



SDTMIG v3.1.1 to SDTMIG v3.1.2 Course

Course Benefits

The first benefit of taking this course is to understand the changes that were made between SDTM v1.1 / SDTMIG v3.1.1 and SDTM v1.2 / SDTMIG v3.1.2. The second benefit is to learn about the new domains and new concepts that were added to SDTM v1.2 / SDTMIG v3.1.2.

Prerequisites

1. Have taken the SDTM Theory and Application course and/or
2. Been actively developing/mapping data to the SDTMIG v3.1.1 structure

Ideal Course Attendees

1. Will have taken the SDTM Theory and Application course and/or
2. Been actively developing/mapping data to the SDTMIG v3.1.1 structure

Topics Covered in the Course

- Most major changes to the SDTM v1.2
 - Changes to General Observation Class Tables
 - Changes to Trial Design Tables
- Most major changes to the SDTMIG v3.1.2
 - Major Assumptions changes in Section 4
 - Splitting domains
 - Natural keys
 - Grouping variables
 - How to submit free text
 - Addition of new timing variables
 - Standardization of results
 - Explanation of new variable --PRESP
 - Major changes in the domains
 - Demography - "Race, Other Specify"
 - New variables added to existing domains
 - Discussion of new domains
 - Clinical Events
 - Microbiology
 - PK
 - Findings About
 - Changes to Trial Design
 - Guidelines to which Observation Class data belongs
 - Changes in how controlled terminology is documented