Post Graduate Diploma in Clinical Trials Management
(For Medical Professionals Only)
October 2010 Batch - Weekend
(Limited Scholarships Available – 100% Placement Support)

Clinical research industry is growing at 40% per annum. According to McKinsey Report, by year 2012, industry turnover would be over US$2 billion, with qualified manpower need of 50,000 professionals. Out of this over 15 - 20% professionals are needed who have medical degrees. Globally industry size is over US$40 billion. Medical professionals play a very important role in the conduct and management of Clinical Trials. Medical professionals are most suitable to play a leadership role in any organization which is involved in the clinical trials. With the increasing emphasis on drug safety, demand for medical professionals in clinical research industry is increasing at rapid pace. There are several opportunities with leading multinational and Indian pharmaceutical companies; clinical research organizations, knowledge companies, hospitals and international organizations, with excellent career growth. Listed below are some key job titles:

Job Opportunities for Doctors

- Clinical Research Coordinator
- Clinical Research Associate
- Medical Monitor
- Drug Safety Associate
- Drug Safety Physician
- Drug Safety Expert
- Regulatory Affairs
- Medical Advisor
- Principal Investigator & Co-Investigator
- Medical Advisor
- Medical & Scientific Writer
- Quality Assurance / Quality Control Associate

Starting Salaries: Rs.2 to Rs.6 lakhs per annum, with excellent annual growth. This is subject to qualifications, experience, performance in interview, company and several other factors.

Why to choose Clinical Research as Career Option?

- Part of the booming global drug development industry
- Integral part of the clinical research process
- Excellent career option and attractive salaries
- Excellent work environment
- Attractive jobs in Multinational and leading Indian research and pharmaceutical companies
- International opportunities

In order to be a part of this industry, you need to acquire specialized skills, required to develop career in this space. Cliniminds offers specialized 6 months program in clinical trials management for medical professionals along with excellent placement support. Key details are:

Mode **:** Classroom **-** Part time (classes on Sunday), E-Learning System & Videoconferencing.

Duration **:** 6 Months

Eligibility **:** MBBS, BDS, BHMS, BAMS.

Examination **:** MCQs; Project work; Paper based examination and Viva.

Certificate **:** Certificate would be awarded upon successful completion of the Program. Program is certified & Accredited by the Pharmaceutical Society of India.

Course Fee **:** Rs. 95,000 (Payable in two installments) – HDFC Bank Loan facility available.

Job Assistance **: 100%** Placement support would be provided to the successful candidates. We have excellent placement track record.
(Our Students are placed in Quintiles, Novartis, Ranbaxy, Pfizer, ICON, Max Neeman ,GSK, Rajiv Gandhi Cancer Institute and many more other companies and research centres)

Program Detail **:**

- Clinical Research Introduction & Terminology
- Introduction to Pharmaceutical Industry & Global Challenges
- Global Clinical Research Environment & Opportunities
- Principles of Pharmacology & Drug Discovery & Development
- ICH GCP Principles, Indian GCP & Schedule Y
- Regulatory Affairs
- Roles & Responsibilities of Key Stakeholders
- Ethics in Clinical Research
- Preparations & Planning for Clinical Trials
- Essential Documentation in Clinical Research & Regulatory Submissions
- Clinical Trials Project Planning & Management
- Study Start up Process
- Clinical Monitoring Essentials & Medical Monitoring
- Compliance, Auditing & Quality Control in Clinical Research
- Clinical Data Management, Biostatistics, Analysis & Reporting
- Pharmacovigilance

- Bioavailability and Bioequivalence Studies
- Management of Cancer Clinical Trials
- Organizational Behavior & Human Resource Management
- Fundamentals of Financial Management

Course Objectives :

- To provide a comprehensive introduction to the clinical research process, conduct & management of clinical trials.
- Learn the skills, knowledge and competencies that are required for the key positions.
- Become more familiar with roles/jobs as part of the study team.
- Extensive Knowledge & application in different aspects of Clinical Research.

