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Clinical Research Future Aspects

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Abstract

India is emerging as a global hub for clinical research. According to projections from McKinsey & Company, the Indian clinical research industry could attract US $1.5 billion of revenue from U.S. and European sponsors by 2010, creating a demand for more than 10,000 investigators trained in good clinical practice (GCP) and supported by nearly 50,000 clinical research professionals. The revenue expected to be reaching US $ 20 billion in India till 2015.With increased outsourcing from the U.S. and Europe to India, global pharmaceutical companies and Indian entrepreneurs have set up contract research organizations (CROs) in India. They are attracting highly competent professionals, both in the clinical research profession and the knowledge process outsourcing sector.

Key Words: Clinical research, Clinical trials,

Introduction

Clinical trials are studies performed with human subjects to test new drugs or combinations of drugs, new approaches to surgery or radiotherapy or procedures to improve the diagnosis of disease and the quality of life of the patient [1]. In this article, we 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 [2].

According to a recent report from McKinsey & Co., if the Indian economy continues on its current high-growth path, then the Indian pharmaceuticals market will undergo a major transformation in the next decade. The market will triple to $20 billion by 2015 and move into the world's top 10 pharmaceutical markets. This growth in the worldwide pharmaceutical landscape will have an additive effect on the contract research landscape [3].

Evolution of Clinical Research in India

Contract clinical research is a new phenomenon in India. A decade ago, the industry focused only on monitoring clinical operations. Most pharmaceutical companies and the evolving CROs performed only clinical operations. Hence, career opportunities came only to clinical research associates (CRAs) and project managers who could monitor and handle clinical studies. In the beginning, pharmacists had an edge over other clinical research professionals, but slowly the science graduates and medical and alternate medical professionals entered the industry as CRAs and project managers [4-5].

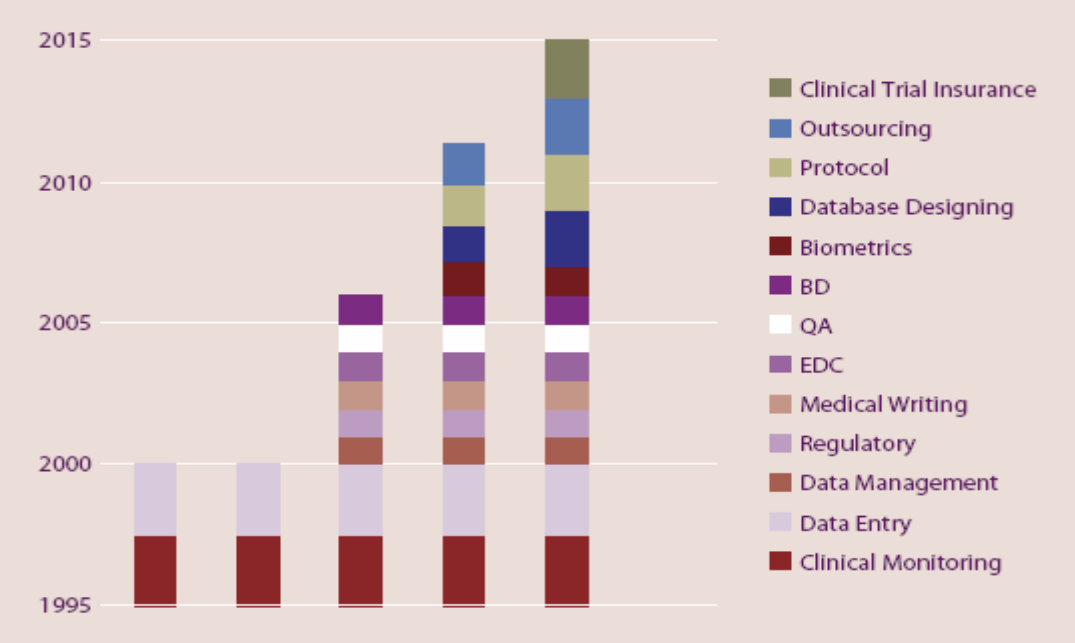

Figure-1 Evolution of Clinical Research in India1995-20159

(Source: Chiltern International Private Ltd. Mumbai)

