THE PHARMA RESEARCH

An International Journal of Pharmacy Research

Published on: 15-12-2013 **ISSN: 0975-8216**

IC Value: 4.54

Impact Factor: 0.591*

CURRENT CHALLENGES IN CLINICAL TRIALs IN INDIA

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ABSTRACT

Clinical trials are the studies in which the new drugs or devices are tested on people volunteers. Doctors use clinical trials to learn whether a new treatment works and is safe for people. Now a days India is a first choice for clinical studies for most of the multinational companies because India has dense population, poor regulation, illiteracy and economically less expensive as compare to other country. 5% of the clinical trials conducted across the world will be in India by 2012. Clinical trial in India has become a controversial issue in the last two years by using peoples as volunteers without their knowledge a lot of incidence were held in India because people are illiterate, economically poor and unaware with clinical trials Volunteers must be asked some basic question related to clinical hazards before join a clinical trial and Drugs Controller General of India must give a instruction to all clinical hub in India to asked these question orally or gives in regional language to avoid miss-happening during clinical trials and follow proper guidelines.

Keywords: Clinical trials, volunteers, trial-related deaths

INTRODUCTION

The global clinical trial industry is worth Rs 1,56,800 crore. Clinical trials conducted in India in 2008 were worth Rs 1,345 crore, shows data collected by Ziven Consulting, a Gurgaon-based clinical trial consulting firm. The figure may seem small but is growing at a staggering 65 per cent every year. The trial business is likely to reach Rs 8,951 crores by 2012.Five per cent of the clinical trials conducted across the world will be in India by 2012.

The total cost of research and development (R&D) almost 70 per cent is spent on conducting trials. US spent Rs 2,12,446 crore on R&D in 2008. In the third phase the drug companies spent a whopping Rs

69,022 crore. This calculates to 32.5 per cent of the total amount. Clinical trials are conducted in four phases. It is the third phase which is most expensive. Conducted on 1,000-3,000 patients, it confirms the therapeutic benefits of a new drug. Therefore India, Central Africa, China and Russia is best market for conducting clinical trials.

Why do multinational pharmaceutical companies prefer India as a first choice for clinical studies?

- Lack of regulation related clinical trail
- Economically less expensive as compare to developed countries
- Lack of awareness of peoples (related to clinical trials)
- Phase III needs 1000-3000 volunteers and India is a dense populated country.
- India boasts of well-trained and qualified manpower
- There are numerous government-funded medical and pharmaceutical institutions where clinical trial facilities are available.

India has become a hub of clinical trials for drugs over the last few years, mostly by pharmaceutical companies from abroad. Clinical trial in India has become a controversial issue in the last two years, with a few health activists and politicians claiming that pharma companies and clinical research companies enrolled patients without their consent into trials and used them as guinea pigs in the name of research. Swasthiya Adhikar Munch (SAM) is one of the NGOs that had filed public interest litigation against the health ministry and the drug controller for giving approvals to Following the PIL, the Supreme Court ordered the government to regulate trials. In September 2013, the court stayed the approval of 162 trials and asked the drug controller to provide evidence that proper norms were followed for drug related research. PACR (People for the Advancement of Clinical Research), which claims to be committed to setting the record straight about the importance of clinical research in India, has disputed most of the charges which NGOs like SAM have presented in court. They have also disputed the figures of people who died due to trials.

