ADVANCED POST GRADUATE DIPLOMA IN CLINICAL RESEARCH, PHARMACOVIGILANCE AND DATA MANAGEMENT

100% Placement Support | Industry Accredited Program | Specialization | Triple Certification

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 Americas 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. Number of global drug companies have started 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.

With India now clearly positioned as the preferred Clinical Trials destination, outsourcing Clinical Data Management and Biostatistics services to India is attracting major Pharmaceutical and R&D Organizations and CROs globally. India today offers excellent IT infrastructure, skilled manpower ethics and cost efficient solutions in this field. Most global companies have now presence in India, and several other companies are in the process of setting up data management and biostatistics business in India.

Course Objectives:

- Programs offered by most institutes does not conform the industry standards and are merely theoretical in nature. However, industry needs today ready to deploy workforce which can work with minimal additional training and have necessary certifications.
- As a student you need a program which provides you the holistic hands on training on all major aspects of clinical research, pharmacovigilance, data management, SAS, regulations and medical & scientific writing. This would help in you moving up in the organizational ladder rapidly.

Program Structure:

- Comprehensive practical knowledge in the following areas :
  - Clinical Trials Management
  - Pharmacovigilance
  - Data Management
  - SAS
  - Regulatory Affairs & Medical Writing
  - General Management & Soft Skills

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Email: info@cliniminds.com, admissions@cliniminds.com **Website:** www.cliniminds.com,
India : Delhi | Bangalore| Bhopal | Chandigarh | Chennai |Coimbatore | Hyderabad | Jammu| Kolkata | Mumbai| Pune |Surat | Thrissur | Trivandrum |Vijayawada
International : US | UK

- Internship in leading Hospitals, CROs, SMOs, Pharma Companies.
- Online Pharmacovigilance Internship with leading US Company KYRON and Clinical Data Management software.

Career Options Upon Successful Completion of the Program:

- Clinical Research Operations
- Clinical Research Co-coordinator
- Clinical Trial Assistant.
- In-house CRA
- Phramacovigilance Officer
- Drug Safety Associate
- Drug Safety Officer
- Data Management Associate
- Data Entry Operators
- Data Validation Executive
- Junior Programmer
- SAS Programmer

These positions are at CROs, pharmaceutical companies, IT companies, consulting firms and pure data management companies.

Once you gain experience, you can grow into middle to senior positions, with significant professional and salary growth.

Advantages of Cliniminds Programs:

- 100% Placement Support
- Internship at leading Hospitals, CROs, SMO, IT/ Software Companies
- Shorter Duration with weekend classes
- Mentoring by Medical Doctors, Clinical Research & data management Experts, IT professionals
- Skill Development, Placement & Career Development Focus
- Short Duration
- 10 Seats
- Industry Accredited & Certified
- Hands on Practical Training on Clinical Data Management and SAS in real clinical research environment using licensed software
- Software Access
- Training by the team of industry experts – both full time and visiting senior faculty
- Triple Certification – Add On Certificate in Clinical Data Management.
- Guided by expert team.

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cliniminds™
Academy for Clinical Research and Healthcare Training & Management
An ISO 9001:2008 Certified Academy

MEDRIO

KYRON PHARMA CONSULTING

About Cliniminds

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 2,000 professionals and successfully placed them in the industry.

Cliniminds flagship program, Post Graduate Diploma in Clinical Research & Pharmacovigilance, is in existence for the last 6 years and over 18 batches have passed and have been placed in the pharmaceutical companies, CROs and other clinical research organizations. Our students have been placed with the leading companies.

Mode : Classroom/Online/Webinar

Duration : 6 months + 3 months Internship

Eligibility : MBBS**,** BDS, BHMS, BAMS, BUMS, BPT, B.Pharms, Graduate/Post Graduate Degree in Statistics, Life Sciences, Mathematics, Pharmacology, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and Hospitals.

Methodology : 6 Months Full time (5 days a week – 400 hours of intense training) class Room + 3 Months Internships, 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 & Accredited by the **Pharmaceutical Society of India.**

Accreditation : Accreditation would be awarded upon successful completion of the program. Program is Certified & Accredited by the **Swiss Association of Pharmaceutical Professionals** (SwAPP) & **Swiss Society of Pharmaceutical Medicine.**

Job Assistance : Extensive Placement support would be provided to the successful candidates. CVs of successful candidates would be discussed with employers 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.

Program Details: The program would cover

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International : US | UK

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

Pharmacovigilance

- 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
- 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
- Expedited Reporting Requirements
- Pharmacovigilance Software

Clinical Data Management

- Introduction to Data Management
- Study Set Up
- CRF Design Considerations
- Data Entry, Remote Data Entry
- Identifying and Managing Discrepancies
- Medical Coding
- Database Closure
- Clinical Database & Types
- Data Management Plan
- Electronic Data Capture
- Tracking CRF Data
- Managing Lab Data
- Collecting Adverse Event Data

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International : US | UK

- Creating Reports and Transferring Data
- Enterprise Clinical Data Management Tools

Clinical Data Analysis and Reporting Using SAS Software

- Study set-up
- Introduction to Clinical Database
- Documents, guidelines used in CDM
- Data Entry
- Data Review/Data Validation, Query Management
- Database QC
- CRF Design (Introduction)
- Database Design (Introduction)
- Edit Check & Edit Check Testing
- UAT (User Acceptance Testing)
- SOPs
- Quality Assurance, Audits

SAS programming

- Setting Started with SAS
- Components of SAS
- Reading various types of Raw data
  Working with SAS Datasets
- Combining datasets
- Working with SAS Arrays
- Proc SQL
- SAS Macro Language
- Basic Statistical Procedures

Clinical Data Analysis and Reporting Using SAS Software

- Introduction to Clinical Trials
- Understanding and Reviewing Statistical Analysis Plan
- Annotating the Mock Tables
- Creating Dataset Specifications
- Creating Analysis Datasets
- Creating Tables/Listings/Figures