Key Faculty Members :

- ***Dr. Shivamurthy Nanjundappa, MD (Pharmacology)***
  ***(*Director - Clinical Research and Business Development, Quartesian Clinical Research Pvt Ltd.)**

  He has more than 10 years experience in drug development and has worked on more than 120 clinical projects. The client list includes: Merck Sereno, Astrazeneca, Sanofi Aventis, Astellas, Merz, Daiichi-Sankyo, Ranbaxy, Cipla, Lupin, Zydus Cadila, Microlabs and Strides Arco labs. This experience includes conducting Pre-clinical trials, Phase 1, 2, 3 and 4 trials, BA/BE trials and Pharmaco-epidemiology projects. Dr. Murthy has also developed clinical research departments in India for ICON, Fortis and Lotus. He has undergone training in GCP, BLS, ACLS, Clinical operations, Pharmacogenomics, Pharmacovigilance, Medical Affairs related activities.

- **Paul Benninger**

  Paul Benninger has twenty years of global Clinical and Bioanalytical research experience in which the last 10 years have been in the pharmaceutical CRO sector. He has a complete hands-on experience in over 600 Phase 1/BE/BA studies, and over 50 single-centre Phase 2 and multi-centre Phase 3 clinical trials.

  During the past 10 years he has grown a privately held full service CRO from 6 employees to over 600 employees from Canada and US. Mr. Paul also has a significant regulatory compliance experience with all major regulatory agencies including the FDA, EMEA, TPD and ANVISA. He has been involved in numerous successful North American FDA and TPD inspection as well as providing independent auditing services for Indian CROs. In 2006 while under his leadership, Allied Research International become one of the most successful CROs in North America.

- **Ms. Deepti Goel**

  Deepti Goel has an overall 10 years of experience in clinical research working with Pharma companies, CRO and training academy. By Training, she is an M.Pharm with specialization in Pharmacology. She has passed out from Delhi Institute of Pharmaceutical Sciences and Research (DIPSAR), Delhi in the year 1999. She has worked across various clinical research verticals including clinical operations, quality assurance, regulatory and training. She has monitored, managed projects, mentored teams and trained clinical research professionals. She has been instrumental in setting up a QA and Training unit in one of the Pharma companies in the past. As a monitor she has prepared many sites for inspections and faced many external audits. As an auditor, she has carried various types of audits at the sites, CROs and Central labs. She has conducted various training programmes for internal team as well as corporate on Basic and advanced GCP and related issues.

  In her current assignment she is the Head of Training and Operations at Cliniminds and is responsible for oversight of operations and training needs and development of Cliniminds across India. She is responsible for all academic related plans, tasks and activities for all courses offered by Cliniminds

- **Gary R. Slizgi, (VP Clinical Operations,Quartesian Clinical research Pvt ltd)**

  Gary Slizgi brings 20+ years of experience in both big Pharma and biotech industry overseeing senior management positions in clinical operations for companies including:

  - Dupont
  - Dupont-Merck
  - Agouron
  - Pfizer

  In addition, he has contributed to several NDA submissions in the fields of cardiovascular, CNS, oncology, and HIV.

- **Dr. Vijay Venkatraman Janarthanan**

  Dr. Vijay Venkatraman Janarthanan is a medical doctor specialized in Diabetology. He started his career in the pharmaceutical industry at Accenture's Global Pharmacovigilance & Epidemiology unit as a Medical Review Safety Physician (Drug Safety Physician / Drug Regulatory Doctor).

  He continued his career at ICON Clinical Research as a Clinical Research Physician and have accumulated three years of industry and academic experience to my credit. While at ICON, he handled the tasks of a Medical Monitor as well as those of a Project Manager, along with the responsibilities

of a Pharmacovigilance Physician. He now functions as a consultant physician and trainer in Pharmacovigilance, and currently heads Cliniminds in Tamil Nadu, India.

He has been training students in Pharmacovigilance and Drug Safety for several years.

