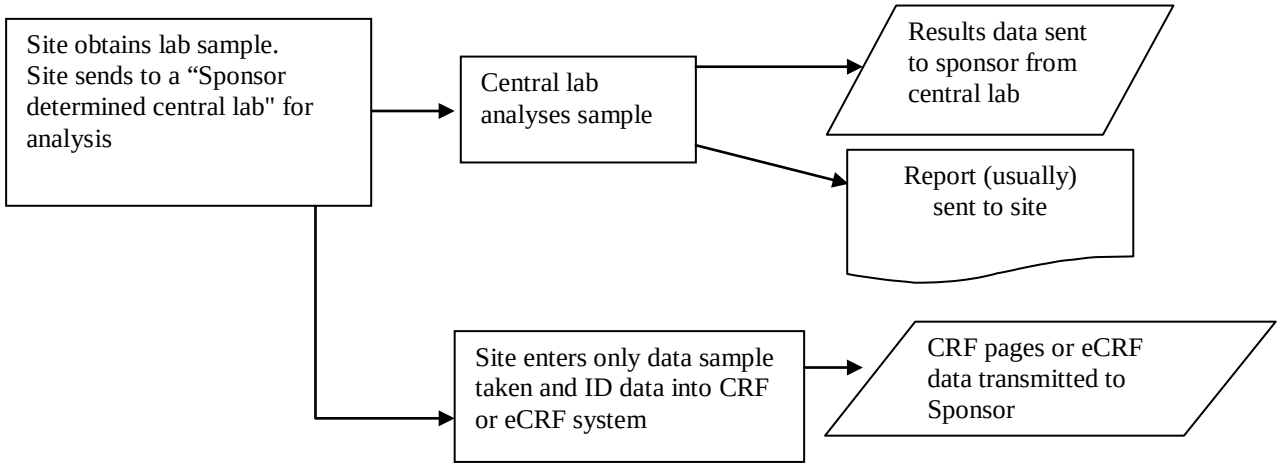
- All procedures must be performed and the subject's eligibility determined within <protocol-specified time period> prior to study medication administration.
- Complete the Inclusion / Exclusion Worksheet as source document for recording a "Yes" or "No" response to each criterion.
- Record ONLY the Inclusion or Exclusion criteria that the subject did NOT meet on this CRF.

# 3.11 Lab Test Results (LB)

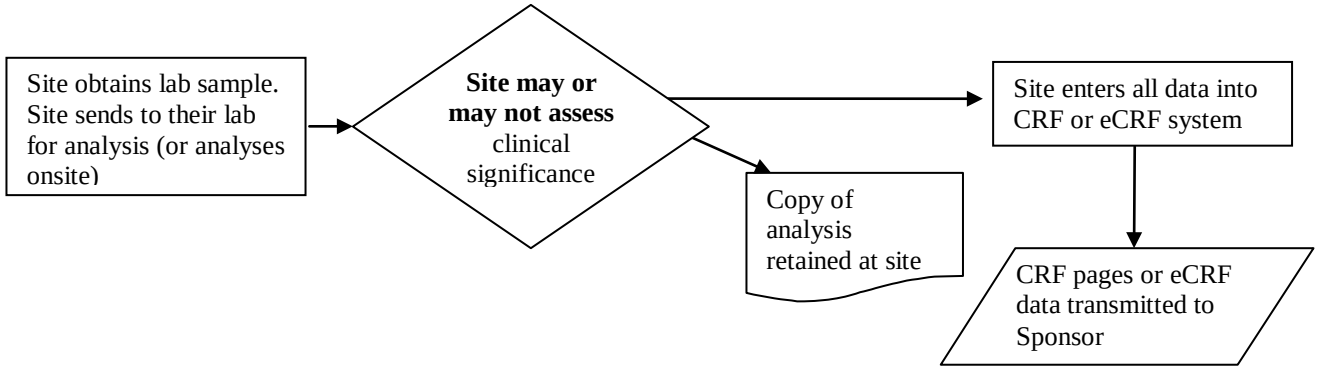
## 3.11.1 Lab Scenario Flowcharts (LB)

CDASH provides guidance on collection lab data under three different scenarios represented in the following process flow diagrams:

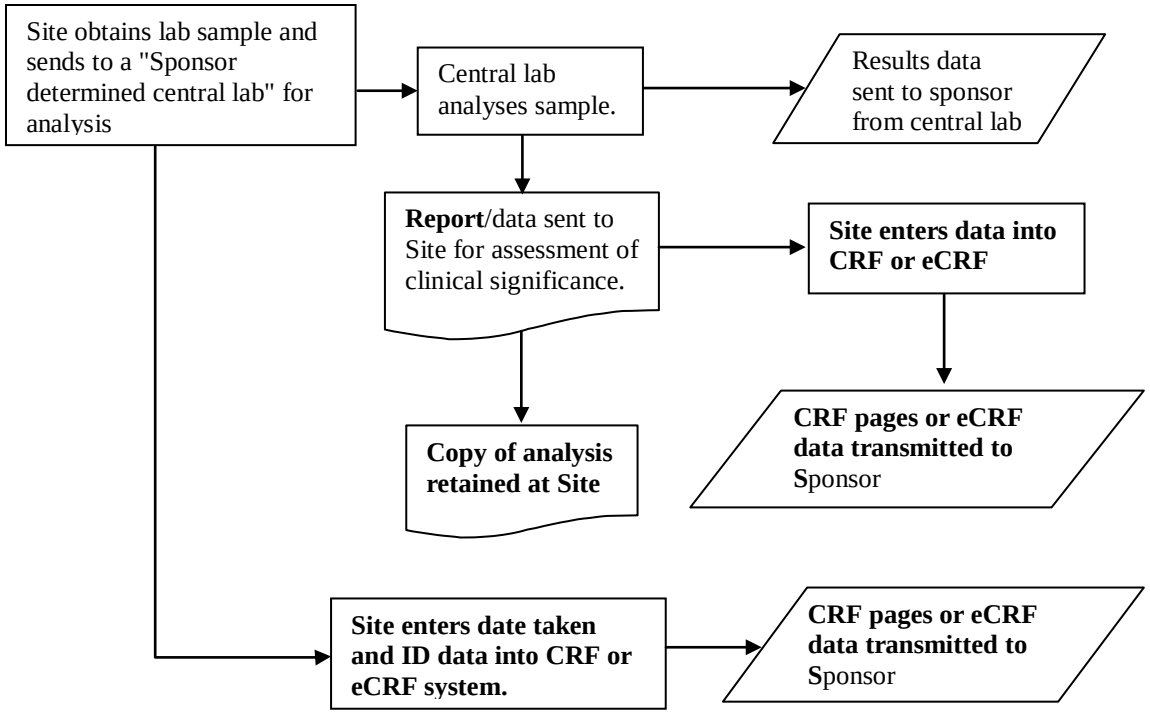
**Scenario 1: Central Processing**




**Scenario 2: Local Processing**



**Scenario 3: Central Processing with Secondary Site Assessment of Clinical Significance**



### 3.11.2 CDASH to SDTM Mapping—LB

Although labs have three scenarios, this does not affect the variables to be submitted, therefore, there is just one mapping table included in this User Guide. All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Was the sample collected?<br><br>OR<br><br>Was the lab performed? | LBPERF | Scenario 1: HR<br>Scenario 2: HR<br>Scenario 3: HR | **Not Specified** | Not Specified | May be used to derive a value into the SDTM variable LBSTAT. If LBPERF = "N", the value of LBSTAT will be "NOT DONE". If LBPERF = "Y", LBSTAT should be null. |
| 2. | What was the lab specimen collection date? | LBDAT | Scenario 1: R/C<br>Scenario 2: R/C<br>Scenario 3: R/C | LBDTC | Exp | **For the SDTM dataset**, the SDTM variable --DTC is derived by concatenating CDASH Date and Time (if time is applicable) into --DTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 3. | What was the lab specimen collection time? | LBTIM | Scenario 1: R/C<br>Scenario 2: R/C<br>Scenario 3: R/C | | | |
| 4. | What was the lab panel name? | LBCAT | Scenario 1: R/C<br>Scenario 2: R/C<br>Scenario 3: R/C | LBCAT | Exp | Maps directly to SDTM. |
| 5. | What was the lab sub-panel name? | LBSCAT | Scenario 1: R/C<br>Scenario 2: R/C<br>Scenario 3: R/C | LBSCAT | Perm | Maps directly to SDTM. |
| 6. | What was the planned time point of the lab? | LBTPT | Scenario 1: R/C<br>Scenario 2: R/C<br>Scenario 3: R/C | LBTPT | Perm | Maps directly to SDTM. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 7. | Were the protocol-defined testing conditions met? | LBCOND | Scenario 1: R/C<br>Scenario 2: R/C<br>Scenario 3: R/C | LBFAST<br>(if condition is fasting, otherwise, *Not Specified)* | Perm | May be used to derive a value into the SDTM variable LBFAST. |
| 8. | What was the condition of the specimen? | LBSPCCND | Scenario 1: *Not Specified*<br>Scenario 2: R/C<br>Scenario 3: *Not Specified* | LBSPCCND | Perm | Maps directly to SDTM. |
| 9. | What is the test name? | LBTEST | Scenario 1: *Not Specified*<br>Scenario 2: HR<br>Scenario 3: HR | LBTEST<br>and<br>LBTESTCD | Req | Maps directly to SDTM.<br>LBTESTCD may be derived from the value collected in LBTEST. Both LBTESTCD and LBTEST are required in SDTM |
| 10. | What was the result of the test? | LBORRES | Scenario 1: *Not Specified*<br>Scenario 2: HR<br>Scenario 3: R/C | LBORRES | Exp | The value collected in LBORRES maps directly to the SDTM variable LBORRES. |
| 11. | What were the units for the result? | LBORRESU | Scenario 1: *Not Specified*<br>Scenario 2: R/C<br>Scenario 3: *Not Specified* | LBORRESU | Exp | The value collected in LBORRESU maps directly to the SDTM variable LBORRESU. |
| 12. | What was the lower limit of the reference range for this test? | LBORNRLO | Scenario 1: *Not Specified*<br>Scenario 2: R/C<br>Scenario 3: *Not Specified* | LBORNRLO | Exp | Maps directly to SDTM. |
| 13. | What was the high limit of the reference range for this test? | LBORNRHI | Scenario 1: *Not Specified*<br>Scenario 2: R/C<br>Scenario 3: *Not Specified* | LBORNRHI | Exp | Maps directly to SDTM. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 14. | Was the result for this test abnormal? | LBNRIND | Scenario 1: *Not Specified*<br>Scenario 2: R/C<br>Scenario 3: *Not Specified* | LBNRIND | Exp | Maps directly to SDTM. |
| 15. | Was this result clinically significant? | LBCLSIG | Scenario 1: *Not Specified*<br>Scenario 2: R/C<br>Scenario 3: HR | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPLB dataset. The value of LBCLSIG may be used to populate SUPPLB.QVAL where SUPPLB.QNAM = LBCLSIG. |
| 16. | What was the name of the laboratory used? | LBNAM | Scenario 1: *Not Specified*<br>Scenario 2: R/C<br>Scenario 3: *Not Specified* | LBNAM | Perm | Maps directly to SDTM. |
| 17. | What was the accession number? | LBREFID | Scenario 1: R/C<br>Scenario 2: R/C<br>Scenario 3: R/C | LBREFID | Perm | Maps directly to SDTM. May be used to create RELREC to link this record with a record in another domain. |

### 3.11.3 Implementation Examples

### 3.11.4 Form Level Completion Instructions—LB

- As required or defined by the study protocol, clinically significant results may need to be reported on the Adverse Event CRF.
- As required or defined by the study protocol, changes that are worsening may need to be reported on the Adverse Event CRF.
- Verify lab results against laboratory <protocol-specific> requirements.
- Ensure that all pertinent laboratory normal ranges/units and laboratory certification for all laboratories used during the study have been provided to the sponsor with a copy in your Study Files. This is required for regulatory and database purposes.

