MCAZ Medicines Control Authority of Zimbabwe

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To: All Investigators and Researchers

RE: CONDUCT OF CLINICAL TRIALS DURING THE COVID-19 PANDEMIC

The Medicines Control Authority of Zimbabwe (MCAZ) recognises that the COVID-19 pandemic will impact the conduct of clinical trials as a result of the 21- day lockdown imposed, quarantine of infected people or suspected cases, site closures, travel restrictions, as well as possible interruptions to the supply chain for medicines.

Although the necessity and impact of COVID-19 control measures on clinical trials will vary depending on many factors, such as the nature of the study, the trial design, or the geographical location, the MCAZ recommends the following measures to assist investigators in assuring the safety of trial participants and research staff, maintaining compliance with current good clinical practice (GCP), and minimising risks to trial integrity:

1. MCAZ Oversight of clinical trials

    1.1 Critical operations of the MCAZ remain functional, and submissions from researchers will continue to be received.
    1.2 New applications for the conduct of clinical trials should be done online, using the MCAZ e-CTR system. The system can be accessed from the MCAZ website under online services, or by following the link: https://e-ctr.mcaz.co.zw.
    1.3 For all other clinical trials submissions, it is recommended to submit electronically via email to pvct@mcaz.co.zw. Please note that there is a restriction on the maximum size that the MCAZ email server allows for email attachments, and it is recommended to compress attachments. Where it is not possible to compress the files, file sharing sites such as Drop Box or Google Drive can be used.
    1.4 Payment for application fees should be made electronically, using the available channels. No payments will be accepted at the MCAZ premises.
    1.5 All Committee meetings scheduled for the month of April have been deferred, as previously advised. Decisions that require Authority approval will be handled administratively and by round-robin resolutions.

2. Conduct of Clinical Trials

    2.1 On-going non-COVID-19 Clinical Trials
        2.1.1 The safety of participants should be the main focus for investigators, and all physical contact with participants should be deferred, except for circumstances where the safety, rights and well-being of the participants

would be jeopardised. In such exceptions, the MoHCC recommendations and social distancing principles should be adhered to.

2.1.2 Principal Investigators and site personnel have a critical role in the conduct of Clinical Trials and assuring safety of trial participants. Where it is absolutely necessary for participants to visit the study site, the PI should ensure that all necessary and reasonable steps are taken to ensure that participants face minimal challenges in travelling to and from the study site, and minimal exposure to risk of COVID-19 infection.

2.1.3 The need to implement new processes or to modify existing processes will vary by the protocol and local situation (e.g. delay some assessments for ongoing trials, stop recruitment, or withdrawal of ongoing trial participants).

2.1.4 Since trial participants may not be able to come to the study site for protocol-specified visits, investigators should explore alternative methods (e.g. telephone contact, home delivery for self-administered medicines, etc.).

2.1.5 Investigators should ensure continued access to study medicines for those studies where study product withdrawal would be detrimental to the participants. In all cases, MoHCC recommendations and social distancing principles should be observed.

2.1.6 COVID-19 screening procedures that may be mandated by the healthcare system in which a clinical trial is being conducted do not need to be submitted as an amendment to the MCAZ, even if done during clinical study visits, unless the sponsor is incorporating the data collected as part of a new research objective.

2.1.7 Protocol amendments should not be implemented before review and approval by the Authority, the MRCZ and relevant IRBs.

2.1.8 Where protocol deviations occur, it should be indicated which trial participants were impacted, and how those trial participants were impacted.

The Authority will endeavour to process any notifications, requests, protocol amendments and deviations submitted to the MCAZ as promptly as possible, but delays may be inevitable. Where submissions are urgent, the PI is required to submit a signed request to the Director-General, providing justification for the urgency. Such requests will be considered on a case by case basis.

2.2 COVID-19 Clinical Trials

The MCAZ is aware that the current operating environment is restrictive, but has put in place measures to ensure that the evaluation of any COVID-19 clinical trials that may be submitted is expedited, and approved within the shortest possible timeframe.

Investigators are encouraged to utilise the available electronic methods of submitting clinical trial applications stated above. Any queries that may arise concerning submission of clinical trial applications using the e-CTR system should be emailed to pvct@mcaz.co.zw.

The Authority remains committed to ensuring that it fulfils its mandate of ensuring that accessible medicines and medical devices are safe, effective and of good quality, during these trying times and beyond.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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G. N. MAHLANGU (Ms)
DIRECTOR-GENERAL