Clinical research is an indispensable part of drug discovery and development process. Clinical trials are conducted on human volunteers to assess the safety and efficacy of new drugs, treatments, therapies, surgical procedures and new medical devices before making it publicly available.¹

Most of the drugs that we prescribe to our patients, to treat conditions ranging from a simple cough to a fatal malignancy, are the outcome of painstaking human clinical trials. Without these trials there is no way by which pharmaceutical research can advance to improve disease management and the very quality of life. That is probably the reason why, even though stringent guidelines govern the conduct of clinical trials worldwide, the conduct of clinical research is also looked upon as an area of humanitarian concern. Since 2005, there has been a phenomenal increase in outsourcing of clinical research to India. We have become a preferred destination for conducting clinical trials due to large pool of treatment-naïve patients, highly skilled investigators, excellent technological infrastructure and lower drug development costs.²

India has exploited the potential for clinical research by attracting various international and domestic pharmaceutical companies. The clinical trial market in India has recorded significant growth trends in the recent past. Clinical trials and research is now a major business in India.

Many pharmaceutical companies, based in India as well as MNCs, are currently conducting clinical trials in India which involve many compounds and generics.

The clinical trial market in India looks very lucrative. India has several unique features for being a hot spot for the clinical trial market. There is increased awareness among various health care professional regarding ICHGCP (The International Conference on Harmonization-Good Clinical Practice) guidelines for conduct of clinical trials.³ As a signatory to the World Trade Organization agreements, India is looked upon as a favorable destination for conducting global clinical trials.⁴ ICMR has revised and released comprehensive guidelines that give clear directions to biomedical research in India.⁵ In this situation, the move of the Indian government to encourage clinical trials in India must be viewed with concern.

There are many opportunities and challenges for conducting global clinical trials in India. In a majority of cases, these drugs are aimed at providing answers to unmet medical needs. However, the drug development process requires 10 to 12 years on average to reach the marketing approval. Participation in clinical trials provides an opportunity to experience the benefits of these new drugs. By carefully evaluating the eligibility criteria, a clinical investigator can offer new hope to patients across a wide range of therapeutic areas. Participation in clinical trials also provides research professionals opportunities to offer the best care to patients. A well-designed and executed study has built-in provisions to ensure patient rights and safety.

Further, contract research organizations (CROs) which conduct clinical trials in India have shown the trend lately to shift the focus from big cities to smaller towns. Many CROs are developing the infrastructure for trials by making inroads into small towns, identifying trial sites in small private hospitals and developing databases of potential trial participants.⁶ Changes have been made in the law to permit international trials. Staff and infrastructure improvements and regulatory changes are meant to speed up processing of applications. Monitoring systems are being set up to ensure high data quality and meet the requirements of drug regulatory authorities abroad.

The thing that needs to be remembered is that, our major concern as investigators in clinical trials has to be regarding the rights and safety of the patients. For that we need to plug the loopholes and implement existing laws stringently to ensure that clinical trials are conducted with utmost transparency and diligence. In any way, the participating patients should
not feel that they are being used as experimental tools in
the clinical trial.

Considering that it typically takes 10 to 12 years and
millions of dollars to bring one new drug to market, and
the low success rate, it is very difficult to invest such
time and resources for discovering drugs in the
developing world. However, Participation of Indian
investigators in global trials will motivate the
researchers to develop research protocols for domestic
healthcare issues which will nurture a culture of medical
research of international standards. Being the second
most populated country in the world, India can
contribute significantly to global drug development
programs. Indian investigators and clinical research
professionals have already demonstrated their medical
and scientific skills by participating in multiple global
clinical trials. Let us continue to contribute to the well-
being and welfare of the world.

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