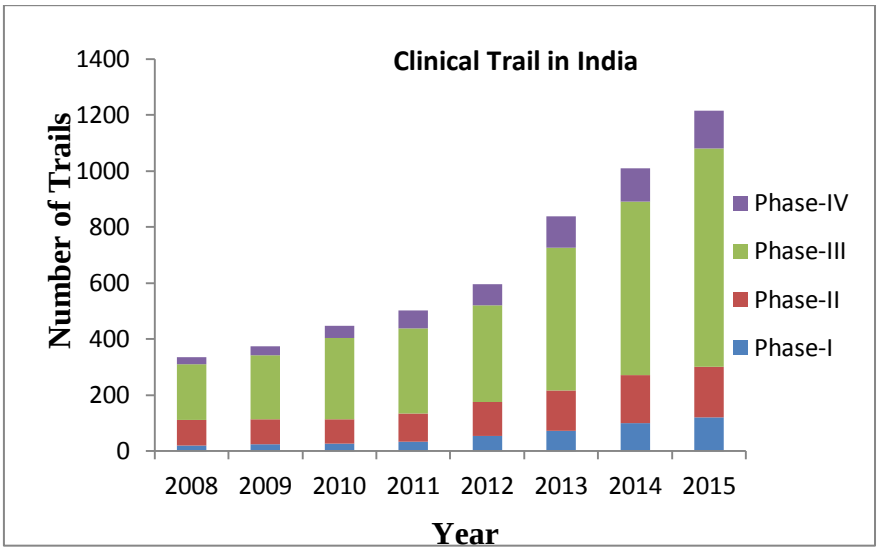

Fig. 1. Graphical representation of year wise clinical trials data

Why people not aware of clinical risk?

- **Because they don't want to read direction manual before signature because it is a lengthy task**
- **Illiteracy of the peoples**

The data that 2,868 people died during clinical trials of 475 new drugs between 2005 and 2012 is very misleading and done purposely so that newspapers sell and websites attract visitors, the petitioners write. They say out of the estimated 451,000 people, who participated in clinical trials between 2005 and 2012, 89 died of trial-related causes.

"No standard protocol was followed; there were no post-mortems; so how can they arrive at this figure?" According to SAM activist, Compensation is paid only if a death was said to have been caused by the clinical trial.

Government documents also say that around 11,972 "serious adverse events" (excluding death) were reported from Jan. 1, 2005 to Jun. 30, 2012, of which 506 were said to have been caused by clinical trials. These figures may be raised in coming years. The Economic Offence Wing of the state government had recorded 36 deaths between 2006-2010 during clinical trials in Madhya Pradesh state alone. Now other populated states also be choice of pharmaceutical companies.

Why peoples want to become a subject in clinical trials?

- **As a hope that they can be treated**
- **Economically poor and they want to earn money**
- **They have no fund for their treatment**
- **They want to parts of novel cause**

The Indian Society for Clinical Research (ISCR) in India, the official lobby group of clinical trial companies and pharma companies in India, has said the petition is encouraging as it comes from the stakeholders. "It is these stakeholder groups who are most impacted by the slowdown in clinical trials as their access to better and more effective treatment is impeded by the current regulatory environment. In the larger interest of patients and our growing disease burden, we need clinical trials to address our country's unmet medical needs"

Volunteers should be asked some basic question before join a clinical trial and Drugs Controller General of India must give a instruction to all clinical hub in India to gives these question in regional language before conducting a clinical trial and must fill a direction manual with given all pros and cons of clinical trials (in regional language) with signature and thumb impression of volunteer. There are different question that people should want to ask before part of clinical trials

What to ask before you join a clinical trial

What is the purpose of the study, and who is sponsoring it?

What were the results in earlier studies of this treatment? How likely are they to apply to me?

How much experience do you have with this particular treatment? with clinical trials in general?

Will I be able to take my regular medications during the trial?

What medical procedures are involved?

What are the risks and benefits of participating?

Will the study researchers work with my doctor while I am in the study?

How long will the study last, and how much of my time will it take?

What do I do if I want to stop participating in the study after it has begun?

What are the possible immediate and long-term side effects?

Will my information be kept confidential?

How could the study treatment affect my daily life?

What kinds of treatments and tests would I need to have in this study? How often are they done?

After asking these questions volunteers must be aware with clinical hazards.

Governed by Schedule ‘Y’ of the Drugs and Cosmetics Act, 1940, clinical trials must be monitored by the Drugs Controller General of India (DCGI) and ethics committees. No trial can begin without the

ethics committee's consent. A body of at least seven members comprising professionals like pharmacologists, lawyers and sociologists, an ethics committee can be institutional or independent. It is this body's responsibility to safeguard the rights, safety and well-being of a trial subject.

CONCLUSION:

Heath care providers, clinical trial sponsors, the media, and the public must maintain open communication to overcome real and perceived barriers to clinical research participation. Government must take corrective action & carefully planned design, implementation, and enrollment strategies contribute to the efficiency and success of clinical research trials for avoiding clinical hazards.

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