SDTM Theory and Application

2 day course

Language: English

The Study Data Tabulation Model (SDTM) is a specification for the submission of pre-clinical and clinical data to the U.S. Food and Drug Administration in support of marketing applications.

This two-day course consists of:

- A detailed review of SDTM concepts, SDTM-based domain models for human clinical data, relationship tables, and trial design
- A discussion of common implementation issues
- Exercises including the annotation of CRFs and the creation of datasets that reinforce attendees' understanding of the SDTM and the SDTM Implementation Guide for clinical data

Recommendation: A basic understanding of relational database design and clinical data flow is helpful but not required.


SDTM Course Attendee Comments:

"Fabulous instructor! The class was engaging, and very relevant to my current job. We had ample time to ask questions about specific topics from our personal experiences, lots of time for discussion, but still covered the material adequately. Time very well spent!"

-SDTM 'In-House' Private Course on 13-14 Feb 2012

"The instructor was great in explaining the concept of SDTM. She seems very engaged in the subject which made the course much more interesting. She encouraged to ask questions. She was well aware which parts of SDTM that may be unclear and she focused on explaining them in details. I was happy with the course materials provided on a usb stick. It was easier to follow them on computer than browsing through the pile of paper."
"The course did a great job of covering a lot of material in a relatively short amount of time. The instructor was very knowledgeable and took the time to explain things when necessary or questioned. Overall, it was a great course."

-SDTM Public Course in Palo Alto, CA on 12-13 July 2012

"The instructor for this course is to be commended. He was extremely knowledgeable in the subject matter, but also quite comfortable responding to questions whose answer was outside the scope of the training. I have attending many computer-related training classes in over 20 years as a computer programmer, and this was by far one of the most engaging and useful. put the concepts into the context of our specific company standards and process approaches."

-SDTM 'In-House' Private Course on 3 April 2012

"… the training was excellent and was very helpful to me in particular, because of my non-existent exposure to SDTM … I had read the documentation, but none of that information stuck in my head or created a useful picture of the SDTM model for me. The instruction and exercises, although seemingly simple, really solidified my understanding of the model’s ‘macro’ features.

(…another) element that was truly priceless, was getting an understanding of how the documentation is laid out and figuring out where in the documentation to go for answers.

… it was great to have a class with other professionals… Just hearing the discussions and questions gave me ideas and insights into the common problems and what the possible solutions were."

-SDTM Public Course at International Interchange on 22-23 Oct 2012

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

Links: