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Mapping Unique Aspects of Implantable Medical Device Study Data to CDISC SDTM Medical Device Domains

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ABSTRACT

The Clinical Data Interchange Standard Consortium (CDISC) recently released a set of standards specifically aimed at medical device studies. These standards consist of seven proposed domains supplemental to the main Study Data Tabulation Model (SDTM). We review current methods of reporting implantable medical device study data in light of the CDISC device supplement. We report methods of modeling the general features of device-related data in the new domains. Additionally, we include a description of a custom surgery domain, SG, to capture information arising from medical devices requiring multiple concurrent, or sequential, implants as well as procedural data associated with implantation.

INTRODUCTION

Clinical trials that evaluate medical therapies typically generate complex data sets. Relative to pharmaceutical therapy, studies of medical treatment by implantable device may possess an added level of complexity in that the delivery of treatment often involves an initial implantation surgery, adjustment of device parameters following implantation, or some other medical procedure. Medical devices themselves often have multiple parts or electronic components or require other devices for delivery. The devices may be functionally permanent, or may be absorbed by the body after implantation, and often need to be monitored for lengthy periods during clinical studies. Consequently, implantable device studies can generate data of a type not typically found in drug studies.

Over the past several years, the CDISC (Clinical Data Interchange Standards Consortium) Submission Data Standards (SDS) device team, has designed a set of supplemental device-related domains for the Study Device Tabulation Model (SDTM) to handle device data (Smoak, 2008). These domains cover the proper description, identification and tracking of each device in study, the details of deployment, and the recording of malfunction or other device-related events. As of the writing of this paper, the proposed set of SDTM standards have been released (Jan 24th, 2012) for a period of public comment which has ended (March 9th, 2012). After reviewing comments, the SDS device team released a Provisional set of SDTM device domain descriptions on December 4, 2012.

This paper describes the application of the new SDTM device domains to model clinical data arising from the study of implantable medical devices in a variety of therapeutic areas. The devices may differ substantially from each other in their design, mode of action, material composition, location of administration, planned duration in the body and delivery/surgical procedures. The data from the study of these devices embody, in large part, the spectrum of clinical data produced by non-electronic implantable devices. It is hoped that, by applying the new standards to these data, we can inform the process of modeling device data in the SDTM, identify deficiencies in the collection and reporting of current data, and aid future endeavors in this new area.

As part of our research, the authors have applied the new device SDTM standards to study data obtained from studies of several medical devices, but the observations made and methodologies proposed can apply to a wide range of therapeutic areas. This paper focuses on the way the SDTM standards can accommodate 1) data from devices that may require multiple implants within a single patient, and 2) data for device observations and adjustments, both at the time of implant and multiple adjustment procedures after implant or placement. Examples of multiple placement include devices implanted or placed at the same time (e.g., spinal fixation devices placed on multiple vertebrae or dermal fillers implanted in multiple facial regions), devices placed bilaterally (e.g., ophthalmic implants placed in the right and left eye, orthotics placed on the right and left foot, or breast implants placed in the right and left breast), or multiple devices placed sequentially (e.g., urinary catheters, venous infusion sets, external insulin pump cannulas or disposable in-dwelling glucose sensors). Multiple follow-up procedures after placement are common in devices where adjustment of treatment parameters are made over time in order to maximize therapeutic benefits, and include cardiac pacemakers and defibrillators, gastric banding for weight loss, and external insulin pumps.

In this manuscript, where possible, domain names will be referenced by their name followed by the two letter domain code in parentheses, *for example,* Device Properties (DO); SDTM variables will be referenced by their names, in capital, followed by labels in parentheses, *for example* USUBJID (Unique Subject Identifier); and potential values for a variable will be put in quotes (*e.g.,* "size").

IMPLANTABLE DEVICE STUDY DATA AND THE STUDY DATA TABULATION MODEL

In an implantable device study, most of the standard clinical data (demographics, disposition, adverse events, etc) will be covered by the existing SDTM model, version 1.4. Some device-related data fall outside of this model, however, since it was developed initially for pharmaceutical studies. These data can be captured by the proposed domains of the SDTM device supplement. SDTM device domains all contain descriptive data concerning the device(s) under study and can, in some domains, also contain subject data. In some instances, existing SDTM domains, such as AE(Adverse Events), can directly relate to device data. For an excellent review of the structure of the device domains and their relationships with the existing SDTM and each other, refer to Chapter 2 of the SDTM Implementation Guide for Medical Devices.

NEWLY PROPOSED SDTM DEVICE DOMAINS

The device supplement model is divided into seven domains. As discussed below, the Device Identifiers (DI), Device Properties (DO) and Device-Subject Relationship (DR) domains describe the devices and their relationship to the subjects in the study. Device Exposure (DX) and Device-in-Use(DU) domains describe the deployment of the devices. Device tracking and disposition(DT) and Device Events(DE) record tracking and any events that occurred to the devices.

