

AN ISO 9001:2015 Certified Academy

"Nurturing Minds and Touching Lives"



Business Opportunities in Health Sciences Industry







Team Cliniminds

Questions we all ask what next after completion of my graduate or post Graduate degree?

- Where are the jobs?
- Where will I work?
- What should I study further?
- What are the long term career opportunities?
- Is Masters the only choice to go further in career?
- What if I don't get admission in Masters of my choice?
- What is the career ladder after my masters education?
- What are the new generation career options after my degree?
- After entry level Job what next?
- I am already working, what is there for me?



Presentations Objectives

To provide you with useful information on various new economy career options in the health sciences domain.

To explain what are the career options and entrepreneurship opportunities in:

- Clinical Research
- Pharmacovigilance
- Pharmaceutical Data Analytics
- Drug Regulatory Affairs, IPR & Patents
- Clinical Data Management & SAS
- Healthcare & Healthcare Insurance
- Medical & Scientific Writing



New Economy Career Options – Corporate Sector





Key Facts – Drug Development

It takes 10 – 12 years to develop new drug It costs US\$1 billion to develop new compound

After 1500 compounds screened only 1 makes to the market



What is Clinical Research

Applied research –Testing of drugs in humans to know about "safety" and "efficacy" of drug.

This is called together as "Drug Discovery and Development"

Testing on human subjects is Highly regulated

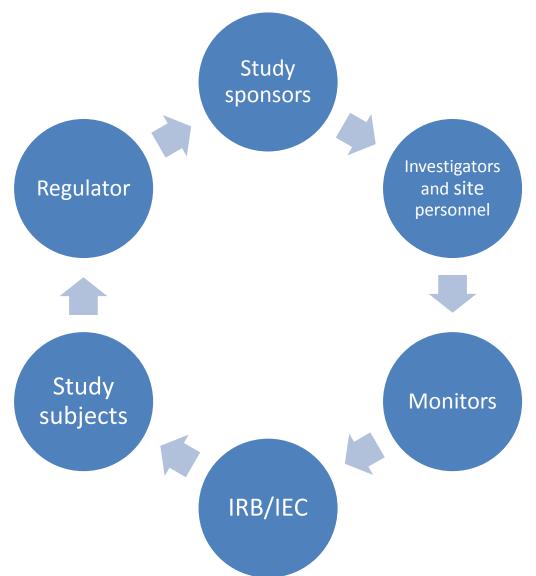


What is Clinical Research...Cont...

- Multi disciplinary effort :
 - Medical, non-medical teams
 - Managers & Scientists
- Requires Multidisciplinary team :
 - Pharmaceutical companies Sponsor, PM
 - CROs CRAs, PM, CRC, Line Manager's
 - Hospitals/SMO, PI, Sub-I, CRC, Pharmacist
 - Laboratories

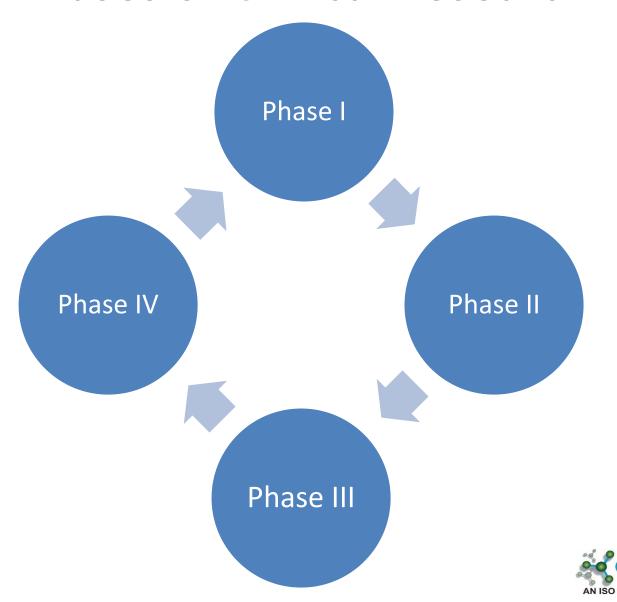


Key Stakeholders





Phases of Clinical Research



Why Regulations in Clinical Trials

Nazi Human Experimentations during second world war (1939-45)

A series of controversial medical experiments on large numbers of prisoners by the German Nazi regime in its concentration camps

Prisoners were coerced into participating

The experiments resulted in death or permanent disability and prisoners suffered intense agony



Nazi Experiments on Twins...



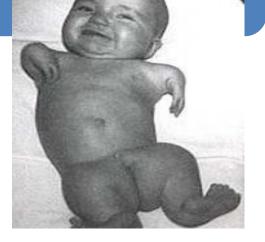


Thalidomide Tragedy

An inadequately tested drug "Thalidomide" without any safety assessment, was prescribed to pregnant women for morning sickness. It proved catastrophic results.

