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CLINICAL TRIALS IN INDIA: A BRIEF OVERVIEW

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ABSTRACT

In recent years, India has begun to establish itself as a prominent site for clinical trials. Given the relatively low costs of R&D in India, critical mass of skilled human resources, diverse genetic pool, institutions with state-of-the-art clinical facilities and a robust regulatory system post-2000, several global clinical research organizations and multinational pharmaceutical companies have welcomed India as a clinical R&D hub. However, informed consent issues related to patient recruitment in trials and improper functioning of institutional ethics committees continue to be worrisome aspects. In this context, the present paper examines the available literature in order to understand the central issues and concerns on clinical trials in India. An efficient and ethical growth of the clinical trials industry in India would need a robust centralized regulatory regime to effectively monitor GCP guidelines, transparency in the functioning of institutional ethics committees and ensuring a balance between economic opportunity and public health concerns.

Keywords: clinical trials, pharmaceuticals, India, regulation

Introduction

In recent decades, India has endeavored to position itself as one of the key players in the domain of clinical trials. Through the delivery of clinical development services, India has begun to establish itself as a site for clinical trials. Given the relatively low costs of R&D in India, several global clinical research organizations and multinational pharmaceutical companies have been eager to constitute India as a clinical R&D hub. In this context, the present paper examines the available literature in order to understand the central issues and concerns on clinical trials in India.

India's strengths in the domain of clinical trials have vested in factors such as a critical mass of well-trained English-speaking personnel, diverse genetic pool, the existence of government-funded and private medical and pharmaceutical institutions with state-of-the-art clinical facilities, the potential for fast recruitment of a large number of patients. Due credit must also be given to the emergence of a regulatory and ethics-based environment post-2000 as well as the setting up of a Clinical Trials Registry, in addition to a revamped regulatory regime. During this period, the relaxation of duties on import of clinical trial samples and the removal of phase lag and permission to conduct Phase 1 trials concurrently in India, along with the rest of the world also led to the burgeoning of clinical trials in the country (FICCI 2005).

However, this period has also witnessed a lack of adequate mechanisms to safeguard illiterate and vulnerable patients, prevent informed consent violations and ensure proper functioning of institutional ethics committees. In this context, the amendments in the Drugs and Cosmetics Act in relation to clinical trials and the increased stringency of the Schedule Y provisions have been welcomed since they confer greater credibility to these trials and speed up international approval. They also enable the sector to capitalize on the emerging opportunities of the market.

This could also prove advantageous in terms of the opportunities for trial participants to avail of cutting-edge biomedical innovation, reimbursements received by hospitals for participation in trials, which could benefit all patients served by the hospital, opportunities for researchers to participate in international standards research,

exposure of Indian health care system to international clinical research, in addition to the gradual maturing of the regulatory environment etc. (Maity and Raghavendra 2007:1-10).

There are also potential benefits of these trials in terms of attracting foreign investment, development in areas such as clinical epidemiology and applied research. In addition, there is also stress on the need for desirable conditions such as the setting up of accreditation centres for investigators and the detailed perusal of informed consent records and other important dossiers by Institutional Ethics Committees and the general stance has been that these desirable conditions would render the burgeoning number of trials in India both useful and profitable.
(Dandona 2006:55-56).

Though local clinical trials for new drug introductions were made mandatory in 1988 itself, there was also a 'phase lag' as permissions for trials were granted for one phase behind the rest of the world. In 2000, the Ethical Guidelines for Biomedical Research on Human Subjects were issued through the joint initiatives of the Central Ethics Committee on Human Research (CECHR) and the Indian Council of Medical Research. In 2001, the Central Drugs Standards Control Organization (CDSCO) set up an expert panel to develop GCP guidelines in accordance with international standards. In 2005, the Drugs Technical Advisory Board (DTAB) made GLP practices mandatory for all laboratories. In 2007, the regulations pertaining to the 'phase lag' were revised and Schedule Y subsequently permitted Phase I trials in India concurrently along with the rest of the world.

However, the move to do away with the phase lag[1]in 2007 also came in for criticism from health activists, who pointed out that this constituted a strategy to enable firms to profit in the relatively liberalized regulatory regime. The argument advanced here was that the scramble by multinational firms to carry out clinical trials in India stemmed from the difficulties that these firms experienced in carrying out trials in their own countries due to the safety and compensation requirements and the dwindling number of patients volunteering for trials. It was also felt that these trials were conducted in diseases which did not really benefit the Indian population, were based on drugs with minimal therapeutic advantage and did not constitute a guarantee that they would be available to the local populace after the trial period(Nundy and Gulati 2005:1633-36)..

Another exploratory study on clinical trials, conducted by the Centre for Studies in Ethics and Rights, Mumbai (Srinivasan 2009:1-44) emphasized on these above-mentioned deficiencies and attempted to look at ethical concerns related to clinical trials conducted in India, the results of which were used in the approval of new drugs in the European Union. It examined biomedical research practices in terms of a) clinical trials in humans, used for drug development and approval; b) trials conducted for marketing purposes; c) research conducted in the 'garb' of clinical practice and d) 'unscientific' and 'unethical' research practices for collecting information towards drug development (*ibid*:i). The investigation especially focused on one trial of *lapatinib*, a drug for breast cancer, carried out by Glaxo-Smithkline; one trial of *resperidone*, a psychiatric drug, carried out by Johnson and Johnson and two trials of *quetiapine*, another psychiatric drug, carried out by Astra Zeneca. The investigation concluded that these trials violated Indian Council of Medical Research's ethical guidelines for biomedical research and the guidelines enshrined in the WMA Declaration of Helsinki and benefited from a weak regulatory apparatus that is over-reliant on local institutional ethics committees and is permissive towards unethically conducted trials. The report also concluded that existing policies seemed to take a neutral stance towards the mushrooming of CROs and the conflict of interests involved in their generation of infrastructure in small towns in the country, their identification of trial sites in small private hospitals, their rush to generate databases of potential trial participants and provide substantial incentives for medical professionals recruiting patients in these trials. The study was also critical of existing policies in the context of their prioritizing the production of good quality data according to Good Clinical Practices (GCP) and treating the ethical considerations involved in these trials as being of secondary importance.

It needs to be emphasized that for an efficient and ethical growth of the clinical trials industry in India, the appropriate mechanisms to be adopted involve the presence of a robust centralized regulatory regime to effectively monitor GCP guidelines and ensure transparency in the functioning of institutional ethics committees.

[1] In January 2005, an amendment to Schedule Y of the Drugs and Cosmetics Rules did away with the phase lag in international clinical trials conducted by foreign sponsors. This practically translated into absence of restrictions on concurrent clinical trials in India and meant that Phase 2 and Phase 3 trials of drugs discovered abroad could now be conducted in India in the same phase and at the same time as they are conducted in other parts of the world.Phase I trials, carried out on a small group of healthy volunteers, collects data pertaining to the safety and adverse reactions of the drug, Phase II, conducted on a larger group, looks at efficacy and safety of the drug, Phase III trials try to validate the results obtained from the earlier phases on a larger group of people and Phase IV trials are carried out after a drug obtains marketing approval. Here trials may be done in order to ascertain new uses of the drug or to monitor drug interactions.

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