New Drugs and Clinical Trial Rules 2019, What is New? Our Views from Ethical Perspective

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Abstract

A good quality research requires the incorporation of good ethical practices throughout the conduct of the study. An efficient Ethics Committee will facilitate such a research at the site, and can achieve the major objective of ICH-GCP (International Conference on Harmonisation -Good Clinical Practice) guidelines. Awareness of the changing rules among the stakeholders of clinical studies will ensure good clinical practice by safeguarding and protecting the rights, safety and well-being of the research participants. The draft of the New Drugs and Clinical Trials Rules was published in the Gazette of India by central government on March 19, 2019. Keeping abreast of the latest rules are essential for the uninterrupted conduct of clinical studies. We sought to give a summary of important changes in the new rules and to assess those rules from ethical perspective.

Background

Ministry of Health and Family Welfare (MoHFW), Government of India has announced New Drugs and Clinical Trials Rules, 2019, on March 19. New rules have made changes in the roles and responsibilities, functioning of all the stake holders involved in the conduct of the clinical trials.¹ We present here, the critical review of these rules in Ethics Committee (EC) functioning and whether these rules upholds the interest of participants in clinical studies.

What is new?

Ethics Committee for Clinical Trial, Bioavailability And Bioequivalence Study in Chapter III in the gazette mentions about the changes in the EC constitution and training of ethical members. As per the rule atleast 50% of the members should be non-affiliated and all the EC members should undergo timely mandatory training to continue as committee members. This is a welcome move as it empowers non-affiliated members in EC deliberations. The non-affiliated members in the EC are lay person and chairperson exclusively, but it can be any members in the committee like legal expert, social scientist/philosopher/ethicist/theologian, basic medical scientist and clinician. This is important because it facilitates a fairer and unbiased decision making in EC meetings. The increasing pressure from the higher hierarchy and ‘publish or perish’ attitude of many of the institutes/organization may influence the affiliated members to approve studies. Fixing the number of non-affiliated members may balance the discussion in the meetings. The rule also makes it mandatory that every member of EC should have training in Good Clinical Practice (GCP) and participate in the developmental programs timely as specified by the central Licensing authority (CLA). This will certainly update the members with latest changes in the guidelines and provide adequate confidence in decision making.

Ethics Committee for Biomedical and Health Research in Chapter IV mentions about a separate EC for research involving basic, applied, operational or clinical research (Biomedical and health research). The institutes/organization should have a separate EC to be registered under the authority designated by the central government in the Ministry of Health and Family Welfare. It also mentions about the functioning and proceedings of such an EC should be in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. This formation of a separate EC from EC’s involved in new drug or investigational new drug studies, will certainly eases the work load and enhances efficiency of EC functioning.

Clinical Trial, Bioavailability and Bioequivalence Study of New Drugs and Investigational New Drugs in Chapter V gives clarification regarding the conduct of research studies at a site which do not have ethics committee. If the site is not having the ethics committee of its own, the study can still be conducted at such sites after obtaining EC approval from another site, provided that such approving EC shall be responsible for the study at the trial site and it is located within 50 km radius from the clinical trial site. This is a welcome move as it ensures to an extent that the members from local ethic community, who represents the actual population of the region are represented as members and they will be reviewing the studies. This also eases the EC to competently monitor the study at the site regularly.

Another incessant and highly debatable component in any study protocol is compensation. Newer rule in chapter VI emphasize on SAE and its compensation. It has significantly shortened the timeline of lengthy regulatory process involved in SAE. The timeline of independent expert committee to give its recommendation with respect to the cause of SAE and quantum of compensation to Central Licensing Authority is sixty days of receipt of SAE report. Earlier, it was 105 days for death as SAE and there was no clarity on timeline for SAE’s other than death. It has also set the timeline for decision making by Central licensing Authority (CLA). The CLA should pass the order to the sponsor regarding the SAE by 90 days (earlier 150 days) of receipt of SAE report both in case of death or SAE’s other than death. By this way the lengthy process of compensation path is shortened, which to some extent gives respite to the grief-stricken family.

Import or Manufacture of New Drug

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Second schedule in the gazette provides provision for Accelerated approval to a new drug if it is intended for the treatment of a serious or life-threatening condition or disease, where treatment in such cases is not addressed adequately by the available therapy. The efficacy observed in phase II for the investigational new drug may be considered for granting the marketing approval. This will encourage the sponsors to take-up more of such studies and enables early care of such needy patients in serious or life-threatening conditions with promising drugs, without having to wait for long regulatory process.

Conclusion

Overall, the newer rules have made more clearer on the roles and functioning of EC’s and has tried to frame rules carefully without relegating the interests of participants involved in the clinical studies.

References