Study Data Tabulation Model Implementation Guide for Medical Devices (SDTMIG-MD)

Version 1.1

Prepared by the

CDISC Device Team

[redacted]

Revision History

Date	Author	Version	Summary of Changes
2018-12-12	Medical Device Team	1.1 Final	Finalized provisional version by confirming all variables approved, and DI and DR domains assigned new roles; minor updates
2012-12-04	Medical Device Team	1.0 Provisional	Provisional SDTMIG-MD. Released version reflecting all changes and corrections identified during the comment period.
2012-01-23	Medical Device Team	1.0 Draft	Released version for public comment

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

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1 Introduction

1.1 Purpose

This Medical Device Implementation Guide (IG) to the Study Data Tabulation Model (SDTM) defines recommended standards for the submission of data from clinical trials in which medical devices were used, and is referred to as the SDTMIG-MD. This implementation guide is based on the original SDTM Implementation Guide (SDTMIG) developed for human clinical trials. The device standards are intended to cover both paper and electronic regulatory submissions. Here, "electronic" means submissions that provide study and other data in machine-readable electronic database format.

Devices are an important and growing part of the medical world, both on their own and in combination with drugs or biologic agents. The ISO 14155 Medical Devices Good Clinical Practices standard defines a "device" as:

> *Any instrument, apparatus, implement, machine, appliance, implant, software, material, or other similar or related article*
>
> - *a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of*
>   - *1) diagnosis, prevention, monitoring, treatment or alleviation of disease,*
>   - *2) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,*
>   - *3) investigation, replacement, modification, or support of the anatomy or of a physiological process,*
>   - *4) supporting or sustaining life,*
>   - *5) control of conception,*
>   - *6) disinfection of medical devices, and*
> - *b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means*
>
> *Note 1 to entry: The term "medical device" is usually defined by national regulations. For the purposes of this International Standard, this definition does not list "in vitro diagnostic medical devices" (see ISO 13485:2003, definition 3.7[1]).*

Although different types of devices have widely varying data requirements, most Class II and III devices requiring regulatory data submissions share some fundamental characteristics. This document contains SDTMIG regulatory data submission standards for some key data shared by most types of devices. It is intended to guide the organization, structure, and format of standard device clinical trial tabulation datasets submitted to regulatory authorities**.** This document also describes SDTM device domains, showing rules and examples implementing these domains specifically for device-related data.

This document does not contain all the domains necessary for sponsors to implement CDISC SDTM-based standards for medical device studies. Specifically, this document does not discuss existing domains that may be common to both device and drug studies, for example, Adverse Events and Demographics. These can be found in the SDTMIG (available for download at https://www.cdisc.org/). In addition, the domains defined in this implementation guide are not necessarily required; sponsors should use those domains that represent the data necessary to address the appropriate scientific and regulatory needs.

The domains defined in this document comprise some of the device-specific data that may be needed for the clinical sections of a regulatory submission involving devices under study. Data may be required to answer protocol questions, to address associated safety questions, or to associate specific devices with subjects. Some data are collected on Case Report Forms (CRF) that are completed by the investigative sites, whereas other data are usually derived by sponsors for the SDTM-based datasets. Other data needed for the submission—such as manufacturing quality information—may be included in other sections of the submission, but are not considered clinical data and

therefore are not included in the SDTM-based domains. The device domains include some non-subject data definitions, such as Device Events and Device Tracking information.

The domains in this document may also be used for studies where devices are used to obtain study measurements or results, but the devices themselves are not the object of the study. For example, a study that uses an MRI to capture images of the brain to measure brain volume for an Alzheimer's trial may choose to use the Device-In-Use domain to capture the field strength and slice thickness setting for each image, even though the MRI machine is not being studied and is already approved for use. The domains used in these circumstances will be determined by the sponsor based on the data needed for submission.

1.2 Organization of This Document

This document contains information on how to format tabulation data for the purposes of submission. Although the document is self-contained with respect to device-specific information, it has been developed to be harmonized with other CDISC standards.

This document is organized into the following sections:

- Section 1, Introduction, provides an orientation to data submitted for medical devices.
- Section 2, SDTM-Based Device Domains, provides an overview of the device domains and their relationship to each other as well as to existing domains described in the SDTMIG.
- Section 3, Device Domain Specifications, describes each of the device domains, including domain models, assumptions, and examples.
- Section 4, Cross-Domain Relationship Examples, describes the relationship between Device-In-Use and results generated from the measurement or output of the device. It illustrates how domains can be linked.
- The Appendices provide additional information regarding the Medical Devices project as well as references and supplemental material relevant to implementation of the SDTMIG-MD.

1.3 Relationship to Prior Documents

This document is not intended to replace the standards defined in the current SDTMIG. The SDTMIG-MD should be implemented together with the SDTMIG (available at https://www.cdisc.org/). The SDTMIG is based on the general SDTM conceptual model for representing data to be submitted to regulatory authorities. The SDTM and SDTMIG should be read prior to reading the SDTMIG-MD. An understanding of both of these documents is needed before attempting to understand this implementation guide. The version used (and whether to update to newer version if relevant) is the sponsor’s decision, based upon their needs and their communications with the FDA.

The sections of the SDTMIG that will be the most relevant are:

- Section 2, Fundamentals of the SDTM
- Section 4, Assumptions for Domain Models (review the introductory paragraphs in the main sections and scan the remainder)
- Section 6, Domain Models Based on the General Observation Classes (introductory paragraphs for each domain and scan the included variables)
- Section 8, Representing Relationships and Data (introductory paragraphs to the main sections, and scan the remainder)
- Appendix C, Controlled Terminology (introductory paragraphs and scan the remainder)

1.4 General Notes and Definitions

1.4.1 Electronic Submission

Different segments of the drug/biologics/devices industry have different underlying assumptions with respect to submitting data to regulatory authorities. "Electronic data" refers to the practice of sending study data to a regulatory agency in an electronic format such as a dataset. In this type of submission, documents are submitted in electronic files such as MS Word or PDF, and subject and device data from clinical trials are submitted as electronic datasets using a defined data format. The following considerations might be useful to sponsors submitting data in an electronic format:

- **Paper versus electronic regulatory submission:** These standards are intended to be applicable for regulatory submissions regardless of whether the data are sent on paper, in electronic document files, or as electronic study data databases.
- **Paper CRFs versus electronic CRFs:** The term "CRF" used throughout this document refers to both paper and electronic formats, unless otherwise specified.
- **Fields versus variables:** The term data collection "fields" refers to questions that are seen on the CRF (i.e., the concept of the information solicited by a question). The term data collection "variables" refers to how data are organized and stored in a clinical database.
- **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). For the purposes of this document, these terms will be used interchangeably. The SDTMIG-MD is designed to accommodate both paper and electronic data capture, although it is assumed that data will be entered into an electronic database at some point.
- **Ancillary:** An "ancillary device" is one that is used in a study but is not the device under study. Information may or may not be captured for ancillary devices.

1.4.2 Differences Between Drug and Device Terminology

Differences exist between drugs and devices in the implementation of specific domains. For example, the terms Accountability, Disposition, and Exposure are used somewhat differently. Currently, many CDISC definitions are aligned with those of the drug sector. Table 1 illustrates the different uses of these terms.

Table 1.4.2.1 Comparison and Contrast of Term Usage in Device Versus Drug Trials

Term	Device Definition	Drug Definition
Accountability	Device Accountability: Tracking where the device is physically; shipping information may be on the CRF; usually between sponsor and site.	Drug Accountability: Tracking where the drug is; accounting for all of the drug (e.g., pill counts); in the clinical trial, usually between the site and the subject; shipping info not usually captured on CRFs.
Disposition	Device Disposition: The final location/status of the device at the time of submission or the end of the trial.	Subject Disposition: The status of the subject's participation in the trial at a given time point (e.g., completed the study, withdrew early).
Exposure	Device Exposure: The interaction or interface between the subject and the device or device constituents. Note that exposure information about a drug delivered via a device would generally be placed in Study Drug Exposure (EX). Sponsors should confer with the regulatory reviewers to determine the correct domain to use.	Study Drug Exposure: The amount of study drug to which the subject is exposed.

2 SDTM-Based Device Domains

2.1 Overview

This Implementation Guide includes five Study Data Tabulation Model (SDTM) Device domains based on the SDTM Events, Findings, and Interventions general observation classes, one Relationships dataset structure, and one Study Reference dataset structure. These domains will accommodate most of the core requirements for the majority of studies with implantable, diagnostic, and imaging devices. When CDASH models are developed, they will be presented in both normalized and non-normalized layouts. Users may employ whichever structure is optimal for their data capture.

Medical Device domains are somewhat different from many other SDTM domains developed thus far, in that they may capture information about entities other than the study subject or the trial itself. The MD domains must also accommodate a more complex set of data, and more variation in the relationship of the device to subjects, than is typical in drug development studies. As a result, developing a relationship structure that is not typically required in most subject-related data (i.e., Device-Subject Relationships domain) was required.

2.2 Domain Descriptions

The following seven SDTM-based domains are included in this implementation guide:

1. Device Identifiers (DI): This is a Study Reference domain designed for the submission of information that identifies a specific device unit. The primary purpose of this domain is to provide a consistent sponsor-defined variable (SPDEVID) for linking data across Device domains, independent of the level of granularity by which a device might be identified by a sponsor in a study. The information included in DI depends upon what is needed to identify the device uniquely within a submission and to meet analysis and regulatory requirements. The domain is not intended to contain information about characteristics that can change without affecting the identification of the device, such as supplier details or dial settings (e.g., imaging devices). Device identifiers exist independently from subjects; therefore, the DI domain does not contain USUBJID.
2. Device-In-Use (DU): DU is a Findings domain that contains the values of measurements and settings that are intentionally set on a device when it is used, and may vary from subject to subject or other target. These are characteristics that exist for the device, and have a specific setting for a use instance. DU is distinct from Device Properties (DO), which describes static characteristics of the device. For example, DO would capture that an MRI machine's field strength has a range from 0.2 to 3 Tesla, whereas the DU domain would capture that the field strength for the MRI scan for Subject 123 was 0.5 T.
3. Device Exposure (DX): DX is an Interventions domain that records the details of a subject's exposure to a medical device under study. This device is prospectively defined as a test article within a study and may be used by the subject, on the subject, or be implanted into the subject. Examples include but are not limited to stents, drug delivery systems, and any other item under study that is defined as a device in the applicable regulations.
4. Device Events (DE): DE is an Events domain that contains information about various kinds of device-related events, such as device malfunctions. A device event may or may not be associated with a subject or a visit. If a device event, such as a malfunction, results in an adverse event, then this information should be recorded in the Adverse Events (AE) domain (see SDTMIG, AE domain). The relationship between the AE and a device malfunction in DE can be recorded using RELREC (see SDTMIG section "Relating Datasets") and appropriate identifying variables such as DESPID and AESPID.
5. Device Tracking and Disposition (DT): The DT domain is an Events domain that represents a record of tracking events for a given device (e.g., initial shipment, deployment, return, destruction). Different events would be relevant to different types of devices. The last record represents the device disposition at the time of submission. The sponsor decides upon the level of granularity that is appropriate for this domain based on the type of device and agreements with the regulatory agencies.
6. Device-Subject Relationships (DR): The DR domain is a Relationships dataset structure that links each subject to devices to which they have been exposed. Information in this table may have been initially

collected and submitted in other domains (e.g., Device Exposure, Device Tracking and Disposition, Device Events). This domain, however, provides a single, consistent location to find the relationship between a subject and a device, regardless of the device or the domain in which subject-related data may have been collected or submitted.

7. Device Properties (DO): The DO Findings domain is used to report characteristics of the device that are important to include in the submission and do not vary over the course of the study but are not used to identify the device. Examples include expiration date or shelf life. Device properties exist independently from subjects and therefore the DO domain does not contain USUBJID.

Although some domains, such as DU, were developed to support submission of device-related data in both device and non-device-focused trials (e.g., where the device is used to generate study measurements and is not itself under study), any of these domains can be used in any trial type, including device/drug and device/biologic combination trials, if deemed appropriate by the sponsor and regulators.

2.3 Observation Classes of the Device Domains

The following list shows the observation class for each device domain.

Study Reference

- Device Identifiers (DI)

Relationships

- Device-Subject Relationships (DR)

Interventions General Observation Class

- Device Exposure (DX)

Events General Observation Class

- Device Events (DE)
- Device Tracking (DT)

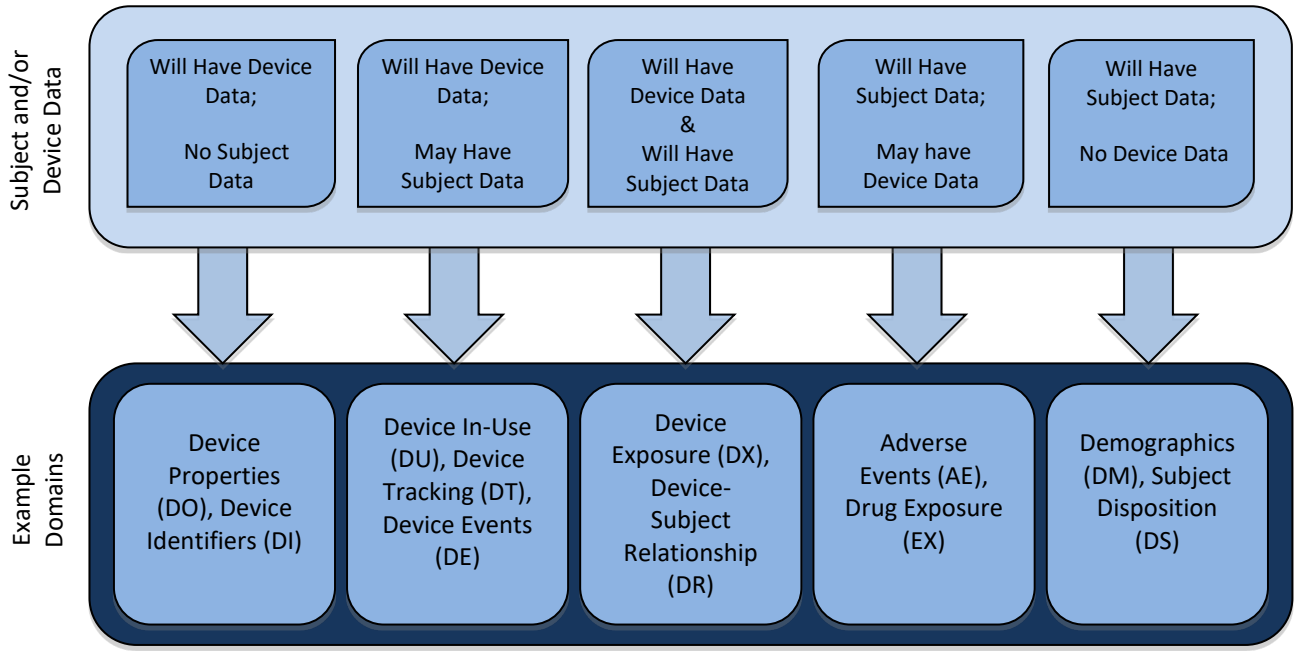
Findings General Observation Class

- Device-In-Use (DU)
- Device Properties (DO)

2.4 How Device Domains Relate to Existing Domains in the SDTMIG

Figure 2.4.1 illustrates device and existing SDTM-based domains, and the combinations of subject and/or device data they might contain. The domains listed below are only examples of those that might or might not contain device and/or subject data.

Figure 2.4.1 Device and Subject Data in Different Domains



2.5 How Device Domains Relate to Each Other

Figures 2.5.1-2.5.6 show simple examples of how the different domains relate to each other through the choice of identifiers present in each. In these examples, Subject 02-1024 in Study ABC-123 had one telescoping titanium orthopedic rod implanted. The rod was sourced from Rods, Co. (DI) and has a length of 4 cm when fully contracted and 8 cm when fully extended (DO). The sponsor would decide whether to model the lengths separately in DO as minimum and maximum lengths, or as a single size characteristic. Here, the sizes are separated.

