An ISO 9001:2008 Certified Academy

## Post Graduate Diploma in Clinical Trials Management (Limited Scholarships Available)

This is a extensive educational program, designed for the Pharma professionals/Life Sciences/Medical Practitioners aspiring to work in the field of clinical research or allied professions like central labs, CROs, Sponsor Company & Pharmacovigilance. The program provides complete overview and practical environment in the field of clinical research. The program would candidates to upgrade their knowledge about ICH GCP Guidelines, regulatory issues and other major aspects of clinical trials management. Program would help Pharma professionals/Life Sciences/Medical Practitioners in developing career in the field of clinical research.

**Mode** : Class Room

**Duration**: 9 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**: Full time class Room + 3 Months Paid Internships, Hands on training, Online access to study

materials, Printed study materials, Workshops

**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 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.

**Loan Facility** : HDFC Bank

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## **Program Details**: The program would cover

- Clinical Research Introduction & Terminology
- Healthcare Management Issues
- Introduction to Pharmaceutical Industry & Global Challenges
- Global Clinical Research Environment & Opportunities
- Regulatory Affairs
- 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
- Pharmacovigilance
- Bioavailability and Bioequivalence Studies
- Management of Cancer Clinical Trials
- Organizational Behavior & Human Resource Management
- Financial Management

## Course Objectives

- To provide a comprehensive introduction to the clinical research process, conduct & management of clinical trials.
- ❖ Learn the skills, knowledge and competencies of a candidate for the Clinical Research Associate and other key positions.
- ❖ Become more familiar with roles/jobs as part of the study team.
- ❖ Extensive Knowledge & application in different aspects of Clinical Research.