# To know more about Clinical Trials Research and Administration

1. What is a Clinical Trial?

A Clinical trial is a comparison test of a medication or other medical treatment (such as medical devices), versus a placebo, other medication or devices or the standard medical treatment for a patient's condition. Clinical trial is investigation in human intended to discover or verify the effects of a drug, and / or to identify any adverse reactions to that investigational drug with the object of ascertaining its safety and /or efficacy.

2. What is the requirement of manpower and professionals in the country?

It is certain that in future as the number of clinical projects expands, there will be demand for qualified personnel. According to a McKinsey report, the global clinical trial outsourcing opportunity in India in the pharmaceutical industry is estimated to be around $2 billion by 2010 and there will be requirement of 50,000 clinical research professionals. Trained pharmacists and clinicians can plug this wide gap. They will be involved in the various aspects of clinical research starting from site-monitoring, site-management, clinical data management, data analysis, report writing, report submission, presentation and publication.

In the field of clinical research, there is an imbalance between demand and supply with the scales tipping in favor of demand. Thus, pharmaceutical houses are hunting for trained professionals and are using bulk y pay packages to lure them.

According to the data from Express Pharma:

Table 1: Projected figures in respect of revenue, human power and patient load for Clinical Research in India

| | **2003** | **2008** | **2010** |
|---|---|---|---|
| Value (Million USD) | 50 | 200 | 1000 |
| Revenue (Crore INR) | 75 | 300 | 875 |
| Full Time Staff Requirement | 800 | 4000 | 20,000 |
| Site-Staff Requirement | 1500 | 6000 | 30,000 |
| Patient Load | 10,000 | 50,000 | 300,000 |

Source: McKinsey Report

3. What are the career opportunities?

Career prospects include a professional career in Clinical Research industry either as a clinical investigator, site coo radiator in at a hospital conducting clinical investigations or CRO (Clinical Research Organization).Jobs are also available in pharmaceutical industry, drug development, medical writing, biostatistics or as a Manager of Clinical Project, Clinical Research Business Development, Clinical Operations, Data Management, Regulatory Affairs and Auditing of Clinical Trials. You can build up your carrier in clinical trials as:

- Clinical Research Associate:

  The main function of a clinical research associate is to monitor clinical trials. He or she may work directly with the sponsor company of a clinical trial, as an independent freelancer o r for a Contract Research Organization (CRO). A clinical research associate ensures compliance with the clinical trial protocol, checks clinical site activities, makes on-site visits, reviews Case Report Forms (CRFs) and communicates with clinical research investigators.

- Clinical Research Investigator:

  TConduct BA/BE studies as per cGCP guidelines, Writing/revising SOP for clinical operations. Review of protocols, Investigators Brochures, ICF and CRFs Protocol, CRF and ICF preparation Plan & conduct of BA/BEIEC/IRB affairs-GC.

- Study Coordinator:

  Study coordinators work directly with study volunteers, providing them safety and protection while collecting and managing the study data. They promote, advertise, and conduct telephone and face-to-face screenings to recruit volunteers. During the study process, they assess volunteer condition and coordinate ongoing clinical/laboratory testing and physical exams. Coordinators may assess vital signs (height, weight, blood pressure, pulse), and some are trained to collect blood/urine specimens and performing function testing. Study coordinators follow up with volunteers after the study and manage a great deal of paperwork, electronic correspondence and data.

- Data Manager / Biostatistician:

  Biostatisticians collaborate with researchers to design studies that may show the seriousness of a disease, predict a specific disease's seriousness, evaluate a new treatment, assess the safety and effectiveness of medications and increase knowledge of environmental issues. Additionally, biostatisticians participate in research design, data collection, choosing and implementing appropriate methodologies, and interpreting the results.

- Regulatory Affairs Manager:

  Responsible for review & registration of documents as per country specific guidelines for ex port. Evaluation of technical data & answer to various related queries as per regulated & semi - regulated requirements. Liaison with regulatory authorities.

- Clinical Trials Auditor:

  Conducts audits for the regulatory/QA function within the Clinical Trials Department in order to help assure compliance with GLP/GCP in accordance with established FDA regulations and company policies and standard operating procedures Job Requirements Normally B.A./B.S. in Science w/1-2 years of experience.

- Clinical Project Manager:

Responsible for ensuring compliance across projects to all applicable Clinical Trial regulations, guidelines, SOPs Protocols and procedures. Coordinate project start-up, project maintenance and project close-out activities, Serve as the primary contact for the Sponsor and all project team members, Direct supervisory responsibility for project Coordinators, project Assistants, CRAs, etc

- Clinical Research Manager :

  Manage interdisciplinary clinical research projects, as Project. Supervise, train, and mentor Clinical Research staff, Approve investigator study budgets and contracts, Review an d approve regulator y and administrative documents, develop protocols and approve Case Report Forms (CRFs), Review Tables and Listings generated from study data. Author Clinical Study Reports. Train CRAs on monitoring, internal procedures, and query, resolution.

- Business Development Manager:

  Identify potential clients & establish business relations & convert into real business. Responsible for all Business Development functions Meeting new clients, following up on leads, CRM. Continuously monitor the Competition and Global Market.

- Drug Safety Associate :

  Manage and relay d rug safety information, maintain current knowledge of global drug safety regulations, summaries clinical safety data, participate in meetings with potential and actual study sponsors, write narratives with medical input from a physician, report SADRs to the Regulatory Authorities, participate in the training of operational staff on drug safety issues, quality control work o f other staff in the department, take on any other task as assigned by the manager or Medical Director within the capabilities of the Drug Safety Associate.

- Medical Writer:

  To prepare high quality documents, manuscripts, abstracts and other communication tools (slide presentations, posters etc.) for publishing in indexed scientific/medical journals or for presentation in scientific/Health Authority meetings.

- Clinical Data Manager:

  The Clinical Data Manager (CDM) ensures complete, accurate and consistent data for reporting to regulatory bodies. A CDM is involved in the setting up, running and reporting of clinical trials. The CDM processes data using a range of computer applications and database systems to support collection, cleaning and management of patient data.

Leading companies in Clinical Trials and Research:

Persons trained in Pharmacovigilance and clinical trials research will find good job options in the following sectors:

- Asian clinical trials serene
- Bioserve

- Clin invent
- Clintec international
- Clinigene
- Dr Reddy's lab
- Elly Lilly
- Glaxo smithkline
- IGATE clinical research
- Intass biopharmaceuticals
- Johnson & Johnson
- Lambda therapeutic research
- Lupin limited
- Matrix laboratories ltd.
- Merck
- Novartis
- Novo Nordisk
- Pfizer
- Pharmanet
- Quintiles
- Ranbaxy
- Roche India
- Sristek
- Siro Clinpharma
- Synchron
- Sanofi Aventis
- Torrent pharma
- Vimta labs
- Zydus
- Reliance life science
- Amed
- Accutest
- Actimus
- Adroit insights
- Alembic
- Asian Clinical Trials

4. Does the Institute provide Placement Assistance?

Placement assistance is provided to all the program participants. The Institute is in touch with several reputed Clinical Trial and Pharma companies where passing out students will be placed. The institute has also tied up with several reputed Recruitment Process Outsourcing