The model name is SuperLynx (DI), and the serial number for the rod is 274962 (DI). These, plus the manufacturer, are the only characteristics needed to identify each rod uniquely. This domain associates the three key identifier characteristics to the single SPDEVID (TEL-3745), used to reference the device across the other domains. The fourth record in DI is the DEVTYPE, which is required for all device submissions where any device-specific information is included, and is encouraged for the remainder. For post-marketing studies, the use of FDAUDI (the FDA's UDI identifier) is also required, but this example represents a pre-approval study.

The rod was shipped from the sponsor to Site 02 on 26-Apr-2011 (DT), and implanted into the subject on 29-Apr-2011 (DT & DX). When implanted, the telescoping length was set to 4 cm (DU). The rod was implanted into the right femur (DX). There were no malfunctions or other events (no DE), and the device was not explanted (no explantation record in DT and no end date in DX). In this case, the relationship between the device and the subject is derived from DX into DR. The purpose of DR is to provide a link between device and subject data independent of the identifiers that exist on each domain, or of the domains that are present for a given submission.

The different identifiers (study, subject, and device) are color and pattern coded in the following figures to facilitate identifying the relationships of the data among the domains and to see how different domains use different

combinations of identifiers. Note that, in order to simplify the display, the tables contain a subset of the available variables.

Figure 2.5.1 Study Device Identifiers (DI) Using Study ID and Sponsor Device ID Only

STUDYID	SPDEVID	DIPARMCD	DIPARM	DIVAL
Study Identifier	*Sponsor Device Identifier*	*Device Identifier Element Short Name*	*Device Identifier Element Name*	*Device Identifier Element Value*
ABC-123	TEL-3745	MANUF	Manufacturer	Rods, Co.
ABC-123	TEL-3745	MODEL	Model	SuperLynx
ABC-123	TEL-3745	SERIAL	Serial Number	274962
ABC-123	TEL-3745	DEVTYPE	Type of device	Telescoping orthopedic rod

Figure 2.5.2 Device Properties Using Study ID and Sponsor Device ID Only

STUDY ID	USUBJID	SPDEVID	DOTESTCD	DOTEST	DOORRES	DOORRESU
Study Identifier	*Unique Subject Identifier*	*Sponsor Device Identifier*	*Device Property Short Name*	*Device Property Test Name*	*Result or Finding in Original Units*	*Original Units*
ABC-123	02-1024	TEL-3745	COMPOS	Composition	Titanium	
ABC-123	02-1024	TEL-3745	MXLENGTH	Maximum Length	8	cm
ABC-123	02-1024	TEL-3745	MNLENGTH	Minimum Length	4	cm

Figure 2.5.3 Device Exposure Using Study ID, Subject ID, and Sponsor Device ID

STUDYID	USUBJID	SPDEVID	DXTRT	DXLOC	DXLAT	DXSTDTC	DXENDTC
Study Identifier	*Unique Subject Identifier*	*Sponsor Device Identifier*	*Name of Device Exposure or Output*	*Location of Device Exposure*	*Laterality of Device Exposure*	*Start Date/Time of Device Exposure*	*End Date/Time of Device Exposure*
ABC-123	02-1024	TEL-3745	SuperLynx Ortho Rod	FEMUR	RIGHT	2011-04-29	*(null)*

Figure 2.5.4 Device-In-Use Using Study ID, Subject ID, and Sponsor Device ID

STUDYID	USUBJID	SPDEVID	DUTESTCD	DUTEST	DUORRES	DUORRESU	DUDTC
Study Identifier	*Unique Subject Identifier*	*Sponsor Device Identifier*	*Device-In-Use Test Short Name*	*Device-In-Use Test Name*	*Result or Finding in Original Units*	*Original Units*	*Date/Time Device Used with Test/ Setting*
ABC-123	02-1024	TEL-3745	ISLENGTH	In situ length	4	cm	2011-04-29

Figure 2.5.5 Device Tracking Using Study ID and Device ID Only

STUDYID	SPDEVID	DTTERM	DTPARTY	DTPRTYID	DTSTDTC
Study Identifier	*Sponsor Device Identifier*	*Reported Term for the Tracking Event*	*Party Responsible for the Device*	*Responsible Party Identifier*	*Start Date/Time of Device Tracking Event*
ABC-123	TEL-3745	SHIPPED	SITE	02	2011-04-26
ABC-123	TEL-3745	IMPLANTED	SUBJECT	02-1024	2011-04-29

Note: when a subject appears in this domain, it is a value of DTPARTY/DTPRTYID.

Figure 2.5.6 Device-Subject Relationship Using Study ID, Subject ID, and Sponsor Device ID

STUDYID	USUBJID	SPDEVID
Study Identifier	*Unique Subject Identifier*	*Sponsor Device Identifier*
ABC-258	04-1027	TEL-8526

Figures 2.5.7-2.5.15 show more complex examples of domain relationships. In Study ABC-258, Subject 04-1027 had a telescopic titanium orthopedic rod implanted. The rod's maximum extended length is 8 cm, its minimum length is 4 cm, and the rod's composition is of titanium (DO). The test device's manufacturer (Rods, Co.) appears in DI, along with the model (SuperLynx) and serial number (562987) to ensure uniqueness. In this case, there is a comparator device (not shown), and similar information would be added for the comparator device. DR links device and subject data regardless of what identifiers exist.

The rod was shipped from the sponsor to Site 04 on 23-May-2011 (DT), and implanted into the subject on 12-Jun-2011 (DT & DX). It was explanted on 01-Jul-2011, and shipped back to the sponsor on 25-Jul-2011 (DT & DX). Note that the implantation and explantation data in DT is for device accountability and not for exposure. In other cases it may not mirror exposure as closely. When implanted, the telescoping length was set to 6 cm (DU).

The device developed a fissure (DE), considered a malfunction (DECAT), at which point the subject developed inflammation at the incision site (AE). This AE caused the device to be explanted (DE, and could also appear in DX) and the subject to discontinue from the study (DS). If the appropriate links are collected, the malfunction and its associated AE can be linked via RELREC records. Note that this implementation guide does not include the AE and DS domains, because they are defined in the SDTMIG.

As with the preceding examples, the different identifiers (study, subject, and device) are color and pattern coded in the data tables below to facilitate identifying the relationships of the data between the domains. Note that, in order to simplify the display, the tables contain a subset of the available variables.

Figure 2.5.7 Study Device Identifiers Using Study ID and Sponsor Device ID Only

STUDYID	SPDEVID	DIPARMCD	DIPARM	DIVAL
Study Identifier	*Sponsor Device Identifier*	*Device Identifier Element Short Name*	*Device Identifier Element Name*	*Device Identifier Element Value*
ABC-258	TEL-8526	MANUF	Manufacturer	Rods, Co.
ABC-258	TEL-8526	MODEL	Model	SuperLynx
ABC-258	TEL-8526	SERIAL	Serial Number	562987
ABC-258	TEL-8526	DEVTYPE	Type of device	Telescoping orthopedic rod

Figure 2.5.8 Device Properties Using Study ID and Sponsor Device ID Only

STUDYID	USUBJID	SPDEVID	DOTESTCD	DOTEST	DOORRES	DOORRESU
Study Identifier	*Unique Subject Identifier*	*Sponsor Device Identifier*	*Device Property Short Name*	*Device Property Test Name*	*Result or Finding in Original Units*	*Original Units*
ABC-258	04-1027	TEL-8526	MXLENGTH	Maximum Length	8	cm
ABC-258	04-1027	TEL-8526	MNLENGTH	Minimum Length	4	cm
ABC-258	04-1027	TEL-8526	COMPOS	Composition	Titanium	

Figure 2.5.9 Device Exposure Using Study ID, Subject ID and Sponsor Device ID

STUDYID	USUBJID	SPDEVID	DXTRT	DXLOC	DXLAT	DXSTDTC	DXENDTC
Study Identifier	*Unique Subject Identifier*	*Sponsor Device Identifier*	*Name of Device Exposure or Output*	*Location of Device Exposure*	*Laterality of Device Exposure*	*Start Date/Time of Device Exposure*	*End Date/Time of Device Exposure*
ABC-258	04-1027	TEL-8526	SuperLynx Ortho Rod	FEMUR	LEFT	2011-06-12	2011-07-01

Figure 2.5.10 Device-In-Use Using Study ID, Subject ID, and Sponsor Device ID

STUDYID	USUBJID	SPDEVID	DUTESTCD	DUTEST	DUORRES	DUORRESU	DUDTC
Study Identifier	*Unique Subject Identifier*	*Sponsor Device Identifier*	*Device-In-Use Test Short Name*	*Device-In-Use Test Name*	*Result or Finding in Original Units*	*Original Units*	*Date/Time Device Used with Test/ Setting*
ABC-258	04-1027	TEL-8526	ISLENGTH	In situ length	6	cm	2011-06-12

Figure 2.5.11 Device Tracking Using Study ID and Sponsor Device ID Only

STUDYID	SPDEVID	DTTERM	DTPARTY	DTPRTYID	DTSTDTC
Study Identifier	*Sponsor Device Identifier*	*Reported Term for the Tracking Event*	*Party Responsible for the Device*	*Responsible Party Identifier*	*Start Date/Time of Device Tracking Event*
ABC-258	TEL-8526	SHIPPED	SITE	04	2011-05-23
ABC-258	TEL-8526	IMPLANTED	SUBJECT	04-1027	2011-06-12
ABC-258	TEL-8526	EXPLANTED	SITE	04	2011-07-01
ABC-258	TEL-8526	SHIPPED	SPONSOR		2011-07-25

Note: when a subject appears in this domain, it is a value of DTPARTY/DTPRTYID.

Figure 2.5.12 Device Events Using Study ID, Subject ID, and Sponsor Device ID

STUDY ID	USUBJID	SPDEVID	DESPID	DETERM	DEDECOD	DECAT	DEACNDEV	DESTDTC	DEENDTC
Study Identifier	*Unique Subject Identifier*	*Sponsor Device Identifier*	*Sponsor-Defined Identifier*	*Reported Term for Device Event*	*Device Events Dictionary-Derived Term*	*Category of Device Event*	*Action Taken with Device*	*Start Date/Time of Device Event*	*End Date/Time of Device Event*
ABC-258	04-1027	TEL-8526	2	Fissure formation	FISSFORM	MALFUNCTION	Device Explanted	2011-06-25	

Figure 2.5.13 Device-Subject Relationship Using Study ID, Subject ID, and Sponsor Device ID

STUDYID	USUBJID	SPDEVID
Study Identifier	*Unique Subject Identifier*	*Sponsor Device Identifier*
ABC-258	04-1027	TEL-8526

At the time of this publishing, the mechanism of linking the specific AE to the specific device has not yet been established. Figure 2.5.14 shows what the data might look like in the AE domain. The linkage could be accomplished using --SPID variables in data capture, and this could permit the construction of a RELREC dataset.

Figure 2.5.14 Adverse Events Using Study ID and Subject ID

STUDYID	USUBJID	AESPID	AEDECOD	AETERM	AEACNDEV	AESTDTC	AEENDTC
Study Identifier	*Unique Subject Identifier*	*Sponsor-Defined Identifier*	*Dictionary-Derived Term*	*Event Verbatim Term*	*Other Action Taken For AE*	*Event Start Date/Time*	*Event End Date/Time*
ABC-258	04-1027	3	INFLAMMATION	Incision site inflammation	Device removed	2011-06-25	2011-07-10
ABC-258	04-1027	4	HEADACHE	Headache	None	2011-06-30	2011-07-02

The event in Figure 2.5.15 is Discontinuation from the Study Due to an AE. The “start” date is also used for a point in time event, which is the case here. If the specific device needs to be linked to this event, it could be accomplished in data capture using --SPID variables, which can then be reflected here in a RELREC dataset.

Figure 2.5.15 Subject Disposition Using Study ID and Subject ID only.

STUDYID	USUBJID	DSDECOD	DSTERM	DSSTDTC
Study Identifier	*Unique Subject Identifier*	*Standardized Disposition Term*	*Disposition Event Reported Term*	*Disposition Event Start Date/Time*
ABC-258	04-1027	ADVERSE EVENT	Adverse event	2011-07-01

3 Device Domain Specifications

3.1 Device Identifiers (DI)

di.xpt, Device Identifiers - Study Reference, Version 1.1. One record per device identifier per device, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Code List, or Format[a]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DI	Identifier	Two-character abbreviation for the domain.	Req
SPDEVID	Sponsor Device Identifier	Char		Identifier	Sponsor-defined identifier for the device. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, combination of identifiers).	Req
DISEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a parameter within a device (SPDEVID) within dataset. If there is only one value for DIPARMCD for each value of SPDEVID, then DISEQ will be 1 for all records. DISEQ must be a valid number.	Exp
DIPARMCD	Device Identifier Element Short Name	Char	*	Topic	Short name of the identifier characteristic of the device (e.g., "SERIAL", "MODEL"). A record with DIPARMCD = "DEVTYPE" should be included (see below).	Req
DIPARM	Device Identifier Element Name	Char	*	Synonym Qualifier	Name of the identifier characteristic of the device. Examples: Serial Number, Model. A record with DIPARM = "DEVTYPE" should be included (see below).	Req
DIVAL	Device Identifier Element Value	Char	*	Result Qualifier	Value for the parameter. Value for the parameter. When DIPARMCD=DEVTYPE it should use controlled terminology defined by FDA in their Preferred Term codelist. FDA has stated a preference for the Global Medical Device Nomenclature (GMDN), but as of the date of this publication, the GMDN is not freely available to the public. In its Unique Device Identification rule, FDA indicated that GMDN will not be required unless it is available to the public at no cost. There is a lookup tool on the FDA website to map GMDN codes to FDA PT codes.	Req

[a]Asterisk indicates variable may be subject to controlled terminology.

3.1.1 Assumptions for the Device Identifiers Domain Model

1. Definition: Device Identifiers (DI) is a Study Reference domain that provides a mechanism for using multiple identifiers to create a single identifier for each device.
2. The primary purpose of this domain is to provide a consistent variable (SPDEVID) for linking data across Device domains, independent of the level of granularity by which a device might be identified by a sponsor in a study. One of the challenges of identifying devices consistently is that different types of devices use different characteristics and different numbers of characteristics as identifiers. For example, it may be sufficient to use a serial number only to identify an MRI machine, but identifying a box of screws may require a batch number and a box number. In study-specific datasets this could be accomplished by using different numbers of identifier variables, but this is not feasible for a general standard. SPDEVID is a mechanism for aggregating any number of identifiers into one, allowing for a consistent structure for identifying all devices. SPDEVID is a surrogate identifier that represents all the characteristics of a device in the Study DI domain, but is a simple, short identifier that can appear in each dataset. Having different identifier variables in different submissions does not help interoperability, and this approach allows for a single identifier while preserving access to the identifying information needed for the submission. It also facilitates merging datasets.
3. DI was modeled as a Study Reference domain because it has none of the characteristics (except identifiers) of a Findings domain, and is clearly not an event or intervention. This is separated from the Device Properties (DO) domain because DI contains the total set of characteristics necessary for device identification, whereas DO contains information important for submission but that are not part of the device identifier.
4. In order to determine the right level of granularity for the parameters defined in DI, it is critical that the sponsor think carefully about how the devices will need to be tracked (e.g., in Device-In-Use, Device Events) and design SPDEVID to reflect that level of specificity. For example, if surgical screws only need to be tracked by box and not by individual screw, then the value in SPDEVID might be a box number. If each screw needs to be tracked, then the parameters would need to include the identifier on each screw.
5. The DI domain must exist if SPDEVID is used in any domain in a study. It is required when any device-specific information is submitted. This includes information about the device under study as well as parameters captured for devices not under study (e.g., MRI slice thickness, field strength). If none of this applies (e.g., ECG machine used to generate a tracing, but no information about the machine is needed), then DI is not required.
6. If the DI domain exists, at a minimum it must contain a record with DEVTYPE populated.
7. SPDEVID should not change during a specific device's lifetime.
8. DISEQ must be unique within each value of DIPARMCD within a SPDEVID. If there is only 1 value of DIPARMCD per device, then DISEQ will always be 1.
9. The DI domain was designed to be able to handle situations where SPDEVID is needed to identify individual devices. In some situations, such as studies in which a device is not the product under study and is used only to conduct assessments, SPDEVID may need only to identify a kind of device. For example, an oncology trial might need to identify the kind of device used to image a tumor, in which case SPDEVID might be used to distinguish MRI, CT, and X-Ray devices. In such cases, the minimum requirement for a SPDEVID for a kind of device is DEVTYPE (DIPARMCD=DEVTYPE). Sponsors should define the appropriate level of granularity for unique identification; in some cases it may be a serial number, whereas in others it may be a box, lot, or batch number, or some combination of these or other identifiers.
10. The DI domain is often referred to as the Study DI domain to help distinguish it from the FDA's Unique Device Identifier (UDI).
11. This domain should not be used for device characteristics other than identifiers. Any additional non-identifier attributes that the sponsor needs to submit should be placed in DO instead.
12. This structure allows for the association between one SPDEVID and as many identifiers as a sponsor feels necessary to support all the submitted data. This easily transforms into a one-record-per-SPDEVID structure for potential merging with other device-related datasets that would contain the SPDEVID variable, as shown in these samples for a set of Study DI records for a single device.