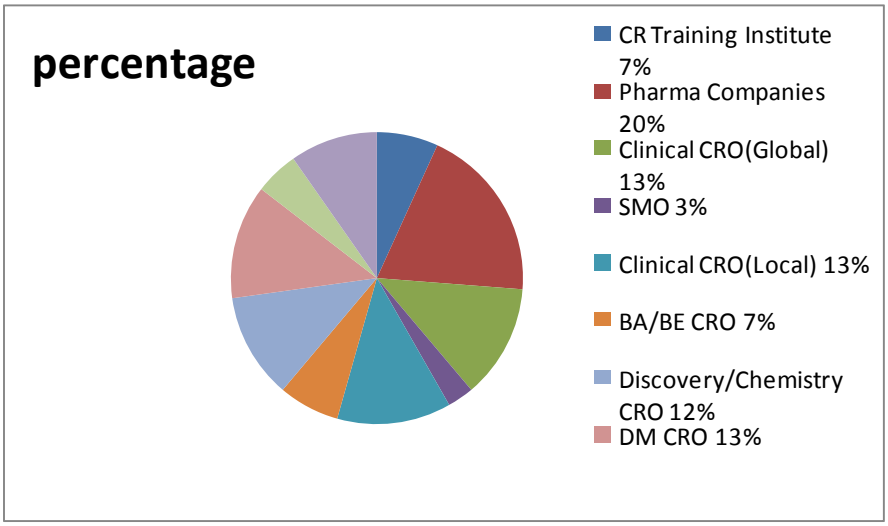

Figure-2 Percentage of Different Models Emerged in Clinical Research

(Source: Chiltern International Private Limited, India)

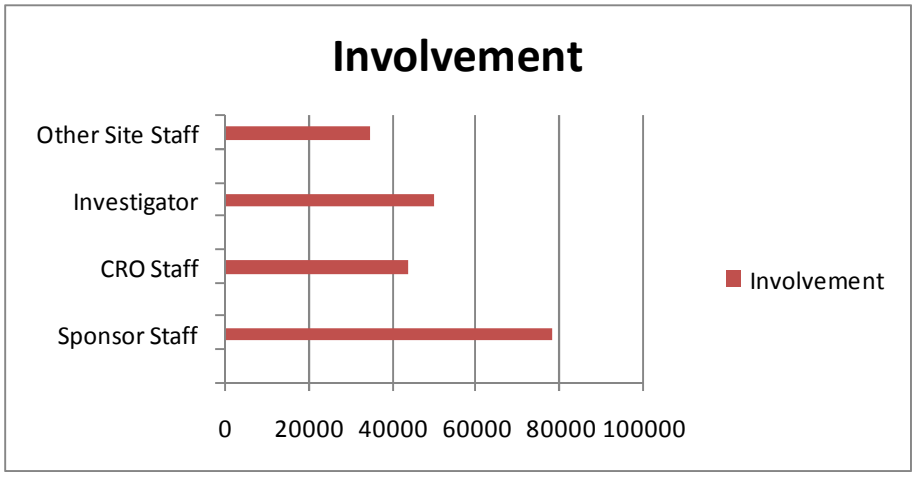

Figure-3 Involvement of Different staff in Clinical Research
(Source: Center Watch 2001 survey)

