Current Trends in Clinical Research: Indian Perspective

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**Previous Article Reference:** http://www.webmedcentral.com/article_view/2856
**Article ID:** WMC002996
**Article Type:** Clinical Trials
**Submitted on:** 11-Mar-2012, 06:06:30 AM GMT  **Published on:** 11-Mar-2012, 04:35:32 PM GMT
**Article URL:** http://www.webmedcentral.com/article_view/2996
**Subject Categories:** CLINICAL TRIALS
**Keywords:** Current Trends, Clinical Research, Indian Perspective

**How to cite the article:** Karmarkar A B. Current Trends in Clinical Research: Indian Perspective . WebmedCentral CLINICAL TRIALS 2012;3(3):WMC002996

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Abstract

Clinical research is booming sector in healthcare industry of India. Increase in development due to improved education systems and infrastructure as well as information technology sector driving India towards a hub of clinical research industry. Many new companies are starting their operations in India where as new contract research organizations from Indian origin are also opening. New trials on products such as nanotechnology based products, stem cells, biotech products are also coming to India. Governmental regulations regarding clinical research are getting more stringent but this will cause approval process streamlined. Growth of Indian clinical industry will continued ahead in next year and decades also.

Introduction

The new wave of 21st century has brought many upcoming fields in healthcare industry. Clinical Research industry with joining hands with IT industry is becoming largest profit making industry around the world. It is the only industry that has survived in the recent global meltdown. This is evident from the business of $ 250 – 300 billions in the year 2009.¹ Driving force behind this is might be human quest for gaining new knowledge and frustration due to gap in our existing knowledge.

Global Scenario

Over the years the cost of inventing new drugs (NCEs) or biological is increasing due to global inflation and this is increased from $ 802 million in 2003 to $ ~1.2 billion in 2010.² Due to this high cost incurred the companies around the world are focusing more on development of existing drugs with new dosage forms. Norman Goldfarb conducted a quarterly review of clinical research industry in May 2011.³ According to his research the industry is healthier than it was in the first quarter of 2010. This might be due to the steps taken by leading economies around the globe to reduce inflation and to improve the economic status. But the first quarter of the industry might not be of full relevance unless you have all the details of remaining quarters. This statement will be of great value because of the phenomenon of reducing the USA economic rating from AAA to AA+. This can cause the set back to US based healthcare companies leading to reducing drug development research and hence clinical research ultimately.⁴ This situation is same around the many countries in the world. European countries such as Belgium and Bulgaria which conduct pediatric clinical trials especially are also facing regression.

Off shoring Clinical Trials – Indian perspective

Indian FDA and CTRI (Clinical Trials Registry of India) reported dramatic increase in multicentre, multinational clinical trials in India. This is in accordance with current trend of off-shore outsourcing of clinical trials from North America to Eastern Europe, China and India. India offers a promising solution to clinical industry due to its established pharmaceutical and biotech industries environment, contract research, R&D alliances, clinical trials, R&D for neglected diseases, in – licensing of pre-clinical as well as clinical drug molecules, strong IT workforce and data management, and its herbal heritage. Low cost of innovation and development, skilled manpower, large patient pool offers advantage to clinical companies. In the year 2011, however Indian clinical industry is facing slight lag phase. It might be due to various possible reasons. India is in the transition state per se. Regulatory approvals in India are taking around 6- 9 months now a days where as in US it takes 30 days. This is due to bureaucracy in the Indian politics. The outcome of which is Indian largest CRO Siro ClinPharm is opening their site and offices at Malaysia and third world countries such as Philippines, Indonesia, etc. Also in India, only those drugs that have already passed Phase 1 safety trials in the country of their origin can be tested on Indians. This policy also interfere the Indian Clinical industry growth.

The things are getting complicated but after few years the process of approvals and regulations will be streamlined. Despite this case India still has 120 CRO (Contract Research Organizations) focusing clinical studies and 1500 approved sites. This situation will change soon as government is taking these issues seriously by making process streamlined and devising new regulations and provisions.

Technical and scientific trends
From the regulatory point of view, conducting clinical trials now requires lots of approvals. The situation is getting more complex. Thus it is now more difficult for a clinical researcher to adhere all regulations and guidelines. Same is the case with finding and enrolling the subjects in trials. Central Drug Standards Control Organization (CDSCO) has released new draft guidance on approval of clinical trials on 24th July, 2011. Prior to that CDSCO has approved a guideline on clinical trials inspection. Thus regulations in India are also becoming tougher and tight in order to have clinical research according to bioethics principles.

New technologies on which research is going on include protein chips, transgenic animals, stem cells, medical devices, bioinformatics, chemoinformatics, in silico experimentations, functional genomics, molecular modeling, pharmacogenomics, protein modeling and proteomics, etc. Impact of which is shift in R&D view from clinical definition of disease diagnosis to molecular definition of disease diagnosis and predisposition.

Therefore to cope up with current competition of drug development and healthcare market, multinationals have devised new plans. For example, Novartis, a world leader in pharmaceutical market has announced “critical path” method for drug development that consist of scientific tools and test that will determine how safe and effective will be drug product is. This model can save costs, streamline clinical trial process thus minimizes risk in specific patient population.

Similar initiative called Innovative Medicine Initiative (IMI) has been devised that will be joint venture of public and private collaborations.

**Miscellaneous issues**

Apart from scientific innovations trends can be stated as the central lab requirements getting complex; sponsors demanding more predictability, accountability, transparency and integration from vendors; sponsors are working more closely with institutional review boards (IRBs); adoption of new software like SAS, SPSS, STATA for data processing is increasing; studies are becoming more focused; personalized medication trials increasing in case of oncology; biosimilar trials and observational studies showing increase; more CROs entering Phase I trials; preclinical research is getting hike, etc.

**Conclusion**

Despite of global meltdown and economic crisis the financial results seem to be encouraging. New inventions and regulations are creating complexities but we will soon get the fruits of it. India is in the transforming phase of preparation of guidelines and rules for clinical research. This will take some time to streamline the clinical research process. New destinations such as Latin America, Africa, Indonesia, Malaysia and Philippines have been emerging as a hub of clinical research. Industry is still moving with hope and will be able to progress with continuing challenges.

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