

MATRIX-003: Table of Contents

V2.2, 03MAY2024

Current MATRIX-003 CRFs by Study Visit

V1: Screening		
Required CRFs	Type of CRF	Version # & Date
Establish PTID	Clinical	V1.0, 05Jan2024
Demographic (DEM) CRF	Socio-Behavioral	V2.0 22Dec2023
ICF Summary	Clinical	V1.0, 05Jan2024
Baseline Medical and Menstrual History	Clinical	V1.0, 05Jan2024 V1.1, 26Feb2024
Screening Physical Exam and Vital Signs	Clinical	V1.0, 05Jan2024
Pelvic Exam	Clinical	V1.0, 05Jan2024
Hematology and Chemistry Results	Clinical	V1.0, 05Jan2024
HIV, STI, and Urine Test Results	Clinical	V1.0, 05Jan2024
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 05Jan2024
Pre-existing Conditions Log	Clinical	V1.0, 05Jan2024
Protocol Deviation Log	Clinical	V1.1, 12Apr2024

V2: Enrollment, Stage 1 (Day 0) Ring Assignment (1st ring)		
Required CRFs	Type of CRF	Version # & Date
MATRIX-003 Randomization Assignment	Clinical	V1.0, 05Jan2024
Pelvic Exam	Clinical	V1.0, 05Jan2024
HIV, STI and Urine Test Results	Clinical	V1.0, 05Jan2024
Updated Medical and Menstrual History	Clinical	V1.0, 05Jan2024
Specimen Storage	Clinical	V1.0, 05Jan2024
Visit Summary	Clinical	V1.0, 05Jan2024
Baseline behavioral (BEH) CRF	Socio-behavioral	V2.0 22Dec2023
Baseline acceptability (BL) CRF	Socio-behavioral	V2.0 22Dec2023
Clinician Observation for Insertion (COI) CRF	Socio-behavioral	V2.0 22Dec2023
Post-insertion acceptability (FU1) CRF	Socio-behavioral	V2.0 09Jan2024
PRN CRFs	Type of CRF	Version # & Date
PRN Hematology and Chemistry Results	Clinical	V1.0, 05Jan2024
PRN Symptom-directed Physical Exam	Clinical	V1.0, 05Jan2024
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 05Jan2024
Pre-existing Conditions Log	Clinical	V1.0, 05Jan2024
Protocol Deviation Log	Clinical	V1.1, 12Apr2024
Adverse Event Log	Clinical	V1.0, 05Jan2024
Social Harms and Benefits Assessment Log	Clinical	V1.0, 05Jan2024

V3: Stage 1, Day 7		
Required CRFs	Type of CRF	Version # & Date
Updated Medical and Menstrual History	Clinical	V1.0, 05Jan2024
Visit Summary	Clinical	V1.0, 05Jan2024

Brief acceptability (FU2) CRF	Socio-behavioral	V2.0 22Dec2023
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V4: Stage 1, Day 14

Required CRFs	Type of CRF	Version # & Date
Pelvic Exam	Clinical	V1.0, 05Jan2024
HIV, STI and Urine Test Results	Clinical	V1.0, 05Jan2024
Updated Medical and Menstrual History	Clinical	V1.0, 05Jan2024
Specimen Storage	Clinical	V1.0, 05Jan2024
Visit Summary	Clinical	V1.0, 05Jan2024
Follow-up behavioral and acceptability (FU3) CRF	Socio-behavioral	V2.0 22Dec2023
PRN CRFs	Type of CRF	Version # & Date
PRN Hematology and Chemistry Results	Clinical	V1.0, 05Jan2024
PRN Symptom-directed Physical Exam	Clinical	V1.0, 05Jan2024
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 05Jan2024
Pre-existing Conditions Log	Clinical	V1.0, 05Jan2024
Protocol Deviation Log	Clinical	V1.1, 12Apr2024
Adverse Event Log	Clinical	V1.0, 05Jan2024
Social Harms and Benefits Assessment Log	Clinical	V1.0, 05Jan2024

