

## **Advanced Post Graduate Diploma in Clinical Research & Clinical Data Management**

This is a comprehensive educational program, designed for the Pharma /Medical/Life Sciences professional aspiring to work in the field of clinical research or allied professions like central labs, CROs, Sponsor Company. The program provides complete overview and practical environment in the field of clinical research. The program would help candidates to upgrade their knowledge about ICH GCP Guidelines, regulatory issues and other major aspects of clinical trials management. Program would help in developing career in the field of clinical research. In the second part of the program we would cover the Clinical Data Management in detail. We have divided the course in two parts.

In First part, we cover aspects of Clinical Research. In the second part, we cover basic and core CDM knowledge like data validation and data development etc.

Cliniminds has been at the forefront of providing clinical research training and consulting solutions to the life sciences industry for the last several years. We have already trained over 4,500 professionals and successfully placed them in the industry. Cliniminds boasts of various programs, running for the last 10 years and over 50 batches have passed and have been placed in the pharmaceutical companies, CROs, KPOs and other clinical research organizations. Our students have been placed with the leading companies.

**Program Details** : The program would cover

### **Clinical Research Modules I & II**

- Clinical Research Introduction
- Principles of Pharmacology & Drug Discovery & Development
- Roles & Responsibilities of Key Stakeholders
- Preparations & Planning for Clinical Trials
- Essential Documentation in Clinical Research & Regulatory Submissions
- Clinical Trials Project Planning & Management
- Study Start Up Process
- Clinical Monitoring Essentials
- Compliance, Auditing & Quality Control in Clinical Research
- Clinical Data Management, Biostatistics, Analysis & Reporting

C-101 First Floor, Sector-2, Noida - 201301 (U.P), India

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India: Delhi - NCR | Gurgaon | Guwahati | Bangalore | Bhopal | Kolkata | Pune | Mumbai | Trivandrum | Varanasi | Visakhapatnam International: Russia | Saudi Arabia | US | UK

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**Clinical Data Management  
Module I**

- 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**

- 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

**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 Books, Online, E-learning System

**Examination** : Online MCQs

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- Certificate** : Certificate would be awarded upon successful completion of the program. Program is Certified by the **Pharmaceutical Society of India.**
- Accreditation** : Program is 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 relevant organization.
- Fee payment** : Fee Payable by Cash, Cheque/Bank draft in the name of “**TENETHEALTH 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 research process.
  - Learn the skills, knowledge and competencies of a candidate for the Clinical Research Associate / Clinical Research Coordinator position.
  - Become more familiar with roles/jobs as part of the study team.
  - 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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