PharmaSUG2012 – DS05

Seven New SDTM Domains for Medical Devices

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ABSTRACT

Medical devices are an important part of the healthcare industry, and device approvals (PMAs) by the FDA increased by more than 50% from 2000 to 2009. In May 2006, an SDTM Device sub-team was formed. This team was expanded in February 2009 to include CDASH team members. The goal of this Device sub-team is to develop a set of content standards for a core set of data collection fields and submission datasets. Towards that goal, seven new SDTM domains have been developed: Device Identifiers (DI); Device Properties (DO); Device In-Use Properties (DU); Device Exposure (DX); Device Events (DE); Device Tracking and Disposition (DT) and Device-Subject Relationships (DR). Several new SDTM variables (including identification of the device under study) will be needed for these seven new SDTM domains.

INTRODUCTION

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 have widely varying data requirements, most Class II and III (see Smoak 2010 for definitions of Classes I, II and III) devices requiring regulatory data submissions share some fundamental characteristics. This paper describes the Study Data Tabulation Model (SDTM) regulatory data submission standards for some key data shared by most types of devices and is intended to describe the organization, structure, and format of standard device clinical trial tabulation datasets**.** Furthermore, this paper introduces seven new SDTM domains, showing rules and examples on implementing these domains specifically for devices. This paper does not discuss domain also used in drug and biologics studies (e.g., Adverse Events, Demographics) since these have been previously described in the SDTM Implementation Guide (available for download at www.cdisc.org).

The data elements and domains defined in this paper are those 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 (CRFs) that are completed by investigative sites or derived by sponsors. Also included are some non-clinical data definitions, such as Device Events and Device Tracking and Disposition information. Other data needed for the submission, such as manufacturing quality information, may be included in other sections of the submission, but have not been included in any SDTM-based domains to date.

Most device submissions today are paper-based. SAS transport files and define.pdf files may be submitted to CDRH, the define.pdf file submitted to CDRH may not be hyperlinked to SAS transport files and blank CRFs as it would be for a submission to either CDER or CBER. Therefore, this effort to define new device domains seeks to develop collection and submission standards to support electronic submission of data for PMAs, 510K and Biological License Applications (BLAs).

For further information, please refer to previously published papers on CDISC for medical devices which include the following:

- differences between medical devices and pharmaceutical products and the goals of the CDISC devices

team (Smoak 2007)
- early domain design of device properties and the unique device identifier (Smoak 2008)
- FDA approval/clearance process for medical devices, the growing importance of medical devices in the healthcare industry and types of medical devices studies needed for approval/clearance (Smoak 2010)
- comparison of medical device CRFs with CDASH standards (Shiralkar et al 2010)

DOMAIN REVIEW

Medical device 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 those in typical drug development studies. This necessitates developing a level of relationship structure that is not typically required in most subject-related data (e.g., including the Device-Subject Relationship domain).

Seven new SDTM-based domains are described below. As of the publication of this paper, these domains have undergone a public review, and comments from the public review are being reviewed by the CDISC Devices Team. Once the comments have been addressed, the domains will be finalized and posted on the CDISC website (www.cdisc.org).

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 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. The domain does not contain information about items that can change without affecting the identification of the device, such as dial settings (e.g., imaging devices). Device Identifiers exist independently from subjects and therefore the DI domain does not contain USUBJID.

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, and that 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.

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.

DEVICE EXPOSUE (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.

DEVICE EVENTS (DE)

Device Events 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 to a subject, 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 the SDTM RELREC table.

DEVICE TRACKING AND DISPOSITION (DT)

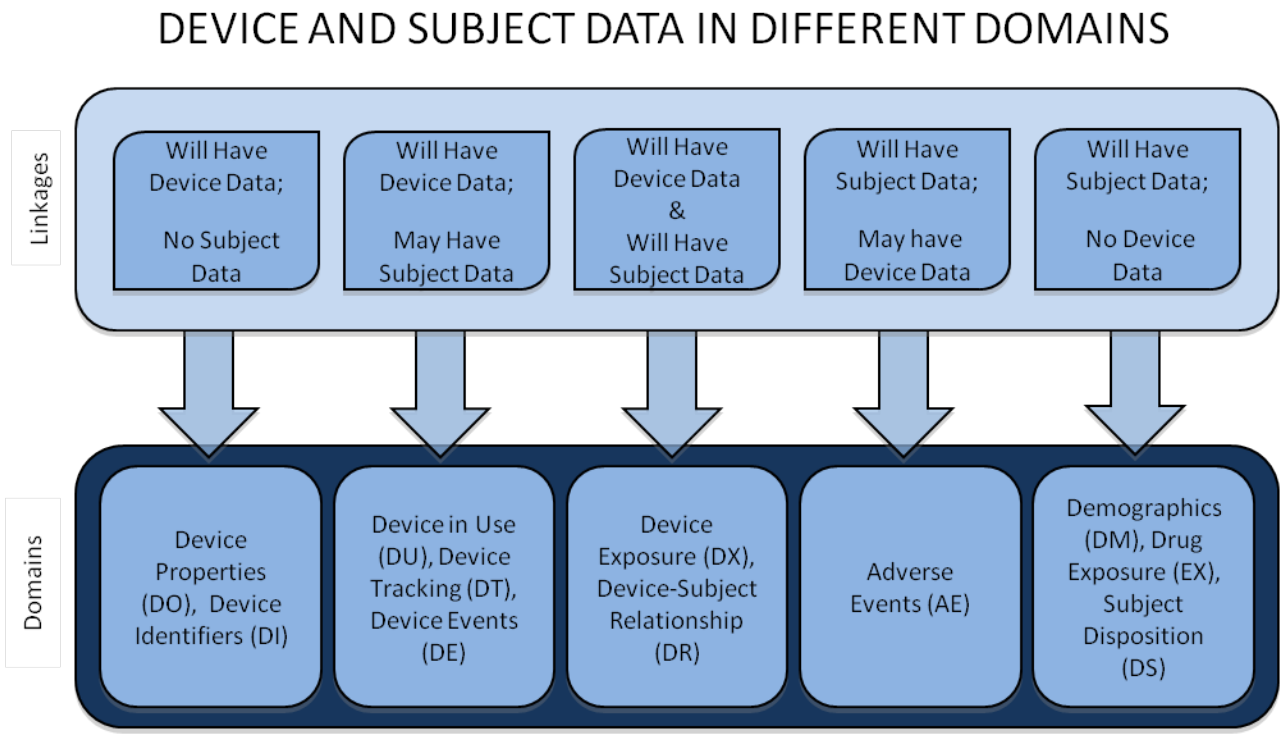
The Device Tracking domain is an Events domain that represents a record of tracking events for a given device. This could include initial shipment, deployment, return, destruction, etc. Different events would be relevant to different types of device. The last record represents the final disposition of the device. 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.

DEVICE-SUBJECT RELATIONSHIP (DR)

The Device-Subject Relationship 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, Device Events); however, this domain 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.

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



CONCLUSION

Devices are an important and growing part of the medical world, both on their own and in combination with drugs or biologic agents. Most device submissions today are paper-based. Therefore, this effort to define new device domains seeks to develop collection and submission standards to support electronic submission of data for PMAs, 510K and Biological License Applications (BLAs). Towards this goal (electronic device submissions), seven new SDTM domains have been developed: Device Identifiers (DI); Device Properties (DO); Device In-Use Properties (DU); Device Exposure (DX); Device Events (DE); Device Tracking and Disposition (DT) and Device-Subject Relationships (DR). Two new SDTM variables (generic and unique device identifiers) will be needed for these seven new SDTM domains.

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