

Careers in Clinical Research- Opportunities, Demand and Challenges

Deepti Goel M.Pharm (pharmacology)
Head- Training and Operations
Cliniminds
Delhi

cliniminds

Table of Contents

- What is Clinical Research?
- Scenarios of CR (now and then)
- Why Clinical Research?
- Career Pathways
- Career Pipelines
- Career Development Plans
- Professional Skill-sets
- Education & Training

What is Clinical Research?

cliniminds

A Multidisciplinary Approach

Clinical research is applied research.

The purpose is to evaluate whether the medication is safe and effective when it is used for the disease under question.

Clinical trials also tell us what is the appropriate dose and route of administration.

Initial testing called Phase-I is carried out on healthy volunteers to understand the safety profile and observe how the body handles the drug.

The subsequent phases, Phase-II and III are carried out on patients suffering from the disease to understand the efficacy (whether it really works) and safety of the medication



Types of Clinical Research

- Investigator Initiated (**your idea; know-how; study design**)
 - Federal Agency (NIH,)
 - Contract research (Big/Small Pharma/Med Device Co, ...)
 - Collaborative research (another institution)
- Sponsor Initiated (**their ideas; drug/device/biologic; protocol**)
 - Clinical trials (Phase I, II, III, IV)
 - Contracted professional services
 - Consulting services -tests & evaluations

Regulations & Guidelines

Drugs & Cosmetics Act

- Schedule Y
- Indian GCP Guidelines
- Clinical Trial Permission
- Import License
- Export License
- BA BE Guidelines

ICMR Guidelines for Medical Ethics

ICH GCP Guidelines

USFDA

EU Directives

Clinical Research- Then and Now

cliniminds

Clinical Research—Earlier (late 1990's)

- Clinical research is a relatively new business and profession in India.
- During the previous decade, not even a single contract research Organization (CRO) existed in India.
- Pharmaceutical companies who were doing Clinical Trials managed regulatory work on their own and used to run the trial on their shoulders.
- Only a handful of senior doctors represented investigators participating in global multi-centric study

Scenario now has changed....

Today there are at least ten different types of clinical research players who provide career opportunities to prospective CR professionals.

These players are involved in various types of CR business:

- bio-availability management,
- site management,
- bio-equivalence studies,
- Phase II-IV trials Trial Monitoring
- data management,
- central laboratories,
- biotech, chemistry and biology,
- bio-IT solutions
- CR training

Facts and Figures

- India has produced 300 GCP trained investigators and approximately 600 trained CR professionals, who are successfully handling several global multi-centric studies.
- McKinsey estimated that the Indian CR market will grow to US\$ 1.5 billion in value by 2010

Why Clinical Research?

