

The moral case for clinical trials

Trials will improve standards in our entire health sector and save many lives. That justifies trials even without considering the (very considerable) commercial benefits, argues Swaminathan S Anklesaria Aiyar.

IS IT immoral for India to seek a big chunk of the global market for clinical trials for new drugs? Critics say, don't convert Indians into guinea pigs. I disagree. The size of the global clinical trials market is at least \$10 billion today, and could rise to \$26 billion by 2007 according to one US estimate. The CII thinks India could earn \$200 million from clinical trials by 2007, and \$1 billion by 2010. McKinsey thinks the figure could go up to \$1.5 billion.

India has the advantages of low wage costs, low research costs, and patients with all the diseases you could wish to conduct trials for. Furthermore, many have not taken any other drugs, and so trials involving them are not contaminated by side-effects from other drugs. The cost of trials in India may be just 20-60% of the cost in western countries. Hence foreign drug companies are flocking to India for trials.

Eli Lilly is reported to have 17 research projects across 40 Indian hospitals. Pfizer has picked six cities to test an anti-malaria cocktail of drugs. Smith-Kline-Glaxo plans to shift one-third of its entire global trials to developing countries like India. Many Indian companies (Biocon, Ranbaxy) are conducting trials on their own behalf, and as contract partners with MNCs.

The volunteers in trials include sick people from all classes of society. Many of these are poor and in hospital. They are happy to earn thousands of rupees by participating in trials, and some look forward to a new drug that might work where old ones have not.

Critics, however, say that many poor and illiterate patients are being exploited. Despite formal requirements, many are not fully informed of the risks they undergo. Left-wing critics scream that MNCs are using Indians as "guinea pigs". Many other critics are humanists, with genuine moral apprehensions.

I agree that trials in India should take place under stringent regulations to ensure that poor illiterates are not exploited. Yet, on balance, a big push by India to become a global player can be justified on

moral grounds alone. Trials will improve standards in our entire health sector, and save many lives. That justifies trials even without considering the (very considerable) commercial benefits.

First, people participating in trials are not guinea pigs. No guinea pig is asked to volunteer, informed of the risks, paid for services, or given the freedom to opt out at any stage. Human volunteers are. Guinea pigs are deliberately infected and then tested with new drugs. No human is deliberately infected: patients already infected are given the option to volunteer for drug trials that may cure them.

Second, it is immoral to take the position that Indians can benefit from trials that use Americans as "guinea pigs", but not the other way round. On purely moral grounds, Indians cannot claim the right to benefit from a new drug if the deaths and disabilities of testing have

been borne exclusively by foreign countries. There can, of course, be a commercial justification: the drug manufacturers will make a profit without requiring any reciprocity in clinical trials. But that ignores the underlying moral issue.

Third, clinical trials for new drugs may cure those who are not responding to existing drugs, and are desperately searching for a new remedy. New, promising drugs are not available to all sick people, only to participants in trials.

IN THE US, many experts urge that patients should be given access to drugs that show promise while still under trial. So do patients and their relatives. But the Food and Drug Administration (FDA) refuses, on the ethical ground that the drug has not cleared all trials. The patients retort that it is utterly unethical to condemn them to death when there is a chance that

a new drug can cure them.

Reasonable people can disagree on this issue. But, unquestionably, trials allow some participants to survive, who would otherwise have died. Critics opposing trials in India are condemning to death many who might be saved by trials.

In a recent case, some NGOs launched a legal suit regarding two clinical trials where some patients died. I empathise with their anger and anguish. But many patients will die whether or not they participate in trials: it is wrong to think that all deaths in trials are caused by the new drug. It will be true in some cases. That is a sad, inescapable part of testing.

There is no risk-free alternative. If we release new drugs without tests, there could be many more deaths. If we neither test nor approve new drugs, many sick people will die. Rigorous testing is the least damaging solution. The volunteers are covered by insurance, which is more than can be said for patients who do not volunteer.

Let us be clear about one thing. No MNC will come to India for low costs alone. Drug regulators in the west are tough, and under pressure to attain higher standards. These regulators simply will not approve clinical trials that are low-cost, if their integrity is dubious.

Standards in India are generally low. We tolerate water, electricity, schools and roads of abysmal quality. We endure corruption, adulteration and bad quality to a degree unthinkable in the west. Many institutions fudge data and have shoddy oversight.

These standards will improve only under immense pressure from abroad. No amount of moralising will improve standards. But the promise of earning billions from clinical trials will make it worthwhile for government and private agencies to pull up their socks in this sector and reach global standards. There will be many hitches and occasional scandals. But at the end of it all, our health sector will have greatly improved quality and institutional integrity. For that reason alone we must encourage clinical trials.