DI data arranged vertically (normalized) showing correspondence between identifiers and SPDEVID (Study Data Tabulation Model, SDTM, structure):

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
DEVM-0004-0003	DI	ABC001	1	DEVTYPE	Device Type	STENT
DEVM-0004-0003	DI	ABC001	2	MANUF	Manufacturer	Acme Stents
DEVM-0004-0003	DI	ABC001	3	MODEL	Model	45-JFI
DEVM-0004-0003	DI	ABC001	4	BATCH	Batch identifier	2011-1307
DEVM-0004-0003	DI	ABC001	5	LOT	Lot Identifier	45678
DEVM-0004-0003	DI	ABC001	6	SERIAL	Serial Number	456789132-AXQ
DEVM-0004-0003	DI	ABC001	7	Y	Manufacturer Y-code	32110
DEVM-0004-0003	DI	ABC001	8	Z	Manufacturer Z-code	6A-55

DI data arranged horizontally (non-normalized) showing identifiers and SPDEVID on a single record (non-SDTM structure):

SPDEVID	DEVTYPE	MANUF	MODEL	BATCH	LOT	SERIAL	IDENTIFIER Y	IDENTIFIER Z
ABC001	STENT	Acme Stents	45-JFI	2011-1307	45678	456789132-AXQ	32110	6A-55

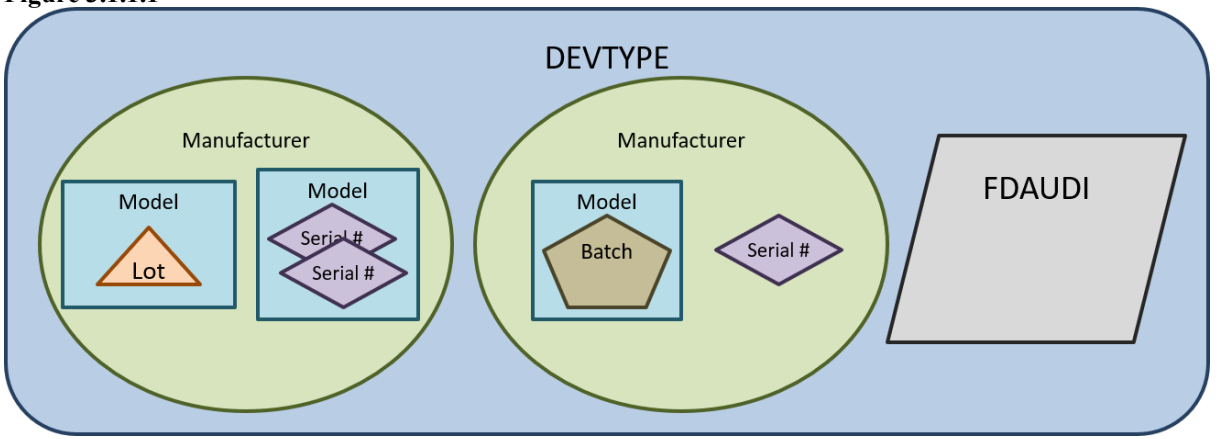
13. The data in this domain may be derived (manually or electronically), captured on DI case report forms (CRFs), or a combination of these.
14. No date variables have been included in this domain because the characteristics defined in Study DI should not change over the course of the trial and because temporal associations will generally be captured in other domains, for example, Device Exposure (DX) or Device Tracking and Disposition (DT).
15. No additional variables can be added to this dataset.
16. DIPARMCD values are limited to 8 characters and cannot begin with a number or underscore, as they can be used as variable names when the dataset is transposed to a non-normalized structure.
17. If FDAUDI is used, it is intended to hold the FDA's UDI assigned after device approval. For post-approval studies, SPDEVID could be the FDAUDI value only. If the device is pre-approval, this variable would be null.
18. If the FDAUDI can be populated, the DEVTYPE should still be included. Sponsors may include additional parameters as needed.
19. An incomplete list of DIPARMCD and DIPARM values is shown in the following table.

DIPARMCD	DIPARM
FDAUDI	FDA Unique Device Identifier
DEVTYPE	Device Type
MANUF	Manufacturer
MODEL	Model
BATCH	Batch identifier
LOT	Lot Identifier
SERIAL	Serial Number

20. Generally, the SPDEVID should include the set of parameters necessary for identifying the device uniquely, and would also have all of the higher level parameters. For example, if Serial Number were sufficient to identify the device, generally Model and Manufacturer and Device Type would be included (if available or relevant). Figure 4.1.1 shows the usual relationships among identifier parameters. In the smallest shapes, Lot, Batch, and Serial

Number are usually considered to be on the same level. The FDAUDI is effectively a surrogate key for the rest of the identifiers, so the combination of FDAUDI and DEVTYPE could be sufficient to identify each device for a post-marketing study. Alternatively, if information embedded in the FDAUDI is needed for data aggregation, analysis, or appropriate interpretation of the data, other identifier variables can also be extracted from FDAUDI and included.

Figure 3.1.1.1



Graphic showing common relationships between identifier parameters for devices.

3.1.2 Examples for the Device Identifiers Domain Model

Example 1

This example shows records for 2 devices where the sponsor felt that the type, manufacturer, model number, and serial number were necessary for unique identification. In addition, there was a post-marketing UDI identifier available for the first device.

Rows 1-5: Show the records for a device given a SPDEVID of ABC001
Rows 5-8: Show the records for a device given a SPDEVID of ABC999

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	2011-001	DI	ABC001	1	DEVTYPE	Device Type	MRI
2	2011-001	DI	ABC001	2	MANUF	Manufacturer	Acme Imaging
3	2011-001	DI	ABC001	3	MODEL	Model Number	45-JFI
4	2011-001	DI	ABC001	4	SERIAL	Serial Number	456789132-AXQ
5	2011-001	DI	ABC001	5	FDAUDI	FDA Unique Device Identifier	456789123xyz
6	2015-001	DI	ABC999	1	DEVTYPE	Device Type	MRI
7	2015-001	DI	ABC999	2	MANUF	Manufacturer	Acme Imaging
8	2015-001	DI	ABC999	3	MODEL	Model Number	62-PLC
9	2015-001	DI	ABC999	4	SERIAL	Serial Number	215964564-NFS

Example 2

This example shows a case where a single device was used for all subjects at a given site. The device under study is an extracorporeal shock wave treatment (ESWT) for treatment of plantar fasciitis, and a single machine is used at each site. All devices in the study would be included in this table and therefore multiple devices are listed. Because SITEID is not a part of identifying each device, this table does not include SITEID and therefore does not record what device went to what site/device. The model and serial numbers are necessary to identify each device, and the device will be assigned to each subject via the Device-Subject Relationships domain (DR).

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABCXYZ	DI	XYZ001	1	DEVTYPE	Device Type	ESWT
2	ABCXYZ	DI	XYZ001	2	MODEL	Model	UR4000
3	ABCXYZ	DI	XYZ001	3	SERIAL	Serial Number	47821B
4	ABCXYZ	DI	QRS002	1	DEVTYPE	Device Type	ESWT
5	ABCXYZ	DI	QRS002	2	MODEL	Model	UR4000
6	ABCXYZ	DI	QRS002	3	SERIAL	Serial Number	87232A

Example 3

This example shows records for a device for which it was important to collect the type and manufacturer, but no more granular information was needed.

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	2011-537	DI	ABC003	1	DEVTYPE	Device Type	Cardiac Stent
2	2011-537	DI	ABC003	2	MANUF	Manufacturer	Stents, Ltd.

Example 4

This example shows records for a study where 2 devices were used for treatment: a thrombectomy device, which was identified using the type, model and serial number; and a stent, which was identified using only the type and a serial number.

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABCXYZ	DI	XYZ001	1	DEVTYPE	Device Type	Thrombectomy Device
2	ABCXYZ	DI	XYZ001	2	MODEL	Model	TR300
3	ABCXYZ	DI	XYZ001	3	SERIAL	Serial Number	452209BB
4	ABCXYZ	DI	QRS002	1	DEVTYPE	Device Type	Coronary Stent
5	ABCXYZ	DI	QRS002	2	SERIAL	Serial Number	87232A

Example 5

This example shows records for a device used in a study solely for obtaining measurements, and the device is not under study. The only record required is a DEVTYPE record.

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	2011-537	DI	ABC003	1	DEVTYPE	Device Type	MRI

3.2 Device-In-Use (DU)

du.xpt, Device-In-Use - Findings, Version 1.1. One record per property or setting per time point per visit or test date per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Code List, or Format[a,b]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DU	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Expected in this domain as devices may have settings or uses that either may not involve subjects (e.g., diagnostic tools) or devices that are removed from the study prior to contact with a subject (e.g., device has malfunction).	Exp
SPDEVID	Sponsor Device Identifier	Char		Identifier	Sponsor-defined identifier for the device. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, or combination of identifiers).	Exp
DUSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of device records within subject records within a domain. May be any valid number. It should be unique within every subject/device combination.	Req
DUGRPID	Group ID	Char		Identifier	Identifier for a group or block of related records. Used to tie together a block of related records in a single domain for a subject or a group of subject related records (e.g., group records specifying all the settings for a specific imaging scan, such as field strength, repetition time and echo time).	Perm
DUREFID	Reference ID	Char		Identifier	Internal or external identifier. This could be a scan code or equivalent.	Perm
DUSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm
DUTESTCD	Device-In-Use Test Short Name	Char	(DUTESTCD)	Topic	Short name of the measurement, test, or examination described in DUTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DUTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). DUTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "COILSTR", "CNTMEDIA".	Req

Variable Name	Variable Label	Type	Controlled Terms, Code List, or Format[a,b]	Role	CDISC Notes	Core
DUTEST	Device-In-Use Test Name	Char	(DUTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in DUTEST cannot be longer than 40 characters. Examples: "Coil Strength", "Contrast Media".	Req
DUCAT	Category for Device-In-Use	Char	*	Grouping Qualifier	Defines a category of related records. It can be used to define the type of device for which settings are recorded if DI is not used (e.g., if the device is not under study); may also be used to record the type of setting (e.g., "HARDWARE" vs. "SOFTWARE").	Perm
DUSCAT	Subcategory for Device-In-Use	Char	*	Grouping Qualifier	A further categorization of a measurement or examination. For example, if DUCAT = "SOFTWARE", DUSCAT might be "NOMINAL" or "POST-ADJUSTMENT".	Perm
DUORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement as originally received or collected. DUORRES should contain the setting or other device condition in effect at the time the device was used.	Exp
DUORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for DUORRES. Examples: Tesla, mm.	Exp
DUSTRESC	Result or Finding in Standard Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from DUORRES in a standard format or standard units. DUSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in DUSTRESN. For example, if a test has results "NONE," "NEG," and "NEGATIVE" in DUORRES, and these results effectively have the same meaning, they could be represented in standard format in DUSTRESC as "NEGATIVE".	Exp
DUSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format. Copied in numeric format from DUSTRESC. DUSTRESN should store all numeric test results or findings.	Exp
DUSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for DUSTRESC and DUSTRESN. The unit for standardized results may or may not be the same as for the original results.	Exp
VISITNUM	Visit Number	Num		Timing	A clinical encounter number. A Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	Protocol-defined description of clinical encounter. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics. This value is usually derived.	Perm

Variable Name	Variable Label	Type	Controlled Terms, Code List, or Format[a,b]	Role	CDISC Notes	Core
DUDTC	Date/Time Device Used with Test/ Setting	Char	ISO 8601	Timing	Date/time that the device was used with this setting. This is not the date/time that the setting was set on the device, but rather that date/time that a measurement or test was done using that setting.	Exp
DUDY	Study Day of Observation	Num		Timing	Study day of Device-In-Use measurement, measured as integer days. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm

[a]Asterisk indicates variable may be subject to controlled terminology.
[b]Parentheses indicates CDISC/NCI code list code value.

3.2.1 Assumptions for the Device-In-Use Domain Model

1. Definition: The Device In-Use (DU) domain represents properties of the study device or ancillary device that are intentionally set when the device is used in the context of a study.
2. An "ancillary device" is a device used within a clinical trial to collect subject data/information (device or human subject), but that is not the target of the study (e.g., an MRI or CT machine whose settings must be recorded in a clinical trial studying heart failure, as required in the protocol). If settings for an ancillary device in a study need to be recorded and the device needs to be identified in the data, DI must be used for that identification.
3. Unlike Device Properties (DO), which describes device characteristics that do not change for the device during the trial, the DU domain captures characteristics and properties of a device that can vary from subject to subject or usage to usage over the course of a study. For example,
    a. The full range of field strengths for a given MRI machine might be 0.5 to 3 Tesla, and these values would be captured in DO. DU would record the specific settings used for a given subject (e.g., the field strength for the MRI scan for Subject 123 was 0.5 T for Visit 1).
    b. The software for a pacemaker may start at Version 1, and be updated to Version 2 during the study. This change can be captured here. It would not go in DO, as DO holds only characteristics that do not change during the study.
4. There are two primary identifiers in this domain: USUBJID and SPDEVID. Both are Expected. Either one or the other or both must be used. For example, a device under study will always have a SPDEVID, but may or may not have a USUBJID. An ancillary device (one not under study) for which in-use data are required may have a USUBJID but may or may not have SPDEVID. In all cases where SPDEVID is used, it must be defined in the Device Identifiers (DI) domain.
5. There are cases where settings on devices used in studies might be reported in Device Exposure (DX) or DU, such as when the settings are changed to affect an efficacy response. Sponsors should confer with the appropriate regulatory authorities to determine where to submit this information
6. This domain is not intended to capture manufacturer-set (i.e., nominal) settings, but rather the customized settings for a given usage.
7. Because any number of device settings (e.g., coil strength, placement of leads) can be reported in this domain, each setting is represented by a separate row and is defined in the topic variable DUTESTCD. The original result goes into DUORRES.
8. DUREFID is the identifier for a unique scan or other test result to link a group of settings (e.g., field strength or slice thickness in an MRI scan) to the results obtained from the reading or interpretation of the test (e.g., the MRI image).
9. The DUSPID variable can be used to link this domain to other domains if necessary, such as Adverse Events (AE), Exposure, and/or Device Events.
10. Note that in some of the examples that follow, variables that would be blank may have been dropped to conserve space. This does not mean that the variables cannot be used in the illustrated use case, merely that in the specific example they were not populated.

11. The following Qualifiers would not generally be used in DU: --MODIFY, --BODSYS, --POS,--ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STNRC, --NRIND, --RESCAT, --REASND, --XFN, --NAM, --LOINC, --SPEC, --SPCCND, --LOC, --METHOD, --FAST, --DRVFL, --EVAL, --TOX, --TOXGR, --SEV, --DTHREL, --LLOQ.