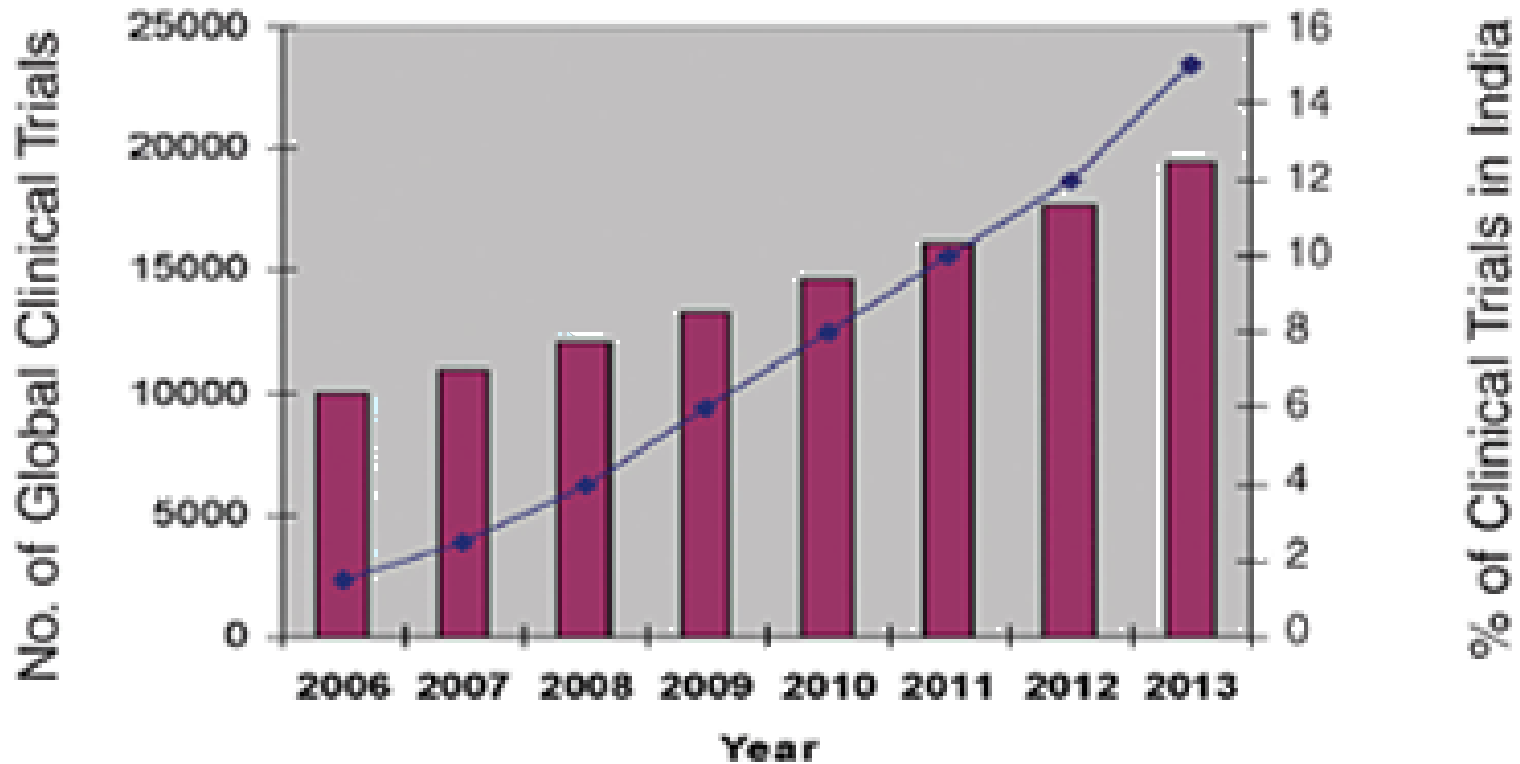
cliniminds

Why A Career in Clinical Research?

