

## India: A Hotspot for Clinical Trials

**Arvinder Kaur** May 29, 2006

India is fast emerging as an attractive destination for conducting global clinical trials due to availability of vast pool of patients and also well-trained medical professionals and sophisticated technological infrastructure.

The clinical research outsourcing market in India was valued at Rs 3.1 billion in 2005 and is expected to grow to Rs 13.2 billion by 2010. Most of the US and European nations are outsourcing clinical trials to India, says Mahesh Sawant of Healthcare Practice, Frost & Sullivan, a market research company.

"A huge patient population, genetically distinct groups, speciality hospitals with state-of-the-art facilities, nearly 700,000 hospital beds and 221 medical colleges, skilled English speaking investigators are India's trump cards," says Sawant.

"The entire world is watching the growth and performance of India in this segment of business. There are positive signals and reports which justify the trends for pharmaceutical sponsors to look seriously at India for carrying forward their drug development initiatives," notes Dr Umakanta Sahoo, head, India Operations, Chiltern International, a clinical research organisation.

A CII study predicts that the clinical trials market will grow to \$200 million by 2007 and anywhere between \$500 million and \$1 billion by 2010, Sahoo says.

Global consultancy McKinsey also estimates that by 2010, India will grow to \$1.5-2 billion, notes Sahoo. "Increased globalisation has brought about fundamental changes in the way clinical trials are conducted here. Increased awareness of Good Clinical Practices requirements, stronger international acceptability of research done in India has brought favourable changes in the attitude of clinicians in India towards participation in clinical trials," says Sawant.

Today, there are nearly 100 players, who are involved in several outsourcing business related to clinical research in India. They include Pfizer, Novartis, Eli Lilly, Dr Reddy's, Ranbaxy, Dabur, Merk and Astra Zeneca, says Sahoo.

The fact that entire education in modern medicine in India is in English, is an added attraction. All source documents, hospital papers, lab reports, clinical notes are generally written and printed in English, avoiding need of translation as in China or Japan for auditors from the west, those in the field say. The trials are going on in diverse areas. The highest number of studies have been done in infection and oncology areas in the last few areas.

However, there are several trials also being carried out in psychiatry, neurology, cardiology, gastroenterology, endocrinology, dermatology, respiratory and ophthalmic areas, Sahoo says. "India's experience in clinical trials, while most of them are for USFDA and European submission, suggest that the quality of the data is acceptable to meet the global standards, he says.

However, key to growth in this industry is to ensure implementation of these guidelines in true letter and spirit and in maintaining consistency in data quality and proven data security," he says.

"The success of clinical research in India is entirely dependent on the availability of sufficiently high-end, skilled personnel to work on trials for the global sponsors.

Being an emerging business of the last decade, today we lack matured and trained clinical research professionals with more than 10-15 years of industry experience," rues Sahoo.

However, several initiatives both by industry and private institutes have started to train people in clinical research areas, and it is emerging as a very lucrative career option for bioscience, medical and pharma graduates," says Rajiv Verma, Dean, Institute of Clinical Research, New Delhi.

Verma says to train international quality professionals, they have tied up with Cranfield University for the PG course. "The demand for trained professional is so high that even during internship programmes, the researchers are paid between Rs 30,000 - 50,000 per month."

Today India's regulatory framework is also compliant to international standards in areas such as Good Manufacturing Practice and Good Laboratory Practice and the country has its own Good Clinical Practice guidelines.

The 2005 amendment to the Schedule Y of the Drugs & Cosmetics Act is moving India towards acceptance of International Conference on Harmonisation guidelines for clinical research, he says. Also, the implementation of the Product Patient Act confirms the willingness to accept global confidentiality and data security norms. Even the Medical Devices Guideline is also in place since March this year, he says.

Some groups are raising this fear that the Indian patients are being treated as guinea pigs but experts rule this out saying the laws are very stringent for such a thing to happen.

"The accountability is very well laid on paper. Besides the ethics committees of hospitals which monitor the trials, there international agencies like the FDA which have to finally approve the drug, also keep an eye on these trials. The controls are so strict that if anything wrong is found happening, the drug is immediately rejected," says Dr B K Rao, Chairman, Sir Ganga Ram Hospital there.

"It thus becomes in the interest of these research agencies to keep their house in order," he says adding "the patients know that they are participating in the trial. They have to sign a legal document or consent form, which is made available in their local language," says Dr Rao.

"It will be unwise to say that the Indian patients are made guinea pigs. The Drugs Controller General of India office and other Indian regulatory bodies have been stringent in this case in the approval of clinical trials carried out in India," says Sawant, noting "generally compensation is provided to the patient for participating in the trials and also insurance is provided in case of some trials for any adverse event."

Jennifer Khan, an American writer, who travelled to a hospital in Sevagram to write about how clinical trials are being conducted here, said "from what I have seen, the worst offenders seem to be Indian pharma companies rather than multinationals - a surprise to me."

According to Sahoo, "first time exposure of new drugs (of other countries) in Indian healthy volunteers is not allowed as per the regulations here. Participating in trials, which are mostly in phase II, III and IV, Indian patients benefit in terms of improved care and decreased expenses as the drugs are available free."

Sawant says that most teaching hospitals have now well constituted ethics committees that comply with ICH requirements for compensation. Though there are currently no functional central

ethics committees in India, some pharmaceutical companies have taken initiative for formation of such committees to facilitate clinical trials with general practitioners.

However, Dr Roy notes that as the volume of clinical trials in India goes up, the government will have to think about setting up a Central Regulatory Authority, which could act as a watchdog. "Although fraught with the unusual amount of bureaucratic red tape in government offices, import licensing and clearances and local ethics committees, the system allows the setting up of multi-centric trials in not more than six months," notes Sawant.

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