Device Identifiers (DI) domain

The DI domain contains the information necessary for identifying device units and defines SPDEVID, which is a primary key for the inventory of devices. SPDEVID is a unique identifier variable which is required in all of the device domains. It is essential for device tracking and accountability and for the Device-Subject Relationship.

Each DI record requires a DIPARM and DIPARMCD (Device Identifier Name) which specify the level of granularity (e.g., Type, Manufacturer, Model, Serial Number) etc. and DIVAL (Device Identifier Value) which specifies the value for that identifier name. In this way, a natural key consisting of a group of multiple device information records can be related to SPDEVID. At the least, each SPDEVID (Unique Device Identifier) must have one record in which DIPARMCD equals "TYPE". In this record, DIVAL (Device Identifier Value) specifies the type of device being studied.

Table 1 is an example of Device Identifiers records for a single medical device implant unit:

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	BR12A	DI	ABC034	1	TYPE	Type	Catheter
2	BR12A	DI	ABC034	2	MANUF	Manufacturer	BII
3	BR12A	DI	ABC034	3	CAT	Catalog Number	A28-120355
4	BR12A	DI	ABC034	4	LOT	Lot Number	ZY9876

Table 1. Sample DI records for single medical device implant unit

Device in Use (DU) Domain

The Device In Use Domain captures device settings that are intentionally set within the study. Many implantable devices do not have adjustable settings which are captured in the DU domain. This domain may be more relevant to devices which reside outside the body, such as diagnostic instruments, than to implantable devices.

Device Exposure (DX) Domain

The DX domain contains the information related to a subjects' exposure to a device, usually the device under study. It is analogous to the Exposure (EX) domain for pharmaceutical study treatments in the main SDTM. As in EX, DX specifies the name of the investigational treatment (*e.g.,* Breast Implant); the dose of the treatment (normally set to 1 to reflect the number of implanted devices, where dose does not apply); the dose regimen (*e.g.,* the length of time implanted); the category of treatment, such as active comparator; the location (e.g., right Breast); the route (e.g., surgical implantation); the start date (expected or actual); and end date of treatment. The EX variables, EXDOSFRM (Dose Form), EXTRTV (Treatment Vehicle) and EXLOT, do not have counterparts in the DX domain. DXMETHOD (Method of Device Exposure) is a newly added variable in the DX domain. An example for DXMETHOD is "catheter".

Figure 1 shows a comparison of the EX and DX domains, including a selection of their variables.

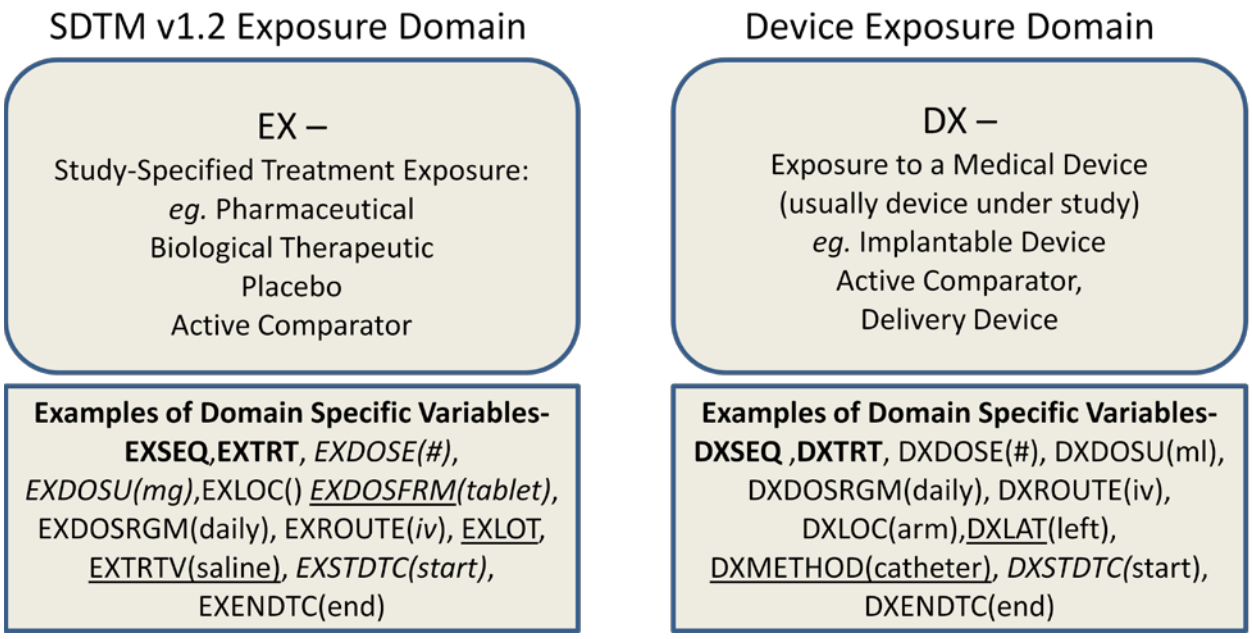

Figure 1. EX and DX domain-specific variables. Required variables are shown in bold. Expected variables are italicized. Variables which are not common between the two domains are underlined. Examples of responses to the variables are shown in parentheses.

