

Advanced Post Graduate Diploma in Clinical Research & Clinical Data Management

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

100% Placement Track Record | Industry Accredited Program | Specialization | Dual Certification | Hands on Software Training

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 softwares. 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.

Program Details: The program would cover

Module - 1

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 - 2

- 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)

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Mobile: +91-9311172560, +91-9810068241 **Email:** info@cliniminds.com **Website:** www.cliniminds.com

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Disclaimer - This course brochure is for the purpose of creating an awareness about the program and career options. The exact information on course structure would be given to you at the time of orientation, and may vary from this brochure.

- SOPs
- Quality Assurance, Audits

Mode	: Class Room – Weekend
Duration	: 6 Months (3 Months Class Room + 3 Months Industry 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 CDM software's 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 Accreditation Council for Clinical Research Education, US .
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

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.

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