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RESEARCH ARTICLE

An audit of clinical trials registered at clinical trial registry of India in 2017

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ABSTRACT

Background: Clinical trial registry of India (CTRI) was launched in 2007. In this audit, we tried to assess the clinical research scenario over last year by looking at the information about clinical studies registered at the CTRI from January 1, 2017, to December 31, 2017. **Aims and Objectives:** We undertook this audit of clinical trials registered at the CTRI. **Materials and Methods:** We accessed the official website of the CTRI, i.e., www.ctri.nic.in, and the required information was collected and descriptive statistics were used. **Results:** We found a total of 3433 studies were registered from January 2017 to December 2017. Majority of the studies were of interventional in nature as compared to observational and bioavailability and bioequivalence studies. Majority of the studies were Phase 3, Phase 2 followed by Phase 4 and Phase 1. **Conclusion:** The clinical research in the country has improved in 2017 as compared to last decade even though decrease in pharmaceutical industry studies. This could be due to increase in research institutes, medical colleges, investigator, and government-funded studies.

KEY WORDS: Clinical Trial Registry of India; Clinical Research; India; Clinical Trial

INTRODUCTION

The clinical research includes academic clinical studies and studies sponsored by pharmaceutical industries in India. Pharmaceutical industries publish data of their studies in various journals through publication and at http://www.clinicaltrials.gov. However, the data of studies done by postgraduate students and investigators are not available if it is not published. Many studies are not published due to insignificant results or negative results. Many of the studies may be stopped due to same results by investigators.[1] Hence, to increase accountability, transparency, and trust, the ICMR's National Institute of Medical Statistics has started the clinical trials registry of India (CTRI). It is an online and free public registry of clinical trials being conducted in India. CTRI was launched on July 20, 2007, on voluntary basis thereafter Drug Controller General of India has made registration of trials mandatory since June 15, 2009.[2] It was of great interest to find out clinical research scenario of last year in India. Hence, we undertook this audit of clinical trials registered at the CTRI from January 1, 2017, to December 31, 2017.

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MATERIALS AND METHODS

This was a retrospective study. We obtained information about registered studies from publicly accessible databases at the website www.ctri.nic.in (last date on January 25, 2018).

The objectives of the study were as follows:

1. To assess the total number of studies registered at the CTRI from January 1, 2017, to December 31, 2017.

2. To assess the month wise distribution of studies
3. To assess different types of clinical trial
4. To evaluate phase wise distribution of studies
5. To assess the state wise distribution of studies
6. To evaluate status of studies.

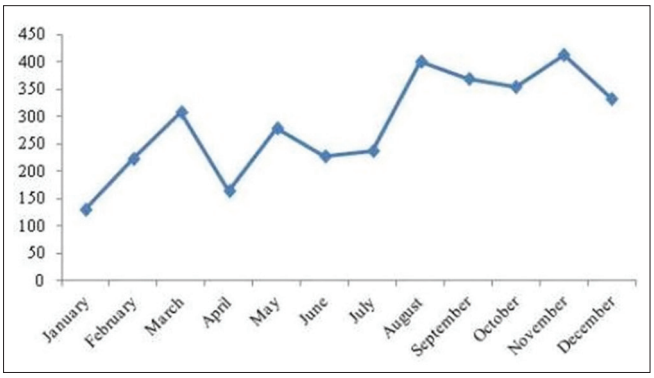

Figure 1: Month wise distribution of studies registered in 2017

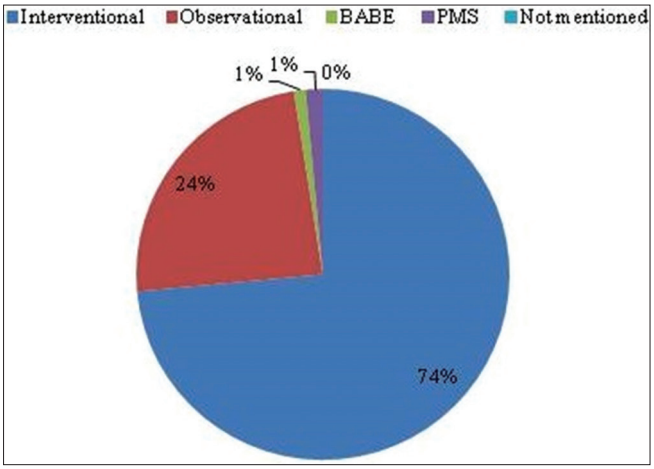

Figure 2: Type of studies

In addition, we also accessed clinicaltrials.gov site to find the number of studies done in India from 2017. The data were analyzed using descriptive statistics.

