PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

GOOD CLINICAL PRACTICE (GCP) INSPECTION PUBLIC ASSESSMENT REPORT

Part 1: GENERAL INFORMATION

MCAZ Clinical Trial reference:	CT282/2024
Inspection Reference Number:	4/2025
Protocol Number:	N/A
Title of Clinical Trial:	Assessing acceptability of Annovera contraceptive vaginal ring use (compared to other contraceptive method use) among women seeking family planning services.
Final Approved Protocol Version used for Inspection:	Version 5.4 dated 04 December 2024
Name of Principal Investigator(s):	Dr G. Hangaika
Clinical Trial Site and Address:	1. Mbare Poly Clinic, Mzengeli Way, Off Ardbennie Rd, Mbare, Harare 2. Matapi Clinic, Harare Rd South, Mbare, Harare
Sponsor:	The Population Council, 1188 York Avenue, Weiss 5th Floor, New York, NY 10065, USA
Date of Contact:	29 August 2025
Date of Report:	12 January 2026
Names of gazetted inspectors:	Ms Rumbidzai Manyevere (Lead Inspector) Mr Tatenda Nyamandi (Inspector)

Part 2: SUMMARY

2.1 Scope

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

2.2 Objective

The objective of the GCP inspection was to verify readiness of the principal investigator (P.I.), study team and study sites before study commencement and to ensure compliance with GCP, according to relevant GCP Guidelines, the approved protocol and the conditions of clinical trial authorisation in line with Medicines and Allied Substances Control Act (MASCA).

2.3 Background

This is a study evaluating acceptability of a contraceptive vaginal ring, Annovera, compared to other contraceptive methods specifically oral contraceptive pills (OCPs) or depot medroxyprogesterone acetate (DMPA) in women seeking family planning services using acceptability surveys and continuation rates. Women seeking family planning services at the study sites will be presented with their free choice, at no cost, of Annovera or other locally available contraceptive methods. Those selecting Annovera, and a subset of those selecting another contraceptive method will be given information on the study and if interested in participation, screened for eligibility.

3.1 Documents

3.1.1. Approved study protocol
3.1.2. Regulatory approvals from Medicines Control Authority of Zimbabwe (MCAZ), Medical Research Council of Zimbabwe (MRCZ) and Research Council of Zimbabwe (RCZ)
3.1.3. Delegation log
3.1.4. Approved informed consent forms
3.1.5. Approved recruitment materials
3.1.6. GCP certificates, curriculum vitae (CVs) and practicing certificates

3.2 Personnel

According to the delegation log, the staff compliment for the Mbare Poly clinic-Edith Opperman study site is composed of fourteen (14) personnel. Valid GCP certificates and practising certificates for the study staff were available on file.

3.3 Facilities

Mbare Poly Clinic-Edith Opperman: The clinic's outside reception area and consultation room were inspected. The consultation room was clean and well equipped. Study documents were kept in a lockable steel cabinet stored at the clinic.

Part 4: OBSERVATIONS

4.1 Findings

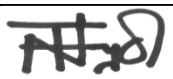
One minor finding was noted. There were no critical or major findings.

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 finding noted during the inspection. The CAPA was reviewed and the Pharmacovigilance and Clinical Trials Committee **agreed** that the CAPA was satisfactory. The clinical trial was regarded as ready to commence.

Name of Evaluator:	R. Manyevere	Signature:		Date:	12/01/2026
Name of 2nd Evaluator	T. Nyamandi	Signature:		Date:	12/01/2026