BioSpectrum the business of Bio & Health Sciences

Trail Blazing Trials

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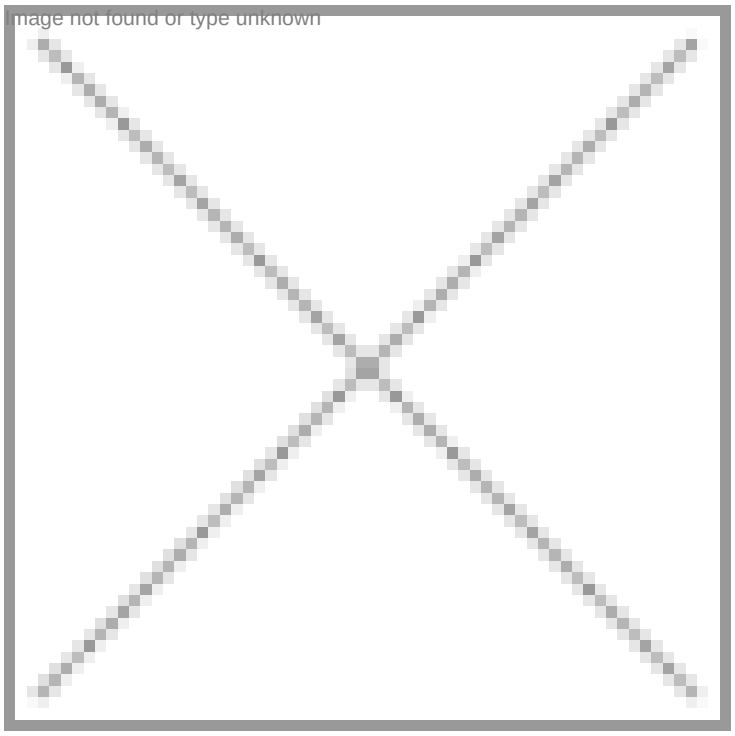


Clinical development of a new drug comprises about two thirds of the total development costs. With focus on cost containment across the global pharma companies, speedier, low cost and reliable clinical trials are the order of the day. And India is emerging as a natural choice for contract clinical research services.

Projected growth of the Indian clinical research industry

Resources	2010
Clinical research market	$1.5 Billion
GCP Studies	1,500-2,000
GCP trained Investigators	10,000-15,000
Subjects required	2,00,000-3,00,000
Clinical research professionals	50,000

Source: McKinsey Report

Clinical trial is the most significant direct cost factor related to drug discovery and development. On an average it costs $282 million and takes about seven years to complete. According to industry estimates, the cost of phase I trial is 50 percent and phase II, 60 percent lower in India. Moreover, cost saving alone is not the only obvious advantage. The ability to find and qualify the right patient pool is an appealing factor for Indian trials as the country offers genetically and culturally diverse population where treatment-naive patients are willing to participate. According to Kiran Mazumdar-Shaw, CMD, Biocon and president, ABLE, "The Indian advantage in clinical development is clearly the speed of patient enrolment and thereby shorter timelines for clinical trials."

According to Mc Kinsey report, the clinical research industry will witness a business of Rs 10,000 crore creating a demand of 50,000 professionals in the next five years. Analysts project that by 2008 upto 30 percent of global clinical trials will take place outside US and Western Europe and India would emerge a favorable destination.

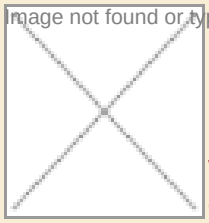
Widening operations of CROs

The number of companies participating in clinical research and trials is going up. Some big Indian pharmaceutical companies like Wockhardt, Lupin and Sun Pharma are working on new chemical entities and have established their own clinical research units to conduct trials for their new molecules. Referral labs such as Dr Lal's lab, Metropolis health services and SRL Ranbaxy are offering clinical trial services. IT companies like Cognizant, Eassar, HCL, IBM, Infosys and TCS are keen on making investments on data management.

Today there are over 25 CROs working in India, with many pharma companies having their own clinical research units conducting clinical trials in over 80 government and private hospitals. Clinical trials are conducted by the clinical research outfits of multinationals like Eli Lilly, Pfizer, Novartis and Aventis and some in-house clinical research is being done by Indian majors. For instance, Eli Lilly India is presently conducting 17 global and local trials in 65 locations in the country.

