**Rheumatology Clinical Trials in India: Past, Present and Future**

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**Abstract**

Clinical trials are essential for new drug discovery. Properly designed clinical trials help in evaluating the new drugs. There has been more than 50% drop in clinical trials after stringent regulations were put in place last year. Now Indian government is contemplating relaxing norms for clinical trials in India.

**Keywords:** Rheumatology, clinical trials, good clinical practice

Clinical trials are important in India, as it is an essential in new drug discovery. The only robust way to evaluate a new medicine is by doing properly designed clinical trials. In addition to advancing science, clinical trials offer myriad benefits to the participants. The recent hue that created in India about clinical trials is probably an exaggeration of facts. However, these points to the need for ensuring proper compliance with the regulatory norms and proper training of concerned personnel in good clinical practice (GCP). This will ensure that India continues to reap the benefits of clinical trials and also become a world leader in this field.

The submission requires (a) the sponsor's undertaking of providing medical treatment and compensation in case of clinical trial related injury/death (b) the sponsor's commitment that they will market the drug in India after the trial is completed (c) submission of regulatory documents for New Drug Advisory Committee (NDAC) (d) changes in the informed consent form (ICF) to include compensation related clauses and (e) changes in the investigator undertaking to include safety reporting and compensation related clauses and (f) submission of the investigator's list containing 50% government sites.

The review of CT application is done by the Central Drugs Standard Control Organizations (CDSCO), New Drug Advisory Committees (NDAC), Technical Committee and Apex Committee. Due to these changes, the regulatory approval takes around 9 months.

The Indian media in general, with the exception of a few domain expert journalists, have failed to comprehend the complexities involved in the clinical trial process. In the run up to the deadline-based coverage of a story, a majority of them fall short in conveying the right perspective to readers, but nevertheless they have been successful in sensationalizing an event in this arena. Possibly by unintended misrepresentation, or mostly out of ignorance of the nuance involved in the clinical trials process, the media has done more harm than good, and got
away with it. On the other side, the industry has been reluctant to engage with the media in a meaningful dialog for too long now. It bears not only the consequences of damage to its professional reputation following such reportage, but also the repercussions of unnecessary clampdowns by the regulators. Science journalism in India has yet to rise as a profession.

Indian government is contemplating relaxing norms for clinical trails in India. There has been more than 50% drop in clinical trials after stringent regulations were put in place last year. Govt. did it to improve transparency, but that should not happen at the cost of innovation. Industry feels that regulations we have made are too difficult. We need to strike a balance, considering the rise in some deadly diseases.

Last year, the Union health ministry made sweeping changes to the rules of the Drugs and Cosmetics Act, 1940, which governs clinical trials following a Supreme Court order. The government made it mandatory for the pharmaceutical company to reveal the contract between the subject and the company to the Drugs Controller-General of India. Companies were obliged to video record the consent given by volunteers. It laid down tough rules to make companies liable for the death of, or injury to, any drug trial subject. Even permission for such trials is given after a rigorous process.

“The less than conducive environment for clinical trials in India is forcing researchers to take their studies to other global regions outside India, resulting in a setback to Indian patients,”

The number of clinical trials intended to be conducted in India fell to 97 in 2013 from 189 a year earlier, data from the U.S. National Institutes of Health showed. This was down from a high of 267 trials in 2010.

Latest update: DCGI started giving new approvals, hoping 2014 is going to be good for clinical trials in India.

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