# 3.12 Medical History (MH)

## 3.12.1 CDASH to SDTM Mapping—MH

All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Has the subject experienced any past and/ or concomitant diseases or past surgeries? | MHYN | O | *Not Specified* | *Not Specified* | Does not map to SDTM.<br>The CRF should be annotated to indicate that this field is NOT SUBMITTED. |
| 2. | What is the medical history identifier? | MHSPID | O | MHSPID | Perm | Maps directly to SDTM.<br>May be used to create RELREC to link this record with a record in another domain. |
| 3. | *Not Specified* | MHCAT | R/C | MHCAT | Perm | Maps directly to SDTM. |
| 4. | *Not Specified* | MHSCAT | R/C | MHSCAT | Perm | Maps directly to SDTM. |
| 5. | What is the verbatim term for the medical history condition/event? | MHTERM | HR | MHTERM | Req | Maps directly to SDTM.<br>. |
| 6. | Is the medical history disease/condition or event still ongoing? | MHONGO | O | *Not Specified* | *Not Specified* | May be used to derive a value into an SDTM relative timing variable such as MHENRF or MHENRTPT.<br>When populating MHENRF, if the value of MHONGO is "Y", the value of "DURING", "AFTER" or "DURING/AFTER" may be derived.<br>When populating MHENRTPT, if the value of MHONGO is "Y", the value of "ONGOING" may be derived. Note: MHENRTPT must refer to a "time point anchor" described in MHENTPT.<br>See SDTMIG section 4.1.4.7 for more information. |
| 7. | Is the medical history disease/condition under control? | MHCTRL | O | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPMH dataset. The value of MHCTRL may be used to populate SUPPMH.QVAL where SUPPMH.QNAM = MHCTRL. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 8. | Does the subject have <*specific condition*>?<br><br>Example:<br>Does the subject have high blood pressure?<br><br>OR<br><br>Has the subject had <*specific procedure*>?<br><br>Example:<br>Has the subject had an appendectomy? | MHOCCUR | O | MHOCCUR | Perm | Maps directly to SDTM. |
| 9. | What was the date the medical history event or condition started? | MHSTDAT | O | MHSTDTC | Perm | **For the SDTM dataset,** the SDTM variable --STDTC is derived by concatenating CDASH Start Date and Time (if time is applicable) into --STDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 10. | What was the date the medical history event or condition ended? | MHENDAT | O | MHENDTC | Perm | **For the SDTM dataset,** the SDTM variable --ENDTC is derived by concatenating CDASH End Date and Time (if time is applicable) into --ENDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 11. | What was the date that the medical history was collected? | MHDAT | O | MHDTC | Perm | **For the SDTM dataset,** the SDTM variable --DTC is derived by concatenating CDASH Collection Date and Time (if time is applicable) into --DTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |

### 3.12.2 Implementation Examples—MH

The following Medical History CRF is provided as an example of one possible way to represent the CDASH model in a simple Medical History form. The table that follows the CRF example is the sample output from the operational database for this subject's CRF. The output has not yet been converted to SDTM even though some of the variables, such as MHTERM, will map directly to an SDTM variable.

| Protocol: 287CL4569 | Site: OR9803 | Investigator: Johnston, M.T. |
|---|---|---|
| Subject #: R245 | Subject Initials: PwR | Visit Date (DD-MON- YYYY): 04-May-2009 |

MHTERM MHSTDAT MHONGO

| | Medical History Condition | Onset Date | Ongoing? Yes | Ongoing? No |
|---|---|---|---|---|
| 1 | Psoriasis | 2000-2001 | X | |
| 2 | CHF | DEC 1999 | X | |
| 3 | Kidney stones - left kidney | 31 OCT 1982 | | X |
| 4 | Broken wrist (right arm) | March 2005 | | X |
| 5 | Tonsillectomy | 1975 | | X |
| 6 | Mumps | 1964 | | X |
| 7 | Fractured R tibia | 1963 | | X |

| STUDYID | DOMAIN | Subject | VISITDAT | MHTERM | MHSTDAT | MHONGO |
|---|---|---|---|---|---|---|
| 287CL4569 | MH | R245 | 04-MAY-2009 | PSORIASIS | 2000-2001 | Y |
| 287CL4569 | MH | R245 | 04-MAY-2009 | CHF | DEC 1999 | Y |
| 287CL4568 | MH | R245 | 04-MAY-2009 | KIDNEY STONES – LEFT KIDNEY | 31OCT1982 | N |
| 287CL4568 | MH | R245 | 04-MAY-2009 | BROKEN WRIST (RIGHT ARM) | MARCH 2005 | N |
| 287CL4568 | MH | R245 | 04-MAY-2009 | TONSILLECTOMY | 1975 | N |
| 287CL4568 | MH | R245 | 04-MAY-2009 | MUMPS | 1964 | N |
| 287CL4568 | MH | R245 | 04-MAY-2009 | FRACTURED R TIBIA | 1963 | N |

### 3.12.3 Form Level Completion Instructions—MH

- Any relevant abnormalities, surgeries, allergies, diseases or disorders that start <protocol-specified time period> must be included on this record. Any relevant abnormalities, diseases or disorders that start after the <protocol-specific time period> must be recorded as an adverse event. If a condition listed on the Medical History page worsens in intensity and/or frequency after the start of <protocol-specific time period>, record on the Adverse Events page.
- <Protocol medical history "of interest"> must be recorded on the <name of special medical history CRF>.

# 3.13 Physical Exam (PE)

## 3.13.1 CDASH to SDTM Mapping—PE

### 3.13.1.1 Best Practice Approach

Following this approach, if the sponsor chooses to create a PE CRF to capture 'Was the Physical Examination performed?' and Date/Time of Examination, these optional fields are intended for monitoring and data cleaning only. Data collected would not be submitted in a PE dataset since they are collected on the Medical History and Adverse Events forms, however an operational data set may still exist to capture whether or not the PE was performed. When using the PE Best Practice Approach, the SDTM PE dataset is not expected, and there would be no data to submit in the SDTMIG PE dataset.

### 3.13.1.2 Traditional Approach

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Was the physical examination performed? | PEPERF | O | *Not Specified* | *Not Specified* | May be used to derive a value into the SDTM variable PESTAT. If PEPERF = "N", the value of PESTAT will be "NOT DONE". If PEPERF = "Y", PESTAT should be null. |
| 2. | What was the physical examination date? | PEDAT | R/C | PEDTC | Exp | **For the SDTM dataset**, the SDTM variable --DTC is derived by concatenating CDASH Date and Time (if time is applicable) into --DTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 3. | What was the physical examination time? | PETIM | O | | | |
| 4. | What is the sponsor-defined ID? | PESPID | O | PESPID | Perm | Maps directly to SDTM. |
| 5. | What was the body system examined? | PETEST | HR | PETEST<br>And<br>PETESTCD | Req | Maps directly to SDTM.<br>PETESTCD may be derived from the value collected in PETEST. Both PETESTCD and PETEST are required in SDTM. |
| 6. | Were the results normal, abnormal or not done? | PERES | HR | PEORRES<br>and<br>PESTRESC | Exp | May be used to derive a value into the SDTM variable PEORRES. If PERES = "Normal", populate PEORRES with the value of PERES. If PERES = "Abnormal", populate PEORRES with the value of PEDESC.<br>PESTRESC is the standardized value for PEORRES and should be populated for any record where PEORRES has a value. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core | Mapping Instructions |
|---|---|---|---|---|---|---|
| 7. | If the result was abnormal, what were the findings? | PEDESC | HR | PEORRES<br>and<br>PESTRESC | Exp | May be used to derive a value into the SDTM variable PEORRES. If PERES = "Normal", populate PEORRES with the value of PERES. If PERES = "Abnormal", populate PEORRES with the value of PEDESC.<br>PESTRESC is the standardized value for PEORRES and should be populated for any record where PEORRES has a value. |
| 8. | Was the physical examination result clinically significant? | PECLSIG | O | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPPE dataset. The value of PECLSIG may be used to populate SUPPPE.QVAL where SUPPPE.QNAM = PECLSIG. |
| 9. | What was the role of the person performing the physical examination? | PEEVAL | O | PEEVAL | Perm | Maps directly to SDTM. |

All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

## 3.13.2 Implementation Examples—PE

### 3.13.2.1 Best Practice Approach

- **Row 1:** Shows an example of a subject whose physical examination was completed on a specified date.
- **Row 2:** Shows an example of a subject whose physical examination was completed at a specified date and time.
- **Row 3:** Shows an example of a subject whose physical examination was not performed on a specified date.

| Row | SUBJID | PEYN | PEDAT | PETIM |
|---|---|---|---|---|
| 1 | 101-001 | Y | 08-APR-2009 | - |
| 2 | 101-001 | Y | 15-APR-2009 | 15:30 |
| 3 | 101-002 | N | 16-APR-2009 | - |

#### 3.13.2.2 Traditional Approach

These examples use PERES & PEDESC

- **Row 1:** Shows an example of a subject whose physical examination was performed with a normal result.
- **Row 2:** Shows an example of a subject whose physical examination was performed with an abnormal result.
- **Row 3:** Shows an example of a subject whose physical examination was performed. However, this body system was not examined.
- **Row 4:** Shows an example of a subject whose physical examination was not performed.

| Row | SUBJID | PEPERF | PEDAT | PETIM | PESPID | PETEST | PERES | PEDESC | PECLSIG | PEEVAL |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 123-001 | Y | 08-APR-2009 | 10:15 | 1 | Skin | Normal | - | - | - |
| 2 | 123-001 | Y | 08-APR-2009 | 10:15 | 2 | Heart | Abnormal | Heart murmur | N | - |
| 3 | 123-001 | Y | 08-APR-2009 | 10:15 | 3 | HEENT | Not Done | - | - | - |
| 4 | 123-103 | N | 10-MAY-2009 | - | - | - | - | - | - | - |

These examples use PEORRES in place of PERES & PEDESC

- **Row 1:** Shows an example of a subject whose physical examination was performed with a normal result.
- **Row 2:** Shows an example of a subject whose physical examination was performed with an abnormal result.
- **Row 3:** Shows an example of a subject whose physical examination was performed. However, this body system was not examined. Where PEORRES is 'Not Done', 'Not Done' can be mapped to PESTAT and PEORRES set to null when creating the SDTM dataset.
- **Row 4:** Shows an example of a subject whose physical examination was not performed and the test is populated with 'Physical Examination'

| Row | SUBJID | PEPERF | PEDAT | PETIM | PESPID | PETEST | PEORRES | PECLSIG | PEEVAL |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 123-001 | Y | 08-APR-2009 | 10:15 | 1 | Skin | Normal | - | - |
| 2 | 123-001 | Y | 08-APR-2009 | 10:15 | 2 | Heart | Heart murmur | N | - |
| 3 | 123-001 | Y | 08-APR-2009 | 10:15 | 3 | HEENT | Not Done | - | - |
| 4 | 123-103 | N | 10-MAY-2009 | - | 1 | Physical Examination | - | - | - |

### 3.13.3 Form Level Completion Instructions—PE

- The physical examination must be performed by a qualified health care professional (i.e., MD, PA or NP) listed on the FDA form 1572.
- Abnormalities at <protocol-specific time period> must be recorded on the Medical History or AE Record CRF. If the physical finding started prior to <protocol-specific time period> then it must be recorded on the medical history page. If the physical finding started after <protocol-specific time period> , it must be recorded as an AE.

