

India's amended trials regulations spark research exodus

Changes to trials regulations in India, designed to improve patient safety, have caused some research funders to halt their clinical work in the country. Shubhlakshmi Shukla reports.



The fate of India's thriving clinical trials industry hangs in the balance after amendments aimed to regulate clinical trials in the country were introduced 8 months ago. Researchers in India believe the changes were introduced in haste without gathering opinions from all stakeholders in government and non-governmental organisations.

The amendment called the Gazette of India notification on Compensation was announced on Jan 30. It outlined specific procedures to be followed in reporting serious adverse events, including deaths occurring during clinical trials, and rules for payment of compensation to participants.

Researchers have taken issue with a provision regarding free medical treatment for patients in the event of any injury irrespective of whether it is related to a clinical trial or not. "There are provisions in the bill that ensure that all persons who are harmed by participation in clinical trials shall have to be compensated", says Rajeev Gupta, clinical director of academics and research at Jaipur's Fortis Escorts Hospital. But "even if a non-drug-related event happens (eg, road accident or murder), patients would have to be reimbursed and compensation paid, according to the guidelines provided by the government", he says.

This situation has led some American and Canadian research institutes to halt the clinical trials they are running in the country. The US National Institutes of Health reportedly suspended 40 uncompleted clinical trials in India in July.

President of the Indian Society for Clinical Research, Suneela Thatte, says: "We cannot comment specifically where the withdrawn trials will be done, but know that several countries in Asia Pacific are emerging as options."

Meanwhile, other sources say that there is a possibility that these trials may move to North America, or other countries in Asia with less stringent norms.

Thatte adds: "Those impacted [by the regulations] include clinical research organisations, biopharma companies, non-profit organisations, and also local health-care institutions that do a lot of independent research."

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"Our concern is that with the recent developments not only would these entities hesitate to do trials in the country, but there would be a severe impact on local innovation and academic research, of which there is a lot taking place in some of our most prestigious and well known hospitals", Thatte tells *The Lancet*.

According to a report published by the Central Drugs Standard Control Organisation, 262 clinical trials were approved by the Drug Controller General of India and registered in the Clinical Trials Registry of India in 2012. But experts expect applications will be much lower this year because of the new regulations.

"There is no doubt that the biggest group hit by the regulatory developments are patients whose access to better and more cost-effective medicines will be affected", says Thatte. She notes that India has 16% of the world's population and 20% of the global disease burden but less than 2% of global trials take place in the country. "We need clinical research to develop new and effective medicines and vaccines to tackle our mammoth disease burden", she says. "If we have

to find better and more cost-effective cures for diseases in a population that is multiracial and heterogeneous, it is imperative to conduct clinical research in India."

Only a few modifications to the current regulations are needed, say experts. "The government has formed a Drug Technical Advisory Board, which met recently and has suggested modifications to revise areas of concern", notes Gupta.

"The middle path to regularise clinical trials is to ensure that trials are conducted at sites with good infrastructure, and by experts who have a good knowledge of how to conduct them", says Prem Pais, head of St John's Medical College Trial Division in Bangalore. According to Pais, the regulator should try to promote trials that are relevant to India. "There should be a statement required from the sponsor about how the trial will benefit the health needs of India, and about the drug's availability, and affordability in the Indian market if it is licensed and approved."

Thatte says: "The quality of clinical research being done in India is of a very high order as evidenced by the fact that inspections of sites by the US and European regulatory authorities in the last several years have reported no critical findings. That said, there have been a few instances of irregularities, which we do not condone, reported [by others]."

She concludes: "The development of a policy cannot be a knee-jerk reaction to external environmental pressures as we have seen in the last few months, but must be part of a larger and longer-term commitment to securing the growth of an industry that is critical to meeting our health-care needs."

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