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Clinical trials: the new mantra for growth

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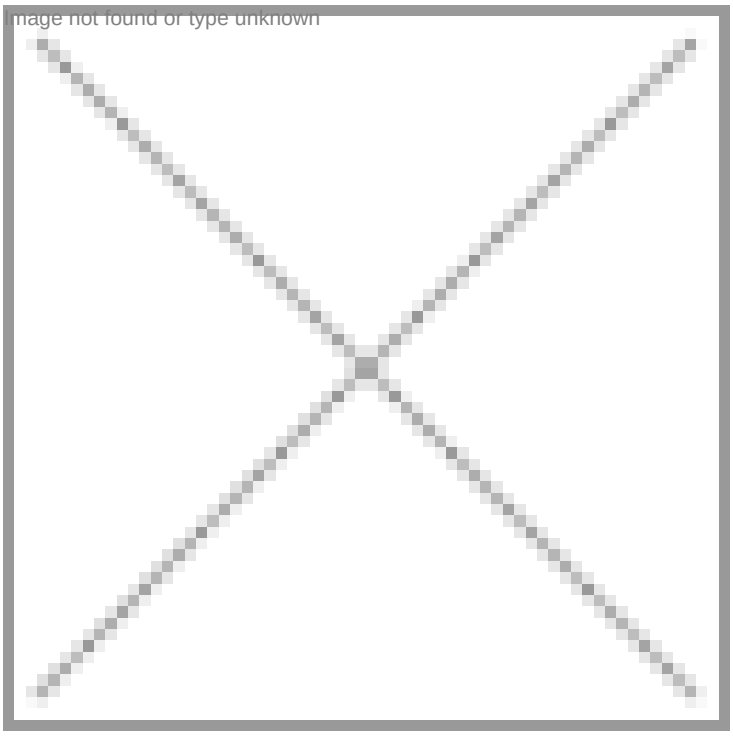

Every year over 80,000 clinical trials of various drugs and treatments are conducted in the world. Estimated to cost around $ 13 billion (Rs 60,000 crore), these trials happen mostly in the developed countries. Out of this, approximately $ 4 billion (Rs 19,000 crore) is spent on doctors and the remaining $ 9 billion (Rs 41,000 crore) goes to organizations conducting the trials.

A large number of these trials could be conducted at much lower costs in developing countries like India. However, due to a variety factors including regulatory issues, inadequate facilities and issue related to safety of sensitive data, this has not been happening in a big way. According to a Rabo-India Finance report, China seems to have attracted more interest in clinical trials despite India's English-speaking doctors and technicians.

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But thing may be changing. Thanks to the emphasis on outsourcing in the nearly stagnant economies to cut costs and retain competitiveness, India is being considered as a destination for clinical trials. The recent global guidelines making it mandatory for testing new drugs across a variety of gene pools may have increased the interest in India. This country definitely offers a large patient diversity and the numbers. It is easier to do multi-center, large scale trials in India for many diseases. For example, India has over 25 million patients suffering from type II diabetes, accounting for 20 percent of the global diabetic population.

After a new drug or treatment is ready, government regulations in most countries require it to go through four phases of clinical trials prior to approval for sale to the people without too many restrictions. Phase I trials is the toughest where the new drug or treatment has to be tested on a small group of 20 to 80 healthy people. This has to be done to evaluate the drug's safety, determine the dosage requirement and identify any side effects. In phase II trials, the drug or treatment is

administered to a select group of patients ranging from 100-300 to test its effectiveness and safety further. In phase III trials, the drug has to be given to a large group of patients (usually 1000-3000) to consolidate data on effectiveness and side effects. This data is then compared with existing drugs or treatments to facilitate permission for large scale. In the post-marketing era, phase IV trials are done to collect additional information on the drug's addition risks and benefits and study its optimal use. On an average it takes $ 800 million and 12 to 15 years to develop a new drug and bring it to the market. However, the alternatives based on biotechnology cut down the costs and time by more than half due to limited side effects. Industry studies show that some 371 biotech -based drugs are now under development by 144 companies worldwide against 200 diseases. So far, the US government has approved 95 biotechnology drugs.

