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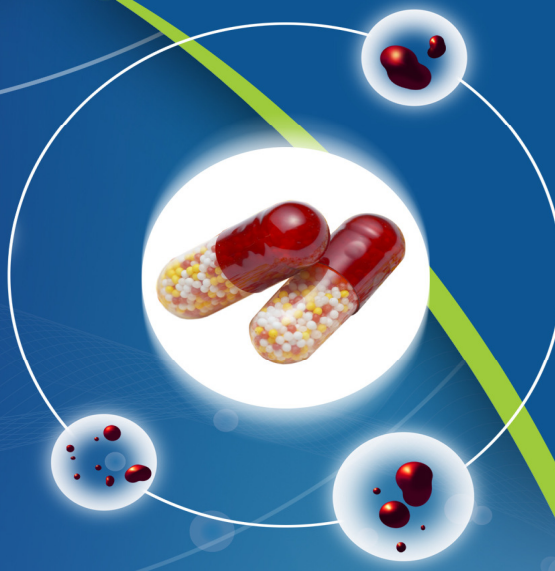

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Short Communication

CLINICAL RESEARCH IN INDIA: SCOPE, OPPORTUNITIES AND CHALLENGES

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ABSTRACT

Indian pharmaceutical industry is one of the fastest growing sectors of the Indian economy and has made rapid strides over the years. From being import dependent in the 1950s, the industry has achieved self-sufficiency and gained global recognition as a producer of low cost, high quality bulk drugs and formulations. Having proved itself in the international market, India is ready to face the challenges of proving its efficiency as the preferred destination for global clinical trials. A number of factors favour India as a clinical research hub. Firstly, there are numerous government funded medical and pharmaceutical institutions with state of the art facilities, which can serve as ideal centers for multi-centered clinical trials. Secondly, India boasts of well-trained and qualified manpower, well versed in English. More importantly, there is vast clinical material, which can be utilised.

Keywords- *Clinical research, Bulk drugs, Clinical trials, Pharmaceutical industry.*

INTRODUCTION

Clinical research is defined as trial conducted on human beings to check the safety and efficacy of new drugs. The pharmaceutical and biotechnological companies are competing for development of new drugs, drug delivery systems, dosage regimen etc. and this is possible only with the help of clinical research.Clinical research is a relatively new concept in India. A decade ago, most of the pharmaceutical companies and the contract research organizations in India performed only clinical operations.

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In the early phase, pharmaceutical professionals had an edge over other clinical research professionals, but slowly the science graduates, medical, and alternate medical professionals entered the industry.

Since then, there has been a significant increase in the number of players in the clinical research industry on India's stage. Global and domestic clinical research organizations (CROs) are now providing a wide spectrum of services at different stages of drug development, creating abundant opportunities not only for medical, pharmaceutical and paramedical professionals, but also for regulatory authorities, government and the society at large [1, 2].

Indian pharmaceutical industry is one of the fastest growing sectors of the Indian economy and has made rapid strides over the years. From being import dependent in the 1950s, the industry has achieved self-sufficiency and

gained global recognition as a producer of low cost, high quality bulk drugs and formulations. Having proved itself in the international market, India is ready to face the challenges of proving its efficiency as the preferred destination for global clinical trials. Moreover, India being a land of diversity where Ayurveda, Unani, Siddha, and Homeopathy are practiced with the same fervour as allopathy, clinical studies for evaluation of various alternate systems of medicine can also be conducted with ease. Owing to this myriad of factors, India is attracting collaborative contract proposals for conducting clinical trials and many entrepreneurs have already come forward to set up their CROs [3].

Irrespective of the fact that a drug has been developed in India or abroad, or whether its clinical studies have already been conducted abroad, every new drug needs evidence from clinical research to support its launch. Similarly, launch of new formulations, drug delivery systems or even new fixed dose combinations, require clinical data before it can be marketed. It is obvious that the area of clinical research holds immense scope and promise, as without the supporting data, drug launches are not feasible. Hence, rather than viewing clinical research as a subsidiary to pre-clinical research, it is important to understand that clinical research has to be conducted even in cases where pre- clinical studies are not warranted [4, 5].

SCOPE

Clinical research holds tremendous scope and opportunities not only for trained medical, pharmaceutical and paramedical professionals, but also for regulatory authorities, government and the society at large. A mechanism of knowledge transfer can be worked out which would lead to a definite improvement in hospital infrastructure. It will make the state-of-the-art therapy available for many deserving Indian patients who were hitherto deprived of such therapeutic advances. Consequently, the projected figures for the various aspects of clinical research (marketvalue, revenue, staff requirement) for the next five years, promise a growth at a rate greater than 20 percent [6].