# 3.14 Protocol Deviations (DV)

## 3.14.1 CDASH to SDTM Mapping—DV

All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. Protocol Deviations CRFs are not required if the deviations can be determined and derived in the analysis dataset from data collected in other domains. (e.g., Findings collected outside of scheduled time points, protocol excluded treatments recorded on a CM page.) See Section 3.1 for details on common identifier variables.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Were there any protocol deviations? | DVYN | O | *Not Specified* | *Not Specified* | Does not map to SDTM.<br>The CRF should be annotated to indicate that this field is NOT SUBMITTED. |
| 2. | What was the protocol deviation? | DVDECOD | R/C | DVDECOD | Perm | Maps directly to SDTM. |
| 3. | What was the protocol deviation term? | DVTERM | R/C | DVTERM | Req | Maps directly to SDTM. |
| 4. | What was the protocol deviation start date? | DVSTDAT | O | DVSTDTC | Perm | **For the SDTM dataset**, the SDTM variable --STDTC is derived by concatenating CDASH Start Date and Time (if time is applicable) into --STDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 5. | What was the protocol deviation start time? | DVSTTIM | O | | | |
| 6. | What was the protocol deviation end date? | DVENDAT | O | DVENDTC | Perm | **For the SDTM dataset**, the SDTM variable --ENDTC is derived by concatenating CDASH End Date and Time (if time is applicable) into --ENDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 7. | What was the protocol deviation end time? | DVENTIM | O | | | |
| 8. | What is the protocol deviation ID? | DVSPID | O | DVSPID | Perm | Maps directly to SDTM. |

## 3.14.2 Implementation Examples—DV

### 3.14.2.1 Example 1

This section provides an example of data collected on a protocol deviations' CRF. The DVDECOD column is for controlled terminology, whereas the DVTERM is free text.

- **Row 1**: Shows an example of a subject that does not have any protocol deviations to report.
- **Row 2**: Shows an example of a subject who took a prohibited medication during the study (only collecting Start Date since only one occurrence).
- **Row 3**: Shows an example of a subject who took a prohibited concomitant medication over a period of time.
- **Row 4**: Shows an example of a subject participating in a prohibited activity.
- **Row 5**: Shows an example of a subject who took a prohibited medication during a study (using the DVDECOD rather than DVTERM).

| Row | SUBJID | DVSPID | DVYN | DVTERM | DVDECOD | DVSTDAT | DVSTTIM | DVENDAT | DVENTIM |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 123101 | 1 | N | - | - | - | - | - | - |
| 2 | 123102 | 1 | Y | TOOK ASPIRIN | - | 08-AUG-2008 | - | - | - |
| 3 | 123103 | 1 | Y | DRUG XXX ADMINISTERED DURING STUDY TREATMENT PERIOD | - | 05-SEP-2007 | - | 10-SEP-2007 | - |
| 4 | 123103 | 2 | Y | PARTICIPATED IN XXXX PROHIBITED ACTIVITY | - | 01-AUG-2008 | 12:20 | 01-AUG-2008 | 14:40 |
| 5 | 123104 | 1 | Y | - | PROHIBITED MEDS | 06-SEP-2007 | - | - | - |

## 3.14.3 Form Level Completion Instructions—DV

- Provide explanations for any protocol deviations. Enter a brief description or explanation.
- Do not use abbreviations.

## 3.15 Subject Characteristics (SC) (Findings)

The SDTM model (Version 1.1) states that “the demographics domain describes the essential characteristics of the study subjects and is used by reviewers for selecting populations for analysis." (p. 13). Neither the SDTM nor the SDTMIG explicitly define what data are in the Subject Characteristics domain, but the SDTMIG does say that:

- "...data in this domain is collected only once per subject" (p. 29)
- "Subject Characteristics is for data not collected in other domains that is subject-related." (p. 83) and
- "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 SDTM Observation Class and is an extension of the demographics data, allowing the reporting of "non-essential" subject characteristics that might be useful as additional population selection criteria for analysis. Subject Characteristics consists of data that are collected once per subject (per test) and that is not expected to change during the trial. The SDTMIG states that "Subject Characteristics contains data such as additional information about race, subject initials, economic information, and eye color." (p. 83)

The example CRFs reviewed for this domain indicated a wide variety of data collected as Subject Characteristics. Some examples of these questions include: Marital status, Economic status, Education level achieved. These data might be useful for risk-benefits analyses or for quality of life analyses. Another is "Gestational age at birth".

The SDTM SC domain utilizes a normalized data structure, i.e., one variable, SCTEST, is used to capture the test name and another variable, SCORRES, is used to capture the result. If Subject Characteristics are collected then the table below describes what variables should be collected.

### 3.15.1 CDASH to SDTM Mapping—SC

All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Have relevant subject characteristics been collected? | SCPERF | O | *Not Specified* | *Not Specified* | May be used to derive a value into the SDTM variable SCSTAT. If SCPERF = "N", the value of SCSTAT will be "NOT DONE". If SCPERF = "Y", SCSTAT should be null. |
| 2. | What is the subject's <characteristic>?<br>Or<br>What was the subject's <characteristic>? | SCTEST | HR | SCTEST<br>and<br>SCTESTCD | Req | Maps directly to SDTM.<br>SCTESTCD may be derived from the value collected in SCTEST. Both SCTESTCD and SCTEST are required in SDTM. |
| 3. | [Subject Characteristic Answer/Result] | SCORRES | HR | SCORRES<br>and<br>SCSTRESC | Exp | The value collected in SCORRES maps directly to the SDTM variable SCORRES.<br>SCSTRESC is the standardized value for SCORRES and should be populated for any record where SCORRES has a value.<br>*If the value in SCSTRESC is a numeric value, it should also be copied into the SCSTRESN variable.* |

***Examples of Subject Characteristics Questions***

| | Question Text | Variable Name | Definition | Case Report Form Completion Instructions | Additional Information for Sponsors |
|---|---|---|---|---|---|
| 1. | What is the subject's Gestational Age at Birth? | SCTEST | The age (in weeks) of the newborn infant, counted from the woman's last menstrual period (LMP) or health status indicators/Clinical Estimate (CE). | *Not Specified.* | A constant that may be useful for analysis in pediatric or neonatal study analyses. |
| 2. | What is the subject's childbearing potential? | SCTEST | Subject's childbearing potential. | Check the correct box to indicate the subject's childbearing potential, or postmenopausal or sterilized as required for the form. | *Not Specified.* |
| 3. | What is the subject's highest education level achieved? | SCTEST | Education level achieved at start of study (Reference date). | *Not Specified.* | *Not Specified.* |

| | Question Text | Variable Name | Definition | Case Report Form Completion Instructions | Additional Information for Sponsors |
|---|---|---|---|---|---|
| 4. | What is the subject's skin classification | SCTEST | A classification system used to categorize the sensitivity of a subject's skin to sunlight. | Skin Classification | Skin type rating in the Fitzpatrick Skin Type classification system. |
| 5. | What is the subject's marital status? | SCTEST | A demographic parameter indicating a person's current conjugal status. | Current Marital Status | *Not Specified* |
| 6. | [Sub-study Participation Question] | SCTEST | Sub-study participation information. | *Not Specified.* | For some studies sub-study information is captured, such as "subject is on fasting sub-study" or "subject is on PK sub-study". |

## 3.15.2 Implementation Examples—SC

### 3.15.2.1 Example 1

This section provides an example SDTM data from various SC questions:

| SCTEST | SCORRES |
|---|---|
| Subject Initials | JEN |
| Childbearing Potential | Sterilized |
| Eye Color | Hazel |
| Skin Classification | Type3 |
| Marital Status | Married |

### 3.15.2.2 Example 2

In the following example, subject level data is collected with the Demographics (DM) data, and mapped to Subject Characteristics (SC)

The first two tables display the data collected in the Demographics CRF:

| | STUDYID | INVID | SUBJID | VISITNUM | INITIAL | DMDAT | BRTHDAT | SEX | RACE |
|---|---|---|---|---|---|---|---|---|---|
| 1 | ABC-124 | 001 | 001 | 1 | D-C | 04/15/03 | 10/19/39 | Male | Caucasian |
| 2 | ABC-124 | 001 | 002 | 1 | DMK | 10/06/03 | 01/31/83 | Female | Caucasian |
| 3 | ABC-124 | 001 | 003 | 1 | DEC | 09/09/03 | 09/19/62 | Male | Caucasian |
| 4 | ABC-124 | 001 | 004 | 1 | JMK | 09/18/03 | 08/13/47 | Female | Caucasian |
| 5 | ABC-124 | 001 | 005 | 1 | AAC | 09/15/03 | 07/06/63 | Female | Caucasian |

| | HSGRAD | SOMCOLL | COLGRAD | GRADDEG | EYESBRN | EYESBL | EYESGR | EYESHZ |
|---|---|---|---|---|---|---|---|---|
| 1 | 1 | | | | | | 1 | |
| 2 | | | 1 | | | 1 | | |
| 3 | | | 1 | | 1 | | | |
| 4 | | | 1 | | | 1 | | |
| 5 | 1 | | | | | 1 | | |

This table displays the SDTM SC dataset that is produced from the data collected in the Demographics CRF above.

| Study Identifier (STUDYID) | Domain Abbreviation (DOMAIN) | Unique Subject Identifier (USUBJID) | Sequence Number (SCSEQ) | Subject Characteristic Short Name (SCTESTCD) | Subject Characteristic (SCTEST) | Result or Finding in Original Units (SCORRES) | Character Result/Finding in Std Format (SCSTRESC) | Date/Time of Collection (SCDTC) |
|---|---|---|---|---|---|---|---|---|
| ABC-124 | SC | ABC-124-001-001 | 1 | EDU | Education | High School Graduate/GED | High School Graduate/GED | 2003-04-15 |
| ABC-124 | SC | ABC-124-001-001 | 2 | INIT | Subject Initials | D-C | D-C | 2003-04-15 |
| ABC-124 | SC | ABC-124-001-001 | 3 | EYECLR | Eye Color | Green | Green | 2003-04-15 |
| ABC-124 | SC | ABC-124-001-002 | 1 | EDU | Education | College Graduate | College Graduate | 2003-10-06 |
| ABC-124 | SC | ABC-124-001-002 | 2 | INIT | Subject Initials | DMK | DMK | 2003-10-06 |
| ABC-124 | SC | ABC-124-001-002 | 3 | EYECLR | Eye Color | Blue | Blue | 2003-10-06 |
| ABC-124 | SC | ABC-124-001-003 | 1 | EDU | Education | College Graduate | College Graduate | 2003-09-09 |
| ABC-124 | SC | ABC-124-001-003 | 2 | INIT | Subject Initials | DEC | DEC | 2003-09-09 |
| ABC-124 | SC | ABC-124-001-003 | 3 | EYECLR | Eye Color | Brown | Brown | 2003-09-09 |
| ABC-124 | SC | ABC-124-001-004 | 1 | EDU | Education | College Graduate | College Graduate | 2003-09-18 |
| ABC-124 | SC | ABC-124-001-004 | 2 | INIT | Subject Initials | JMK | JMK | 2003-09-18 |
| ABC-124 | SC | ABC-124-001-004 | 3 | EYECLR | Eye Color | Blue | Blue | 2003-09-18 |
| ABC-124 | SC | ABC-124-001-005 | 1 | EDU | Education | High School Graduate/GED | High School Graduate/GED | 2003-09-15 |
| ABC-124 | SC | ABC-124-001-005 | 2 | INIT | Subject Initials | AAC | AAC | 2003-09-15 |
| ABC-124 | SC | ABC-124-001-005 | 3 | EYECLR | Eye Color | Blue | Blue | 2003-09-15 |

### 3.15.3 Form Level Completion Instructions—SC

CDISC does not have recommended specific form level help for the Subject Characteristics Domain.