3.2.2 Examples for the Device-In-Use Domain Model

Example 1

This example shows data from 1 subject collected at 2 visits about parameters from an MRI imaging protocol. In this case, the image was used to obtain brain volume measurements, and the results of the image interpretation are reported in the Neurological domain. The parameters in DU can be linked to the measurement results using RELREC; see Section 4 Example 1. DUSPID is the same for each timepoint, as the device settings were collected on a single record for each image taken.

Rows 1-7: Represent 7 example DU records collected at the screening visit for a given subject.
Rows 8-14: Represent 7 example DU records collected at the first treatment visit for the same subject.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUGRPID	DUREFID	DUSPID	DUTESTCD	DUTEST	DUORRES
1	STUDYX	DU	2324-P0001	ABC174	1	DUNV1	222333-444555	1	COILSTR	Coil Strength	1.5
2	STUDYX	DU	2324-P0001	ABC174	2	DUNV1	222333-444555	1	ANTPLANE	Anatomical Plane	CORONAL
3	STUDYX	DU	2324-P0001	ABC174	3	DUNV1	222333-444555	1	STHICK	Slice Thickness	1
4	STUDYX	DU	2324-P0001	ABC174	4	DUNV1	222333-444555	1	MATRIX	Matrix	256X256
5	STUDYX	DU	2324-P0001	ABC174	5	DUNV1	222333-444555	1	SFTWRVER	Software Version	15.0
6	STUDYX	DU	2324-P0001	ABC174	6	DUNV1	222333-444555	1	FLDVIEW	Field of View	24
7	STUDYX	DU	2324-P0001	ABC174	7	DUNV1	222333-444555	1	RCBDWTH	Receiver Bandwidth	16
8	STUDYX	DU	2324-P0001	ABC174	8	DUNV2	444555-666777	2	COILSTR	Coil Strength	1.0
9	STUDYX	DU	2324-P0001	ABC174	9	DUNV2	444555-666777	2	ANTPLANE	Anatomical Plane	CORONAL
10	STUDYX	DU	2324-P0001	ABC174	10	DUNV2	444555-666777	2	STHICK	Slice Thickness	2
11	STUDYX	DU	2324-P0001	ABC174	11	DUNV2	444555-666777	2	MATRIX	Matrix	256X256
12	STUDYX	DU	2324-P0001	ABC174	12	DUNV2	444555-666777	2	SFTWRVER	Software Version	15.1
13	STUDYX	DU	2324-P0001	ABC174	13	DUNV2	444555-666777	2	FLDVIEW	Field of View	25
14	STUDYX	DU	2324-P0001	ABC174	14	DUNV2	444555-666777	2	RCBDWTH	Receiver Bandwidth	16

Row	DUORRESU	DUSTRESC	DUSTRESN	DUSTRESU	VISITNUM	VISIT	VISITDY	DUDTC	DUDY
1 (cont)	T	1.5	1.5	T	1	SCREENING	-7	2011-04-19	-7
2 (cont)		CORONAL			1	SCREENING	-7	2011-04-19	-7
3 (cont)	mm	1	1	mm	1	SCREENING	-7	2011-04-19	-7
4 (cont)		256X256			1	SCREENING	-7	2011-04-19	-7
5 (cont)		15.0	15.0		1	SCREENING	-7	2011-04-19	-7
6 (cont)	cm	24	24	cm	1	SCREENING	-7	2011-04-19	-7
7 (cont)	kHz	16	16	kHz	1	SCREENING	-7	2011-04-19	-7
8 (cont)	T	1.0	1.0	T	2	IMPLANTATION	1	2011-04-26	1
9 (cont)		CORONAL			2	IMPLANTATION	1	2011-04-26	1
10 (cont)	mm	2	2	mm	2	IMPLANTATION	1	2011-04-26	1

Row	DUORRESU	DUSTRESC	DUSTRESN	DUSTRESU	VISITNUM	VISIT	VISITDY	DUDTC	DUDY
11 (cont)		256X256			2	IMPLANTATION	1	2011-04-26	1
12 (cont)		15.1	15.1		2	IMPLANTATION	1	2011-04-26	1
13 (cont)	cm	25	25	cm	2	IMPLANTATION	1	2011-04-26	1
14 (cont)	kHz	16	16	kHz	2	IMPLANTATION	1	2011-04-26	1

Example 2
This example shows a software update applied to a pacemaker during the study.

Row 1: Represents an example DU record collected at the screening visit; records the software version in use.
Row 2: Represents an update to the software for the same device in the same subject from Version 3.0 to Version 3.02.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUGRPID	DUREFID	DUTESTCD	DUTEST	DUORRES	DUORRESU
1	QL1059	DU	1059-001	BOEN37P	1	DUNV1	222333-444555	SFTWRVER	Software Version	3.0	
2	QL1059	DU	1059-001	BOEN37P	1	DUNV1	222333-444555	SFTWRVER	Software Version	3.02	

Row	DUSTRESC	DUSTRESN	DUSTRESU	VISITNUM	VISIT	VISITDY	DUDTC	DUDY
1 (cont)	3.0	3.0		1	SCREENING	-7	2011-04-19	-7
2 (cont)	3.02	3.02		5	VISIT 4	21	2011-05-16	21

3.3 Device Exposure (DX)

dx.xpt, Device Exposure - Interventions, Version 1.1. One record per recorded intervention occurrence or constant treatment interval per subject, Tabulation

Variable Name	Variable Label	Data	Controlled Terms, Code List, or Format[a,b]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DX	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
SPDEVID	Sponsor Device Identifier	Char		Identifier	Sponsor-defined identifier for the device. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, or combination of identifiers).	Req
DXSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of device records within subject records within a domain. May be any valid number. It should be unique within every subject/device combination.	Req
DXGRPID	Group ID	Char		Identifier	Identifier that ties together a block of related records in a single domain for a subject. For example, if a device is inserted that delivers radiation, DXGRPID could be used to tie the records for the device and the radiation together for each course of therapy.	Perm
DXSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Examples: a number pre-printed on the CRF as an explicit line identifier or record identifier defined in the sponsor's operational database.	Perm
DXTRT	Name of Device Exposure or Output	Char		Topic	Name of the device or the exposure outputs that are delivered or administered via the device. This should match the definitions as described in the trial summary domain and/or the protocol. Example: "coronary stent", "extracorporeal shock wave treatment", "hyaluronic acid".	Req
DXCAT	Category for Device Exposure	Char	*	Grouping Qualifier	Used to define a category of device exposures. For example, for a subject who had radiation delivered through an implanted catheter, DXCAT could be used to group the radiation records versus the catheter records.	Perm
DXSCAT	Subcategory for Device Exposure	Char	*	Grouping Qualifier	A further categorization of device exposures. If DXCAT captures the radiation versus catheter records (see DXCAT), then DXSCAT might capture the type of catheter if more than one was used.	Perm

Variable Name	Variable Label	Data	Controlled Terms, Code List, or Format[a,b]	Role	CDISC Notes	Core
DXDOSE	Exposure per Administration	Num		Record Qualifier	Amount of DXTRT administered/delivered per administration. Dose if captured as a numeric value. Dose should only appear once in DXDOSE, DXDOSTXT, or DXDOSTOT.	Perm
DXDOSTXT	Device Exposure Description	Char		Record Qualifier	Exposure amount or a range of exposure information collected in text form. Units may be stored in DXDOSU. Example: 200-400, 15-20. Dose should only appear once in DXDOSE, DXDOSTXT, or DXDOSTOT.	Perm
DXDOSU	Device Exposure Units	Char	(UNIT)	Variable Qualifier	Units for DXDOSE, DXDOSTXT, and DXDOSTOT. Examples: "pulses", "ml".	Perm
DXDOSFRQ	Device Exposure Frequency per Interval	Char	(FREQ)	Variable Qualifier	Exposure frequency per interval. Usually expressed as the number of repeated administrations of DXDOSE within a specific time period. Examples: "CONTINUOUS", "PRN", "Q2M" (every 2 months).	Perm
DXDOSTOT	Total Daily Device Exposure	Num		Record Qualifier	Total daily exposure of DXTRT using the units in DXDOSU. Total exposure over a period other than day could be recorded in a separate Supplemental Qualifier variable.	Perm
DXDOSRGM	Intended Device Exposure Regimen	Char		Variable Qualifier	Text description of the (intended) schedule or regimen for the Intervention. Examples: "TWO WEEKS ON, TWO WEEKS OFF".	Perm
DXROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for DXTRT. Examples: "EXTRACORPOREAL", "INTRA-ARTICULAR, HEMODIALYSIS".	Perm
DXLOC	Location of Device Exposure	Char		Record Qualifier	Anatomic location of exposure. Examples: "Knee", "Eye".	Perm
DXLAT	Laterality of Device Exposure	Char		Variable Qualifier	Qualifier for anatomical location further detailing laterality. Examples: "RIGHT", "LEFT", "BILATERAL".	Perm
DXADJ	Reason for Exposure Adjustment	Char		Record Qualifier	Describes reason why the exposure was adjusted from protocol-specified or expected exposure levels. Example: "PAIN".	Perm
DXSTDTC	Start Date/Time of Device Exposure	Char	ISO 8601	Timing	Start date and time of exposure. Defined by the sponsor.	Exp
DXENDTC	End Date/Time of Device Exposure	Char	ISO 8601	Timing	End date and time of exposure. Defined by the sponsor.	Perm
DXSTDY	Study Day of Start of Device Exposure	Num		Timing	Study day of start of exposure relative to the sponsor-defined RFSTDTC.	Perm
DXENDY	Study Day of End of Device Exposure	Num		Timing	Study day of end of exposure relative to the sponsor-defined RFSTDTC.	Perm

Variable Name	Variable Label	Data	Controlled Terms, Code List, or Format[a,b]	Role	CDISC Notes	Core
DXDUR	Duration of Device Exposure	Char	ISO 8601	Timing	Collected duration for a treatment episode. Used only if collected on the CRF and not derived from start and end date/times.	Perm

[a]Asterisk indicates variable may be subject to controlled terminology.
[b]Parentheses indicates CDISC/NCI code list code value.

3.3.1 Assumptions for the Device Exposure Domain Model

1. Definition: The Device Exposure (DX) domain records the details of a subject's direct interaction or contact with a medical device or the output from a medical device, usually but not always the device under study. This device may be used by the subject, on the subject, or implanted into the subject. Examples include but are not limited to stents, drug delivery systems, and any other item under study that is defined as a device in the applicable regulations.
2. The DX data may be captured on a CRF, downloaded from a device, or derived. The appropriate method is determined by the sponsor.
3. The structure of the DX domain is 1 record per exposure intervention episode or constant-exposure interval per subject. It is the sponsor's responsibility to define an intervention episode. This definition may vary based on the sponsor's requirements for review and analysis. The submission dataset structure may differ from the structure used for collection. One common approach is to submit a new record when there is a change in the exposure regimen. Another approach is to collapse all records for an exposure to a summary level with exposure range. Other approaches may also be reasonable as long as they meet the sponsor's evaluation requirements.
4. A DX domain is expected whenever there is individual subject exposure to a device under study. Device studies in which only pooled samples are used (e.g., some diagnostic devices) may not require a DX domain. In these cases, a subject's sample is part of a pooled sample, and the subject is never in contact with the device, therefore there is no exposure to report. Note that contact can be directly between subject and device, or between subject and a device output.
5. In cases where a device-drug combination is being studied, the device exposure data would generally be submitted in DX and the drug exposure data would generally be submitted in EX, but each sponsor should confer with the appropriate regulatory authorities to determine the appropriate datasets.
6. There are cases where settings on devices used in studies might be reported in DX or Device In-Use (DU), such as when the settings are changed to affect an efficacy response. Sponsors should confer with the appropriate regulatory authorities to determine where to submit this information.
7. Categorization and Grouping: DXCAT and DXSCAT may be used when appropriate to categorize treatments into categories and subcategories. For example, if a study uses several different devices, DXCAT may be set to "ACTIVE COMPARATOR." Such categorization may not be useful in most studies, so these variables are permissible and not expected.
8. Device Exposure Treatment Description: DXTRT captures the name of the investigational medical device and is the topic variable. It is a required variable and must have a value. DXTRT should avoid unnecessarily repeating characteristics found in the Device Properties (DO) domain.
9. Timing Variables: The timing of exposure to the study device is captured by the start/end date and start/end time of each intervention episode or constant exposure interval, as defined by the sponsor.
10. Additional Interventions Qualifiers: Other additional Qualifiers from the SDTM Interventions Class may be added to this domain.
11. Note that in some of the examples that follow, variables that would be blank may have been dropped to conserve space. This does not mean that the variables cannot be used in the illustrated use case, merely that in the particular example they were not populated.
12. The DXSPID variable can be used to link the DX domain to other domains if necessary, such as AEs, Exposure, and/or Device Events.

3.3.2 Examples for the Device Exposure Domain Model

Example 1

In this example, the study is investigating the safety and efficacy of the device 'Hyaluronic Acid' given into the intra-articular space of the knee joint to relieve the pain associated with osteoarthritis through lubrication. The product is administered once a week for three weeks. Hyaluronic acid provides physical lubrication in the joint, and is considered to be a device by the manufacturer and the regulators, even though it has many of the characteristics of a drug.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXSPID	DXTRT	DXDOSE	DXDOSU
1	ABCXYZ	DX	001-001	LOTABC	1	1	HYALURONIC ACID	2	mL
2	ABCXYZ	DX	001-001	LOTABC	2	2	HYALURONIC ACID	2	mL
3	ABCXYZ	DX	001-001	LOTXYZ	1	3	HYALURONIC ACID	2	mL

Row	DXDOSFRQ	DXDOSRGM	DXROUTE	DXLOC	DXSTDTC	DXENDTC	DXSTDY	DXENDY	DXDUR
1 (cont)	ONCE	1X/WK FOR 3 WEEKS	INTRA-ARTICULAR	LEFT KNEE	2010-05-02T12:15	2010-05-02T12:17	1	1	
2 (cont)	ONCE	1X/WK FOR 3 WEEKS	INTRA-ARTICULAR	LEFT KNEE	2010-05-09T13:15	2010-05-09T13:17	8	8	
3 (cont)	ONCE	1X/WK FOR 3 WEEKS	INTRA-ARTICULAR	LEFT KNEE	2010-05-13T13:15	2010-05-13T13:17	12	12	

Example 2

In this example, a device that delivers shock wave pulses is used to treat plantar fasciitis (inflammation of the plantar fascia in the heel). The study is investigating the safety and efficacy of this single device treatment that has is used in two orientations within the heel receiving pulses (in-line, and 45 deg medial to plantar). The orientation information is captured in Device in Use (DU). This example shows a patient that had an aborted treatment due to an adverse event.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXSPID	DXTRT	DXDOSE	DXDOSTXT	DXDOSFRQ	DXDOSTOT	DXDOSU
1	ABCXYZ	DX	001-001	SERAZZ3	1	1	EXTRACORPOREAL SHOCK WAVE TREATMENT	500		ONCE		PULSES
2	ABCXYZ	DX	001-001	SERAZZ3	2	2	EXTRACORPOREAL SHOCK WAVE TREATMENT	400		ONCE		PULSES

Row	DXDOSRGM	DXROUTE	DXLOC	DXADJ	DXSTDTC	DXENDTC	DXSTDY	DXENDY	DXDUR
1 (cont)	500 pulses/treatment session	Extracorporeal	Right Plantar Fascia		2010-05-02T12:15	2010-05-02T12:30	1	1	
2 (cont)	500 pulses/treatment session	Extracorporeal	Right Plantar Fascia	Adverse Event	2010-05-03T14:31	2010-05-03T14:45	2	2	

Example 3

This study is investigating the functional delivery of the radiation treatment to the breast via a balloon catheter system. The system is inserted into a tumor cavity post excision. After surgery the catheter is left inside the cavity for 5 days. During the time of implant the radiation is delivered from a HDR device ("seed") through the part of the catheter system remaining outside the body twice per day in two separate fractions. In this example there is a recording of the surgical placement of the catheter system, and the first 4 fraction records. The location of the placement and radiation delivery is coded. In this example, the radiation information is submitted in DX, but there may be cases where it would more appropriately be recorded in Device In-Use (DU).

