Good Clinical Practices: Challenges and the Road Ahead

Clinical trials are emerging as an important activity in India as it is an essential component of the drug discovery and development program to which India is committed. The only robust way to evaluate a new medicine is by doing properly designed clinical trials. This article depicts clinical research scenario in India and historical perspective on Good Clinical Practices, challenges and future of clinical research in India.

India has a robust platform and an equal potential to contribute meaningfully towards the global clinical research and drug development. India presents an attractive platform with a vast population and patient-pool, minimal research costs and quality skill sets in the form of medical practitioners. However, despite the previously targeted growth projections and expansion reports, growth of Indian clinical research has not materialised due to several challenges. The past two decades have seen the rise and fall of clinical trials in India. The Indian clinical trial market grew by 20.3 per cent compound annual growth rate (CAGR) between 2005 and 2010 and decreased by - 14.6 per cent CAGR between 2010 and 2013. The slowdown in the clinical trial market was a result of the unprecedented regulatory framework, slow regulatory approval process, unwarranted and negative media coverage along with activist engagement, lack of awareness in the public and recuperative initiatives.

Indian Clinical Trial Framework

The Indian clinical trial set-up is mainly governed by: (a) regulations of Schedule Y along with rules 122A, 122B, 122D, 122DA, 122DAC and 122E of the Drugs and Cosmetics Act, 1940 (D&C Act); (b) the Ethical Guidelines for Biomedical Research on Human Subjects prescribed by the Indian Council of Medical Research; and (c) the Indian Good Clinical Practice (GCP) guidelines. Per law, it is mandatory that all clinical research that falls under the ambit of Schedule Y complies with the necessary requirements, which inter-alia comprises of formats for clinical trial protocols, informed consent forms, responsibilities of the sponsors, investigators and monitors, templates for independent ethics committee (IEC) approval and format for reporting of serious adverse events. On the other hand, compliance with Indian GCP guidelines are only recommended and does not have a statutory status.

GCP Genesis

GCP is a standard for clinical studies or trials that encompasses the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of the studies. It ensures that the studies are implemented and reported in such a manner that there is public assurance that the data from clinical trials is credible, accurate and that the rights, integrity and confidentiality of the subjects are protected. The guidelines seek to establish two cardinal principles: (i) protection of the rights of human subjects; and (ii) authenticity of biomedical data generated.

The Indian GCP guidelines have been prescribed by the Central Drugs Standard Control Organisation (CDSCO).

The genesis of GCP surfaces from the aftermath of World War II, when the importance of protecting participants in clinical research was recognised and the first code addressing the ethical conduct of biomedical research, the Nuremberg Code, 1947 was released. In fact, the Declaration of Helsinki was developed using principles of the Nuremberg Code and the Declaration of Geneva. GCP is now considered the international ethical and quality "standard for the design, recording, performance, monitoring, auditing, recording, conduct and reporting of clinical trials that involve participation of human subjects." Internationally, the International Conference on Harmonization (ICH) GCP guideline is being revised to keep pace with the scale and complexity of clinical trials. The primary responsibility of maintaining GCP
lies on the sponsors, clinical investigators, ethics committees, institutional review boards, contract research organizations, monitors etc.

**Regulatory Concerns and Changes**

Currently, to conduct a clinical trial in India one needs: (a) permission of the Drugs Controller General, India and permission of the new drug advisory committees consisting of sector experts; (b) approval from ethics committee; and (c) mandatory registration on the ICMR maintained website www.ctri.in.

Following the judgment of the Supreme Court in Swasthya Adhikaar Manch and in response to the 59th report of the Parliamentary Standing Committee, the Indian regulators passed several amendments to Schedule Y of the D&C Act, many of which lead to immediate fall out of pharmaceutical industry sponsored clinical trials. While mandatory registration of clinical research organisations is a clinical trials. While mandatory registration on the ICMR

Differences between ICH-GCP and Indian GCP

Indian GCP is largely based on the ICH-GCP, has certain areas stricter than the ICH-GCP and endorses all the internationally endorsed principles. Certain Indian GCP requirements are more progressive and stringent as compared to those formulated at the international level, for example registration of IEC, clinical trials with the registry and usage of language to encourage participants diverse cultural and economic backgrounds.

**Conclusion**

Good clinical practices are important for quality products, safety of patients and also general good health of the industry. Although, lot needs to be done, with the recent amendments and progressive changes to the conduct of clinical trial process, the government is taking the right steps in promoting and encouraging clinical trials in India. India is primarily known for its generics capability and with the right changes, India has the capability, and can do well, as a drug innovator also.

**References**


4. **Swasthya Adhikar Manch And Anr. v Union of India (UOI) and Others (WP(C)No. 33/2012 with WP(C)No. 79/2012)**


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