



# **Device Supplement to the Study Data Tabulation Model Implementation Guide**

**Prepared by the  
CDISC Device Team**

## **DRAFT Revision History**

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# 1. Introduction

## 1.1. PURPOSE

This draft Devices Supplement to the Study Data Tabulation Model Implementation Guide (SDTMIG) defines recommended standards for the submission of data from clinical trials in which medical devices were used. The Device standards are intended to cover both paper and electronic regulatory submissions. Here, “electronic” means submissions that provide study and other data in 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, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used on human beings for the purpose of:*

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

*and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.*

While different types of devices do have widely varying data requirements, most Class II and III devices requiring regulatory data submissions share some fundamental characteristics. This document contains Study Data Tabulation Model (SDTM) regulatory data submission standards for some key data shared by most types of devices and it is intended to guide the organization, structure, and format of standard device clinical trial tabulation datasets submitted to a regulatory authorities. document introduces new SDTM-based domains, showing rules and examples on implementing these domains specifically for devices-related data. This document does not contain 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 standards (available for download at [www.cdisc.org](http://www.cdisc.org)). This version does not contain all the domains necessary for sponsors to implement CDISC standards for medical device studies.

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 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.

The data defined in this document are the data needed for the clinical sections of a regulatory submission involving devices under study. They are required either to answer the protocol questions, to address associated safety questions, or to associate specific devices to subjects. They are generally collected on Case Report Forms that are completed by the investigative sites or derived by sponsors for the SDTM 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 definitions. It also includes some non-clinical data definitions, such as Device Malfunction and Device Tracking information.

Because the term “devices” is so broad, this document uses the term “device” to refer to implantable devices, grafts, procedure delivery kits, device software ( i.e., the items/treatments described by the ISO 14155 standard referenced above).

This document does not include Clinical Data Acquisition and Harmonization (CDASH) data capture standards. These will be developed during the CDISC review process, and the final Device standards will incorporate both.

## 1.2. ORGANIZATION OF THIS DOCUMENT

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

This document has been organized into the following sections:

- **Section 1: Introduction** - This section provides an orientation to data submitted for medical devices.
- **Section 2: New SDTM-Based Device Domains** - Provides an overview of the new device domains and their relationship to each other as well as to existing domains described in the SDTMIG.
- **Section 3: Proposed Additions to the Study Data Tabulation Model** - Describes proposed new variables needed to be added to the SDTM for implementation in device domains.
- **Section 4: Device Domain Details** - Describes each of the new device domains, including domain models, assumptions, and examples.
- **Section 5: Cross-Domain Relationship Examples** - This section describes the relationship between Device In-Use and results generated from the measurement or output of the device.
- **Section 6: Glossary, Acronyms and Definitions** - This section provides information on common terms, acronyms and definitions.
- **Appendices** - This section provides additional supplemental material regarding the Medical Devices project as well as references and supplemental information relevant to implementation of Medical Devices Standard

## 1.3. RELATIONSHIP TO PRIOR DOCUMENTS

This document is not intended to replace the standards defined in the current SDTMIG. This SDTMIG addendum should be implemented together with the current version of the SDTMIG (available at <http://www.cdisc.org/standards><<http://www.cdisc.org/standards>>). The SDTMIG is based on the general conceptual model for representing clinical study data that defined is submitted to regulatory authorities and should be read prior to reading the SDTMIG. An understanding of both of these documents is needed before attempting to understand this device addendum. The sections that will be the most relevant are:

Section 2: Fundamentals of the SDTM

Section 4.1: Assumptions for All Domain Models (Intro paragraphs to the main sections, and scan the remainder to know what is included)

Section 5: Models for Special Purpose Domains (intro paragraphs for each domain and scan the included variables)

Section 6: Domain Models Based on the General Observation Classes (intro paragraphs for each domain and scan the included variables)

Section 8: Representing Relationships and Data (Intro paragraphs to the main sections, and scan the remainder to know what is included)

Appendix C: Controlled Terminology (Intro paragraphs and scan the remainder to know what is there)

## 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 the regulatory authorities. Electronic Data refers to the practice of sending study data to a regulatory agency in a standardized electronic format such as a dataset. In this type of submission, documents are submitted in electronic files such as MS Word, and subject and device data from clinical trials are submitted in as electronic datasets using a defined data format. The following considerations might be useful to sponsors submitting data in an electronic format:

- **Paper vs. 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 electronic study data databases.

- **Paper CRFs vs. Electronic CRFs:** The term “CRF” used throughout this document refers to both paper and electronic formats, unless otherwise specified.
- **Fields vs. Variables:** The term data collection “fields” refers to fields that are commonly seen on the CRF. The term data collection “variables” refers to how data is 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 Devices standard is designed to accommodate both paper and electronic data capture, although it does assume that data will be entered into an electronic database at some point. It assumes that the full suite of CDISC standards is utilized.

#### 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 lays out the different uses of these terms.

**Table 1: Comparison and Contrast in Term Usage Between Drug and Device Trials**

<b>Term</b>	<b>Device Definition</b>	<b>Drug Definition</b>
Accountability	<u>Device Accountability:</u> Tracking where the device is physically; shipping information may be on the CRF; usually between sponsor and site	<u>Drug Accountability:</u> Tracking where the drug is; accounting for all the drug; in the clinical trial, usually between the site and the subject; shipping info not usually captured on CRFs, just the pill counts
Disposition	<u>Device Disposition:</u> The final location/status of the device at the time of submission or the end of the trial	<u>Subject Disposition:</u> The status of the subject’s participation in the trial at a given time point (e.g., did they complete the study or withdraw early)
Exposure	<u>Device Exposure:</u> The exposure of the device or device constituents to the subject.  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.	<u>Study Drug Exposure:</u> The amount of study drug to which the subject is exposed.

# 2. New SDTM Device Domains

## 2.1. OVERVIEW

This Implementation Guide includes seven new SDTM-based domains based on the SDTM Events, Findings, and Interventions domains, and one new special-purpose domain. These domains will accommodate most of the core requirements for the majority of studies with implantable, diagnostic, and imaging devices. Where applicable, the domains are presented in normalized (tall and narrow) format, which is required for data submission to the regulatory authorities. When CDASH models are developed, they will show both normalized and non-normalized layouts. Users may employ whichever structure is optimal for them for data capture, provided that the normalized structure can be generated for submission.

Medical Devices domains are somewhat different from many other SDTM-based domains developed thus far in that they capture information about entities other than the study subject or the trial itself. They must also accommodate a more complex and variable set of data than that in typical drug development studies. In order for the domains to be as flexible as possible, their structure is a bit more relational than other SDTM-based domains. This necessitates developing a relationship structure that is not typically required in most subject-related data (e.g., Device-Subject Relationships domain).

## 2.2. NEW DOMAIN DESCRIPTIONS

The following seven new SDTM-based domains are included in this version:

1. **Device Identifiers (DI):** This is a special-purpose 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 (UDEVID) 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 reported in DI depends solely upon what is needed to identify the device uniquely, that is, those characteristics that define the “natural key.” The domain does not 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 and therefore the DI domain does not contain USUBJID.
2. **Device In-Use (DU):** Device In-Use 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. This is distinct from Device Properties, which describes the static characteristics of the device. For example: Device Properties would capture that an MRI machine’s field strength has a range from 0.2 to 3 Tesla, whereas the Device In-Use domain would capture that the field strength for the MRI scan for Subject 123 was 0.5 T.
3. **Device Exposure (DX):** Device Exposure 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 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 the AE-related information should be recorded in the Adverse Events (AE) domain (see SDTMIG v3.1.2, Section 6.2.1). The relationship between the AE and the Device Malfunction can be recorded using DESPID.
5. **Tracking and Disposition (DT):** The Device Tracking and Disposition domain is an Events domain that represents a record of tracking events for a given device. This could include initial shipment, deployment, return, destruction, etc. Different events would be relevant to different types of device. 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 Device-Subject Relationships domain is a special-purpose domain that links each subject to devices to which they may 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, and 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.

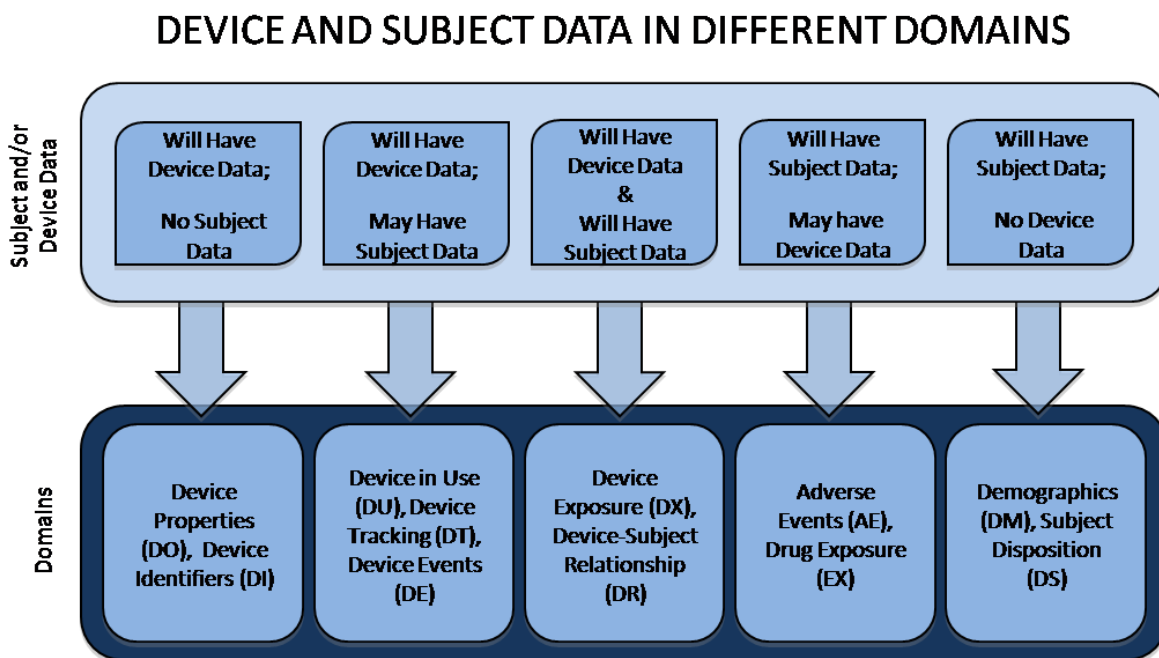
7. **Device Properties (DO):** The Device Properties special purpose domain is used to report characteristics of the device that are important to include in the submission, do not vary over the course of the study but are not used to identify the device. Examples include expiration date or shelf life.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

Although some domains, such as Device In-Use, were developed specifically 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 if deemed appropriate by the sponsor and regulators.

### 2.3. HOW DEVICE DOMAINS RELATE TO EXISTING DOMAINS IN THE SDTMIG

Figure 1 illustrates new and existing SDTM-based domains, and the combinations of subject and/or device data they can contain.

**Figure 1. Device and Subject Data in Different Domains**



## 2.4. HOW DEVICE DOMAINS RELATE TO EACH OTHER

Figure 2 shows an example of how the different domains relate to each other. In this case, Subject 02-1024 in Study ABC-123 had one telescoping orthopedic rod implanted. The rod was sourced from Rods, Co. and has a length of 4 cm when fully contracted and 8 cm when fully extended (DO). The sponsor would decide whether to model this as minimum and maximum lengths separately, or a single size range variable. Here the sizes are separated.

