



## 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	2.0	24Apr2024	<ul style="list-style-type: none"> <li>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.</li> </ul>
10	Counseling Considerations	1.0	20Feb2024	

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

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 Communiques/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	DocuSigned by: <i>Kathryn Mngadi</i>  Signer Name: Kathryn Mngadi Signing Reason: I approve this document Signing Time: 5/3/2024   8:32:10 AM SAST 47BABD7EC7E34514B2BCD37BADCE1810
Protocol Chair	All Sections	Krishnaveni Reddy, MMedSci	DocuSigned by: <i>Krishnaveni Reddy</i>  Signer Name: Krishnaveni Reddy Signing Reason: I approve this document Signing Time: 5/2/2024   7:48:06 AM PDT FD61E76308C545159BF066CAF1360CF3
Matrix CTH CRM	All Sections	Ingrid Macio, PA-C	DocuSigned by: <i>Ingrid Macio</i>  Signer Name: Ingrid Macio Signing Reason: I approve this document Signing Time: 5/2/2024   11:24:27 AM EDT 094F6DED86E34692B5DD30070D4181BE
MATRIX CTH DMSS	Sections 5, 7, 8, 12, 13, 14	Leslie Meyn, PhD	DocuSigned by: <i>Leslie Meyn</i>  Signer Name: Leslie Meyn Signing Reason: I approve this document Signing Time: 5/2/2024   4:42:32 PM EDT B4E1CC5F63DF4052A48978550B4DCB6D

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**SSP Approval Sheet**

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 3.0, dated 24Apr2024*