DRAFT DEVICE SUPPLEMENT TO THE SDTM IG V3.1.2
SOON OUT FOR PUBLIC REVIEW

The CDISC device team was originally a SDS sub-team led by Carey Smoak. In 2009 the team was expanded to include other CDISC team members and AdvaMed member device companies. The goal of the team is to identify the basic data collection fields (CDASH), the submission (SDTM) variables, associated metadata and mappings to support the majority of device studies and modalities, i.e. diagnostic devices, implantable devices and imaging devices.

Significant progress has been made and the device team plans to post a draft Device Supplement to the SDTM IG v3.1.2 for a 30-day public review early next year. Once the 30-day public review is completed and all comments have been addressed the first version of Device Supplement to the SDTM IG v 3.1.2 will be published on CDISC.org.

This draft document contains six proposed new SDTM domains that are designed to capture information about medical devices. These domains have been modeled on, and work in concert with, existing SDTM constructs:

1. Device Information (DI): The DI domain is a findings domain that provides a description of immutable key aspects of a specific device.
2. Device in Use (DU): The Device in Use domain represents measurements and settings that are intentionally set on a device when it is used with a subject or other target.
3. Device Exposure (DX): The Device Exposure domain records the details of a subject’s exposure to a medical device under study.
4. Device Events (DE): The DE domain is intended to contain information about various kinds of device-related events, such as malfunctions.
5. Tracking and Disposition (DT): The Device Tracking domain represents a record of all tracking events for a given device (e.g. initial shipment, deployment, return, destruction, etc.).
6. Device Subject Relationship (DR): The Device Subject Relationship domain is intended to contain information that links the subject to the device.

Once this initial device document is published the team will focus on the following next steps:

- CDASH data collection field gap analysis. Based on this analysis, the needed CDASH collection fields will be developed to support the SDTM submission fields.

A device sub-team has completed a foundational CRF-Analysis. This team collected and reviewed ~ 170 device CRFs from 42 device companies. The results of this analysis revealed that the current CDASH domains and collection fields developed for drug trials meet almost all the requirements of medical device trials.
• Controlled Terminology gap analysis. Based on this analysis, the needed device specific terminology will be developed and these new terms will be requested according the terminology change control process located on the NCI-EVS webpage.

The team is comprised of representatives from AdvaMed member device companies, CDISC experts and FDA-CDRH, FDA-CBER. Without the support of FDA, AdvaMed, the volunteers and their sponsoring companies, progress on this evolving and important device standard would not have been possible.

We anticipate that in the coming years there will be a series of continuing enhancements and additions to this initial device standard document. All CDISC community members are encouraged to download the draft document, review and send comments during the public review period. Keep an eye on CDISC.org for the announcement of the commencement of the public review.

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