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 2.0	12October2023 20August2024	• Addition of SA protocol version and CM #01
02	Documentation Requirements	1.0 2.0	12October2023 15May2024	• 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	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	• 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 2.0	12October2023 15May2024	• 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. • 11.2.1: Information added to reflect guidance provided in Operational Guidance #2 regarding capture of film expulsions on CRFs • 11.2.3.311.2.3.3: Reference to Operational Guidance #1 added for additional information about managing the IDI guide length and time availability for the participant. • 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. • 11.4.3: The timeline for completing IDI debrief reports is updated from 24 hours to 1 business day • Appendix 11-2: Update to process for sites to access their SFTP username
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 Communiques/Operation Guidance memos**

SSP Approval Sheet

Entity/Role	Sections Approved*	Name	Signature/Date
Protocol Chair	All Sections	Nyaradzo M. Mgodi, MBChB, MMed	Signed by: Nyaradzo Mgodi Signer Name: Nyaradzo Mgodi Signing Reason: I approve this document Signing Time: 8/20/2024 | 11:20:23 AM PDT CA2EE955FFE04C83BFE4F075EC10A21E
Protocol Chair	All Sections	Alexandra Minnis, PhD	Signed by: Alexandra Minnis Signer Name: Alexandra Minnis Signing Reason: I approve this document Signing Time: 8/20/2024 | 10:43:55 AM PDT 27C3DB1DC76E4B2ABA2539342371BAA3
Matrix CTH CRM	All Sections	Ingrid Macio, PA-C	Signed by: Ingrid Macio Signer Name: Ingrid Macio Signing Reason: I approve this document Signing Time: 8/20/2024 | 12:31:05 PM EDT 094F6DED86E34692B5DD30070D4181BE
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	
MATRIX CTH Safety Physician	Sections 7, 8	Catherine Chappell, MD	
RTI/D2D Team	Section 11, 13	Mary Kate Shapley-Quinn, MPH	
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**Applicable section version numbers and dates as listed in Overview and Control Document table, Version 4.0, dated 20August2024*