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Colonialism of clinical trials

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Item Type	Article
Authors	Mamdani, Bashir;Mamdani, Meenal
Publisher	Forum for Medical Ethics Society
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Download date	2026-07-03 17:58:10
Link to Item	http://hdl.handle.net/20.500.12424/176785

Colonialism of clinical trials: discerning the positive spin offs

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Nundy S, Gulhati CM. A New Colonialism? — Conducting Clinical Trials in India N Eng J Med 2005; 352: 1633-6.

Summary

It has become increasingly difficult and expensive to test drugs in western countries, with their strict regulations, elaborate safety requirements, and small populations, all of which make the recruitment of research subjects difficult. Consequently, many organisations are now outsourcing some of their trials to developing countries such as China, Indonesia, Thailand, and India.

Under pressure from pharmaceutical multinationals, among others, the government of India removed the phase-lag rule and now allows foreign pharmaceutical companies to conduct drug trials in India simultaneously with same-phase trials in other countries. The old rule was designed to protect Indians from being used as guinea pigs in the testing of unproved drugs of foreign origin; trials of domestically discovered drugs were not subject to this provision.

Advantages of India as a site for clinical trials

Cheap labour, low infrastructure costs and a genetically diverse, drug-naive population of over a billion people with myriad diseases, make India an attractive site for drug studies. Moreover, Indian doctors speak English and many have postgraduate qualifications from UK or the US.

Disadvantages

The major disadvantage for the pharmaceutical industry is that trial reports are in the public domain and may be used by generic manufacturers. Furthermore, the Drugs Controller General of India (DCGI) is understaffed and lacks the expertise to evaluate protocols. Fewer than 200 investigators have been trained in good clinical practice. Only 150 hospitals have the infrastructure to conduct trials, and there are fewer than a dozen pathology laboratories that meet the criteria for compliance with good laboratory practice. Only about half of the large hospitals have institutional review boards, and even these do not have standard operating procedures and lack the expertise to evaluate protocols. Information about conflicts of interest is neither sought nor voluntarily provided. Financial inducements to participants, while legal, are ethically dubious. Widespread illiteracy compromises informed consent, and research protocols are often misrepresented to patients as required treatment.

Study protocols seldom offer to provide free medications if the trial is successful.

Nundy and Gulhati argue that India itself would not benefit greatly: the much-hyped earning potential is likely to remain a distant dream. Last year, although US companies spent a total of US\$33 billion on new-drug research, US and other western companies combined spent only US\$30 million in India. Even with relaxed rules, India makes as much in one day by exporting computer software (which offers no direct risk to anyone's health) as it can in a year by offering up its citizens as study subjects. Second, according to the FDA, no more than 20 per cent of the drugs introduced during the past decade have been breakthrough agents. The rest represent marginal improvements over existing therapies that are more expensive than the older drugs and are often aimed at extending the patent life of a therapy without offering any major new benefit for patients. Third, there is no guarantee that drugs tested in India will be made available locally at affordable prices. Only one per cent of the new drugs discovered in the past 25 years have been for tropical diseases.

Safeguards before liberalisation

Adequate safeguards must be put in place to protect participants. Such safeguards might include improved review of study protocols by the DCGI; registration of trials and publication of results on accessible web sites; mandatory health insurance and compensation of subjects for adverse effects from a study drug and free/affordable access to the drug after the trial; improved and third party-verified informed consent. Trials should be conducted only by trained investigators at designated research hospitals. Truly independent institutional review boards should be formed, and a system should be created to enable these boards to share

information about trials they have rejected. All projects should be scrutinised for their value to the Indian people. It is of paramount importance to protect the most vulnerable — women, children, the poor, and the illiterate.

Commentary

Nundy and Gulhati argue that India does not have the clinical and research infrastructure necessary to carry out quality research and, therefore, India should prohibit clinical drug trials by foreign institutions. While we sympathise with their sentiments, prohibiting such trials will not help the country to improve its clinical research infrastructure. Even ideological political hardliners recognise that isolationism is not viable in this era of globalisation (1). The status quo will not change without a strong push. Just as pharmaceutical manufacturing standards in India improved dramatically when manufacturers had to adopt far more stringent Western standards to sell their products abroad, we feel that clinical research in India will only improve when foreign institutions invest funds in India to carry out research and thereby demand a higher standard. Multi-national corporations (MNC) and for-profit contract research organisations are already here. Clearly, we need to be pro-active, allocating our energies and resources to influence and direct the way research is carried out. In the process, we can enhance our capacity to conduct high-calibre research.

The deficiencies that Nundy and Gulhati cite need to be addressed, irrespective of who is sponsoring the research. To this end, the Government of India (GoI) has appointed many committees to recommend a course of action. Starting with the Hathi Committee of 1975 to the latest, the Mashelkar committee of 2003 (2), the bulk of their recommendations have been ignored. It is only after the GoI recognised the potential of foreign investment in this sector that we saw any move to strengthen the regulatory infrastructure such as the recent ICMR initiative to improve ethical conduct of research (3). We need programmes to train doctors, nurses and others to understand research principles and analytic methods. The objective would be to develop a cadre of well-trained staff not only to conduct research studies but also to serve on research committees. Similarly, we have to train people to evaluate proposed studies from an ethical viewpoint, to assess how well the researchers are adhering to and implementing their protocols and obtaining informed consent. To assure a continued supply of well-trained personnel, our graduate and post-graduate medical and social sciences training must emphasise medical ethics, research ethics, research methods and analysis. Our abysmal medical records compromise our clinical and research efforts and this must be addressed immediately.

Needless to say, the safeguards enumerated by Nundy and Gulhati must be enforced for all trials, whether of Indian or western origin. This would require well-trained personnel to staff local scientific committees and review bodies. Given the current scarcity of such staff, we may borrow a concept from New Zealand and set up regional, rather than institutional, review boards. Such regional bodies will have a broader overview and will avoid local loyalties that often hamper their work in the US. A nominal fee on each trial in India could provide the funds for improving infrastructure and training personnel. The centralised regulatory structure in India would facilitate a central registry of clinical trials. India can demand that all subjects participating in a successful trial continue to receive the study drug after the trial ends and are compensated for any adverse outcomes. Currently too many institutions are designated as research centres simply as a tax dodge. To be designated a research centre, an institution must demonstrate ongoing participation in ICMR-approved research and have a track record of publications in peer-reviewed journals.

Nundy and Gulhati's contention that India is unlikely to benefit from facilitating MNC-sponsored clinical trials has little validity. If earning foreign exchange by "selling" its people for research were the only reason for the GoI to modify its laws, this would be ethically reprehensible. However, if the intent is also to import good clinical practice and improve the conduct of research, the GoI deserves full support. When our research facilities equal those in the West, research expenditures in India by western MNCs will grow exponentially. Adoption of international standards will ensure protection of our patients and also help the local drug industry. The lack of adequate facilities for conducting trials has led major Indian manufacturers, with new molecules of clinical significance, to test them abroad (with a royalty

sharing agreement) in order that the clinical trials are conducted expeditiously and the data has more credibility (4). With a better infrastructure, our manufacturers can keep all the royalties within India.

Fifty years of protection of the indigenous pharmaceutical industry have not resulted in any significant capacity building or indigenous development of new drugs. Having benefited from basic and clinical research done primarily in western countries on western populations, we should welcome the opportunity to conduct trials in India and use the experience to enhance our research capabilities. This will not only benefit the research community and industry; the ripple effect will enhance clinical practice standards for all.

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