# 3.16 Substance Use (SU)

## 3.16.1 CDASH to SDTM Mapping—SU

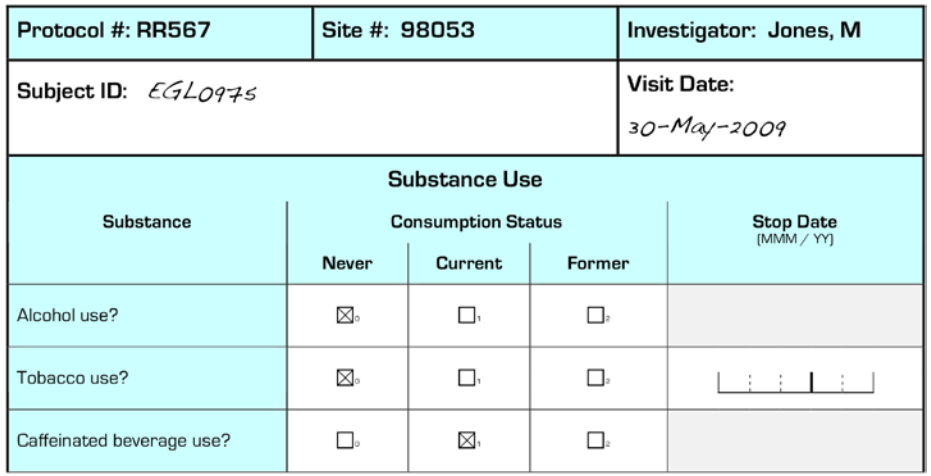
All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | What was the type of substance used? | SUTRT | HR | SUTRT | Req | Maps directly to SDTM. |
| 2. | Has the subject ever used the substance? | SUNCF | HR | SUOCCUR | Perm | May be used to derive a value into the SDTM variable SUOCCUR. If SUNCF = "Never", the value of SUOCCUR will be "N". If SUNCF = "Current" or "Former", the value of SUOCCUR will be "Y". |
| 3. | What was the category of substance used? | SUCAT | O | SUCAT | Perm | Maps directly to SDTM. . |
| 4. | What was the amount of substance used? | SUDSTXT | O | SUDOSTXT or SUDOSE | Perm | Numeric values map to SUDOSE in SDTM.<br>Non-numeric values (e.g., 200-400) map to SUDOSTXT in SDTM. |
| 5. | What was the unit of the substance used? | SUDOSU | O | SUDOSU | Perm | Maps directly to SDTM. |
| 6. | What was the frequency of substance use? | SUDOSFRQ | O | SUDOSFRQ | Perm | Maps directly to SDTM. |
| 7. | What was the start date of substance use? | SUSTDAT | O | SUSTDTC | Perm | **For the SDTM dataset,** the SDTM variable --STDTC is derived by concatenating CDASH Start Date and Time (if time is applicable) into --STDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 8. | What was the end date of substance use? | SUENDAT | O | SUENDTC | Perm | **For the SDTM dataset,** the SDTM variable --ENDTC is derived by concatenating CDASH End Date and Time (if time is applicable) into --ENDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 9. | What was the duration of substance use? | SUCDUR | O | SUDUR | Perm | **For the SDTM dataset,** the SDTM variable SUDUR is derived by converting the information in SUCDUR and SUCDURU into ISO 8601 duration format. See SDTMIG Section 4.1.4.3. |
| 10. | What was the unit of duration of substance use? | SUCDURU | O | | | |

### 3.16.2 Implementation Examples—SU

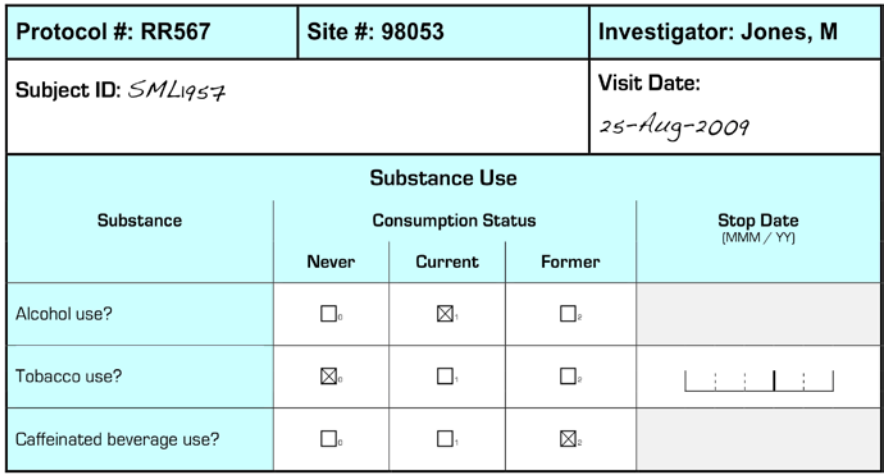
These CRFs show examples of CDASH-conformant collection of alcohol use, tobacco use and caffeinated beverage use data.



| Protocol #: RR567 | Site #: 98053 | Investigator: Jones, M |
|---|---|---|
| Subject ID: EGL0975 | | Visit Date: 30-May-2009 |

Substance Use

| Substance | Consumption Status | | | Stop Date (MMM / YY) |
|---|---|---|---|---|
| | Never | Current | Former | |
| Alcohol use? | ☒ 0 | ☐ 1 | ☐ 2 | |
| Tobacco use? | ☒ 0 | ☐ 1 | ☐ 2 | |
| Caffeinated beverage use? | ☐ 0 | ☒ 1 | ☐ 2 | |



| Protocol #: RR567 | Site #: 98053 | Investigator: Jones, M |
|---|---|---|
| Subject ID: SML1957 | | Visit Date: 25-Aug-2009 |

Substance Use

| Substance | Consumption Status | | | Stop Date (MMM / YY) |
|---|---|---|---|---|
| | Never | Current | Former | |
| Alcohol use? | ☐ 0 | ☒ 1 | ☐ 2 | |
| Tobacco use? | ☒ 0 | ☐ 1 | ☐ 2 | |
| Caffeinated beverage use? | ☐ 0 | ☐ 1 | ☒ 2 | |

| STUDYID | SUBJID | VISITDAT | SUTRT | SUNCF | SUENDAT |
|---|---|---|---|---|---|
| RR567 | EGL0975 | 30-MAY-2009 | ALCOHOL | NEVER | |
| RR567 | EGL0975 | 30-MAY-2009 | TOBACCO | NEVER | |
| RR567 | EGL0975 | 30-MAY-2009 | CAFFEINATED | CURRENT | |
| RR567 | SML1957 | 25-AUG-2009 | ALCOHOL | CURRENT | |
| RR567 | SML1957 | 25-AUG-2009 | TOBACCO | NEVER | |
| RR567 | SML1957 | 25-AUG-2009 | CAFFEINATED | FORMER | |

### 3.16.3 Form Level Completion Instructions—SU

- Record the substance(s) usage of the subject.
- Be sure the information regarding substance(s) usage is in compliance with any specific inclusion/exclusion criteria of the protocol.

# 3.17 Vital Signs (VS)

## 3.17.1 CDASH to SDTM Mapping—VS

All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See Section 3.1 for details on common identifier variables.

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 1. | Were vital signs collected? | VSPERF | O | *Not Specified* | *Not Specified* | May be used to derive a value into the SDTM variable VSSTAT. If VSPERF = "N", the value of VSSTAT will be "NOT DONE". If VSPERF = "Y", VSSTAT should be null |
| 2. | On what date were the measurements performed? | VSDAT | R/C | VSDTC | Exp | **For the SDTM dataset**, the SDTM variable --DTC is derived by concatenating CDASH Date and Time (if time is applicable) into --STDTC using the ISO 8601 format. See SDTMIG Section 4.1.4.1. |
| 3. | At what time were the measurements performed? | VSTIM | R/C | | | |
| 4. | What is the Sponsor-Defined Identifier? | VSSPID | O | VSSPID | Perm | Maps directly to SDTM. |
| 5. | What is the vital sign test name? | VSTEST | HR | VSTEST<br>and<br>VSTESTCD | Req<br><br>Req | Maps directly to SDTM.<br>VSTESTCD may be derived from the value collected in VSTEST. Both VSTESTCD and VSTEST are required in SDTM. |
| 6. | What was the result of the measurement? | VSORRES | HR | VSORRES<br>and<br>VSSTRESC<br>and<br>VSSTRESN | Exp | The value collected in VSORRES maps directly to the SDTM variable VSORRES.<br>VSSTRESC is the standardized value for VSORRES and should be populated for any record where VSORRES has a value.<br>*If the value in VSSTRESC is a numeric value, it should also be copied into the VSSTRESN variable*. |
| 7. | What was the unit of the measurement? | VSORRESU | R/C | VSORRESU<br>and<br>VSSTRESU | Exp | The value collected in VSORRESU maps directly to the SDTM variable VSORRESU.<br>VSSTRESU is the standardized value for VSORRESU and should be populated for any record where VSORRESU has a value.<br>. |

| | Question Text | CDASH Variable Name | CDASH Core | SDTM Variable Name | SDTM Core (v. 3.1.2) | Mapping Instructions |
|---|---|---|---|---|---|---|
| 8. | Was the result clinically significant? | VSCLSIG | O | *Not Specified* | *Not Specified* | This information could be submitted in a SUPPVS dataset. The value of VSCLSIG may be used to populate SUPPVS.QVAL where SUPPVS.QNAM = VSCLSIG. . |
| 9. | At what location was the measurement taken? | VSLOC | O | VSLOC | Perm | Maps directly to SDTM. |
| 10. | In what position was the subject during the measurement? | VSPOS | R/C | VSPOS | Perm | Maps directly to SDTM. |
| 11. | *Not Specified* | *Not Specified* | *Not Specified* | VSBLFL | Exp | This EXPECTED variable in SDTM is not accounted for in the CDASH standard since it is a value that is ASSIGNED or DERIVED by the Sponsor and is not a data collection field that would appear on the CRF itself. Sponsors will populate this through classification routines in preparation for creating and submitting SDTM datasets and/or sponsors will include an Origin in the define data definition document to indicate that the data were ASSIGNED or DERIVED. |
| 12. | What is the planned time point for this measurement? | VSTPT | R/C | VSTPT | Perm | Maps directly to SDTM. |

## 3.17.2 Implementation Examples—VS

### 3.17.2.1 Normalized Examples

These first two sets of examples show vitals collected by visit on individual CRFs vs. in a log style form.

- **Row 1:** Shows an example of a test performed at a specific time point.
- **Row 2:** Shows an example of a test that was not done at a specific time point.
- **Rows 3 and 4:** Show a pair of tests performed at a specific time point, by location and position, noted as clinically significant.
- **Row 5:** This example shows a test performed at a visit without a specific time point.

In this set of examples, one set of vitals is collected at each visit. Pre-printed line numbers are not included on the CRF. Some visits have pre-printed planned time points, others have only a visit name on the collection day.