Device Events (DE) Domain

The DE Domain reports all events that occur to the device while it is under study. DE primarily specifies device malfunctions but could also specify other types of events, such as maintenance or adjustment. The main DE variables include DETERM (Device Event Name), DEMODIFY(Modified Device Event Name), DEDECOD (Device Events Dictionary Derived Term), DEPRESP (Y/N flag specifying whether a specific event was solicited on the Case Report Form - CRF), DEOCCUR (Y/N flag specifying whether a solicited event occurred), DESEV(Event Severity), DEANDE (Action Taken), DESTDTC (Start Date/Time of Device Event),DEENDTC (End Date/Time of Device Event).

Device Tracking and Disposition (DT) Domain

The DT domain provides device accountability throughout the study.

According to the SDTM Implementation Guide for Medical Devices, devices can be tracked through events such as shipment, deployment, return, destruction, loss, etc. If this domain is populated there should be at least 1 unit in this domain for every tracked unit of the device. The last record for a given device represents the final disposition of the device.

The level at which devices can be tracked (by unit, by lot, by batch, etc.) is determined by the granularity of the information used to create the SPDEVID in the DI domain.

Device –Subject Relationships (DR) Domain

The DR domain keeps track of all subjects and their device(s). There are only three variables in this domain, STUDYID, USUBJID and SPDEVID. There is one record for each device-subject combination in the study. One:many or many:many relationships between USUBJID and SPDEVID can account for situations where more than one device is used for each patient (common) or where the same device is used in multiple patients (rare). According to the SDTM-Device Supplement Implementation Guide, the purpose of this domain is to create an index of the device/subject association. This permits other domains to determine the correct associations without having to store relationship data in every domain.

Here is an example of the DR records for one patient implanted with two devices:

Row	STUDYID	USUBJID	SPDEVID
1	BR12A	BR12A-05-123	ABC034

Row	STUDYID	USUBJID	SPDEVID
2	BR12A	BR12A-05-123	ABC075

Table 2. Sample DR records for a study patient implanted with two devices.

Device Properties (DO) Domain

The DO domain contains information about the properties of a device that are not necessary to identify it. There should be at least one record per property. DOTEST(Device Property Test Name) and DOPARMCD(Device Property Short Name) specify the property. Valid responses to these variables can include any device property relevant to the study. Examples range from "mesh size" to "software version". DOORRES gives the value for the property And DOORRESU gives the unit for that value.

MAPPING DEVICE-RELATED CLINICAL DATA TO THE NEWLY PROPOSED DOMAINS

General considerations in the mapping of the device data

The majority of our device-related study data was captured easily by the current SDTM device model. The features of each domain which in general work well for this data modeling exercise are discussed below. Of the data which didn't fit well, most belong to special attributes of devices similar to the examples described above. These data, the challenges they represent in modeling, and the potential solutions to these challenges for each area are described in the three following subsections.

The implantable devices we have studied require six of the seven domains for a full description of the clinical data. However, DU, which captures settings made to the device prior to implant, may be essential for other types of implantable devices, such as an electronic pacemaker. In general, the SDTM parameter/value variable construct (e.g., DOTEST/DOORRES, DIPARM/DIVAL) is extremely powerful for including features of the data which were not anticipated by the initial model. The qualities of the SDTM device domains which worked well for our purposes are discussed below. Of these, the Device-in-Use (DU) domain, is the least used for non-electronic implantable device data.

Device Identifiers (DI) and Device Tracking (DT) domains work well for the identification and accountability of our study-related devices. The DIPARM (Device Identifier Element Name) and DIVAL(Device Identifier Element Value) combination can uniquely specify a device by a combination of various means- serial number, lot identifier, batch identifier, model, manufacturer, type, etc. Using these separate values for DIPARM, one can specify multiple levels of granularity for different device types and easily specify a SPDEVID which is appropriate in each case.

The special-purpose Device-Subject Relationship (DR) domain is an organizational tool which, as it name implies, keeps a record of the devices that are associated with a patient at any point during the study. It provides a useful link between the device domains and the main SDTM subject data. Given that it has only three variables, it has a straightforward structure and is simple to implement.

Device Properties (DO) contains the device structural and functional properties that are not required for identification in the study. It is therefore a repository of information which can be correlated to device effectiveness and safety at the end of the study. It has a relatively free format compared to the other device domains and can accept a wide variety of data.

During the implementation of the Device SDTM, issues come up which are common to many therapeutic areas. In particular, procedural data and delivery device data are not well represented in this version of the device SDTM. To capture this type of information easily we added a surgery domain, SG, which is dedicated to device-related procedural data. This custom domain is discussed in the section below, "Alterations to Newly-Proposed Device SDTM Domains".

Mapping data from post-implant adjustment procedures and device events in the device SDTM

For devices that may undergo multiple post-implant adjustment procedures, DI (Device Identifier): SPDEVID (Unique Device Identifier) can be mapped from the Device serial number. Note that there may be some extraneous information, such as an accessory serial number, that is captured on the CRF for some patients. This information was deemed to be not required for mapping.

