

Foundations of Clinical Trials Programming Exam Content

Describe the fundamentals of clinical trials research process

- Introduction to Clinical Trials Research
- Introduction to the Drug Approval Process

Explain the CDISC Study Data Tabulation Model (SDTM) guidelines

- Introduction to Clinical Data Interchange Standards Consortium (CDISC)
- Fundamentals of the Study Data Tabulation Model (SDTM)
- The General Observations Class
 - Interventions Class
 - Events Class
 - Findings Class
- Datasets Other than General Observation
 - Models for Special-Purpose Domains – DM, SUPPDM, Custom Domain (XP)
 - Trial Design Model (TDM) Datasets
 - Relationship Datasets
 - Study Reference Datasets
- Assumptions for Domain Models

Explain how to implement the CDISC SDTM with Base SAS

- Base SAS Programs for SDTM Conversions
- Building SDTM Datasets
 - Building the Special-Purpose DM and SUPPDM Domains
 - Building the AE Events Domain
 - Building the LB Finding Domain
 - Building the EX Interventions Domain
 - Building a sponsor-specific custom Domain

Explain how to Implement the CDISC SDTM with SQL

- Use SQL Procedure to create Data sets
 - Use CREATE TABLE query to create Study Tabulations and Analysis Datasets, derive variables
 - Use Join and Union clauses to combine multiple tables

Describe the CDISC Analysis Dataset Model (ADaM) guidelines

- Fundamentals of ADaM
- Subject-Level Analysis Dataset (ADSL)
- Occurrence Data Structure Datasets (OCCDS)
- Basic Data Structure (BDS)

Explain how to implement the CDISC ADaM with Base SAS

- Building the Subject-Level Analysis Dataset (ADSL)
- Building the Adverse Events Analysis Dataset (ADAE)

Explain how to implement the CDISC SDTM with Macros

- Use Macro Programming to automate tasks
 - Understand how to use a macro to derive ISO8601 date string from SAS date or datetime component variables
 - Understand how to use a macro to derive SDTM study day variable
 - Understand how to use a macro to calculate change from baseline