RESULTS

A total of 3433 studies were registered from January 2017 to December 2017. Figure 1 shows month wise distribution of registered studies in 2017. The highest numbers of studies (412) were registered in November 2017, while the lowest numbers of studies (130) were registered in January [Figure 1].

Of all registered studies, 74% of studies were of interventional type while 24% were of observational type. Bioavailability and bioequivalence (BABE) and postmarketing type of studies were 1% and 1%, respectively, as shown in Figure 2. No, any study was found in which type of study was missing [Figure 2].

There were 22% studies in Phase 3 and Phase 2 followed by Phase 4 (18%) and Phase 1 (9%). Phase 1/2, 2/3, and PMS had the least number of studies [Figure 3].

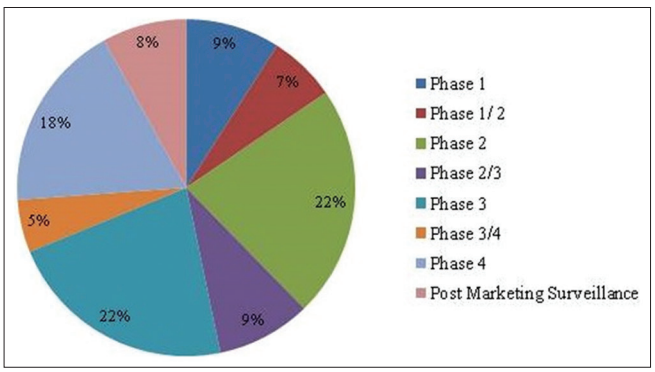

Figure 3: Phase wise distribution of studies

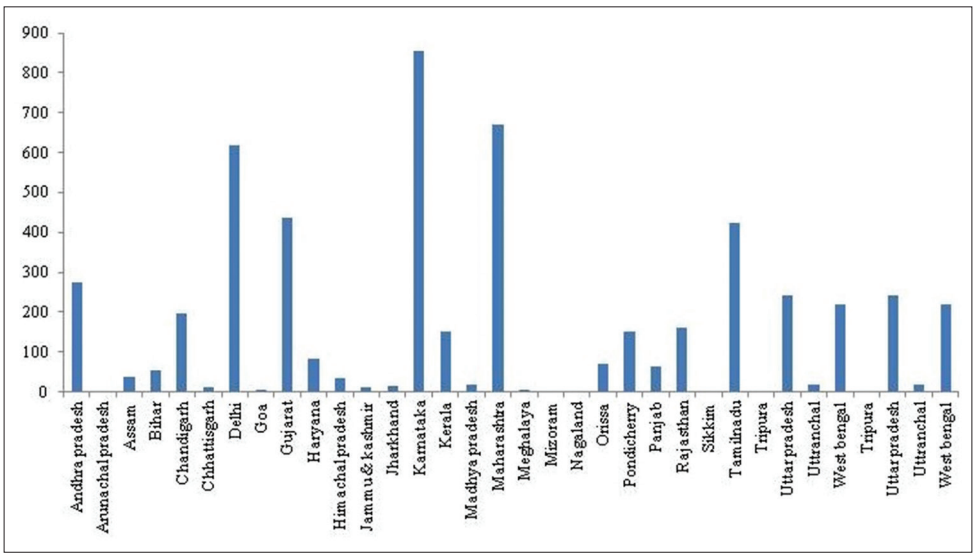

Figure 4: State wise distribution of studies registered in 2017

The studies were being conducted in all the states. Karnataka (854) was topped in the list followed by Maharashtra (671), Delhi (619), Gujarat (437), and Tamil Nadu (423). While states such as Mizoram, Arunachal Pradesh, and Nagaland had only one study site [Figure 4].

The recruitment of participant was not started in 35% of studies while recruitment was started in 34% studies. A total of 26% of studies were completed while one study was suspended. In 5% of studies, participant recruitment was closed while in 0.3% of studies, recruitment was not applicable [Figure 5].

A total of 2729 (80%) studies were trails among 3433 studies. Among those trials, 782 were randomized, parallel group trial followed by 623 of single arm trial. The least were randomized factorial trial which was only 6 [Figure 6].

