India is under pressure to handle the growing demand for outsourced clinical trials.

Firms discovering reality of clinical research in India

Country unprepared for increased demand in trials

K. S. Jayaraman

The annual Indian Pharmaceutical Congress is normally a domestic event, but the last meeting, held in Hyderabad at the beginning of December, was an altogether different affair.

An unusually large international presence — 55 participants from nearly 40 countries — showed the level of international interest in India's capabilities as a hub for clinical research.

The potential to reduce clinical development times and costs is attracting the attention of international companies, as well as domestic companies eager to run clinical trials thanks to the promise of large funds.

"India has a number of strengths in clinical research, including therapeutic diversity, English-speaking physicians and computing infrastructure, leading to faster clinical trial execution," says Michelle D'Souza, spokesperson for Pfizer, which has about 20 ongoing trials in India.

But the reality is that India is unprepared for this surge in interest. "India is ready to take on outsourcing of clinical trials and in many areas is already doing so quite well," says Falguni Sen, Professor of Management at Fordham University, and expert on strategic management of technology and innovation. "Can it take on an unprecedented growth in clinical trials activity? That remains to be seen."

A white paper released last November by the Federation of Indian Chambers of Commerce and Industry (FICCI) concurred, documenting a shortage of trained investigators, a dismal state of institutional ethics committees (IECs) and an absence of law to prevent unethical trials. "As all stakeholders are still learning," says the FICCI paper, "the journey towards achieving global quality [in clinical research] is unlikely to be smooth."

Clinical trial activity in India is only "a fraction" of what is possible, says D'Souza. India reportedly earned about US$17 million through clinical trials in 2003, rising to $75 million in 2005. The government's Department of Biotechnology (DBT) has set a target of earning $1.5 billion by 2010.

India is in a good position to tap into new business opportunities in clinical research, says DBT secretary Maharaj Kishan Bhan. However, he admits "the infrastructure required to identify, document and monitor patients under clinical trials needs to be put in place before India can partake in this activity."

> "Can [India] take on an unprecedented growth in clinical trials activity? That remains to be seenworldwide."

Scaling this up "will be difficult", says D'Souza, unless institutes and regulators invest in capacity building by "strengthening infrastructure, processes and resources", including investigators and ethics committees.

Josef von Rickenbach, Chairman of the American Contract Research Organization (ACRO), says they "regard the creation of a regulatory environment that ensures ethical clinical trials as a key to the growth of India's market for clinical research." Adds ACRO's Executive Director, Douglas Peddicord: "The question may be less whether India is 'ready' to undertake an expanding research portfolio than how it should go about doing so."

For instance, India is ill-equipped to guarantee an adequate level of patient safety standards in Phase I studies, says Sen. "The regulatory capacity has to be increased immediately; it is stretched to its limits," he says. An insurance system or a national fund created through a levy on trial sponsors for trial subjects, disincentives to conduct unregistered trials and mandatory community involvement in vaccine trials could help address these problems, suggests Sen.

Government officials say they are addressing concerns as quickly as they can. The adoption of Good Clinical Practices (GCP) guidelines, removal of import duty on clinical trial supplies, permission for concurrent trials (in India and abroad) and removing restrictions on export of clinical samples all illustrate the seriousness of their intent.

Creating a culture of global GCP quality trials is an ongoing process, with several logistical barriers. "We are setting up a registry and have just concluded the training of the first batch of inspectors who will audit clinical trials," says Ashwini Kumar, the Drug Controller General of India. He added, though, that the inspectors are hired from outside and are paid by a World Health Organization grant, as he has no budget or staff to spare.

India needs to solve these issues quickly to prevent overseas attention drifting towards other regions promoting clinical resources, such as China and Eastern Europe, and to maintain the excitement and expectation from domestic quarters.

Nowhere is this excitement more obvious than the many coaching institutes set up in the past few years by private groups that will, for a fee of a few thousand dollars, train technicians for clinical trial sites. "Science and pharmacy graduates need not hunt for jobs now that clinical research is here," one such Bangalore-based company states in a front-page advertisement in the best-selling English-speaking newspaper *Times of India*. "Some 50,000 jobs will hunt for them instead."