GENERAL NOTICE

FOR: ETHICS COMMITTEES, RESEARCH CENTERS AND SPONSORS.

FROM: THE NATIONAL INSTITUTE OF DRUG AND FOOD SURVEILLANCE - INVIMA

SUBJECT: PROPOSAL FOR EXTRAORDINARY MEASURES AND ACTIONS TO BE IMPLEMENTED UNDER THE NATIONAL COVID-19 CONTINGENCY IN ORDER TO DECREASE THE RISK TO SUBJECTS PARTICIPATING IN CLINICAL STUDIES.

DATE: MARCH 2020

In order to address the domestic public health situation concerning the possible spread of the COVID-19 disease and the new guidelines issued by the National Government, the National Institute of Drug and Food Surveillance considers it necessary to implement measures to help prevent, contain, mitigate and ensure the safety of subjects participating in clinical trials.

The conduction of a clinical trial includes medical care for participating subjects and It is important that all activities are maintained as well as the implementation of those required to minimize risk and ensure the safety, well-being and continuity of treatment while preserving the quality of the results obtained in clinical trials.

It is important that both the Sponsors/Contract Research Organization (CRO) and the Research Centers perform a risk analysis for patients and the conduction of protocols relating to the current COVID-19 contingency, giving priority to critical activities and how they should be carried out. These measures may be updated to adapt to epidemiological developments as determined by Invima.

Scheduled follow-up visits, access by off-site personnel, and trial monitoring at research sites could be compromised in this context, for which we recommend remote monitoring plans.

Any of these extraordinary measures that are implemented must be duly documented in the Research Center's operational plan and must be reported to the Ethics Committee and the Clinical Research Group by e-mail: invimabpc@invima.gov.co; prior approval is not required by Committees or Invima to implement these measures.

1. Scheduled on-site clinical trial patient visits:

The Sponsor/CRO, along with the research site, must consider the possibility of conducting visits by telephone or expanding the window for those studies that do not require the research site to administer drug products. They must ensure that critical scheduled site visits take place. If visits are rescheduled, these protocol deviations will not be considered to be serious violations unless the patient's safety is at risk.

For patients receiving oral or subcutaneous treatments, the Sponsor/CRO will ensure that the investigational drug/molecule is shipped from the research site to the patient's home and/or to a person authorized by the patient to administer the drug, if necessary.

This procedure will be documented, and sample processing will be carried out under the conditions set forth in each center's implementation of Good Clinical Practices.

In any case, patients should be guaranteed access to the trial medicine and procedures (e.g. laboratory
tests) under the same safety conditions that were being provided.

2. Safety measures for patients visiting research centers:

For all participating subjects for whom the implementation of the above measures is not possible and whose presence at the Research Centers is required for the administration of treatment and the collection of laboratory samples, the Sponsors/CROs should provide the necessary protective elements to minimize the risk of infection and ensure a means of transport in which the patient has minimal contact with other persons.

We recommend carrying out periodic evaluations in order to determine when to suspend the study for cases in which the risks outweigh the benefits in order to avoid unnecessary risks and ensure quality care for participants, taking into account the measures or possible restrictions implemented by the government agencies of each city in terms of going to Health Service Providing Institutions.

3. Recruitment

Recruitment of new patients will proceed, taking into account the measures or possible restrictions implemented by each of the government agencies of each city in terms of going to health service providing institutions. We reiterate that the extraordinary implementation of these recommendations and measures will be carried out exclusively while the COVID-19 crisis lasts in the country.

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