The model name is SuperLynx, and the serial number for the rod is 274962 (DI). These are the only 2 characteristics needed to identify each rod uniquely. This domain associates the 2 key variables to the single UDEVID (TEL-3745), used to reference the device across the other domains.

The rod was shipped from the sponsor to Site 02 on 26Apr2011 (DT), and implanted into the subject on 29Apr2011 (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 the domains that are present for a given submission.

**Figure 2. How Different Domains Relate to Each Other**

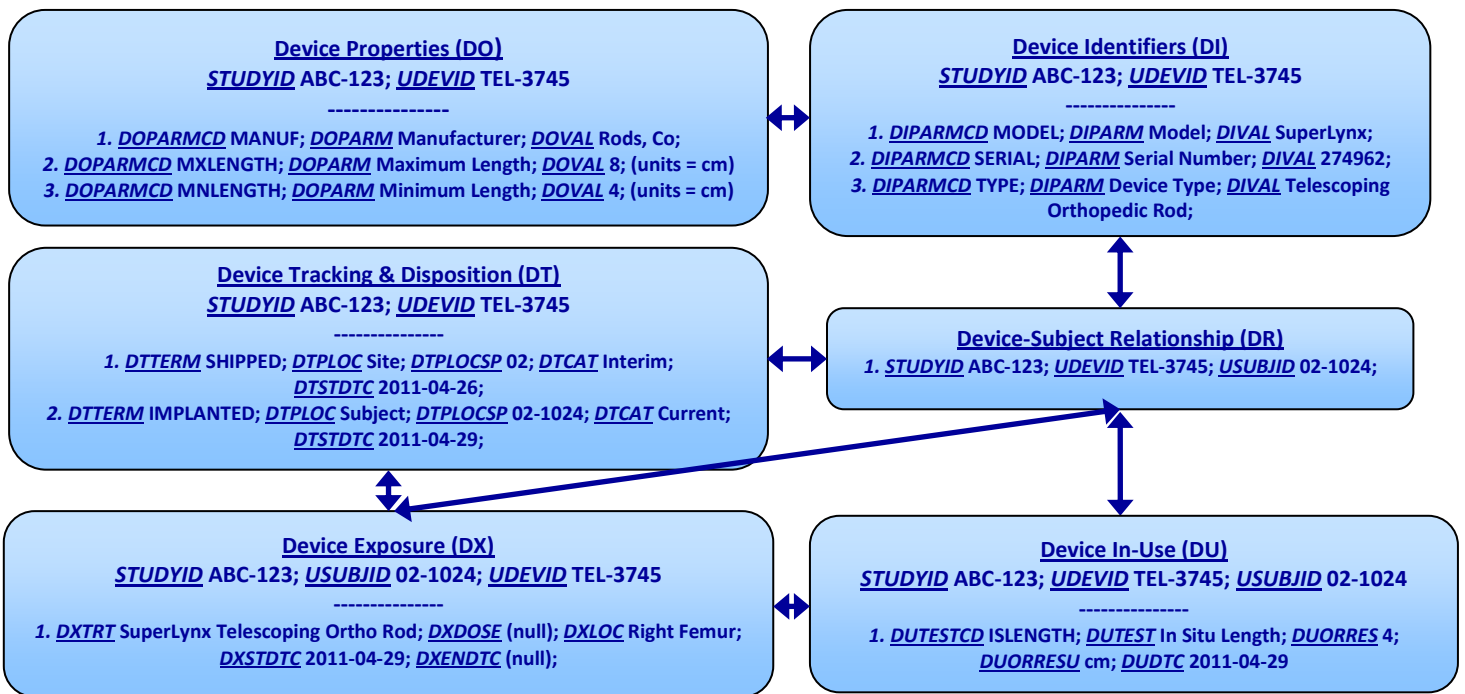
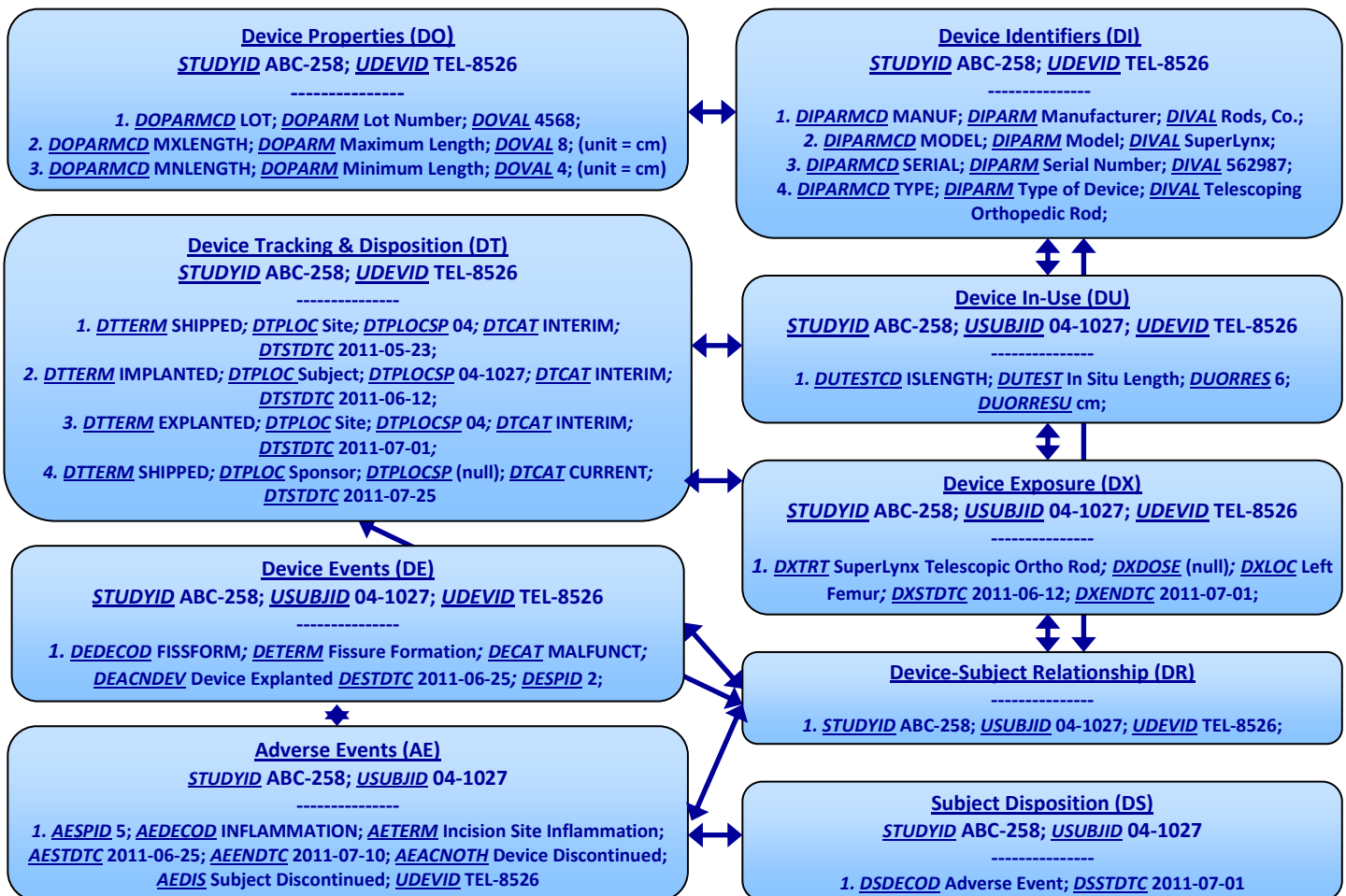


Figure 3 shows a more complex example of domain relationships. Subject 04-1027 had a telescopic orthopedic rod implanted. The rod's maximum extended length is 8 cm, its minimum length is 4 cm, and the Lot Number was 4568 (DO). In this case, there is a comparator device (not shown) and the manufacturer (Rods, Co.) has been added to DI along with the model (SuperLynx) and serial number (562987) to ensure uniqueness. DR links device and subject data regardless of what identifiers exists.

The rod was shipped from the sponsor to Site 04 on 23May2011 (DT), and implanted into the subject on 12Jun2011 (DT & DX). It was explanted on 01Jul2011, and shipped back to the sponsor on 25Jul2011 (DT & DX). The category variable indicates if the tracking record was in the past (Interim) or is the most current location (Current), which may not be the final location. 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, could also appear in DX) and the subject to discontinue from the study (AE, DS). The malfunction and its associated AE are linked via AEDENO and DESPID. AEDENO will be a CDASH (data capture) variable that will enable the creation of a RELREC record that can link these two records across the datasets in SDTM (see the SDTMIG for further discussion of RELREC). Note that this implementation guide does not include the AE and DS domains as they are defined in the SDTMIG v3.1.2.

**Figure 3. More-Complex Domain Relationships**



# 3. Proposed Additions to the Study Data Tabulation Model

## 3.1. PROPOSED ADDITIONS AND MODIFICATIONS TO SECTION 2.2.4, IDENTIFIERS FOR ALL CLASSES

Qualifier Variables						
UDEVID	Unique Device Identifier	Char	Identifier	Sponsor-defined identifier for a device	√	

Variable order should be as follows:

UDEVID	After USUBJID
--------	---------------

## 3.2. PROPOSED ADDITIONS AND MODIFICATIONS TO SECTION 2.2.2, THE EVENTS OBSERVATION CLASS

Variable Name	Variable Label	Type	Role	Description	SDTMIG	SEND
Qualifier Variables						
--PLOC	Physical Location	Char	Record Qualifier	Physical location of an object, such as a study device. Example: SITE for devices physically located at the investigative site, or SPONSOR for devices shipped to the sponsor. This is distinct from --LOC, which is Anatomical Location	√	
--PLOCSP	Physical Location Specify	Char	Record Qualifier	Specific location identifier. Used in conjunction with --PLOC.	√	
--ACNDEV	Action taken with device	Char	Record Qualifier	Action taken with respect to a device in a study, which may or may not be the device under study	√	

Variable order should be as follows:

--PLOC --PLOCSP	In order, after --LOC
--ACNDEV	After --ACNOTH

# 4. Device Domains

## 4.1. DEVICE IDENTIFIERS - DI

di.xpt, Device Identifiers - Special Purpose, Version 0.1 One record per device identifier per device, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	Draft BRIDG Mapping	Definition	Implementation Notes	Core	Reference
STUDYID	Study Identifier	Char		Identifier	Tbd	Unique identifier for a study.	Unique identifier for a study.	Req	
DOMAIN	Domain Abbreviation	Char	DI	Identifier	Tbd	Two-character abbreviation for the domain.	Two-character abbreviation for the domain.	Req	
UDEVID	Unique Device Identifier	Char		Identifier	Tbd	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	
DISEQ	Sequence Number	Num		Identifier	Tbd	Sequence number given to ensure uniqueness within a dataset	Sequence number given to ensure uniqueness within a dataset.	Req	
DIPARMCD	Device Identifier Short Name	Char	*	Topic	Tbd	Short name of the identifier characteristic of the device.	Examples: SERIAL, MODEL.	Req	
DIPARM	Device Identifier Long Name	Char	*	Synonym Qualifier	Tbd	Long name of the identifier characteristic of the device.	Examples: Serial Number, Model.	Req	
DIVAL	Device Identifier Value	Char		Result Qualifier	Tbd	Value for the parameter.	Value for the parameter.	Req	

### 4.1.1. ASSUMPTIONS FOR THE DEVICE IDENTIFIERS DOMAIN MODEL

1. Device Identifiers is a special-purpose 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 (UDEVID) 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.

