MCAZ Medicines Control Authority of Zimbabwe

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CIRCULAR 16 of 2025

Date: 12th of June 2025

TO: ALL INVESTIGATORS AND SPONSORS OF CLINICAL TRIALS

RE: PUBLICATION OF SUMMARISED PUBLIC ASSESSMENT REPORTS FOR CLINICAL TRIAL APPLICATIONS AND PUBLIC INSPECTION REPORTS FOR GOOD CLINICAL TRIAL PRACTICE (GCP) INSPECTIONS

We wish to advise that the Medicines Control Authority of Zimbabwe (MCAZ) will be publishing summarised public assessment reports (PAR) for clinical trial applications and public inspection reports (PIR) for GCP inspections on the MCAZ website and/or e-Clinical Trial Registry Platform. All the clinical trial applications which were authorised or rejected from January 2025 and GCP inspections conducted from January 2025 will be impacted by this procedure.

On closure of the GCP inspection and once the clinical trial application has been authorised or rejected, a copy of the PAR or PIR shall be sent to the Principal Investigator (PI) for comments, and if there are any comments, these should be submitted within ten (10) working days of the receipt of the report. If no comments are received within ten (10) working days, the Authority will proceed to publish the report. The public GCP inspection report shall remain valid until the next inspection following which the most recent inspection report will be published.

Publication of summarised PAR for clinical trial applications and PIR for GCP inspections shall be included as conditions of authorisation for all the clinical trials that will be authorised by the MCAZ.

The PAR and PIR shall contain non- confidential information as guided by section 73 of the Medicines and Allied Substance Control Act [Chapter 15:03]. Any confidential and intellectual property will be redacted prior to publication of the reports.

Please note that these new developments are in line with the WHO Global Benchmarking Maturity Level 4 requirements and international good regulatory practices to promote transparency, accountability and communication.

Yours sincerely,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R. T. Rukwata (Mr.)
DIRECTOR-GENERAL
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