Table 1

| Row | SUBJID | VSDAT | VSTIM | VSTPT | VSTEST | VSORRES | VSORRESU | VSCLSIG | VSLOC | VSPOS |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 101-001 | 08-APR-2009 | 11:15 | POST DOSE—2 HRS | HEIGHT | 72 | IN | - | - | - |
| 2 | 101-001 | 08-APR-2009 | 11:15 | POST DOSE—2 HRS | WEIGHT | - | - | - | - | - |
| 3 | 101-001 | 08-APR-2009 | 13:15 | POST DOSE—4 HRS | SYSTOLIC BLOOD PRESSURE | 150 | mmHg | Y | RIGHT ARM | SITTING |
| 4 | 101-001 | 08-APR-2009 | 13:15 | POST DOSE—4 HRS | DIASTOLIC BLOOD PRESSURE | 80 | mmHg | Y | RIGHT ARM | SITTING |
| 5 | 101-001 | 12-APR-2009 | - | - | PULSE | 65 | BEATS/MIN | - | - | - |

In this set of examples, vitals are collected log style with pre-printed line numbers. Note the addition of VSSPID.

Table 2

| Row | SUBJID | VSDAT | VSTIM | VSSPID | VSTPT | VSTEST | VSORRES | VSORRESU | VSCLSIG | VSLOC | VSPOS |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 101-001 | 08-APR-2009 | 11:15 | 1 | POST DOSE—2 HRS | HEIGHT | 72 | IN | - | - | - |
| 2 | 101-001 | 08-APR-2009 | 11:15 | 2 | POST DOSE—2 HRS | WEIGHT | - | - | - | - | - |
| 3 | 101-001 | 08-APR-2009 | 13:15 | 1 | POST DOSE—4 HRS | SYSTOLIC BLOOD PRESSURE | 150 | mmHg | Y | RIGHT ARM | SITTING |
| 4 | 101-001 | 08-APR-2009 | 13:15 | 2 | POST DOSE—4 HRS | DIASTOLIC BLOOD PRESSURE | 80 | mmHg | Y | RIGHT ARM | SITTING |
| 5 | 101-001 | 12-APR-2009 | - | 1 | - | PULSE | 65 | BEATS/MIN | - | - | - |

In this set of examples, vitals are collected on different days with only the date and result entered. Units are pre-printed on the CRF.

- **Rows 1 and 2:** Show an example of two tests planned for the same visit. The first is performed and the second is not done.
- **Rows 3 and 4:** Show a pair of tests with one set of units.
- **Rows 5 and 6:** This is an example where all tests for a planned visit are not performed.

**Table 3**

| Row | SUBJID | VSDAT | VSTEST | VSORRES | VSORRESU |
|---|---|---|---|---|---|
| 1 | 101-001 | 08-APR-2009 | HEIGHT | 72 | IN |
| 2 | 101-001 | 08-APR-2009 | WEIGHT | - | - |
| 3 | 101-001 | 10-APR-2009 | SYSTOLIC BLOOD PRESSURE | 150 | mmHg |
| 4 | 101-001 | 10-APR-2009 | DIASTOLIC BLOOD PRESSURE | 80 | mmHg |
| 5 | 101-001 | 12-APR-2009 | PULSE | - | - |
| 6 | 101-001 | 12-APR-2009 | TEMPERATURE | - | - |

### 3.17.2.2 De-normalized Examples

This set of examples demonstrates the above vitals collected log style with pre-printed line numbers in de-normalized format.

- **Row 1:** Shows an example of a four tests collected at a specific time point. One of the tests, Weight, was skipped. Blood pressure was noted by location and body position.
- **Row 2:** Shows an example of a two tests performed at a specific time point.
- **Row 3:** This example shows missed vitals measurements at a visit without a specific time point.

**Table 1**

| Row | SUBJID | VSDAT | VSTIM | VSSPID | VISIT | VSTPT | HEIGHT | HEIGHTU | HEIGHTND | WEIGHT | WEIGHTU | WEIGHTND |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 101-001 | 08-APR-2009 | 11:15 | 1 | DAY 1 | POST DOSE—2 HRS | 72 | IN | - | - | - | X |
| 2 | 101-001 | 08-APR-2009 | 11:15 | 2 | DAY 1 | POST DOSE—4 HRS | - | - | - | - | - | - |
| 3 | 101-001 | 12-APR-2009 | - | 1 | WEEK 12 | - | - | - | - | - | - | - |

| Row | SYSBP | DIABP | BPU | BPND | BPLOC | BPPOS | PULSE | PULSEU | PULSEND |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 150 | 80 | mmHg | - | RIGHT ARM | SITTING | 65 | BEATS/MIN | - |
| 2 | 140 | 90 | mmHg | | LEFT ARM | STANDING | 70 | BEATS/MIN | - |
| 3 | - | - | - | X | RIGHT ARM | SITTING | - | - | X |

### 3.17.3 Form Level Completion Instructions—VS

- If several vital signs measurements fall within the visit window, use the <protocol-specific process for reporting the measurement for the window>.
- If there is a change in the vital signs that is deemed clinically significant by the investigator, record the finding as an Adverse Event.

## 3.18 Fields Considered Not Necessary to Collect on CRFs

The data collection fields in tables below were reviewed and determined to be generally unnecessary to collect on the CRF. However, sponsors may include some of these fields if required by study design. The reason for this determination is included in the rationale column of the tables. As a result of this determination they are not included in the CDASH domains tables nor recommended for inclusion in CRFs. The tables below are a sampling of what was observed on the CRFs provided by volunteers and are not intended to be an exhaustive list of all possible variables.

Due to the nature of these domains there are no fields listed for Comments (CO), Physical Exam (PE), Subject Characteristics (SC) and Vital Signs (VS) domains. For CO and PE, CDASH recommends only minimal fields, if any. Further information on these domains can be found in the CDASH standard.

### 3.18.1 Common Identifier and Timing Variables

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Domain Abbreviation | Two-character abbreviation for the domain most relevant to the observation. | This is usually derived or pre-set in database. |
| Sequence Number | Sequence number given to ensure uniqueness within a dataset for a subject. Can be used to join related records. | This is usually applied programmatically in a submission. |
| Group ID | Used to tie together a block of related records in a single domain to support relationships within the domain and between domains. | Usually programmatically derived. Not collected on the CRF. |
| Reference ID | Optional internal or external identifier. | There is no standard use for this field. Implementation is up to the Sponsor. |
| Planned Study Day of Visit | Planned study day of the start of the visit based upon RFSTDTC in demographics. | This is usually derived or pre-set in database. |
| Date/Time of collection | The date/time of collection of the data. | All appropriate dates & times are included in the individual domains. An additional date/time of collection does not provide information about the event. |
| Study Day of Collection | Study day of medical history collection, measured as integer days. | This is almost always a derived variable and not recorded by the investigator. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC. This formula should be consistent across a submission. |

### 3.18.2 Adverse Events

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Adverse Event Occurrence | Used when the occurrence of specific adverse events is solicited to indicate whether an adverse event occurred or not. | Not included in order to prevent cross checking with AEs. When specific AEs must be addressed these instructions can be included in the clinical protocol and/or in the |

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| | | monitoring AE procedures/CRF completion guidelines. |
| Continuing Flag | Identifies an event that is ongoing at the time of a subject's discontinuation from a study. | Considered a duplicate of the AEONGO field that is included in the CDASH standard. |
| Expected Criteria | Representation of the expectedness of the event. | Handled in Clinical Investigative Brochure. |
| Duration/Time Course | Collected duration and unit or time course of an adverse event. | This information is usually derived from the start and end date/time. |
| Event diagnosis | Provides the sender with an opportunity to combine signs and symptoms that were reported into a succinct diagnosis. | This is Sponsor specific. It is recommended that a decision be made to record either symptoms or diagnosis in the AE field on a clinical program level and kept consistent in the individual clinical trials. |
| Ongoing as of Date | Gives reference to when the subject was last contacted to determine if the AE was still ongoing. | Generally this information can be drawn from other fields, i.e., blank AE Stop Date and AE Outcome, date of last contact from the Disposition form. |

### 3.18.3 Concomitant Medications

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Generic Dispensed | An indicator that the drug name provided is a generic name. | The CDASH standard recommends that the full trade name or proprietary name be recorded if there is a choice. Dictionaries can be used to identify the equivalent generic. In this scenario this fields is not needed on the CRF. If the dictionary used does not have this functionality then sites can be instructed to record generic names. |
| Response | Did the condition for which the medication was taken respond to treatment? | Applies to medications of interest which are study specific and not applicable to general medication CRFs. |
| Prescription or OTC | Indicate whether the drug required a prescription or if the subject obtained it OTC. | This level of detail is not required for general medication CRFs. |
| Device used to admin drug | For some drugs, such as asthma medications, the delivery device can affect the response | This field applies to medications of interest and devices which are study specific and not generally applicable to general medication CRFs. |
| Was drug admin for exacerbation | Used to identify medications taken for a specific indication which has worsened | Applies to medications of interest which are study specific and not generally applicable to all general medication CRFs. |
| Was drug admin as a rescue Medication | Used to identify medications taken for a specific indication which has worsened | Applies to medications of interest which are study specific and not generally applicable to all general medication CRFs. |
| Cumulative dose used | Calculated total exposure over a specified duration | This can be calculated from other variables on the CRF (dose and frequency or total daily dose and the start and stop dates [optional]). |
| Was drug ever used? | Asking if a specific medication was used (e.g., Was aspirin ever used?). | Applies to medications of interest which are study specific and not generally applicable to all general medication CRFs. |
| Total duration | Length of time subject was exposed to a drug | Can be calculated from Start Date/Time and Stop Date/Time. |
| Total duration unit | Unit of time for subject exposure (e.g., minutes, hours, days, etc.). | Dependent on how the duration algorithm is written. |
| Was Medication | Did the medication reach toxic levels, requiring it to be discontinued? | Applies to medications of interest which are study specific and not generally |

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| stopped due to toxicity? | | applicable to all general medication CRFs. |
| General Comments | - | CDASH does not recommend the capture of general comments. See the CDASH comments domain for a detailed explanation. |
| None Taken | A single box that can be marked to indicate that no concomitant medications were taken | Instead of this question, a Y/N question "Were any drugs taken?" is recommended to avoid ambiguity if this box is not marked, but no medication details are present. This recommended option is listed on Table 3. This approach is consistent with other CDASH domains. |
| Category of Medication | - | Applies to medications of interest that are study specific and not generally applicable to all general medication CRFs.<br>These can generally be derived from a medication dictionary. |
| Type of Medication | - | Applies to medications of interest that are study specific and not generally applicable to all general medication CRFs.<br>These can generally be derived from a medication dictionary. |

### 3.18.4 Demographics

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Subject Reference Start Date/Time | 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 (if screen failures are submitted). | Stored in SDTM DM domain, but is assigned by the Sponsor and not captured on the CRF. |
| Subject Reference End Date/Time | Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to 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 (if screen failures are submitted). | Stored in SDTM DM domain, but is assigned by the Sponsor and not captured on the CRF. |
| Planned Arm Code | Short name for ARM (may be up to eight characters). | Stored in SDTM DM domain, but is assigned by the Sponsor and not captured on the CRF. |
| Description of Planned Arm | Name of the Arm to which the subject was assigned. | Stored in SDTM DM domain, but is assigned by the Sponsor and not captured on the CRF. |

### 3.18.5 Disposition

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Category for Disposition Event | Used to define a category of related records (e.g., DISPOSITION EVENT or PROTOCOL MILESTONE). | This is assigned programmatically based on the event code and therefore does not appear on the CRF. |