Many biotech companies are looking at India for clinical trials, said Dr Vijay Kumar, MD, Neeman Medical International, Delhi. These companies are attracted by the availability of medical expertise, legal and regulatory frameworks and access to a large and diverse patient populations. He argued that participation in global clinical trials is a win-win situation for the medical profession, patients, medical institutions, laboratories and data management specialists. Because, patients will have access to 'state of the art' medical care at no expense and medical professionals will get an opportunity to work with 'cutting' edge technologies and exposure to modern research methods. In addition, participating medical centers will get the latest equipment to facilitate these trials, the standard of laboratories will increase to match global levels. The IT industry will benefit from data manager service orders. And the nation will earn on average $ 3,000 per patient taking part in the trials.

Some companies have already started doing clinical trials in India. American giant, Eli Lilly is a major user of Indian expertise. " We are already one of the biggest players in terms of doing clinical trials in India. We are currently running close to 18 projects, some of them in phase II and others in phase III stage. Last year our total spent on clinical trials was Rs 10 crore which was almost 10 percent of our total turnover in India, way ahead in terms of percentage to sales than in any other pharma company," revealed Eli Lilly India's chairman and managing director Rajiv Gulati.

Bangalore- based Biocon Group company Clinigene International has positioned itself well to offer clinical trials to foreign companies. "We have initiated clinical studies in diabetes in collaboration with a California-based bitoech company," revealed Clinigene chief operating officer (COO) AS Arvind. These studies are expected to extend to other disease segments -asthma, lipidemia and arthritis-in the coming years.

Clinigene also has the capability to conduct drug-related bio studies, pharmacogenomics based clinical studies as well as other specialized longitudinal studies on select patient populations. Clinigene's competencies include conducting bioequivalence, bioavailability studies, phase I to phase IV clinical trials and other special clinical studies in line with internationally accepted norms and practices. Dr Arvind said Clinigene has India's first CAP (College of American Pathologists) and NABL approved clinical laboratory.

Irish company ICON Clinical Research has started operations in India in April 2002 to conduction clinical trails for foreign companies. " We are doing trials for a foreign company now, " said ICON Clinical Research (India operations) manager Larisa Nagra Singh. The company claims to be the world's first ISO 9002 certified organization for conducting clinical trials at all its 20 global offices.

ICON offers a range of services including biometrics and statistics, clinical laboratory services, clinical research consultancy, clinical research management, data management, interactive voice response system, medical writing, pharmacovigilance and regulatory and consultancy services.

Many other companies such as Quintiles, SIRO Clinpharm, Wellquest, Lambda, Lotus Labs, Synchron are active in this area. Besides Eli Lilly, MNCs like Novartis and Pfizer have established data analysis centers in India, according to a Rabo bank-India research report.

There are however several hurdles which hamper the growth of clinical trials in India. Government regulations do not permit conducting of phase I trials (on small group of healthy volunteers) except when the drug or treatment originates in India. Apparently these restrictions have been retained to prevent potential risks to Indian volunteers from untested drugs. Lack of full-scale protection to intellectual property rights (IPRs) is another dampener. Till end-2004, India will not allow product patents and only manufacturing processes can be patented. In view of this, protection to research data (data exclusivity) is an area of concern to foreign companies. They can do nothing if other Indian players manage to get the trial data and use it to form alternate products.

Eli Lilly's Rajiv Gulati said the long time period (four to nine months) to get regulatory approvals, unpredictability of regulatory guidelines are some of the other hurdles. On an average such approvals are available in countries such as Australia, Germany, Belgium, Norway, UK and South Africa in six to 12 weeks.

Dr V Srivatsan, director, Lambda Therapeutic Research Pvt. Ltd, said the government has to strengthen the implementation and monitoring of adherence to Indian Council for Medical Research (ICMR) guidelines on good clinical practices (GCP), train professionals in GCP and good laboratory practices (GLP) in tune with global standards, and ensure accreditation to laboratories.

"We need to develop facilities of international standards established by World Health Organization (WHO) or Federal Drug Authority of the US (FDA). India has the human capital. But at the same time Indian patients shouldn't be treated as guinea pigs. Hence scientific evaluation and strict monitoring of clinical trials is essential," advised Prof. G Padmanabhan, leading genetic expert and honorary professor, Indian Institute of Science, Bangalore.