There are many independent Clinical Research Organizations (CRO) in the fray too, which are consolidating their base and expanding operations. Mumbai-based SIRO Clinpharm, a contract CRO, conducts clinical trials in various therapeutic segments and offers a spectrum of clinical development services. Ahmedabad-based Synchron Research offers services in phase I, high through put screening for rapid PK analysis, qualitative and quantitative medical imaging and in silico drug metabolism studies. It has conducted over 200 bioavailablity studies. Bangalore-based Lotus Labs has completed more than 450 bio studies and is conducting several phase III trials. It has set up facilities in Bangalore and Chennai for conducting clinical research and has recently tied up with St John's National Academy of Health Sciences, Bangalore for conducting Phase I trials. Mumbai-based ClinInvest Research focuses on all phases of clinical trials mainly in the areas of oncology, neuro-psychiatry, cardiology and diabetes drugs. Clingene International, a Biocon subsidiary, concentrates on Phase I-IV clinical trials, bio analytical, bio statistical and data management services to its clients. The company recently inaugurated a human pharmacology unit at Sagar Apollo Hospital, Bangalore. Quintiles Spectral (India), a subsidiary of Quintiles Transnational, a BioSpectrum Top 20 company and the market leader in the clinical services segment, conducts studies in oncology, psychiatry, neurology, anti-infectives, etc.

"Clinical research is a human resource intensive enterprise"



Pfizer India, an affiliate of Pfizer Inc-a global research based health care company, has contributed to the development of clinical research and biometrics in India, being among the first multinational to establish clinical research operations in the country. Dr Chandrashekhar N Potkar, head, Clinical Trials function for Pfizer India, spoke about the opportunities in this segment.

What are the current trends in the clinical trials segment? What kind of people does this sector attract?

More and more pharma companies/clinical research organizations/site management organizations are entering the clinical research industry in India. There is clearly a high potential for clinical trial segment and clinical research is a rapidly growing industry. Basically, clinical research is a human resource intensive enterprise. Each step in the process of planning and conducting a clinical trial requires appropriately and often highly qualified individuals. Some of the most knowledge intensive parts of the process relate to planning a clinical research program and designing individual clinical studies within the program - activities that require knowledge of the therapeutic area, clinical expertise, and research experience.

What are the job categories at Pfizer? What are the skill sets required and the future growth prospects?

Presently we have a strong team of about 41 people who work as clinical research associates (CRAs), medical advisors, clinical study managers, manager-clinops. We take in candidates with bachelor/masters in science/pharmacy. For CRAs we do recruit fresh candidates though, prior clinical research experience helps.

Pfizer offers competitive salaries by industry standards and one can charter an excellent career path with us with many training opportunities and an inbuilt flexibility in working.

How can the quality of human resources be developed/improved for this segment?

Clinical research as a discipline must be incorporated for pharmacy/science and medical students. Also, it must be incorporated as a subject at the postgraduate level, as well. In this direction, we have partnered with Academy for Clinical Excellence (based at Bombay College of Pharmacy) to offer certificate as well as diploma course in clinical research.

Competency requirement

The CRO industry is a major employer of medical and scientific staff and hence the demand for qualified personnel is on the increase. "Clinical trial is a very data and quality intensive work and may involve high percentage of travel. The scope of any error is very limited and involves high degree of ethics both personal and professional," commented Rajiv Gulati, managing director and chairman, Eli Lilly and Company (India). The segment requires the services of a diverse range of specialists like medical professionals with specialization in internal medicine and pharmacology, nurses, phlebotomists, quality control and quality assurance personnel, data entry personnel, pharmacokinetic specialists, bio statisticians, analytical chemists, laboratory technicians, medical writing group, diagnostic technicians, etc. "From a qualifications perspective we look for PhDs, post doctorates, medical doctors, post graduates in the fields of organic chemistry, molecular biology, micro biology, biotechnology, pathology, biochemistry, pharmacology etc," said Dr Nirupa Bareja, group head (HR), Biocon India. "A potential candidate is judged on the basis of merit, qualifications, motivation, team spirit, passion etc. We look for traits that will help the organization as well as the individual reach their goals," she added. Most of the CROs recruit both fresh graduates as well as personnel with experience depending on the job profile and requirements. But since the field is nascent, most of the companies do not insist on prior experience, though it does provide a selection edge. An ability to reach out to the target audience is also accorded top priority by many companies. "A potential candidate will have an edge if he has experience, but more than that he needs to have good communication skills," sums up Sampath Kumar, CEO, Sristek Consulting, a Hyderabad-based CRO. The bottomline is clearly defined by Raman Akella, head administration, Shantha Biotechnics, Hyderabad, "In the contract industry, the people should be highly skilled and versatile to take up different projects and execute them at low cost in order to be competitive and effective".

