



3S BUSINESS CORPORATION
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SAS CLINICAL TRAINING

Presented By

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Table of Contents

S.No	TOPICS
1	Introduction to Clinical Trials
2	Introduction to Clinical Trial Data
3	Using SAS to Create Analysis Data sets
4	Generate Customized Clinical Trials Tables, Listings and Graphs/Figures
5	Clinical Trials Process

SAS CLINICAL COURSE CONTENT

1. Introduction to Clinical Trials

Overview of highly regulated drug development process, from discovery to bringing a biopharmaceutical product to market

- Pharmaceutical Industry vocabulary
- Programmer work description
- The Drug/Device Development Process
- Overview of Good clinical practice (GCP)
- What is a clinical trial? What are the different types of clinical trials?
- Why participate in a clinical trial?
- Where do the ideas for trials come from?
- Who sponsors clinical trials?
- What is a protocol?
- What is informed consent?
- What is a placebo?
- What is a control or control group?
- What are the phases of clinical trials? Understanding major phases (Phase I – IV) and clinical data management.
- Learning rationale for each phases of drug development cycle and introducing role of SAS programmer in each phase.
- Different types of reports generated by programmer in clinical trials.
- Food and Drug Administration (FDA) regulations and Guidance (21 CFR part 11, GCP, eCTD)
- Regulatory overview and approval process including IND/NDA to FDA

2. Introduction to Clinical Trial Data

- Learn to prepare and clean clinical trial data
- Know how to categorize and summarize clinical data
- Studying and classifying different types of clinical trial data {Safety (ISS) and Efficacy (ISE) Data}
- Getting acquainted with new Clinical Data Interchange Standards Consortium (CDISC) implementation in categorizing clinical data
- Working with real pharmaceutical industry data (demographics, concomitant medication, medical history, laboratory data, adverse event, end point data, etc.)

3. Using SAS to Create Analysis Data sets

- Learning tips and tricks to create and manage analysis data sets
- Key concepts for creating and transforming analysis data sets (Using DATA steps and PROC TRANSPOSE)
- Comparing Data sets using PROC COMPARE
- Learning about use of Medical Dictionaries (MedDRA and WHO Drug) in generating Adverse Event dataset
- Understanding and creating Time-to-Event, Change-from-Baseline, Critical variables data sets

4. Generate Customized Clinical Trials Tables, Listings and Graphs/Figures

- Creating Tables and Listings
- Using PROC TABULATE to create clinical trial tables
- Using PROC REPORT to report clinical trials tables and listing
- Creating summaries of Adverse Event, Concomitant medication, Laboratory data using DATA steps and various SAS Procedures
- Creating Kaplan-Meier Survival Tables using PROC LIFETEST or PROC GPLOT

- Using ODS with PROC REPORT and PROC TABULATE to generate nice looking tables and listings
- Generating Graphs and Plots using SAS/BASE, SAS STAT and SAS/GRAPH
- Producing Bar and Pie charts using PROC GPLOT and PROC GCHART
- Creating Box and Scatter Plot using PROC BOXPLOT, PROC GPLOT and PROC UNIVARIATE
- Creating Kaplan-Meier Plot using PROC GPLOT or PROC LIFETEST

5. Clinical Trials Process

- Interpret a Statistical Analysis Plan (SAP).
- Derive programming requirements from an SAP and an annotated Case Report Form (CRF).
- 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
- Efficiently import and subset SAS data sets.
- Examine and explore clinical trials input data - Find outliers, missing vs. zero values, etc.
- Apply categorization and windowing techniques to clinical trials data.
- Apply ‘observations carry forward techniques’ to clinical trials data (LOCF, BOCF, WOCF).
- Calculate ‘change from baseline’ results.
- Obtain counts of events in 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 (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.
- Macro Programming for Clinical Trials
- Report Clinical Trials Results
- 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).