Opportunities and Challenges for Clinical Research in India

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Clinical Research may be defined as organised research conducted on human beings, intended to provide adequate information on drug use as a therapeutic agent on its safety, efficacy and adverse effects. Globally, clinical research is becoming a thrust area, essential for development of new drugs, new formulations, drug delivery systems, dosage regimen, surgical and diagnostic techniques, devices and therapies. With the advent of high throughput screening, drug discovery programmes have expedited clinical evaluation. Globally, there is a paradigm shift in the pharmaceutical market, and nearly two thirds of R&D costs go into drug development. Of this, clinical research accounts for 70 percent of time and resources spent.

India: The clinical research hub

Indian pharmaceutical industry is one of the fastest growing sectors of the Indian economy and has made rapid strides over the years. From being import dependent in the 1950s, the industry has achieved self-sufficiency and gained global recognition as a producer of low cost, high quality bulk drugs and formulations. Having proved itself in the international market, India is ready to face the challenges of proving its efficiency as the preferred destination for global clinical trials.

A number of factors favour India as a clinical research hub. Firstly, there are numerous government-funded medical and pharmaceutical institutions with state-of-the-art facilities, which can serve as ideal centers for multi-centered clinical trials. Secondly, India boasts of well-trained and qualified manpower, well versed in English. More importantly, there is vast clinical material, which can be utilised.

In terms of the cost efficiency, India is a better bet as the cost to conduct a trial here is lower by 50 to 75 percent than in United States or European Union. R&D costs in India are substantially less than those in the developed world and it is possible to conduct both new drug discovery research and novel drug delivery system programmes at competitive rates. In addition, while clinical trials cost approximately $300 to $350 million abroad, they cost about Rs 100 crore in India. There is a good communication link, which favours fast recruitments and approvals. Thus, studies can be completed quickly, providing an edge over competitors.

Moreover, India being a land of diversity where Ayurveda, Unani, Siddha, and Homeopathy are practiced with the same fervour as allopathy, clinical studies for evaluation of various alternate systems of medicine can also be conducted with ease. Owing to this myriad of factors, India is attracting collaborative contract proposals for conducting clinical trials and many entrepreneurs have already come forward to set up their Clinical Research Organisations (CRO).

Table 1: Projected figures in respect of revenue, human power and patient load for clinical research in India

	2003	**2008**	**2010**
Value (million USD)	50	200	1000
Revenue (crore INR)	75	300	875
Full time staff requirement	800	4000	20,000
Site-staff requirement	1500	6000	30,000
Patient load	10,000	50,000	300,000

Source: McKinsey report

Scope of clinical research

Irrespective of the fact that a drug has been developed in India or abroad, or whether its clinical studies have already been conducted abroad, every new drug needs evidence from clinical research to support its launch. Similarly, launch of new formulations, drug delivery systems or even new fixed dose combinations, require clinical data before it can be marketed. It is obvious that the area of clinical research holds immense scope and promise, as without the supporting data, drug launches are not feasible. Hence, rather than viewing clinical research as a subsidiary to pre-clinical research, it is important to understand that clinical research has to be conducted even in cases where pre- clinical studies are not warranted.

Clinical research holds tremendous scope and opportunities not only for trained medical, pharmaceutical and paramedical professionals, but also for regulatory authorities, government and the society at large. A mechanism of knowledge transfer can be worked out which would lead to a definite improvement in hospital infrastructure. It will make the state-of-the-art therapy available for many deserving Indian patients who were hitherto deprived of such therapeutic advances. Consequently, the projected figures for the various aspects of clinical research (market value, revenue, staff requirement) for the next five years, promise a growth at a rate greater than 20 percent.

Lucrative job opportunities

It is certain that in future as the number of clinical projects expands, there will be demand for qualified personnel. According to a McKinsey report, the global clinical trial outsourcing opportunity in India in the pharmaceutical industry is estimated to be around $2 billion by 2010 and there will be requirement of 50,000 clinical research professionals. Trained pharmacists and clinicians can plug this wide gap. They will be involved in the various aspects of clinical research starting from site-monitoring, site-management, clinical data management, data analysis, report writing, report submission, presentation and publication.