Aprox 10,000 children were born with severe malformities, including phocomelia with

- Fin-like hands grown directly on the shoulders
- Stunted or missing limbs
- Deformed eyes and ears
- Ingrown genitals
- Absence of a lung





Then came "Codes of Ethical Conduct"

Codes of Clinical Trial Ethics

- Nuremberg Code 1947 Set of research ethics principles for human experimentation set as a result of the Subsequent Nuremberg Trials at the end of the Second World War.
- Declaration of Helsinki 1964 Ethical Principles for Medical Research Involving Human Subjects.
- **Belmont Report 1979** Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Guidelines Regulations for Clinical Trial Conduct

- ICH GCP 1996
- Indian GCP 2005 Amendments



Regulatory bodies and framework in India

Schedule Y - The **Central Drugs Standard Control Organization** under the Ministry of Health and Family Welfare, largely works on developing standards and regulatory measures for drugs, diagnostics and devices; laying down regulatory measures by amending acts and rules; and regulating the market authorisation of new drugs.

Other Important Regulations to know – USFDA & EMA



Clinical Research Global Scenario

The total worldwide R&D spending for pharmaceutical and biotech companies (Pharma) in 2007 was \$117 Billion, of which 70% represented development costs. This spending is expected to grow at 11% annually and will be \$240 billion in 2015.

The global CRO market for Phase 1 through Phase 3 trials is approx. US\$40 billion, growing @ 12% per annum.

ClinicalTrials.gov currently lists 204,952 studies with locations in in 191 countries

India has over 622 active clinical trials as per the published data.

Six therapy areas, oncology, central nervous system, respiratory, endocrinology, cardiovascular and infectious diseases, account for 68% of all clinical trial protocols and 74% of all sites analyzed.



Clinical Trials Business in India

Pre-2005 20	005-2013	2013 Onwards
 Market less than US\$20 million 8 – 10 players 3 – 4 cities BA BE driven market – Ranbaxy, Dr. Reddy's No / Low regulation Lack of ethical guidelines 	New Regulations – Schedule Y – 2005 Rapid growth – from US\$20 million to US\$750 million Over 100 companies 15 cities Spin Offs – Lab, PV, CDM, Medical Writing Regulatory Challenges & Litigations	 Better Policy Framework Subject Compensation New Ethics Committee Regulation Audio-Video Recording of Informed Consent Process Accreditation Process Industry will be US\$2 billion by 2020 Pan India by 2020

Western India: Mumbai. Ahmedabad

- Accutest Research Labs
- Ace Biomed
- Adroit Insights
- •BA Research
- •Bioarch Research Solutions
- •Chiltern International
- •Clininvent Research Pvt Ltd
- Diagno Search
- •PPD
- •PRA International
- •Siro ClinPharm Pvt Ltd
- Lambda Therapeutic Research Ltd
- •Reliance Clinical Research Services
- Synchron Research
- Quiniles
- Vedic Life Sciebces
- •Veeda Clinical Research
- Ycelric

Southern India

- •Clin Tec International
- •Clinigene International
- •Clinitac International
- •ICON
- •Lotus Labs
- Ercon Acunova
- •Omnicare Clinical Research
- •PharmaOlam-International
- Pharmanet/Anapharm
- Tiesta Sciences



Job Opportunities in the next 4 -5 years

Clinical Monitors / CRAs - 5,000

Clinical Research Coordinators / Site Coordinators 15,000

Drug Safety & Pharmacovigilance Personnel 4,000

Investigators – 6,000

Project Personnel 1,500

Medical Monitors 1,000

Regulatory Affairs Personnel 3,000

Medical Writers 1,000

Quality Control / Assurance Personnel 2,000

Data Management Personnel 7,000

Bio Statisticians 500

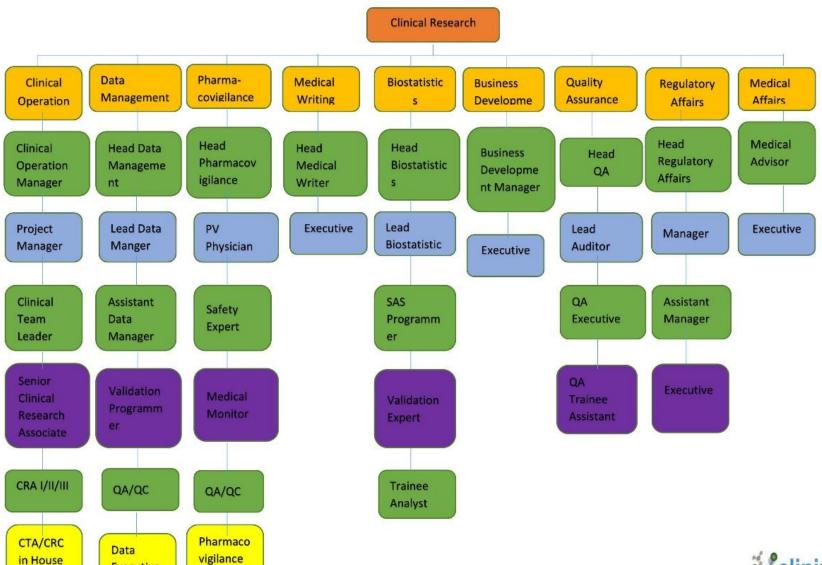
Research Scientists 2,000

Lab Personnel 1,500

Management & Administrative Personnel 2,000



A Typical Organogram of Clinical Research Organization



Executive

/Analyst

Associate

CRA



CR Career Pathway

Pharmaceutical Companies

Clinical CROs (Contract Research Organizations)