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXSPID	DXCAT	DXTRT	DXDOSE	DXDOSFRQ	DXDOSU
1	ABCXYZ	DX	001-001	SER56XA	1	1	CATH	ABC balloon catheter system		ONCE	
2	ABCXYZ	DX	001-001	SER44531	1	2	RAD	APBI	3.4	BID	Gy
3	ABCXYZ	DX	001-001	SER44531	2	3	RAD	APBI	3.4	BID	Gy
4	ABCXYZ	DX	001-001	SER44531	3	4	RAD	APBI	3.4	BID	Gy
5	ABCXYZ	DX	001-001	SER44531	4	5	RAD	APBI	3.4	BID	Gy

Row	DXDOSTOT	DXDOSRGM	DXROUTE	DXLOC	DXSTDTC	DXENDTC	DXSTDY	DXENDY	DXDUR
1 (cont)		ONCE	Intradermal	LUO	2010-05-02T12:15	2010-05-010T13:30	1	9	
2 (cont)		5 DAYS	Intradermal	LUO	2010-05-03T08:31	2010-05-03T08:45	2	2	
3 (cont)		5 DAYS	Intradermal	LUO	2010-05-03T15:31	2010-05-03T15:45	2	3	
4 (cont)		5 DAYS	Intradermal	LUO	2010-05-04T08:31	2010-05-04T08:45	3	3	
5 (cont)		5 DAYS	Intradermal	LUO	2010-05-04T15:31	2010-05-04T15:45	3	3	

Abbreviation: LUO, left upper outer breast.

Example 4

This is an example of a study investigating the safety and efficacy of a cervical disc replacement. In this example there are two separate patients, one who had the device implanted and evaluated throughout the study (001-001), and the second (002-001) who had the device explanted on Day 7.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXSPID	DXTRT	DXDOSE	DXDOSTXT	DXDOSU	DXDOSFRQ
1	ABCXYZ	DX	001-001	SER45001	1	1	Artificial Cervical Disc	1		UNIT	ONCE
2	ABCXYZ	DX	002-001	SER86002	1	1	Artificial Cervical Disc	1		UNIT	ONCE

Row	DXLOC	DXSTDTC	DXENDTC	DXSTDY	DXENDY	DXENRTPT	DXENTPT
1 (cont)	C3-4	2010-05-02T12:15		1		ONGOING	CLOSEOUT
2 (cont)	C3-4	2010-05-02T13:15	2010-05-09T13:17	1	8		

Example 5

This is an example of a study investigating the safety and efficacy of a particular suture material in closing wounds. In this example, the same subject had two wounds. One was on the left forearm and was sutured using the material under study, while the other was on the right thigh and was sutured using a control.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXTRT	DXDOSE	DXDOSTXT	DXDOSU
1	P47-923	DX	923-021	STRONG2	1	Strong Suture No 2	15		cm
2	P47-923	DX	923-021	COMP465	1	GenSuture	12		cm

Row	DXLOC	DXLAT	DXSTDTC	DXENDTC	DXSTDY	DXENDY
1 (cont)	FOREARM	LEFT	2011-12-24T15:25	2001-12-30T09:38	1	7
2 (cont)	THIGH	RIGHT	2011-12-24T15:45	2001-12-30T09:32	1	7

3.4 Device Events (DE)

de.xpt, Device Events - Events, Version 1.1. One record per event per device, Tabulation

Variable Name	Variable Label	Data Type	Controlled Terms, Code List, or Format[a,b]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DE	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Expected rather than required because events may happen to or with a device that do not involved subjects, and may even be before the device was in contact with a subject. In these cases there may not be a value for USUBJID.	Exp
SPDEVID	Sponsor Device Identifier	Char		Identifier	Sponsor-defined identifier for the device. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, combination of identifiers).	Req
DESEQ	Device Events Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of device records within subject records within a domain. May be any valid number. It should be unique within every subject/device combination. If there is no USUBJID associated with the event, DESEQ should be unique within each SPDEVID.	Req
DESPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Note that it does not have to be numeric.	Perm
DETERM	Reported Term for Device Event	Char		Topic	Verbatim name of the observed event. Examples: "Screw Breakage", "Fissure Formation", "Battery Issue".	Req
DEMODIFY	Modified Device Event Name	Char		Synonym Qualifier	The modified text for DETERM. If DETERM is modified, then the modified text is placed here.	Perm
DEDECOD	Device Events Dictionary-Derived Term	Char	*	Synonym Qualifier	Dictionary-derived form of the event described in DETERM. Dictionary-derived text description of DETERM or DEMODIFY. The name and version of the dictionary used to map terms must be provided in a Define.XML ExternalCodeList element.	Req
DECAT	Category of Device Event	Char	*	Grouping Qualifier	Used to define a categorization level for events. For example, "MALFUNCTION" vs. "CALIBRATION".	Perm
DESCAT	Subcategory of Device Event	Char	*	Grouping Qualifier	Used to define a further category level for events. For example, "EXTERNAL" vs. "INTERNAL".	Perm

Variable Name	Variable Label	Data Type	Controlled Terms, Code List, or Format[a,b]	Role	CDISC Notes	Core
DEPRESP	Pre-Specified Device Event	Char	(NY)	Record Qualifier	Used to indicate whether (Y/null) information about a specific event was solicited on the CRF. For example, DETERM could contain a list of malfunctions that are being specifically evaluated. DEPRESP would identify those (Y), whereas any spontaneous events would have DEPREST null.	Perm
DEOCCUR	Device Event Occurrence	Char	(NY)	Record Qualifier	When information about specific events is solicited, DEOCCUR is used to indicate whether or not (Y/N) a particular pre-specified event occurred. Values are null for events not specifically solicited.	Perm
DESTAT	Device Event Collection Status	Char	(ND)	Record Qualifier	The status indicates that the pre-specified question was not answered. For example, if equipment operation requires checking, such as checking an event log to detect events. Capturing that the checks were not completed may be relevant to interpreting the study data.	Perm
DEREASND	Reason Device Event Not Collected	Char		Record Qualifier	Reason DESTAT was "NOT DONE". This variable should only be used if there are pre-specified events.	Perm
DESEV	Device Event Severity	Char	*	Record Qualifier	Describes the severity of the event, (e.g., the severity of a malfunction).	Perm
DEACNDEV	Action Taken with Device	Char	*	Record Qualifier	Describes Action Taken with respect to the device. Action Taken may include removal, calibration, reprogramming, and so on. Action is usually in response to some event, for example, a subject's adverse event.	Perm
VISITNUM	Visit Number	Num		Timing	Clinical encounter number. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	Protocol-defined description of clinical encounter. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics. This value is usually derived.	Perm
DEDTC	Date of Device Event Data Collection	Char	ISO 8601	Timing	Date the device event information was collected. This may be reported if the event (e.g., malfunction) is discovered on a different date from the event.	Perm
DESTDTC	Start Date/Time of Device Event	Char	ISO 8601	Timing	Start date/time of the device event. If the event happened at a single point in time, DESTDTC is used.	Perm
DEENDTC	End Date/Time of Device Event	Char	ISO 8601	Timing	End date/time of the device event. If an event lasted over a period of time, DEENDTC can be used to capture the end date/time.	Perm
DEDY	Study Day of Start of Tracking Event	Num		Timing	Study day of Device Event observation, measured as integer days. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm

Variable Name	Variable Label	Data Type	Controlled Terms, Code List, or Format[a,b]	Role	CDISC Notes	Core
DESTDY	Study Day of Device Event Start	Num		Timing	Study day of start of Device Event, measured as integer days. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm
DEENDY	Study Day of Device Event End	Num		Timing	Study day of end of Device Event, measured as integer days. Algorithm for calculations must be relative to the sponsor-defined RFENDTC variable in Demographics.	Perm

[a]Asterisk indicates variable may be subject to controlled terminology; sponsor will identify the controlled terminology in Define-XML.
[b]Parentheses indicates CDISC/NCI code list code value.

3.4.1 Assumptions for the Device Events Domain Model

1. Definition: The Device Events (DE) domain captures information about a variety of activities that can occur to or with the device, for example, malfunctions, calibrations, or parts replacement. It is an optional domain, to be used only if the sponsor has events that should be reported. Records are specific to an individual device. The entries may be related to one or many subjects and visits, depending upon the type of device and scope of its use.
2. USUBJID is Expected in this domain. See CDISC Notes for further explanation.
3. In some cases, a device event may occur but have no effect on a study (e.g., a malfunction occurring if a device is damaged in transit or setup before its use in a study). It is assumed that these events will be reported elsewhere.
4. Depending upon the type of device, an event such as a malfunction may affect 1 subject (e.g., implantable, disposable, single-use devices) or many subjects, visits, and findings (e.g., diagnostic, imaging devices). This could require multiple records, one for each event for each associated subject (USUBJID) or device, as appropriate. In this case, a single DEREFID value would identify multiple records representing the subject-by-subject impact of the malfunction.
5. There are 2 broad cases in which device events (e.g., malfunctions) may be recorded: (1) the device is under study, or (2) the device is ancillary, that is, used simply to obtain a finding, but some properties of the device are recorded within the study.
6. If there is a malfunction, Device Exposure (DX) and Device-In-Use (DU) may also be recorded. In some cases, it is possible that only the most general definition of the device (e.g., X-Ray, CT, and ultrasound) may be identified.
7. If a malfunction or other event results in an adverse event, then that information should be recorded in the AE domain (see SDTM Implementation Guide, SDTMIG, AE domain). The relationship between the AE and DE can be recorded on the CRF using DESPID and/or DEAENO. DEAENO would be a data capture (CDASH) variable that is not submitted in SDTM-based datasets, but is used to create a RELREC that links the event records.
8. The present revision of DE assumes that a device event such as a malfunction is associated with one or more subjects and visits, and at most one AE per subject. More complex cases are deferred to future revisions.
9. DEENDTC can be used, for example, if a malfunction occurs during a deployment and it is repaired.
10. If this domain is used to capture device malfunctions, and the FDA's Device Problem Code (part of FDA's MDR Reporting) controlled terminology list is used, then any codes beyond the Preferred Term can be included as Supplemental Qualifiers. See SDTMIG Appendix C2 and SDTMIG v3.2 section 8.4 for information about including hierarchies of terms.
11. Note that in some of the examples that follow, variables that would be blank may have been dropped to conserve space. This does not mean that the variables cannot be used in the illustrated use case, merely that in the particular example they were not populated.
12. The following Qualifiers would not generally be used in DE: --BODSYS, --SER,--ACN, --REL, --RELNST, --PATT, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE, --CONTRT, --TOX, -TOXGR.

3.4.2 Examples for the Device Events Domain Model

Example 1
In this example, 2 units of the device have suffered a series of failures. Each failure is recorded separately.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DESEQ	DETERM	DEDECOD	DECAT	DESEV	DEDTC	DESTDTC
1	ABCXYZ	DE	1001	1001001	1	Minor screw breakage	Screw breakage	Equipment Failure	Minor	2009-11-02	2009-11-01
2	ABCXYZ	DE	1001	1001001	2	Shallow fissure formation	Fissure	Equipment Failure	Minor	2009-12-15	2009-12-13
3	ABCXYZ	DE	1002	999981	1	Battery will not charge	Battery charge failure	Equipment Failure	Major	2009-10-13	2009-10-10
4	ABCXYZ	DE	1002	999981	2	Firmware Consistency Fail 103	Firmware failure 103	Software Malfunction	Major	2010-01-03	2010-01-03

Example 2
Row 1: Shows a malfunction of an MRI calibration affecting 1 subject. In this case the individual MRI unit is not under study (e.g., when the MRI is used to obtain study measurements), and the sponsor decided to use the site number in SPDEVID.
Row 2: Shows a malfunction of the device under study where all subjects for the day were affected. If this single record is sufficient detail for the sponsor's requirements, then no further records would be added; if there were a need to associate the malfunction with each subject (e.g., it led to several AEs), then a record could be added for each affected subject. USUBJID is null because this device malfunction was not specific to one subject.
Row 3: Shows a malfunction for a specific device under study and the associated subject.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DESEQ	DETERM	DEDECOD	DECAT	DESEV	DEDTC	DESTDTC
1	ABC-123	DE	2022	Site 22	1	First calibration failed	Calibration failed	Calibration Failure	Minor	2010-01-01	2009-12-28
2	ABC-456	DE		15033	1	Data Loss	Data failure	Data Storage Failure	Major	2009-01-06	2009-01-05
3	ABC-789	DE	2222	334-XRS-09	1	Alignment Failure	Calibration failed	Calibration Failure	Major	2009-01-05	2009-01-05

Example 3
This example shows how failures for implanted devices could be modeled.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DESEQ	DETERM	DEDECOD	DECAT	DESEV	DEDTC	DESTDTC
1	ABCXYZ	DE	2022	X1010785	1	Calibration Failed	Calibration failed	Equipment Failure	Medium	2010-01-01	2009-12-28
2	ABCXYZ	DE	2133	15033	1	Internal communication failure	Communications failure	Equipment Failure	Medium	2009-01-05	2009-01-05
3	ABCXYZ	DE	2133	334-XRS-09	2	Internal communication failure	Communications failure	Equipment Failure	Medium	2009-01-05	2009-01-05

Example 4

Row 1: Shows maintenance and calibration checks associated with a QA schedule of an MRI calibration where all subjects after the event were affected. The DEDTC variable captures when the information was recorded and/or discovered. DESTDTC records when the event happened. In this case, a software update occurred, and a maintenance event recorded some issue, which was only found subsequently on 6Jan2009. This allows sponsors to determine if anything of importance happened during that interval (e.g., if any subjects were exposed to the device). If this single record is sufficient detail for the sponsor's requirements then no further records would be added, but if there were a need to associate the QA event with each subject (e.g., if the information collected during the maintenance event were needed to calibrate results for subsequent cases) then a record could be added for each affected subject.

Row 2: Shows a software version update for a specific device under study. USUBJID is null because the software update applies to all subjects.

Row	STUDYID	DOMAIN	SPDEVID	USUBJID	DESEQ	DETERM	DEDECOD	DECAT	DESEV	DEDTC	DESTDTC
1	ABC-456	DE	15033		1	Routine device diagnostics performed	Scheduled Maintenance	Scheduled Maintenance	Minor	2009-01-06	2009-01-05
2	ABC-789	DE	15033		2	Control software updated	Software Update	Software Update	Major	2009-01-05	2009-01-05

3.5 Device Tracking and Disposition (DT)

dt.xpt, Device Tracking and Disposition - Events, Version 1.1 One record per device tracking event, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Code list or Format[a]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DT	Identifier	Two-character abbreviation for the domain.	Req
SPDEVID	Sponsor Device Identifier	Char		Identifier	Sponsor-defined identifier for the device. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, combination of identifiers).	Req
DTSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of device records within subject records (if applicable) within a domain. May be any valid number. Should be unique within each SPDEVID.	Req
DTTERM	Reported Term for the Tracking Event	Char	*	Topic	Verbatim or preprinted term for the activity that occurs. Example: "Shipped", "Returned", "Installed", "Implanted", "Explanted".	Req
DTMODIFY	Modified Reported Term	Char		Synonym Qualifier	Modified term entered to allow mapping of verbatim term to dictionary term. If DTTERM is modified to facilitate coding, then DTMODIFY will contain the modified text.	Perm
DTDECOD	Standardized Tracking Term	Char	*	Synonym Qualifier	Dictionary-derived text description of DTTERM or DTMODIFY. If an external controlled terminology is used, the name and version of the dictionary used to map terms must be provided in a Define-XML ExternalCodeList element.	Perm
DTCAT	Category for Device Tracking Event	Char	*	Grouping Qualifier	Defines a categorization level for a group of related records. Examples: categorize by tracking event type (e.g., "DOMESTIC" vs. "INTERNATIONAL").	Exp
DTSCAT	Subcategory for Device Tracking Event	Char		Grouping Qualifier	Defines a further categorization level for a group of related conditions or events.	Perm
DTPARTY	Party Responsible for the Device	Char	*	Record Qualifier	Person or organization accountable for the device at the conclusion of the action specified in DTTERM. Describes the person or organization that is accountable for the device defined in DTTERM. For example, if DTTERM=SHIPPED, DTPARTY would contain the transfer recipient (e.g., SITE). If DTTERM=IMPLANTED, DTPARTY would contain SUBJECT.	Req

Variable Name	Variable Label	Type	Controlled Terms, Code list or Format[a]	Role	CDISC Notes	Core
DTPRTYID	Responsible Party Identifier	Char		Variable Qualifier	An identifier for the responsible group/role (e.g. site, subject). The value of the responsible party identified in DTPARTY. For example, if DTPARTY is SUBJECT, DTPRTYID would contain the subject number.	Exp
DTDTC	Date/Time of Tracking Event Collection	Char	ISO 8601	Timing	Date/Time the tracking event information was collected. Will generally be the same as the date the tracking event started, but it can differ.	Perm
DTSTDTC	Start Date/Time of Tracking Event	Char	ISO 8601	Timing	Start date/time of tracking event. A tracking event (e.g., SHIPPED, RECEIVED) is usually a point in time, which is why only the start date/time is included. If an event occurs over a longer period, the stop date/time may be included from the SDTM model.	Req

[a]Asterisk indicates variable may be subject to controlled terminology; sponsor will identify the controlled terminology in Define-XML.

