

Trials registered in clinical trials registry of India in 2013: A descriptive study

Kiran A Bhav¹, Sweta B Tondare^{2*}

¹Additional Professor Addl, ²Tutor, Department of Pharmacology, H.B.T. Medical College & Dr R. N. Cooper Hospital, Juhu, Mumbai.

Email: shweta.tondare@gmail.com

Abstract

Aim: To describe the clinical trials registered in Clinical Trials Registry of India (CTRI) in 2013. **Methods:** All clinical trials registered in CTRI in 2013 and that recruitment status is complete were included for this study. The information about these trials were retrieved from the website of CTRI and summarized. **Results:** A total of 370 trials were registered in CTRI in 2013, out of which 96.4% trials are randomized clinical trial and 3.6% are non-randomized. Many (88%) of them were registered retrospectively and 12% were registered prospectively. Fifteen percent of these trials were on paediatric population, 81.6% were involving adults and 3.4% had both adults and children as their participants. Three fourth (75%) of the total registered trials are interventional, 10% are non-interventional, 10% are bioavailability/bioequivalence studies and the rest (2%) are post-marketing studies. **Conclusion:** Three hundred and seventy trials were registered in CTRI in 2013 and most are randomized controlled trials on adults evaluating the efficacy of an intervention. **Key words:** Clinical trials, CTRI, registration.

*Address for Correspondence:

Dr. Sweta Baburao Tondare, Tutor, Department of Pharmacology, H.B.T. Medical College & Dr R. N. Cooper Hospital, Juhu, Mumbai, Maharashtra, INDIA. 400056

Email: shweta.tondare@gmail.com

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INTRODUCTION

With the globalization of clinical trials, Asia, contributing to nearly 60% of the world population, started venturing into clinical research arena.¹ In recent years, registration of clinical trials has progressed from being desirable and voluntary to being essential and mandatory. This is mainly due to the editorial activism of leading medical journals and the vigilance of academic researchers.²⁻⁵ A 2011 letter in the Indian Journal of Medical Research from CTRI noted that many doctors are involved in multiple trials, a particular one was involved in as many as 25 clinical trials.⁶ The Clinical Trials Registry – India (CTRI) (www.ctri.nic.in), an online system for registration of clinical trials, not only establishes an

unbiased, scientific public record of clinical trials but has also ushered in an era of transparency accountability and accessibility of clinical trials being conducted in the country.^{7,8} All clinical trials including BA/BE, PMS, MD theses, AYUSH are being registered in the CTRI. Currently, ongoing and completed trials are also being registered. Trials should be registered either by Principal Investigator (PI) or the Primary Sponsor. Contract Research Organizations may also register a trial. The Clinical Trials Registry encourages the registration of all clinical trials conducted in India before the enrolment of the first participant. “The registry is meant to bring transparency to clinical trials conducted in India.”⁹

The objective of present study was to describe the clinical trials registered in Clinical Trials Registry of India (CTRI) in 2013.

MATERIALS AND METHODS

The descriptive study was done based on an internet search from the clinical trial registry India for total number of clinical trial registered for a period of one year i.e 2013.¹⁰ Since the study was done to find out the status of clinical trials in India registered in CTRI, we chose CTRI as a source of information. We analysed the registries for the total number of clinical trials registered

during the above mentioned period. Trials that had completed recruitment in 2013 were included. All the registries registered were categorized into

1. Study design: whether randomised or nonrandomised clinical trial
2. Type of trial which captures information regarding whether trial observational interventional, post marketing surveillance, BA/Be studies
3. Age wise distribution of clinical trial subjects
4. Registration of trial-prospectively or retrospectively
5. Number of clinical trials done in major diseases.

Data was analyzed by percentages.

RESULTS

The total number of clinical trial registered in CTRI during study period was found to be 370. Of this, 96.4% clinical trials were randomized and 3.6% were non-randomized clinical trials Figure 1. Type of trials: interventional trials registered were 78%, observational 10%, BA/Be studies and PMS were 2% Figure 2. 15 % registries were of pediatrics population 81.6% adults and 3.4 % includes both population Figure 3. 88% trials were registered retrospectively and 12 % prospectively figure 4. Table 1 shows disease wise distribution of clinical trial registries.

