



SDTM Data Conversion

Classes Now Available

Day 1: 9 am – 4 pm

Day 2: 9 am – 3 pm

Upon completing this course, all participants will be able to:

- Accurately summarize the key principles of data conversion as articulated in SDTM V1.2
- Possess a clear understanding of the core concepts of SDTM conversion implementation as outlined in SDTM IG V3.1.2
- Outline the key roles and functions in the multidisciplinary team-based approach and comprehend the importance of good planning and communication from the outset of the project
- List all steps required to convert a generic, raw data set to an SDTM-compliant format
- Convert several example data sets to SDTM-compliant format using a range of existing technology tools including: SAS Base, SAS Data Integration Studio, Microsoft Excel, Allora, WebSDM and StudyCTMS
- Identify several common pitfalls inherent in the general SDTM conversion process
- Propose a data set conversion strategy or work plan to culminate in data submission to the FDA in relation to each participant's roles in his or her respective organization
- Discuss several key issues surrounding the FDA's anticipated migration to SDTM V3.1.2
- Discuss pro's and con's of the various methods for converting submission data, especially with respect to each participant's organizational role
- Identify and discuss some benefits and efficiencies to both industry and the FDA of submitting well-harmonized SDTM study data that meets the FDA's technical requirements and loads in Janus on the first pass
- Discuss the expected impact of SDTM conversion requirements against the backdrop of recent, well-publicized regulatory reversals, e.g.: COX-2 inhibitors, Acomplia, Avandia, etc...

To learn more about SDTM data conversion and our new classes, call 410-435-0663.



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