Pharmacovigilance Companies

BA/BE Centers

SMOs (Site Management Organizations)

Data Management CROs / IT Companies in Healthcare / Clinical Domain

EDC Service Providers

Central Laboratories

Trial supplies, Packaging, Labelling & Contract Manufacturers

Investigator & Site Staff

Training Centres



Pharmacovigilance

By 2020, marketing size would be US\$15 billion.

Requires highly skilled professionals

Science of drug safety

Pharmacovigilance During Clinical Trials

Post Marketing Pharmacovigilance

Pharmacovigilance is mandatory in US, Europe and other developed markets, and most countries globally are changing regulations for the stringent implementation of drug safety reporting.

India has set up new National Phamacovigilance Program

This is opening up huge opportunity for the pharmacy, medical and heal sciences professionals

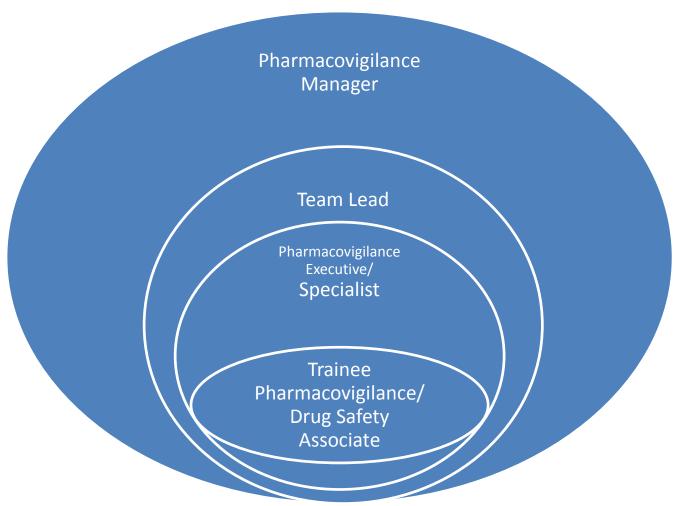


Pharmacovigilance

- Major global drug companies are outsourcing Pharmacovigilance from India. These include, Pfizer, Novartis, BMS, Merck, as India has certain inherent advantages.
- Excellent career pathway for medical and pharmacy students in pharmaceutical companies, CROs, pharmacovigilance service companies & IT / Consulting firms.



Pharmacovigilance





Pharmacovigilance/Drug Safety Associate

Triage of incoming reports for completeness, legibility and validity

Initial data entry of case reports into safety database / tracking system

Assessment of case reports for seriousness, causality and expectedness

Requesting follow-up i.e. written, telephone

Adverse event (AE) and drug coding

Writing case narratives

Create and maintain project specific working files, case report files and project central files

Assist with additional Drug Safety Specialist activities as required



What is Pharmaceutical Data Analytics?



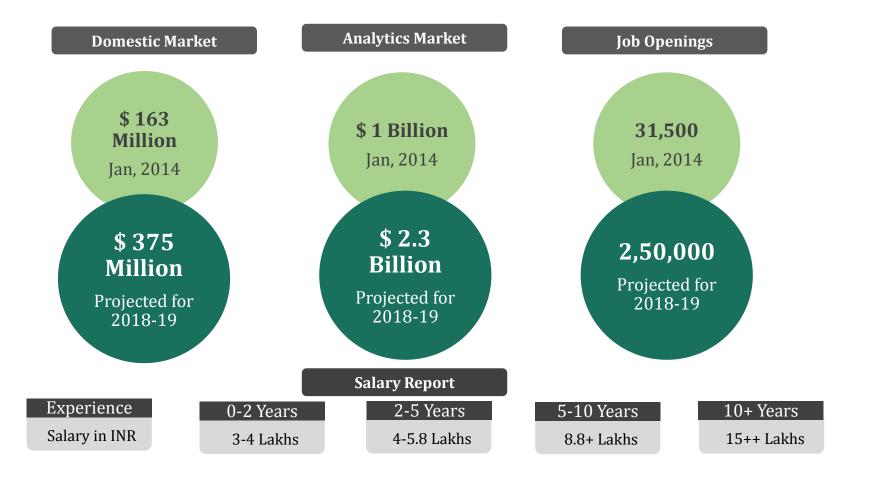
Data on its own is useless unless you can make sense of it!

WHAT IS ANALYTICS?