For the DU (Device in Use) domain, the initial setup of the device may or may not be required to be recorded. For example, during implant surgery, the surgeon may adjust the device as per patients physiology, however the postoperative adjustments may be done following a protocol-based algorithm. In these cases, the DU domain cannot be mapped from the available procedure data.

DX (Device Exposure): For many medical devices, multiple post-implant device adjustments are done based on physical examination and subject input (e.g., adjusting stimulation parameters of a spinal cord stimulator for pain

management, or adding or removing saline from a gastric band to achieve optimal weight loss). The following is a hypothetical example of the device exposure records for a single patient who is initially implanted with a gastric band, and subsequently receives two adjustments consisting of injection of saline via an access port.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXTRT	DXDOSE	DXDOSU
1	BD01	DX	1001	123456	1	Saline	0	mL
2	BD01	DX	1001	123456	2	Saline	4	mL
3	BD01	DX	1001	123456	3	Saline	3	mL

Row	DXSTDY	DXROUTE	DXDOSRGM
1 (Cont.)	4/1/2010	Access Port	Initial
2 (Cont.)	7/15/2010	Access Port	Adjustment
3 (Cont.)	11/1/2012	Access Port	Adjustment

Device Events (DE): If a device is not successfully implanted then various reasons may be captured on a device observations CRF. The information collected may include the time interval of observation, the relation of the observation with any of the components of the device or placement procedure, such as a surgical introduction tool or manipulation handle, the main device, or an accessory or other part of the device such as tubing, electrical leads, anchors or a device remote control unit. Further details of the device observation may include maintenance of the device (such as charging or replacing batteries, or damage to the main device or any of its components.) Some procedure-related observations, such as the suturing of the device, or positioning of a component correctly could not be mapped into proposed domain, as it was unclear whether the device or patient's physiology caused any problems while implanting the device in patients. The following example shows hypothetical device events observed during the placement and maintenance of a pacemaker in two patients.

STUDYID	DOMAIN	USUBJID	SPDEVID	DESEQ	DETERM	DEDECOD	DECAT	DEDTC
BD01	DE	1001	123456	1	Battery Depleted	BATDEP	Equipment Failure	2010-04-01
BD01	DE	1001	123456	2	Lead Broken	LEADBRK	Equipment Failure	2010-04-01
BD01	DE	1002	121212	1	Pacing Unit Not Responding	PACEFAIL	Equipment Failure	2010-06-01
BD01	DE	1002	121212	2	Placement Tool Broken	PLCTOOLBRK	Equipment Failure	2010-06-01

DT (Tracking and Disposition) – In the case of a device requiring subsequent surgery, the status of the implant may include whether it was explanted with replacement or without replacement, or may simply capture that it was revised without being explanted. We could track such device events based on the serial number i.e. SPDEVID (Unique Device ID)

DR (Device Subject Relationship) – the information from all other domains can be mapped to this domain.

STUDYID	USUBJID	SPDEVID
BD01	1001	123456
BD01	1002	121212
BD01	1003	123123

Mapping data unique to bilateral implants in the device SDTM

Device Identification (DI), DeviceTracking (DT) and Device-Subject Relationship (DR) are straightforward in the case of most implanted devices. In the DI domain, Model Number and Lot Number provide a natural key for the unique device identifier, SPDEVID. The device-subject relationship is usually one to one for single-implant devices, and two devices to one patient in bilateral implants, although there are exceptions in both cases.

Since patients can have two devices implanted or utilized, such is often the case with breast implants and ophthalmic treatments, it is necessary to account for devices and keep track of data by implant as well as by patient. In this case, the side designation, L or R, provides an easy way to define each device within a patient. After implantation, the side designation is crucial to relate potential device events to the proper device and, in the case of a patient having only one implant, to determine whether localized adverse events (i.e., events occurring only on one side) are device-related.(See The Importance of Sidedness in Bilateral Implant Studies section, below.)

Two specific attributes of device events were not captured easily by the DE domain. These are the degree of confidence in the event (e.g., the occurrence of an event may be suspected or confirmed) and the source of the report (e.g., the event is reported by the patient, by the treating physician, or based on an objective measure such as

an radiologic image). An example of this type of event is the rupture of a breast implant. Rupture may or may not be accompanied by an adverse event, may be reported by patient or physician, and may be suspected, or confirmed based on a diagnostic image such as an MRI, or by explant of the device. All of these observations should be captured as part of the rupture description so that a confirmation and/or confidence level can be assigned to the event. Events may be detected by observation via patient, physician, local MRI reviewer and explant. Each of these types of observations will have different confidence levels, such as “suspected” or “confirmed positive” or “confirmed negative”. Observations typically proceed through physician detected, MRI and explant and should be recorded as a set of observation in order to understand the confidence level associated with the device event. Additional Device Event parameters may be required in order to describe these attributes properly .