3.5.1 Assumptions for the Device Tracking and Disposition Domain Model

1. Definition: The Device Tracking and Disposition (DT) domain represents tracking events for a given device. This could include initial shipment, deployment, return, destruction, loss, and so on. Different tracking events would be relevant to different types of devices. For example, an MRI machine might be shipped to a hospital and remain there, whereas an implantable stent might be shipped to a site and then shipped back to the sponsor if found to be defective.
2. Only tracking events that are the sponsor's responsibility are captured in this domain. If that responsibility is formally passed to another entity, such as hospital staff tracking an MRI machine within their facility, then tracking data will not generally appear in DT. This is governed by local regulations and sponsor/site practices.
3. This domain is intended to demonstrate "device accountability," and can be submitted in 2 ways. Tracking data can be captured and submitted that indicate each party who is accountable for the device from the time it leaves the sponsor facility to its final state such that the dataset accounts for the device at all times. The last record would effectively be the final disposition of the device. Alternatively, a single disposition record for each device could be submitted, representing the status of each device at the time of submission; the individual tracking event information remains at the site and sponsor locations and is available for inspection. This flexibility allows sponsors to track devices either at every move or only report a final disposition at study end.
4. This domain is not intended to report details about the deployment of a device to a subject except insofar as the device is physically with the subject (e.g., implantation of a stent). Subject-specific deployment information would usually more appropriately be captured in the Device Exposure (DX) domain. In some cases this may result in some duplication of data between DX and DT, but the data are intended for very different purposes and will often capture different details.
5. The level of granularity of the device identification in this domain will vary by device type and sponsor practice, and is defined in Device Identifiers (DI). In cases where a group of devices is tracked together, such as a box of orthopedic screws, a given SPDEVID may represent multiple individual units that are not individually tracked and may be split and shipped to different sites. Capture of this information may require the use of the Findings About domain (see SDTMIG Section 6.4).

6. In cases where a device comprises a number of components (e.g., a pacemaker with leads and software), the sponsor may choose to track the overall device using its SPDEVID or track the identifiers for the individual components, or both, whichever is more appropriate. Subsequent versions of this document will address the details of tracking components and of associating them with a device.
7. If this domain is populated, there should be at least 1 record in this domain for every tracked unit of the device under study associated with a study that leaves the sponsor's facility or manufacturing location. There may be multiple records per device.
8. DTPARTY and DTPRTYID together identify the individual or organization that takes responsibility for the device as a result of the action in DTTERM. For example, if DTTERM is SHIPPED, DTPARTY would be a general term defining the type of responsible party, such as SITE, and DTPRTYID would contain the site identifier, such as 02.
9. Usually DTPARTY and DTPRTYID refer to who has possession of the device after the action in DTTERM. In the cases where a device is lost, destroyed or removed, for example, DTPARTY and DTPRTYID may be null.
10. Tracking events do not have start and end dates because they do not span an interval (e.g. shipped date) but rather occur at a single date/time (e.g., implantation date).
11. Relative study days (--DY) are not included in this domain as there may be no association with a subject, and relative days are calculated in comparison to a subject's reference start date. If sponsors need to include this information, they may include –DY, but its derivation must follow the rules in the SDTMIG.
12. The data in this domain may come from a variety of sources, such as a CRF, a shipping log or a transfer document (e.g., when devices are issued as supplies or samples for engineers to take to sites), and may be partly or wholly derived.
13. Note that in some of the examples that follow, variables that would be blank may have been dropped to conserve space. This does not mean that the variables cannot be used in the illustrated use case, merely that in the particular example they were not populated.
14. The following Qualifiers would generally not be used in DT: --BODSYS, --LOC, --SER,--ACN,--ACNOTH, --REL, --RELNST, --PATT, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE, --CONTRT, --TOX, -TOXGR.

3.5.2 Examples for the Device Tracking and Disposition Domain Model

Example 1
These examples show individual device tracking at each change of location.

Rows 1-2: Device S001 was shipped to the site and implanted in the subject, where it is at the time of reporting. The device could be an orthopedic rod.
Rows 3-5: Device was shipped to Site 01, then it was returned to the sponsor, and then the same device was shipped to Site 02. The device could be a diagnostic tool that is used on multiple subjects, so it is redeployed when the first site has completed use of it.
Row 6: Device was shipped to the site but no further activity has happened.
Rows 7-10: Device was shipped to the site, implanted in a subject, and then explanted and returned to the sponsor.
Rows 11-14: Device was shipped to the site and implanted in subject. Subsequently, the device was explanted and destroyed by site personnel.
Rows 15-17: The device, a tympanostomy tube, was shipped to the site and implanted in a subject. After the subject returned home, the tube dislodged and was lost.

Row	STUDYID	DOMAIN	SPDEVID	DTSEQ	DTTERM	DTDECOD	DTPARTY	DTPRTYID	DTCAT	DTDTC	DTSTDTC
1	ABC-123	DT	S001	1	Shipped	SHIPPED	SITE	02		2010-06-25	2010-06-25
2	ABC-123	DT	S001	2	Implantation	IMPLANTED	SUBJECT	02-1024		2010-07-15	2010-06-30
3	ABC-123	DT	S002	1	Shipped	SHIPPED	SITE	01		2010-11-03	2010-11-03

Row	STUDYID	DOMAIN	SPDEVID	DTSEQ	DTTERM	DTDECOD	DTPARTY	DTPRTYID	DTCAT	DTDTC	DTSTDTC
4	ABC-123	DT	S002	2	Returned	RETURNED	SPONSOR			2011-01-05	2011-01-05
5	ABC-123	DT	S002	3	Shipped	SHIPPED	SITE	02		2011-01-15	2011-01-15
6	ABC-123	DT	S003	1	Shipped	SHIPPED	SITE	05		2010-09-29	2010-09-29
7	ABC-123	DT	S004	1	Shipped	SHIPPED	SITE	04		2010-08-30	2010-08-30
8	ABC-123	DT	S004	2	Implanted	IMPLANTED	SUBJECT	04-1009		2010-11-05	2010-10-20
9	ABC-123	DT	S004	3	Explanted	EXPLANTED	SITE	04		2010-11-05	2010-11-01
10	ABC-123	DT	S004	4	Shipped	SHIPPED	SPONSOR			2010-11-02	2010-11-02
11	ABC-123	DT	S005	1	Shipped	SHIPPED	SITE	04		2010-11-01	2010-11-01
12	ABC-123	DT	S005	2	Implanted	IMPLANTED	SUBJECT	04-1009		2010-12-06	2010-11-12
13	ABC-123	DT	S005	3	Explanted	EXPLANTED	SITE	04		2010-12-06	2010-12-01
14	ABC-123	DT	S005	4	Destroyed	DESTROYED				2010-12-10	2010-12-09
15	ABC-123	DT	Z045-2	1	Shipped	SHIPPED	SITE	05		2010-12-06	2010-11-12
16	ABC-123	DT	Z045-2	2	Implanted	IMPLANTED	SUBJECT	05-5005		2010-11-12	2010-11-16
17	ABC-123	DT	Z045-2	3	Lost	LOST				2010-11-18	2010-11-17

Example 2

Implantable Device – Disposition Usage Only. This example shows the tracking of an implantable device where the only information of interest is the final disposition of the device, rather than tracking of every individual change of responsible party.

Row	STUDYID	DOMAIN	SPDEVID	DTSEQ	DTTERM	DTDECOD	DTPARTY	DTPRTYID	DTCAT	DTDTC	DTSTDTC
1	ABC-123	DT	S001	1	Implanted	IMPLANTED	SUBJECT	02-1024		2010-07-15	2010-06-30
2	ABC-123	DT	S002	2	Shipped	SHIPPED	SITE	02		2011-01-15	2011-01-15
3	ABC-123	DT	S003	3	Shipped	SHIPPED	SITE	05		2010-09-29	2010-09-29
4	ABC-123	DT	S004	4	Shipped	SHIPPED	SPONSOR			2010-11-02	2010-11-02
5	ABC-123	DT	S005	5	Destroyed	DESTROYED				2010-12-10	2010-12-09
6	ABC-123	DT	Z045-2	6	Lost	LOST				2010-11-18	2010-11-17

Example 3

This example shows the tracking of a 2-part spray gun for applying skin cells to burns.

Rows 1, 3: The spray gun body is sent to the site and returned to the sponsor.
Rows 2-4: The disposable cartridge that holds the cells is shipped to the site, and then destroyed after use.

Row	STUDYID	DOMAIN	SPDEVID	DTSEQ	DTTERM	DTDECOD	DTPARTY	DTPRTYID	DTDTC	DTSTDTC
1	Z937m	DT	SSG124	1	Shipped	SHIPPED	SITE	01	2011-06-29	2011-06-29
2	Z937m	DT	SSC2160	2	Shipped	SHIPPED	SITE	01	2011-06-29	2011-06-29
3	Z937m	DT	SSG124	3	Shipped	SHIPPED	SPONSOR		2011-08-30	2011-08-30
4	Z937m	DT	SSC2160	4	Destroyed	DESTROYED			2011-07-05	2011-07-05

3.6 Device-Subject Relationships (DR)

dr.xpt, Device-Subject Relationships - Relationships, Version 1.1. One record per device/subject combination

Variable Name	Variable Label	Type	Controlled Terms, Code list, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DR	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. Required, as the purpose of this domain is to link each USUBJID to one or more devices.	Req
SPDEVID	Sponsor Device Identifier	Char		Identifier	Sponsor-defined identifier for the device. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, combination of identifiers) as defined in DI.	Req

3.6.1 Assumptions for the Device-Subject Relationships Domain Model

1. Definition: The Device-Subject Relationships (DR) domain is a Relationships domain that links each subject to the associated device(s).
2. Information in this table may have been initially collected and submitted in other domains (e.g., Device Exposure, DX, Device Tracking and Disposition, DT, Device Events, DE). This domain, however, provides a consistent location for the relationship between a subject and a device, regardless of the device or the domain in which subject-related data may have been collected or submitted.
3. This domain is a Relationships domain and does not have a topic variable.
4. This domain allows for many-to-many relationships such that a single subject may be associated with several devices (e.g., blood glucose test meters), a single device or class of devices may be associated with several subjects (e.g., an MRI machine), or several devices may be associated with several subjects. In effect, this creates an index of the device-subject associations that permits other domains to determine the correct associations without having to store all relationship data in every domain.
5. Sponsors are responsible for defining SPDEVID such that device-subject relationships are described with the necessary level of detail for the submission.

3.6.2 Examples for the Device-Subject Relationships Domain Model

Example 1

In this example, the study requires collection of MRI data at specified time intervals. The MRI equipment is not under study; the product under investigation may not even be a device. The study protocol requires collection of specific settings on the MRI equipment at each encounter, but there is no requirement to track the specific MRI machine(s) with which subjects were scanned.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID
1	ABC-123	DR	101	MRI
2	ABC-123	DR	103	MRI
3	ABC-123	DR	201	MRI
4	ABC-123	DR	202	MRI

Example 2

In this example, the study protocol requires that some subjects be implanted with a pacemaker prior to enrollment, whereas others are not. The pacemakers are not under study; the product under investigation may not even be a device. The study protocol requires analysis stratified by whether or not subjects have a pacemaker, and if they do, the type of pacemaker (single- or dual-chamber). There is no requirement to track the specific pacemaker implanted in each subject. At some point during the study, subject C13 has a single-chamber pacemaker replaced with a dual-chamber model. Information on when and why this happened would not be discernible from DR, but could be captured in DX.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID
1	ABC-456	DR	A11	Dual Chamber Pacemaker
2	ABC-456	DR	A12	Dual Chamber Pacemaker
3	ABC-456	DR	B21	Single Chamber Pacemaker
4	ABC-456	DR	C13	Single Chamber Pacemaker
5	ABC-456	DR	C13	Dual Chamber Pacemaker

Example 3

In this example, a new coronary stent and delivery catheter system is being submitted for approval to market. Delivery catheters are tracked by manufacturing lot; stents are tracked by individual unit serial number.

Subject 103 was exposed to 2 investigational stents, but the DR table provides no further information.

Subject 202 (Row 10) had an adverse event during the PCI procedure that was related to the Venotrate Introducer (a tool used in the procedure). The DR table captures the relationship between the subject and the device, but all additional information about the AE would be captured in the AE domain.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID
1	STUDY42	DR	101	Lot EZN123
2	STUDY42	DR	101	S/N BBS1001
3	STUDY42	DR	103	Lot EZN123
4	STUDY42	DR	103	S/N BBS1045
5	STUDY42	DR	103	S/N BBS1047
6	STUDY42	DR	201	Lot EZN201
7	STUDY42	DR	201	S/N BBS1067
8	STUDY42	DR	202	Lot EZN217
9	STUDY42	DR	202	S/N BBS1012
10	STUDY42	DR	202	Lot VI321

3.7 Device Properties (DO)

do.xpt, Device Properties - Findings, Version 1.1 One record per property per device, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Code List, or Format[a,b]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DO	Identifier	Two-character abbreviation for the domain.	Req
SPDEVID	Sponsor Device Identifier	Char		Identifier	Sponsor-defined identifier for the device. It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, combination of identifiers).	Req
DOSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of device records within subject records within a domain. May be any valid number. It should be unique within every subject/device combination.	Req
DOGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a device.	Perm
DOREFID	Reference ID	Char		Identifier	Internal or external identifier. This could be a scan code or equivalent.	Perm
DOSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number.	Perm
DOTESTCD	Device Property Short Name	Char	(DOTESTCD)	Topic	Short name of the measurement, test, or examination described in DOTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DOTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). DOTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "SHLFLIFE", "INDC", "COMPOS".	Req
DOTEST	Device Property Test Name	Char	(DOTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in DOTEST cannot be longer than 40 characters. Examples: "Shelf Life", "Indication for use", "Composition" (of device).	Req
DOCAT	Category for Device In-Use	Char	*	Grouping Qualifier	Defines a category of related records. For example, it can be used to define the type of property being defined, such as "DIMENSIONS" versus "MATERIAL".	Perm
DOSCAT	Subcategory for Device In-Use	Char	*	Grouping Qualifier	A further categorization of a measurement or examination. For example, if DOCAT = "DIMENSION", DOSCAT might be "LENGTH" or "WIDTH" or "THICKNESS".	Perm

Variable Name	Variable Label	Type	Controlled Terms, Code List, or Format[a,b]	Role	CDISC Notes	Core
DOORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the Device Property as originally observed or collected. DOORRES should contain the result or value of the property defined in DOTEST. For example, if DOTEST is LIFE (shelf life), then DOORRES might be 6 (months).	Exp
DOORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for DOORRES. Examples: "MONTHS", "cm".	Exp

[a]Asterisk indicates variable may be subject to controlled terminology; sponsor will identify the controlled terminology in Define-XML.
[b]Parentheses indicates CDISC/NCI code list code value.

