Clinical SAS

PART1:

- SAS BASICS
- SAS software installation
- Getting familiarity with SAS

Import and Export Clinical Trials Data

- Combine SAS data sets.
- Efficiently import and subset SAS data sets.
- Access data in an Excel workbook (LIBNAME and PROC IMPORT/EXPORT).
- Create temporary and permanent SAS data sets.
- Apply regulatory requirements to exported SAS data sets (SAS V5 requirements).

Manage Clinical Trials Data

- Investigate SAS data libraries using base SAS utility procedures (PRINT, CONTENTS, FREQ).
- Access DICTIONARY Tables using the SQL procedure.
- Sort observations in a SAS data set.
- Create and modify variable attributes using options and statements in the DATA step.

Transform Clinical Trials Data

- Process data using DO LOOPS
- Retain variables across observations.
- Use assignment statements in the DATA step.
- Use SAS functions to convert character data to numeric and vice versa.
- Use SAS functions to manipulate character data, numeric data, and SAS date values.
- Transpose SAS data sets.

Macro Programming for Clinical Trials

- Create and use user-defined and automatic macro variables.
- Automate programs by defining and calling macros.
- Use system options to debug macros and display values of macro variables in the SAS log (MPRINT, SYMBOLGEN, MLOGIC, MACROGEN).

Report Clinical Trials Results

- Use PROC REPORT to produce tables and listings for clinical trials reports.
- Use ODS and global statements to produce and augment clinical trials reports. Validate Clinical Trial Data Reporting
- Explain the principles of programming validation in the clinical trial industry.
- Utilize the log file to validate clinical trial data reporting.
- Use programming techniques to validate clinical trial data reporting (PROC COMPARE).
- Identify and Resolve data, syntax and logic errors.

Apply Statistical Procedures for Clinical Trials

- Use SAS procedures to obtain descriptive statistics for clinical trials data (FREQ, UNIVARIATE, MEANS, SUMMARY).
- Use PROC FREQ to obtain p-values for categorical data (2x2 and NxP test for association).
- Use PROC TTEST to obtain p-values for continuous data (one-sample, paired and two-sample t-tests).
- Create output data sets from statistical procedures.
    - Apply 'observation carry forward' techniques to clinical trials data (LOCF, BOCF, WOCF).

Part 2: Clinical Trials Process

- Describe the clinical research process (phases, key roles, key organizations).
- Interpret a Statistical Analysis Plan.
- Derive programming requirements from an SAP and an annotated Case Report Form.
- Describe regulatory requirements (principles of 21 CFR Part 11, International Conference on Harmonization, Good Clinical Practices).

Clinical Trials Data Structures

- Identify the classes of clinical trials data (demographic, lab, baseline, concomitant medication, etc.).
- Identify key CDISC principals and terms.
- Describe the structure and purpose of the CDISC SDTM data model.
- Describe the structure and purpose of the CDISC ADaM data model.
- Describe the contents and purpose of define.xml.

CDISC - SDTM

- Introduction of CDISC
- Why CDISC and DATA standards
- What are the versions of CDISC
- Impact of CDISC Standards on Clinical Activities
- CDISC Models
- Study Data Tabulation Model (SDTM)
- Analysis Dataset Models (ADaM)

Fundamentals of SDTM

- What is SDTM?
- Observations and Variables in SDTM
- Special Purpose Datasets
- General Observation Classes in SDTM
- SDTM Standard Domain Models
- Creating New Domain

Submitting Data in Standard Format

- Assumptions for Domain Models
- General Assumptions for all Domains

Models for Special Purpose Domains

- DM, CO, SE and SV

Domain Models Based on the General Observation Classes

1. Interventions

- CM, EX

2. Events

- AE, DS

3. Findings

- LB, EG, VS

4. Trial Design Domains

- TA, TE, TS, TI and TV

5. REL REC

6. **Supplemental Qualifies**

- SDTM-supplementary domains Mapping Programming Using SAS
- SDTM Annotation on CRF
- SDTM Mapping Specifications
- Real time Project on SDTM
- Define.xml

Part 3: CDISC - ADaM:

- Introduction to ADaM
- Why ADaM
- Key Concepts
- ADaM naming conventions
- ADaM Implementation
- Fundamentals of the ADaM Standards
- Variables in General
- ADSL variables
- BDS Variables
- Real time Project on ADAM
- ADSL
- ADAE
- ADLB
- ADEX

Part 4: TLFs

- Summary Reports (Tables Listings and Fig)
- Introduction about the ICH E6,E9 and E3
- Mock shells
- Introduction about the statistical reports
- Introduction about the clinical study report
- SAS programs development, and validation (QC)
- MeDRA Guidelines
- Generating Summary Reports
- Generating Listings
- Generating Graphs
- Real time Project
- Interview preparation.
- Assignments will be given based on ongoing topic.