JOURNAL OF CLINICAL AND DIAGNOSTIC RESEARCH

How to cite this article:
GHOSH RK , CHAWLA S , GHOSH SM .THE PROMISING FUTURE OF CLINICAL TRIALS IN INDIA- NEW CAREER OPPORTUNITIES FOR DOCTORS. Journal of Clinical and Diagnostic Research [serial online] 2010 February [cited: 2010 February 1]; 3:2144-2146.

Available from
http://www.jcdr.net/back_issues.asp?issn=0973-709x&year=2010 &month= February &volume=4&issue=1&page=2144-2146 &id=552

POSTGRADUATE RESEARCH

The Promising Future Of Clinical Trials In India- New Career Opportunities For Doctors

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Key Words: Clinical Trial. Job Opportunities, Indian Doctors

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Clinical research refers to the entire biography of a drug from its inception in the lab to its introduction to the consumer market and beyond. The entire process of the development of an experimental drug takes about 10 – 15 years and costs approx $802mn - US$1.2bn, with nearly half of the cost being spent on clinical trials (Phase I-IV) [1],[2]. The delay in bringing the drug to the market by each day costs approximately $ 1 million [1]. It is becoming increasingly difficult to conduct clinical trials in Western countries for new drugs due to difficulties in patient recruitment, mainly because of their strict regulations, elaborate safety requirements and small populations [3]. India's ability to offer end-to-end services in clinical research covering trials, data management, biostatistics and central laboratory services, makes it a preferred destination for the conduct of trials and research [Table/Fig1][1],[4],[5],[6],[7]. According to the consultancy firm KPMG, the cost of developing a drug and filing an NDA (New Drug Application) in India is one tenth of that in the US [8]. The cost of

conduct of phase I and phase II clinical trials in India is cheaper by 50% and 60%, respectively [9].

(Table/Fig 1) Reasons for India emerging as preferred destination for clinical research [1,4-7]

- Huge genetically diverse population base (15% of total world population)
- Indians react differently to drugs as compared to Caucasians
- Diverse pool of diseases of both developing and developed country
- 40 million asthmatics, 34 million diabetics, 8-10 million HIV+,3 million cancer patients
- Large patient population is treatment naïve
- Wide spread self medication with CAM helps in better understanding of drug-drug and drug- food interaction
- Fewer competitor trials as compared to North America and Europe
- Opportunity to penetrate one of the fastest growing pharmaceutical markets in the world
- Quicker enrolment of patient volunteer
- Supportive Government policies and improved regulatory environment (amended schedule Y)
- Highly affordable cost of running business
- IPR protection (2005 drug product patent law)
- State of art hospitals and laboratories in metro cities
- Large number of qualified doctors who are familiar with healthcare system in UK and US
- Information technology superpower (efficient data entry, data management)
- English is a primary language of education and communication among Indians

CAM- Complementary and alternative medicine
IPR- Intellectual Property Right

India has emerged as the third most attractive destination for the conduct of clinical trials in the AT Kearney global survey after US and China [10]. The Boston Consulting Group estimated that the contract manufacturing market for global companies in India would touch US$ 900 million by 2010 [8]. As per the Mckinsey report, the clinical trial industry in India is poised to touch $1.5 bn in two years [11]. Pharmaceutical companies are saving a substantial amount of their revenues by outsourcing major trial related activities to India.

Nearly all major pharmaceutical/biotech companies and contract research organisations are establishing their presence in India**.**

One of the biggest hurdles before the Indian clinical research industry is the lack of trained professional manpower [12],[13],[14],[15]. As per a McKinsey report, by 2012, the Indian pharmaceutical industry size is expected touch $2 billion and during the same time, the requirement for professionals manpower would grow up to approximately 50,000 [12]. Presently, only 10,000 skilled and experienced clinical research associates (CRAs) are available in India [12]. There are no government run institutes offering training in clinical research in India, while those offered by private institutes do not have a formal Indian University accreditation [16]. As more clinical research work pours into India, trained and enterprise-ready resources will be increasingly sought after. Rapid expansion of many CROs and pharma companies and intense competition is giving way to unhealthy practices of poaching trained and experienced talent [17]. Since clinical research is still very nascent in India, most medical and life science graduates are still not aware of careers and growth paths in this field.

Clinical research holds tremendous scope and promising career options before Indian doctors. Career in clinical research can offer international opportunities, higher job satisfaction, attractive remuneration and a wider job horizon. The most prominent role of a doctor in the clinical research industry is that of principal investigator (PI). The PI is responsible for the proper and ethical conduct of a trial at a study site [5]. By becoming an investigator, a clinician is benefited in many ways [Table/Fig 2] [7],[18]. As of today, only a handful doctors in India are trained and experienced in good clinical practice (GCP) and in conducting international standard clinical trials [7]. Quality control, huge data generation and maintaining data integrity are other important aspects of clinical research, which require trained manpower to accomplish them. There is a huge requirement of doctors and pharmacy graduates in various capacities in a CRO or at trial site, for managing trial related activities [Table/Fig 3] [19],[20],[21].

The world's perception about the Indian clinical research industry requires a change in outlook from being a '*low cost'* to a *'high value'* destination. One of the ways of meeting this enormous challenge could be by producing a large number of trained clinical research professionals through collaborative efforts between the industry, academia and the government.

(Table/Fig 2) Advantages of clinicians who become investigators in clinical trials

- Training in the internationally accepted Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) guidelines
- Firsthand experience with the most recent drugs
- Working on the same platform with renowned international experts
- Have access to the latest medicines for their patients
- Publications
- Attractive remuneration

(Table/Fig 3) Career opportunities of doctors in clinical research industry

- Principal investigators
- Co- investigators
- Clinical site monitors
- Clinical research coordinators
- Regulatory affairs personnel
- Quality control personnel
- Bio statistician
- pharmacovigilance expert
- Clinical data manager
- Medical writing expert

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