

Advanced Post Graduate Diploma in Clinical Data Management

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, data validation, data entry system tools, data programming and e-learning software.

We have divided the course in two 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.

Mode : Online/Distance Learning

Duration : 6 Months

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 : Printed Training Modules; Online E learning System

Examination : Online MCQs

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.

International Payments : Through Debit/Credit cards using Paypal or wire payment through banks

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

- 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

Course Objectives :

- ❖ To provide a comprehensive introduction to the Clinical Data Management process.
- ❖ Learn the skills, knowledge and competencies of a candidate for the CDM.
- ❖ Become more familiar with roles/jobs as part of the study team.
- ❖ Understanding of Databases & management of clinical data.
- ❖ Understanding of key enterprise clinical data management tools.