

Benefits of Conducting Clinical Trials in Developing Countries like India

Nishant Singh*

Department of Clinical Research, SRL Diagnostics, Kolkata, India

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Short Communication

Clinical trials are research studies which are done to know the efficacy, therapeutic use, safety and adverse effect of any drug [1]. These sophisticated experiments are done on human or animals to answer a lot of specific questions like biomedical aspects of drugs like its efficacy in treatment, prevention, mitigation and cure of a disease with proper knowledge of its adverse effects, therapeutic effect. Clinical trials provide very vital information about the safety and efficacy of drugs. It is done once it gets prior permission from the concerned health authority/ethics committee of that state or nation. Depending upon product size and developmental stage investigators enroll volunteer or patients into small pilot studies and subsequently conduct progressively larger scale comparative studies. Most conducted in developed nations as the cost of clinical trials is too high. Cost of performing clinical trials varies from million dollars to billions of dollars per drug which got approval. But it is a fact that only less than 9 percent of all drugs started in human clinical trial gets approval and termed as approved drugs. The sponsor may be governmental organization, Multinational Pharma Company, Biotech Company or Medical Device Manufacturing Company. The credit for conducting the first modern clinical trial goes to Ronald A. It is estimated that 20-30 % of global clinical trial activities are conducted in developing countries. In India regulation of clinical trials is controlled by the Central Drugs Standard Control Organization (CDSCO), through the Drug Controller General (DCG) which operates under Ministry of Health and Family Welfare (MoH and FW). The importance of drug trials in promoting health services cannot be overemphasized. New drugs and therapies can improve the quality and lifespan of patients. While it is imperative that the number of clinical trials increase, the Government is also trying to ensure that the rights and safety of the subjects are protected and the quality of the trials performed in India improve to international standards. The regulatory guidelines in terms of serious adverse events (SAEs) reporting, informed consent, compensation in case of injury or death in clinical trials have been recently modified. It is essential that now all clinical trials conducted in India should as per the International conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP) for clinical trials and follow the recently amended Schedule Y of the Drugs and Cosmetics Act [2].

Clinical trials in India are divided into two categories

1. Type A trials: Trials for which study protocol has been approved by an authorized regulatory body in one or more developed countries like USA, Canada, UK, Switzerland, Australia, Germany and amongst several others. Such trials are approved by using a fast-track mechanism within 2-6 weeks after required documents are filed with the DGCI.

2. Type B trials: All those trials which fall outside the type A category. The DGCI takes 8 to 12 weeks to give approval for these trials. Ethical and Legal concerns in performing clinical trials in developing countries like India:

Indian Council of Medical Research (ICMR) is responsible for coordination, formulation and promotion of biomedical research in India. In 2000 it issued a Policy Statement "Ethical Guidelines for

Biomedical Research on Human Subjects" ("Ethical Guidelines") in terms of which all clinical trials in India must be conducted in compliance with the Ethical Guidelines as in the last five years from 2010-15 more than 2500 people died in clinical trials in India. This led to hue and cry that humans are not guinea pigs. The current clinical trial in India is dominated by multinational companies, although the volume of clinical trials conducted is low. Based on the current clinical trials pipeline, Boehringer Ingelheim was ranked first, closely followed by Novo Nordisk, Novartis, Eli Lilly and Astra Zeneca in the top five. Increasing incidence of many diseases including diabetes, cancer and other diseases have made these indications a focus of clinical trials.

Phases of clinical trials: There are four phases of clinical trial [3]. Phase first has its own objective to find out the maximum tolerated dose of the drug and around 10 subjects are chosen for this purpose. Phase two (Therapeutic exploratory trial) is the dose determination phase and a short data of effectiveness is obtained and around 100 subjects are chosen. Phase three (Therapeutic confirmatory trial) is the phase population of various age group and for this purpose around thousand subjects are chosen. Phase four (Post marketing trial) is the last and final step of any clinical trial study also known as post market study which is performed after the drug comes in the market. This post marketing trials provides very vital information about the drug, its effects and regarding improvement of the drug for making it more efficient. Trial design: Phase 2 and 3 are designed as randomized, double-blind and placebo controlled. Randomized: Each subject in which study is to be done is randomly assigned to receive either placebo drugs or the study treatment. Blind: The subjects are unaware about what treatment they are receiving and if the study is double-blind, the researchers are also unaware about what treatments the subjects are receiving Placebo Control: The use of Placebo (fake treatment) allows the researchers to isolate the effect of the study treatment for the determination of safety and efficacy in different ethnic groups.

Why clinical trials are needed

- To check if a new drug or device is safe and effective [4-6].
- To compare existing treatments and determine which is better.
- To study different ways to use already existing treatments to make them more effective and easier to use, and/or to decrease side effects.
- To learn how best to use a treatment in a different population, such as patients in whom the treatment was not tested previously.

*Corresponding author: Nishant Singh, Department of Clinical Research, SRL Diagnostics, Kolkata, India, E-mail: nishantsingh311@rediffmail.com

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Advantages of Emerging Countries like India for Conducting Clinical Trials

- India is a country having diverse patient pool holds good business potential.
- Clinical research is emerging as a big business opportunity in India.
- Cost effectiveness clinical trial for one drug in US cost 1 billion \$ while in India it cost less than 40 Million \$.
- India is having advantage over other countries as availability of large number of patients, highly educated, English speaking and skilled medical professionals, state of the art hospitals, presence of strong and reliable information of Information Technology (IT Support).

- Availability of certified laboratories.
- Sizeable population of treatment-naive patients.

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