
Advanced Post Graduate Diploma in Clinical Research & Clinical Data Management

Program accredited by Accreditation Council for Clinical Research Education, USA

100% Past Placement Track Record | Industry Accredited Program | Specialization | Job Oriented
Best Clinical Research & Health Sciences Business Management Institute in India – 2011 to 2020

Certified & Accredited by ACCRE, US & Pharmaceutical Society of India

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 8,000 professionals and successfully placed them in the industry. Cliniminds boasts of various programs, running for the last 15+ years and over 100+ 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

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.

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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

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- 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: , Online learning System

Examination: Online MCQs

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.

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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.

Technology & Knowledge Partners



Cliniminds, Unit of Tenet Health Edutech Pvt. Ltd.

NOIDA ONE 602, Tower B Plot B8, Sector 62, NOIDA 201309, UP

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