GUIDANCE TO SPONSORS OF CLINICAL TRIALS IN NIGERIA INCLUDING COVID-19 RELATED TRIALS

1. Introduction

The National Agency for Food and Drug Administration and Control (NAFDAC), has the mandate to regulate the conduct of the clinical trials in Nigeria. The Agency is committed to supporting sponsors with appropriate guidance to expedite the development of effective interventions to treat or prevent COVID-19. This document serves to provide clarity on the conduct of clinical trials in Nigeria, especially for the COVID-19 pandemic.

2. Authorization Process

a. NAFDAC grants authorization for all Clinical Trial including COVID-19 related trials, subject to ethical clearance by the Independent Ethics Committee.
b. An expedited review process for COVID-19 related trial shall follow the NAFDAC guideline for clinical trials in emergencies; https://www.nafdac.gov.ng/drugs/clinical-trial-guidelines/
c. The Applicant should download and complete the NAFDAC's clinical trial application form (https://www.nafdac.gov.ng/clinical-trial-forms/).
d. The duly completed form, together with the protocol and other relevant documents should be submitted to the Director; Drug Evaluation and Research (D/DER) via email @ der.headquarters@nafdac.gov.ng or using the link below.
(https://www.nafdac.gov.ng/wp-content/uploads/Publications/Others/QMS_Documents/GUIDELINES-FOR-CLINICAL-TRIAL-APPLICATION.pdf)

e. Upon satisfactory review of the Clinical Trial Application (CTA), an authorization for the conduct of the trial will be issued, within fifteen (15) days after payment of statutory fees. https://www.nafdac.gov.ng/resources/nafdac-tariff/

f. Where the Investigational medicinal Product (IMP) is to be imported, an import permit will be issued accordingly, within two (2) days of receipt of application. For further guide on labeling requirements for IMP, please click: https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/DRUG_GUIDELINES/Guidelines-For-Labeling-Of-Investigational-Medicinal-Products-Rev.-01.pdf

g. For locally manufactured IMP, records of current GMP status of the manufacturer will be required to review the application.

h. If the clinical trial is to be conducted at one to three centres, ethical clearance would be from the institutional ethics committee (IEC) and for trials that will be conducted at more than 3 centres, clearance will be from National Health Research Ethics Committee (NHREC). (https://nhrec.net/download-nchre/).

For further enquiries, please contact: Director, Drug Evaluation and Research: (Email: der.headquarters@nafdac.gov.ng