An ISO 9001:2008 Certified Academy

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Advanced Post Graduate Diploma in Clinical Data Management, Biostatistics & SAS

(3 Months Class Room + 3 Months Paid Industry Internship at CRO)

Designed primarily for students of pharmacy, clinical research, and allied health professions, Introduction to Statistics in Pharmaceutical Clinical Trials will also be invaluable to professionals entering the pharmaceutical, biotechnology, and contract research organization industries who wish to gain a broader understanding of study design, research methodology, and statistical analysis and interpretation in clinical trials.

We have divided the course in five modules. In First module, we cover the basic aspects of Clinical Data Management. In the second module, we cover core CDM knowledge like data validation and data development etc. In the third module, we cover the basic aspects of Biostatistics which help the learner to understand the subject thoroughly. In the fourth module, we are focusing on SAS programming. In the fifth module, we cover clinical data analysis and reporting using SAS software

Mode : Class Room – Weekend

Duration : 6 Months (3 Months Class Room + 3 Months Paid Internship at CRO)

Eligibility : MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharms, Graduate/Post Graduate Degree in Life Sciences, Mathematics ,Pharmacology, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and Hospitals.

Methodology : Weekend Classroom Contact Program; Printed Training Modules; Online E learning System and Hands **on training on Clinical Data Management & SAS software** in actual Clinical Research environment.

Examination : Classroom exams & Project work.

Certificate : Certificate would be awarded upon successful completion of the program. Program is Certified & Accredited by the **Pharmaceutical Society of India.**

Accreditation : Accreditation would be awarded upon successful completion of the program. Program is Certified & Accredited by the **Swiss Association of Pharmaceutical Professionals** (SwAPP) & **Swiss Society of Pharmaceutical Medicines.**

Job Assistance : Placement support would be provided to the successful candidates. CVs of successful candidates would be forwarded to CROs Hospitals and Pharmaceutical companies and, Interviews would be organized.

Fee payment : Fee Payable by Cash, Cheque/Bank draft in the name of **"TENET HEALTH**

EDUTECH PVT LTD." payable at Delhi. Fee can also be deposited in company bank account. We also accept Credit/Debit Cards.

Loan Facility : HDFC Bank

Program Details : The program would cover

Module I

Clinical Data Management

- Introduction to Data Management
- Study Set Up
- CRF Design Considerations
- Data Entry, Remote Data Entry
- Identifying and Managing Discrepancies
- Medical Coding
- Database Closure
- Clinical Database & Types
- Data Management Plan
- Electronic Data Capture
- Tracking CRF Data
- Managing Lab Data
- Collecting Adverse Event Data
- Creating Reports and Transferring Data
- Enterprise Clinical Data Management Tools

Module II

Basics of biostatistics

- Introduction to Research and Statistics/Descriptive Statistics/Probability
- Distributions
- Sampling Distributions/Statistical Inference
- Correlation and Regression
- Choosing Statistical Tests/ T-Test, Chi-Square Test, ANOVA, etc
- Analysis of Categorical Data and Non Parametric Tests
- Introduction to Statistical Software's

Module III

CLINICAL DATA ANALYSIS AND REPORTING USING SAS SOFTWARE

- Study set-up
- Introduction to Clinical Database
- Documents, guidelines used in CDM
- Data Entry
- Data Review/Data Validation, Query Management
- Database QC
- CRF Design (Introduction)
- Database Design (Introduction)

- Edit Check & Edit Check Testing
- UAT (User Acceptance Testing)
- SOPs
- Quality Assurance, Audits

Module IV

SAS programming

- Setting Started with SAS
- Components of SAS
- Reading various types of Raw data
- Wo rking with SAS Datasets
- Combining datasets
- Working with SAS Arrays
- Proc SQL
- SAS Macro Language
- Basic Statistical Procedures

Module V

Clinical data analysis and reporting using SAS software

- Introduction to Clinical Trials
- Understanding and Reviewing Statistical Analysis Plan
- Annotating the Mock Tables
- Creating Dataset Specifications
- Creating Analysis Datasets
- Creating Tables/Listings/Figures

Course Objective :

- To provide a comprehensive introduction to the Clinical Data Management, Biostatistics & SAS in Clinical Research process.
- Understanding of key enterprise SAS & Clinical Data Management tools.
- Become more familiar with roles/jobs as part of the study team.
- Basic concepts, importance of Clinical Data Management, Biostatistics & SAS.