3.7.1 Assumptions for the Device Properties Domain Model

1. Definition: Device Properties (DO) is a Findings domain and defines important characteristics of a device that the sponsor wishes to include in the submission but that do not form part of the unique sponsor-defined identification of the device. If there are no non-identifier characteristics to submit, this domain may not be necessary.
2. Each property is identified using controlled terminology and is stored in DOTESTCD/DOTEST, which allows the property names to be values in DOTESTCD in an SDTM-based vertical (normalized) structure and variable names in a CDASH horizontal (non-normalized) structure, if necessary. The controlled terminology has not yet been identified.
3. There should be one record per device property.
4. Sponsors define the properties and levels of granularity that are appropriate to include in this domain.
5. DO supports all device types (e.g., implantable, imaging, diagnostic), although implementation may vary by device type.
6. This domain does not define the relationships between tracked components and the overall device. This will be addressed in a future version of the standard.
7. DO should not contain characteristics that may change during the course of the study for a given device (e.g., dial settings on an imaging machine, software versions). As a result, the domain does not include Timing variables (SDTM Table 2.2.5).
8. Sponsors may choose whether to include in DO characteristics of approved products or components that are used in the study in accordance with the approved labeling.
9. The DO domain can contain data about devices that were not deployed, as there is no subject identifier in DO. It should contain only data that should be submitted with the clinical data; additional manufacturing and quality data may exist elsewhere in the submission and do not need to be included in DO unless the sponsor has a specific reason to do so.
10. DO data would generally be assembled by a sponsor, rather than by an investigative site. The data can be captured using a CRF, assembled on a worksheet to support entry of the information into the clinical database, derived manually, or derived electronically from data in other domains or elsewhere.
11. DOTESTCD values are limited to 8 characters and cannot begin with a number or underscore as they can be used as variable names when the dataset is transposed to a non-normalized structure.
12. Note that in some of the examples that follow, variables that would be blank may have been dropped to conserve space. This does not mean that the variables cannot be used in the illustrated use case, merely that in the particular example they were not populated.

13. The following Qualifiers would not generally be used in DO: --MODIFY, --BODSYS, --POS,--ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STNRC, --NRIND, --RESCAT, --STAT, --REASND, --XFN, --NAM, --LOINC, --SPEC, --ANTREG, --SPCCND, --LOC, --LAT, --DIR, --METHOD, --LEAD, --BLFL, --FAST, --DRVFL, --EVAL, --TOX, --TOXGR, --SEV, --DTHREL and LLOQ

3.7.2 Examples for the Device Properties Domain Model

Example 1

This example shows characteristics of 2 kinds of nylon mesh filter. The characteristics will not change, so the date is not relevant.

Row	STUDYID	DOMAIN	SPDEVID	DOSEQ	DOTESTCD	DOTEST	DOCAT	DOSCAT	DOORRES	DOORRESU
1	STUDYX	DO	ABC174	1	CLASS	Class	RISK PROFILE		3	
2	STUDYX	DO	ABC174	2	PORESIZE	Pore Size	DIMENSION		20	um
3	STUDYX	DO	ABC174	3	THCKNESS	Mesh Thickness	DIMENSION		52	um
4	STUDYX	DO	ABC174	4	OPENAREA	Mesh Open Area	DIMENSION		14	%
5	STUDYX	DO	ABC259	1	CLASS	Class	RISK PROFILE		3	
6	STUDYX	DO	ABC259	2	PORESIZE	Pore Size	DIMENSION		43	um
7	STUDYX	DO	ABC259	3	THCKNESS	Mesh Thickness	DIMENSION		35	um
8	STUDYX	DO	ABC259	4	OPENAREA	Mesh Open Area	DIMENSION		22	%

Example 2

The two data points being conveyed to the regulators are the color of the kit box and the Lot ID of the kit's reagents. In this case, the color is associated with the number of tests contained in the kit, with the red box containing 6 tests and the blue box containing 8 tests.

Row	STUDYID	DOMAIN	SPDEVID	DOSEQ	DOTESTCD	DOTEST	DOORRES	DOORRESU
1	ABC-125	DO	423-001	1	TESTNUM	Number of Tests	6	
2	ABC-125	DO	423-001	2	REAGLOT	Reagent Lot ID	123-56	
3	ABC-125	DO	876-523	1	TESTNUM	Number of Tests	8	
4	ABC-125	DO	876-523	2	REAGLOT	Reagent Lot ID	123-60	

4 Cross-Domain Relationship Examples

4.1 Device-In-Use and Test Results

This section illustrates the way that the settings of the device used can be related to the results generated from the measurement or output of the device. This uses the example in the Device-In-Use (DU) domain earlier in this document that shows settings on an MRI and relates it to Neurological results obtained from the MRI scan.

Example 1
This example shows data about parameters from an MRI imaging protocol collected from 1 subject at 1 visit. It assumes the image was used for obtaining neurological observations, as shown by the choice of DULNKID. DULNKID can be used to link to the Neurological Findings (NV) records, as shown below.

Rows 1-7: Represent 7 example DU records collected at the screening visit for a given subject.
Rows 8-14: Represent 7 example DU records collected at the first treatment visit for the same subject.

du.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUREFID	DUSPID	DULNKID	DUTESTCD	DUTEST	DUORRES	DUORRESU
1	STUDYX	DU	2324-P0001	ABC174	1	223-45	1	DUNV1	COILSTR	Coil Strength	1.5	T
2	STUDYX	DU	2324-P0001	ABC174	2	223-45	2	DUNV1	ANTPLANE	Anatomical Plane	CORONAL	
3	STUDYX	DU	2324-P0001	ABC174	3	223-45	3	DUNV1	STHICK	Slice Thickness	1	mm
4	STUDYX	DU	2324-P0001	ABC174	4	223-45	4	DUNV1	MATRIX	Matrix	256X256	
5	STUDYX	DU	2324-P0001	ABC174	5	223-45	5	DUNV1	SFTWRVER	Software Version	15.0	
6	STUDYX	DU	2324-P0001	ABC174	6	223-45	6	DUNV1	FLDVIEW	Field of View	24	cm
7	STUDYX	DU	2324-P0001	ABC174	7	223-45	7	DUNV1	RCBDWTH	Receiver Bandwidth	16	kHz
8	STUDYX	DU	2324-P0001	ABC174	8	445-77	1	DUNV2	COILSTR	Coil Strength	1.0	T
9	STUDYX	DU	2324-P0001	ABC174	9	445-77	2	DUNV2	ANTPLANE	Anatomical Plane	CORONAL	
10	STUDYX	DU	2324-P0001	ABC174	10	445-77	3	DUNV2	STHICK	Slice Thickness	2	mm
11	STUDYX	DU	2324-P0001	ABC174	11	445-77	4	DUNV2	MATRIX	Matrix	256X256	
12	STUDYX	DU	2324-P0001	ABC174	12	445-77	5	DUNV2	SFTWRVER	Software Version	15.1	
13	STUDYX	DU	2324-P0001	ABC174	13	445-77	6	DUNV2	FLDVIEW	Field of View	25	cm
14	STUDYX	DU	2324-P0001	ABC174	14	445-77	7	DUNV2	RCBDWTH	Receiver Bandwidth	16	kHz

Row	DUSTRESC	DUSTRESN	DUSTRESU	VISITNUM	VISIT	VISITDY	DUDTC	DUDY
1 (cont)	1.5	1.5	T	1	SCREENING	-7	2011-04-19	-7
2 (cont)	CORONAL			1	SCREENING	-7	2011-04-19	-7
3 (cont)	1	1	mm	1	SCREENING	-7	2011-04-19	-7
4 (cont)	256X256			1	SCREENING	-7	2011-04-19	-7
5 (cont)	15.0			1	SCREENING	-7	2011-04-19	-7
6 (cont)	24	24	cm	1	SCREENING	-7	2011-04-19	-7
7 (cont)	16	1	kHz	1	SCREENING	-7	2011-04-19	-7

Row	DUSTRESC	DUSTRESN	DUSTRESU	VISITNUM	VISIT	VISITDY	DUDTC	DUDY
8 (cont)	1.0	1.0	T	2	IMPLANTATION	1	2011-04-26	1
9 (cont)	CORONAL			2	IMPLANTATION	1	2011-04-26	1
10 (cont)	2	2	mm	2	IMPLANTATION	1	2011-04-26	1
11 (cont)	256X256			2	IMPLANTATION	1	2011-04-26	1
12 (cont)	15.1			2	IMPLANTATION	1	2011-04-26	1
13 (cont)	25	25	cm	2	IMPLANTATION	1	2011-04-26	1
14 (cont)	16	16	kHz	2	IMPLANTATION	1	2011-04-26	1

Row 1-7: Represent 6 possible organ measurement tests and 1 physician interpretation at a screening visit. This shows data reported in the original result and unit in NVORRES and NVORRESU and standardized in NVSTRESC, NVSTRESN, and NVSTRESU. It also shows the standard terminology for NVTESTCD and NVTEST. NVLNKID can be used to capture the link to the device used to obtain the data listed in this table (e.g., the SPDEVID for the device that performed the scan). NVREFID can hold the unique identifier for that specific scan and could link to the scan results in a different domain (not shown).

Row 8-14 Represent the same data as Rows 1-7 but for Visit 2.

Row 15-20: Represent the same 6 tests run on a calibration sample (there are no interpretation or derived records for the calibration sample). The NVLNKID has been set to CALIBRATION to distinguish it from the subject tests.

nv.xpt

Row	STUDYID	DOMAIN	USUBJID	NVSEQ	NVREFID	NVSPID	NVLNKID	NVTESTCD	NVTEST	NVORRES	NVORRESU	NVSTRESC
1	STUDYX	NV	2324-P0001	1	223-45	1	DUNV1	TOTVOL	Total Volume	1120000	mm3	1120000
2	STUDYX	NV	2324-P0001	2	223-45	2	DUNV1	VOLUME	Volume	2725	mm3	2725
3	STUDYX	NV	2324-P0001	3	223-45	3	DUNV1	VOLUME	Volume	2685	mm3	2685
4	STUDYX	NV	2324-P0001	4	223-45	4	DUNV1	VOLUME	Volume	15635	mm3	15635
5	STUDYX	NV	2324-P0001	5	223-45	5	DUNV1	VOLUME	Volume	15650	mm3	15650
6	STUDYX	NV	2324-P0001	6	223-45	6	DUNV1	VOLUME	Volume	7505	mm3	7505
7	STUDYX	NV	2324-P0001	7	223-45	7	DUNV1	ABBSI	Annualized Brain Boundary Shift Int			-1.5
8	STUDYX	NV	2324-P0001	8	445-77	1	DUNV2	TOTVOL	Total Volume	1120000	mm3	1120000
9	STUDYX	NV	2324-P0001	9	445-77	2	DUNV2	VOLUME	Volume	2725	mm3	2725
10	STUDYX	NV	2324-P0001	10	445-77	3	DUNV2	VOLUME	Volume	2685	mm3	2685
11	STUDYX	NV	2324-P0001	11	445-77	4	DUNV2	VOLUME	Volume	15635	mm3	15635

Row	STUDYID	DOMAIN	USUBJID	NVSEQ	NVREFID	NVSPID	NVLNKID	NVTESTCD	NVTEST	NVORRES	NVORRESU	NVSTRESC
12	STUDYX	NV	2324-P0001	12	445-77	5	DUNV2	VOLUME	Volume	15650	mm3	15650
13	STUDYX	NV	2324-P0001	13	445-77	6	DUNV2	VOLUME	Volume	7505	mm3	7505
14	STUDYX	NV	2324-P0001	14	445-77	7	DUNV2	ABBSI	Annualized Brain Boundary Shift Int			-1.5
15	STUDYX	NV		1	4567-8901	1	CALIBRATION	TOTVOL	Total Volume	1130000	mm3	1130000
16	STUDYX	NV		2	4567-8901	2	CALIBRATION	VOLUME	Volume	2740	mm3	2740
17	STUDYX	NV		3	4567-8901	3	CALIBRATION	VOLUME	Volume	2670	mm3	2670
18	STUDYX	NV		4	4567-8901	4	CALIBRATION	VOLUME	Volume	15752	mm3	15752
19	STUDYX	NV		5	4567-8901	5	CALIBRATION	VOLUME	Volume	15685	mm3	15685
20	STUDYX	NV		6	4567-8901	6	CALIBRATION	VOLUME	Volume	7597	mm3	7597

Row	NVSTRESN	NVSTRESU	NVLOC	NVLAT	NVMETHOD	NVBLFL	NVDRVFL	VISITNUM	VISIT	VISITDY	NVDTC	NVDY
1 (cont)	1120000	uL	BRAIN		MRI	Y		1	SCREENING	-7	2011-04-19	-7
2 (cont)	2725	uL	BRAIN, HIPPOCAMPUS	LEFT	MRI	Y		1	SCREENING	-7	2011-04-19	-7
3 (cont)	2685	uL	BRAIN, HIPPOCAMPUS	RIGHT	MRI	Y		1	SCREENING	-7	2011-04-19	-7
4 (cont)	15635	uL	TEMPORAL LOBE	LEFT	MRI	Y		1	SCREENING	-7	2011-04-19	-7
5 (cont)	15650	uL	TEMPORAL LOBE	RIGHT	MRI	Y		1	SCREENING	-7	2011-04-19	-7
6 (cont)	7505	uL	BRAIN, VENTRICLE		MRI	Y		1	SCREENING	-7	2011-04-19	-7
7 (cont)	-1.5	%	BRAIN		MRI		Y	2	IMPLANTATION	1	2011-04-26	1
8 (cont)	1120000	uL	BRAIN		MRI			2	IMPLANTATION	1	2011-04-26	1
9 (cont)	2725	uL	BRAIN, HIPPOCAMPUS	LEFT	MRI			2	IMPLANTATION	1	2011-04-26	1
10 (cont)	2685	uL	BRAIN, HIPPOCAMPUS	RIGHT	MRI			2	IMPLANTATION	1	2011-04-26	1
11 (cont)	15635	uL	TEMPORAL LOBE	LEFT	MRI			2	IMPLANTATION	1	2011-04-26	1
12 (cont)	15650	uL	TEMPORAL LOBE	RIGHT	MRI			2	IMPLANTATION	1	2011-04-26	1
13 (cont)	7505	uL	BRAIN, VENTRICLE		MRI			2	IMPLANTATION	1	2011-04-26	1
14 (cont)	-1.5	%	BRAIN		MRI		Y	2	IMPLANTATION	1	2011-04-26	1

Row	NVSTRESN	NVSTRESU	NVLOC	NVLAT	NVMETHOD	NVBLFL	NVDRVFL	VISITNUM	VISIT	VISITDY	NVDTC	NVDY
15 (cont)	1130000	uL	BRAIN		MRI						2011-04-18	
16 (cont)	2740	uL	BRAIN, HIPPOCAMPUS	LEFT	MRI						2011-04-18	
17 (cont)	2670	uL	BRAIN, HIPPOCAMPUS	RIGHT	MRI						2011-04-18	
18 (cont)	15752	uL	TEMPORAL LOBE	LEFT	MRI						2011-04-18	
19 (cont)	15685	uL	TEMPORAL LOBE	RIGHT	MRI						2011-04-18	
20 (cont)	7597	uL	BRAIN, VENTRICLE		MRI						2011-04-18	

Rows 1-2: Represents the RELREC relationship between du.xpt and nv.xpt above. Note that CALIBRATION, the NVGRPID value for the calibration run, does not appear here because there is no corresponding subject. See the SDTMIG (RELREC section) for further discussion and examples of RELREC.

relrec.xpt

Row	STUDYID	USUBJID	RDOMAIN	IDVAR	IDVARVAL	RELTYPE	RELID
1	STUDYX		NV	NVLNKID		MANY	NVDU1
2	STUDYX		DU	DULNKID		MANY	NVDU1

Appendices

Appendix A: Glossary and Abbreviations

The following abbreviations and terms may be used in this document. Additional definitions can be found in the CDISC Glossary available at http://www.cdisc.org/glossary/index.html.