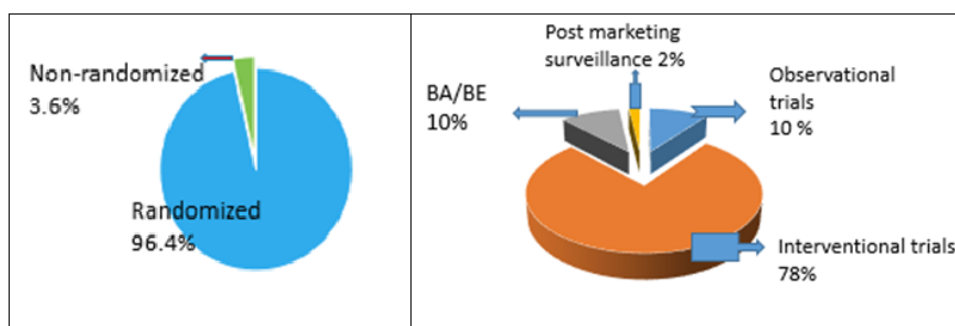


Figure 1

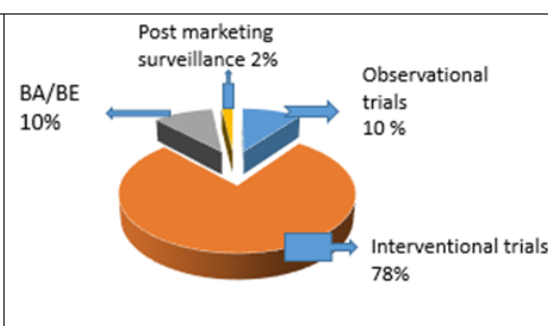


Figure 2

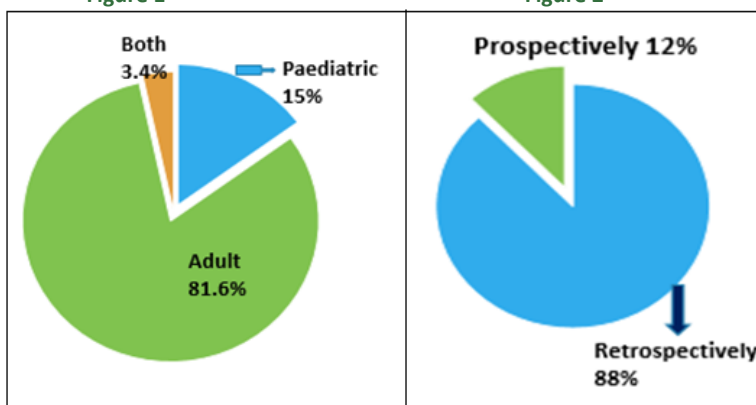


Figure 3

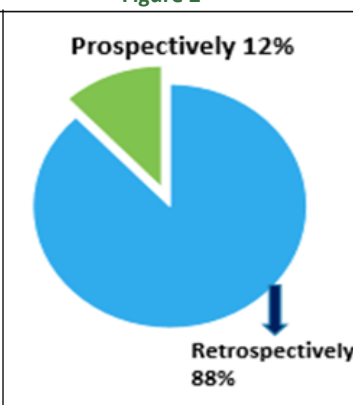


Figure 4

Legend

Figure 1: Study design of clinical trials registered in CTRI in 2013

Figure 2: Type of trials registered in CTRI in 2013

Figure 3: Age wise distribution of trial subjects registered in CTRI 2013

Figure 4: Registration of clinical trial in CTRI in 2013

Table 1: Disease wise distribution of clinical trials

Disease	Clinical Trials (%)
CVS and metabolic diseases	17
Cancer	12.4
Infectious diseases	9.7
Eye diseases	7.4
Respiratory conditions	5.3
CNS	4.2
Others (skin, GIT, Musculoskeletal, anaemia)	44

DISCUSSION

Clinical trials are research tool for increasing medical knowledge and patient care. The number of clinical trials registered in CTRI in 2013 were 370 among which most were on CVS and metabolic diseases, cancer. Out of 370 trials registered most (96.4%) were randomised clinical trial. Three fourths (75%) are interventional trials as currently it is mandatory to register only for interventional trials not observational trials. Yadav *et al*¹¹, found 8.6% trials on paediatric population were registered while in our study it was 15% of this population. Even though there is increase in trials registered in paediatric population over 2 years it is still lower in number. This could mean that there are lesser trials conducted or trials are not registered in this population. Our study showed most of trials (88%) were registered retrospectively while only 12% were prospective. One of the reasons could be lack of awareness among researchers to register clinical trials in the registry. According to Selvarajan *et al*¹ even though there was a 3.7% increase in number of trials registered since 2009 in India, we are still lagging behind developed and other Asian countries like Japan and China in registering clinical trials. To increase awareness and enhance trial registration DCGI made it mandatory for trials requiring DCGI permission to be registered in CTRI prospectively, this should be made applicable to other trials as well. Ethics committee should advocate registration as a precondition to trial approval. 11 major Indian biomedical journals declared that only registered trials would be considered for publication, others journals also should ask for registration before publication. Numerous CTRI workshops and advocacy meetings should be frequently conducted across the country. Even though so many clinical trials have been registered, but there is still no legal obligation to register. Steps are being taken to encourage voluntary registration, including the clinical trials registry workshops to which people likely to be conducting clinical trials – medical colleges, research

institutions, state drug controllers, and nongovernmental organizations – are invited, but for some, such steps are inadequate.

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