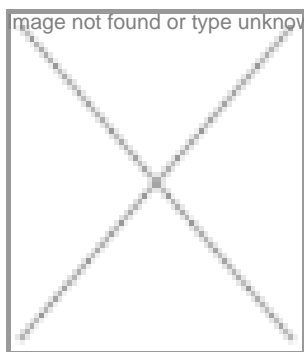


India: Clinical research hot-spot

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man, board of directors, Institute of Clinical Research, New Delhi

Shiv Raman Dugal is the chairman of the board of directors at the Institute of Clinical Research (ICRI), the first and the world's largest institute in clinical research education. He has been responsible for raising the organization's delivery capability to world-class standards. With over 30 years of experience, Dugal has been a part of the ICRI since its inception in 2003. He is an active member of many industry associations and societies, and has served these bodies in various g their programs

Clinical research industry has been growing exponentially in the past few years. It has opened up a opportunities to medical, pharma and all interdisciplinary fields.

In Asia, the major destinations for clinical research are Singapore and India – estimated to be worth ~~11,500 crore (\$2.5 billion)~~ ^{11,500 crore (\$2.5 billion)} by 2010. Currently 2,50,000 positions in clinical research are said to be available worldwide; with 50,000 job openings in India, within next 3-5 years.

Singapore is already a hub in the APAC for biopharma firms and contract research organizations (CROs) to conduct their regional clinical development activities. Growth of global clinical research.

Clinical research industry has grown around the world at an unparalleled rate in the past few years. It has opened up new vistas of employment for a large number of people.

Currently, the worldwide clinical research market is worth ~~23,920 crore (\$52 billion)~~ ^{23,920 crore (\$52 billion)}, 70 percent of the business is

generated within the US, employing an estimated 210,000 individuals. UK is considered as the hub for clinical trials in Europe with over 70,000 individuals in the industry.

Clinical research in India

India is increasingly recognized as the most promising hub for global clinical research. The clinical trial outsourced market in India is forecasted to grow at a CAGR of around 31 percent during 2010-12. "Registered clinical trials in India have gone up from 221 in 2007 to around 1,300 in 2009. Eighty Indian hospitals are presently involved in clinical trials. This figure is likely to go up to 14,000; and will mean involvement of five-lakh doctors, seven-lakh beds, 17,000 medical graduates in 160 medical colleges.

India is fast emerging as a favored destination for clinical trials in new products by multinational pharmaceutical companies. Two major reasons for its popularity can be attributed as easy access, and availability of a large, diverse and therapy-naïve population, with vast gene pool and a lower cost of technical services; resulting into lowest per patient trial cost.

According to an analysis done last year by Rabo India Finance, conducting a clinical trial in a low-cost destination such as India, can cost up to 60 percent less than in the US. Cost savings are a significant dream for many pharma companies when deciding to outsource clinical research to countries in emerging markets such as India. Unlike the US, India has favorable government regulations and approval process.

Trials and tribulations

The challenges India faces for expansion of its clinical research market are: insufficient number of hospital sites and trained personnel meeting international conference on harmonisation-good clinical practice (ICH-GCP) norms, equipments at hospitals/ sites for conducting trials not always on par with trial sites in western countries, apart from bureaucratic hurdles for regulatory approvals for global clinical trials.



Phase I trial is not allowed in India unless the molecule is developed in India, the industry is looking forward to this being allowed. Phase II and III studies take 45 to 90 days to get approval. Also the lack of protection for the data generated in these trials is the matter of concern.

There have been concerns over ethical issues in patient recruitment and conduct of trial, along with the lack of sufficient infrastructure for central laboratory services.




The key expectations from CRO market are consistent high quality, credibility, reliability, offering a range of services, broad and focused therapeutic expertise, timeliness, global reach local expertise approach and expertise in developing newer drug delivery systems (NDDS) packages.

To meet the challenges and address the key issues, India need to devise policies and insure implementation in legislative, IPR structure and regulatory issues. India also needs to help develop CROs with adequate capacity and competency in carrying out clinical research activities in compliance with ICH/GCP guidelines. Clinical research to boost industry.

According to McKinsey report, India is emerging 'as hub for global clinical research'. The global clinical trial outsourcing opportunity in India is estimated to be around Rs 5,000 crore by 2010, and there will be a requirement of approximately 50,000 clinical research professionals.

Today, there are more than 2,50,000 positions vacant worldwide. And salaries vary from a minimum  18.4 lakh (\$40,000) per annum for a clinical research coordinator, to almost  4.6 lakh (\$10,000) per annum for a business development manager. What this means is that clinical research is definitely the next big career.

India, at present, has a requisite of clinical research professionals and personnel in allied services; such as data management, biostatistics and medical welfare. But the current numbers of skilled professionals are only 2,000 and 3,000. The clinical trial market is growing at the rate of 30 percent annually.

It takes about  4,600 crore (\$1 billion) and some eight to 10 years for a new drug discovery. But if clinical trials were to be conducted in countries like India, the cost could come down to as much as 60 percent. In terms of career, a fresher could get jobs in clinical research segment with a pay packet of about  2.5 lakh annually which eventually goes higher to  5-6 lakh annually.

Some of the career options available are clinical research associate, clinical research coordinator, clinical data management

executive, pharmacovigilance executive, clinical trial analysts, medical writer, drug reviewer and many more.

ICRI addresses the need for qualified and trained clinical research professionals by offering various programs in clinical research at its centre of excellence campuses in New Delhi, Mumbai, Ahmedabad, Dehradun, Hyderabad and Bangalore.

ICRI is India's first and only clinical research institute dedicated to promoting ethical research and high-quality clinical research education in India.

The courses offered by ICRI are in collaboration with Cranfield University, UK. ICRI is the only institute in India offering courses at multiple campuses throughout the country, thus giving the courses a national character.

Quality in clinical research is of paramount importance. Ethical and social considerations should be kept in mind while conducting a clinical trial. All clinical trials performed in the country should meet the specifications laid down in ICH-GCP guidelines.

For this our country needs skilled professionals having in-depth knowledge and understanding of the basic principles that are considered as prerequisites for conducting clinical trials.

India has various systems of medicines like homeopathy, unani, ayurveda and other traditional systems that offer a wide scope for clinical trials. These practices need to be integrated in traditional products to generate superior knowledge-based products.

Future scenario

As the drug development is a high-risk investment global pharmaceutical companies under pressure from stakeholders are trying to find ways for cost-containment and to increase the productivity. India with its intellectual powerhouse, patient population, world-class scientific and technical skills and discipline is an attractive destination for global players, for cost and time containment. This is the reason why MNCs are outsourcing clinical research and trials to India.

With government initiatives in full swing, a favorable environment is being created not only for the conduct of outsourced clinical research but also for the growth of local pharmaceutical industry at a rapid pace. With full efforts from the government and cooperation from Indian CRO industry to meet the challenges in this field, India is set to become the 'global hub of clinical research'.