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Research Article

Impact of new regulations on clinical trials in India

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ABSTRACT

Background: India is one of the major destination for conducting clinical trials. The Drug Controller General of India (DCGI) is the governing body responsible for all pharmaceutical-research and regulatory issues in India. While conducting clinical trials in India, regulations have come to ensure safety and wellbeing of the study subjects in the trial. The present study was planned to see the number of trials approved by DCGI and their trend over the last 8 years in view of new regulatory guidelines.
Methods: Data obtained from website of the Regulatory Authority i.e. Central Drugs Standard Control Organization (CDSCO) regarding DGCI Approval of clinical trials from 2007 till 2014 are noted for analysis.
Results: Total 1799 Trials Approved. 2007 had lowest approvals with 3 clinical trials & 2010 being highest with 500 trial approvals. Mean ± SD Approval of 224.88 ± 172.46 with Median rate of 206 per year was observed. Trend of Trials approved by DCGI shows sharp peak around 2008-2010 which follows sharp fall around 2013.
Conclusion: The present study highlights the impact of these new regulations on Clinical Trials registered for approval of DCGI.

Keywords: Regulations, Approval, DCGI, Drug Controller General of India, Clinical Trial, India

INTRODUCTION

India is an attractive destination for conducting clinical trials. A young, highly educated work-force and a large population concentrated in a few urban centres, high prevalence of all major diseases, and knowledge of English makes it easy to set up clinical trial sites in India.[1,2] India is still relatively new to the scene contributing to only about 1% of all global clinical trials.[3]

As per the revised Schedule 'Y' of the Drugs & Cosmetic Act (2005), "a clinical trial is a systematic study of new drug(s) in human subject to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetics), and/or adverse effects with the objective of determining the safety and/or efficacy of the new drugs". Clinical trial of drugs is a randomised single or double blind controlled study in human participants, designed to evaluate prospectively the safety and effectiveness of new drugs/ new formulations.[4]

The new drug as defined under the Drugs and Cosmetic Rules 1945 (DCR), and subsequent amendments include:

i. A new chemical entity (NCE)

ii. A drug which has been approved for a certain indication, by a certain route, in a certain dosage regimen, but which is now proposed to be used for another indication, by another route, or in another dosage regimen.

iii. A combination of two or more drugs which, although approved individually, are proposed to be combined for the first time in a fixed dose combination (FDC).

Drugs Controller General (India) (DCGI) is equivalent to the US Food and Drug Administration (FDA) and European Medicines Agency (EMEA). The DCGI is the official governing body responsible for all pharmaceutical research and regulatory issues in India described in the Drugs and Cosmetics Rules, 2005 (DCR). Clinical trials are regulated per Schedule Y of the DCR.[4]

It has been observed that due to unethical practices, falsified data, noncompliance of GCP guidelines and conducting clinical trials without DCGI approval were some of the existing discrepancies. There are several reports of exploitation of poor illiterate Indian citizens for clinical trials with increasing reports of trial participant fatalities resulting for the need of strict vigilance and regulations. Conducting trial in India was easier than in North America or Europe. In India, trial participants were exploited because of illiteracy, poverty and unawareness of basic rights of study participants.[5-7] Though, there is a need to promote clinical trials in India, regulations are necessary to ensure safety and wellbeing of the trial subjects through adequate health insurance and compensations. The Central Drugs Standard Control Organization (CDSCO) has taken a noteworthy step by launching online Clinical Trial Registry –India (CTRI) ensuring accountability, transparency and information sharing on clinical trials in the public domain.

Present study was planned to see the number of trials approved by the DCGI and their trend over the years in view of new regulatory guidelines.

METHODS

1) Data obtained from website of regulatory authority i.e. The Central Drugs Standard Control Organization (CDSCO) regarding DGCI Approval of clinical trials.

2) Trials approved by DCGI from 2007 till 2014 were noted for analysis.

3) Trials approved in 2015 were excluded.

4) Microsoft Excel 2013 was used for analysis.

5) Values Expressed as Total, Mean ± SD, Median.

6) Trend expressed as Line Diagram.

RESULTS

Analysis of Trials approved by DCGI shows the following results.

Total 1799 Trials were granted approval.