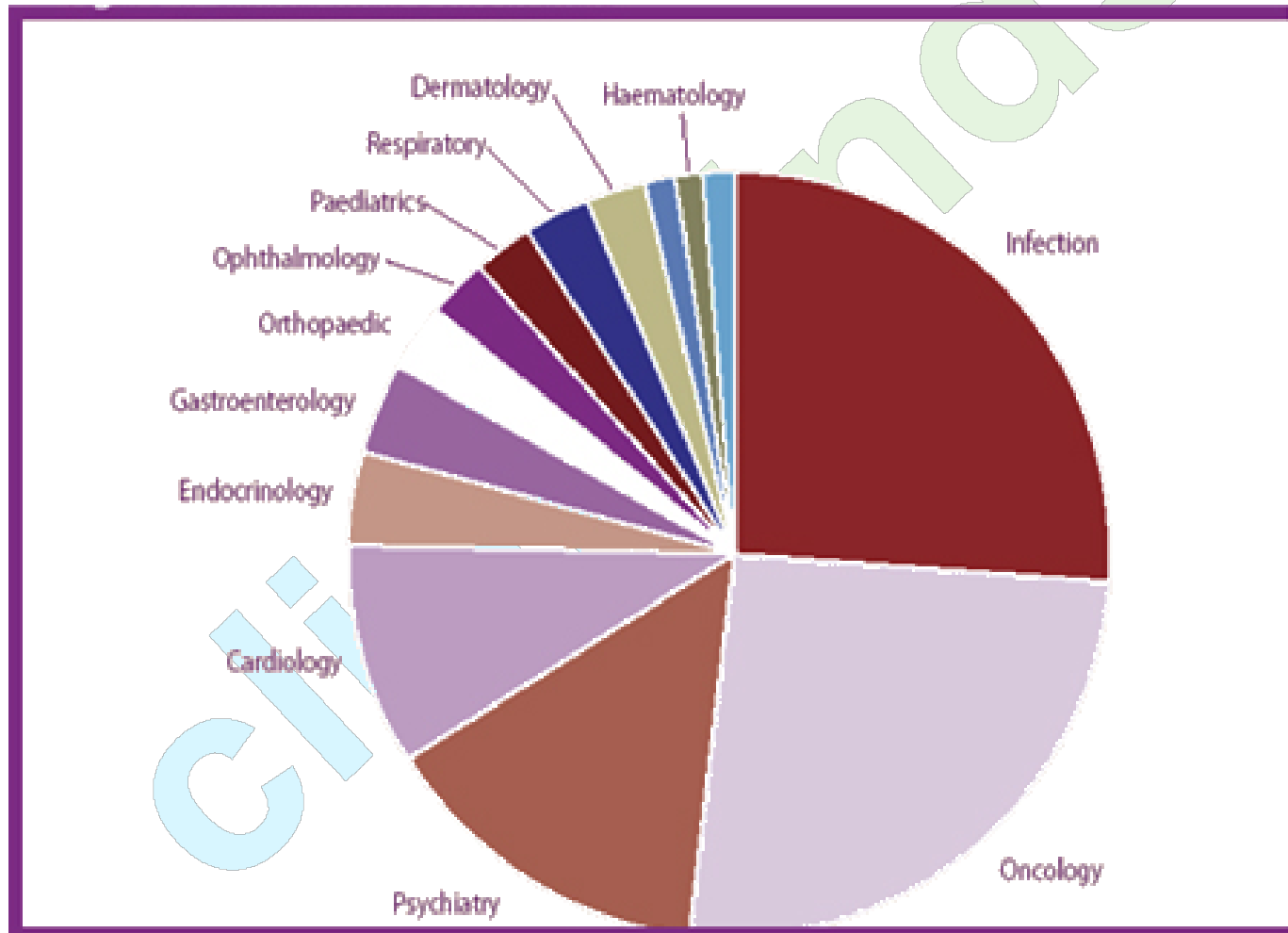
- Sunrise Industry, Booming Market
- Huge Demand & Supply Gap, Easy Entry
- White Collared, Knowledge Intensive Job vis-à-vis Boring Sales/Marketing/Production Jobs & Unstable and Uncertain Clinical Practice
- Good Career Prospects
- Quickies (quick money, growth on the ladder)
- National & International Travel, Cross-cultural Exposure
- Increased Contacts, Marketability
- Understanding of Drugs, Diseases & Management
- I Love Research, Documentation, Paper Work

