Recent Changes in Regulations Related to Clinical Trials Approval in India

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India with its huge genetically, culturally and socio-economically diverse population base of more than 1.2 billion is a home for a variety of diseases as well as for qualified, English-speaking and GCP-trained clinical research professionals.

Last 7 years have witnessed mammoth and concentrated efforts in the area of clinical research, both by the regulators and industry. Schedule Y of the Drug and Cosmetics Rules, 1945 governs the conduct of clinical trials in India. The amendment of this in January 2005, paved way for increased number of global clinical trials in India. The patent amendment bill covering pharmaceutical business was also adopted in 2005 confirming India's patent legislation with the World Trade Organization's Trade Related Intellectual Property Rights patent regime, which further boosted clinical research industry growth. Moreover, Central Drugs Standard Control Organization (CDSCO) is continuously attempting to bring more transparency and accountability in the regulation of clinical trials by releasing various guidance documents for industry, adaptation of CTD format for submission of applications, mandatory registration of clinical trials in clinical trial registry of India, duty free import of clinical trial products, etc which has helped to attract global companies worldwide to conduct their global clinical programs in India and thus contributed in making India as one of the preferred destinations for conducting clinical trials.

At the same time, couple of press reports regarding unethical practices in conduct of clinical trials in India throws light on the lacunae in regulating the same. To mitigate the growing unrest in the community, the Indian Health Ministry with the assistance of CDSCO has published draft rules to amend Drugs and Cosmetics Rules 1945, regarding compensation to be provided to clinical trial participants in case of trial related injury. Recently, CDSCO has started pre-screening all clinical trial applications to ensure completeness of submission files. A pre-screening documents' check-list has been published on their website for various categories of submissions for both drugs (chemical and biological) and medical devices. In order to further strengthen the scientific review and approval of new drugs/devices, the ministry has appointed 12 New Drug Advisory Committee's (NDAC) and 7 Medical Device Advisory Committee's (MDAC) to advise the CDSCO in making their decisions on approval of new drugs and global clinical trials. While the draft rules regarding compensation to trial participants are under revision to incorporate inputs from all the stakeholders, the expert committees have started reviewing the global clinical trial documents, from mid 2011. CDSCO, after a prescreening, accepts the applications. After an initial technical review, especially of the administrative documents, CDSCO refers the files to relevant advisory committee for their expert opinion. It is expected that the experts have to revert within 6 weeks of time and based on the opinion of the experts CDSCO takes further decision on the approval of studies. When there are no sufficient responses from the experts even after 45 working days or when further clarifications are required by the committee, CDSCO organizes a face-to-face meeting of the committee members and applicant company representation may also be requested.

At present all global clinical trials with new drugs/devices are reviewed by these experts and there has been a mixed opinion on this new system of review among the industry. Although the review by these expert groups is adding highest scientific value and giving confidence to all the stakeholders of clinical research especially the study participants in India, the delays due to long turn-around timelines, inadequate follow-up by authorities, busy schedules of these experts who are mainly drawn from a pool of department heads of premier institutes of India, and mix-ups due to referral to inappropriate committees are a set-back.

CDSCO office is making all the efforts to streamline this process and with the cooperation from experts and industry, the current situation is expected to improve in the coming days. Figure 1 represents the current process of review of clinical trial applications.

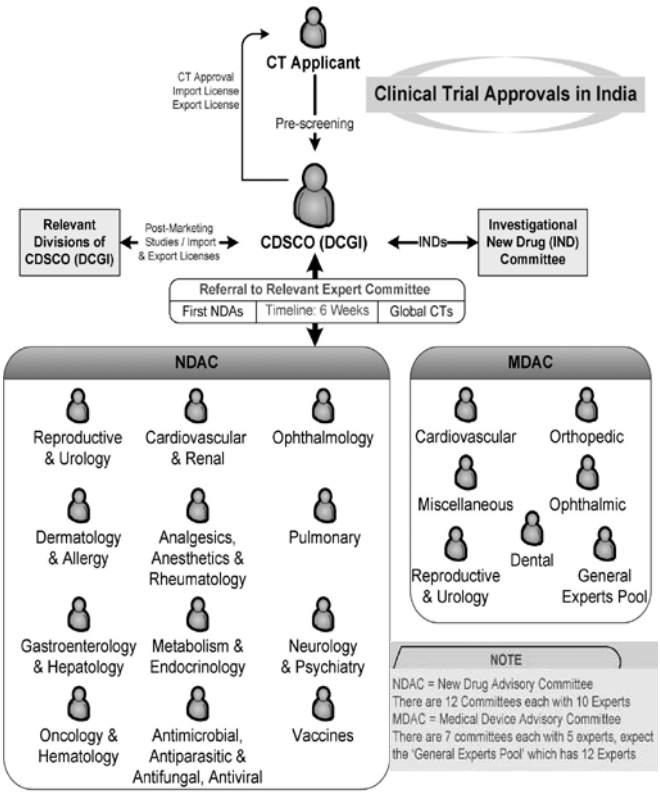

Figure 1: Clinical Trial Approval Process in India

Reference:

http://www.cdsco.nic.in/

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