# Clinical Trials Programming Using SAS 9 Accelerated Version

## 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.

## Import and Export Clinical Trials Data

- Apply regulatory requirements to exported SAS data sets (SAS V5 requirements).

## Manage Clinical Trials Data

- Access DICTIONARY Tables using the SQL procedure.
- Examine and explore clinical trials input data (find outliers, missing vs. zero values, etc).

## Transform Clinical Trials Data

- Apply categorization and windowing techniques to clinical trials data.
- Transpose SAS data sets.
- Apply 'observation carry forward' techniques to clinical trials data (LOCF, BOCF, WOCF).
- Calculate 'change from baseline' results.
- Obtain counts of events in clinical trials.

## 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.

## 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, MSGLEVEL).
- Identify and Resolve data, syntax and logic errors.