The scientific process of transforming data into insight for making better decisions, offering new opportunities for a competitive advantage



Demand for Analytics Professionals in India





New Analytics Jobs By Industry

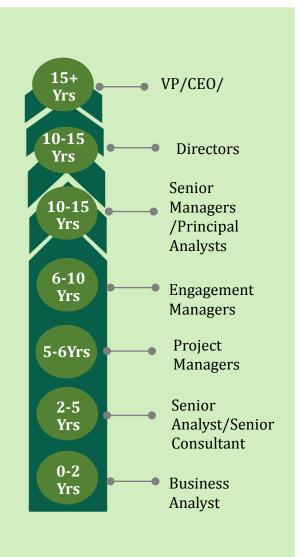


Analytics Services and Pharma lead the pack in the highest percentage of Analytics jobs being created in developing nations.

	US	INDIA	CHINA	UK	BRAZIL	JAPAN	SINGAPORE
PHARMA ANALYTICS SERVICES	11%	54%	25%	9%	14%	6%	9%
PHARMA	14%	24%	32%	19%	30%	44%	26%
INSURANCE	39%	7%	8%	32%	11%	27%	24%
BANKING	20%	11%	22%	25%	19%	14%	25%
OIL & GAS	14%	3%	10%	13%	23%	8%	9%
COMMUNICATIONS TECHNOLOGIES	2%	1%	3%	2%	3%	1%	7%
TOTAL NUMBER OF JOBS	38,700	31,500	30,500	7,000	6,200	2,400	1,300



Career Path and Indicative Salaries



Skills require to succeed in the Industry

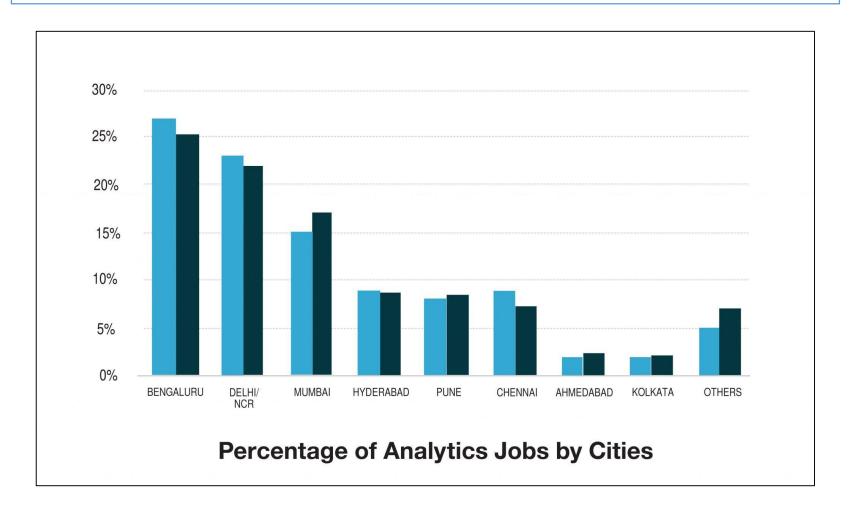
Average Salaries

- Strong analytical and critical thinking skills
- Pharmacology
- Predictive Analytics
- Clinical Research
- Understanding complex data & tools for Analytics
- Soft Skills & Communication
- Business Understanding

	Average Salaries
Directo	Do 40 Lal-ba (Abayya
r	Rs. 40 Lakhs & Above
AVP	Rs. 18-24 Lakhs
Manager	Rs. 9-15 Lakhs
C	
Senior Analyst	Rs. 6-8 Lakhs
Analyst	Rs 4-6 Lakhs



Analytics jobs by cities



Source Type: https://analyticsindiamag.com/analytics-and-data-science-india-jobs-study-2017-by-edvancer-aim/



Cliniminds Pharmaceutical Data Analytics Course Focus and Goal

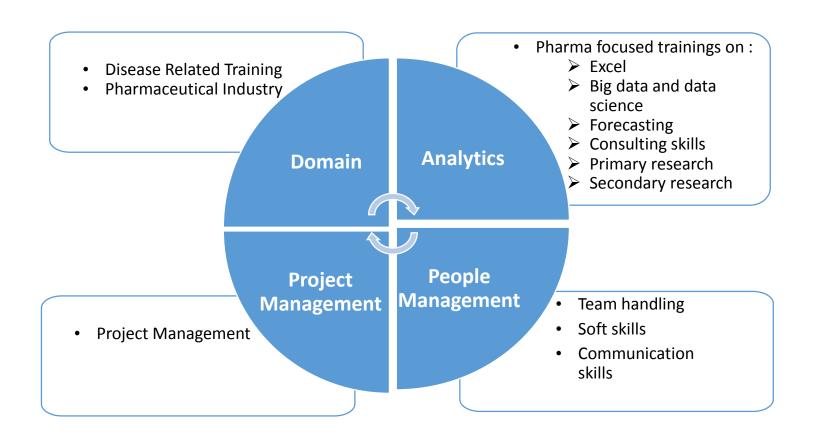
<u>Pharmaceutical Data Analytics course is designed to cater skill gaps</u> <u>through</u>

- Intense focus on domain and analytics
- Case based curriculum, with real life examples from healthcare industries
- Overview of big data in the context of health care industry

GOAL of this course is to empower student to take up analytics role in healthcare industry and have a successful career in this exciting field



Cliniminds Pharmaceutical Data Analytics Course will build required skills through 4 Modules





Medical & Scientific Writing

Critical process for drug companies and other life sciences organisations.