Mapping data unique to injectable medical devices in the device SDTM

Injection is a common route of administration for pharmaceutical drugs. Medical devices may also be implanted via injection. Examples of injectable implants include hyaluronic acid (HA) for the treatment of osteoarthritis, dermal fillers for augmenting facial characteristics, cement bone substitutes, and biomaterials such as sponges for delivery of biological therapeutics.

Clinical trials of injectable medical devices can be randomized or nonrandomized, and, if randomized, may be single-blinded or double-blinded. In randomized studies, the control arm could either be a 'No treatment' or an active control group. Treated patients will typically have an (Lemperle et al, 2010) initial treatment, and may have optional supplemental treatments to achieve for optimal therapeutic effect. Finally, treatments may be repeated at some later timepoint once the patient has completed a specified amount of time in the study.

Many injectable medical devices are shipped in a pre-filled syringes, to which a syringe needle is then attached to perform the implantation. As a result, it may be necessary to capture both the syringe and the needle used as separate device records. In this case, the needle is considered a delivery device for the implant and is mapped in the Device Identifier (DI) domain.

Device Identifier Domain:

Syringes, filled with implant material, are identified through lot numbers. Patients may receive multiple syringes in the course of a single treatment (resulting in multiple lot numbers). Type and manufacturer are two variables mapped to the DI domain for the device.

The following example shows how the device and two possible delivery devices (two sizes of needles) could be mapped to DI.

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
AGN02	DI	DF001	1	TYPE	TYPE	IMPLANT
AGN02	DI	DF001	2	MANUF	MANUFACTURER	COMPANY1
AGN02	DI	ND001	1	TYPE	TYPE	NEEDLE
AGN02	DI	ND001	2	MANUF	MANUFACTURER	COMPANY2
AGN02	DI	ND001	3	MODEL	MODEL NUMBER	25G
AGN02	DI	ND002	1	TYPE	TYPE	NEEDLE
AGN02	DI	ND002	2	MANUF	MANUFACTURER	COMPANY2
AGN02	DI	ND002	3	MODEL	MODEL NUMBER	29G

Device Exposure Domain:

Most of the treatment variables are mappable to the DX domain, with the exception of a few variables which are specific to injectable devices. The treatment dataset captures the device identifier, SPDEVID. We chose to use DXDOSE and DXDOSEU to specify the volume injected. Other exposure variables capture the specifics of the treatment, such as total number of syringes used, type of needle used, the location of injection, the depth of injection, injection start and end time, as well as multiple techniques used for implantation. These variables were not easily mapped to the current DX domain. However, they can be addressed in the custom surgery domain (SG) discussed below.

Our attempt to map the treatment dataset to DX domain is shown below. The Treatment event is mapped to DXDOSRGMN and can have values such as “Initial” or “Repeat”. We chose to use the DXROUTE variable to map the “plane of injection”. DXDOSE is used to capture the Volume of device injected, DXLOC variable represents the location of the treatment. Depending on the Indication, Treatment Region could have multiple subregions. For example, in a study involving treatment of the lips, there can be multiple lip regions (Lemperle et al, 2010) e.g.: Upper Lip, Lower Lip etc,.Thus the DXLOC can have values like ULREG1, ULREG2, LLREG1, LLREG2, REG3, REG4 etc, with UL- and LL- referring to the upper lip and lower lip, respectively, and –reg1 though –reg4 referring to regions

within the lip area. In order to calculate total volumes injected within a particular region such as UL, we use the variable DXGRPID to group together multiple subregions.

The Mapping to DX domain would look this way:

STUDYID	DOMAIN	SPDEVID	USUBJID	DXTRT	DXDOSRGM	DXSEQ	DXGRPID	DXLOC	DXROUTE	DXDOSE	DXDOSEU	DXMETHOD
AGN02	DX	DF001	PT-001	DF01	INITIAL	1	UL	ULREG1	PLN1	6	ML	NEEDLE
AGN02	DX	DF001	PT-001	DF01	INITIAL	2	UL	ULREG1	PLN2	6	ML	NEEDLE
AGN02	DX	DF001	PT-001	DF01	INITIAL	3	UL	ULREG2	PLN1	6	ML	NEEDLE
AGN02	DX	DF001	PT-001	DF01	INITIAL	4	UL	ULREG2	PLN2	6	ML	NEEDLE
AGN02	DX	DF001	PT-001	DF01	INITIAL	1	LL	LLREG1	PLN1	4	ML	NEEDLE
AGN02	DX	DF001	PT-001	DF01	INITIAL	2	LL	LLREG1	PLN2	4	ML	NEEDLE
AGN02	DX	DF001	PT-001	DF01	INITIAL	3	LL	LLREG2	PLN1	4	ML	NEEDLE
AGN02	DX	DF001	PT-001	DF01	INITIAL	4	LL	LLREG2	PLN2	4	ML	NEEDLE

Injection treatments may also include other procedures, such as the use of a topical anesthetic. Type of anesthesia is not captured in the DX domain, but may be captured in the custom surgery domain (SG) discussed below.