"The quality of our data is comparable to that from developed countries"

Quintiles India, a BioSpectrum Top 20 company, and a leader in the clinical research segment in the country has the experience in working on over 90 clinical studies involving more than 600 sites and 13,000 patients. Dr Narges Mahaluxmivala, President, Clinical Development Services, Quintiles Research India elaborates about the future of India in clinical research.

Is India emerging as a new destination for clinical trials?

Clinical research in India is at a relatively nascent stage, but the potential for growth is enormous in all aspects. Clinical trials in Phases 2 and 3 and some in Phase 1 and data management are already being conducted in India by us to internationally accepted standards viz. ICH GCP. In-house and sponsor audits have demonstrated beyond doubt that the quality of data is comparable to that obtained from developed countries and that all other necessary parameters including patient rights are observed. Regulatory authorities in the US and in Europe are accepting data which have a substantial proportion from India and three trials conducted by us solely in India, have been accepted by the US FDA as part of a larger program for each indication respectively and the molecules of two of them have been approved by that body.

With the improvement in connectivity and in telecommunications, web-based trials where data are captured electronically have been successfully implemented and data management of these trials is ongoing. Data entry and management of clinical trial data, both of studies in Phases 1, 2 and 3 and in Phase 4 have already begun and indications of opportunities for growth are tremendous.

India's lower infrastructure costs and the rapidity of recruitment, which compresses timelines, offer a favorable cost benefit to clients.

How can a potential candidate have an edge in the selection process?

All persons in clinical operations require a graduate or postgraduate qualification in a science subject or a medical qualification since our staff comprises project assistants/associates, clinical research associates, clinical team leaders and project managers. In addition, there are medical monitors, quality assurance personnel, drug safety and regulatory personnel and clinical trial supplies management personnel.

Specifically for data management, IT-related and experience in data management would help in addition to the basic qualification. At Quintiles we require the services of data entry assistants, clinical data coordinators, clinical data specialists, database programmers and group managers. For all these functions though prior experience is not a must but is definitely preferable.

Professional training in clinical research

Till recently there was a dearth of structured formal training courses focusing on clinical research and trials. It was difficult to get trained manpower through tailor-made courses that are recognized and accepted by the industry. As Dr Shiv Prakash, MD, Synchron, commented, "There are many investigators who are not GCP trained but are highly inclined to get involved in conducting clinical trials and such enthusiastic investigators, if trained for GCP will create an ocean of good investigators for almost all indications." Now this gap is being filled. For instance, the Manipal University, in association with the Purdue University, offers a one-year diploma in cGMP training. The Institute of Clinical Research (India) offers a range of tailor-made courses in the clinical research segment at its Dehradun and Mumbai campus. Lotus Labs plans to start formal GCP / GLP training programs soon and is in the process of setting up training centers. Pfizer has partnered with the Mumbai-based Academy for Clinical Excellence to offer certificate as well as diploma course in clinical research.

Growth Opportunities

The segment offers rapid growth prospects once skills are acquired to conduct and manage clinical trials as per global requirements. Employees are given every opportunity to excel, challenge boundaries, and go beyond expectations. With performance as the key driver, employees are given attractive emoluments, much above the average salaries in the medical sector or pharma industry, with liberal incentives. On an average salaries vary from Rs 8,000 per month for an entry level to anywhere between Rs 40,000-60,000 per month for middle managerial positions.

Rolly Dureha