

'Clinical research will play a major role in India's biotech future'

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TERI's microbial biotechnology research area has made rapid strides in micropropagation of useful plant species and development of oil-destroying bacterial strains that clean the environment, while keeping the commercial viability of the end product as the bottom line. It is now focusing on clinical research, mainly for quick detection of pathogenic organisms and gene-sequencing methods. Senior fellow and area convener **Dr Banwari Lal** spoke to **Sudhir Chowdhary** of The Financial Express on the quality of clinical research in India and more. Excerpts:

How is India placed in the area of clinical research?

India is strategically located in the arena of global clinical research and trials. I feel there is an enormous opportunity for growth and development. A large number of international companies are looking at India as a potential centre of knowledge, skill and resource base, to synergise capabilities and create a scenario for clinical research and trials to be conducted here. Home-grown companies are also increasingly building inhouse capacities in this domain.

There are also benefits to be expected from significant funding and investment that will come into the country from overseas.

Don't you feel that Indian biotech firms need to have a global outlook to tap the market for clinical research?

In my opinion, there is a strong case for Indian biotech as well as biopharmaceutical firms to tap the market for global research. The country has a huge qualified manpower and several research institutions. They can be engaged in cutting-edge research, comparable to world standards.

However, what is lacking is the necessary research grant and infrastructural facility for them to harness their potential. If the government and the pharmaceutical industry do not spend money in clinical research, survival in the global market would be tough.

But, what is the present quality of clinical research here?

Due to acute paucity of research grant and inavailability of infrastructural facilities, very few institutions are engaged in world-class clinical research which focus on the commercial viability of the end product.

In India, the research work, unfortunately, is not of international standards. That is because the pharmaceutical industry is not spending enough money in research work.

This, despite the fact that the pharmaceutical industry is one of the fastest growing sectors of the Indian economy and has made rapid strides over the years.

However, in the last few years, several pharma firms have demonstrated that they possess the ability to engage in commercially viable research and development activities and become significant players in the international market.

MNCs are looking for destinations where costs are low and quality meets the regulatory environment. Can India meet these challenges if it has to emerge as a leading player in clinical research?

One of the most important strengths that India has to offer is markedly lower cost and increased benefits at such price points. This reduction on expenditure eases the pressure on total R&D spend and acts as a potential boon to the country.

There is a pool of highly skilled and well-trained doctors, investigators and medical personnel in India.

The country also has a rich resource pool of GCP (good clinical practice) compliant ethics committees and GCP compliant investigators, and moreover, the effort towards greater harmonisation is ongoing.

Any comments on the the Mashelkar committee recommendations on clinical research?

The future era of research would be clinical research and therefore, private entrepreneurs and institutions should invest money to create the infrastructural facility for clinical research. The Mashelkar committee has given the right suggestions so that India can meet the challenges in the patenting era and become a global player in clinical research.

However, it needs to build greater capability and capacity; this would include a sound infrastructure system and a regulatory structure.

Don't you think the quest for clinical research must shift from cost to quality standards?

An important trend to keep in mind is that clinical drug development costs account for over 2/3rd of the total R&D spend, and most companies find it more practical and cost effective to outsource this specialised activity to other agencies. This is where India stands to gain significantly, given its inherent strengths.

Most importantly, the ability to conduct quality research requires the highest level of expertise, and clinical trials are the mechanism for knowledge transfer.

Conduct of clinical trials here would allow for Indian population representation in the total population analysed for the effect of the therapy. Local experience of the drug should be made available to the healthcare community.