

INDIA

Clinical Research Careers Looking Up

History of Career Development in India

In any developing economy, the educational system and prospects for career development should complement each other. Essentially, careers are built around the economic growth indicators of the country. In India, immediately after independence, the country was more focussed on shaping Indian economy through government controlled institutions and public sector organisations. Hence in the 1950s and 1960s, career opportunities and options in government and public sector organisations were much more lucrative than private sector organisations. This led to a trend amongst the educated masses to pursue a career in government, with there being a variety of positions set up at different levels in administrative roles.

As the country moved towards industrialisation in late 1960s and 1970s, there was a massive demand for engineers and technocrats. The education systems were revamped to create newer branches of education to produce engineers in different streams such as civil, electrical, and mechanical engineering for the manufacturing industry. Many government and private engineering colleges were opened with these streams to educate young professionals to be future engineers, the most lucrative jobs at the time.

The 1980s and 1990s saw the emergence of private sector organisations because of a drive in privatisation and liberalisation. The country required management professionals to run its industries and businesses, and hence emerged the other attractive profession of management education. Universities and private colleges were set up to impart management educations to produce MBA qualified individuals, who would become future managers.

During the last decade, India has revolutionised globally in the area of information technology (IT), IT enabled services (ITES), business process outsourcing (BPO), and knowledge process outsourcing (KPO) areas. This recognition is essentially because of the highly skilled IT and service industry professionals the country has produced to support the industry globally.

Most recently, India has become attractive to contract research businesses because of the huge talent pool of investigators and clinical research (CR) professionals, in addition to other key enablers such as the lower cost of operations, availability of high quality infrastructure, facilitating regulatory support, and increased outsourcing opportunities.

In this article, the author analyses the career prospects for the professionals in the clinical research industry and discusses how India would meet the growing demand for quality and trained professionals to support local and global pharmaceutical companies for the conduct of international standard clinical research.

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Clinical Research— The Career Prospects

Clinical research is a relatively new business and profession in India. During the previous decade, not even a single contract research organisation (CRO) existed in India. Pharmaceutical companies, which were undertaking clinical research, were mostly aiding their parent company in regulatory support and medical marketing. Professionally qualified pharmacists and medical doctors who were interested in pursuing a career in the industry were not considering CR as one of the best career options; rather they preferred a career in pharmaceutical sales and medico marketing. Only a handful of senior doctors represented investigators participating in global

multi-centric study under the direct monitoring of global sponsors.

But today, we can find at least ten different types of clinical research players who provide career opportunities to prospective CR professionals (see Table 1). It took some of these companies considerable time before they realised the potential of India and only recently set up business here.

These players are involved in various types of CR business: bio-availability and bio-equivalence studies, Phase II-IV trials management, site management, data management, central laboratories, biotech, chemistry and biology, bio-IT solutions, and CR training.

Today, there are approximately 100 CR players (see Figure 1) who are ready with a global standard infrastructure and

the manpower to support the drug development initiatives of several pharma companies and entrepreneurs. This number is growing quickly, from merely a handful of players a few years ago to a wide variety at present.

While there is no clear-cut listing and information available, these players are contributing in a prominent way in terms of drug discovery, bioinformatics, chem-informatics, contract manufacturing (in formulations, bulk drugs, generics, novel drug delivery systems), biotechnology and contract research. According to the information available, in last few years, 46 GCP trials in different therapeutic areas have been carried out in India (see Figure 2), where some of these players have been directly involved.

With this transformation, today India has produced 300 GCP trained investigators and approximately 600 trained CR professionals, who are successfully handling several global multi-centric studies. The career prospects in CR business continue to look positive from the growing number of studies being carried out and this conforms to the market estimates of several top analysts. McKinsey estimated that the Indian CR market will grow to US\$ 1.5 billion in value by 2010 (see Figure 3).