India has emerged as a global hub for clinical research. According to a report by McKinsey, the global clinical trial outsourcing opportunity in India in the pharmaceutical industry is estimated to be around $2 billion by 2010, and there will be the demand for more than 10,000 investigators trained in good clinical practice (GCP), and 50,000 clinical research professionals. Analysts project that by 2008, an estimated 30 per cent of global clinical trials are being undertaken in developing countries. In India alone, the clinical trials market of $300 million is expected to grow to nearly $2 billion by 2012. With increased outsourcing from the US and Europe to India, global pharmaceutical companies and Indian entrepreneurs have set up contract research CROs in India. They are attracting highly competent professionals, both in the clinical research profession and the knowledge process outsourcing sector [7].

In terms of the cost efficiency, India is a better bet as the cost of conducting a trial here is lower by 50 to 60 per cent than in the United States or the European Union. More importantly, because of the huge patient load, the recruitment rate can be greatly accelerated which in turn leads to shorter study duration. This provides a major advantage in terms of shortening the time to launch a new drug in the market. Based on these advantages, the number of clinical trials in India is expected to grow exponentially over the next five to ten years [8].

OPPORTUNITIES

India is hub of clinical research and this is possible by following factors:

***Low cost*:**

Research and Development (R & D) costs are low in India and cost of conducting clinical trials for new drugs, new formulations and novel drug delivery system is lower by 50 to 75% in India than in developed countries like United states or European union. Where the cost of conducting trials is $ 300 to $ 350 million abroad, in India it costs about 100 crore only. That's why,

multinational companies (MNCs) choose India for cost-effective studies.

***Government aid*:**

In India, there are numerous government funded medical and pharmaceutical institutions with high technical facilities, which serve as ideal centers for clinical trials.

***Manpower*:**

India is rapidly growing health care sector, has sufficient and well qualified medical community and qualified manpower like trained doctors, nurses and technical personnel etc. which makes India a preferred destination for research activities.

***Easy Access*:**

Availability and accessibility of population for clinical studies in India is not a big deal and also there are variations in genetic pool of population.

***Job opportunities*:**

As the clinical projects will be expanded, there will be demand for qualified personnel for site monitoring, site management, clinical data management, data analysis, report submission, presentation and publication etc. This will provide better job opportunities for pharmacists and clinicians in India.

***Infrastructure*:**

India is having world class medical hospitals, which are equipped with advanced technologies, strong information technology infrastructure make it a hub for clinical trials [9].

CHALLENGES

No doubt that India is favorite destination for pharmaceutical companies for conducting trials, but opportunities and challenges are like two sides of a coin. If there are so many opportunities, side by side, there are so many challenges faced for expansion of clinical research market. These are as follows:

Ehtical issues:

Ethical committee plays an important role from design of clinical study. Ethics should be followed during the whole process of clinical trials. During the study process it may be possible that people participating in research may face abuse and harm. Protecting human life is the first priority of health care team. But following all these ethical factors is itself a challenging task and there are chances of non-compliance of rules.

***Regulatory hurdles*:**

The regulatory requirements vary from country to country and no doubt India is country of hurdles with many regulations. For Phase I study, where western countries take 30 days for approval, in India it takes 90 days.

***Training for Clinical Trials*:**

Most medical schools lack a formal course in training for clinical research, and investigators have relied on mentors to learn how to conduct clinical trials. There is a shortage of trained manpower. India has about 500–1000 investigators in the country, as compared to 50,000 in the United States. With the projections made for the industry in 2010, India would need about ten times its present number of investigators.

***Good Clinical Practices (GCP)*:**

The experience of conducting global GCP trials is limited. GCP is a shared responsibility amongst sponsors, investigators, regulators and ethics committees. In a country, which boasts a large medical fraternity, only 400-500 investigator sites have taken part in global GCP trials. 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 ethics committees (ECs) go a long way towards creating a culture of global GCP quality trials.

***Ethical Recruitment of Participants*:**

To protect the interests of the study participants, a written informed consent is usually required

before recruitment. Low literacy levels and poverty in India, when added to the pressure from the sponsors for early completion of patient enrolment, do at times lead to unethical recruitment. An increase in literacy and socio-economic levels is expected to expand the awareness of patients regarding the consent they give for clinical trial studies. The GCP guidelines stress the need for the implementation and documentation of the informed consent process. A strict adherence to the study protocol by investigators and study team members at the sites, as emphasised by the GCP guidelines, will help protect the rights of the study participants [10].

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