

India's drug tests

Drug companies are converging on India to conduct low-cost clinical trials. But is it ready to become the outsourcing centre for the world? **T. V. Padma** investigates.

The average cost of a clinical trial in the United States is US\$180 million. The average cost in India is US\$100 million. No surprise, then, that multinational companies are flocking to India to launch their trials. "It's a lot cheaper to do things in India," says Sameer Deb, general manager of government affairs at Glaxo-SmithKline's office in Mumbai.

Multinational companies are not the only ones to benefit financially from these studies — India does too. The consultancy firm McKinsey estimates that US and European pharmaceutical companies will spend US\$1.5 billion per year on clinical trials in India by 2010.

India has several advantages as a host for such trials. Its biggest asset is probably the size of its population at more than 1 billion. In addition, Indians are increasingly suffering from the same illnesses as Americans and Europeans — diseases for which companies are desperate to find cures. For instance, at least 70 million Indians suffer from heart disease and 35 million have diabetes. It also has the edge over most developing countries because of its sophisticated hospitals and because many of its medical personnel speak English.

But India does not have the robust infrastructure needed to sustain this expansion. It does not even have a central database listing

all the trials currently under way, despite each one having to be cleared by the Drug Controller General of India.

In addition, contract research organizations (CROs) are struggling to recruit enough participants to its trials, despite India's enormous population. An even greater obstacle is the lack of trained staff. Trials of this size will need an estimated 3,000 investigators, 600 medical institutions and 9,000 other professionals — numbers India cannot produce at present. Some CROs, in partnership with educational institutes and trial sponsors, are addressing this by setting up specialized institutes and centres of clinical excellence.

The bureaucracy-ridden Indian system is no small barrier, either. Officially, the government has limited the time it takes to accredit trials to 90 days for phase I, 45 days for phase II and 45 days for phase III trials. But "we are yet to see such speedy approvals in reality", notes Dhananjay Bakhle, director of regulatory affairs at Aventis Pharma, based in Mumbai.

The thorniest issue by far may be the ethics of conducting these trials. In one instance, scientists at Johns Hopkins University in Baltimore, Maryland, and the Regional Cancer Centre in Thiruvananthapuram, India, tested two experimental anticancer molecules on 27

oral cancer patients from 1999 to 2000 (see *Nature* 412, 466; 2001). But the researchers tested the drugs without the required federal or university approvals and without adequate preliminary tests in animals (see *Nature* 414, 835; 2001).

Following this incident, the Indian government ordered a full review of the ethics and safety of all trials. In 2000, the Indian Council of Medical Research (ICMR), the country's premier agency for biomedical research, issued guidelines for research on humans. The following year, the health ministry released its policy on good clinical practice.

But scandals continued to surface. In 2003, private clinics across India used a generic version of the anticancer drug letrozole to treat more than 435 women with fertility problems. This trial did not have clearance from the health ministry, and the women involved did not know that the drug was not approved for this use. The manufacturer, Mumbai-based Sun Pharmaceuticals, denies ordering this trial.

Government agencies concede that the regulations need to be tightened. "We are looking into strengthening institutional ethics committees and are conducting training workshops for them," says Vasantha Muthuswamy, deputy director-general of the ICMR.

Tightening the regulations will protect the trial participants, but it may be possible to go further. "Participants should benefit from any drugs that result from the trials," says Prasanta Ghosh, president of the biotechnology division of Cadila Pharmaceuticals, based in Ahmedabad. In which case, expansion of clinical trials in India could benefit everyone. ■

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India's enormous population makes it an attractive destination for clinical drug trials.

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