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Subcategory for Disposition Event | A further categorization of disposition event. | This is assigned programmatically based on the event code and therefore does not appear on the CRF. |
| Date/Time of Collection | The date that the disposition of the subject was collected. | The date of collection of the disposition is not needed since the date of interest is the actual disposition date. The disposition event is used to create analysis populations, and the actual dates are analyzed. |
| Study Day of Start of Disposition Event | Study day of start of the disposition event relative to the sponsor-defined RFSTDTC. | It can be derived using RFSTDTC and the disposition event date. |
| Death details | Information such as Date of Death (if not the disposition event for a specified trial epoch and/or if required for every subject in order that a survival analysis can be performed), Cause of Death (if not requested on disposition CRF), whether autopsy done, etc. | This information generally appears on a SAE form and does not usually appear in clinical databases. It is not strictly required for the description of subject disposition; but if required, it should be collected on a separate CRF module.<br>A Clinical Events module is proposed by the SDS team in the draft SDTM Implementation Guide that could be used to submit such data. |
| Follow-up/vitals information | Information such as:<br>• method of contact<br>• frequency of contact attempts<br>• whether subject is dead or alive, etc. | Administrative information, such as method and frequency of contact attempts, is not strictly required for the description of subject disposition; if required, it should be collected on a separate CRF module.<br>Subject death should be captured on the DS CRF module. |
| Additional blind break information | Information such as when blind was broken, reason for blind break, treatment administered to subject, etc. | This information is not strictly required for the description of subject disposition; if required, it should be collected on a separate CRF module. |
| Date of Withdrawal of Consent | The date on which consent was withdrawn. | Considered redundant field when date of completion or discontinuation is collected. |
| Comments | Open comment field | Any additional information should be recorded as a specification of the reason for discontinuation.<br>CDASH does not recommend the capture of general comments. See the CDASH comments domain for a detailed explanation. |

### 3.18.6 Drug Accountability

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Capsules actually taken | The number of capsules actually taken by the subject. | When collected, Exposure is the most appropriate domain because this is assessing exposure rather than tracking medication.<br>If needed, it can be derived based on Dispensed less Returned.<br>This may be covered by one of the DATESTCD values. |
| Was study medication dispensed during the study? | Was study medication dispensed during the study? | This Y/N question was present on an electronic data capture screen for navigation purposes.<br>This data can be derived from date of medication dispensation and amount dispensed. If none was dispensed then the amount is 0. |
| Was study medication taken during the study? | Was study medication taken during the study? | When collected, Exposure is the most appropriate domain because this is assessing exposure rather than tracking medication.<br>This question was present on an electronic data capture screen for navigation purposes.<br>This data can be derived from exposure. |
| Was the study medication dose modified during the study? | Was the study medication dose modified during the study? | When collected, Exposure is the most appropriate domain because this is assessing exposure rather than tracking medication.<br>This question was present on an electronic data capture screen for navigation purposes.<br>If this degree of specificity is needed then the exposure domain should be structured to capture each dosage level. This data can be derived from exposure. |
| Did subject receive correct treatment? If no, explain. | Did subject receive correct treatment? If no, explain. | This information will probably be obtained from reviewing the site's drug accountability logs and/or randomization records post-blinding. It may not be possible to answer this question on the CRF prior to breaking the blind.<br>Derivable from other data. |
| Was correct treatment delivered? | Was correct treatment delivered? | This information will probably be obtained from reviewing the site's drug accountability logs and/or randomization records post-blinding. It may not be possible to answer this question on the CRF prior to breaking the blind.<br>Derivable from other data. |

### 3.18.7 ECG Test Results, Scenario 1

For central ECG processing these data are expected to be provided separately by the ECG vendor or are not considered necessary to collect on the CRF.

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Test Name | Verbatim name of the test or examination used to obtain the measurement or finding. | In this scenario this information is coming from the vendor by definition and therefore is not needed on the CRF.<br>If clinical significance is not present in the electronic data and the sponsor needs to collect this on the CRF instead, Scenario 3 should be used. |
| Test Result | Result of the measurement or finding as originally received or collected. | |
| Units | Original units in which the data were collected. | |
| Vendor Name | Name of vendor providing ECG data | |
| Evaluator | Role of the person who provided the evaluation. This should only be used for results that are subjective (e.g., assigned by a person or a group) and do not apply to quantitative results (e.g., ADJUDICATION COMMITTEE, VENDOR). | |
| Clinical Significance | Whether ECG results were clinically significant. | |
| Abnormal flag | Reference Range Indicator Indicates where value falls with respect to reference range defined by high and low ranges, or by an expected character result (e.g., NORMAL). | |
| Investigator Comment | Investigator comment on ECG test or results. | CDASH does not recommend the capture of general comments. See the CDASH comments domain for a detailed explanation. It is expected that comments related to specific tests will be coming from the electronic data, not collected on the CRF. |

### 3.18.8 ECG Test Results, Scenario 2

Local reading: When results of ECG are reported directly on the CRF.

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Investigator Comment | Investigator comment on ECG results. | If the comment is an interpretation of the ECG as a whole or indicating the presence of a particular condition, this is expected to be captured in the ECG finding field (EGORRES). If it is a comment on clinical significance, this should be collected in the clinical significance field (EGCLSIG).<br>CDASH does not recommend the capture of general comments. See the CDASH comments domain for a detailed explanation. |
| Vendor Name | Name of vendor providing ECG data | In this scenario there is no vendor because it is a local reading; therefore vendor name does not apply. |
| ECG Reference ID | Internal or external ECG identifier. | If ECG is read locally, there is no need for a unique reference number on the CRF as all data are present on the CRF. |

### 3.18.9 ECG Test Results, Scenario 3

Central processing but CRF includes site assessment of clinical significance.

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Abnormal flag | Reference Range Indicator Indicates where value falls with respect to reference range defined by high and low ranges, or by an expected character result (e.g., NORMAL). | In this scenario this information is coming from the vendor by definition and therefore is not needed on the CRF.<br>If clinical significance is not present in the electronic data and the sponsor needs to collect this on the CRF instead, Scenario 3 should be used. |
| Units | Original units in which the data was collected. | In this scenario this information is coming from the vendor by definition and therefore is not needed on the CRF.<br>If clinical significance is not present in the electronic data and the sponsor needs to collect this on the CRF instead, Scenario 3 should be used. |
| Investigator Comment | Investigator comment on ECG test or results. | If the comment is an interpretation of the ECG as a whole or indicating the presence of a particular condition, this is expected to be captured in the ECG finding field (EGORRES). If it is a comment on clinical significance, this should be collected in the clinical significance field (EGCLSIG).<br>CDASH does not recommend the capture of general comments. See the CDASH comments domain for a detailed explanation. |
| Evaluator | Role of the person who provided the evaluation. This should only be used for results that are subjective (e.g., assigned by a person or a group) and do not apply to quantitative results (e.g., ADJUDICATION COMMITTEE, VENDOR). | In this scenario this information is coming from the vendor by definition and therefore is not needed on the CRF.<br>If clinical significance is not present in the electronic data and the sponsor needs to collect this on the CRF instead, Scenario 3 should be used. |

### 3.18.10 Exposure

These fields were all seen on various Exposure/Dosing CRF examples, and are not included in the CDASH EX domain because they are collected in a different DOMAIN.

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Body Surface Area (BSA) | The total surface area of the human body.<br>BSA = the square root of product of the weight in kg times the height in cm divided by 3600 | Although BSA may be used to calculate dosage it is a vital signs variable that is collected on the vital signs CRF. |
| Actual Body Weight | - | Although body weight may be used to calculate dosage it is a vital signs variable that is collected on the vital signs CRF. |
| Was any sedation or topical anesthetic given? | - | Unless this is a specified by protocol, this is usually collected on the concomitant medication CRF. |
| Weight used to prepare infusion | - | Although weight may be used to calculate dosage it is a vital signs variable that is collected on the vital signs CRF. |
| Any pre-medications given? | - | Unless this is a specified by protocol, this is usually collected on the concomitant medication CRF. |
| Total input/output amounts and types (PRBC, Enteral nutrition, pre-enteral nutrition, con med, other/Other blood loss including drainage, other) | - | In most cases these are not considered exposure data and may appear on other CRFs. |
| Date of Dose Change | Date that a modified dose was started. | If collecting detailed dosing information, date of dose change is equivalent to either start or stop date on one or another dosing record. |
| AE # associated with Dose Change | An administrative field used to match AEs with dose changes | This appeared in a small minority of forms sampled and was not identified as an 80/20 match |
| Was entire dose administered? | Was the entire expected dose administered to the subject? | This appeared in a small minority of forms sampled and was not identified as an 80/20 match |
| Did subject receive at least one dose? | Did the subject receive any dose of study drug? | This appeared in a small minority of forms sampled and was not identified as an 80/20 match. |
| Was the dose stopped early? | Did the subject stop receiving study drug without completing the expected dosing regimen? | This is collected on the disposition CRF. |
| Dose Administered? Yes/No | Was the dose of study drug administered to the subject? | This appeared in a small minority of forms sampled and was not identified as an 80/20 match. Can be used if individual doses are being tracked but generally derivable from presence of exposure data. |
| Gauge of needle used to administer investigational product | A numeric value that indicates the size of a needle used to administer an injectable study article. | This appeared in a small minority of forms sampled and was not identified as an 80/20 match. |
| Total Volume Prepared | A numeric value that indicates the total volume of study | This appeared in a small minority of forms sampled and was not identified as an 80/20 |

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| | article and other media prepared for an injectable dose administration. | match. |
| Total Volume Prepared Unit | The unit in which to total volume of study drug was recorded. | This appeared in a small minority of forms sampled and was not identified as an 80/20 match. |

## 3.18.11 Inclusion/Exclusion

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Consent Date | The date that this subject signed the Informed Consent Form | Consent date should be collected on the disposition CRF. |
| Consent Time | The time that this subject signed the Informed Consent Form | Consent time should be collected on the disposition CRF. |
| ICF Signed? | Did the subject sign the Informed Consent Form? | If required, confirmation of ICF signed is collected on the disposition CRF or derived from the date and time consent signed. |
| Optional Consent Signed? | Some organizations use separate consent forms to obtain research samples (e.g., pharmacogenomics samples), or medical histories that will be included in a separate study database (e.g., natural history of a disease). | This appeared in a small minority of forms sampled and was not identified as an 80/20 match. |
| Written or Oral Fluency? | Is the subject fluent in the language in which the study documents are printed? | If required by protocol, this is usually included as an entry criterion, or verified through monitoring practices. |
| Exception<br>or<br>Waiver | A description of the reason this subject did not meet all of the entry criteria. | This appeared in a small minority of forms sampled and was not identified as an 80/20 match. |
| Exception Approved?<br>or<br>Waiver Granted? | This is used to verify that a Sponsor-authorized individual approved the subject to be enrolled in a study, in spite of the subject not meeting all entry criteria. | This appeared in a small minority of forms sampled and was not identified as an 80/20 match. |
| Date exception approved?<br>or<br>Date waiver granted? | This variable collected the date on which a Sponsor-authorized individual approved a subject to be enrolled in a study, in spite of the subject not meeting all entry criteria. | This appeared in a small minority of forms sampled and was not identified as an 80/20 match. |
| Exception approved by<br>or<br>Waiver granted by | This variable collected the name of the Sponsor-authorized individual who approved a subject to be enrolled in a study, in spite of the subject not meeting all entry criteria. | This appeared in a small minority of forms sampled and was not identified as an 80/20 match. |
| Criterion Number | The number that corresponds to a protocol-defined entry criterion. | Since not all Sponsors use a numeric value to identify each criterion, the more flexible term “Criterion Identifier” was included in the standard. |

### 3.18.12 Laboratory Test Results, Scenario 1

These are either expected to be received from the Central lab or are not considered necessary**.** For central specimen processing these data are expected to be provided separately by the processing lab or are not considered necessary to be collected.

