cliniminds™
Academy for Clinical Research Training & Management
An ISO 9001:2000 Certified Academy

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Integrated Post Graduate Diploma in Clinical Research & Pharmacovigilance

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

In the first phase we would provide a comprehensive practical knowledge to the clinical research processes, drug development process, regulatory affairs, essential documentation, roles and responsibilities, ethics, monitoring, conduct and management of trials and various other related issues.

In the second phase extensive training on Pharmacovigilance (PV) is provided. PV is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines. In general terms, pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbals and traditional medicines with a view to:

- Identifying new information about hazards associated with medicines
- Preventing harm to patients.

Mode	:	Class Room – Weekend Distance/Online Learning
Duration	:	Classroom: Six months Distance / E-Learning: Eleven months
Classroom Locations	:	Delhi, Bangalore, Hyderabad, Kerala
Eligibility	:	MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharma, Graduate/Post Graduate Degree in Life Sciences, Pharmacology, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and hospitals.
Methodology	:	Weekend Classroom Contact Program; Printed Training Modules; Online Learning System; Workshops.
Examination	:	Online MCQs, Exercises, 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.
Job Assistance	:	Placement support would be provided to the successful classroom candidates. CVs of successful candidates would be forwarded to CROs Hospitals and Pharmaceutical companies and, Interviews would be organized. Limited placement support would also be provided to Distance/Online Learning students.
Fee	:	Please refer website or enclosed Fee schedule.
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 – for classroom programs.
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
- 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
- General Overview of Pharmacovigilance
- Medical Dictionary for Drug Regulatory Activities MedDRA
- Regulatory Aspects in Pharmacovigilance
- Diagnosis And Management of Adverse Drug Reactions
- Medical Evaluation of Adverse Events
- Quality System in Pharmacovigilance
- Expedited Reporting Requirements
- Periodic Safety Update Reports (PSURs) For Marketed Drugs (ICH E2C)
- Pharmacovigilance Database And Signal Detection Tools
- Risk Assessment, Evaluation And Management
- EudraVigilance
- Suspected Unexpected Serious Adverse Reaction (SUSAR) Reporting

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 and pharmacovigilance jobs.
- Become more familiar with roles/jobs as part of the study team.
- Basic concepts, importance of Pharmacovigilance and Global Pharmacovigilance regulations.
- Practical aspects of important Pharmacovigilance activities as per the global standards like medical evaluation, casualty assessment, expectedness assessment, case narratives, MedDRA, case processing preparation of safety report etc.