



## MATRIX-001 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	18October2023	
02	Documentation Requirements	1.0	18October2023	
03	Accrual and Retention	1.0	18October2023	
04	Informed Consent	1.0	18October2023	
05	Study Procedures	1.0	18October2023	
06	Study Product Considerations for Non-Pharmacy Staff	1.0	18October2023	
07	Clinical Considerations	3.0	28May2024	<ul style="list-style-type: none"> <li>Updated 7.7 Prohibited Medications, Products and Practices</li> <li>Corrected Table 1</li> <li>Added Appendix 1: antibiotic/antifungal algorithm</li> </ul>
08	Adverse Event Reporting and Safety Monitoring	1.0	18October2023	
09	Laboratory Considerations	3.0	19March2024	
10	Counseling Considerations	1.0	18October2023	
11	Behavioral Measures	1.0	18October2023	
12	Data Collection	1.0	18October2023	
13	Data Communiqués and Operational Guidance**	1.0	18October2023	
14	Study Reporting Plan for Clinical Data	1.0	18October2023	

\* 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-001 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	Leila E Mansoor, B.Pharm, PhD	<p><b>Signature:</b> <i>Leila Mansoor</i> <small>Electronically signed by: Leila Mansoor Reason: I have read this document and approved via Esignature Date: May 30, 2024 13:24 GMT+2</small></p> <p><b>Email:</b> leila.mansoor@caprisa.org</p>
Protocol Chair	All Sections	Nelly R Mugo, MBChB, MMed, MPH	<p><b>Signature:</b> <i>Nelly Mugo</i> <small>Electronically signed by: Nelly Mugo Reason: I have read this document and approved via Esignature Date: Jun 5, 2024 19:43 GMT+3</small></p> <p><b>Email:</b> rwamba@uw.edu</p>
MATRIX CTH CRM	All Sections	Ingrid Macio, PA-C	<p><b>Signature:</b> <i>Ingrid Macio</i> <small>Electronically signed by: Ingrid Macio Reason: I have read this document and approved via Esignature Date: Jun 3, 2024 10:11 EDT</small></p> <p><b>Email:</b> maciis@upmc.edu</p>
CONRAD CPM	All Sections	Karen Dominguez, MPH	<p><b>Signature:</b> <i>Karen Dominguez</i> <small>Electronically signed by: Karen Dominguez Reason: I have read this document and approved via Esignature Date: May 29, 2024 16:32 EDT</small></p> <p><b>Email:</b> domingk@evms.edu</p>

# MATRIX-001 Study Specific Procedures Manual

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

### SSP Approval Sheet

Entity/Role	Sections Approved*	Name	Signature/Date
MATRIX CTH Safety Physician	Sections 7, 8	Katherine Bunge, MD, MPH	<b>Signature:</b> <i>Katherine Bunge</i> <small>Electronically signed by: Katherine Bunge Reason: I have read this document and approved via Esignature Date: May 29, 2024 16:24 EDT</small> <b>Email:</b> bungke@upmc.edu
MATRIX CTH Lab Support	Section 9	May Beamer, BS Edward Livant, BSMT (ASCP), MPH	N/A
RTI/D2D Team	Section 11	Ellen Luecke, MPH	N/A
FHI360 DM	Section 12	Michele Fanton, BS	N/A

*\*Applicable section version numbers and dates as listed in Overview and Control Document table*












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