3. The Device Identifiers domain must exist if UDEVID is used in any domain in a study. At a minimum, a DIPARMCD = TYPE must exist.
4. This structure was created because of the high level of variability in the variables (or combinations of variables) that are used to identify different types of devices. For example, one device might be identified using model and serial number, while another uses lot number and box number. Any combination of identifiers can be linked to one UDEVID value, which, in most cases, is a unique identifier for each device and is defined by the sponsor. Having different identifier variables in different submissions does not help interoperability, and this approach allows for a single identifier while preserving access to the real natural key.
5. In cases where the device is not under study but is used to generate results of a protocol-defined test or procedure (e.g., an MRI used to image a tumor in an oncology drug trial), a UDEVID indicating the TYPE (DIPARMCD = TYPE) of device may be sufficient identification for all MRIs in the trial (and thus not be unique to a particular device), but in any case where specific devices must be associated with individual subjects, UDEVID should be unique to the device. 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.
6. Device identifiers are not expected to change during a specific device's lifetime.
7. 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 Device Properties (DO) instead.
8. This structure allows for the association between one UDEVID and as many identifiers as a sponsor feels necessary to support all the submitted data. This easily transforms into a one-record-per-UDEVID structure for potential merging with other device-related datasets that would contain the UDEVID variable.

UDEVID	TYPE	MANUF	MODEL	BATCH	LOT	SERIAL	IDENTIFIER Y	IDENTIFIER Z
ABC001	STENT	Acme Stents	45-JFI	2011-1307	45678	456789132-AXQ		

9. The data in this domain may be derived (manually or electronically), captured on DI CRFs, or a combination of these.
10. No date variables have been included in this domain because the characteristics defined in 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).
11. No additional variables can be added to this dataset.
12. An incomplete list of DIPARMCD and DIPARM values is shown in the following table:

DIPARMCD	DIPARM
TYPE	Type
MANUF	Manufacturer
MODEL	Model
BATCH	Batch identifier
LOT	Lot Identifier
SERIAL	Serial Number

#### 4.1.2. EXAMPLES FOR THE DEVICE IDENTIFIERS DOMAIN MODEL

Example 1

This shows records for two devices where the type, manufacturer, model number, and serial number were necessary for unique identification.

- Rows 1-4 show the records for a device given a UDEVID of ABC001
- Rows 5-8 show the records for a device given a UDEVID of ABC999

Row	STUDYID	DOMAIN	UDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	2011-001	DI	ABC001	1	TYPE	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	ABC999	1	TYPE	Device Type	MRI
6	2011-001	DI	ABC999	2	MANUF	Manufacturer	Acme Imaging
7	2011-001	DI	ABC999	3	MODEL	Model Number	45-JFI
8	2011-001	DI	ABC999	4	SERIAL	Serial Number	674589132-AXQ

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 ESWT (extracorporeal shock wave treatment) for treatment of plantar fasciitis, and a single machine is used at each site. 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	UDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABCXYZ	DI	XYZ001	1	TYPE	Device Type	ESWT
2	ABCXYZ	DI	XYZ001	2	MODEL	Model	UR4000
3	ABCXYZ	DI	XYZ001	3	SERIAL	Serial Number	47821B
4	ABCXYZ	DI	XYZ001	1	TYPE	Device Type	ESWT
5	ABCXYZ	DI	QRS002	2	MODEL	Model	UR4000
6	ABCXYZ	DI	QRS002	3	SERIAL	Serial Number	87232A

Example 3

This shows records for a device for which it was important to collect the type and manufacturer.

Row	STUDYID	DOMAIN	UDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
-----	---------	--------	--------	-------	----------	--------	-------

1	2011-537	DD	ABC003	1	TYPE	Device Type	MRI
2	2011-537	DD	ABC003	2	MANUF	Manufacturer	Acme Imaging

Example 4

This shows records for a study where subjects had two different devices implanted, one a thrombectomy device, which was identified using the type, model and serial number, and the other a stent, which was identified using only the type and a serial number.

Row	STUDYID	DOMAIN	UDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABCXYZ	DI	XYZ001	1	TYPE	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	TYPE	Type	Coronary Stent
7	ABCXYZ	DI	QRS002	4	SERIAL	Serial Number	87232A

Example 5

This 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 TYPE record.

Row	STUDYID	DOMAIN	UDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	2011-537	DD	ABC003	1	TYPE	Device Type	MRI

## 4.2. DEVICE IN-USE - DU

du.xpt, Device In-Use - Findings, Version 0.1. One record per property or setting per time point per visit or test date per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	Draft BRIDG Mapping	Definition	Implementation Notes	Core	Reference
STUDYID	Study Identifier	Char		Identifier	DocumentIdentifier.identifier	Unique identifier for a study.		Req	SDTM 2.2.4
DOMAIN	Domain Abbreviation	Char	(DU)	Identifier	Device	Two-character abbreviation for the domain.		Req	SDTM 2.2.4, SDTMIG 4.1.22
USUBJID	Unique Subject Identifier	Char		Identifier	SubjectIdentifier.identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.		Perm	SDTM 2.2.4, SDTMIG 4.1.2.3
UDEVID	Unique Device Identifier	Char		Identifier	tbd	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	

DUSEQ	Sequence Number	Num		Identifier	tbd	Sequence Number given to ensure uniqueness of subject records within a domain.	May be any valid number.	Req	SDTM 2.2.4
DUGRPID	Group ID	Char		Identifier	tbd	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. Example: group records specifying all the settings for a specific imaging scan, such as field strength, repetition time and echo time.	Perm	SDTM 2.2.4, SDTMIG 4.1.2.6
DUREFID	Reference ID	Char		Identifier	tbd	Internal or external identifier.	This could be a lab "accession" number or equivalent.	Perm	SDTM 2.2.4, SDTMIG 4.1.2.6
DUSPID	Sponsor-Defined Identifier	Char		Identifier	tbd	Sponsor-defined reference number.	Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm	SDTM 2.2.4
DUTESTCD	Device In-Use Test Short Name	Char	(.DUTESTCD)	Topic	tbd	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	SDTM 2.2.3, SDTMIG 4.1.2.1, SDTMIG 4.1.2.7.3
DUTEST	Device In-Use Test Name	Char	(.DUTEST)	Synonym Qualifier	tbd	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	SDTM 2.2.3, SDTMIG 4.1.2.1, SDTMIG 4.1.2.4,
DUCAT	Category for Device In-Use	Char	*	Grouping Qualifier	tbd	Defines a category of related records.	Used to define 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, for example, if the device is not under study.	Perm	SDTM 2.2.3, SDTMIG 4.1.2.6,
DUSCAT	Subcategory for Device In-Use	Char	*	Grouping Qualifier	tbd	A further categorization of a measurement or examination		Perm	SDTM 2.2.3, SDTMIG 4.1.2.6
DUORRES	Result or Finding in Original Units	Char		Result Qualifier	tbd	Result of the Imaging measurement as originally received or collected.		Exp	SDTM 2.2.3, SDTMIG 4.1.5.1

DUORRES U	Original Units	Char	(.UNIT)	Variable Qualifier	tbd	Original units in which the data were collected.	The unit for DUORRES. Examples: Tesla, mm.	Exp	SDTM 2.2.3, SDTMIG 4.1.3.2, SDTMIG 4.1.5.1
DUSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	tbd	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	SDTM 2.2.3, SDTMIG 4.1.5.1
DUSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	tbd	Used for continuous or numeric results or findings in standard format.	Is copied in numeric format from DUSTRESC. DUSTRESN should store all numeric test results or findings.	Exp	SDTM 2.2.3, SDTMIG 4.1.5.1
DUSTRESU	Standard Units	Char	(.UNIT)	Variable Qualifier	tbd	Standardized unit used for DUSTRESC and DUSTRESN.		Exp	SDTM 2.2.3, SDTMIG 4.1.3.2, SDTMIG 4.1.5.1
VISITNUM	Visit Number	Num		Timing	PlannedSubjectAct ivityGroup.sequenc eNumber	A clinical encounter number.	A Numeric version of VISIT, used for sorting.	Exp	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
VISIT	Visit Name	Char		Timing	PlannedSubjectAct ivityGroup.name	Protocol-defined description of clinical encounter.	May be used in addition to VISITNUM and/or VISITDY.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
VISITDY	Planned Study Day of Visit	Num		Timing	PlannedSubjectAct ivityGroup.studyD ayRange	Planned study day of the visit based upon RFSTDTDC in Demographics.		Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4

DUDTC	Date/Time of Measurements	Char	ISO 8601	Timing	PerformedActivity. dateRange			Exp	SDTM 2.2.5, SDTMIG 4.1.4.1, SDTMIG 4.1.4.2, SDTMIG 4.1.4.8
DUDY	Study Day of Device Use	Num		Timing	PerformedActivity: PerformedObservation.studyDayRange	Study day of Imaging /Device In-Use measurement, measured as integer days.	Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.4, SDTMIG 4.1.4.6

#### 4.2.1. ASSUMPTIONS FOR THE DEVICE IN-USE DOMAIN MODEL

1. DU Definition: The Device In-Use domain represents properties of the study device or ancillary device (if necessary to document) that are intentionally set when the device is used in the context of a study. 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., a MRI or CT machine whose settings must be recorded in the clinical trial data, as required in the protocol).
2. 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.
  - a. For example, 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 Device Properties. 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 Tesla for visit 1.
3. This domain is not intended to capture ongoing changes in settings for devices where adjustments are made to enhance efficacy or safety (for example, pacemakers). These would generally be captured in Device Exposure (DX).
4. This domain is not intended to capture manufacturer-set (that is, nominal) settings, but rather the customized settings for a given usage.
5. Since any number of device settings (for example, 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.
6. DUREFID is the identifier for a unique scan or other test result for a group of settings (for example, field strength or slice thickness in an MRI scan) to the results obtained from the reading or interpretation of the test (for example, the MRI image).
7. The DUSPID variable can be used to link this domain to AEs, Exposure and/or Device Events (e.g., malfunctions) if such linkages are necessary.
8. 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, --BLFL, --FAST, --DRVFL, --EVAL, --TOX, --TOXGR, --SEV, --DTHREL, --LLOQ.

## 4.2.2. EXAMPLES FOR THE DEVICE IN-USE DOMAIN MODEL

### Example 1:

This example shows data from one subject collected at two visits about parameters from an MRI imaging protocol. In this case, the image was used for Organ Measurement, and the results of the image interpretation are reported in the Organ Measurement domain. The parameters in DU can be linked to the measurement results using RELREC, and an illustration of this can be found in Section 5 Cross-Domain Relationship Examples.

**Table 1, Rows 1-8:** Represent 7 example Device In-Use records collected at the screening visit for a given subject.

**Table 1, Rows 9-16:** Represent 7 example Device In-Use records collected at the first treatment visit for the same subject.

