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Institute of Health Sciences Training & Management
AN ISO 9001:2015 Certified Academy

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ACCRE
Assuring and Advancing Quality in Clinical Research Education since 1965

Advanced Post Graduate Diploma in Clinical Research & Bioequivalence & Bioavailability Studies

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 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 **Accreditation Council for Clinical Research Education**, **US.**

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

- Clinical Research Introduction
- Principles of Pharmacology & Drug Discovery & Development
- Roles & Responsibilities of Key Stakeholders
- Preparations & Planning for Clinical Trials

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- 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
- Overview of Clinical Data Management and biostatistics
- Basics of Pharmacokinetics
- The concept of Bioavailability and Bioequivalence-Regulatory Terminology
- Regulatory aspects of BE studies
- Need of Bioequivalence Studies- NCEs & Generic Drugs
- Intellectual Property Rights & TRIPs agreement
- Generic Drugs
- ANDA approval, Reference List of Drugs & Orange book
- Approaches to Bioequivalence studies
- Types of BA/BE studies
- Design and Conduct of Bioequivalence Studies
- Study personnel required for conduct of BE studies and their role and responsibility
- Facilities for conducting BA/BE studies (CRO checklist)
- Departments - Clinical, Bio-Analytical and Quality Assurance
- Managing BE Studies
- Measurement Methodology
- Analysis of BE Studies
- Food effect BE studies
- Biowaivers

Course Objective :

The objective of this program is to provide complete understanding of the clinical research and Bioequivalence & Bioavailability study process and to provide working knowledge to the students, which would enable them to work in the industry with minimal training.

Cliniminds, Unit of Tenet Health Edutech Pvt. Ltd.
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