Percent of global trials in India

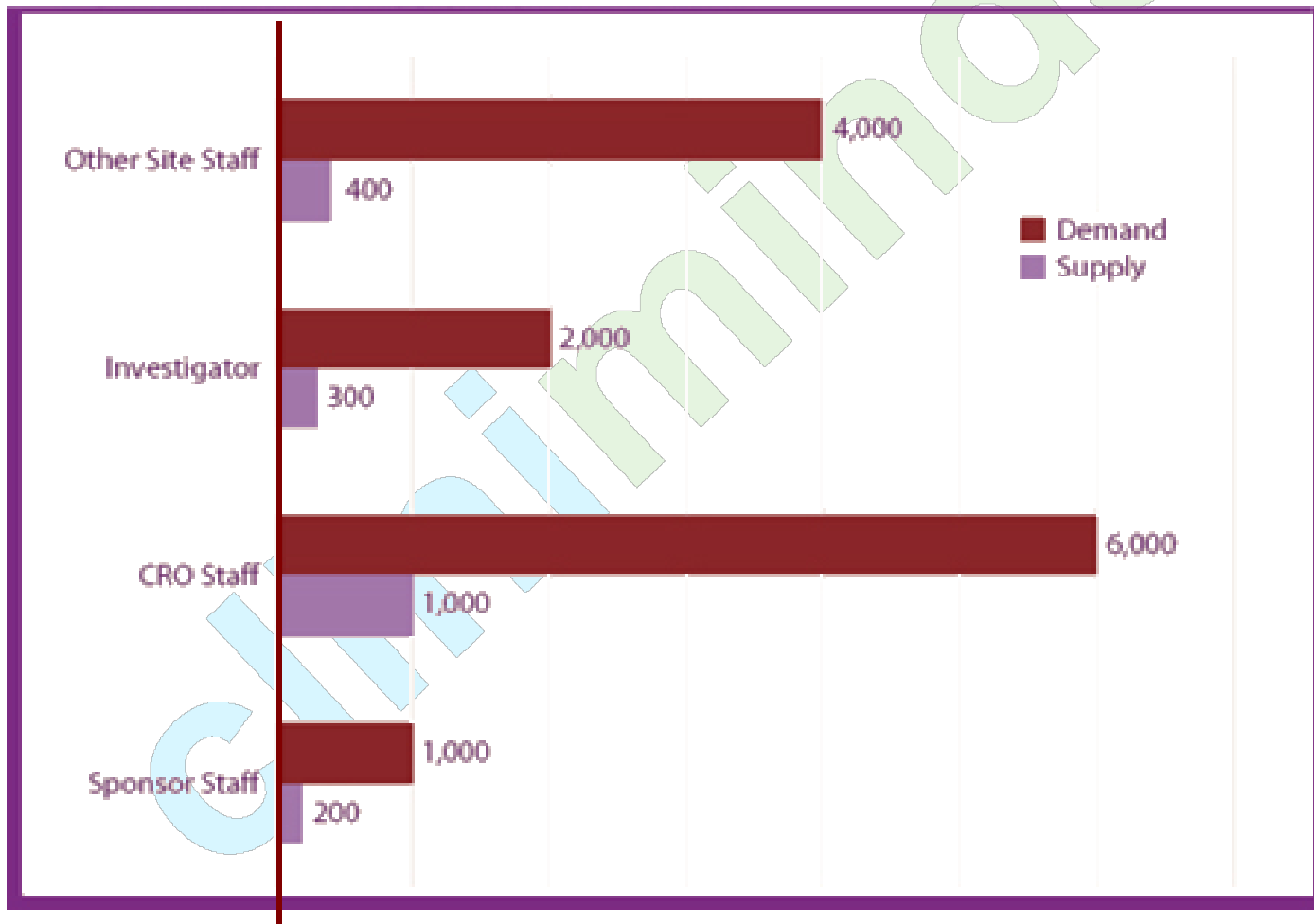
Number of Global Trials and % In India



Clinical trials done in India



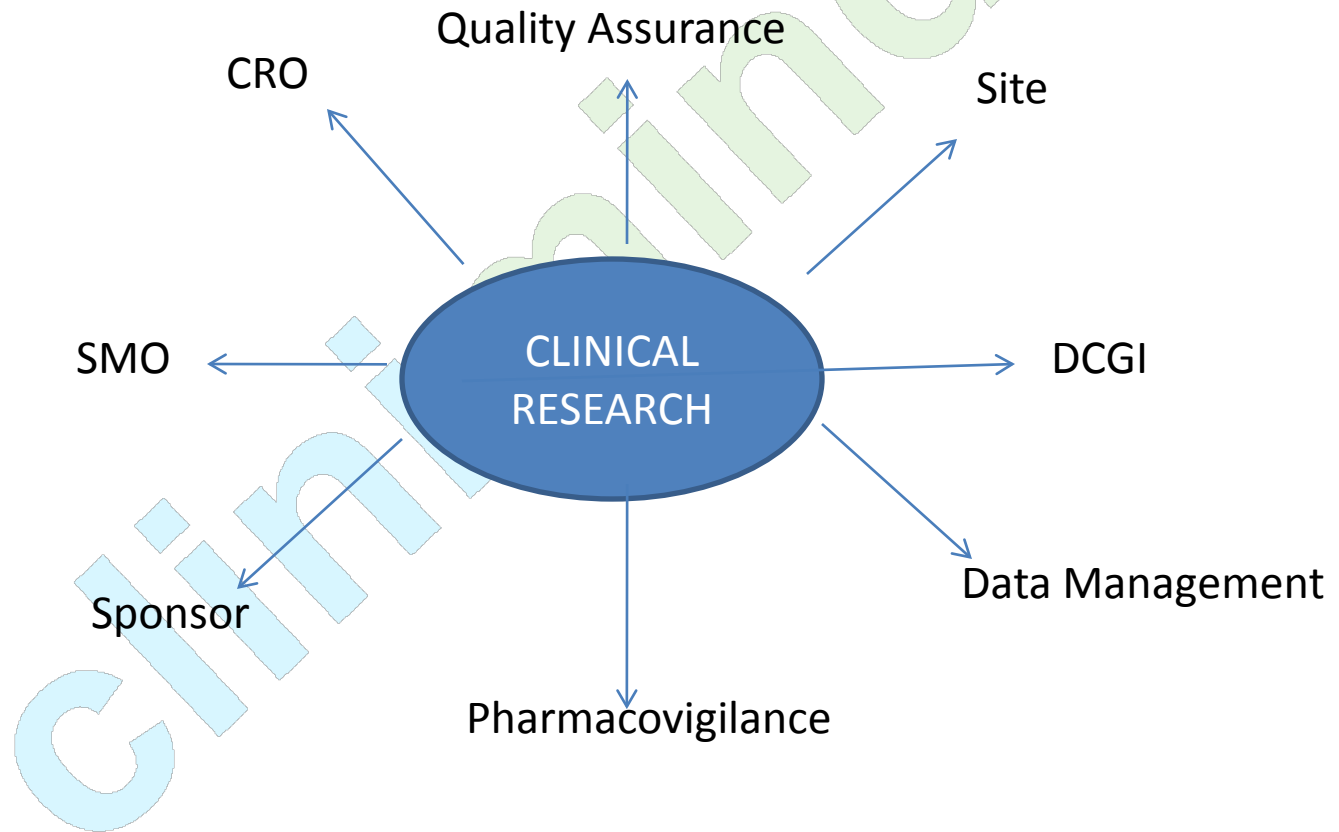
Demand Supply Gap in India



CR Career Pathway

- Pharmaceutical Companies
- Clinical CROs (Contract Research Organizations)
- BA/BE Centers
- SMOs (Site Management Organizations)
- Data Management CROs
- IT Companies in Healthcare / Clinical Domain
- EDC Service Providers
- Central Laboratories
- Packaging & Labeling & Contract Manufacturers
- Investigator & Site Staff
- Training Centers.

Functions in Career Pathways



Career in CROs / Pharma / Biotech Companies

- Clinical Trial Assistant (CTA)
- Clinical Research Associate (CRA)
- Senior CRA
- Clinical Team Leader
- Project Manager
- Senior Project Manager
- Manager Medical & Regulatory
- Manager –Safety / Patents
- Manager Quality Assurance
- Medical Director
- Associate Director –Clinical
- Associate Director –Projects
- Director –Business Development
- Director / Head (Clinical Operations)
- General Manger / CEO / President

Phase I / II / III / IV Trial

Project Management

Drug Development Planning

Monitoring

Source Data Verification

Safety Reporting

Regulatory Approval

QA Audits

Business Development

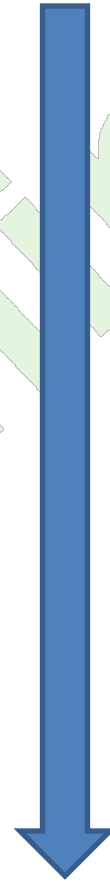
