cliniminds™
Institute of Health Sciences Training & Management
An ISO 9001:2008 Certified Academy

Assuring and Advancing Quality in Clinical Research Education since 1965

ICH GCP Certificate Program in Clinical Research

This is a comprehensive GCP Certification program, designed for the Medical Practitioners and other clinical research professionals aspiring to work in the field of clinical research or allied professions like Investigator Site, Ethics Committee & 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 in developing career in the field of clinical research.

Program Details : The program would cover

- Introduction to Clinical Research & Phases in Clinical Research
- Principles of Good Clinical Practices - ICH GCP
- Ethical Considerations in Clinical Trials
- Regulations in Clinical Research
- Sponsor/Investigator Responsibilities
- Investigator Responsibilities
- Clinical Trial Design
- Protocol Design
- CRF Design
- Essential Documents in Clinical Research
- IND Application
- Clinical Study Report
- NDA Submission
- Informed Consent Process & Documentation
- Site Selection & Pre-study Visits
- Site Initiation
- Subjects Recruitment & Retention Plan
- Site Contracts & Budgeting
- Routine Site Monitoring
- CRF Review & Source Data Verification
- Adverse Event Reporting
- Drug Safety Reporting
- Drug Accountability
- Site Close-out
- Standard Operating Procedures for Clinical Research
- Sponsor Compliance & Audits
- Site Audit

Mode : Online/Distance Learning

Duration : 3 Months - Flexible

C-101 First Floor, Sector-2, Noida - 201301 (U.P), India
Mobile: +91-9311172560, +91-9810068241 **Email:** info@cliniminds.com **Website:** www.cliniminds.com
India: Delhi - NCR | Ahmadabad | Bangalore| Bhopal | Chandigarh | Chennai |Coimbatore | Hyderabad | Kolkata | Mumbai | Trivandrum International: US | UK

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Eligibility : Investigators, Site Staff, Project Teams, CRAs, Ethics Committee Members, and other Clinical Research, Pharmaceutical & Healthcare Professionals.

Methodology : Printed Training Modules; Online e-learning System

Examination : Online MCQs

Accreditation : Program is Accredited by **Accreditation Council for Clinical Research Education**, **US.**

Certificate : Certificate would be awarded upon successful completion of the program.

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 : This course is intended to provide the necessary ICH GCP training for investigators and other senior site personnel, to better understand the regulations regarding clinical research in human subjects, ethics and a better understanding of roles and responsibilities in planning and conducting clinical trials.