Clinical Trials Approved by DCGI from 2007 to 2014 are shown in Table 1.

Trials Approved in 2007 were lowest i.e. 3 and highest in 2010 i.e. 500 with Mean ± SD Approval of 224.88 ± 172.46 with Median rate as 206 per Year.

Figure 1 shows the trend of DCGI approved clinical trials over the last 8 years with an initial rising trend peaking in 2010 followed by a sharp fall and decreasing trend.

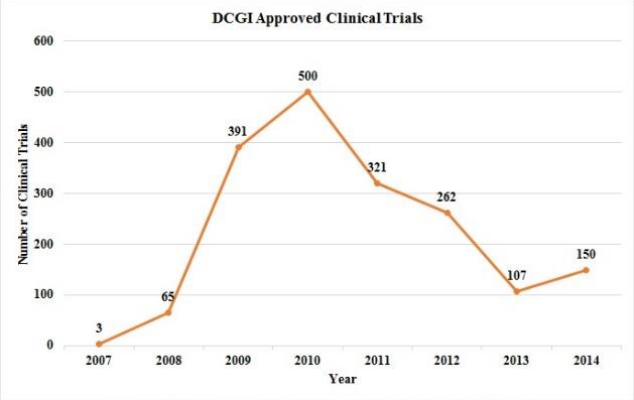

Figure 1: Trend of clinical trial approval in India from 2007 - 2014.

Table 1: Clinical trials approved by Drug Controller General of India (DCGI).

Year	Approved Trials by DCGI
2007	3
2008	65
2009	391
2010	500
2011	321
2012	262
2013	107
2014	150
Total (n)	1799
Mean	224.88
Median	206
Standard Deviation (SD)	172.46

DISCUSSION

The clinical trial market in India is very lucrative and untapped. India promises to be one of the major destinations for global clinical trials, owing to a huge patient pool, easy recruitment of study participants and low cost of clinical trials. The availability of a large drug naive patient population and well-trained medical professionals have made India an attractive destination for conducting global clinical trial.[5]

According to a 2012 study by international consultancy Ernst & Young and the Federation of Indian Chambers of Commerce and Industry, India had a share of 7% of all global Phase III and 3.2% of all global Phase II trials.[6] The market research firm RNCOS had forecasted the

clinical trial outsourcing market in India to grow at an annual growth rate of over 30% during 2010-2012.[7] "Booming Clinical Trials Market in India" also had forecasted the clinical trial market in India to grow at a rate of 31% during 2010-2012. Presently phase III and phase II trials constitute more than 80% of the clinical trials in India.[8,9]

Recent amendments in Schedule Y are initiatives taken for further strengthening of clinical trial regulations to ensure the protection of rights, safety and wellbeing of Clinical Trial subjects generating authentic bio medical data.[10-14]

These regulations can be briefly summarised as:

1) *GSR 53 E; 30th Jan. 2013*: Serious Adverse Event (SAE) Reporting and Compensation for study Related Injury.

2) *GSR 63E; 1st Feb. 2013*: Conditions to be fulfilled by Sponsor to conduct clinical trial in India

3) *DCGI order dated 19th Nov. 2013*: Audio visual Recording of Informed Consent Process.

4) Expert committees have been constituted for examination of Serious Adverse Events other than death related to clinical trials.

5) *GSR 889E; 12th Dec. 2014*: Notification about specific provisions in respect of compensation for ineffectiveness and placebo controlled trials.

6) The National Accreditation Board for Hospitals and Healthcare Providers (NABH) has finalized the report on Accreditation Standards for Clinical Trials for Ethics Committee, Investigator and Clinical Trials.

Our study highlights the impact of these new regulations on the clinical trials done in India justifying the need of these new regulations in keeping unethical practices at bay and ensuring wellbeing of the study participants.

Our study shows the trend of Booming Trials from 2007 i.e. 3 to 2010 i.e. 500 with Mean ± SD Approval of 224.88 ± 172.46 with Median rate as 206 per year showing a sharp decline after 2010 justifying the data obtained from www.clinicaltrials.gov showing that 1.4% of global clinical trials are currently carried out in India.[15]

We hope as more and more researchers accept these norms and follow the Ethical Principles and Good Clinical Research Practices (GCP) there will be more clinical trials done in India in near future.

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