Career in SMO

- Clinical Research Coordinators (CRC) / Study Coordinators
- Principal Investigators / Co-Investigators
- Medical Monitors
- Project Manager / Senior Project Manager
- Manager Medical & Regulatory
- Manager Quality Assurance
- Manager –Business Development
- Medical Director
- Associate Director –Clinical
- Associate Director –Projects
- Director / Head (Clinical Operations)
- General Manager / CEO / President



Career opportunities in DM

- Data Entry Operator
- Data Validation Executive
- QA Executive
- Data Manager
- QA Manager
- Statistical Programmer
- Statistician
- Data Reviewer
- Data Base Designer
- Medical Writer
- Head –Data Management



Key Organizations into this area

- **Companies into clinical research Sponsor companies:** Johnson & Johnson, Biocon, GlaxoSmithKline Beecham, Allergan, Astra Zeneca, Ranbaxy Laboratories, Nicholas Piramal, Dr.Reddys Laboratories, Novo Nordisk, Pfizer etc.
- **CROs:** Quintiles, Manipal Acunova, ICON International, Clintec, Clinigene International, Accenture, Paraxel, Asian Clinical trials, Paragon, etc.
- **Hospitals :** St.Johns Hospital, M S Ramiah Memorial Hospital, Kidwai Memorial Hospital, Bangalore Institute of Oncology, Bangalore Diabetes Hospital, Wockhardt Hospital, Apollo Hospitals etc.

