SDTM for Medical Devices

1/2-day or 2 day Course

Language: English

The Study Data Tabulation Model (SDTM) is a specification for the submission of pre-clinical, clinical and device data to the U.S. Food and Drug Administration in support of marketing applications. The SDTM Implementation Guide for Medical Devices (SDTMIG-MD) is used in conjunction with the SDTM and SDTMIG for Human Clinical Trials to support medical device submissions.

CDISC Education offers two options for learning about the SDTMIG-MD standards.

Option 1: 2-day SDTM IG for Medical Devices

This course combines instruction on using the SDTM IG for Human Clinical Trials (the foundational SDTMIG) and device-specific domains and practices. It uses device-based examples to illustrate the key principles of the SDTM model and implementation guide, and covers the device domains in detail. Device-specific implementations of some core domain, such as AEs, are also included.

Topics covered in the 2-day SDTM for Medical Devices course focus on subject-related data and device data, and include:

- SDTM Model
- Demographics Model
- General Observation Classes - Model
- Timing and Grouping
- Creating Custom Domains
- General Observation Classes - Implemented
- Findings About
- Relationships
- Device-specific Domains

Exercises are included in numerous places to reinforce the material.

The course merges the foundational SDTM 2-day course and the Medical Devices ½-day course, and duplicates much of the material in both. Students should take either the 2-day medical device SDTM course OR the combination of the 2 day SDTM course plus the ½-day devices course, but not all three.

Prerequisite: A basic understanding of clinical data flow and relational database design is helpful but not required.
Option 2: ½-day SDTM for Medical Devices

This ½-day course focuses almost exclusively on the medical device domains and the associated implementation guide. Topics include:

- Context and scope of the SDTMIG-MD
- The types of devices covered by the standard
- Differences in use of terminology between drug and device studies
- Full review of the 7 device domains
- Representing device & subject data in different domains

A case-based, hands-on exercise reinforces the use of the 7 device domains.

This course does not cover the basics of SDTM, and assumes the student already has this knowledge.

Prerequisite: 2-day SDTM Theory and Application, or equivalent experience with SDTM. A basic understanding of relational database design and clinical data flow is helpful but not required.

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Source URL: http://www.cdisc.org/device-sdtm-course

Links: