Training Course: SAS Certified Clinical Trials Programmer using SAS V9

Day1-day5

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, and Good Clinical Practices)

Clinical Trials Data Structures

Identify the types 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

Clinical Trials Data Validation and Management

Process data using DO LOOPS and SAS arrays
Retain variables across observations
Create LAG variable and LEAD variables
Transpose clinical trials data
Use clinical trials techniques of LOCF, BOCF, WOCF
http://onbiostatistics.blogspot.com/2010/08/locf-bocf-wocf-and-mvtf.html
Calculate “change from baseline” results
Create and use user-defined and automatic macro variables
Automate programs by defining and calling macros
Use system options (MPRINT, SYMBOLGEN, MLOGIC, MACROGEN) to debug macros program and macro variables
Access Dictionary Tables using the SAS SQL procedure

Clinical Trials Reporting

Use PROC REPORT to produce table reports
Use ODS to produce clinical trials reports
Use ODS Statistical Graphing to create graphs reports

Use PROC SGPLOT to create matrix scatter plots for clinical trials reports
Use programming techniques to validate clinical trial data reporting (PROC COMPARE, MSGLEVEL)

Clinical Trials Data Analysis
Use SAS procedures to obtain descriptive statistics for clinical trials data (FREQ, UNIVARIATE, MEANS, SUMMARY and UNIVARATE).
Use PROC FREQ to obtain p-values for categorical data (2×2 and NxP test for association).
Use PROC TTEST to obtain p-values for continuous data (one-sample, paired and two-sample t-tests)
Identify and describe SAS procedures used to perform ANOVA, ANCOVA and MANOVA

Adv. Statistical Analysis for Clinical Trials Data
Obtain statistics for clinical trials data (REGGRESSION including testing assumptions that are required for regression, CATEGORICAL LOGISTIC, GLM, COUNT MODELS AND REPEATED MEASURES ANALYSIS). MULTIVARIATE MULTIPLE REGRESSION, SURVIVAL ANALYSIS, LEFTTEST & POWER ANALYSIS may be covered in the class or clinical trial data project

Day6

Discuss and finish you clinical trial data project

Day7

Review and pass exam