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Test Name | Verbatim name of the test or examination used to obtain the measurement or finding. Any test normally performed by a clinical laboratory is considered a lab test. | In this scenario this information is coming from the vendor by definition and therefore is not needed on the CRF.<br>If clinical significance is not present in the electronic data and the sponsor needs to collect this on the CRF instead, Scenario 3 should be used. |
| Test Result | Result of the measurement or finding as originally received or collected. | |
| Lab Name | Name of lab analyzing specimen | |
| Specimen Status | Free or standardized text describing the condition of the specimen. | |
| Clinical Significance | Whether lab test results were clinically significant. | |
| Abnormal flag | Reference Range Indicator Indicates where value falls with respect to reference range defined by high and low ranges. | |
| Units | Original units in which the data were collected. | |
| Normal Range | Normal range for continuous measurements in original units.<br>Normal values for non-continuous measurements in original units. | |
| Investigator Comment | Investigator comment on lab test or results. | CDASH does not recommend the capture of general comments. See the CDASH comments domain for a detailed explanation. It is expected that comments related to specific tests will be coming from the electronic data, not collected on the CRF. |

### 3.18.13 Laboratory Test Results, Scenario 2

Local processing: When results of specimen analysis are reported directly on the CRF, these data are not considered necessary to be collected.

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Investigator Comment | Investigator comment on lab test or results. | CDASH does not recommend the capture of general comments. See the CDASH comments domain for a detailed explanation. It is expected that comments related to specific tests will be coming from the electronic data, not collected on the CRF. |

### 3.18.14 Laboratory Test Results, Scenario 3

Central processing but CRF includes site assessment of clinical significance, these data are not considered necessary to be collected.

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| specimen Status | Free or standardized text describing the condition of the specimen (e.g., HEMOLYZED, ICTERIC, LIPEMIC, and so on). | In this scenario this information is coming from the vendor by definition and therefore is not needed on the CRF. |
| Abnormal flag | Reference Range Indicator Indicates where value falls with respect to reference range defined by high and low ranges. | |
| Units | Original units in which the data were collected. | |
| Normal Range | Normal range for continuous measurements in original units.<br>Normal values for non-continuous measurements in original units. | |
| Investigator Comment | Investigator comment on lab test or results. | CDASH does not recommend the capture of general comments. See the CDASH comments domain for a detailed explanation. It is expected that comments related to specific tests will be coming from the electronic data, not collected on the CRF. |

### 3.18.15 Medical History

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Modified Reported Term | If MHTERM is modified, then MHMODIFY will contain the modified text. | The MODIFY term is only required in SDTM if the Sponsor modifies a term using an internal Self Evident Correction or other convention without querying the Investigator for the modification. This is derivable from audit trail history. See SDTMIG for instructions. |
| Dictionary-Derived Term | Dictionary-derived text description of MHTERM or MHMODIFY. Equivalent to the Preferred Term (PT in MedDRA). The sponsor should specify the dictionary name and version in the Sponsor Comments column of the Define data definition document. | Coding is generally not recorded on the CRF. This appeared in a small minority of forms sampled and was not identified as an 80/20 match. |
| Medical History Event Pre-specified | Medical history events that are pre-specified on the CRF. | This variable (MHPRESP) should only be used if pre-specified conditions are collected, which is rarely done. See the SDTMIG v 3.1.2 for instructions. |
| Medical History Status | The status that the question was not asked. | This variable (MHOCCUR) should only be used if pre-specified conditions are collected, which is rarely done. See the SDTMIG v 3.1.2 for instructions. |
| Reason Medical History Not Collected | Describes the reason medical history was not collected. Used in conjunction with MHSTAT when value is NOT DONE. | This variable should only be used if pre-specified conditions are collected, which is rarely done. See the SDTM IG v 3.1.2 for instructions. |
| Body System or Organ Class | Body system or organ class (Primary SOC) that is involved in an event or measurement from the standard hierarchy (e.g., MedDRA). | This variable can be derived from the coding dictionary. MHBODSYS should be reserved for the body system categories (SOCs) used in the sponsor's coding dictionary. |

## 3.18.16 Protocol Deviations

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Source of Protocol Deviation | Point of reference for protocol deviation or CRF source of protocol deviation. | In general, CDASH does not recommend the use of a protocol deviation CRF page. Because Investigators complete CRFs and most deviations are identified using other means, the protocol deviations CRF is likely to be very incomplete which limits its usefulness. A general structure that maps to SDTM is provided if Sponsors choose to collect protocol deviations on the CRF. |
| CRF Page # of Deviation | CRF page number where protocol deviation occurs | |
| Page Sequence Number | CRF page number within collection of Protocol Deviations CRF pages | |
| Check if Last Page | Check box if this is the last page of protocol deviations | |
| Protocol Déviation Page _ of _ Pages | The number of the specific page of total pages of protocol deviations. | |
| Check if None | Check if no protocol deviations were reported. | |
| Was Protocol Deviation approved by sponsor? | Check if protocol deviation was approved by sponsor. | |
| Approver's Name | Name of staff approving protocol deviation. | |
| Date of Notification | Date sponsor was notified of protocol deviation. | |
| Excluded Days | | |
| Date of Approval | Date protocol deviation was approved. | |

## 3.18.17 Substance Use

| Variable Label | Definition | Reason Excluded From CDASH Standard |
|---|---|---|
| Subcategory for Substance Use | A further categorization of substance use. | In general, the terms that are going to be collected are defined by the protocol and the sub-categories are pre-set as part of the implementation and are not captured by the Investigator. |
| Substance Pre-specified | Substances that are pre-specified on the CRF. | |
| Substance Use Occurrence | Used when the use of specific substances is solicited to indicate whether a substance was taken or not (e.g., Tobacco Consumption, Alcohol Consumption). | This can be derived from the data that is collected per the CDASH recommendations.<br>See Implementation/Rationale for SUNCF. |
| Substance use Consumption | Amount of SUTRT consumed | If the dose is part of a planned analysis, then the use of SUDOSE should be considered. |
| Dose Form | Dose form for SUTRT (e.g., INJECTABLE, LIQUID, POWDER). | This appeared in a small minority of forms sampled and was not identified as an 80/20 match. |
| Route of Administration | Route of administration for SUTRT (e.g., ORAL, INTRAVENOUS, INHALATION). | This appeared in a small minority of forms sampled and was not identified as an 80/20 match. |
| Modified Reported Term | If SUTRT is modified, then the modified text is placed here. | The MOD term is only required in SDTM if the Sponsor modifies a term using an internal Self Evident Correction or other convention without querying the Investigator for the modification. This is derivable from audit trail history. See SDTM IG for instructions. |
| Standardized Substance Name | Standardized or dictionary-derived text description of SUTRT or SUMODIFY if a sponsor chooses to code the substance use. The sponsor should specify the dictionary name and version in the Sponsor Comments column or the Define data definition document. | This variable appeared in a small minority of forms sampled and was not identified as an 80/20 match.<br>If sponsors code substance use information, SUMODIFY and SUDECOD may be necessary. |
| Substance Use Status | Used to indicate the question was not asked. | These variables appeared in a small minority of forms sampled and was not identified as an 80/20 match. |
| Reason Substance Use Not Collected | Describes the reason substance use was not collected. Used in conjunction with SUSTAT when value is NOT DONE. | |
| Substance Use Class | May be used when coding substance use such as alcoholism or drug abuse. | |
| Substance Use Class Code | May apply when coding substance abuse use cases. | |
| Total Daily Consumption using SUDOSU | Total daily use of SUTRT using the units SUDOSU | |

# Appendices

## Appendix A: Information for End Users

| User | Section |
|---|---|
| All | Introduction |
| All | Purpose |
| All | Organization of this document |
| All | Information for End Users |
| All | General Information |
| All | Review the CDASH Standard and User Guide |
| All | Conformance Rules for CDASH |
| All | 2-Tier Conformance |
| All | Terms Used in this document |
| CRF Designers | General Recommendation on Screen Failures |
| CRF Designers | Form Level CRF Instructions |
| CRF Designers | General Design Considerations for Completion Instructions |
| CRF Designers | General Content Considerations for Completion Instructions |
| CRF Designers | AE - Implementation Examples |
| CRF Designers | AE - Completion Instructions |
| CRF Designers | CM - Implementation Examples |
| CRF Designers | CM - Completion Instructions |
| CRF Designers | DM - Implementation Examples |
| CRF Designers | DM - Completion Instructions |
| CRF Designers | DS - Implementation Examples |
| CRF Designers | DS - Completion Instructions |
| CRF Designers | DA - Implementation Examples |
| CRF Designers | DA - Completion Instructions |

| User | Section |
|---|---|
| CRF Designers | EG - Scenario Flowcharts |
| CRF Designers | EG - Implementation Examples |
| CRF Designers | EG - Completion Instructions |
| CRF Designers | EX - Implementation Examples |
| CRF Designers | EX - Completion Instructions |
| CRF Designers | IE - Implementation Examples |
| CRF Designers | IE - Completion Instructions |
| CRF Designers | LB - Scenario Flowcharts |
| CRF Designers | LB - Implementation Examples |
| CRF Designers | LB - Completion Instructions |
| CRF Designers | MH - Implementation Examples |
| CRF Designers | MH - Completion Instructions |
| CRF Designers | PE - Implementation Examples |
| CRF Designers | PE - Completion Instructions |
| CRF Designers | DV - Implementation Examples |
| CRF Designers | DV - Completion Instructions |
| CRF Designers | SC - Implementation Examples |
| CRF Designers | SC - Completion Instructions |
| CRF Designers | SU - Implementation Examples |
| CRF Designers | SU - Completion Instructions |
| CRF Designers | VS - Implementation Examples |
| CRF Designers | VS - Completion Instructions |
| Database Administrators, Programmers | Variables and How to Use Them |
| Database Administrators, Programmers | CDASH Core Designations |
| Database Administrators, Programmers | Definitions |
| Database Administrators, Programmers | Highly Recommended |
| Database Administrators, Programmers | Implementation Examples of Highly Rec. Fields |

| User | Section |
|---|---|
| Database Administrators, Programmers | Recommended/Conditional |
| Database Administrators, Programmers | Implementation Examples of Recommended/Conditional |
| Database Administrators, Programmers | Optional |
| Database Administrators, Programmers | Implementation Examples of Optional Fields |
| Database Administrators, Programmers | Using fields that do exist in CDASH |
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| Database Administrators, Programmers | Data Structures: Normalized vs. De-normalized |
| Database Administrators, Programmers | Comparison of Normalized vs. De-normalized Data Structures (Advantages and Disadvantages) |
| Database Administrators, Programmers | LB Domain: De-normalized Example |
| Database Administrators, Programmers | LB Domain: Normalized Example |
| Database Administrators, Programmers | VS Domain: De-normalized Example |
| Database Administrators, Programmers | VS Domain: Normalized Example |
| Database Administrators, Programmers | QS Domain: De-normalized Example |
| Database Administrators, Programmers | QS Domain-Normalized Example |
| Database Administrators, Programmers | Domain Implementation Reference |
| Database Administrators, Programmers | Common Identifier Variables- CDASH to SDTM Mapping |
| Database Administrators, Programmers | AE - CDASH to SDTM Mapping |
| Database Administrators, Programmers | CM - CDASH to SDTM Mapping |
| Database Administrators, Programmers | DM - CDASH to SDTM Mapping |
| Database Administrators, Programmers | DS - CDASH to SDTM Mapping |
| Database Administrators, Programmers | DA - CDASH to SDTM Mapping |
| Database Administrators, Programmers | EG - CDASH to SDTM Mapping |
| Database Administrators, Programmers | EX - CDASH to SDTM Mapping |
| Database Administrators, Programmers | IE - CDASH to SDTM Mapping |
| Database Administrators, Programmers | LB - CDASH to SDTM Mapping |
| Database Administrators, Programmers | MH - CDASH to SDTM Mapping |
| Database Administrators, Programmers | PE - CDASH to SDTM Mapping |

| User | Section |
|---|---|
| Database Administrators, Programmers | DV - CDASH to SDTM Mapping |
| Database Administrators, Programmers | SC - CDASH to SDTM Mapping |
| Database Administrators, Programmers | SU - CDASH to SDTM Mapping |
| Database Administrators, Programmers | VS - CDASH to SDTM Mapping |
| Programmers | Mapping from CDASH to SDTM Datasets |
| Programmers | Examples of SDTM Variables Not Included in CDASH |
| Programmers | Examples of CDASH Variable Names Not Included in SDTM |
| Programmers | Order of Fields in Each Domain |
| Programmers | CDASH ODM |
| Programmers | ODM: Introduction |
| Programmers | ODM: Description |