CR Career Pathway

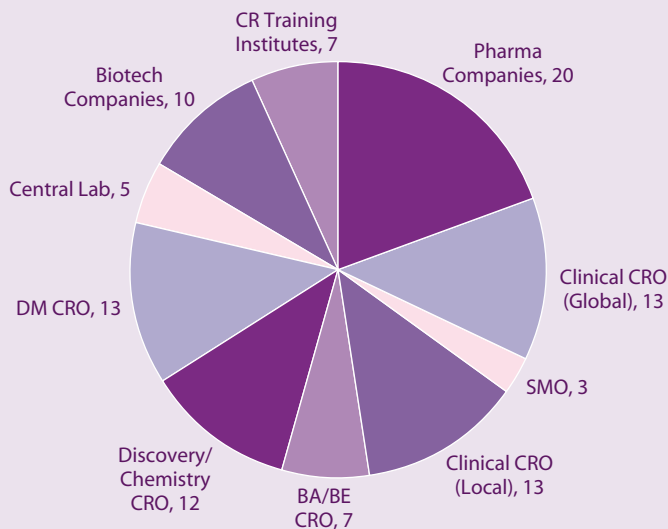
The growing industry scenario always demands good quality professionals to lead the business. India already had a talent pool of scientific personnel to handle the pharmaceutical manufacturing, chemistry, discovery, biotech, and laboratory aspects of the business. But the profession of clinical research is entirely new in India and requires certain specific cognitive and communication skills. This new profession demands roles such as a clinical research associate, clinical team leader, project manager, manager-clinical trial supplies, quality assurance manager, medical and regulatory affairs manager, data manager, data entry operator, and head of clinical operations.

Table 1. CR Players—India

Types (number)	CR Players
Pharmaceutical Companies (20)	Pfizer, Eli Lilly, Dabur, Novartis, Dr Reddy's, Ranbaxy, Sanofi Aventis, Astra Zeneca, Torrent, Zydus, Altana, Sun, Merck, GSK, Wyeth, Credence, Auron Healthcare, Claris Lifescience, Lupin, Galderma
Clinical CRO (Global) (13)	Quintiles, Chiltern, PPD, Covance, Pharmanet, Parexel, ICON, Kendle, Pharm Olam, IGate, KARD Scientific, PRA International, Inversk
Site Management Organization (SMO) (3)	Neeman Medical, Odyssey Research, Accunova
Clinical CRO (Local) (13)	SIRO, Synchron, ClinInvent, Sterling, Clingene, ClinWorld, ClinRx, Clintec, Pharma Intel, ACT/Suven, Reliance, Apothecaries, Clinquest
Bioequivalence / Bio-availability CRO (7)	Synchron, Lambda Therapeutics, Lotus Lab, Vimta Lab, Wellquest, Jubilant, LG Lifescience
Discovery /Chemistry / Toxicology CRO (12)	Chembiotec, DnO, Rallis Research, Avra, Indian Institute of Toxicology, Intox, Syngene/Biocon, Aurigene/Dr Reddy's, Medreich, Rubicon, Natco, Bilcare
Data Management Service Providers (13)	Quintiles, Synchron, Cognizant, SIRO, Accenture, DnO, ClinInvent, TCS, IBM, HCL, Infosys, Persistent Technologies, Sristek
Central Laboratories (5)	Specialty Ranbaxy, Clinigene International, Metropolis Health Services, Max Healthcare, Dr Lal's Pathlab
Biotech Companies (10)	Biocon, Shanta Biotec, Bharat Serums & Vaccines, Panacea Biotech, Wipro Health-science, Haffkine Bio-Pharmaceuticals, Krebs Biochemicals, Bio-Rad Labs, Indian Immunological
CR Training Institutes (7)	Academy of Clinical Excellence, Catalyst Clinical Services, Institute of Clinical Research, Kundnani College of Pharmacy, SIES College of Management, Kriger, Bio-informatics Institute

Source: Chiltern International Private Limited, India

Figure 1. Number of CR Players



Source: Chiltern International Private Limited, India

Similarly, the industry needs GCP trained and experienced investigators, co-investigators, clinical research coordinators, and study nurses at hospitals and clinics. The industry also needs qualified ethics committee members who will uphold the safety and ethical standards to protect patients participating in studies. As the demand for these professionals grows, training institutes and trainers in different segments of the CR business are absolutely essential.

