



MATRIX-003 Study Specific Procedures Manual Overview and Control Document-Version History and Notice of Changes

Section Number	Section Title	Version Number(s)*	Version Date(s)*	Notice of Changes*
01	Introduction	1.0	20Feb2024	
		2.0	18Sep2024	<ul style="list-style-type: none"> Updated to reflect SA protocol v 1.2 and clarification memos to date. Added reference that abstinence and vaginal product use restrictions referred to in SSP manual may be not applicable for SA protocol v 1.2
02	Documentation Requirements	1.0	20Feb2024	
		2.0	22May2024	<ul style="list-style-type: none"> 2.3.7: Updated to reflect change to process for Protocol Deviations for events already recorded in SBR CRFs, to parallel changes made to section 11.
03	Accrual and Retention	1.0	20Feb2024	
04	Informed Consent	1.0	20Feb2024	
05	Study Procedures	1.0	20Feb2024	
06	Study Product Considerations for Non-Pharmacy Staff	1.0	20Feb2024	

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07	Clinical Considerations	1.0	20Feb2024	
08	Adverse Event Reporting and Safety Monitoring	1.0	20Feb2024	
09	Laboratory Considerations	1.0	20Feb2024	
		2.0	24Apr2024	<ul style="list-style-type: none"> The MATRIX CTH Management Team decided to designate a CTH Management Team member to perform the final database lock and apply his/her e-signature in place of a protocol chair. This provides consistency across MATRIX studies and eliminates the need to train new protocol chairs to perform this activity.
10	Counseling Considerations	1.0	20Feb2024	
11	Behavioral Measures	1.0	20Feb202	
		2.0	28Mar2024	<ul style="list-style-type: none"> Corrected the visit timing for the participant IDI from "within one month" to "within 3 weeks" of V9, as indicated in the protocol. Updated the timing for completion of Debrief Reports from "24 hours" to "one working day" to accommodate for holidays/weekends. Updated the timing for submission of Debrief Reports from "72 hours" to "three working days" to accommodate for holidays/weekends.

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		3.0	22May2024	<ul style="list-style-type: none"> Throughout: language has been added to reinforce the importance of preserving rapport built between interviewers and participants, and guidance for management when SBR interviewers are required to share information learned from participants with other study staff. Throughout: updated references to SSP Sections within document 11.2.1: Information added to reflect guidance provided in Operational Guidance #1 regarding capture of ring expulsions on CRFs 11.3: Information added to guide staff on the management of participant reports during SBR CRF completion or IDIs of events that may fall under the category of a Protocol Deviation. The new guidance instructs staff not to complete a PD log if the PD is already captured in the SBR CRF. A figure has also been added to show reporting flow for AEs, SHs, SBs, and PDs. Appendix 11-2: Update to process for sites to access their SFTP username
12	Data Collection	1.0	20Feb2024	
13	Data Communiqués and Operational Guidance**	1.0	20Feb2024	
14	Study Reporting Plan for Clinical Data	1.0	20Feb2024	

* Highest version number/date listed is current and supersedes all previous listed version(s). Notice of Changes summarizes any significant changes that have been made.

** Will only be updated if content of SSP changes, will not be updated for individual Data Communiqués/Operation Guidance memos

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SSP Approval Sheet

Entity/Role	Sections Approved*	Name	Signature/Date
Protocol Chair	All Sections	Kathryn T. Mngadi, MDChB, MSc, MSc Clin Trials, MPhil Pall Med, Dip HIV Man SA, Dip Epi	<p>Signed by: <i>Kathryn Mngadi</i></p> <p> Signer Name: Kathryn Mngadi Signing Reason: I approve this document Signing Time: 9/19/2024 9:43:58 AM SAST 47BABD7EC7E34514B2BCD37BADCE1810</p>
Protocol Chair	All Sections	Krishnaveni Reddy, MMedSci	<p>Signed by: <i>Krishnaveni Reddy</i></p> <p> Signer Name: Krishnaveni Reddy Signing Reason: I approve this document Signing Time: 9/20/2024 4:37:31 AM PDT FD61E76308C545159BF066CAF1360CF3</p>
Matrix CTH CRM	All Sections	Ingrid Macio, PA-C	<p>Signed by: <i>Ingrid Macio</i></p> <p> Signer Name: Ingrid Macio Signing Reason: I approve this document Signing Time: 9/18/2024 3:36:32 PM EDT 094F6DED86E34692B5DD30070D4181BE</p>
MATRIX CTH DMSS	Sections 5, 7, 8, 12, 13, 14	Leslie Meyn, PhD	

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Entity/Role	Sections Approved*	Name	Signature/Date
MATRIX CTH Lab Support	Section 9	Edward Livant, BSMT	
MATRIX CTH Safety Physician	Sections 7, 8	Katherine Bunge, MD, MPH	
RTI/D2D Team	Section 11, 13	Cecilia Milford, PhD	
MATRIX Pharmacy Consultant	Section 6	Cindy Jacobson, PharmD	

**Applicable section version numbers and dates as listed in Overview and Control Document table, Version 5.0, dated 18Sep2024*