



PHARMA ANALYTICA

Clinical SAS Curriculum

Course : Online /Offline

Duration : 4 months

Course contents/Topics

1. Getting Started Using SAS Software

- a. Introduction to SAS
- b. SAS Windows
- c. Reading Data into a SAS Data Set
- d. SAS Libraries
- e. SAS system options

2. Understanding DATA Step Process and PDV

- a. Writing Basic DATA Steps
- b. How SAS Processes Programs
- c. Compilation Phase
- d. Execution Phase
- e. Debugging a DATA Step

3. Getting Data Into SAS

- a. Different methods to read data from .txt/.xls files.
- b. Creating new dataset
- c. Different input methods to create dataset

4. Procedures

- | | |
|-------------|--------------|
| a. Sort | g. Means |
| b. Contents | h. Freq |
| c. Format | i. Transpose |
| d. Print | j. Report |
| e. Import | l. Compare |
| f. Export | |



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5. Combining Datasets

- a. Concatenating Datasets
- b. Appending Datasets
- c. Interleaving Datasets
- d. Merging Datasets

6. Working with SAS Datasets

- a. Output statement
- b. Creating and modifying variables
- c. WHERE statement
- d. IF-THEN/ELSE statements
- e. RETAIN
- f. DO LOOPS
- g. ARRAYS
- h. Global Statements (Title, Footnote)

7. Functions

- a. Character Functions
- b. Numeric Functions
- c. Data and Time Functions

8. SAS Macros

- a. Macro Concepts
- b. Macros and Macro Variables
- c. Creating Macro Variables
- d. Using Macro Variables
- e. Invoking a Macro
- f. Passing Arguments to Macros
- g. Macro Quoting Functions
- h. Macro Options
- i. Macro Expressions



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9. PROC SQL

- a. Introduction to SAS/SQL
- b. Proc Sql Statements
- c. Proc Sql Options
- d. Set Clause
- e. Where Clause
- f. Order by Clause
- g. Group by Clause
- h. Having Clause
- i. Distinct Clause
- j. Formatting Output
- k. Case Expression and Conditional Logic
- l. Sql Set Operators
- m. Joins in Sql
- n. Creating, Populating & Deleting Tables
- o. Alter Table Statement
- p. Aggregate Functions

10. SAS GRAPHS

- a. GPLOT procedure
- b. Annotating the graph
- c. Multiple Plots & Overlay
- d. Symbol Statement

11. Clinical Trails Process

- a. Describe the clinical research process (phases, key roles, key organizations).
- b. Describe regulatory (FDA) requirements (principles of 21 CFR Part 11, International Conference on Harmonization, Good Clinical Practices).
- c. Learning about the general department structure of pharmaceutical industry, roles and responsibilities of SAS programmer in the company.
- d. Understanding clinical study and documents (e.g. Protocols, Case Report Form (CRF), annotated and electronic Case Report Form (aCRF and eCRF), Statistical Analysis Plan (SAP)
- e. Types of analysis in clinical trials (Safety, Efficacy, etc.)



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12. CDISC SDTM STANDARDS

- a. What is SDTM
- b. Purpose of SDTM
- c. Domains
- d. Variables
- e. Role Concept
- f. Core Variable Concept
- g. General Observation Classes
- h. Controlled Terminology

13. Touch Base of SDTM Domains:

- a. Special Purpose Domains
 - Demographics (DM)
 - Comments (CO)
 - Subject Visits (SV)
 - Subject Element (SE)
- b. Interventions
 - Concomitant Medications (CM)
 - Exposure (EX)
 - Exposure as Collected (EC)
 - Procedures (PR)
- c. Events
 - Adverse Events (AE)
 - Disposition (DS)
 - Protocol Deviations (DV)
 - Medical History (MH)
- d. Relationship Domains
 - Supplemental Qualifiers (SUPP-- domains)
 - Related Records (RELREC)
- e. Findings
 - Vital Signs (VS)
 - Laboratory Test Results (LB)
 - ECG Results (EG)
 - Findings About (FA)
- f. Trail Designs Domains
 - Trail Arms (TA)
 - Trail Elements (TE)
 - Trail Inclusion/Exclusion Criteria (TI)
 - Trail Visits (TV)
 - Trail Summary (TS)



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14. CDISC ADAM Standards

- a. What is ADAM?
- b. Fundamental principles
- c. Subject Level Analysis Dataset (ADSL)
 - Treatment Variables
 - Timing Variables
 - Baseline Characteristics Variables
 - Population Flags
 - Grouping Variables
 - Numeric Variable Creation and Purposes
- d. Basic Dataset Structure (BDS)
Datasets (ADVS, ADLB, ADEG)
 - Structure and Common Variables Creation
 - ABLFL, BASE, ANLXXFL, CRITXXFL, CHG and PCHG variables
 - Analysis Flags and their purposes
 - Criterion variables and Criterion Flags Creation and their Purposes
 - PARAMTYP, DTYPE, BASETYPE Variables Creation
 - LOCF, BOCF, WOCF Concepts
- e. Occurrence Data Structure:
Adverse Event Analysis Dataset (ADAE)
 - Partial Date Imputations
 - Imputation Flag
 - Occurrence Flags

15. TABLES & LISTINGS

- a. Understanding of Mock shells
- b. Descriptive statistics generation
- c. Summary statistics Generation
- d. Big N calculation
- e. Percentage calculation
- f. Explanation of Disposition, Demographics, Concomitant, Medical History, Adverse Events, Change from base line and Shift tables
- g. Listing Generation
- h. Relationship Between Tables and Listings