



## 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	
02	Documentation Requirements	1.0	20Feb2024	
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	
07	Clinical Considerations	1.0	20Feb2024	
08	Adverse Event Reporting and Safety Monitoring	1.0	20Feb2024	
09	Laboratory Considerations	1.0	20Feb2024	
10	Counseling Considerations	1.0	20Feb2024	
11	Behavioral Measures	1.0 2.0	20Feb2024 28Mar2024	<ul style="list-style-type: none"> <li>Corrected the visit timing for the participant IDI from "within one month" to "within 3 weeks" of V9, as indicated in the protocol.</li> <li>Updated the timing for completion of Debrief Reports from "24 hours" to "one working day" to accommodate for holidays/weekends.</li> <li>Updated the timing for submission of Debrief Reports from "72 hours" to "three working days" to accommodate for holidays/weekends.</li> </ul>
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


# MATRIX-003 Study Specific Procedures Manual

## Overview of Section Contents and Identification of Current Section Versions

### 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>DocuSigned by:</p> <p><i>Kathryn Mngadi</i></p> <p>Signer Name: Kathryn Mngadi            Signing Reason: I approve this document            Signing Time: 4/5/2024   9:49:33 AM SAST            47BABD7EC7E34514B2BCD37BADCE1810</p>
Protocol Chair	All Sections	Krishnaveni Reddy, MMedSci	<p>DocuSigned by:</p> <p><i>Krishnaveni Reddy</i></p> <p>Signer Name: Krishnaveni Reddy            Signing Reason: I approve this document            Signing Time: 4/4/2024   12:31:51 AM PDT            FD61E76308C545159BF066CAF1360CF3</p>
Matrix CTH CRM	All Sections	Ingrid Macio, PA-C	<p>DocuSigned by:</p> <p><i>Ingrid Macio</i></p> <p>Signer Name: Ingrid Macio            Signing Reason: I approve this document            Signing Time: 4/3/2024   11:59:07 AM 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	<p>DocuSigned by:  <i>Cecilia Milford</i>   Signer Name: Cecilia Milford            Signing Reason: I approve this document            Signing Time: 4/4/2024   3:13:24 AM EDT            6779E78A18E64C6E8D04EBE85AA9AF9E</p>
MATRIX Pharmacy Consultant	Section 6	Cindy Jacobson, PharmD	

\*Applicable section version numbers and dates as listed in Overview and Control Document table, Version 2.0, dated 28Mar2024