Row	STUDYID	DOMAIN	USUBJID	UDEVID	DUSEQ	DUGRPID	DUREFID	DUTESTCD	DUTEST	DUORRES	DUORRESU
1	STUDYX	DU	2324-P0001	ABC174	1	DUOM1	222333-444555	COILSTR	Coil Strength	1.5	Tesla
2	STUDYX	DU	2324-P0001	ABC174	2	DUOM1	222333-444555	ANTPLANE	Anatomical Plane	CORONAL	
3	STUDYX	DU	2324-P0001	ABC174	3	DUOM1	222333-444555	STHICK	Slice Thickness	1	mm
4	STUDYX	DU	2324-P0001	ABC174	4	DUOM1	222333-444555	MATRIX	Matrix	256X256	
5	STUDYX	DU	2324-P0001	ABC174	5	DUOM1	222333-444555	SFTWRVER	Software Version	15.0	
6	STUDYX	DU	2324-P0001	ABC174	6	DUOM1	222333-444555	FLDVIEW	Field of View	24	cm
7	STUDYX	DU	2324-P0001	ABC174	7	DUOM1	222333-444555	RCBDWTH	Receiver Bandwidth	16	kHz
8	STUDYX	DU	2324-P0001	ABC174	1	DUOM2	444555-666777	COILSTR	Coil Strength	1.0	Tesla
9	STUDYX	DU	2324-P0001	ABC174	2	DUOM2	444555-666777	ANTPLANE	Anatomical Plane	CORONAL	
10	STUDYX	DU	2324-P0001	ABC174	3	DUOM2	444555-666777	STHICK	Slice Thickness	2	mm
11	STUDYX	DU	2324-P0001	ABC174	4	DUOM2	444555-666777	MATRIX	Matrix	256X256	
12	STUDYX	DU	2324-P0001	ABC174	5	DUOM2	444555-666777	SFTWRVER	Software Version	15.1	
13	STUDYX	DU	2324-P0001	ABC174	6	DUOM2	444555-666777	FLDVIEW	Field of View	25	cm
14	STUDYX	DU	2324-P0001	ABC174	7	DUOM2	444555-666777	RCBDWTH	Receiver Bandwidth	16	kHz

Row	DUSTRESC	DUSTRESN	DUSTRESU	VISITNUM	VISIT	VISITDY	DUDTC	DUDY
1 (cont)	1.5	1.5	Tesla	1	SCREENING	-7	2011-04-19	-7
2 (cont)	CORONAL			1	SCREENING	-7	2011-04-19	-7
3 (cont)	1	1	mm	1	SCREENING	-7	2011-04-19	-7
4 (cont)	256X256			1	SCREENING	-7	2011-04-19	-7
5 (cont)	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
8 (cont)	1.0	1.0	Tesla	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

### 4.3. DEVICE EXPOSURE - DX

dx.xpt, Device Exposure — Interventions, Version 0.1. One record per recorded intervention occurrence or constant-dosing interval per subject, Tabulation

Variable Name	Variable Label	Data	Controlled Terms, Code list or Format	Role	Draft BRIDG Mapping	Definition	Implementation Notes	Core	References
STUDYID	Study Identifier	Char		Identifier	DocumentIdentifier.identifier	Unique identifier for a study.		Req	SDTM 2.2.4
DOMAIN	Domain Abbreviation	Char	DX	Identifier	tbd	Two-character abbreviation for the domain.		Req	SDTM 2.2.4, SDTMIG 4.1.2.2
USUBJID	Unique Subject Identifier	Char		Identifier	SubjectIdentifier.identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.		Req	SDTM 2.2.4, SDTMIG 4.1.2.3
UDEVID	Unique Device Identifier	Char		Identifier	tbd	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	tbd	Sequence Number given to ensure uniqueness of subject records within a domain.	May be any valid number.	Req	SDTM 2.2.4
DXGRPID	Group ID	Char		Identifier	tbd	Identifier that ties together a block of related records in a single domain for a subject.		Perm	SDTM 2.2.4, SDTMIG 4.1.2.6
DXSPID	Sponsor-Defined Identifier	Char		Identifier	tbd	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	SDTM 2.2.4
DXTRT	Name of Actual Device or Device Output Exposure	Char		Topic	tbd	Name of the device, as described in the trial summary domain or in the protocol, or the exposure outputs that are delivered or administered via the device.	Example: coronary stent, extracorporeal shock wave treatment, hyaluronic acid	Req	SDTM 2.2.1
DXCAT	Category for Device Exposure	Char	*	Grouping Qualifier	PerformedActivity.PerformedProcedure.e > DefinedActivity.categoryCode	Used to define a category of device exposures		Perm	SDTM 2.2.1, SDTMIG 4.1.2.6
DXSCAT	Subcategory for Device Exposure	Char	*	Grouping Qualifier	PerformedActivity.PerformedProcedure.e > DefinedActivity.subcategoryCode	A further categorization of device exposures		Perm	SDTM 2.2.1, SDTMIG 4.1.2.6

DXDOSE	Exposure per Administration	Num		Record Qualifier	tbd	Amount of DXTRT administered/delivered.	Dose if captured as a numeric value. Dose should only appear once in DXDOSE, DXDOSTXT or DXDOSTOT	Perm	SDTM 2.2.1
DXDOSTXT	Device Exposure Description	Char		Record Qualifier	tbd	Exposure amounts 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	SDTM 2.2.1
DXDOSU	Device Exposure Units	Char	(UNIT)	Variable Qualifier	tbd	Units for DXDOSE, DXDOSTXT, and DXDOSTOT.	Examples: pulses, ml	Perm	SDTM 2.2.1, SDTMIG 4.1.3.2
DXDOSFRQ	Device Exposure Frequency per Interval	Char	(FREQ)	Variable Qualifier	tbd	Exposure frequency per interval.	Usually expressed as the number of repeated administrations of DXDOSE within a specific time period. Examples: once/wk. 3X/wk	Perm	SDTM 2.2.1
DXDOSTOT	Total Daily Device Exposure	Num		Record Qualifier	tbd	Total exposure over a period other than day could be recorded in a separate Supplemental Qualifier variable.	Total daily exposure of DXTRT using the units in DXDOSU.	Perm	SDTM 2.2.1
DXDOSRGM	Intended Device Exposure Regimen	Char		Variable Qualifier	tbd	Text description of the (intended) schedule or regimen for the Intervention.	Examples: TWO WEEKS ON, TWO WEEKS OFF.	Perm	SDTM 2.2.1
DXROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	tbd	Route of administration for DXTRT.	Examples: extracorporeal, intra-joint, catheter	Perm	SDTM 2.2.1
DXLOC	Location of Device Exposure	Char		Record Qualifier	tbd	Anatomic location of exposure	Examples: Left knee, OD	Perm	SDTM 2.2.1
DXMETHOD	Method of Device Exposure	Char	*	Record Qualifier	tbd	Method of device exposure.	Example: Catheter	Perm	SDTM 2.2.1
DXADJ	Reason for Exposure Adjustment	Char		Record Qualifier	tbd	Describes reason of why the exposure was adjusted from protocol-specified or expected exposure levels.	Examples: PAIN	Perm	SDTM 2.2.1
DXSTDTC	Start Date/Time of Device Exposure	Char	ISO 8601	Timing	tbd	Start date and time of exposure		Exp	SDTM 2.2.5, SDTMIG 4.1.4.1, SDTMIG 4.1.4.3
DXENDTC	End Date/Time of Device Exposure	Char	ISO 8601	Timing	tbd	End date and time of exposure.		Perm	SDTM 2.2.5, SDTMIG 4.1.4.1, SDTMIG 4.1.4.3
DXSTDY	Study Day of Start of Device Exposure	Num		Timing	tbd	Study day of start of exposure.	Study day of start of exposure relative to the sponsor-defined RFSTDTC.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.4, SDTMIG 4.1.4.6

DXENDY	Study Day of End of Device Exposure	Num		Timing	tbd	Study day of end of exposure	Study day of end of exposure relative to the sponsor-defined RFSTDTC.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.4 , SDTMIG 4.1.4.6
DXDUR	Duration of Device Exposure	Char	ISO 8601	Timing	tbd	Collected duration for a treatment episode.	Used only if collected on the CRF and not derived from start and end date/times.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.3

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

#### 4.3.1. ASSUMPTIONS FOR THE DEVICE EXPOSURE DOMAIN MODEL

1. DX Definition: The Device Exposure domain records the details of a subject's exposure to a medical device, usually but not always the 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 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 one record per exposure intervention episode, constant-exposure interval, or pre-specified exposure assessment per subject. It is the sponsor's responsibility to define an intervention episode. This definition may vary based on the sponsor's requirements for review and analysis. The submission dataset structure may differ from the structure used for collection. One common approach is to submit a new record when there is a change in the 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, for example, diagnostic devices, would not require a DX domain.
5. In cases where a device/drug combination is being studied, the device exposure data would be generally be submitted in DX and the drug exposure data would be generally be submitted in EX, but each sponsor should confer with the appropriate regulatory authority to determine the right datasets. This is also the case for devices that deliver radiation or use contrast media, for example, as there has historically been inconsistency about the domain to use.
6. There are cases where settings on devices used in studies might be reported in Device Exposure or Device In-Use, such as when the settings are changed to effect an efficacy response. Sponsors should confer with the appropriate regulatory authorities to determine where to submit this information.
7. Categorization and Grouping
  - a. 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
  - a. DXTRT captures the name of the investigational medical device and it 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
  - a. The timing of exposure to study device is captured by the start/end date and start/end time of each intervention episode.

10. Additional Interventions Qualifiers

- a. Other additional Qualifiers from the SDTM Interventions Class may be added to this domain.

**4.3.2. EXAMPLES FOR THE DEVICE EXPOSURE DOMAIN MODEL**

**Example 1: Injection of hyaluronic acid (HA) into knee for treatment of osteoarthritis**

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 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	UDEVID	DXSEQ	DXGRPID	DXSPID	DXTRT	DXCAT	DXSCAT	DXDOSE	DXDOSTXT	DXDOSU
1	ABCXYZ	DX	001-001	LOTABC	1		1	HYALURONIC ACID			2	2	mL
2	ABCXYZ	DX	001-001	LOTABC	2		2	HYALURONIC ACID			2	2	mL
3	ABCXYZ	DX	001-001	LOTXYZ	3		3	HYALURONIC ACID			2	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	PT2M
2 (cont)	ONCE	1X/WK FOR 3 WEEKS	INTRA-ARTICULAR	LEFT KNEE	2010-05-09T13:15	2010-05-09T13:17	7	7	PT2M
3 (cont)	ONCE	1X/WK FOR 3 WEEKS	INTRA-ARTICULAR	LEFT KNEE	2010-05-13T13:15	2010-05-13T13:17	14	14	PT2M

**Example 2: ESWT (extracorporeal shock wave treatment) for treatment of plantar fasciitis**

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 two locations within the heel receiving pulses (in-line, and 45 deg medial to plantar). This example shows a patient that had an aborted treatment due to an adverse event.