FAQs for Medical Professionals

Is M.Sc. Clinical Research essential or preferred qualification for clinical research jobs for medical professionals?

NO – M.Sc. is neither a preferred qualification nor you would receive any extra benefit after spending two years and several lakhs? As a medical professionals, you need to understand the ICH GCP Principles, clinical research processes, monitoring, drug safety, documentation, regulations, guidelines, and trial management. For understanding these topics you do not need to go through two years M.Sc. program. Cliniminds programs are well established for over 5 years and we have large number of doctors at good salaries. Over the years these doctors have grown to very senior and important positions in multinational and Indian companies, and their salaries have jumped 3 – 4 times from where they started.

Is 6 month program good enough to learn clinical research?

YES - 6 month weekend program is perfect duration for the medical professionals. You are already a qualified medical professional and your learning abilities are much better. There are several things which you are aware as medical professionals. A good clinical research program would help you in learning the various clinical trials issues at the right pace. The program would provide you over 100 hours of solid clinical trials training.

I am a practicing medical professional – can I be part of the clinical research industry and continue to practice without working full time with the Pharma companies or CROs?

YES - You can either work as a full time clinical research professional in the pharmaceutical company; CRO **OR** can become certified Principal or Co-Investigator for the trials conducted by the sponsor companies. This allows you to function independently, continue to practice and still be a part of the clinical trials industry. Pharmaceutical companies provide grants to conducts such clinical trials and you are an integral part of the clinical trial process.

What are the other part time opportunities I can work on as medical professionals with clinical research qualification?

- Medical & Scientific Writer
- Medical Monitor
- Medical Advisor / Co-Investigator at BA/BE Centres
- Consultant

Would you provide guaranteed placement?

In the last few years we have done 100% placements. We have excellent placement record. Placing a candidate after successful completion of the program is our key responsibility. However, placement activity requires not only commitment from our side, but equal amount of commitment from your side as well, in the form of good learning, attendance, completion of assignments and passing exams, and prepare yourself well for attending the interviews.

Is your program UGC, AICTE or MCI approved?

At present there are no guidelines for the approval of the clinical research programs. The subject at present is out of the purview of these organizations. Our programs are more professional or skill enhancement in nature. These programs help you to become better clinical research professionals. Companies do not have any such requirements for the clinical research programs as well. However, our programs are certified / accredited by the leading industry association – Pharmaceutical Society of India. We are also an ISO 9001 : 2000 Certified Institution. In addition, Cliniminds has several industry collaborations with the companies like Fortis Clinical Research Limited, Quartesian, USA and other organizations for the practical training required in certain programs.

Is Medical Professional with Clinical Trials Management program preferred in jobs?

YES - Medical professionals with Clinical Trials Management program preferred over several other life sciences qualifications. However, every pharmaceutical company or CRO has several positions. Medical qualifications are essential for some positions. For several positions candidates with medical qualifications are preferred. However, any leading company would have good mix of professionals from medical, pharmacy/pharmacology, bio chemistry, microbiology, bio technology and other life sciences back ground. Different qualifications bring different expertise in any organization. This is healthy for any organization, as there is lot to learn from each other.

How much I can grow as a medical doctor in a pharmaceutical company or CRO?

There is no limit to growth. Hard work, performance, commitment, long term vision for the organization and continuous up gradation of skills would allow you to grow to the topmost position of the organization. Your medical background would always help you to achieve that level. There are several examples of successful CEOs, Medical Directors or other top managers from the medical background.

Can I start my own CRO?

YES - once you acquire sufficient experience, you could set up your own clinical research organization and offer services to the sponsor companies. However, acquiring experience is extremely essential before you start your own CRO. In future, government may introduce the compulsory licensing of CROs, and as medical professional you could have advantage, if you have right qualifications and experience.

There are several CROs and SMOs are being successfully run by medical professionals.

If you have more questions, please feel free to contact us at info@cliniminds.com or 9810068241.