PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

GOOD CLINICAL PRACTICE (GCP) INSPECTION PUBLIC ASSESSEMENT REPORT

Part 1: GENERAL INFORMATION

MCAZ Clinical Trial reference:	CT262/2023
Inspection Reference Number:	2/2025
Protocol Number:	N/A
Title of Clinical Trial:	An adaptive multi-arm trial to improve clinical outcome among children recovering from complicated severe acute malnutrition
Final Approved Protocol Version used for Inspection:	Version 0.16 dated 15 January 2024
Name of Principal Investigator(s):	Prof M. Bwakura-Dangarembizi
Clinical Trial Site and Adress:	1. Parirenyatwa Hospital, Mazowe Street, Harare 2. Chitungwiza Central Hospital, Zengeza 4, Chitungwiza 3. Sally Mugabe Central Hospital, Harare
Sponsor:	Queen Mary University of London
Date of Contact:	13 June 2025
Date of Report:	13 October 2025
Names of gazetted inspectors:	Ms Rumbidzai Manyevere (Lead Inspector-Gazetted) Mr Tatenda Nyamandi (Inspector-Gazetted) Mr Steny Marekera (Inspector-Gazetted) Ms Chantelle Chinyamunyamu (Not gazetted, attending as part of training) Miss Tracey Matambo (Not gazetted, attending as part of training)

Part 2: SUMMARY

2.1 Scope

This was a routine Good Clinical Practice (GCP) inspection for the study.

2.2 Objective

The objective of the GCP Inspection was to verify and ensure that the trial was being conducted in line with GCP according to relevant local and international GCP Guidelines and conditions of authorisation in line with Medicines and Allied Substances Control Act (MASCA).

2.3 Background

This is an adaptive 5-arm randomized unblinded phase III clinical trial to evaluate the efficacy of each interventional arm against standard-of-care in children discharged from hospital following complicated severe acute malnutrition. In Zimbabwe, the study is being conducted at three sites, Sally Mugabe Hospital, Parirenyatwa Hospital, Chitungwiza Central Hospital. The Zvitambo Institute for Maternal and Child Health Research is the administrative site for all the sites and study medicines are being stored and managed by the University of Zimbabwe Clinical Research Centre (UZ CRC) pharmacy. For Zimbabwe, the study population is 422 children, aged 6-59 months, hospitalised with complicated severe acute malnutrition. The children will be randomised into 1 of the following 5 arms with the ratio 2:1:1:1:1, Arm 1)-Standard of care, Arm 2)-Antimicrobial package (isoniazid, rifampicin, azithromycin), Arm 3)- Reformulated ready to use therapeutic food (RUFT), Arm 4)-Psychosocial package and Arm 5-Antimicrobial package + reformulated RUTF + psychosocial package.

Primary objective
1. To evaluate the efficacy of each interventional arm against standard-of-care in children discharged from hospital following complicated severe acute malnutrition (SAM) in Zimbabwe, Zambia and Kenya.

3.1 Documents
1. Regulatory file with approval letters for the protocol and corresponding amendments
2. Clinical Trial Master File
3. GCP certificates, Curriculum Vitae (CVs) and practicing certificates
4. Binders for 11 selected participants which constituted 10% of all the binders for total number of participants enrolled in the study
5. All 24 Informed Consent Forms (ICFs) for participants enrolled from Parirenyatwa hospital
6. Standard Operating Procedures
7. Staff training records
8. Delegation log
9. Prescriber's log
10. Screening and enrolment log
11. Monitor's reports
12. Serious Adverse Event (SAE) reports
13. Insurance certificate
14. Sponsor financial agreement
15. Proof of PACTR submission, number – PACTR202311478928378
16. UZ-CRC Research pharmacy license

3.2 Personnel
The P.I., the trial manager and the study medical officer were interviewed by the inspectors.

3.3 Facilities
The Zvitambo Institute for Maternal and Child Health Research Laboratory, Paediatric Ward at Parirenyatwa hospital and the UZ-CRC Research pharmacy were inspected.

Part 4: OBSERVATIONS

4.1 Findings
Six major findings and seven minor findings were noted.

4.2 Regulatory Actions
The GCP inspection report was sent to the P.I. The P.I. was given 14 working days to respond with the corrective and preventative actions (CAPA).

Part 5: CONCLUSION
The P.I. responded submitting the CAPA for the findings noted during the inspection. The CAPA was reviewed and the Pharmacovigilance and Clinical Trials Committee agreed that the CAPA was satisfactory. The clinical trial and study site were regarded as operating at a **satisfactory level of compliance with GCP.**

Name of Evaluator: R. Manyevere Signature:  Date: 13/10/2025

Name of 2nd Evaluator: T. Nyamandi Signature:  Date: 13/10/2025