Row	STUDYID	DOMAIN	USUBJID	UDEVID	DXSEQ	DXGRPID	DXSPID	DXTRT	DXCAT	DXDOSE	DXDOSTXT	DXDOSU
1	ABCXYZ	DX	001-001	SERAZZ3	1		1	ESWT	IN-LINE	500	500	PULSES
2	ABCXYZ	DX	001-001	SERAZZ3	2		2	ESWT	45DEG MEDIAL TO PLANTAR	400	400	PULSES

Row	DXDOSFRQ	DXDOSTOT	DXDOSRGM	DXROUTE	DXLOC	DXADJ	DXSTDTC	DXENDTC	DXSTDY	DXENDY	DXDUR
1 (cont)	ONCE	500	500 pulses/treatment session	Extracorporeal	Right Plantar Fascia		2010-05-02T12:15	2010-05-02T12:30	1	1	PT15M
2 (cont)	ONCE	400	500 pulses/treatment session	Extracorporeal	Right Plantar Fascia	Adverse Event	2010-05-02T12:31	2010-05-02T12:45	1	1	PT15M

**Example 3 : APBI (Accelerated partial breast irradiation) with radiation delivery device**

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	UDEVID	DXSEQ	DXGRPID	DXSPID	DXTRT	DXCAT	DXSCAT	DXDOSE	DXDOSU
1	ABCXYZ	DX	001-001	SER56XA	1			ABC balloon catheter system	INSERTION		1	catheter
2	ABCXYZ	DX	001-001	SER44531	2			Radiation	APBI		3.4	Gy
3	ABCXYZ	DX	001-001	SER44531	3			Radiation	APBI		3.4	Gy
4	ABCXYZ	DX	001-001	SER44531	4			Radiation	APBI		3.4	Gy
5	ABCXYZ	DX	001-001	SER44531	5			Radiation	APBI		3.4	Gy

Row	DXDOSFRQ	DXDOSTOT	DXDOSRGM	DXROUTE	DXLOC	DXSTDTC	DXENDTC	DXSTDY	DXENDY	DXDUR
1 (cont)	ONCE		ONCE	Intradermal	LUO*	2010-05-02T12:15	2010-05-010T13:30	1	8	
2 (cont)	BID	6.8	5 DAYS	Intradermal	LUO	2010-05-03T08:31	2010-05-03T08:45	2	2	PT15M
3 (cont)	BID	6.8	5 DAYS	Intradermal	LUO	2010-05-03T15:31	2010-05-03T15:45	3	3	PT15M
4 (cont)	BID	6.8	5 DAYS	Intradermal	LUO	2010-05-04T08:31	2010-05-04T08:45	4	4	PT15M
5 (cont)	BID	6.8	5 DAYS	Intradermal	LUO	2010-05-04T15:31	2010-05-04T15:45	5	5	PT15M

\* This abbreviation does not exist in the CDISC controlled terminology. The sponsor would have to submit this and its definition with the other dictionary information. Alternatively, the sponsor could request to have the term added to the controlled terms, although it would need to have the part of the body added and the abbreviation spelled out.

**Example 4: Implanted Cervical Disc**

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	UDEVID	DXSEQ	DXGRPID	DXSPID	DXTRT	DXCAT	DXSCAT	DXDOSE	DXDOSTXT
1	ABCXYZ	DX	001-001	SER45001	1		1	Artificial Cervical Disc			1	
2	ABCXYZ	DX	002-001	SER86002	1		1	Artificial Cervical Disc			1	

Row	DXDOSU	DXDOSFRQ	DXDOSTOT	DXMETHOD	DXLOC	DXADJ	DXSTDTC	DXENDTC	DXSTDY	DXENDY	DXDUR
1 (cont)	DISC	1	1	SURGICAL	C3-4		2010-05-02T12:15		1		
2 (cont)	DISC	1	1	SURGICAL	C3-4		2010-05-02T13:15	2010-05-09T13:17	1	7	

## 4.4. DEVICE EVENTS - DE

de.xpt, Device Events - Events, Version 0.1. One record per event per device, Tabulation

Variable Name	Variable Label	Data type	Controlled Terms, Code list or Format	Role	Draft BRIDG Mapping	Definition	Implementation Notes	Core	References
STUDYID	Study Identifier	Char		Identifier	DocumentIdentifier.identifier	Unique identifier for a study.		Req	SDTM 2.2.4
DOMAIN	Domain Abbreviation	Char	(DE)	Identifier	PerformedProductInvestigationResult	Two-character abbreviation for the domain.		Req	SDTM 2.2.4, SDTMIG 4.1.2.2
USUBJID	Unique Subject Identifier	Char		Identifier	SubjectIdentifier.identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.		Exp	SDTM 2.2.4, SDTMIG 4.1.2.3
UDEVID	Unique Device Identifier	Char		Identifier	tbd	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	
DESEQ	Device Events Sequence Number	Num		Identifier	tbd	implementation specific record identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req	SDTM 2.2.4
DEGRPID	Group ID	Char		Identifier	tbd		Identifier used to tie together a block of related records in a single domain for a subject.	Perm	SDTM 2.2.4, SDTMIG 4.1.2.6
DEREFID	Reference ID	Char		Identifier	tbd			Perm	SDTM 2.2.4
DESPID	Sponsor-Defined Identifier	Char		Identifier	tbd	Sponsor-defined reference number.	Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm	SDTM 2.2.4
DETERM	Device Event Name	Char		Topic	PerformedProductInvestigationResult.deviceMalfunctionCode.CD.originalText	Verbatim name of the observed event.	The value in DETEST cannot be longer than 40 characters. Examples: Screw Breakage, Fissure Formation, Battery Issue	Req	SDTM 2.2.2, SDTMIG 4.1.3.6
DEMODY	Modified Device Event Name	Char		Synonym Qualifier	tbd	The modified text for DETERM	If DETERM is modified, then the modified text is placed here.	Perm	SDTM 2.2.2, SDTMIG 4.1.3.6
DEDECOD	Device Events Dictionary-Derived Term	Char	* FDA's Device Problem Codes	Synonym Qualifier	PerformedProductInvestigationResult.deviceMalfunctionCode.CD.displayName	Dictionary-derived form of the event described in DETERM.	Dictionary-derived text description of DETERM or DEMODIFY. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the define.xml external code list attributes	Req	SDTM 2.2.2, SDTMIG 4.1.3.5, SDTMIG 4.1.3.6
DECAT	Category of Event	Char	*	Grouping Qualifier	PerformedProductInvestigationResult.defectTypeCode	Used to define a categorization level for events.		Perm	SDTM 2.2.2, SDTMIG 4.1.2.6
DESCAT	Subcategory of	Char	*	Grouping	tbd	Used to define a further category		Perm	SDTM 2.2.2,

Variable Name	Variable Label	Data type	Controlled Terms, Code list or Format	Role	Draft BRIDG Mapping	Definition	Implementation Notes	Core	References
	Event			Qualifier		level for events.			SDTMIG 4.1.2.6
DEPRESP	DE Pre-Specified	Char	(NY)	Record Qualifier	tbd		Used to indicate whether (Y/null) information about a specific event was solicited on the CRF.	Perm	SDTM 2.2.2, SDTMIG 4.1.2.7, SDTMIG 4.1.5.7
DEOCCUR	DE Occurrence	Char	(NY)	Record Qualifier	tbd		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	SDTM 2.2.2, SDTMIG 4.1.5.7
DESTAT	Event Collection Status	Char	<ND>-	Record Qualifier	tbd	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	SDTM 2.2.2, SDTMIG 4.1.5.1, SDTMIG 4.1.5.7
DEREASND	Reason Event Not Collected	Char			PerformedActivity.PerformedObservation.negationReason	Reason DESTAT was not done	This variable should only be used if there are prespecified events.	Perm	SDTM 2.2.2, SDTMIG 4.1.5.1, SDTMIG 4.1.5.7
DESEV	Event Severity	Char	*		tbd	Severity of Event	Terms Describing Severity of Event (e.g., Malfunction )	Perm	SDTM 2.2.2
DEACNDV	Action Taken with Device	Char	*		PerformedProductInvestigationResult > ProductActionTakenRelationship > PerformedActivity > DefinedActivity.name Code WHERE DefinedActivity.name Code = an action taken as a result of a product problem.	Describes Action Taken with respect to the device	Action Taken may include removal, calibration, reprogramming, etc.	Perm	SDTM 2.2.2
VISITNUM	Visit Number	Num		Timing	PlannedSubjectActivityGroup.sequenceNumber	Clinical encounter number.	Numeric version of VISIT, used for sorting.	Exp	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
VISIT	Visit Name	Char		Timing	PlannedSubjectActivityGroup.name	Protocol-defined description of clinical encounter.	May be used in addition to VISITNUM and/or VISITDY.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
VISITDY	Planned Study Day of Visit	Num		Timing	PlannedSubjectActivityGroup.studyDayRange	Planned study day of the visit based upon RFSTDTC in Demographics.		Perm	SDTM 2.2.5, SDTMIG 4.1.4.5,

Variable Name	Variable Label	Data type	Controlled Terms, Code list or Format	Role	Draft BRIDG Mapping	Definition	Implementation Notes	Core	References
									SDTMIG 7.4
DEDTC	Date of Device Event Data Collection	Char	ISO 8601	Timing	PerformedActivity.dateRange where the name of the activity is "collect malfunction information.	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	SDTM 2.2.5, SDTMIG 4.1.4.1
DESTDTC	Start Date/Time of Device Event	Char	ISO 8601	Timing	PerformedObservation:PerformedProductInvestigation.focalDateRange	Start date/time of the device event.	If the event happened at a single point in time, DESTDTC is used.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.1, SDTMIG 4.1.4.2
DEENDTC	End Date/Time of Device Event	Char	ISO 8601	Timing	PerformedObservation:PerformedProductInvestigation.focalDateRange	End date/time of the device event.		Perm	SDTM 2.2.5, SDTMIG 4.1.4.1, SDTMIG 4.1.4.2
DEDY	Study Day of Device Event Data Collection	Num		Timing	PerformedActivity:PerformedObservation:PerformedProductInvestigation.studyDayRange	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	SDTM 2.2.5, SDTMIG 4.1.4.4
DESTDY	Study Day of Device Event Start Date/Time	Num		Timing	PerformedActivity:PerformedObservation:PerformedProductInvestigation.studyDayRange	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	SDTM 2.2.5, SDTMIG 4.1.4.4
DEENDY	Study Day of Device Event End Date/Time	Num		Timing	PerformedActivity:PerformedObservation:PerformedProductInvestigation.studyDayRange	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	SDTM 2.2.5, SDTMIG 4.1.4.4

\* Indicates variable may be subject to controlled terminology; sponsor will identify the controlled terminology in the define file.

#### 4.4.1. ASSUMPTIONS FOR THE DEVICE EVENTS DOMAIN MODEL

1. Device Events Definition: The Device Events domain captures information about a variety of activities that can occur to or with the device. This domain has been modeled to show its application to malfunctions, but can be extended as needed.
2. 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.
3. In some cases, a device event may occur but have no relationship to a study, for example, a malfunction occurring if a device is damaged in transit or setup. It is assumed that these events will be reported elsewhere.
4. Depending upon the type of device, an event such as a malfunction may impact one 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 DEREVID value would identify multiple records representing the subject-by-subject impact of the malfunction.

5. There are two 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 settings (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, ultrasound) may be identified. For example, the same finding may be obtained using different methods, but each possibly associated with a different level of confidence in a diagnosis.
7. If a malfunction or other event results in an adverse event, then that information should be recorded in the Adverse Events (AE) domain (see SDTMIG v3.1.2, Section 6.2.1). The relationship between the AE and the Device Events can be recorded using DESPID and/or DEAENO. DEAENO is usually a data capture (CDASH) variable that is not submitted in SDTM, 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. If this domain is used to capture Device Malfunctions, and the FDA's Device Problem Code controlled terminology list is used (available at <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/ucm134845.htm>), then the coded terms should be included as Supplemental Qualifiers. See SDTMIG Appendix C5 for information about including the hierarchy of terms as well.
10. 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.

#### 4.4.2. EXAMPLES FOR THE DEVICE EVENTS DOMAIN MODEL

**Example 1:** Malfunction Events: In this example, two units of the device have suffered a series of failures. Each failure is recorded separately.

Row	STUDYID	DOMAIN	USUBJID	UDEVID	DESEQ	DETERM	DEDECOD	DECAT	DESEV	DEDTC	DESTDTC
1	ABCXYZ	DE	1001	1001001	1	Screw breakage	SCREWBRK	Equipment Failure	Minor	2009-11-02	2009-11-01
2	ABCXYZ	DE	1001	1001001	2	Fissure formation	FISSURE	Equipment Failure	Minor	2009-12-15	2009-12-13
3	ABCXYZ	DE	1002	999981	1	Battery will not charge	BATISS	Equipment Failure	Major	2009-10-13	2009-10-10
4	ABCXYZ	DE	1002	999981	2	Firmware Consistency Fail 103	FFAIL103	Software Malfunction	Major	2010-01-03	2010-01-03

**Example 2:**

**Row 1:** This example shows a malfunction of an MRI calibration affecting one 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 UDEVID.

