F. No-DCGI/MISC/2020 (104)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

FDA Bhawan,

Kotla Road, New Delhi

Dated:- 30/3/2020

NOTICE

Subject:-Conduct of clinical trial in present situation due to outbreak of COVID-19-Reg.

Clinical trial of new drug is regulated under the New Drugs and Clinical Trials Rules, 2019. As per the rules, clinical trial is required to be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Trial Practices guidelines and the provisions of the said rules.

In present situation, CDSCO understands that various challenges may arise during conduct of clinical trial in the wake of outbreak of COVID-19 in the country. This may lead to difficulties to maintain complete adherence to the approved protocol, regulatory provisions / procedures and applicable guidelines in respect of various activities involved in conduct of clinical trial including recruitment of trial subjects, laboratory testing, diagnosis, administration of investigational product, reporting of SAEs, scheduled visits, assessment of safety and efficacy parameters, etc. Such impact on conduct of clinical trial will vary depending on nature of trial, disease condition, locality/region where the trial site is located, government restrictions including that of local administration, etc.

In this regard, it is reiterated that protection of rights, safety and wellbeing of trial subjects is of paramount importance. In case of ongoing clinical trial, the sponsor in coordination with the investigator and the respective ethics committee should decide whether to continue the trial or otherwise in interest of the trial subject. In some cases, however, protocol amendment/ deviation/ modification in the procedures may be necessary due to the unavoidable circumstances.

The sponsor should assess such impact and take appropriate decision, wherever necessary , in consultation with the investigator and the ethics committee to ensure rights, safety and well-being of trial subjects, as well as integrity of the

clinical data and maintain complete records of the same including the reasons for such amendments/ deviations, etc.

In view of the present situation, the communications between sponsor, investigator and EC required for implementation of such amendments/deviations/ modifications may be made through email or any other electronic mode. Submission/reporting of such activities to the CDSCO may also be made through mail at dci@nic.in with a copy to the concerned division of CDSCO(HQ).

This notice is being issued for general consideration of all stakeholders involved in clinical trial in light of present situation arising due to outbreak of COVID-19 in the country and the same is subject to comment, if any, from the stakeholders for further consideration and appropriate action.

V.G.S

(Dr. V.G. Somani)
Drugs Controller General (India)

To:

All stakeholders

Copy for information to :

JS(R), MoHFW, Nirman Bhawan, New Delhi.