CLARIFICATION MEMO #01 TO:

MATRIX-003

Phase I (Placebo Only) Trial to Assess Acceptability and Safety of Two Placebo Intravaginal Ring (IVR) Designs

Cooperative Agreement #7200AA22CA00002

A Non-IND Study

Version 1.2 / May 16, 2024

Clarification Memo Date: August 21, 2024

Section 1: Summary of Clarifications and Rationale

The procedures clarified in this Clarification Memorandum (CM) have been approved by the MATRIX Prime-Clinical Trials Hub, MATRIX-003 Protocol Co-Chairs, and MATRIX-003 Product Developer (PD)/Sponsor and are to be implemented immediately upon issuance. IRB/IEC approval of this CM is not required by MATRIX prior to implementation; however, investigators may submit the CM to the IRB/IEC overseeing the study at their site for the IRB/IEC's notification. This CM is official MATRIX-003 documentation and is effective immediately. A copy of this CM must be retained in the PD/Sponsor's and in each study site's Essential Documents file for MATRIX-003. No changes in the sample informed consent form or schedule of visits/procedures are included in this CM.

This document updates the Protocol Team Roster to replace the Investigator of Record for the CAPRISA Vulindlela site.

Section 2: Implementation

With the exception of updates to the protocol team roster, text to be deleted is noted below with a ~~strikethrough~~, text to be added is in **bold**, and text in ***bold italics*** is not to be added, but to serve as a clarification of the implementation item in question. This information will be included in the protocol the next time the protocol is updated.

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1. Protocol Team Roster – Deletions: Gabriella Benadé.

2. Protocol Team Roster – Additions:

Disebo Potloane, MBChB
Site Investigator of Record
CAPRISA Vulindlela CRS
Adjacent to Mafakathini Primary Healthcare Clinic
Road P402, Ward 9, Msunduzi Municipality
uMgungundlovu District, KwaZulu-Natal
South Africa, 3291
Phone: +27 (0)31 665 0687
Email: disebo.potloane@caprisa.org

The above information will be incorporated into the next version of the protocol at a later time if it is amended.