INTRODUCTION

By virtue of its large patient pool and lower cost, India has been considered as an attractive destination for clinical drug trials.\(^1\)\(^2\) Though the growth appeared very much encouraging till 2009, the year 2010 witnessed plateau globally and the same was reflected in India as well.\(^3\) Though the pace of growth in clinical drug trials seems to be halted, the major share of clinical drug trials still is enjoyed by developed world. India and China both hosting one-third of diabetic population of the world have contributed to less than 15% of drug trials in diabetic subjects,\(^3\) suggesting that a huge potential still remains unexplored. Various quantitative and qualitative challenges including lack of trained investigators, trained staff, and need for better compliance with ICH GCP were perceived by various pioneers in the industry.\(^4\) A journalistic investigation on clinical drug trials in India further raised concerns over ethics in clinical research.\(^5\) Delay in regulatory approvals has also been considered as a hurdle, a major hurdle by some investigators.\(^6\) It has been observed that these issues are not typical for India; rather, they are common to all developing countries.\(^7\) Though the drug lag due to delay in regulatory approvals has declined over last decade, it still remains 370 days in BRIC and N11 countries.\(^8\) Recently, a survey among 29
investigators regarding their perception of research ethics in India was published. It would be worth having a relook at the various obstacles in the growth of clinical drug trial industry in India so as to take necessary actions. In order to assess the overall opinion of various stakeholders regarding these issues, an online survey among various professionals involved in the industry regarding some key issues was planned.

MATERIALS AND METHODS

Using Google documents, an online form was created and was made available online. The online form had questions starting with the role of person completing the form, though the identity of person was not asked for. In response to the first question—"Your perception regarding the clinical drug trial industry in India," the respondent could choose one among—"Growing," "Declining," "Plateaued," or "I Don't Know." The respondent was given options of "Yes" or "No" while responding to the question—"Do you think India is utilizing its full potentials in clinical drug trials industry?" In the next four questions, the respondent was asked to rate in the scale of 1-10, 1 being the worst and 10 being the best. On this scale, the respondents were asked to rate—the performance of Investigator sites in India, the performance of Industry (CRO/SMO/Sponsors) in India, the performance of Regulatory in India, and training of various stakeholders in clinical drug trial industry in India. In response to the question—What in your opinion are the hurdles for growth of clinical drug trial industry in India?—the respondents were allowed to choose one or more options among—Lack of trained investigators, Lack of trained staff at sites, Delay in regulatory approvals, Increasing cost of clinical research in India, Lack of patient population, Lack of awareness among general public, Unethical practices, and Others. Respondents were allowed to enter free text if they opt for "Others" in response to above question. Additional option was available to enter free text in response to suggestions to improve the current scenario and any other comments.

The form was made available online and colleagues from connections and groups on LinkedIn were mailed with a link to the form. Additionally, the colleagues were mailed from the personal mail Id of the authors. The responses were received starting from February 28, 2011 and the data were analyzed after a month with responses received till March 27, 2011.

RESULTS

A total of 181 responses were received during the period of one month. Participants largely included clinical research coordinators and clinical research assistants, though other stakeholders including investigators, managers, and directors also participated in the study.

77.3% participants responded that the clinical drug trial industry in India is growing, while 13.8% felt that it is plateaued. 7.7% felt that the industry is declining, while 1.1% responded with the option—"I Don't Know" [Figure 1]. 78.5% participants felt that India is not utilizing its full potential in clinical drug trial industry [Figure 2]. On the scale of 1-10, the mean score in response to questions related to performance of investigator sites, performance of SMO/CRO/Sponsor, performance of regulatory bodies, and overall training of various stakeholders was 5.5, 6.5, 5.0, and 5.6, respectively. Number of respondents with various scores is shown in Figures 3 to 6. In response to the question regarding hurdles for growth of clinical drug trials in India, delay in regulatory approvals appeared to be the major issue, followed by lack of trained investigators, lack of awareness among general public, unethical practices, and lack of trained staff. Lack of patient population or cost of clinical drug trials did not seem to be perceived as hurdle by majority [Figure 7]. A few other hurdles suggested by the respondents...
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were related to functioning of ethics committees, clinician mindset of investigators, high investigator fees, investigators being money driven, ignorance of Indian pharmaceutical companies, and lack of authentic source records. A few other suggestions received were shifting focus from quantity to quality, complete transparency in the system, better organized and academic investigator groups, investigators must allocate sufficient time and be updated with regulatory requirements, publication of studies, focus on investigator-initiated studies, system for displaying blacklisted sites and investigators, substitution of paper work by electronic documentation, awareness among general public with the help of media, and use of properly trained CRCs through SMOs.

DISCUSSION

Though this survey has limitations in terms of its small sample size, it provides a good enough representation of various stakeholders. This survey concludes that the general perception among various stakeholders is that though India is not utilizing its full potential, the industry is growing. It is high time that we all recognize the issues that might limit sponsors from allocating new drug trials to India. There seems to be potential for improvement in terms of training of various stakeholders, while delay in regulatory still appears to be a big hurdle. Most of the respondents seem to have suggested need for change in mindset of investigators.

In order to change the mindset of investigators, we will need to have comprehensive and ongoing training of investigators. Currently, the training is largely limited to attending the investigator's meetings which mainly focus on the particular protocol. Involvement of investigators in societies like Indian Society for Clinical Research (ISCR) and their active participation in various ongoing activities of the society would surely be of great help. Industry ought to focus more on ongoing training of its employees and should also extend it to investigator site team members so as to train them on broader issues like ethics and basics of ICH GCP. Any change in the regulatory system would be possible only at the level of Government of India, but stakeholders like us can surely take efforts in bringing these issues and their repercussions to the notice of concerned authorities.

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