In the field of clinical research, there is an imbalance between demand and supply with the scales tipping in favour of demand. Thus, pharmaceutical houses are hunting for trained professionals and are using bulky pay packages to lure them.

Regulatory requirements for conducting clinical research in India

In 1988, as a regulatory requirement, government made it mandatory for all new drug introductions to get NCE approval. Schedule Y stipulated that the first applicant for any new drug should generate data in local clinical trials conducted in approximately 100 patients at four to five centers. The schedule also indicates that permission for such clinical trials would be given for one phase behind the development status in the rest of the world. However, for a second and subsequent applicant for the same compound, no clinical trial would be required as they could show bio-equivalence to the first product approved and introduces their brand of the generic in the market. Due to this lack of protection, innovator companies have been losing money, as they are unable to introduce their new and cutting edge research in the Indian market.

Moreover, it discouraged pharmaceutical companies from carrying out global clinical studies by their local subsidiaries in India and preferred to wait for their innovator brands to be approved in source countries and then carry out limited bridging studies for local approvals. Consequently, there has been a gap between their introduction in India with the worldwide market.

Recently, amends in the regulatory requirements have been made and the thrust has shifted from just safeguarding Indian subjects to providing them access for biomedical innovation. India has signed the Trade Related Intellectual Property Rights (TRIPS) agreement as a part of the WTO regulations, which will guarantee intellectual property rights and patent protection to companies holding the patent from 2005.

In the present Intellectual Property Right (IPR) regime, it has become extremely important for conducting timely clinical research. Increasingly, permission for Phase I trials is being granted after thorough appraisal of the protocols, products and claims.

The government by relaxing duties levied on clinical trial samples indicates its commitment in strengthening India's position and propelling it as world leader in clinical research.

The government is likely to exempt pharmaceutical companies from seeking Genetic Engineering Appr-oval Committee (GEAC) clearance for undertaking clinical trials in case of "purified products" of genetically modified organisms (GMOs), used in drugs such as vaccines, interferons and diagnostics.

This is in line with what a joint committee, comprising officials from the Department of Biotechnology and Ministry of Environment and Forests, has suggested to the national task force headed by the CSIR Director-General, Dr R A Mashelkar. This move will primarily decrease the number of steps in the clearance procedure for pharmaceutical companies.

Salary benchmarks for clinical research professionals

Position	Gross annual salary (USD) - 1999	Gross annual salary(USD)-2001	Inflation adjusted annual growth
CRA I	45,000	46,000	-1.50%
CRA II	50,000	52,000	-0.60%
CRA III	59,000	68,000	4.80%
Senior CRA	63,000	72,000	4.30%
Regional CRA	58,000	65,000	3.30%
Project Manager	71,000	74,000	-0.50%
Regulatory affairs	70,000	73,000	-0.50%
Data management	59,000	65,000	2.40%
Medical writing	50,000	58,000	5.00%
Medical affairs	81,000	84,000	-0.80%
Business development	83,000	90,000	1.50%
Clinical research co-ordinator	34,000	40,000	5.90%

Source: CenterWatch

Need for clinical training institutes

Despite the availability of infrastructure and manpower, clinical research is still in its infancy in India. This calls for the development of its capacities and capabilities in terms of infrastructure, regulatory structure, and formulation of specialised pool of research investigators.

Increasingly, a need is being felt for development of institutes that may provide training and education in the clinical research segment and meet the growing demands of skilled manpower by the industry. In a survey conducted on training needs, around 40 percent of the respondents felt that there was a need for training centres in clinical research methodology.

Conclusion

Considering the fact that less than one third of the drugs tested in clinical trials actually reach the market, study of drugs in humans needs to be logical, with sound scientific basis in both conception and execution (Berkowitz, 2004). The rigours of research should be adopted so as to maximise the benefits to mankind at minimum costs and risks. The challenge lies in integrating physician, regulatory authorities and pharmaceutical houses to optimise the risk-benefit profile with experience and not empiricism so as to minimise the abuse or misuse of the subjects (Cohen, 1994; Nowak, 1994). The drugs to be tested should conform to Good Manufacturing Practice guidelines and tested pre-clinically with Good Laboratory Practice and finally in clinical accordance with Good Clinical Practices. We still have a long way to go before we resolve issues pertaining to clinical research.

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