Table 2 shows different potential career pathways for CR professionals. These are grouped into different career options on the basis of careers that share similar business characteristics and employment requirements. CR Professionals within a career pathway share many common interests, strengths, and competencies. These career pathways help professionals to understand the broad range of career options with a range of vertical growth opportunities available. This also helps professionals to select a career based on their personal strengths, abilities, and interests to suit to the rapidly changing workplace and reminds them of the need to continue learning appropriate skills.

The Emerging Career Models/Pipelines

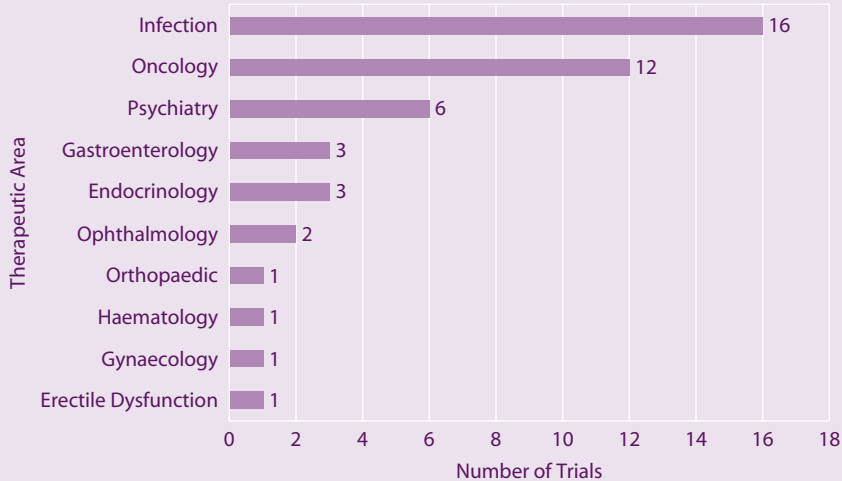
The CR business in India has created several career models for graduates and postgraduates. This gives a plethora of opportunities to professionals from science, pharmacy, biotechnology, and medical sciences streams to look for a promising future career. India has today approximately 600,000 physicians,

400,000 pharmacists, and 300,000 bio-science graduates and postgraduates. Furthermore, the educational institutions in India generate a further 50,000–60,000 graduates and postgraduates in different streams of science every year. Table 3 lists five distinct career pipelines that have emerged as a result of the growth of the vibrant CR business. Each of these pipelines depicts the career pathways in a succinct manner for the CR career aspirants to assess his capability and choose one that best fits the potential.

PIPELINE 1 describes the career pathways for **medical graduates and post-graduates**. This pipeline supports the clinical trial management in critical areas such as safety monitoring and management, regulatory submission and approval, medical writing, therapeutic training to the clinical operations, and study team. This pipeline is essentially the scientific and medical support arm of any organisation and contributes in an important way for the “make or break” decision making.

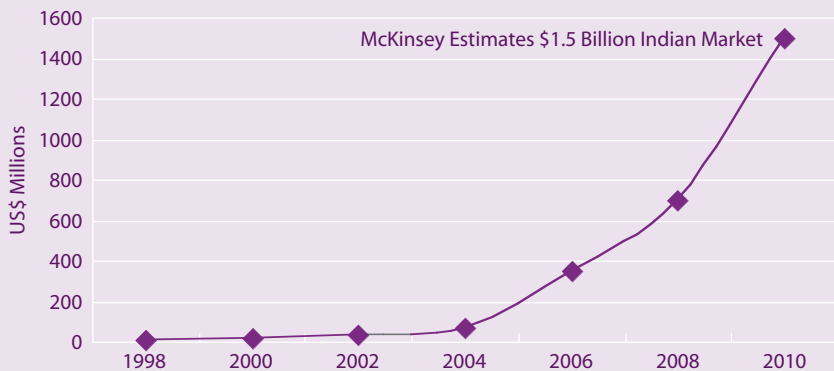
PIPELINE 2 is very crucial, and called the **management** arm of the CR business. This arm contributes to the bottom line of the CR business and constitutes 60%–70% of the CR manpower. The professionals in greatest demand in this

Figure 2. Therapeutic Area Distribution of Trials in India



Source: Chiltern International Private Limited, India

Figure 3. Indian CR Market



Source: McKinsey's Report

pipeline are the CRAs and project managers, who are essentially the field force and revenue earners for most CROs and pharma companies and are required in large numbers—almost 70%–80% of the total professionals in this pipeline. This

pipeline ensures that the trial is initiated, carried out as per the desired global and local regulatory standards, properly monitored for safety, efficacy and ethics, and completed within the required time and budget.

