DEVICE Team
2014 Team Charter

Leadership Team

Kit Howard (CDISC)
Fred Wood (Accenture)
Rhonda Facile (CDISC)
Carey Smoak (Roche Molecular Systems, Inc.)

Team Mission

The Device Team is a cooperative effort between members of the CDISC CDASH and SDS Teams, industry experts, FDA CDRH, and FDA CBER that seeks to define data collection and submission standards for clinical research associated with medical devices.

Stakeholders/Constituency

- Regulatory Authorities
- Standards Development Organizations
- Pharmaceutical Sponsors
- Medical Devices
- Contract Research Organizations & Consultants

Team Characteristics

The Device team includes representatives from other CDISC Foundational Teams and a set of sub-teams representing different facets of the CDISC Device standards.

In addition to the Leadership Team, other key contributors include:
Bob Pearsall, Axon;
Paul Franson, Medtronic (Linking & Components)
Jennifer Duggan, St. Jude Medical
Erin Muhlbradt, NCI-EVS (Terminology Liaison)
Lynn Henley, FDA-CDRH (FDA Liaison)
Priya Gopal, Novella Clinical (ADaM)

Scope

This project is developing collection (CDASH) and submission (SDTM) standards with associated controlled terminology to support electronic submission of PMAs, 510Ks and Biologics License Applications (BLAs). It also supports implementation of CDISC standards for drug/device combination products, and the use of devices in non-device studies (e.g., Therapeutic Area studies).

Current Projects

Address the outstanding issues that were identified during the device CRF analysis; Explore ADaM standards for devices and develop plan; Develop a core set of domains to support diagnostic (IVD) studies; Explore piloting a device submission with CDRH; Develop a solution for linking a device to its components; Develop a solution for linking more than one device and/or drug to an AE; Develop controlled terminology for approved and new device domains.

2014 Deliverables

- Finalized CDASH device domains matching SDTM device domains
- Outstanding CRF analysis issues resolved, documented and implemented where applicable
- ADaM ADDL model (Equivalent to ADSL for subject data)
- Two draft diagnostics (IVD) domains developed
- Solution for linking a device to its components
- Solution for linking more than one device and/or drug to an AE
- Finalized Devices IG v1.1, conversion from Provisional
- Devices IG v2.0

Collaborations

SDTM, CDASH, ADaM, NCI EVS, FDA (CDRH, CBER).

Operating Model & Meetings

The full Device Team meets monthly on Thursdays at 10 am CDT.

Device leadership team meets monthly.

Sub-teams meet monthly, bi-weekly or weekly as needed. The sub-teams are:

- CDASH/CRF
- Controlled Terminology
- Diagnostics domains
- ADaM
- Granularity & Components
- FDA pilot (sponsored by PhUSE)

Project documents are stored on the CDISC team portal located here: www.portal.cdisc.org/Teams%20Projects/DEVICES/