Global market size is US\$1 billion

Requires specialised skill set

Excellent command over written English

Some of the key medical & scientific writing areas:

- Documents in Clinical Research & Drug Safety
- Documents in Medico-marketing
- Publication / Manuscript / Abstract / Poster Writing
- Poster Writing & Development
- Regulatory Writing
- Handling Statistics in Medical Writing
- Fffective Internet Literature Search
- Referencing guidelines
- Legal / Copyright Issues in Medical Writing



Medical Writing

Scientific Writing

- Writing Manuscripts
- Publications Writing
- Writing of Product Monographs
- Conducting CME
- Medical Speaking in Product launches

Clinical Research Writing

- Writing Protocols
- IBs
- Clinical trial Reports
- Safety / Medical Monitoring
- AEs, ADRs Management
- Preparing Safety narratives
- Providing Therapeutic Training



Regulatory Affairs

The Regulatory Affairs professionals keep track of the changing legislations in the regions in which the company distributes its products.

Regulatory Affairs professionals advise on :

- Legal and scientific restraints and requirements.
- Collect, collate and evaluate the scientific data that their R&D Dept. generates.
- Regulatory and scientific knowledge.
- Expert solutions to FDA and other regulatory agencies' queries.
- Access to Scientific and technical resources.
- Formulation and implementation of regulatory strategies at a global level.



RA Professionals are Employed In the following companies?

Pharmaceutical **Medical Device** In vitro Diagnostics Biologics and Biotechnology **Nutritional Products and Food** Cosmetics **CROs** Veterinary **Government Departments**



Regulatory Affairs Career Ladder

0-3 Years of Experience - Executive Level

3+ years - Middle Level

6+ years – Senior Level

Associate Director – 8 - 10 Years

Director

Vice President

President



Clinical Data Management

What is Clinical Data Management?

Collection, integration and validation of clinical trial data.

What kind of data will I be managing?

All clinical trial data including safety and efficacy data of drugs/agents under study

What kind of data does CDM have?

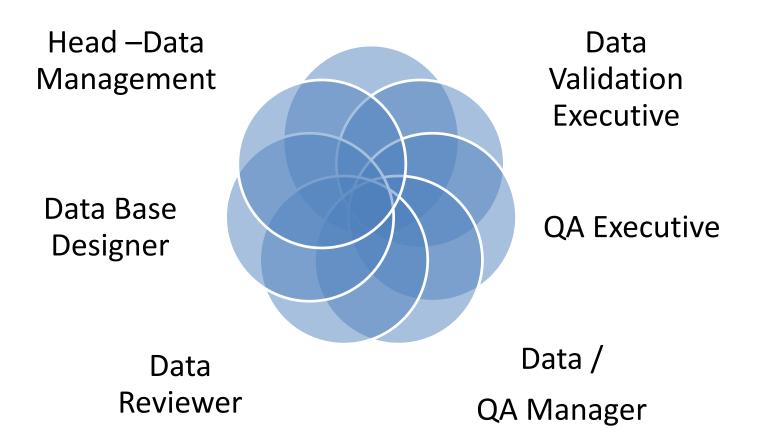
All data coming from CRF from sites (hospitals/clinics) and non-CRF data coming from clinical laboratories.

What exactly will I be doing in CDM?

Collect and validate the trial data, review and querying the investigators, and quality assurance of the trial data



Career Opportunities in DM





Career Opportunities in Biostatistics & SAS

Bio Statistician

SAS Programmer

Lead-Biostatistician

Head Biostatistics



Healthcare Management & Hospital Administration

- Healthcare management & administration is the study of different aspects of health care such as healthcare policy, healthcare insurance, healthcare economy, quality assurance, international healthcare systems in order to prevent, to cure and management of diseases.
- On the other hand, Hospital management and administration is concerned with the organization, coordination, planning, staffing, evaluating and controlling of health services for the masses.

Size of Healthcare Industry

Market Size: As per the IBEF reporting currently the healthcare industry is a 100 billion dollar industry.

It is estimated that till 2020 it will be 280 billion dollar industry.

The market size is expected to grow by 22 percent from 2010 to 2020, faster than the average for all industries.



The Healthcare Market is Split into Five Segments

Hospitals

Pharmaceutical

Diagnostics

Medical Equipment and Supplies

Medical Insurance



Size of the Opportunity?

Pharma Industry: Rs.75,000 crore

Healthcare Services Industry: Rs.400,000 crore

Hospitals: Rs.350,000 crore

Diagnostics: Rs.8,000 crore

Health Insurance: Rs.8,000 crore

Medical Devices: Rs.7,500 crore



Where would I work?

