Notes to Clinical Trials Researchers during the COVID-19 pandemic

A. Preamble

The National Agency for Food and Drug Administration and Control (NAFDAC) recognizes the impact which COVID-19 have on the health system, general society and its effect on clinical trials conduct. These impacts may include the need for participants and trial staff to self-isolate, limit access to hospitals, deployment of healthcare personnel involved in clinical trials to other duties, which results in delays in completing certain trial tasks. The evolving situation may call for more realistic approaches to deal with the challenges of conducting clinical trial at a time as this while ensuring the rights, safety and wellbeing of participants are protected. Sponsors/Investigators must therefore ensure that the clinical trial is conducted in accordance with approved protocol.

B. Objective

This document serves as a guide to all parties involved in clinical trials in Nigeria during the COVID-19 pandemic.

C. Background

In the face of the COVID-19 pandemic, various challenges on existing clinical trials arise which may result in restrictions of visits to healthcare facilities, increased demands on health service and changes to trial staff availability. Participants may also be required to self-isolate, which introduces difficulties for Investigators to maintain medical oversight. These challenges could affect conduct of trials, such as the completion of trial assessments, evaluation, completion of trial visits and provision of Investigational Medicinal Products (IMPs). Other aspects of ongoing clinical trials that may be affected due to travel restrictions include opening new trial site, recruitment and continued involvement of participants in the trial, or on starting of new trials.

Where a trial participant is unable to attend a site visit, other means may be required to ensure continuous medical care oversight through home nursing and phone contact. However, the limitations and risks of such methods as it affects data protection should be considered and adequately documented.

Note: All Parties should note that due to the rapidly evolving situation, further updates to this document are likely. Please refer to NAFDAC specific guidelines on clinical trials to complement this guidance. https://www.nafdac.gov.ng/drugs/clinical-trial-guidelines/

The following points should be noted for parties involved in clinical trials at this time.

1. The need to initiate new trials or include new trial participants in an ongoing trial should be critically assessed by sponsors.
2. Sponsors/investigators may consider using risk assessment to evaluate changes they may want to apply to ongoing trials during COVID-19 e.g.
    i) A temporary halt of the trial at some or all trial sites.
    ii) Suspension or slowing down of recruitment of new trial participants.
    iii) Site closure.

    Whatever the decision maybe, safety and well-being of patients already participating is paramount and must not be compromised, likewise data validity.
3. Priority will be given to any (new) clinical trial applications for the treatment or prevention of COVID-19 infection, and/or substantial amendment applications to existing clinical trials necessary as a result of COVID-19
4. Changes to informed consent or new collection by Sponsors during this critical time will warrant alternative procedures to obtain informed consent legally bearing in mind such subjects may be in quarantine. In case of emergency situations, where trial participants are incapable of giving informed consent (e.g. when under intensive medical care), sponsors shall adhere to the provisions set out in NAFDAC Good Clinical Practice Guidelines, 2016. https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/DRUG_GUIDELINES/NAFDAC-GCP-GUIDELINES-2016.pdf . Visit to the investigator sites for the sole purpose of obtaining re-consent should be avoided, except for reasons related to COVID-19 and alternative ways of obtaining such re-consents should be considered and adequately documented.
5. For changes in the distribution of the IMP, sponsors must assess the risks relating to the product and consider any alternative shipping and storage arrangements to ensure the IMP and other medications categorized as non-IMPs are provided the participants without compromising the treatment blinding.
6. NAFDAC acknowledges that COVID-19 situation is likely to introduce more protocol deviations than normal. It is expected that the sponsor escalates and manages such protocol deviations in accordance with their standard procedures and all protocol deviations must be reported to the responsible regulatory bodies (Ethics and NAFDAC).

Sponsors/investigators are encouraged to consider the submission of applications for an accelerated assessment when possible. For more information, visit https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/DRUG_GUIDELINES/Guidelines-For-Clinical-Trials-In-Emergencies-In-Nigeria.pdf

For further questions, please contact the Director General; cm.adeyeye@nafdac.gov.ng.

Reference: EMA/141885/2020; Guidance to sponsors on how to manage CT during COVID-19 Pandemic

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