Editorial

Investigator initiatives for academic trials: Dilemmas and difficulties

The strength of a country's medical research capability can be gauzed by the number and quality of academic studies initiated and conducted in that country. Academic studies help bridge the knowledge lacunae between clinical trials and real-world scenarios and are pivotal in repurposing of existing drugs. The population-specific data generated by academic studies can help solve population-specific clinical queries and help in formulating precise guidelines and policies tailored to the specific population.

To bolster the academic clinical trials arena in India, the Central Drugs Standard Control Organization has laid down precise rules and regulations pertaining to definition and conduct of academic clinical trials in "New Drugs and Clinical Trials Rules (NDCT), 2019."

As per NDCT 2019, an Academic clinical trial "means a clinical trial of a drug already approved for a certain claim and initiated by any investigator, academic or research institution for a new indication or new route of administration or new dose or new dosage form, where the results of such a trial are intended to be used only for academic or research purposes and not for seeking approval of the Central Licensing Authority or regulatory authority of any country for marketing or commercial purpose."[1]

Further, the rules state that, academic clinical trials should be conducted in accordance with the ethical principles specified in the National Ethical Guidelines for Biomedical and Health Research involving human participants provided by Indian Council of Medical Research.[2] However, unlike regulatory clinical trials, academic clinical trials require approval only from an ethics committee registered with Department of Health research. In addition, they have the overall responsibility of oversight, monitoring, audit, and compensation for adverse event related to the trial.

The potential challenges of conducting Academic clinical trials as per NDCT 2019 and ICMR Ethical guidelines, 2017, have been expounded in excellent articles by Bhatt and Konwar *et al.*[3,4] Despite the release of NDCT 2019, the current academic clinical trial scenario is India is still in its infancy and lagging behind other developed countries.

To understand the current landscape of academic clinical trials in India, a multicenter study published in this issue of the journal[5] was conducted among 100 academicians from 3 tertiary care centers, located at Mumbai, Maharashtra. The study was conducted in two phases: phase 1 focused on estimating the approximate number of academic clinical trials in India by analyzing academic interventional studies registered in Clinical Trials Registry of India between April 2019 and October 2022, while phase 2 of the study utilized a questionnaire consisting of four domains on knowledge, awareness, practical experience, and potential challenges faced in conduct of academic clinical trials.

The present study was fairly designed with a validated questionnaire and conducted at institutions which are at the forefront of academic research in India. Although the results of the study are encouraging in terms of knowledge and awareness about academic clinical trials, there still exists some ambiguity regarding knowledge on approvals and compensation of academic clinical trials. An intriguing finding of the study is the paradoxical increase in the registration of academic clinical trials during the COVID year of 2020 with a progressive decline in the subsequent 2 years. Alarmingly, despite 89% of the academicians received training specifically on academic clinical trials, only 50% have actually conducted an academic clinical trial in the past 3 years.

One of the major challenges which the investigators reported was related to obtaining approval from ethics committee and funding. Ethics committees have a challenging task of balancing science and ethics as they are the final authority for approval, monitoring, audit, and compensation of academic clinical trial. To add to this complexity, there is still a lot of ambiguity around rules for compensation of academic clinical trials as per ICMR. There is scope for standardization of standard operating procedures of ethics committees regarding oversight, audit, and compensation of academic clinical trials. This highlights the need for accreditation of ethics committees and robust training of ethics committee members to empower them to effectively assess, monitor, and audit the academic clinical trials.

Yet, another challenge for the investigator and ethics committees is regarding industry sponsorship and use for commercial purpose. Despite signing a contract stating that the company will not use the results for commercial purposes, the ethics committees and investigators lack the time, financial, and legal resources necessary to ensure that the outcomes of academic clinical trials are not used for commercial purposes anywhere in the world.

A few limitations, however, exist within this study. First a small and arbitrarily taken sample size from a single geographical center in a vast country like ours, limits the generalizability. Second, because the NDCT rules were released in March 2019 and CTRI registration typically occurs after ethics committee approval but before enrolling the first participant, the studies registered between April 2019 and August 2019 may not accurately reflect how the NDCT rules affected academic studies. Third, the number of academic clinical trials may be confounded, as the authors did not specifically study the funding of studies and CTRI does not yet have a clear demarcation between registration of academic clinical trials and investigator-initiated sponsored clinical trials. For both investigator-initiated studies (IIS) and academic clinical trials, the sponsor is the investigator, yet there is subtle difference in terms of funding and use of results for commercial purpose. Unlike an IIS, which can be used for commercial purpose, the rules are clear that the academic clinical trial results cannot be used for commercial purpose. Finally, the authors could also have studied the mechanism in place by the investigators and their institutes to ensure that academic clinical trials are not used for commercial purpose. It is a humongous task for the investigators and ethics committees to ensure that the results are not used for commercial purpose in any country despite having a legal agreement, especially so in this era of information and technology.

To make scientific progress without commercial interests, it is essential to train academic investigators at an early stage to conceptualize, design, and conduct academic clinical trials. Further, there is imminent need to increase funding and formulate policies at an institute level to manage issues related to medical management and compensation for handling serious adverse event during an academic clinical trial. Perhaps, we as the clinical research community need to evolve our training methods to bridge the gap between training and actual implementation of academic clinical trial.

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