Hospitals

Physician practices

Public health departments

Mental health organizations

Rehabilitation centers

Universities and research institutions

Nursing homes

Consulting firms

Health insurance organizations



Healthcare Associations

Diagnostic Centers

Business Development

QA/QC

Eye / Dental Chains

Specialized Clinics

Specialized Maternity hospitals

Nutrition & Diet Clinics

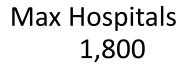
Emergency Medicine

Lifestyle Clinics...and many more



Key Healthcare Players





CARE Hospitals

1,912





Apollo Hospitals Enterprise Ltd 7,496

Manipal Group of Hospitals 4,400



Introduction of Health Insurance Management.

Attractive career opportunities in health insurance companies, TPAs and hospitals.

Jobs in claims management; medical underwriting, provider insurance management; customer care; patient care; corporate marketing.

Attractive salaries and incentives.

Corporate function.



Indian health insurance market size (USD million)

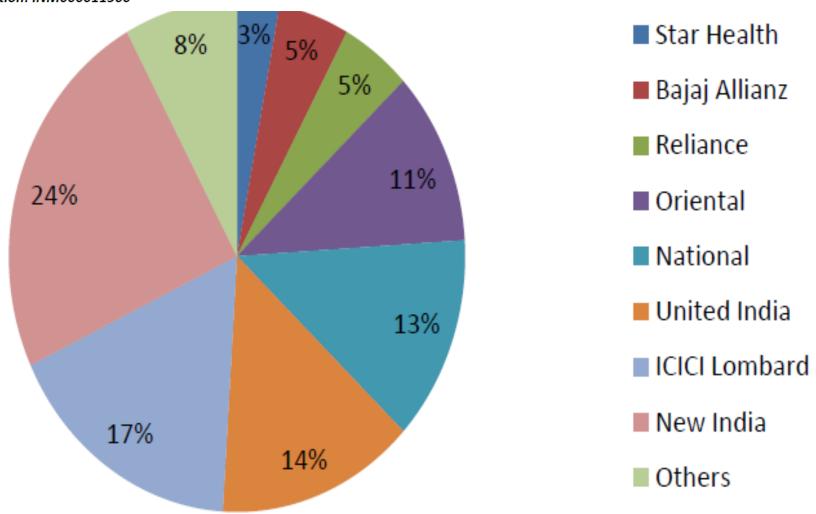




Source: IRDA, Towers Watson Aranca Research Note: CAGR - Compounded annual growth rate

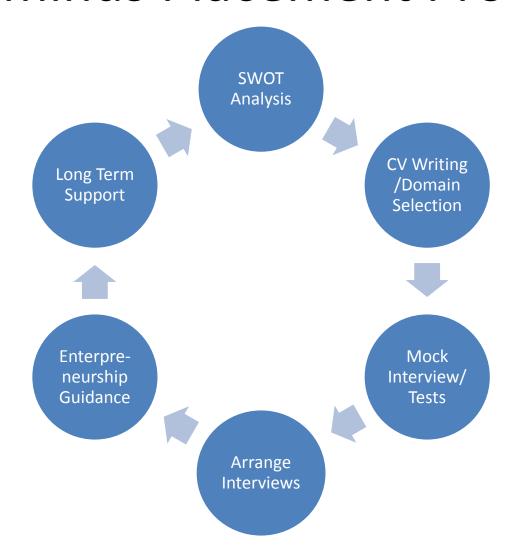
Market Share of Key Players in Health Insurance Companies (2008)

Northbridge Capital is an Investment Bank(Category I Merchant Bank) regulated by the SEBI Sebi Registration: INM000011500





Cliniminds Placement Process





Student Placements @



Quartesian





Apollo Hospitals







AUROBINDO



















Starting Salaries

Job: Clinical Research Associate - **Profile:** Monitoring clinical trails. Ensuring well-being of patients, accuracy of data and adherence to good clinical practices (GCP). Salary: Rs 2 lakh-3 lakh p.a.

Job: Clinical Research Coordinator - **Profile:** Conducting clinical trials using GCPs. Coordinating with various departments. Salary: Rs 1.8 lakh-2.5 lakh p.a.

Job: Pharmacovigilance Personnel - **Profile:** Noting, reporting and analysing side effects to improve research within the company. Salary: Rs 2.5 lakh-3.5 lakh p.a plus.

Job: Clinical Data Management Personnel - **Profile:** Data processing, data quality control, database setup and testing. Salary: Rs 2 lakh p.a.

Job: Project Manager - **Profile:** Overall management of clinical trials or programmes. Salary: Rs 3 lakh-4 lakh p.a.

Job: Medical Monitor - **Profile:** Handling patient safety and providing medical guidance. Salary: Rs 5 lakh-6 lakh p.a.

Job: Regulatory Affairs Personnel - **Profile:** Primary link between the company and regulatory authorities. Salary: Rs 2 lakh-2.5 lakh p.a.



Starting Salaries

Job: Medical Writer

Profile: Creating documents that effectively and clearly describe research results,

product use and other medical information. Salary: Rs 3 lakh-4 lakh p.a.

Job: Quality Assurance Associate

Profile: Handling internal, systems, facility and documentation audits. Salary: Rs 3

lakh-4 lakh p.a.

