M.Sc. Clinical Research, Clinical Data Management & SAS

Degree Awarded by UGC Recognized University | 100% Placement Support | Internship | Industry Accredited Program | Specialization | Dual Certification | Scholarship | International Internship

Clinical research is rapidly growing industry globally with growth rate of over 40% per annum. 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.

This is an educational program, designed for all the candidates aspiring to work in the field of clinical research, data management companies, CROs, pharma companies, or allied professions like central labs. The program provides complete overview and practical environment in the field of clinical research. The program would allow candidates to upgrade their knowledge about ICH GCP Guidelines, regulatory issues and other major aspects of clinical trials management.

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.

Cliniminds offers M.Sc. in Clinical Research, Clinical Data Management & SAS training programs designed primarily for the students of life sciences, biotechnology, statistics, pharmacy, clinical research and allied health professions. Program would be invaluable to professionals entering the pharmaceutical, biotechnology and contract research companies, who wish to gain the broader understanding of clinical data management, study design, data management plan, research methodology, statistical analysis, interpretation in clinical trials and many more topics.

Program Structure:

- Total duration of the program is 2 years
- Classroom training : 18 Months
• Project Internship at Data Management CRO or CDM Software / IT company for the period of 6 Months
• Add on Specialized Certificate Program in Phramcovigilance

Faculty: Full time and visiting faculty members from the clinical research and pharma industry.

Career Options Upon Successful Completion of the Program:
• Clinical Research Coordinator
• Clinical Trial Assistant
• In-house CRA
• Data Management Associate
• Data Entry Operators
• Data Validation Executive
• Junior Programmer
• SAS Programmer
• Biostatisticians

These positions are at Hospitals, 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:
• UGC Certified University Program
• Balance of Traditional & job oriented study
• Industry Accredited & Certified
• Hands on Practical Training on Clinical Data Management & SAS softwares in real clinical research environment on authentic software
• Software Access
• Dual Certification, including certification by leading Data management CRO or Data Management Software Company
• Job Oriented Programs
• 100% Placement Support.

Faculty: Training would be imparted by the full time cliniminds faculty & visiting
experts from the industry.

**Mode** : Classroom Contact Program / Distance

**Duration** : 2 Years

**Eligibility** : MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharms, 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.

**Examination** : Classroom / Online Exams & Project work

**Degree** : After Successful completion of the program PG degree would be awarded by MGU University (Mahatma Gandhi University), UGC Approved University.

**Twinning Certificate** : Cliniminds would offer twinning professional Certificate Program in Pharmacovigilance.

**Job Assistance** : Extensive Placement support would be provided to the successful candidates.

**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.

**Program Details:** The Program would cover the following

**Module I**
- Clinical Research Introduction
- 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

**Module II**
**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
• Creating Reports and Transferring Data
• Enterprise Clinical Data Management Tools

Module III
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

Module IV
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

Module V
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

Course Objective:

❖ To provide a comprehensive introduction to the clinical research process.
❖ Learn the skills, knowledge and competencies of a candidate for the Clinical Research Associate / Clinical Research Coordinator position.
❖ Become more familiar with roles/jobs as part of the study team.
❖ To provide a comprehensive introduction to the Clinical Data Management, & SAS in Clinical Research process.
❖ Understanding of key enterprise SAS & Clinical Data Management tools.
❖ Become more familiar with roles/jobs as part of the study Clinical Research.