DISCUSSION

In India, the clinical research is governed by Schedule Y of Drugs and Cosmetics Act 1940, Rules 1945 which was first introduced in 1988. Schedule Y was also amended time to time thereafter.[3,4] The regulatory authority mainly monitors the pharmaceutical industry-sponsored researches. India had large number of population and low-cost availability of researchers which favors the growing industries of clinical research.[5] Goldman Sachs, in 2008, reported that the pharmaceutical industry of India is growing at an annual rate of 11%, and the clinical research industry is growing an annual rate of 84%. The easy availability of study subjects, cost effectivity, and favorable regulatory process is the other complementary factors. Service tax (12%) exemption was another factor favoring the multinational industries to expand their business in India. Due to all these favoring factors, the pharmaceutical industry is growing faster. The clinical trial applications are approved faster for drugs marketed in India.[6] As compared to previous 10 years, the total number of studies registered in 2017 is much higher. This could be due to increase in awareness about registration of studies in CTRI as well as increase in feasible environment for research in India.[7]

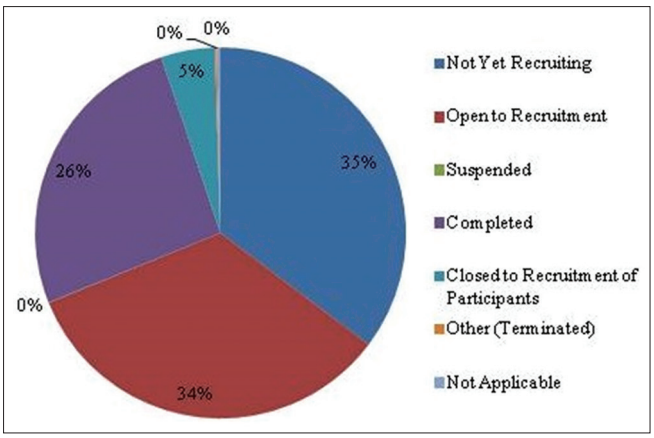

Figure 5: Status of studies

Major sites of studies were Karnataka, Maharashtra, Delhi, and Gujarat while there were few sites from Mizoram, Arunachal Pradesh, and Nagaland. All the clinical studies had ethical approval in place. However, all the ethics committees which approved these studies were not registered with CDSCO. Maharashtra has the highest number of ethics committees registered with CDSCO, but that sites are still lower than the number of sites of Karnataka. States like Mizoram have only one registered ethics committee while Arunachal Pradesh and Nagaland do not have any ethics committees which are registered with CDSCO. This could be possible reason for lower number of sites in these states.

Our study shows that out of all the registered studies, interventional type of studies is in maximum number

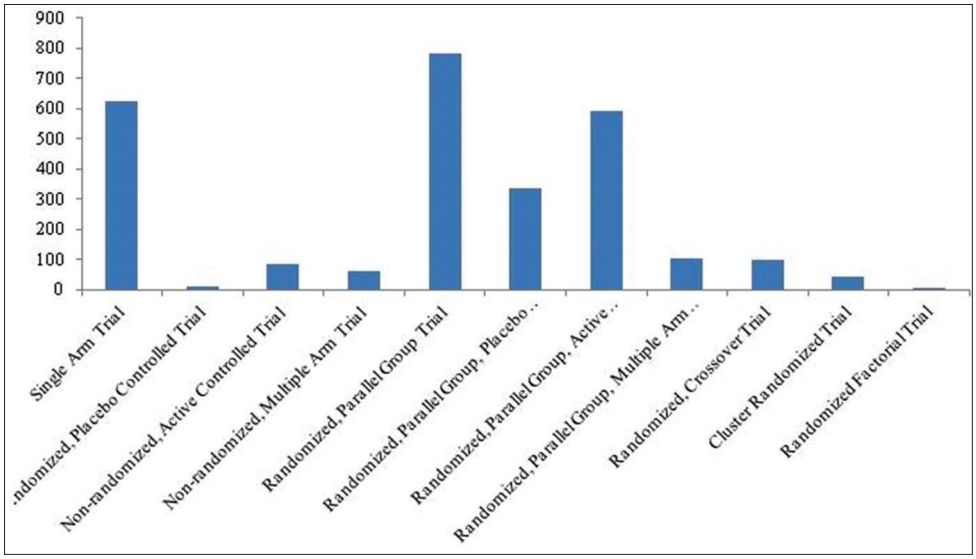

Figure 6: Type of clinical trials

while BABE and postmarketing type of studies are least in numbers. Phase 3 and Phase 2 studies were maximum in number among all registered studies followed by Phase 4 and Phase 1. This could be due to feasible environment for conducting clinical trial. The recruitment of participant was not started in majority of studies because many investigators first register their study in CTRI, then they start recruiting patient. Only one study was suspended. Many investigators did not report when their study was suspended so there may be lower number of study which was suspended.

Clinical trials were highest among all the registered studies which may be due to investigators perception about registration of only clinical in CTRI rather than other types of studies. There are some limitations of our study. We did not evaluate completeness of the study details and therapeutic areas covered. However, it was found that many studies were incomplete. There might be misunderstanding by investigators who must have uploaded the information or might be problems face while collecting the data.

CONCLUSION

The clinical research in the country has improved since last decade even though decrease in pharmaceutical industry studies. This could be due to increase in research institutes, medical colleges, investigator, and government-funded studies.

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