Job: Clinical Research Statistician

Profile: Applying mathematics to design surveys and experiments. Collecting and

analysing data and interpreting results. Salary: Rs 6 lakh-7 lakh p.a.

Job: Clinical Research Scientist

Profile: Involved in the entire drug development process, responsible for technology

transfer from lab scale to commercial scale. Salary: Rs 4 lakh-7 lakh p.a.



What is entrepreneurship?

Entrepreneur is an individual who organizes and operates a business or businesses, taking on financial risk to do so.

Undertakes an Enterprise

Risk

Effort

Ownership and or Operates

Reward

New or Revitalising Old



When can I become entrepreneur?

There is no late or early age

Earlier the better

Acquire some domain expertise or experience – thought not essential

You may have a bright idea, so sooner you do it's better

There are success stories at all stages



How is our Ecosystem & Regulatory Environment?

Ecosystem is evolving for young first time entrepreneurs

With the new Companies Act, company formation time and cost should come down

Life sciences is highly regulated domain, hence, understanding of the landscape is important

Raising capital is hard but changing for good

Depending upon your area of interest understand federal regulations, state level regulations, municipal laws, environmental laws and related business laws

Where do I raise capital from?

Self-Funded, Family & Friends

Angel Investors

Debt

Venture Capital or Private Equity

Government Schemes (State & Federal, e.g. DBT)

University Incubators

Industry Associations (e.g. ABLE)



What to do / what is the way forward?

'Execution' is most important – idea may be great but success is in 'execution'

If you have an idea – find the mentor to discuss and give idea 'shape'

Develop a small core team

Understand the size of the opportunity (local, regional, national or international)

Draw up a business plan

There is no 100% guaranteed fool proof business plan – industry dynamics could change / policies could effect

Do a pilot or proof of concept – find some users of your product / service

Set up the company

Use your capital at early stage – avoid raising capital from VC at 'idea' stage



Once you have proof of concept, then work towards next step of commercialisation and scale up

Focus on revenue and profitability

Raise capital when you want to scale up

Capital comes with huge cost – be emotionally prepared to sell stake if you need to raise capital

Explore debt option before selling stake

Protect IPR for your product / service

Build professional team

Work on scale up

Have an exit plan for your investors

Entrepreneurship is the journey



CLINIMINDS VISION & MISSION

Mission - Cliniminds is committed to provide highest quality training, education and management solutions and develop superior human resource for the global clinical research and healthcare industry.

Vision - To establish a world-class education & training institution that offers the widest range of high-quality clinical research, healthcare and pharmaceutical programs and business solutions.



AWARDS

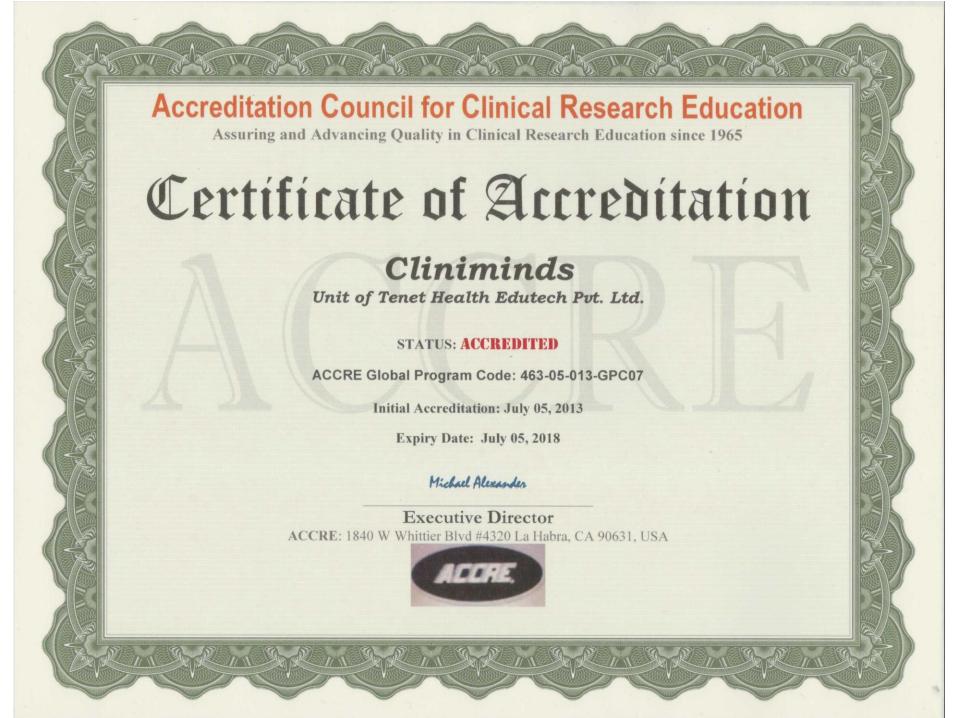
Six years consecutively – 2011, 2012, 2013, 2014 2015 & 2016 -Cliniminds has been awarded as the:

Best Clinical Research Institute in India

& Health Sciences
Business
Management
Institute in India

Reflects our commitment for the quality of professional education, training & employability in the life sciences domain





CLINIMINDS BACKGROUND

Year 2004 – Tenet Health Edutech Pvt. Ltd., promoted by team of Industry professionals and academia

India's first skill development institution in health sciences domain to receive SwAPP, Switzerland Accreditation

Offers wide range of skill development clinical research, pharmaceutical and healthcare educational programs and training solutions

Class room & online programs and corporate workshops

Programs sustained by superior copyright content and faculty with global stand point.