Abbreviation/ Acronym/Term	Definition
510(k)	A kind of regulatory submission in which a device company requests permission from the FDA to market a new device when the device is "substantially equivalent" in safety and efficacy to one that is already marketed. Such devices are generally seen as lower risk, and do not necessarily require clinical trials for FDA to clear them.
Ancillary Device	A device used within a clinical trial to collect subject data information (device or human subject), but that is not the target of the study (e.g., an MRI or CT machine whose settings must be recorded in the clinical trial data, as required in the protocol)
BLA	Biologics License Application: A submission made by the manufacturer of a licensed biologic that also meets the definition of a medical device and which is subsequently subjected to scientific review by CBER (or FDA) to determine the biologics'/device's safety, purity and potency and the acceptability of the manufacturing facilities before approval for marketing.
BRIDG	Biomedical Research Integrated Domain Group
caBIG	cancer Biomedical Informatics Grid™: An information network enabling all constituencies in the cancer community—researchers, physicians, and patients—to share data and knowledge. Largely superseded by NCIP.
CBER	Center for Biologics Evaluation and Research: One of the divisions of the FDA responsible for regulatory evaluation of medical devices, among other responsibilities.
CDASH	Clinical Data Acquisition Standards Harmonization Project: The name for the project that delivers basic data collection fields (this document).
CDISC	Clinical Data Interchange Standards Consortium, a Standards Development Organization
CDM	Clinical Data Management
CDRH	Center for Devices and Radiological Health: One of the divisions of the FDA responsible for regulatory evaluation of medical devices, among other responsibilities.
Class I Device[a]	A device proposed for regulatory review that is perceived to be low risk. Requirements for clearance for marketing are "general controls" and include provisions that relate to adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification, including repair, replacement, or refund; records and reports; restricted devices; and good manufacturing practices. Examples include elastic bandages, handheld surgical tools, and examination gloves.
Class II Device[a]	Devices for which the controls for Class I are not considered sufficient to ensure safety and efficacy, and thus additional controls are required. These may include special labeling requirements, mandatory performance standards, and other controls. Examples include powered wheelchairs, infusion pumps, and surgical drapes.
Class III Device[a]	A device for which Class I and Class II controls do not provide sufficient evidence for its safety and efficacy. These devices are generally of higher risk to humans. Examples include implantable pacemaker, pulse generators, HIV diagnostic tests, automated external defibrillators, and endosseous implants.
Collected	Within this document, "collected" refers to information that is recorded and/or transmitted to the sponsor. This includes data entered by the site on CRFs/eCRFs as well as vendor data such as core lab data. This term is a synonym for "captured."
Controlled Terminology	A finite set of values that represent the only allowed values for a data item. These values may be codes, text, or numeric. A code list is one type of controlled terminology.
CRF	Case report form (sometimes, case record form) A printed, optical, or electronic document designed to record all required information to be reported to the sponsor for each trial subject.
CTCAE	Common Terminology Criteria for Adverse Events
Databased	To have put (data) into a database.
Dataset	A collection of structured data in a single file
Derived	Within this document, "derived" refers to information that is not directly entered into the specific data field by the investigator site or by a core lab. This category includes auto-encoded data, calculated data and similar electronically generated data, but not prepopulated fields.
Domain	A collection of observations with a topic-specific commonality about a subject

eCRF	Electronic case report form
EMA	The European Medicines Agency: A decentralized body of the European Union whose main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.
Epoch	Interval of time in the planned conduct of a study. An epoch is associated with a purpose (e.g., screening, randomization, treatment, follow-up), which applies across all arms of a study.
EVS	Enterprise Vocabulary Services
FAQs	Frequently Asked Questions
FDA	Food and Drug Administration: Part of the US Department of Health and Human Services Agency, the regulatory authority for all pharmaceuticals (including biologics and vaccines) and medical devices in the United States.
GCDMP	Good Clinical Data Management Practices (GCDMP): SCDM publication on clinical data management processes.
GCP	Good Clinical Practice
HL7	Health Level 7
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICH E2A	ICH guidelines on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
ICH E2B	ICH guidelines on Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
ICH E2C	ICH guidelines on Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs
ICH E3	ICH guidelines on Structure and Content of Clinical Study Reports
ICH E4	ICH guidelines on Dose-Response Information to Support Drug Registration
ICH E5	ICH guidelines on Ethnic Factors in the Acceptability of Foreign Clinical Data
ICH E6 (R1)	ICH guideline for Good Clinical Practice
ICH E9	ICH guidelines on Statistical Principles for Clinical Trials
ICH E11	ICH guidelines on Clinical Investigation of Medicinal Products in the Pediatric Population
ICH E14	ICH guidelines on the Clinical Evaluation of QT/QTc Interval
IDE	Investigational Device Exemption. An IDE application is required by the U.S. FDA before some clinical trials of a new medical device may be initiated.
IND	Investigational New Drug. An IND application is required by the U.S. FDA before clinical trials of a new drug or new biological agent may be initiated.
IRB	Institutional Review Board. Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects
ISO 8601	International Organization for Standardization document of character representation of dates, date/times, intervals, and durations of time
Many-to-Many	Describes the relationship between two sets of objects (e.g., data points or observations in datasets) where each object in each dataset has a relationship with many objects in the other dataset. For example, one subject could have many medical history conditions (e.g., headache, toothache, earache), and a given medical history condition (e.g., headache) can be had by many subjects. *See* One-to-One and One-to-Many.
MedDRA	Medical Dictionary for Regulatory Activities: New global standard medical terminology designed to supersede other terminologies (e.g., COSTART, ICD9) used in the medical product development process.
NCI	National Cancer Institute (NIH)
NCI EVS	National Cancer Institute (NIH) Enterprise Vocabulary Services
NDA	New Drug Application
NICHD	National Institute of Child Health and Human Development,
NIH	National Institutes of Health
NLM	National Library of Medicine
ODM	Operational Data Model: Format for representing the study metadata, study data and administrative data associated with a clinical trial.
One-to-One	Describes the relationship between 2 sets of objects (e.g., observations in datasets) where each object in each dataset has a relationship with 1 and only 1 object in the other dataset. For example, Subject 1 is assigned only Lab Kit 1, and Lab Kit 1 is assigned only to Subject 1. *See* Many-to-Many and One-to-Many.
One-to-Many	Describes the relationship between 2 sets of objects (e.g., observations in datasets) where each object in on1e dataset has a relationship with many objects in the other dataset, but the objects in the second dataset each have only one relationship with 1 object in the first dataset. For example, Subject 1 could have many lab tests, but each lab test is assigned only Subject 1. *See* Many-to-Many and One-to-One.
OTC	Over the Counter.

PhRMA	Pharmaceutical Research and Manufacturers Association
PMA[a]	Premarket Approval: A process of scientific review to ensure the device's safety and effectiveness, which must be completed for FDA to consider permitting marketing of the device. Class III devices typically require PMAs.
PRBC	Packed Red Blood Cells
Predicate Device[b]	A legally marketed device that serves as the basis for comparison for a new device in a 510(k) pre-marketing notification.
Pre-Printed	Items that are part of the original printing on a paper CRF. For example, the unit required for a response, such as "years" for an age question. These data may or may not be stored in the database.
Pre-Populated	Items that are part of the eCRF (or data collection device) that are not enterable/modifiable. These data are stored in the study database.
PRN	Latin term, *pro re nata*, meaning "as needed."
Protocol Deviation	A variation from processes or procedures defined in a protocol. Deviations usually do not preclude the overall evaluability of subject data for either efficacy or safety, and are often acknowledged and accepted in advance by the sponsor. *Note*: Good clinical practice recommends that deviations be summarized by site and by category as part of the report of study results so that the possible importance of the deviations to the findings of the study can be assessed. *Cf.* Protocol Violation. *See* ICH E3.
Protocol Violation	A significant departure from processes or procedures required by the protocol. Violations often result in data that are not deemed evaluable for a per-protocol analysis, and may require that the subject(s) who violated the protocol be discontinued from the study. *Cf.* Protocol deviation.
RCRIM	Regulated Clinical Research Information Management
RIM	Reference Information Model
SAP	Statistical Analysis Plan
SCDM	Society for Clinical Data Management,
SDS	Submission Data Standards. Also the name of the team that created the SDTM and SDTMIG
SDO	Standards Development Organization
SDTM	Study Data Tabulation Model
SDTMIG	SDTM Implementation Guide. When written just like this, it represents the original SDTMIG, in which the experimental unit is a subject, as compared to SEND, for example, where the experimental unit is an animal.
SDTMIG-MD	SDTM Implementation Guide for Medical Device trials, where the experimental unit is the device.
SOCs	System Organ Class (from MedDRA)
Study Treatment	The drug, device, therapy, or process under investigation in a clinical trial which has an effect on outcome of interest in a study (e.g., health-related quality of life, efficacy, safety, pharmacoeconomics). Synonyms: *intervention, therapeutic intervention, medical product.*
TA	Therapeutic Area
Uncoded	Not coded. Not having or showing a code.
UUID	Universally Unique Identifier
WHO	World Health Organization
WHO ART	World Health Organization Adverse Reaction Terminology (sometimes, WHO-ART) has been developed over more than 30 years to serve as a basis for rational coding of adverse reaction terms.
WHO Drug	World Health Organization Drug Dictionary

[a]Definition drawn from:

"Device Classification". Medical Devices. U.S. Food and Drug Administration.

"TITLE 21–FOOD AND DRUGS: CHAPTER I–FOOD AND DRUG ADMINISTRATION: DEPARTMENT OF HEALTH AND HUMAN SERVICES: SUBCHAPTER H–MEDICAL DEVICES: PART 860 MEDICAL DEVICE CLASSIFICATION PROCEDURES". CFR – Code of Federal Regulations Title 21. U.S. Food and Drug Administration.

"General and Special Controls". Medical Devices. U.S. Food and Drug Administration.

[b]Definition drawn from the FDA's Medical Device page on "How to find a predicate device," retrieved 31Aug2011 (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm).

Appendix B: Revision History

Overview of Changes:

This release of the Medical Device Implementation Guide Version 1.1 finalizes the Provisional Version 1.0. The changes from Version 1.0 are very minor, consisting primarily of changing Special Domains references to Study References or Relationships and confirming the finalization of variables introduced in Version 1.0. A selection of minor errors, grammar, and typos have also been addressed. The more significant changes include:

Classification	Type	Section	Domain	Variable	Description of Change
Major	Deletion	4.2	DU	All	Removed language suggesting that DI might be optional when information about a device is collected in a study. This makes it consistent with the Assumptions in DI.
Major	Change	2.5, 4.1	DI	TYPE/DEVTYPE	The variable/controlled terminology term TYPE was changed to DEVTYPE to make it more specific. The change was reflected in the Controlled Terminology standard published 2Q2013.
Major	Change	2.1, 2.2, 2.3, 4.6	DR	All	Changed category of DR domain from Special Purpose to Relationships, based on its change in the SDTM model v1.7
Major	Change	2.1, 2.2, 2.3, 4.1	DI	All	Changed category of DI domain from Special Purpose to Study References based on its change in the SDTM model v1.7
Minor	Deletion	Several	All Device domains	SPDEVID, --PARTY, --PARTYID, --ACNDEV	Removed references to the Device domains and variables as "new" domains, as they have now been available for a number of years
Minor	Change	4.2, 5.1	MO/NV	All MO variables	Changed all domain references about the morphology MO domain to Nervous System Findings domain. These appear only in examples. Morphology has been deprecated and replaced by body system-specific domains.
Minor	Change	Specification tables	DT & DE	DTDTC, DTDY, DTSTDY, DEDY, DESTDY	Updated labels to be less than 40 characters
Minor	Change	Controlled Terminology	DE	DEDECOD	Moved reference to FDA's Problem Code list from CT column to Assumptions
Minor	Change	4.3 Example 3	DX	DXGRPID	Changed column header of DXGRPID to DXCAT as the data in the variable are categorizing rather than grouping the records. See SDTM model for variable definitions.
Minor	Change	Section 4	All specification tables	All	Changed specification structure to combine Definition and Implementation Notes columns into CDISC Notes to make them consistent with tables in other IGs.
Minor	Change	Section 5	Cross-domain relationship examples	N/A	Corrected the order of the columns in the example tables; corrected usage of --GRPID, --LNKID, and --SPID in the example tables and explanatory text.

Appendix C: CDISC Controlled Terminology

Terminology applicable to CDISC Device collection and submission fields is either in production or under development by the CDISC Terminology Team. Production terminology is published by the National Cancer Institute's Enterprise Vocabulary Services (NCI EVS) and can be accessed at https://www.cancer.gov/research/resources/terminology/cdisc.

Appendix D: Other Relevant Standards

Beyond those listed here, additional standards that may affect device clinical trials can be found on the FDA CDRH website (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm).

Appendix D1: Unique Device Identifier (UDI)

The FDA Amendments Act of 2007 mandated a physical label on devices, the "unique device identifier" (UDI). The labels have two components:

1. Device Identifier: manufacturer, make and model
2. Production Identifier: serial or lot number and expiration date

Guidelines on the UDI have been published and are available at The UDI attributes are available here. The UDI Help Desk can be contacted here.

The UDI is intended to track individual device units once they are in the marketplace, and the information included is largely only obtainable after manufacture for distribution. As a result, most studies using this SDTM implementation guide for premarket research will be unlikely to require UDIs. If needed, the UDI can be included as a characteristic in Device Identifiers (DI).

Appendix D2: Code of Federal Regulations

The primary U.S. federal regulations affecting medical devices that have an impact on the capture and submission of clinical trials data to regulatory authorities are found in 21CFR:

- 21 CFR Part 601 Licensing
- 21 CFR Part 660 - Additional Standards for Diagnostic Substances for Laboratory Tests
- 21 CFR Part 812 Investigational Device Exemptions
- 21 CFR Part 807 ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES, Subpart E Premarket Notification Procedures
- 21 CFR Part 814 Premarket Approval of Medical Devices
- 21 CFR Part 803 Medical Device Reporting

Appendix D3: International Organization for Standardization (ISO)

The ISO 14155 standard was first developed in 2003 and updated in 2011. This standard "addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes." The following sections of the ISO 14155 relate to this CDISC Device standard:

- CRFs
- Device deficiencies
- Investigational device accountability

Appendix D4: Code Lists and Terminology

Beyond those defined by CDISC and managed by the NCI EVS (see Appendix A, the following code lists and controlled terminologies may affect the structure and content of device study clinical data:

- Product Code Classification Database
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051637.htm
- Event Problem Codes
  http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/default.htm

Appendix E: Participating Companies

These are the organizations at which the participants were working at the time the IG was developed.

Leadership Team	Company affiliation
Carey Smoak	Roche Molecular Systems, Inc.
Kit Howard	Kestrel Consultants
Fred Wood	Octagon Research Solutions
Rhonda Facile	CDISC
Bob Pearsall	Axon
Maureen Lyden	BioStat Inc
Paul Franson	Medtronic, Inc.
Jennifer Duggan	St. Jude Medical
Marc Mucatel	WL Gore
Parag Shiralkar	Independent Consultant
Jennie Tedrow	Boston Scientific

Participating Companies, Agencies and Institutions

Abbott	Edwards Lifesciences
AdvaMed	FDA-CBER
Alcon Labs	FDA-CDER
Allergan	FDA-CDRH
Bayer	Genprobe
Becton Dickinson	Harvard Clinical Research Institute
BioClinica	Innoventz
Biomet	Johnson & Johnson
Buckler Biomedical Sciences	National Cancer Institute
Business Bridge	PRA International
CDISC	Premier Research
Cleveland Clinic	Smith & Nephew
Covidien	Stryker
Dexcom	Synteract
eClinical Solutions	Trireme Medical

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

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