PIPELINE 3 also plays a crucial role and is the **analytical** arm of the CR career model. The professionals involved in this pipeline have a statistical and programming background. They play a major role in the beginning of trial design and at the end to analyse and statistically interpret the data to derive conclusions.

PIPELINE 4 is the **support arm** of the CR model. These individuals bring business, identify and recruit the right professionals, manage finance and provide training to the core teams.

PIPELINE 5, the **investigators**, are the real lifeline of the CR business, and they provide tremendous support as study staff in the hospital—set up for patient care, follow-up, and compliance in clinical trials. Without their support, the CR business would not be able to operate.

Desired Skill Set

The success of the CR profession is dependent on an individual's level of knowledge and skill sets. Since it is an emerging business, India's resource pool has had a limited exposure to GCP trials. The country lacks a mature pool of trained CR professionals with more than 10–15 years of CR industry experience to handle complex issues in the CR business. There are relatively few senior professionals with work experience in global pharmaceutical companies that includes the handling of global clinical trials.

Nevertheless, India has a lot of professionals with the desired cognitive and communication skill sets required to manage the business. Among the cognitive skill sets, the most important ones are the knowledge of human anatomy and physiology, the science of disease and management, understanding of the drug development process, the regulatory framework of the country, and the applicable local and global guidelines. All these professionals need to be trained to GCP standards and should be interested in spending time and energy to participate in CR. The Indian talent pool has the skill sets necessary to orient and train

Table 2. CR Career Pathways

Clinical Operations: CROs/Pharma			
Companies (Global/Local)	Site Management Organisation	Data Management	CR Training Institutes
<ul style="list-style-type: none"> • Clinical Trial Assistant (CTA) • Clinical Research Associate (CRA) • Senior CRA • Clinical Team Leader • Project Manager • Senior Project Manager • Medical & Regulatory Manager • Quality Assurance Manager • Medical Director • Associate Director—Clinical • Associate Director—Projects • Director—Business Development • Director/Head (Clinical Operations) • General Manger/CEO/President 	<ul style="list-style-type: none"> • Clinical Research Coordinators (CRC)/ Study Coordinators • Principal Investigators/ Co-Investigators • Medical Monitors • Project Manager • Senior Project Manager • Medical & Regulatory Manager • Quality Assurance Manager • Manager—Business Development • Medical Director • Associate Director—Clinical • Associate Director—Projects • Director/Head (Clinical Operations) • General Manger/CEO/President 	<ul style="list-style-type: none"> • Data Entry Operator • Data Manager • Data Validation Executive • QA Executive • QA Manager • Statistical Programmer • Statistician • Data Reviewer • Data Base Designer • Medical Writer • Head—Data Management 	<ul style="list-style-type: none"> • Trainer—Clinical Trial Management • Trainer—Data Mgt • Trainer—Bio-Statistics • Trainer—GCP, Regulation • Trainer—Project Mgt • Training Coordinators • Training Director