# Appendix B: Variable Naming Implementation Examples

8-character limitation

If your database is limited to 8-characters or your implementation depends on 8 or less characters to represent the variable, then you should use the available test codes when creating the variables in the horizontal database structure. For associated attributes for these variable values (units, normal range low/high values, etc.) the programmers will need to decide on how to represent these in a way that "flags" these for mapping to the appropriate SDTM variables when transposed. It is recommended that CDISC naming fragments be used as appropriate. Examples below:

HEIGHT
HEIGHTU
WEIGHT
WEIGHTU
DIABP
SYSBP
BPPOS
BPLOC
BPCLSIG (for clinically significant BP result)

Multi-level

This multi-level approach provides up to four levels of information, embedded in the variable name. These components reflect the following details about the underlying data, along with suggested formatting that helps people recognized the division between these components. An alternative to the formatting suggested, would be to provide a visual separator, such as a dot (.) or underscore (_) between the values.

| Category (optional) | Subcategory (optional, but category must be present) | Test code (from CDISC terminology, if available, otherwise need to develop Q standard) | CDASH or SDTM variable. |
|---|---|---|---|
| Capitalize first letter | Capitalize first letter | Capitalize first letter | All capitals |

When following this approach, each level might be included explicitly or might be omitted when that level is implied by certain values in other levels. An example of this is the BPVSLOC below. In that example, an explicit representation would include one record for each test value (SYSBP and DIABP) but omitting the test value provides a single normalized record to report the VSPOS (vital signs position of the subject) for the blood pressure reading (the combination of the SYSBP + DIABP).

| Formatted examples | Separator examples using dots (.) |
|---|---|
| VsallVSSTAT | VSALL.VSSTAT |
| HeightVSSTAT | HEIGHT.VSSTAT |
| HeightVSORRES | HEIGHT.VSORRES |
| HeightVSORRESU | HEIGHT.VSORRESU |
| HeightVSCLSIG | HEIGHT.VSCLSIG |
| WeightVSSTAT | WEIGHT.VSSTAT |
| WeightVSORRES | WEIGHT.VSORRES |
| WeightVSORRESU | WEIGHT.VSORRESU |
| WeightVSCLSIG | WEIGHT.VSCLSIG |
| BpVSSTAT | BP.VSSTAT |
| BpSysbpVSORRES | BP.SYSBP.VSORRES |
| BpDiabpVSORRES | BP.DIABP.VSORRES |
| BpVSORRESU | BP.VSORRESU |
| BpVSLOC | BP.VSLOC |
| BpVSPOS | BP.VSPOS |
| BpVSCLSIG | BP.VSCLSIG |
| PulseVSSTAT | PULSE.VSSTAT |
| PulseVSORRES | PULSE.VSORRES |
| PulseVSORRESU | PULSE.VSORRESU |
| PulseVSLOC | PULSE.VSLOC |
| PulseVSPOS | PULSE.VSPOS |
| PulseVSCLSIG | PULSE.VSCLSIG |
| TempVSSTAT | TEMP.VSSTAT |
| TempVSORRES | TEMP.VSORRES |
| TempVSORRESU | TEMP.VSORRESU |
| TempVSLOC | TEMP.VSLOC |
| TempVSCLSIG | TEMP.VSCLSIG |
| FrmsizeVSSTAT | FRMSIZE.VSSTAT |
| FrmsizeVSORRES | FRMSIZE.VSORRES |
| VrmeanEGORRES | VRMEAN.EGORRES |
| VrmeanEGCLSIG | VRMEAN.EGCLSIG |

| Formatted examples | Separator examples using dots (.) |
|---|---|
| PrmeanEGORRES | PRMEAN.EGORRES |
| PrmeanEGCLSIG | PRMEAN.EGCLSIG |
| QrsdurEGORRES | QRSDUR.EGORRES |
| QrsdurEGCLSIG | QRSDUR.EGCLSIG |
| QtmeanEGORRES | QTMEAN.EGORRES |
| QtmeanEGCLSIG | QTMEAN.EGCLSIG |
| QtcbEGORRES | QTCB.EGORRES |
| QtcbEGCLSIG | QTCB.EGCLSIG |
| IntrpEGORRES | INTRP.EGORRES |
| IntrpEGCLSIG | INTRP.EGCLSIG |
| HematologyCbcWbcLBORRES | HEMATOLOGY.CBC.WBC.LBORRES |
| HematologyCbcWbcLBORRESU | HEMATOLOGY.CBC.WBC.LBORRESU |
| HematologyCbcWbcLBORNRLO | HEMATOLOGY.CBC.WBC.LBORNRLO |
| HematologyCbcWbcLBORNRHI | HEMATOLOGY.CBC.WBC.LBORNRHI |
| HematologyCbcWbcLBNRIND | HEMATOLOGY.CBC.WBC.LBNRIND |
| HematologyCbcWbcLBCLSIG | HEMATOLOGY.CBC.WBC.LBCLSIG |
| HematologyCbcNeutLBORRES | HEMATOLOGY.CBC.NEUT.LBORRES |
| HematologyCbcNeutLBORRESU | HEMATOLOGY.CBC.NEUT.LBORRESU |
| HematologyCbcNeutLBORNRLO | HEMATOLOGY.CBC.NEUT.LBORNRLO |
| HematologyCbcNeutLBORNRHI | HEMATOLOGY.CBC.NEUT.LBORNRHI |

Two-level variable representation

In this database variable naming convention, the right-side component is the SDTM/CDASH variable (in all caps to visually differentiate it from the left-side component) and the left-side component is either the CDISC Terminology test code, a QNAM test name (such as Vsall) or a category (such as Bp in vital signs) and this component has its first letter capitalized.

| |
|---|
| VsallVSSTAT (To indicate if all VS are collected at this time point) |
| |
| HeightVSSTAT (To indicate if Height was collected at this time point) |
| HeightVSORRES |
| HeightVSORRESU |

| |
|---|
| HeightVSCLSIG |
| |
| WeightVSSTAT (To indicate if Weight was collected at this time point) |
| WeightVSORRES |
| WeightVSORRESU |
| WeightVSCLSIG |
| |
| BpVSSTAT (To indicate if BP was collected at this time point) |
| SysbpVSORRES |
| DiabpVSORRES |
| BpVSORRESU (mmHg may be collected or pre-defined) |
| BpVSLOC |
| BpVSPOS |
| BpVSCLSIG |
| |
| PulseVSSTAT (To indicate if Pulse was collected at this time point) |
| PulseVSORRES |
| PulseVSORRESU (BEATS/MIN may be collected or pre-defined) |
| PulseVSLOC |
| PulseVSPOS |
| PulseVSCLSIG |
| |
| TempVSSTAT (To indicate if Temp was collected at this time point) |
| TempVSORRES |
| TempVSORRESU |
| TempVSLOC |
| TempVSCLSIG |
| |
| FrmsizeVSSTAT (To indicate if Framesize was collected at this time point) |
| FrmsizeVSORRES |
| |
| EgallEGSTAT (To indicate if all EG are collected at this time point) |

| |
|---|
| VrmeanEGORRES |
| VrmeanEGORRESU (BEATS/MIN may be collected or pre-defined) |
| VrmeanEGCLSIG |
| |
| PrmeanEGORRES |
| PrmeanEGORRESU (msec may be collected or pre-defined) |
| PrmeanEGCLSIG |
| |
| QrsdurEGORRES |
| QrsdurEGORRESU (msec may be collected or pre-defined) |
| QrsdurEGCLSIG |
| |
| QtmeanEGORRES |
| QtmeanEGORRESU (msec may be collected or pre-defined) |
| QtmeanEGORRES |
| QtmeanEGCLSIG |
| |
| QtcbEGORRES |
| QtcbEGORRESU |
| QtcbEGCLSIG |
| |
| IntrpEGORRES |
| IntrpEGORRESU |
| IntrpEGCLSIG |
| |
| WbcLBORRES |
| WbcLBORRESU |
| WbcLBORNRLO |
| WbcLBORNRHI |
| WbcLBNRIND |
| WbcLBCLSIG |
| |

| |
|---|
| NeutLBORRES |
| NeutLBORRESU |
| NeutLBORNRLO |
| NeutLBORNRHI |
| NeutLBNRIND |
| NeutLBCLSIG |
| |
| LymLBORRES |
| LymLBORRESU |
| LymLBORNRLO |
| LymLBORNRHI |
| LymLBNRIND |
| LymLBCLSIG |
| |
| MonoLBORRES |
| MonoLBORRESU |
| MonoLBORNRLO |
| MonoLBORNRHI |
| MonoLBNRIND |
| MonoLBCLSIG |
| |
| EosLBORRES |
| EosLBORRESU |
| EosLBORNRLO |
| EosLBORNRHI |
| EosLBNRIND |
| EosLBCLSIG |
| |
| BasoLBORRES |
| BasoLBORRESU |
| BasoLBORNRLO |
| BasoLBORNRHI |
| BasoLBNRIND |

| |
|---|
| BasoLBCLSIG |
| |
| RbcLBORRES |
| RbcLBORRESU |
| RbcLBORNRLO |
| RbcLBORNRHI |
| RbcLBNRIND |
| RbcLBCLSIG |

# Appendix C: CDASH User Guide Major Contributors

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| Gary Walker | Quintiles | User Guide Team |
| Jay Leeka | Astra Zeneca | User Guide Team |
| Jian Chen | Edetek | User Guide Team |
| Kim Truett | KCT Data | User Guide Team |
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# Appendix D: Acknowledgements

The CDASH Core Team thanks all CDISC standards teams for their cooperation and collaboration in reviewing the CDASH drafts in accordance with the CDISC COP-001.

The CDASH Core Team also thanks the ~190 team volunteers who have participated in the development and maintenance of the CDASH Standard.

# Appendix E: Revision History

First publication
User Guide Version 1 for CDASH V1.1
30 March 2012

# Appendix F: Representation and Warranties, Limitations of Liability, and Disclaimers

## CDISC Patent Disclaimers

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