**Row 2:** The second record is 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, but 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:** The third record shows a malfunction for a specific device under study and the associated subject.

Row	STUDYID	DOMAIN	USUBJID	UDEVID	DESEQ	DETERM	DEDECOD	DECAT	DESEV	DEDTC	DESTDTC
1	ABC-123	DE	2022	Site 22	1	Calibration Failed	CALFAIL	Calibration Failure	Minor	2010-01-01	2009-12-28
2	ABC-456	DE		15033	1	Data Loss	DATAFAIL	Data Storage Failure	Major	2009-01-06	2009-01-05
3	ABC-789	DE	2222	334-XRS-09	1	Alignment Failure	CALFAIL	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	UDEVID	DESEQ	DETERM	DEDECOD	DECAT	DESEV	DEDTC	DESTDTC
1	ABCXYZ	DE	2022	X1010785	1	Calibration Failed	CALFAIL	Equipment Failure	Medium	2010-01-01	2009-12-28
2	ABCXYZ	DE	2133	15033	1	Communication Failure	COMMFAIL	Equipment Failure	Medium	2009-01-05	2009-01-05
3	ABCXYZ	DE	2133	334-XRS-09	2	Communication Failure	COMMFAIL	Equipment Failure	Medium	2009-01-05	2009-01-05

**Example 4:**

**Row 1:** This example shows a maintenance and calibration checks associated with a QA schedule of an MRI calibration where all subjects after the event were affected. 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 would be needed to calibrate results for subsequent cases) then a record could be added for each affected subject.

**Row 2:** The second record 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	UDEVID	USUBJID	DESEQ	DETERM	DEDECOD	DECAT	DESCAT	DEDTC	DESTDTC
1	ABC-456	DE	15033		1	Scheduled Maintenance	QAQC	Scheduled Maintenance	Minor	2009-01-06	2009-01-05
2	ABC-789	DE	334-XRS-09		1	Software Update	SWUPD	Software Update	Major	2009-01-05	2009-01-05

## 4.5. DEVICE TRACKING AND DISPOSITION - DT

dt.xpt, Device Tracking and Disposition - Events, Version 0.1. One record per device tracking event, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Code list or Format	Role	Draft BRIDG Mapping	Definition	Implementation Notes	Core	References
STUDYID	Study Identifier	Char		Identifier	Tbd	Unique identifier for a study.		Req	SDTM 2.2.4
DOMAIN	Domain Abbreviation	Char	DT	Identifier	MaterialIdentifier.identifier >Material.Product.Device	Two-character abbreviation for the domain.		Req	SDTM 2.2.4, SDTMIG 4.1.2.2
UDEVID	Unique Device Identifier	Char		Identifier	Tbd	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	
DTSEQ	Unique Device Tracking Sequence Number	Num		Identifier	Tbd	Sequence Number given to ensure uniqueness of subject records within a domain in a submission.	May be any valid number.	Req	SDTM 2.2.4
DTTERM	Tracking Event Verbatim Term	Char	*	Topic	DefinedActivity.nameCode.CD.originalText>PerformedActivity where name = ship, return or install device	Verbatim or preprinted term for the activity that occurs.	Example: SHIPPED, RETURNED, INSTALLED, IMPLANTED, EXPLANTED	Req	SDTM 2.2.2, SDTMIG 4.1.3.6
DTMODIFY	Modified Reported Term	Char		Synonym Qualifier	Tbd	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	<a href="#">SDTM 2.2.2</a> , <a href="#">SDTMIG 4.1.3.6</a>
DTDECOD	Dictionary-Derived Term	Char	*	Synonym Qualifier	Tbd	Dictionary-derived text description of DTTERM or DTMODIFY.	If an external controlled terminology is used, the sponsor is expected to provide the dictionary or controlled terminology name and version used to map the terms utilizing the define.xml external code list attributes	Perm	<a href="#">SDTM 2.2.2</a> .

DTPLOC	Product Location Identifier	Char	*		Tbd	Internal or external device physical location tracking identifier.	This identifier defines the type of location where the device will be when the action defined in DTTERM occurs. For examples: if DTTERM = SHIPPED, DTPLOC would contain the shipping destination, e.g., SITE. If DTTERM = IMPLANTED then DTPLOC would contain SUBJECT.	Req	
DTPLOCSP	Product Location	Char		Variable qualifier	Tbd	Specific location identified by DPLOC.	The value of the location identified in DTPLOC. For example, if DTPLOC is SUBJECT, PTPLOCSP would contain the subject number.	Exp	
DTCAT	Category for Tracking Event	Char	*	Grouping Qualifier	Tbd	Define a categorization level for a group of related records.	Examples: categorize by tracking event type (CURRENT, INTERIM, FINAL)	Exp	SDTM 2.2.2, SDTMIG 4.1.2.6
DTSCAT	Subcategory for Medical History	Char		Grouping Qualifier	Tbd	Defines a further categorization level for a group of related conditions or events.	A further categorization of the event.	Perm	SDTM 2.2.2, SDTMIG 4.1.2.6
DTDTC	Date/Time of Tracking Event Collection	Char	ISO 8601	Timing	PerformedActivity.dateRange	Date/Time of the tracking event information was collected.		Perm	SDTM 2.2.5, SDTMIG 4.1.4.1
DTSTDTC	Start Date/Time of Tracking Event	Char	ISO 8601	Timing	PerformedActivity.dateRange	Start date/time of tracking event.		Req	SDTM 2.2.5, SDTMIG 4.1.4.1

\* Indicates variable may be subject to controlled terminology; sponsor will identify the controlled terminology in the define file.

#### 4.5.1. ASSUMPTIONS FOR THE DEVICE TRACKING AND DISPOSITION DOMAIN MODEL

1. DT Definition: The Device Tracking and Disposition domain represents a record of tracking events for a given device. This could include initial shipment, deployment, return, destruction, loss, etc. Different events would be relevant to different types of device. For example, an MRI machine might be shipped to a hospital and remain there, while 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 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 two ways. Tracking data can be captured and submitted that indicate the physical location of 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 and the individual tracking event information remains at the site and sponsor locations and available for inspection.

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 (for example, implantation of a stent). Subject-specific deployment information would usually more appropriately be captured in the Device Exposure 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. In cases where a group of devices is tracked together, such as a box of orthopedic screws, a given UDEVID 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 is comprised of a number of components (e.g., a pacemaker with leads and software), the sponsor may choose to track the overall device using its UDEVID or track the identifiers for the individual components, or both, whatever 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. DTCAT is intended to differentiate the action taken with the device as INTERIM (all records prior to the most recent one reported), CURRENT (the most recent one reported) and FINAL (indicating the last action that could and did occur by the time of submission, e.g., destroyed, returned). Because the tracking status of a device may change between different submissions (e.g., an initial submission vs. a safety update), a given device may have a different value in DTCAT in different submissions. The most recent record for each device should have a status of CURRENT or FINAL.
9. DTPLOC and DTPLOCID together identify the location of the device that results from the action in DTTERM. For example, if DTTERM is SHIPPED, DTPLOC would be a general term defining the shipping destination, such as SITE, and DTPLOCID would contain the site identifier, such as 02. Usually DTPLOC and DTPLOCID will refer to the device's location after the action in DTTERM, but there may be exceptions, such as when DTTERM is REMOVED or EXPLANTED, where it may contain the location from which the device was removed, such as LEFT FEMUR.
10. Tracking events do not have start and end dates since they do not span an interval (e.g. shipped date) but 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 study start. 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 (such as when devices are issued as supplies or samples for engineers to take to sites), and may be partly or wholly derived.
13. 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.

#### 4.5.2. EXAMPLES FOR THE DEVICE TRACKING AND DISPOSITION DOMAIN MODEL

**Example 1 :** These examples shows individual device tracking at each change of location.

Rows 1 and 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 returned to the sponsor, then the same device was shipped to Site 02. The device could be a diagnostic tool that is used on multiple subjects, then redeployed when the first site has completed their use of it.

Row 6: Device was shipped to the site but no further activity has happened

Row 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	UDEVID	DTSEQ	DTTERM	DTDECOD	DTPLOC	DTPLOCID	DTCAT	DTDTC	DTSTDTC	DTSTDY
1	ABC-123	DT	S001	1	Shipment	SHIPPED	SITE	02	INTERIM	2010-06-25	2010-06-25	360
2	ABC-123	DT	S001	2	Implantation	IMPLANTED	SUBJECT	02-1024	CURRENT	2010-07-15	2010-06-30	365
3	ABC-123	DT	S002	1	Shipped to	SHIPPED	SITE	01	INTERIM	2010-11-03	2010-11-03	229
4	ABC-123	DT	S002	2	Returned to	SHIPPED	SPONSOR		INTERIM	2011-01-05	2011-01-05	292
5	ABC-123	DT	S002	3	Shipped	SHIPPED	SITE	02	CURRENT	2011-01-15	2011-01-15	302
6	ABC-123	DT	S003	1	Shipped	SHIPPED	SITE	05	CURRENT	2010-09-29	2010-09-29	264
7	ABC-123	DT	S004	1	Shipped	SHIPPED	SITE	04	INTERIM	2010-08-30	2010-08-30	294
8	ABC-123	DT	S004	2	Implanted	IMPLANTED	SUBJECT	04-1009	INTERIM	2010-11-05	2010-10-20	346
9	ABC-123	DT	S004	3	Explanted	EXPLANTED	SUBJECT	04-1009	INTERIM	2010-11-05	2010-11-01	358
10	ABC-123	DT	S004	4	Shipped	SHIPPED	SPONSOR		FINAL	2010-11-02	2010-11-02	359
11	ABC-123	DT	S005	1	Shipped	SHIPPED	SITE	04	INTERIM	2010-11-01	2010-11-01	209
12	ABC-123	DT	S005	2	Implanted	IMPLANTED	SUBJECT	04-1009	INTERIM	2010-12-06	2010-11-12	220
13	ABC-123	DT	S005	3	Explanted	EXPLANTED	SITE	04	INTERIM	2010-12-06	2010-12-01	239
14	ABC-123	DT	S005	4	Destroyed	DESTROYED	SITE	04	FINAL	2010-12-10	2010-12-09	247
15	ABC-123	DT	Z045-2	1	Shipped	SHIPPED	SITE	05	INTERIM	2010-12-06	2010-11-12	220
16	ABC-123	DT	Z045-2	2	Implanted	IMPLANTED	SUBJECT	05-5005	INTERIM	2010-11-12	2010-11-16	224
17	ABC-123	DT	Z045-2	3	Lost	LOST	SUBJECT	05-5005	FINAL	2010-11-18	2010-11-17	225

**Example 2 : Implantable Device - Disposition Usage Only**

Row	STUDYID	DOMAIN	UDEVID	DTSEQ	DTTERM	DTDECOD	DTPLOC	DTPLOCID	DTCAT	DTDTC	DTSTDTC	DTSTDY
1	ABC-123	DT	S001	1	Implanted	IMPLANTED	SUBJECT	02-1024	CURRENT	2010-07-15	2010-06-30	365
2	ABC-123	DT	S002	2	Shipped	SHIPPED	SITE	02	CURRENT	2011-01-15	2011-01-15	302
3	ABC-123	DT	S003	3	Shipped	SHIPPED	SITE	05	CURRENT	2010-09-29	2010-09-29	264
4	ABC-123	DT	S004	4	Shipped	SHIPPED	SPONSOR		FINAL	2010-11-02	2010-11-02	359
5	ABC-123	DT	S005	5	Destroyed	DESTROYED	SITE	04	FINAL	2010-12-10	2010-12-09	247
6	ABC-123	DT	Z045-2	6	Lost	LOST	SUBJECT	05-5005	FINAL	2010-11-18	2010-11-17	225

*Final disposition is last record of device tracking usage*

## 4.6. DEVICE-SUBJECT RELATIONSHIPS - DR

dr.xpt, Response - Special Purpose Version 0.1. One record per device/subject combination,

Variable Name	Variable Label	Type	Controlled Terms, Code list or Format	Role	Draft BRIDG Mapping	Definition	Implementation Notes	Core	Reference
STUDYID	Study Identifier	Char		Identifier	tbd	Unique identifier for a study.		Req	SDTM 2.2.4
USUBJID	Unique Subject Identifier	Char		Identifier	tbd	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.		Req	SDTM 2.2.4, SDTMIG 4.1.2.3
UDEVID	Unique Device Identifier	Char		Identifier	tbd	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	

### 4.6.1. ASSUMPTIONS FOR THE DEVICE-SUBJECT RELATIONSHIPS DOMAIN MODEL

1. The Device-Subject Relationships domain is a special-purpose domain that links each subject to devices to which they may have been exposed.
2. 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.
3. This domain is a special purpose 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 (for example, blood glucose test meters), a single device or class of devices may be associated with several subjects (for example, 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 UDEVID such that device-subject relationships are described with the necessary level of detail for the submission.

