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

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Accreditation Council for Clinical Research Education

Advanced Post Graduate Diploma in Clinical Research and Pharmacovigilance

Program accredited by Accreditation Council for Clinical Research Education, USA

HANDS ON TRAINING ON PHARMACOVIGILANCE SOFTWARE

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

Clinical research is rapidly growing industry globally with growth rate of over 40% 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 d o p t i o n 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 Safety Scientist; Aggregate Report Scientist; Team Leaders.

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 6500 professionals and successfully placed them in the industry. Cliniminds boasts of various programs, running for the last 13years 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. Cliniminds has been awarded as the Best Clinical Research & Health Sciences Business Management Institute in India for the year 2011 – 2016 consecutively by ASSOCHAM, India.

Program Structure

- 3 Months 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) and various other related issues in intensive Full time Classroom Training is provided.

Program Details:

Clinical Research

- Clinical Research Introduction
- Principles of Pharmacology & Drug Discovery & Development

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Delhi - NCR | Agra | Guwahati | Bangalore| Chennai |Pune | Mumbai | Vadodara| Hyderabad |Kerala
International: Russia | Saudi Arabia | US |UK| South Africa

- 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

Pharmacovigilance

- General Overview of Pharmacovigilance
- Key Terms & Terminologies
- General & Systemic Principles of Pharmacology
- Regulatory Guidelines & Laws in Pharmacovigilance
- ICSR
- Medical Dictionary for Drug Regulatory Activities MedDRA
- Diagnosis And Management of Adverse Drug Reactions
- AE/ADR Reporting Systems & Forms
- Medical Evaluation of Adverse Events
- Narrative Writing
- Expedited Reporting Requirements
- Periodic Safety Update Reports (PSURs) For Marketed Drugs (ICHE2C)
- Signal Detection Tools
- Quality System in Pharmacovigilance
- SOPs in Pharmacovigilance
- Pharmacovigilance Database
- An Overview of Pharmacovigilance Software

Entry Level Career Options Upon Completion of the Program:

- Clinical Research Co-coordinator
- Clinical Research Associate
- Clinical Trial Assistant
- In-house CRA
- Team Lead
- Project Manager

- Senior/Project Planning Manager
- AGM/DGM
- Head/VP
- Pharmacovigilance Officer/ Drug Safety Associate
- Pharmacovigilance Executive/Specialist
- Team Lead
- Pharmacovigilance Manager
- Regional Head

Advantages of Cliniminds Program

- Industry Accredited / Certified
- Application of Clinical Research & Pharmacovigilance in real business like environment.
- Completely Job Oriented – Hands-on Training
- Internship Certificate will be provided by leading CRO/SMO/Hospital
- Accredited by the by Accreditation Council for Clinical Research Education, USA (ACCRE) & Certified by Pharmaceutical Society of India
- 100% placement – Excellent Placement Record
- Training by the team of industry experts – both full time and visiting senior faculty
- Small batch – 15 Seats

Faculty	:	Training would be imparted by the full time cliniminds faculty & visiting Experts from the industry.
Mode	:	Classroom/Online/Webinar
Duration	:	6 Months (3 Month Classroom + 3 Month Optional Internship) 6 Months (6 Months Weekend)
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.
Fee Payment International	:	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.

Methodology	:	Hands on training, online access to study materials, Printed study Materials and Workshops.
Examination	:	Classroom/online exams & Project work
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.**
Job Assistance	:	Extensive Placement support would be provided to the successful Candidates. 100% Past Placement Track Record.

Payments : Through Debit/Credit cards using Paypal or wire payment 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.

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