



CLINICAL SAS

Towards a bright future

Job oriented Program-

- Clinical SAS (Base & Advanced SAS)
- Clinical overview, CDISC (SDTM, ADaM).
- SAS certification preparation.
- Projects / Case study on real-time data.

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Base SAS –

Module1- Essentials

Module2- Data Manipulation Techniques

Accessing Data

- Use FORMATTED and LIST input to read raw data files.
- Use INFILE statement options to control processing when reading raw data files.
- Use various components of an INPUT statement to process raw data files.
- Merge, Concatenate or append the data-set.

- Access an Excel workbook.

o Creating Data Structures

- Create temporary and permanent SAS data sets.
- Create and manipulate SAS dataset values.
- Export dataset in multiple format like HTML , CSV, PDF , Listing etc. .
- Control which observations and variables in a SAS data set are processed and output.

o Managing Data

- Create SAS data libraries.
- Sort observations in a SAS data set & program Back end process.
- Conditionally execute SAS statements.
- Modify variable attributes using options and statements in the DATA step.
- Mathematical calculation with numeric variable.
- Manipulate character data, numeric data, and SAS date values with the help

for Character & Numeric Functions.

- How to handle the data with DO LOOPS, Conditional DO Loops (DO

while & do until)

- Restructuring Data with the TRANSPOSE Procedure

o Generating Reports

- Generate list reports using the PRINT procedure.
- Generate summary reports and frequency tables.
- Calculate the statistical analysis of dataset.
- Enhance reports through the use of user-defined formats, titles, footnotes.
- Generate reports using ODS statements.

o Handling Errors

- Identify and resolve programming logic errors.
- Recognize and correct syntax errors.
- Examine and resolve data errors.

Advance SAS

- Proc sql
- How to read data
- How to create dataset
- Distinct value calculation, applied function & formats ,length , Label etc.
- Macro creation, call macro, functions applying.

Clinical Trials Overview

- Introduction of clinical Research
- Overview of New Drug Development
- Clinical Trial Phases
- Clinical Trial design
- Clinical Trail Protocol

- GCP , Ethics & regulations
- Informed Consent Process
- Essential documents
- Study conduct
- Overview of study documents
- Clinical Research Protocol
- Case Report Form (CRF) Design
- Statistical Analysis Plan (SAP)

CDISC

- SDTM (Study data tabulation model)
 - ADaM (Analysis data model)
- **DM domain-**
 - What is DM (Demographic?)
 - Clinical trial basics
 - Demographic in Trial
 - Contents in demographic
 - Importance of DM
 - DM concept
 - DM data collection
 - DM dataset
 - DM Analysis/ Report generation
 - AdM concept
 - **AE domain –**
 - Definition of Adverse Event
 - Aspect of AE –
 - What
 - When
 - Intensity
 - Seriousness

- Causality
 - Classification
 - ADR
 - TEAE
 - AE-Reporting
 - AE CRF
 - AE CRF to AE SAS dataset
 - SAE & reporting SAE
- **EG Domain-**
 - EG concept
 - Introduction to Heart's Electrical System
 - Introduction of Electrocardiogram (ECG)
 - ECG Parameters
 - QT Interval Correction
 - Standards for Dataset
 - Raw / SDTM datasets
 - Analysis Dataset
 - What to look for in SAP
 - What to look in a mock shell
- **Ex Domain –**
 - Definition of Exposure
 - Aspects of Exposure
 - Dose
 - Duration
 - Number of Patients
 - Who talk about EX ?
 - Protocol
 - CRF
 - SAP
 - CTMS
 - Collection of Exposed Treatments

- Diagrammatic Representations
 - Raw Data Collection
 - Raw Data Table
 - Analysis of Data
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- **LB Domain-**
 - LB Concepts
 - LB Data Collection
 - LB Datasets
 - LB Analysis / Reports
 - LB CRF Data Collection
 - LB Reports Analysis
-
- **VS Domain-**
 - What is Vital sign?
 - Vital Sign parameters
 - Temperature
 - Pulse
 - Respiration Rate
 - Blood Pressure
 - Height & Weight
 - Oxygen Saturation
 - Collection of Vital Sign (VS) data
 - VS CRF
 - VS CRF to VS SAS Dataset
 - Standard for Dataset
 - Raw vs. SDTM Dataset
 - Analysis Dataset

- MH Domain-
 - Concept of Medical History
 - When we have to create MH domain
Raw data to SAS Data Set Creation

Case Study

- 1- Clean the data in multiple conditions (I)
- 2- Clean the Data in multiple conditions (II)
- 3- Restructure the Data & handling the missing values
- 4- Dates imputation based on multiple conditions
- 5- How to compare Dataset, observation, variable

NOTE:

- Case Study will help to understand the Clinical Domain Project Scenario.
- Global SAS certification preparation
- Interview Preparation
- Placement Assistance

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