### 4.6.2. EXAMPLES FOR THE DEVICE-SUBJECT RELATIONSHIPS DOMAIN MODEL

#### Example 1: Generic MRI settings at imaging encounters

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 does require 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	USUBJID	UDEVID
1	ABC-123	101	MRI
2	ABC-123	103	MRI
3	ABC-123	201	MRI
4	ABC-123	202	MRI

**Example 2: Collection of Pacemaker settings**

In this example, the study protocol requires that some subjects be implanted with a pacemaker prior to enrollment, while 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) they have. 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.

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

**Example 3: Approval of Coronary Stent and Delivery Catheter**

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 by individual unit serial number.

Subject 103 was exposed to 2 investigational stents, but it is not possible to determine either the reason 2 stents were used or the disposition of the stents from the Device-Subject Relationships table alone.

On Row 10, Subject 202 had an adverse event during the PCI procedure that was related to the Venotrate Introducer (a tool used in the procedure). The Device-Subject Relationships table captures the relationship between the subject and the device, but not the reason for the relationship (i.e. that there was an adverse event).

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

## 4.7. DEVICE PROPERTIES - DO

do.xpt, Device Properties - Special Purpose, Version 0.1. One record per property. Tabulation

SDTM Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	BRIDG	Definition	Implementation Notes	Core	References
STUDYID	Study Identifier	Char		Identifier	tbd	Unique identifier for a study.		Req	
DOMAIN	Domain Abbreviation	Char	DO	Identifier	tbd	Two letter abbreviation for a domain.		Req	
UDEVID	Unique Device Identifier	Char		Identifier	tbd	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	
DOSEQ	Device Details Sequence Number	Num		Identifier	tbd	Sequence Number given to ensure uniqueness of device serial number records within a domain.	May be any valid number.	Req	
DOGRPID	Group ID	Char		Identifier	tbd	Used to tie together a block of related records in a single domain for a subject.		Perm	
DOPARMCD	Device Detail Short Name	Char	*	Topic	tbd	Short name of the measurement, test, or examination described in DOPARM.	This variable can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DOPARMCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). DOPARMCD cannot contain characters other than letters, numbers, or underscores. Examples: MANUF, LIFE	Req	
DOPARM	Device Detail Name	Char	*	Synonym Qualifier	tbd	Verbatim name of the test or examination used to obtain the measurement or finding.	The value in DOPARM cannot be longer than 40 characters. Examples: Manufacturer, Shelf Life	Req	
DOVAL	Result or Finding in Original Units	Char		Result Qualifier	tbd	Result of the Device Property as originally observed or collected.	Examples of expected values are 6 (months), ACME, INC., STENT	Exp	

\* Indicates variable may be subject to controlled terminology; sponsor will identify the controlled terminology in the define file.

#### 4.7.1. ASSUMPTIONS FOR THE DEVICE PROPERTIES DOMAIN MODEL

1. Device Properties (DO): This special purpose domain defines key characteristics of a device that the sponsor wishes to include in the submission but that do not form part of the unique identification of the device. This domain is not required, and if there are no supplementary characteristics to submit, the domain will not be populated.
2. Each property is identified using controlled terminology (i.e., test codes) that is stored in DOPARMCD/DOPARM, which allows the property names to be values in DOPARMCD in an SDTM vertical (normalized) structure and variable names in a CDASH horizontal (non-normalized) structure. 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 as 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, such as dial settings on an imaging machine.
8. Sponsors may choose whether to include characteristics of products or components that have been approved already and are used in the study within the scope of 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. Because some characteristics can be identifiers in one type of device and just characteristics in another, some characteristics may appear in Device Properties in some studies and Device Identifiers in others. For example, the manufacturer may be part of the identification of a stent used as a comparator device, but not of one made by the sponsor.
11. These data would be assembled by a sponsor, and not by an investigative site. The data can be captured using a case report form, assembled on a worksheet to support entry of the information into the clinical database, derived manually or derived electronically from data in other domains.
12. If the property being described requires a unit, then the measurement or value is placed in one record, and the unit is a second record. The two are tied together through DOGRPID. See example 1 below.
13. DOPARMCD 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.

#### 4.7.2. 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	UDEVID	DOSEQ	DOGRPID	DOPARMCD	DOPARM	DOVAL
1	ABC123	DO	MESH FILTER LARGE	1	MEASU1	PORESIZE	Pore Size	20
2	ABC123	DO	MESH FILTER LARGE	2	MEASU1	PORESIZU	Pore Size Unit	um
3	ABC123	DO	MESH FILTER LARGE	3	MEASU2	THICKNSS	Thickness	52
4	ABC123	DO	MESH FILTER LARGE	4	MEASU2	THICKNSU	Thickness Unit	um
5	ABC123	DO	MESH FILTER LARGE	5	MEASU3	OPENAREA	Open Area	14
6	ABC123	DO	MESH FILTER LARGE	6	MEASU3	OPENAREU	Open Area Unit	%
7	ABC123	DO	MESH FILTER SMALL	7	MEASU1	PORESIZE	Pore Size	16
8	ABC123	DO	MESH FILTER SMALL	8	MEASU1	PORESIZU	Pore Size Unit	um
9	ABC123	DO	MESH FILTER SMALL	9	MEASU2	THICKNSS	Thickness	46
10	ABC123	DO	MESH FILTER SMALL	10	MEASU2	THICKNSU	Thickness Unit	um
11	ABC123	DO	MESH FILTER SMALL	11	MEASU3	OPENAREA	Open Area	31
12	ABC123	DO	MESH FILTER SMALL	12	MEASU3	OPENAREU	Open Area Unit	%

**Example 2:**

This example shows data from 2 units of one type of device, i.e., blood glucose diagnostic kits.

Row	STUDYID	DOMAIN	UDEVID	DOSEQ	DOPARMCD	DOPARM	DOVAL
1	ABC-125	DO	423-001	1	VERSION	Software Version	2.3
2	ABC-125	DO	423-001	2	REAGLOT	Reagent Lot	123-56
3	ABC-125	DO	876-523	1	VERSION	Software Version	2.3.1
4	ABC-125	DO	876-523	2	REAGLOT	Reagent Lot	123-56

# 5. Cross-Domain Relationship Examples

## 5.1. DEVICE IN-USE AND TEST RESULTS

This section illustrates the way that Device In-Use (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 domain earlier in this document that shows settings on an MRI and relates it to Organ Measurement results obtained from the MRI scan.

### *Example 1:*

This example shows data from one subject collected at one visit about parameters from an MRI imaging protocol. It assumes the image was used for Organ Measurement, as shown by the choice of DUGRPID.

**Rows 1-7:** Represent 7 example Device In-Use records collected at the screening visit for a given subject.

**Rows 9-16:** Represent 7 example Device In-Use records collected at the first treatment visit for the same subject.

Table 1

Row	STUDYID	DOMAIN	USUBJID	UDEVID	DUSEQ	DUGRPID	DUREFID	DUTESTCD	DUTEST	DUORRES	DUORRESU
1	STUDYX	DU	2324-P0001	ABC174	1	DUOM1	222333-444555	COILSTR	Coil Strength	1.5	Tesla
2	STUDYX	DU	2324-P0001	ABC174	2	DUOM1	222333-444555	ANTPLANE	Anatomical Plane	CORONAL	
3	STUDYX	DU	2324-P0001	ABC174	3	DUOM1	222333-444555	STHICK	Slice Thickness	1	mm
4	STUDYX	DU	2324-P0001	ABC174	4	DUOM1	222333-444555	MATRIX	Matrix	256X256	
5	STUDYX	DU	2324-P0001	ABC174	5	DUOM1	222333-444555	SFTWRVER	Software Version	15.0	
6	STUDYX	DU	2324-P0001	ABC174	6	DUOM1	222333-444555	FLDVIEW	Field of View	24	cm
7	STUDYX	DU	2324-P0001	ABC174	7	DUOM1	222333-444555	RCBDWTH	Receiver Bandwidth	16	kHz
8	STUDYX	DU	2324-P0001	ABC174	1	DUOM2	444555-666777	COILSTR	Coil Strength	1.0	Tesla
9	STUDYX	DU	2324-P0001	ABC174	2	DUOM2	444555-666777	ANTPLANE	Anatomical Plane	CORONAL	
10	STUDYX	DU	2324-P0001	ABC174	3	DUOM2	444555-666777	STHICK	Slice Thickness	2	mm
11	STUDYX	DU	2324-P0001	ABC174	4	DUOM2	444555-666777	MATRIX	Matrix	256X256	
12	STUDYX	DU	2324-P0001	ABC174	5	DUOM2	444555-666777	SFTWRVER	Software Version	15.1	

Row	STUDYID	DOMAIN	USUBJID	UDEVID	DUSEQ	DUGRPID	DUREFID	DUTESTCD	DUTEST	DUORRES	DUORRESU
13	STUDYX	DU	2324-P0001	ABC174	6	DUOM2	444555-666777	FLDVIEW	Field of View	25	cm
14	STUDYX	DU	2324-P0001	ABC174	7	DUOM2	444555-666777	RCBDWTH	Receiver Bandwidth	16	kHz

Row	DUSTRESC	DUSTRESN	DUSTRESU	VISITNUM	VISIT	VISITDY	DUDTC	DUDY
1 (cont)	1.5	1.5	Tesla	1	SCREENING	-7	2011-04-19	-7
2 (cont)	CORONAL			1	SCREENING	-7	2011-04-19	-7
3 (cont)	1	1	mm	1	SCREENING	-7	2011-04-19	-7
4 (cont)	256X256			1	SCREENING	-7	2011-04-19	-7
5 (cont)	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
8 (cont)	1.0	1.0	Tesla	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

Table 2. Represents the results of the scan using the setting shown in Example 1.

**Row 1-8:** Represent 6 possible organ measurement tests and 2 physician interpretations at a screening visit. This shows data reported in the original result and unit in OMORRES and OMORRESU and standardized in OMSTRESC, OMSTRESN, and OMSTRESU. It also shows the standard terminology for OMTESTCD and OMTEST. OMREFID is the link to the device used to obtain the data listed in this table and referenced above in Table 1 (for example, the unique identifier for that specific scan).

