

Clinical trials in India: pangs of globalization

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Clinical trials in developing countries are exploding. It is estimated that 20-30% of global clinical trial activities are being conducted in developing countries.^[1] The 2002 Indian clinical trials market of \$30-35 million is projected to grow 8-10 times by 2010 to \$ 250-300 million.^[2] The availability of a large drug-naïve patient population and well-trained medical professionals, coupled with sophisticated technological infrastructure have made India an attractive destination for conducting global clinical trials.^{[1],[2]} However, a highly critical article discussed concerns about timelines for regulatory approvals, deficiencies in the functioning of the ethics committees (EC), investigators' unethical approach to the recruitment of subjects and the quality of Indian clinical trials, and concluded that outsourcing clinical trials to India is rash and risky.^[3] Let us briefly review the current scenario for clinical trials.

Regulatory scenario

Regulatory approvals in India can usually take 3 months, which is comparable to most Asian and European countries.^[4] Although the US FDA gives approval in 30 days, most US trials are delayed because suitable subjects are not available in adequate numbers. The timelines for approval are often unpredictable^[4] in India as the Drugs Controller's office depends on external experts and other government agencies such as the Indian Council of Medical Research (ICMR) and the Department of Biotechnology (DBT) for advice and there are additional permissions required for the import of trial samples and export of blood samples to foreign central laboratories. The potential for fast recruitment can partly offset the delay in the regulatory approval. Nevertheless the regulatory situation is a major concern for all pharmaceutical sponsors and Contract Research Organizations (CROs), who continue to press for improvements in the regulatory approval process to make it predictable, accountable and less cumbersome.

The other aspects of regulatory revisions such as adoption of Good Clinical Practices (GCP) guidelines, removal of import duty on clinical trial samples, elimination of restrictions on concurrent trials, anticipated patent law changes have shown India's seriousness about becoming a hub of global clinical trials.^[1]

Functioning of ethics committees

According to a survey conducted by ICMR, ECs are functioning in over 200 institutions. However, there is no accreditation of ECs. Besides, some ECs have an irregular schedule of meetings, lack standard operating procedures, and do not have a composition in line with GCP guidelines. The ICMR has planned to review and audit the functioning of ECs and to introduce a national accreditation system for them. Additionally, the ICMR has also established an independent Forum for Ethics Review Committees, which will organize training programs for the members of ECs. The revised Schedule Y of Drugs and Cosmetic Rules devotes significant attention to the roles and responsibilities of ECs, prescribes the composition of ECs as per the ICMR guidelines and provides formats for the approval letter of ECs. These government initiatives are likely to improve the current situation.

Responsibilities of investigators

In 2002, there were 200-250 GCP trained investigators and 40-50 GCP clinical studies were conducted.^[2] These small numbers imply that many potential clinical investigators do not have the experience of conducting GCP trials. Though this is not considered negative, it does require a major investment in training during study start-up.^[2] For the investigators struggling to balance patient care and research activities, compliance to GCP is an additional new responsibility. In addition, low literacy levels and poverty amongst the patients and the pressure of quick patient recruitment from the sponsors pose significant challenges to an

investigator making efforts to obtain proper informed consent from the patients. The stress on the responsibilities of investigators for the implementation and documentation of the informed consent process in the GCP training programs, and the adverse media publicity to several recent clinical trial mishaps^[5] and subsequent government enquiries have increased the awareness amongst the investigators about ethical and regulatory issues and the need for adequate patient protection.

Quality of clinical trial data

Although, the US FDA has yet to inspect any clinical trials in India, most sponsors and CROs carry out their own audits of clinical trials. Numerous audits in India are a testimony to the level of quality. Data from clinical studies in India have been successfully filed with international regulatory agencies.^[2] Since quality is the hallmark of global acceptance, most sponsors and CROs invest heavily in monitoring, quality control and investigator training. The overall impression is that the data quality is usually excellent.

Conclusions

The evolution of GCP in the West - from the Nuremberg Trials till the development of ICH-GCP guidelines - took almost five decades. India's involvement in global GCP trials is only about a decade old. ICMR's Ethical Guidelines for Biomedical Research on Human Subjects were launched in 2000 and Indian GCP guidelines became available in Dec 2001. The experience of conducting global GCP trials is limited. GCP is a shared responsibility amongst sponsors, investigators, regulators and ethics committees. As all stakeholders are still learning, the journey towards achieving global quality is unlikely to be smooth. The efforts of the government and industry to create awareness through GCP workshops and to provide training to the investigators and ECs will go a long way in creating a culture of global GCP quality trials. Only a sustained will and persistence will help us attain global expectations of quality and speed! Until then, we have to be ready to bear the pangs of globalization!

References

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