ALTERATIONS TO PROPOSED DOMAINS

For the most part, data from device-related clinical studies map into the proposed device domains in a straightforward manner. In the case of some implantable devices, however, slight changes to the model are necessary in order to properly account for specific features of the devices or their associated device events and procedures. These modifications encompass: 1) the inclusion of sidedness (laterality) in the description of location and 2) the inclusion of procedural information, which could easily constitute its own domain. The two points above were submitted as comments during the public comment period.

The response to the comment about sidedness was that CDISC includes the concept of laterality. A variable, DXLAT, was added to the DX domain in the subsequent Provisional version of the SDTM Implementation Guide for Medical Devices, presumably to account for this laterality concept.

The response to the comment about procedural data mentioned that “info related to surgery or procedure has been discussed and that a domain may be developed for these data in the future”. It was suggested that, in the meantime, a custom domain could be used to fill this gap. The following sections introduce a custom surgery domain (SG) to handle surgery and procedural data.

The Importance of Sidedness in Bilateral Implant Studies

Using a Side Designator to Capture Safety Events at the Implant Level

For clinical studies which involve more than one implant per patient, it is necessary to associate safety data with each device implanted. For bilateral studies, a single variable should be used to designate the lateral location (“Left” or “Right”) of each implant. This facilitates the capture of adverse events or device complications (*eg* first occurrence, incidence, and prevalence) at the implant level.

Using a Side Designator to Capture Device Relatedness for Bilateral Implants

As in other implantable device studies, device-relatedness is an important feature of adverse event reporting. Using the side designator, data can be merged between datasets and implant identity, adverse events, device events, action taken, etc, can be properly associated. Thus, the side designator contributes to the continuity of data between domains and helps to track device-related events.

Using a Side Designator to Mask Data in a Bilateral Study Design

Medical devices requiring multiple implants, most often those utilizing bilateral implants, (e.g., treatments of both eyes, both sides of the face, both breasts, or both knees) may be studied using a within-subject design, in which an investigational treatment is used on one side, and a comparator treatment is used on the alternate side. For bilateral studies of this type, it is important to have a single variable to keep track of study devices – treatment on one side, and an active comparator product on the other. Randomization of treatment is based on laterality in these studies and could therefore be masked more easily with a side variable. For example, DXLOC (Location of Device Exposure)

would not need to be masked as long as it does not include lateral information. The comparison of the test article versus active comparator could then be fully masked using a single variable. As an extension, in a case where there are many locations for exposure, the actual location can remain unmasked in the study data as long the side designator variable is masked.

Custom Surgery and Procedure Domain (SG) for Capturing Procedure-related Information

Implanted Devices may require surgery or delivery by a hypodermic needle. Since device-related adverse events can arise directly from the implantation procedure itself, it seems logical that all relevant procedural data should be captured by the SDTM. Procedural data cover the delivery devices used, details of the surgical method, and other important aspects of the deployment of the device. Procedural data is just part of the Time-of-Implant data (Figure 2) for a device study.

