

F. No. 12-09/BA-BE/2020/MISC-18/DC

Government of India

Directorate General of Health Services

Central Drugs Standard Control Organization

BA-BE Study for Export Division

FDA Bhawan, Kotla Road )

New Delhi – 110002

Date: 9/6/2020

**NOTICE**

**Subject: Conduct of BA-BE Study for Export Purpose in present situation due to outbreak of COVID-19 – reg.**

Bioavailability and Bioequivalence (BA-BE) Study of New Drug in human subject is regulated under the New Drugs and Clinical Trial Rules 2019. As per the rules, such BA-BE studies are required to be conducted in accordance with the approved study protocol and other related documents and as per the requirements of GCP guidelines and provisions of the said Rules.

In present situation, CDSCO understands various challenges faced due to 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 studies. Concerns have also been raised by stakeholders regarding the procedures to be followed by volunteers, subjects, staff during screening, testing, conduct of study and other related activities in context of COVID-19 situation.

In this context, it is reiterated that protection of rights, safety and well being of trial subjects is of utmost importance. In some cases, protocol amendments / modifications in the procedures etc may be necessary due to unavoidable circumstances and for the safety of study subjects. The sponsor and BA-BE center 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 study data and maintain complete records of the same including the reasons for such amendments / deviations, etc.

The procedures to be followed by the volunteers, subjects, study team members during screening, testing, conduct of study and other related activities in context of COVID-19 situation must be in accordance with the requirements, guidelines and principles as mentioned above as well as guidelines / orders / circulars issued by the Governments / Local Health Authorities / Administration.



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

NOTICE

**To:**

**All Stakeholders**

**Copy for information to :**

**PS to JS (R), MoHFW, Nirman Bhawan, New Delhi**