Table 3. CR Career Models/Pipeline

0–2 Years' Experience	2-5 Years' Experience	5-15 Years' Experience
PIPELINE 1 CRA, CRC, Study Coordinator	MBBS / MD (Pharmacology) Medical Advisor, Regulatory Affairs Manager, Medical Monitor, Medical Writer	Medical Director, Head (Clinical Operations), Consultants
PIPELINE 2 CRA, Senior CRA, Data Entry Operator, Data Validation Executive, QA Executive, Pharmacy Executive	BPharm / MPharm / Graduates / Post-Graduates (Science, Nursing, Biotech, Alternate Medicines), MBA, PhD Clinical Team Leader, Project Manager, Manager (Clinical Operations), QA Manager, Data Manager, Clinical Study Manager, Clinical Development Manager, Regulatory Manager, Project Manager	Head (Operations), Associate Director (Clinical Operations), Head (Projects), General Manager, CEO
PIPELINE 3 Data Base Designer, Statistical programmer, Data Validation Executive, QC Executive	Graduates / PG / PhD in Mathematics & Statistics, SAS Programmer, etc. Data Manager, Statistician, SAS Programmer, QC Manager	Head Data Management, Biostatistician
PIPELINE 4 Accounts/HR Executive, Business Development Executive	Graduate / Post-Graduates, MBA including HR, Finance Manager Business Development, Manager (Clinical Trial Supplies, Manager (Accounts), Manager (HR), Manager (Training)	Head (HR), Director–Business Development, Head (Logistics), Head (Finance), Head (Training & Development)
PIPELINE 5 Study Coordinator	Physicians / Therapeutic Specialist in Diverse Therapeutic Area Study Coordinator, Co-Investigator, Principal Investigator	Principal Investigator Consultant

them quickly to meet the demand of any growing business. The senior professionals have utilised the transferable skills of related businesses to understand the needs of the CR industry.

Training: An Important Tool to Strengthen CR Career

Training is another important parameter in ensuring success for any profession. This is extremely important for the CR industry, since it is a new industry in India. Naturally, there is a considerable emphasis on training staff to equip them with knowledge and the necessary skills to handle global projects. Many local and global training institutes, such as the Academy of Clinical Excellence (ACE), Institute of Clinical Research (ICR), Kriger Research Institute, Kundnani College of Pharmacy, Bioinformatics Institute of India, and other similar organisations, have started full-time,

short-term, diploma courses, class room based and/or online, in CR management. ACE, through the support from industry professionals, conducts certificate and postgraduate diploma courses to train professionals on the foundations of clinical research and GCP, ethics committee members, and other topics. ACE has trained 700 professionals on short-term programs and awarded 100 professionals with post graduation diplomas. These professionals are graduates of life science, pharmacy, medical, ayurvedic, and homeopathic streams and work as CRAs, study coordinators, quality assurance, study manager in CROs, pharma companies, and hospitals in India. ACE also hosted ACRP examinations in India in 2004 where many CR professionals became certified.

Another institute in Mumbai, SIES Institute of Management, Nerul, has introduced a full-time module on CR management as a part of their PG

Diploma in Pharmaceutical management. From 60 students this year, approximately 15%-20% have chosen to pursue CR careers in CROs and pharma companies. Global organisations like MDS, Barnett International, Thomson Centerwatch, ACRP, etc. are also exploring the possibility of expanding their training programs in India to support the growing demand for quality training.

Is CR an Attractive Career?

The CR business is largely driven and managed by people. A company with good, qualified, experienced, and trained people demonstrates sufficient credibility and capability to attract projects from sponsors. However, a sudden rise in the demand for trained and skilled professionals by many CROs and pharma companies has increased the salary levels and expectations of professionals. Despite this, the cost of skilled professionals in India is still low in comparison to western countries. A clinical trial monitor typically earns approximately 10%–15% of his U.S./European counterpart (see Table 4). But as an ever growing number of global companies are setting up their operations in India and as demands for the skilled professionals are also increasing, salary levels will no doubt rise dramatically over the next few years.

Similarly, as Dr. N. Varawalla of PRA International points out in her article in EPC Spring 2005 on “Unravelling the Advantages of Conducting Clinical Trials in the Emerging World,” the approximate per patient investigator fees in a complex

Table 4. The Salary Benchmark, Comparison

Position	2001	India, 2005	%
	Annual Gross Salary* US\$	Annual Gross Salary US\$	
CRA	52,000	5,555	11
Senior CRA	68,000	7,750	11
Regional CRA	65,000	7,750	12
Project Manager	74,000	17,500	24
Regulatory Affairs	73,000	17,500	24

*Source: CenterWatch

oncology trial is US\$2,000 in India, where as it is more than double this figure in Russia, 3-4 times higher in Europe, and more than 7 times higher in USA. It is definitely attractive for the sponsors and CROs to increase their headcount in India in order to run more trials in comparison to their set up costs elsewhere. It is also a promising situation for CR professionals, including investigators, in comparison to alternative job options or compensations available in India. Besides the salary and compensations, many recruiters have started offering bonuses and stock options as added incentives to retain professionals. Besides the “fast bucks,” the CR profession encourages the professionals by providing them with the opportunity to work in global systems, infrastructure, and facilities.