The Future Outlook and Scope: Indian Scenario

India has implemented product patents since 2005, which will lead to widening of the market for indigenous as they will have the authenticity of internationally recognized product patents. Product patent protection will encourage multinational companies to import technology into India to develop new products. These developments will open up increased opportunities for the clinical trials of bio-tech and medicinal products. India is rapidly improving upon this situation as it seeks to one day emerge as a global leader in the CRO industry [6]. Sponsors are looking at India to leverage the high cost of trials in the U.S. and Europe, and to reduce time to market. An entry-level clinical researcher earning just one-tenth as much as a more experienced colleague from his or her Indian employer could still be hired by a U.S. or European sponsor at a 20–25% savings for the sponsor versus the counterpart abroad [4]. If India's clinical trial business grows to 10% of the scope seen in the U.S. by 2015, then the industry will need approximately 50,000 recruits. India has a huge pool of scientific, pharmaceutical, and medical talent, but the supply of trained professionals in India is approximately one-tenth of its demand [7].

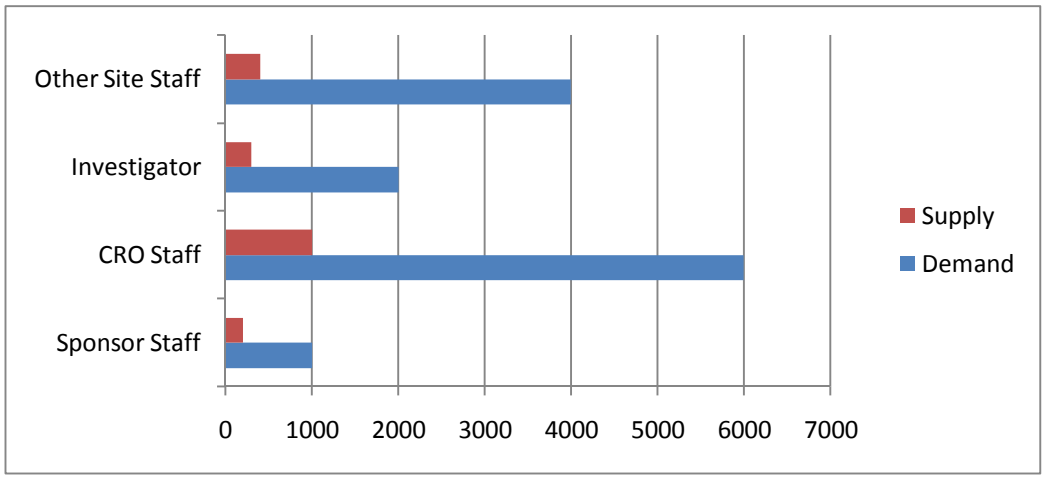

Figure-4: Demand-Supply Gap 2010 in India
(Source: Chiltern International Estimates)

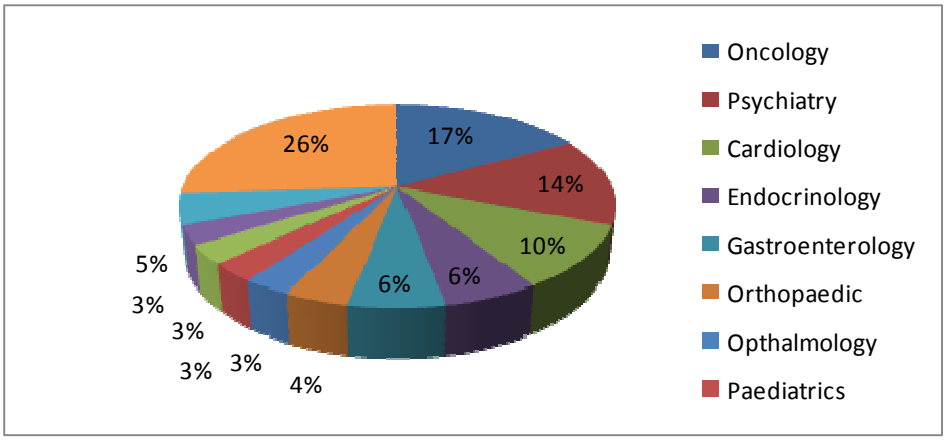

Figure-5: Clinical trial in different sector
(Source: Clinical Trial Registry, www.clinicaltrial.gov, January 2007)

Is Clinical Research an attractive Career?
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 [8].

