



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	1.0	18October2023	
08	Adverse Event Reporting and Safety Monitoring	1.0	18October2023	
09	Laboratory Considerations	2.0	19December2023	<ul style="list-style-type: none"> • removed weighing procedure for BXC for PD HIV (EVMS only) • updated PSA testing, cryovial description for swab collections, EQA submission requirements, formatting of tables
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	

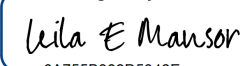
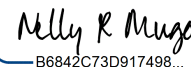


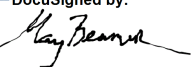

* Highest version number/date listed is current and supersedes all previous listed version(s). Notice of Changes summarizes any significant changes that have been made.

** 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	DocuSigned by:  1/12/2024 <small>6A755B382D5342E...</small>
Protocol Chair	All Sections	Nelly R Mugo, MBChB, MMed, MPH	DocuSigned by:  1/12/2024 <small>B6842C73D917498...</small>
MATRIX CTH CRM	All Sections	Ingrid Macio, PA-C	DocuSigned by:  1/11/2024 <small>094F6DEDE86E3469...</small>
CONRAD CPM	All Sections	Karen Dominguez, MPH	DocuSigned by:  1/11/2024 <small>481BB14CACE043C...</small>
MATRIX CTH Lab Support	Section 9	May Beamer, BS Edward Livant, BSMT (ASCP), MPH	DocuSigned by:  <small>A6E60A1AA579443...</small> 1/11/2024 DocuSigned by:  <small>9E61B06A181441D...</small> 1/11/2024

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SSP Approval Sheet

Entity/Role	Sections Approved*	Name	Signature/Date
MATRIX CTH Safety Physician	Sections 7, 8	Katherine Bunge, MD, MPH	NA
RTI/D2D Team	Section 11	Ellen Luecke, MPH	NA
FHI360 DM	Section 12	Michele Fanton, BS	NA

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