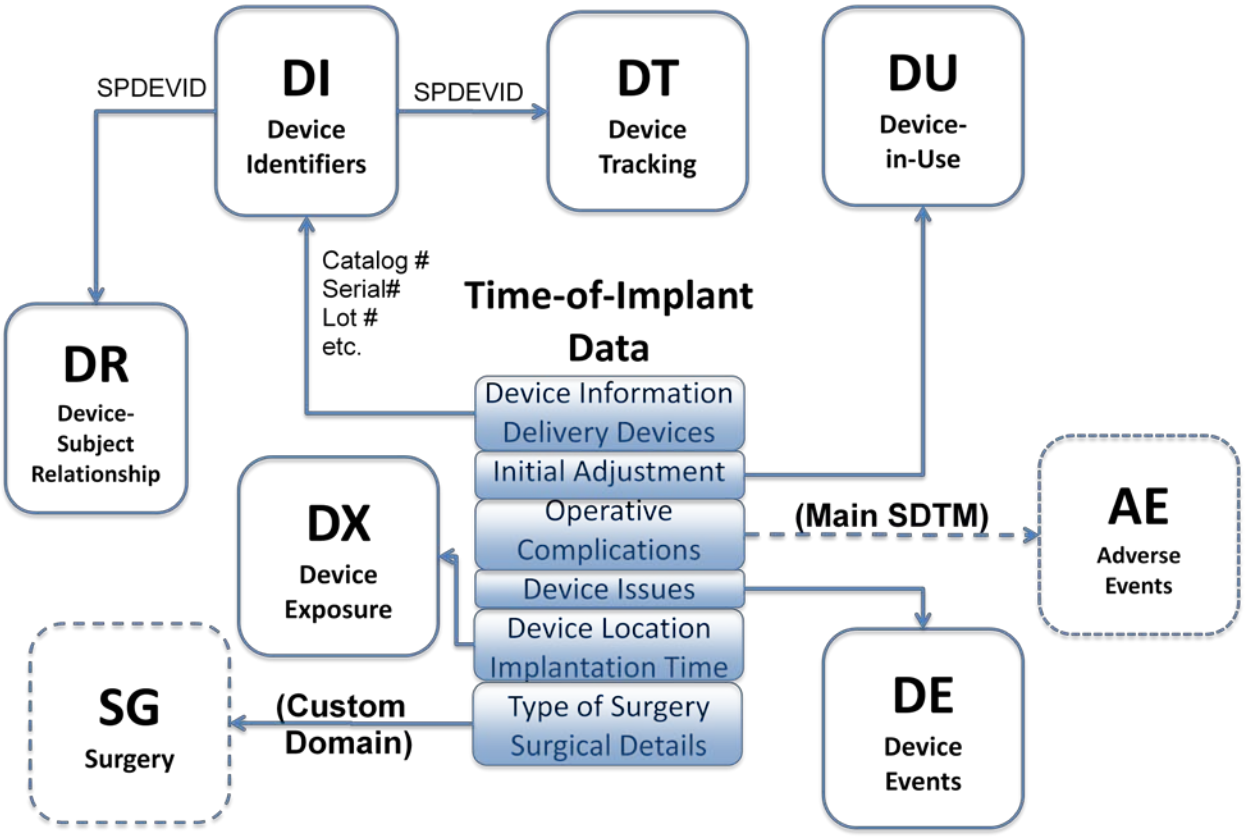

Figure 2. Mapping time-of-implant data into SDTM domains.

From figure 2, it is apparent that most time-of-implant information fits well within existing device domains, some data may be appropriate for the main SDTM domain, AE, and some procedural data calls for a custom domain, SG, which could accommodate various surgical details.

Because implantation surgeries, or other delivery procedures, vary significantly as a function of therapeutic area, the relevant surgical details are quite varied. The newly proposed Device Exposure (DX) domain, having evolved from the Exposure (EX) domain in the main SDTM model (see figure 1), has few delivery specific variables. DXMETHOD is one variable that is added to the new domain that accommodates the type of device used (eg catheter or, in the case of dermal fillers, hypodermic needle). DXLAT is another newly added device specific variable (see above). However, to model all of our procedural data properly, the addition of a custom domain pertaining to surgical and procedural details is necessary. This custom domain can accept several types of surgery and procedure information. Variable definitions for the custom SG domain are shown in Table 3.

Variable Name	Variable Label	Type	Role	Notes	Required, Permitted, or Expected

Variable Name	Variable Label	Type	Role	Notes	Required, Permitted, or Expected
STUDYID	Study Identifier	Char	Identifier	Unique Identifier for a Study.	Required
DOMAIN	Domain Abbreviation	Char	Identifier	The two letter abbreviation for the surgery domain is SG.	Required
USUBJID	Unique Subject Identifier	Char	Identifier	Identifier used to uniquely identify a subject .	Required
SPDEVID	Sponsor Device Identifier	Char	Identifier	Sponsor-defined identifier for a device associated with the procedure.	Permitted
SGSEQ	Sequence Number	Num	Identifier	Sequence number given to ensure uniqueness of subject records within a domain.	Required
SGGRPID	Group ID	Char	Identifier	Used to tie together a block of related records for a single subject within a domain.	Permitted
SGSPID	Sponsor-Defined Identifier	Char	Identifier	Sponsor defined reference number.	Permitted
SGTRT	Name of Treatment	Char	Topic	Name of procedure or type of surgery.	Required
SGCAT	Category for Treatment	Char	Grouping Qualifier	Used to define a category of related records for the procedure	Permitted
SGSCAT	Category for Treatment	Char	Grouping Qualifier	A further categorization of the procedure	Permitted
SGLOC	Location of Procedure	Char	Record Qualifier	Specifies site of procedure (eg breast)	Permitted
SGLAT	Side of Procedure	Char	Record Qualifier	Specifies side of procedure (eg left)	Permitted
SGTECH	Procedural Technique	Char	Record Qualifier	Specifies primary technique used in procedure (eg fanning)	Permitted
SGSTDTC	Start Date/Time of Procedure	Char	Timing	The time/date that the procedure or surgery indicated by SGTRT began.	Expected
SGENDTC	End Date/Time of Procedure	Char	Timing	The time/date that the procedure or surgery indicated by SGTRT ended.	Permitted
SGDUR	Duration of Procedure	Char	Timing	Collected duration and unit of procedure. Used only if collected on the CRF and not derived from start and end date/times	Permitted
SGHOSP	Type of Surgical Facility	Char	Record Qualifier	Type of surgical facility (eg. Doctor's Office, Hospital, or Free Standing Surgical Facility)	Permitted
SGHOSPN	Name of Surgical Facility	Char	Record Qualifier	Verbatim name of surgical facility	Permitted
SGHOSPA	Address of Surgical Facility	Char	Record Qualifier	Verbatim address of surgical facility	Permitted
SGPARMCD	Surgical Parameter Short Name	Char	Topic	Short name of the surgical or procedural parameter. Limited to 8 characters (eg.ANAESTH)	Permitted
SGPARM	Surgical Parameter Name	Char	Synonym Qualifier	Verbatim name of the surgical or procedural parameter (eg Type of Anaesthesia)	Permitted
SGVAL	Surgical Parameter	Char	Result Qualifier	Value of Surgical parameter (eg Local)	Permitted

Table 3. Definition of variables in SG custom domain

The SG custom domain accepts the data stemming from an implantation procedure for a device. Since adverse events may be associated with the procedure itself, it is important that surgical details are captured effectively.