(See figure 6) The market will triple to $20 billion by 2015 and move into the world's top 10 pharmaceutical markets [3].

Figure-6: Growth of clinical trials in India
(Source: McKinsey's Report)

Excellent Career Growth and attractive Salaries Offered – Starting salaries from Rs.1.8 lakh to Rs.2.8 lakh. High Annual Salary Growth – 30 to 35% per annum, in comparison to average 15% growth in salaries [1].

Clinical Research Career Pathway [2]
Table 1 shows different potential career pathways for CR professionals. Table 1 Clinical Research Career Pathway in different type of Models in India.

Clinical Operations: CROs/ Pharma companies(Global/Local)	**Site Management Organization**	**Data Management**	**CR Training Institute**
Clinical Trial Assistant (CTA)	Clinical Research Coordinators (CRC)/ Study Coordinators	Data Entry Operator	Trainer—Clinical Trial Management
Clinical Research Associate (CRA)	Principal Investigators /Co-Investigators	Data Manager	Trainer—Bio-Statistics
Senior CRA	Medical Monitors	Data Validation Executive	Trainer—GCP, Regulation
Clinical Team Leader	Project Manager	QA Executive	Trainer—Project Mgt
Project Manager	Senior Project Manager	QA Manager	Trainer—Data Mgt
Senior Project Manager	Medical & Regulatory Manager	Statistical Programmer	Training Coordinators
Medical & Regulatory Manager	Quality Assurance Manager	Statistician	Training Director
Quality Assurance Manager	Manager-Business Development	Data Reviewer	
Medical Director	Medical Director	Data Base Designer	
Associate Director—Clinical	Associate Director—Clinical	Medical Writer	
Associate Director—Projects	Associate Director—Projects	Head—Data Management	
Director—Business Development	Director/Head (Clinical Operations)		
Director/Head(Clinical Operations)	General Manger/CEO/ President		
General Manger/CEO/President			

The Emerging Career Models [2]

The CR business in India has created several career models for graduates and postgraduates. India has today approximately 600,000 physicians, 400,000 pharmacists, and 300,000 bioscience graduates and postgraduates. Table 2 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.

Model 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.

Model 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 model 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.

Model 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 back ground. They play a major role in the beginning of trial design and at the end to analyze and statistically interpret the data to derive conclusions.

Model 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.

Model 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.

Table 2: Clinical Research Models/Pipelines

0-2 year Experience	**2-5 year Experience**	**5-15 year Experience**
Model 1: MBBS/MD (Pharmacology)		
CRA, CRC, Study Coordinator	Medical Advisor, Regulatory Affairs Manager, Medical Writer, Medical Monitor	Medical Director (Clinical Operations), Head, Consultants
Model 2: B Pharm/M Pharm/Graduates/Post-Graduates(Science, Nursing, Biotech, Alternate Medicines), MBA, PhD		
CRA, Senior CRA, Data Entry Operator, Data Validation Executive, QA Executive, Pharmacy Executive	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
Model 3: Graduates/PG/PhD in Mathematics & Statistics, SAS Programmer, etc.		
Data Base Designer, Statistical programmer, Data Validation Executive, QC Executive	Data Manager, S Programmer, statistician, SAS ,QC Manager	Head Data Management, Biostatistician
Model 4: Graduate/Post-Graduates, MBA including HR, Finance		
Accounts/HR Executive, Business Development Executive	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)

Clinical Research in India vs. World:

Table-3

	India vs. Western countries [9]
+	• Patient enrollment • Diversity • Costs
=	• English competency • Medical infrastructure • Western medicine familiarity

	• Companies with international standards
–	• IPR reputation • Industry standards • Less established infrastructure

Rating: (+) Positive Factor, (=) Equality, (-) Have to be Improve

Table-4 How India Fares in Global Clinical Research [10]

Country	Population (Available patent pool)	Comfort level of sponsors	Intellectual property/regulation	Cost Attractiveness
India	3	2	1	3
China	3	1	1	3
Eastern Europe	1.5	2	2	2
US	1	3	3	1

Ratings: 1 = Low; 2 = Medium; 3 = High; Source: 2005 study by US consultancy Proximare.