**Row 9-14:** Represent the same six tests run on a dummy sample (there are no interpretation records for the dummy sample).

Row	STUDYID	DOMAIN	USUBJID	OMREFID	OMSEQ	OMGRPID	OMTESTCD	OMTEST	OMMETHOD	OMLOC
1	STUDYX	OM	2324-P0001	1234-5678	1	DUOM1	INTP	Interpretation	MRI	BRAIN
2	STUDYX	OM	2324-P0001	1234-5678	2	DUOM1	TOTVOL	Total Volume	MRI	BRAIN
3	STUDYX	OM	2324-P0001	1234-5678	3	DUOM1	VOLUME	Volume	MRI	BRAIN, HIPPOCAMPUS
4	STUDYX	OM	2324-P0001	1234-5678	4	DUOM1	VOLUME	Volume	MRI	BRAIN, HIPPOCAMPUS
5	STUDYX	OM	2324-P0001	1234-5678	5	DUOM1	VOLUME	Volume	MRI	TEMPORAL LOBE
6	STUDYX	OM	2324-P0001	1234-5678	6	DUOM1	VOLUME	Volume	MRI	TEMPORAL LOBE
7	STUDYX	OM	2324-P0001	1234-5678	7	DUOM1	VOLUME	Volume	MRI	BRAIN, VENTRICLE
8	STUDYX	OM	2324-P0001	1234-5678	8	DUOM1	ABBSI	Annualized Brain	MRI	BRAIN

Row	STUDYID	DOMAIN	USUBJID	OMREFID	OMSEQ	OMGRPID	OMTESTCD	OMTEST	OMMETHOD	OMLOC
								Boundary Shift Int		
9	STUDYX	OM		4567-8901	1	BRAIN	TOTVOL	Total Volume	MRI	BRAIN
10	STUDYX	OM		4567-8901	2	BRAIN	VOLUME	Volume	MRI	BRAIN, HIPPOCAMPUS
11	STUDYX	OM		4567-8901	3	BRAIN	VOLUME	Volume	MRI	BRAIN, HIPPOCAMPUS
12	STUDYX	OM		4567-8901	4	BRAIN	VOLUME	Volume	MRI	TEMPORAL LOBE
13	STUDYX	OM		4567-8901	5	BRAIN	VOLUME	Volume	MRI	TEMPORAL LOBE
14	STUDYX	OM		4567-8901	6	BRAIN	VOLUME	Volume	MRI	BRAIN, VENTRICLE

Table 2 (cont.)

Row	OMLAT	OMORRES	OMORRESU	OMSTRESC	OMSTRESN	OMSTRESU	OMBLFL	OMDRVFL
1 (cont)		Normal		Normal			Y	
2 (cont)		1120000	mm3	1120000	1120000	uL	Y	
3 (cont)	LEFT	2725	mm3	2725	2725	uL	Y	
4 (cont)	RIGHT	2685	mm3	2685	2685	uL	Y	
5 (cont)	LEFT	15635	mm3	15635	15635	uL	Y	
6 (cont)	RIGHT	15650	mm3	15650	15650	uL	Y	
7 (cont)		7505	mm3	7505	7505	uL	Y	
8 (cont)				-1.5	-1.5	%	Y	Y
9 (cont)		1120000	mm3	1120000	1120000	uL	Y	
10 (cont)	LEFT	2725	mm3	2725	2725	uL	Y	
11 (cont)	RIGHT	2685	mm3	2685	2685	uL	Y	
12 (cont)	LEFT	15635	mm3	15635	15635	uL	Y	
13(cont)	RIGHT	15650	mm3	15650	15650	uL	Y	
14 (cont)		7505	mm3	7505	7505	uL	Y	

Table 3: Represents the RELREC relationship between Tables 1 and 2. See the SDTMIG v3.1.2 Section 8.2 for further discussion and examples of RELREC.

Row	STUDYID	USUBJID	RDOMAIN	IDVAR	IDVARVAL	RELTYPE	RELID
1	STUDYX		OM	OMGRPID		MANY	OMDU1
2	STUDYX		DU	DUGRPID		MANY	OMDU1

# 6. Glossary, Acronyms, and Definitions

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 CDRH 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., a MRI or CT machine whose settings must be recorded in the clinical trial data, as required in the protocol)
BRIDG	Biomedical Research Integrated Domain Group
caBIG	cancer <b>B</b> iomedical <b>I</b> nformatics <b>G</b> rid™. An information network enabling all constituencies in the cancer community – researchers, physicians, and patients – to share data and knowledge.
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 Collaborative Group Member
CDM	Clinical Data Management
CDRH	Center for Devices and Radiological Health, a division of the FDA responsible for regulatory evaluation of medical devices, among other responsibilities
Class I Device <sup>1</sup>	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 <sup>1</sup>	Devices for which the controls for Class I are not considered sufficient to ensure safety and efficacy, and thus additional controls are required, which may include special labeling requirements, mandatory performance standards and other controls. Examples include powered wheelchairs, infusion pumps, and surgical drapes.
Class III Device <sup>1</sup>	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 (sometime 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 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 autoencoded 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, 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 US.
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
IND	Investigational New Drug. IND application required by the US 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
MedDRA	Medical Dictionary for Regulatory Activities (new global standard medical terminology designed to supersede other terminologies (such as COSTART and ICD9) used in the medical product development process
NCI	National Cancer Institute (NIH)
NCI EVS	National Cancer Institute (NIH) Enterprise Vocabulary Services
NCRR	The National Clinical Research Resources, a Collaborative Group Member
NDA	New Drug Application
NICHHD	The National Institute of Child Health and Human Development, a Collaborative Group Member
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
OTC	Over The Counter.
PhRMA	Pharmaceutical Research and Manufacturers Association
PMA <sup>1</sup>	Premarket Approval. A process of scientific review to ensure the device's safety and effectiveness that must be completed for CDRH to consider permitting marketing of the device. Class III devices typically require PMAs.
PRBC	Packed Red Blood Cells
Predicate Device <sup>2</sup>	A legally marketed device that serves as the basis for comparison for a new device in a 510(k) premarketing notification.
Preprinted (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.
Prepopulated (pre-populated)	Items that are part of the eCRF (or data collection device) that are not enterable/modifiable. (also see preprinted). These data are stored in the study database.
PRN	As Needed (Latin: <i>pro re nata</i> )

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. <i>Compare to protocol violation.</i> [See ICH E3]
Protocol Violation	A significant departure from processes or procedures that were 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 violate the protocol be discontinued from the study. <i>Compare to protocol deviation.</i>
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
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. <i>Synonyms: intervention, therapeutic intervention, medical product.</i>
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 (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

1. Definitions drawn from the following sources, as quoted in Wikipedia "Medical Device" retrieved 31Aug2011.

"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.

2. Definition drawn from the FDA's Medical Device page on "How to find a predicate device"

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm> retrieved 31Aug2011.

# Appendices

## APPENDIX A: SUPPLEMENTAL INFORMATION

### APPENDIX A1: NORMALIZATION OF DATA STRUCTURES

SDTM findings domain data (e.g., vital signs, ECG and Labs) are typically structured as normalized (or vertical) data. This allows for more flexible data for transmission to regulatory authorities. Data capture and most data analysis are much easier when the data are in a non-normalized or horizontal format. This document presents examples of both formats for each findings domain. All other CDISC domains (i.e. special domains, interventions and events) are non-normalized or horizontal structures.

A non-normalized data table is more horizontal and may be easier to understand, while a normalized data table is more vertical and has properties that allow for database consistency during updates, inserts and deletes, and a simpler structure during queries. The rows of a normalized table will repeat items in its columns as needed in order to create a unique key for each row.

Typically, a table is called “normalized” if the data in it are in “third normal form”. First normal form requires that attributes (columns) be identifiable atomic values, rather than a group of values, such as a free entry text string containing date, blood pressure, and pulse. Second normal form requires a key that uniquely identifies each row in the table. In third normal form, all attributes identified by the key for the row are data elements that can be uniquely identified by the key. Even if pulse measurements are the same value on different days (e.g., 80 bpm), each entry represents an actual measurement.

An example of a non-normalized table would have a row for each subject, and a column for each of a series of blood pressure measurements, creating a wide table. Each row would be updated multiple times, as each study visit required vital signs to be recorded, and the number of possible columns would be pre-defined. It would be easy for a human to read across such a table and identify a trend in blood pressure. Another example of a horizontal table would be one that had a subject, a date, a visit number, and a series of vital signs and blood test values in each row. Again, it may be easier for a human reader to understand data in this form and draw clinical conclusions. However, automated queries of such data may be more difficult.

In a normalized table, each row would contain a subject id, date, vital sign type (e.g., blood pressure), and the value recorded. With such a table, subject ID may be repeated many times, but the key consisting of subject ID, blood pressure, and date would be sufficient to identify a unique blood pressure measurement. It would be easy to add more measurements to such a table, for example, if the study is extended for follow-up. Also, other vital signs measurements can easily be added to this table, simply by using a different vital sign type (e.g., pulse). At each visit, a single row would be added for a vital sign type. This is the format used by the Findings domains in SDTM.

### APPENDIX A2: 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 \(NCI EVS\)](http://www.cancer.gov/cancertopics/terminologyresources/CDISC) and can be accessed via the following link: <http://www.cancer.gov/cancertopics/terminologyresources/CDISC>.

In cases where a CDISC Device field has associated controlled terminology, the code list is referenced in the Definition column in the domain tables.

## APPENDIX B: OTHER RELEVANT STANDARDS

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

### APPENDIX B1: UNIQUE DEVICE IDENTIFIER (UDI)

The FDA Amendments Act of 2007 (signed into law on September 27, 2007) mandated that a physical label on devices, which is currently referred to as the “unique device identifier” or UDI. The labels will have two components:

- Device Identifier: manufacturer, make and model
- Production Identifier: serial or lot number and expiration date

The FDA is currently developing guidelines on the UDI. The current focus is on tracking individual device units once they are in the marketplace, and the information to be included is largely only obtainable after manufacture for distribution. For more information on the UDI project, please go to [www.fda.gov/cdrh/ocd/udi](http://www.fda.gov/cdrh/ocd/udi).

## APPENDIX B2: CODE OF FEDERAL REGULATIONS

The primary US federal regulations affecting medical devices that have an impact on the capture and submission of clinical trials data to regulatory authorities are:

- 21 CFR Part 812 Investigational Device Exemptions  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1>
- 21 CFR Part 807 ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES, Subpart E Premarket Notification Procedures  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807&showFR=1&subpartNode=21:8.0.1.1.5.5>
- 21 CFR Part 814 Premarket Approval of Medical Devices  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=814>
- 21 CFR Part 803 Medical Device Reporting  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803>

## APPENDIX B3: INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

The ISO 14155 standard was first developed in 2003 and recently update 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 B4: CODE LISTS AND TERMINOLOGY

Beyond those defined by CDISC and managed by the NCI EVS (see Appendix A2 above), the following code lists and controlled terminologies may affect the structure and content of 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 C: PARTICIPATING COMPANIES**

<b>Leadership Team</b>	<b>Company affiliation</b>
Carey Smoak	Roche Molecular Systems, Inc.
Kit Howard	Kestrel Consultants
Fred Wood	Octagon Research Solutions
Rhonda Facile	CDISC
Bob Pearsall	Sensors
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

## Additional 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	Syneract
eClinical Solutions	Trireme Medical

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