Several surgery-specific variables (e.g., SGTRT, SGTECH, SGHOSP) are included in the domain. Additionally, the generic variable pair, SGPARM/SGVAL, provides a convenient method for documenting features unique to a given therapeutic area.

The following are example records to illustrate the use of the SG domain:

STUDYID	DOMAIN	USUBJID	SPDEVID	SGSEQ	SGGRPID	SGTRT	SGLOC	SGLAT	SGSTDTC
BR12A	SG	1001	123456	1	1	augmentation	breast	right	2008-12-09T14:16
BR12A	SG	1001	123456	2	1	augmentation	breast	right	2008-12-09T14:16
BR12A	SG	1001	123456	3	1	augmentation	breast	right	2008-12-09T14:16
BR12A	SG	1001	123456	4	1	augmentation	breast	right	2008-12-09T14:16
BR12A	SG	1001	123457	1	2	augmentation	breast	left	2008-12-09T14:16
BR12A	SG	1001	123457	2	2	augmentation	breast	left	2008-12-09T14:16
BR12A	SG	1001	123457	3	2	augmentation	breast	left	2008-12-09T14:16
BR12A	SG	1001	123457	4	2	augmentation	breast	left	2008-12-09T14:16

SGENDTC	SGHOSP	SGHOSPN	SGPARMCD	SGPARM	SGVAL
2008-12-09T15:55	Hospital	Community Hospital	ANAESTH	Type of Anaesthetic	Topical
2008-12-09T15:55	Hospital	Community Hospital	DRAINS	Drains Placed	Yes
2008-12-09T15:55	Hospital	Community Hospital	INCISION	Incision Site	Inframammary
2008-12-09T15:55	Hospital	Community Hospital	IMPLOC	Implant Location	Submuscular
2008-12-09T15:55	Hospital	Community Hospital	ANAESTH	Type of Anaesthetic	Topical
2008-12-09T15:55	Hospital	Community Hospital	DRAINS	Drains Placed	Yes
2008-12-09T15:55	Hospital	Community Hospital	INCISION	Incision Site	Inframammary
2008-12-09T15:55	Hospital	Community Hospital	IMPLOC	Implant Location	Submuscular

Table 4. Sample SG domain records for a bilateral breast implant operation.

CONCLUSION

We find that the structure of the proposed CDISC device domains fits implantable device data well. The domains, Device Identifiers (DI), Device Exposure (DX), and Device Events(DE), accept the majority of device related information. The remaining challenges arise chiefly from the special attributes of implantable device classes such as multiple implantation of devices per person, injectable biocompatible materials as devices, devices with multiple parts, multiple delivery devices, etc. In some domains, where there are not predefined variables directly corresponding to these special cases, the structure is generalizable and can handle unanticipated data. For instance, the DOTEST/DOORRES variable pair is a construct which can accept many different device properties according to the needs of the study. The DX domain does not have a corresponding variable pair (ie DXPARM/DXVAL) and the type of exposure-related information captured by this domain is more generic and not specific for each device.

Relative to pharmaceutical studies, device studies have a wealth of surgical and procedural data that needs to be recorded. This amount of data is large enough to warrant its own domain. Therefore, we developed a custom SDTM domain, SG, to accommodate the device-related surgical and procedural data. In this “surgery” domain, we included the variable pair, SGPARMCD/SGVAL, which easily handles the variety in procedural data.

In the public comment period of the proposed device supplement, we suggested a side designator variable to be added to the device exposure (DX) domain. Ideally, the lateral designation should be a separate variable specifying only the implanted side for the device and should not be coded as part of another variable, such as location. The Provisional version of the supplemental implementation guide has included such a variable, DXLAT. This permitted variable is extremely useful for bilateral studies. In a subject who receives different treatments to each side of the body (e.g., eye, face or knee), the side designator is sufficient to specify whether the exposure is a study treatment or active comparator. The DXLAT variable is also useful for keeping track of adverse events or device events at the implant level. Although not currently included in the Provisional domain descriptions, similarly named --LAT variables, in the DI, DE and DU domains, would provide continuity of lateral information between the device domains.

Implantable devices have varied applications, taking on electronic, biomechanical, aesthetic, and structural roles in the body. We have been able to model implantable device clinical data, both straightforward and not so straightforward, using the proposed device domains, sometimes with modification. We find that the SDTM device domain model is robust and very useful to those working in the implantable device area.

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RECOMMENDED READING

- Regulatory Submissions for Medical Devices and Diagnostics: The Basics, C.G. Smoak CDISC Journal, October 2011.

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