Table-5 Cost Competitiveness of Indian R&D [10]

Phase	US Costs	Indian Costs
Phase I	US$ 20 million	<50% of US cost
Phase II	US$ 50 million	<60% of US cost
Phase III	US$ 100 million	<60% of US cost

Source: Business Week, Source: Pharmabiz, Cygnus Research

India overtakes China as No.1 destination for clinical trials [11] India has piped China to become Asia's most popular destination for conducting clinical trials. According to the Planning Commission, around 139 new trials were out sourced to India recently compared to 98 in China.

Advantages of Conducting Clinical Trials in India

- Availability of a large population of treatment-naive patients with multiethnic and multiracial backgrounds.
- Wide spectrum of diseases **i**n India.
- The cost of conducting trials can be reduced up to 30-50% in India.
- Investigators are well trained in Western Europe or the United States, and they now are experienced in participating in multinational trials according to ICH guideline for GCP.
- India offers sponsors the opportunity to recruit subjects quickly while maintaining a high level of quality. The subjects are very compliant and are keen to attend all their study visits.
- India is identified as a major resource center for conducting clinical trials and data management services. With its large patient populations, well-trained and enthusiastic investigators, and per-subject trial costs considerably lower than those in developed

nations, it is widely recognized as a major center for conducting clinical trials. Its increased regulatory control and its acceptance of the ICH guideline for GCP further enhance India's reputation as a place to conduct clinical trials [12].

Recession Not to Hit Indian Clinical Trials: CROs

Indian clinical research organizations (CROs) do not see any near-term impact of recession as large pharma customers such as AstraZeneca and Glaxo continue to send more work to India, where these trials could be conducted at one-fifth of the US cost [13]. The $200-million Indian clinical research outsourcing market will reach up to $600 million by 2010, according to a joint study done by research firm KPMG and the Confederation of Indian Industry (CII). Credit restrictions will prompt global biotech companies to see greater favour in outsourcing clinical trials to India. While the cost of clinical trials vary on the basis of complexity and disease segment, a simple trial in India can cost 15-20% of the US price, while a more sophisticated trial involving imaging systems may be 50-60% of the US price. Studies suggest that R&D expenditure is increasing by 15% per year, making global biopharmaceutical companies look for cheaper options. India scores high due to faster enrollments, speed of completion, large and diverse patient pool as well as increasing private healthcare network. Biopharmaceutical discovery generally involves a commitment of $350-400 million till the pre-clinical phase, writing it off will not be easy. This will put pressure on companies to continue trials. With many bio-pharmaceutical companies' clinical trials already in the pipeline, and with patent expiry dates remaining constant, Indian CROs working for them are somewhat insulated from any slump so far. In India work coming from smaller biotech companies might get affected in the long-term, bigger biotech companies will increasingly seek to leverage India's cost advantages. Moreover, since they manage their own CROs, impact will be neutral to positive. India currently has about 360 trials underway, including phase I to phase IV studies. It is possible that the slowdown could mean a significant increase in revenues over the next year [13].

Conclusion

Acceptance of the clinical research profession by young talents is growing fast. As has been seen with IT professionals, this resource pool will be a source of pride for India that is recognized globally for its sincerity, scientific knowledge, and skills. Although there are often differences between the clinical research professionals of India and western countries in terms of their levels of direct experience in trials and their understanding of the complexities of the drug development process, India is rapidly improving upon this situation as it seeks to one day emerge as a global leader in the CRO industry.

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