



MATRIX-002 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	12October2023	
02	Documentation Requirements	1.0	12October2023	
03	Accrual and Retention	1.0	12October2023	
04	Informed Consent	1.0	12October2023	
05	Study Procedures	1.0	12October2023	
06	Study Product Considerations for Non-Pharmacy Staff	1.0	12October2023	
07	Clinical Considerations	1.0	12October2023	
08	Adverse Event Reporting and Safety Monitoring	1.0	12October2023	
09	Laboratory Considerations	1.0 2.0	12October2023 20February2024	<ul style="list-style-type: none"> • Modify EQA frequency of review to when requested • Modify Swab for microbiota handling procedures, increased time to freezer storage, up to 4 hours after collection • Clarified Gram stain shipping: one set shipped to CTH-LC • Minor corrections and clarifications • Added shipping address for CTH-LC
10	Counseling Considerations	1.0	12October2023	
11	Behavioral Measures	1.0	12October2023	
12	Data Collection	1.0	12October2023	
13	Data Communiqués and Operational Guidance**	1.0	12October2023	
14	Study Reporting Plan for Clinical Data	1.0	12October2023	

* 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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Overview of Section Contents and Identification of Current Section Versions


SSP Approval Sheet

Entity/Role	Sections Approved*	Name	Signature/Date
Protocol Chair	All Sections	Nyaradzo M. Mgodì, MBChB, MMed	<p>DocuSigned by:</p> <p><i>Nyaradzo Mgodì</i></p> <p>Signer Name: Nyaradzo Mgodì Signing Reason: I approve this document Signing Time: 2/20/2024 9:44:24 PM PST CA2EE955FFE04C83BFE4F075EC10A21E</p>
Protocol Chair	All Sections	Alexandra Minnis, PhD	<p>DocuSigned by:</p> <p><i>Alexandra Minnis</i></p> <p>Signer Name: Alexandra Minnis Signing Reason: I approve this document Signing Time: 2/20/2024 2:47:38 PM PST 27C3DB1DC76E4B2ABA2539342371BAA3</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: 2/20/2024 1:00:54 PM PST 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	May Beamer, BS	<p>DocuSigned by:</p>  <p>Signer Name: May Beamer Signing Reason: I approve this document Signing Time: 2/20/2024 1:13:07 PM PST A6E60A1AA5794433B07FA7223D310D27</p>
MATRIX CTH Safety Physician	Sections 7, 8	Catherine Chappell, MD	
RTI/D2D Team	Section 11, 13	Mary Kate Shapley-Quinn, MPH	
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 20Feb2024*