The Challenges Ahead

Today, the CR Profession in India is perceived as a highly lucrative blue collar job. The professionals, especially the clinical research associates, study coordinators, and project managers are in high demand. If such individuals have 2-5 years of experience in a major CRO or pharma company, such personnel fetch a premium value in the job market. The market dynamics and growing number of players have made the CR profession more lucrative. In order to retain employees, global players in India provide considerable employee orientation training, on the job experience on projects, foreign travel, good salary, and financial incentives and perks. For example, Pfizer India supported financially several of their CRAs and study coordinators to embark on ACRP certification programs. The local and the new entrant CROs are also inclined to attract trained and experienced professionals and are raising the salaries and responsibilities for positions.

In spite of many sincere efforts, the CR industry is facing considerable attrition and turn over. An ACRP outlook 2000 survey reveals that 67% of the CR professionals working in CROs have changed their employers in last 3 years.

Market forces also provide alternate options of higher salaries and perks, as well as new geographic and job environments, and this attracts clinical researchers to change employers frequently.

Although this is a global phenomenon, the same trend is going to happen in India as the demand for CR professionals outstrips supplies. Since the CR job is fairly secure, most CRAs feel reasonably happy in their jobs vis-à-vis their comparable sales or medical representative jobs. But once they gather sufficient experience in a few therapeutic areas and studies, they may feel their job has become monotonous, they may become overburdened with the pressure of traveling, and they may feel the impact of peer pressure. Market forces also provide alternate options of higher salaries and perks, as well as new geographic and job environments, and this attracts clinical researchers to change employers frequently. Hence, employee retention and recruitment of desired quality staff is now becoming a tough task for organizations to handle.

The CR profession demands its professionals, especially CRAs to travel frequently to sites located in geographically diverse locations. An ever growing amount of studies have compelled sponsors and CROs to identify good sites and investigators at distant locations where there is no adequate air transportation and the CRA has to travel by a mixed mode of air and road, which consumes a lot of time. This compromises the comfort level of the individual CRA, who may feel as if they are spending too much time away from family and friends. Such factors can lead to job dissatisfaction.

However, the bigger, established CR players have now started experimenting with the regional and home-based models, placing the CRAs in regional offices (preferably nearer to their place of origin) or home offices to increase efficiency and contentment of the employees as a tool to motivate and retain them. Unfortunately, the smaller CR players, with a limited number of projects, are not in a position to afford experimenting with the home-based model, as they feel it will not be cost-effective and may be difficult to control, coordinate, and ensure steady implementation of systems and procedures.

Bangalore today is an outsourcing hub for data management for many CROs and sponsors merely because of the availability of low-cost skilled data entry operators. Such data entry operators are currently very much in demand. But globally, the CR industry is experimenting with newer technologies and innovative methods to reduce the cost and time in drug development initiatives. With the introduction of electronic data capture and remote data entry, the role of CRAs and data managers may blur. EDC requires investigator, site staff, and CRAs to improve their computer skills and learn to use modern hardware and software and, hence, necessitates sizable investment by sponsors for training. With the use of EDC increasing by merely 10% now up to 100% in the future, data management professionals—especially the data entry operators—may have to orient themselves to newer jobs as their roles may become extinct due to this trend in technological advancement.

Overall, there are numerous challenges for employers and CR professionals to nurture and create an environment of learning, to implement global standards to safeguard the interest of all stakeholders in clinical research, and to ensure that India meets the global expectations as an emerging clinical research destination. **ACRP**

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