Key Cities in India for Clinical Research

- Delhi & NCR Region
- Mumbai
- Pune
- Ahmedabad
- Vadodara
- Hyderabad
- Bangalore
- Chennai

There are some new cities like Chandigarh; Bhopal, Indore, Coimbatore; Vizag are emerging as new centres for clinical trials

Knowledge

Basic knowledge

- Drug Development Process
- Clinical Trial Design & Statistics
- Adverse Events & Toxicology
- Regulatory & Ethics (GCP, GMP, GLP)
- Pharmacy, Pharmacokinetics, Pharmacology
- Disease, Diagnosis, Drugs
- Information Technology, Computing Skills

Clinical Profession Advantage

Annual Salary	Rupees	Position in Comparable Industry
CTA / DEO (0.5-1)	150000-200000	Area Manager (2-3)
CRA / Data Coordinator (1-2)	200000-300000	Executive / RM / ZM (6-8)
Senior CRA (2-3)	300000-450000	Manager/ RM/ ZM (6-8)
Regional CRA(2-3)	300000-450000	RM/ZM/SM (6-8)
Project Manager / Data Manager (3-5)	450000-600000	RM/ZM/SM (8-10)
Regulatory Affairs(3-5)	600000-800000	ZM/SM (8-10)
Quality Assurance (3-5)	450000-600000	Executive/ Mgr (QA)

Source:CenterWatch

Role of training

- Every player in clinical research is expected to be a responsible and committed manager.
- Training in clinical research to a great extent helps to build up most of these qualities and develop an insight into the field.
- However, it always depends upon the quality and the methodology of training and trainers' experience in the field.
- A good training will ensure that at the end of the course the student is able to take up responsibilities in the industry without further training by the employer where he would be eventually placed.
- Hence it is not sufficient to have an ambition to do a course in clinical research but also to choose the right institution.

Cliniminds

An Overview

[cliniminds](https://www.cliniminds.com)

Cliniminds Background

- Tenet Health Edutech Pvt. Ltd. was established in 2004. Cliniminds was established December 2006 to offer professional programs in the field of clinical research; healthcare and pharma space.
- **At present we offer over 23 programs in clinical research through Online/Distance Learning; Classrooms; and Workshop Modules. More programs are in pipeline.**
- **Cliniminds is Headquartered at Delhi, and have branches in Bangalore, Hyderabad , Cochin and Bhopal.** Our International offices are located in Prague and London. New branches are being set up in other cities as well.
- All programs are backed up by high quality content and faculty with global perspective.
- Plan to increase the offerings by introducing programs in Healthcare Management & Pharma space as well.
- Also offer E-Learning for the healthcare & pharma companies and CROs.

Key Activities

- Classroom Professional Educational Programs
- Online/Distance Learning – Global market
- Corporate Training
- E-Learning Solutions for Corporates
- Consulting Services & Market Research
- Medical & Scientific Writing

Current Offerings

- Cliniminds has class room training programs in Clinical Research with different variants. All Programs Accredited by the Pharmaceutical Society of India.
- Online & Contact Training Programs for Corporate clients - 1 – 3 days – corporate sponsored & independent events on Clinical Trial issues, viz. ICH GCP Workshop on Clinical Research, Advanced GCP, Pharmacovigilance, Quality Assurance, Auditing & Inspections, Monitoring, Regulatory Affairs and Medical Writing. Programs could be customized.
- Cliniminds currently offer 20 programs on different aspects of clinical research.
- Course Content designed by top Indian and international industry experts.
- Certificates jointly awarded by Cliniminds and Pharmaceutical Society of India.

Opportunities in Clinical Research

- **Question:**
 - Are there really good number of jobs to all the clinical research students passing out of the course?'
- **Answer:**
 - Yes, there are jobs available, but one must be able to move out of their town for a prospective career.
 - Secondly, the students must be able to come up to the high expectations of employers.
 - A mere degree in clinical research will not suffice.
 - There has to be an active effort by the student in understanding the subject and improving his soft skills.

To Conclude....

- A career in clinical research is definitely challenging and satisfying.
- However success is ensured only when one chooses the right course from the right institution after thorough spadework.

**Thank You for your patience
All the Best!**

Please ask questions!!!

cliniminds