Multiple locations in India and international reach.

E-Learning solutions in accordance with industry specific needs.

High quality & experienced faculty.



CLINIMINDS – KEY ACHIEVEMENTS

Established 30 programs with extensive, high quality course content and faculty: Online; E-Learning; Distance Learning & Classroom. More industry oriented programs currently in pipeline.

National Presence – 12 major cities in India

International Centres: USA; UK, Saudi Arabia, South Africa

Programs Accredited by the Accreditation Council for Clinical Research Education, US

Program content is targeted towards all major global markets and address the global regulatory environment. Overseas students are growing from Americas; Europe; Middle East; Africa and other countries.

Developed feature rich state-of-the-art user friendly ONLINE LEARNING SYSTEM. System now used by major pharma companies for in-house training.

Have conducted clinical research training programs for National Institute of Health, USA in the Indian market.



KEY ACHIEVEMENTS

University Technical Collaboration – UGC Approved University

Top of the Line Faculty & Industry Driven academic Council.

Co-certified Training Programs with *NIH USA*, MSD, Bioserve, Max Healthcare., Quartesian US, Fortis Clinical Research and other companies.

Key Clients for Training Workshops and Online Training Programs: Oracle, NIH USA; MSD; Fresenius Kabi, Germany; Dabur; Novartis; Quintiles; Ranbaxy; GSK; Bioserve; Max Healthcare; Johnson & Johnson; Panacea Biotech

Strong & Multiple industry tie ups / collaborations to provide practical orientation

Trained over 5,000 professionals, with increasing number of international students for online programs from North America, South America, Europe and Middle East.

Accreditation / Certification from Pharmaceutical Society of India & ISO 9001:2000 by JAS ANZ.

AN ISO 9001:2015 Certified Academy

KEY ACHIEVEMENTS

Conducted several industry workshops for leading corporates, viz. NIH, MSD (Merck), Novartis, Biocon, Quintiles, Bioserve, Ranbaxy, Panacea, Max Healthcare, Max Neeman, Apollo Hospitals, Fresenius Kabi, Merck & Co., Panacea Biotec, Asian Clinical Trials, Quintiles.

Very High student satisfaction levels and excellent placements.

Experience in conducting multi location training programs using Videoconferencing technology.



Program Structure

Training Profile – Students are provided training in the following areas: Course training Hands on industry training Software training Interview skills & Mock interviews **English Communication Skills** Personality grooming Project report Online and classroom exams



Cliniminds Network

New Delhi – NOIDA – Head Office	
Mumbai	
Agra	
Hyderabad	
Bangalore	
Vadodara	
Chennai	
Guwahati	
Pune	
Indore	
Kerala	
International Representation: USA, Russia, U.K., South Arica, Saudi Arabia	



Cliniminds' International Footprint

India	Africa
USA	U.K.
Canada	Switzerland
France	Brazil
Argentina	Peru
UAE	Kuwait
Saudi Arabia	Russia
Pakistan	South Africa
Malaysia	Japan



INDUSTRY -ACADEMIA COLLABORATION / TRAINING / ACCREDITATIONS

Fortis Clinical Research Ltd.- Bio Analytical Techniques

Oracle – Clinical Trials & Drug Safety Training

Medrio – Clinical Data Management Training

Quartesian - SAS & CDM Training

Apcer- Pharmacovigillance

Medanta – Internship Program

Artemis Institute – CRC Internship

National Institute of Health-United State of America - conducting GCP Training for Research Sites

Pharmaceutical Society of India - Accreditation

JAS ANZ - Certification

Mahatma Gandhi University – UGC Approved Masters Programs

MS University – UGC Approved University Programs.



Industry Academia Collaborations & Accreditations

MSD – GCP / Investigators Training

Fresenius Kabi – Online Clinical Research & Pharma Training

Resmed – Investigator and Medical Device Training

Bioserve – GCP / Clinical Research Training

Max Healthcare – GCP / Investigators' Training

Mediminds – Healthcare

Thinki – Clinical Data Management & Medical Writing

CertifiedPVPro - Pharmacovigilance



Cliniminds Capabilities & Strengths

Top of the line industry experts and faculty with extensive industry experience

Expertise in content development

Strong academic team and faculty

Strong practical training and placement assistance to students

Over 20 years of experience in advising, setting up and managing education, healthcare and clinical research businesses.

Experience in setting up turnkey projects in the clinical research & healthcare sector

Promoters come with strong Industry experience and clear vision for the clinical research and healthcare industry

Strong regulatory experience

Strong understanding of marketing and distribution

