

Clinical Trials Programming Using SAS 9.4

Clinical Trials Process – 5%

- Describe the clinical research process (phases, key roles, key organizations).
- Derive programming requirements from an SAP and an annotated Case Report Form.

Clinical Trials Data Structures – 10%

- Identify the clinical trials domains.
- 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.
- Trace data through the full programming process, from raw data to any of the mapped domains.

Regulatory Submissions – 5%

- Apply regulatory requirements to exported SAS data sets (SAS V5 requirements).
- Describe the contents and purpose of define.xml.

Manage Clinical Trials Data – 5%

- Access DICTIONARY Tables using the SQL procedure.
- Examine and explore clinical trials input data (find outliers, missing vs. zero values).
 - Use DATA STEP functions and features to find anomalous values or to find potential errors.

Transform or Summarize Clinical Trials Data – 15%

- Derive variables by applying categorization and windowing techniques to existing variables.
- Store dates in a form that is acceptable for use with clinical trials
 - Determine if dates are stored in accordance with ISO 8601 standards
 - Use functions to store dates using ISO 8601 standards
- Reshape SAS data sets:
 - with PROC TRANSPOSE
 - with arrays in the DATA step.
- Calculate 'change from baseline' results.
- Obtain counts of events in clinical trials.
- Use FIRST./LAST. variables

Apply Statistical Procedures for Clinical Trials – 15%

- **Use SAS procedures to obtain descriptive statistics for clinical trials data** (FREQ, UNIVARIATE, MEANS, SUMMARY).
- **Given information on data types (categorical vs. quantitative), determine whether a procedure can produce the requested analysis.**
- **Given sample code from a statistical procedure, identify syntax and/or semantic errors.** (PROC FREQ, PROC TTEST, GLM, REG,)
- **Create output data sets from statistical procedures.**
 - ODS OUTPUT
 - OUTPUT statements or options within a procedure
- **Follow instructions to be able to program for both Safety and Efficacy data.**

Macro Programming for Clinical Trials – 15%

- **Create macro variables and set macro parameters.**
- **Access user-defined and automatic variables.**
- **Automate repeated tasks by defining and calling macros.**
- **Use system options to debug macros and display values of macro variables in the SAS log** (MPRINT, SYMBOLGEN, MLOGIC,).

Report Clinical Trials Results – 10%

- **Use PROC REPORT to produce tables and listings for clinical trials reports.**
 - Apply options in the REPORT statement to modify the report style.
 - Use COLUMN statement to select report items, assign aliases to report items, nest report items, and create headers for one or more report items.
 - Use DEFINE statement to apply options to report items. E.g., usages, styles, sort order.
 - Use BREAK and RBREAK statements to add summary rows.
 - Use COMPUTE blocks to execute programming statements during the creation of the report.
 - Use LINE statements to insert new lines into a report.
 - Use CALL DEFINE statements to modify the contents or aesthetics of the report.
 - Produce a data set using the OUT= option.
- **Use ODS statements to produce and augment clinical trials reports.**
 - Use ODS TRACE to identify output object attributes.
 - Use ODS SELECT/EXCLUDE to produce desired output objects.
 - Use ODS statements to open/close an ODS destination (e.g., PDF, RTF, POWERPOINT, LISTING, WORD) and control destination-specific settings. (e.g., resolution, number of columns, pagination)
 - Use the ODS GRAPHICS statement to control graphics environment options.

- **Create and work with graphs**
 - Use PROC SGPLOT or PROC SGPANEL to create standard graphs using VBARBASIC/HBARBASIC, VBARPARM/HBARPARM, VBOX/HBOX, HISTOGRAM, DENSITY, SCATTER, SERIES, HIGHLOW, WATERFALL)
 - Use statements and options in PROC SGPLOT and PROC SGPANEL to create graphs based on grouped data and modify their appearance.
 - Create graphs that include an overlay of multiple graphical elements, including reference lines
 - Use statements and options to modify the attributes of graphical elements, customize axes, and customize legends.

Validate Clinical Trial Data Reporting – 20%

- **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).**
- **Determine why two independent validation programs led to a different result.**
- **Identify elements that are not validated when comparing via PROC COMPARE.** (titles, footnotes, and attributes such as formats or labels depending on how they are added to a PROC-like REPORT)
- **Identify and Resolve data, syntax, and logic errors.**