

Advanced Post Graduate Diploma in Clinical Research and Pharmacovigilance

Program accredited by Accreditation Council for Clinical Research Education, USA

100% Past Placement Track Record | Industry Accredited Program | Specialization | Job Oriented

Clinical research is rapidly growing industry globally with growth rate of over 20% per annum. Sector requires highly specialized and skilled professional workforce, with applied clinical research & pharmacovigilance. Over 50,000 professionals would be required in the next 2 – 3 years. Global industry size is over US\$40 billion and in India, industry is expected to touch the turnover of US\$2 billion in the next two years. Other key global markets like China, South East Asia, Europe and America continue to grow in double digit.

Regulatory bodies such as the USFDA and EMEA are intensifying safety regulations, thereby boosting the adoption rates of pharmacovigilance systems by pharmaceutical companies. Several countries, including India are in the process of implementing stringent regulations for adoption of pharmacovigilance. There is significant potential for outsourcing /off shoring for mid-sized companies as well. Large numbers of global drug companies have starting off shoring their pharmacovigilance activities to the markets like India. In a typical pharmacovigilance department or specialized pharmacovigilance company, there are several positions. Pharmacovigilance offers excellent growth prospects. Some of the positions are Drug Safety Associate; Drug Safe Scientist; Aggregate Report Scientist; Team Leaders.

Cliniminds has been awarded as the Best Clinical Research & Health Sciences Business Management Institute in India for the year **2011– 2020** consecutively by various agencies like **ASSOCHAM**, India

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 8000+ 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 Structure

- 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 ,extensive training on Pharmacovigilance (PV).

Program Details:

Clinical Research

- 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
- Overview of Clinical Data Management & Biostatistics

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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India | Canada | US | UK | Saudi Arabia | Philippines |

Pharmacovigilance

- Module - 1 - Overview of Clinical Research
- Module - 2 –Pharmacology- General Principles
- Module - 3– Introduction, Definition & Methods in Pharmacovigilance
- Module 4- Essentials Documents in Pharmacovigilance
- Module 5- Pharmacovigilance Regulations
- Module 6- Safety Reporting (including Medical Information) and Processing ICSR
- Module 7- Aggregate reports, Signal detection & Risk Management
- Module 8- Audits and Inspections
- Module 9- Advanced Pharmacovigilance & Analytics
- Module 10- Hands On Training on Case Processing and Report generation

Entry Level Career Options Upon Completion of the Program:

- Clinical Research Co-coordinator
- Clinical Research Associate
- Clinical Trial Assistant
- In-house CRA
- Pharmacovigilance Officer/ Drug Safety Associate
- Pharmacovigilance Executive/Specialist
- Pharmacovigilance Scientist

Advantages of Cliniminds Program

- Industry Accredited / Certified
- Application of Clinical Research & Pharmacovigilance in real business like environment.
- Completely Job Oriented
- Accredited by the Accreditation Council for Clinical Research Education, USA (ACCRE) & Certified by Pharmaceutical Society of India
- Excellent Placement Record
- Training by the team of industry experts – both full time and visiting senior faculty

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Faculty	:	Self Learning (Online Distance)
Mode	:	Online Distance learning
Duration	:	06 Months
Eligibility	:	MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharm, 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 access to study materials.
Examination	:	Online exams
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, USA.
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 the company bank account. We also accept Credit/ Debit Cards.
International Payments	:	Through debit/Credit cards using Paypal or wirepayment through banks.

Course Objectives:

- Extensive applied / practical knowledge imparted to equip you to work at any global clinical research organization or pharmaceutical company.
- Learn the skills, knowledge and competencies of a candidate for the Clinical Research Associate and Pharmacovigilance jobs.
- 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.
- Balance of academic and job orientation.

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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