V5: Stage 1, Day 28

Required CRFs	Type of CRF	Version # & Date
Pelvic Exam	Clinical	V1.0, 05Jan2024
HIV, STI and Urine Test Results	Clinical	V1.0, 05Jan2024
Updated Medical and Menstrual History	Clinical	V1.0, 05Jan2024
Specimen Storage	Clinical	V1.0, 05Jan2024
Visit Summary	Clinical	V1.0, 05Jan2024
Clinical Observations for Removal (COR) CRF	Socio-behavioral	V2.0 22Dec2023 V2.1 07Mar2024
Follow-up behavioral and acceptability (FU4) CRF	Socio-behavioral	V2.0 22Dec2023 V2.1 07Mar2024
PRN CRFs	Type of CRF	Version # & Date
PRN Hematology and Chemistry Results	Clinical	V1.0, 05Jan2024
PRN Symptom-directed Physical Exam	Clinical	V1.0, 05Jan2024
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 05Jan2024
Pre-existing Conditions Log	Clinical	V1.0, 05Jan2024
Protocol Deviation Log	Clinical	V1.1, 12Apr2024
Adverse Event Log	Clinical	V1.0, 05Jan2024
Social Harms and Benefits Assessment Log	Clinical	V1.0, 05Jan2024

V6: Stage 2 (Day 0) Ring Assignment (2nd ring)		
Required CRFs	Type of CRF	Version # & Date
Pelvic Exam	Clinical	V1.0, 05Jan2024
HIV, STI and Urine Test Results	Clinical	V1.0, 05Jan2024
Updated Medical and Menstrual History	Clinical	V1.0, 05Jan2024
Specimen Storage	Clinical	V1.0, 05Jan2024
Visit Summary	Clinical	V1.0, 05Jan2024
Clinician Observation for Insertion (COI) CRF	Socio-behavioral	V2.0 22Dec2023
Post-insertion acceptability (FU1) CRF	Socio-behavioral	V2.0 09Jan2024
PRN CRFs	Type of CRF	Version # & Date
PRN Hematology and Chemistry Results	Clinical	V1.0, 05Jan2024
PRN Symptom-directed Physical Exam	Clinical	V1.0, 05Jan2024
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 05Jan2024
Pre-existing Conditions Log	Clinical	V1.0, 05Jan2024
Protocol Deviation Log	Clinical	V1.1, 12Apr2024
Adverse Event Log	Clinical	V1.0, 05Jan2024
Social Harms and Benefits Assessment Log	Clinical	V1.0, 05Jan2024

V7: Stage 2, Day 7		
Required CRFs	Type of CRF	Version # & Date
Updated Medical and Menstrual History	Clinical	V1.0, 05Jan2024
Visit Summary	Clinical	V1.0, 05Jan2024
Brief acceptability (FU2) CRF	Socio-behavioral	V2.0 22Dec2023

V8: Stage 2, Day 14		
Required CRFs	Type of CRF	Version # & Date
Pelvic Exam	Clinical	V1.0, 05Jan2024
HIV, STI and Urine Test Results	Clinical	V1.0, 05Jan2024
Updated Medical and Menstrual History	Clinical	V1.0, 05Jan2024
Specimen Storage	Clinical	V1.0, 05Jan2024
Visit Summary	Clinical	V1.0, 05Jan2024
Follow-up behavioral and acceptability (FU3) CRF	Socio-behavioral	V2.0 22Dec2023
PRN CRFs	Type of CRF	Version # & Date
PRN Hematology and Chemistry Results	Clinical	V1.0, 05Jan2024
PRN Symptom-directed Physical Exam	Clinical	V1.0, 05Jan2024
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 05Jan2024
Pre-existing Conditions Log	Clinical	V1.0, 05Jan2024
Protocol Deviation Log	Clinical	V1.1, 12Apr2024
Adverse Event Log	Clinical	V1.0, 05Jan2024
Social Harms and Benefits Assessment Log	Clinical	V1.0, 05Jan2024

V9: Stage 2, Day 28		
Required CRFs	Type of CRF	Version # & Date
Pelvic Exam	Clinical	V1.0, 05Jan2024
HIV, STI and Urine Test Results	Clinical	V1.0, 05Jan2024
Updated Medical and Menstrual History	Clinical	V1.0, 05Jan2024
Specimen Storage	Clinical	V1.0, 05Jan2024
Visit Summary	Clinical	V1.0, 05Jan2024
Clinical Observations for Removal (COR) CRF	Socio-behavioral	V2.0 22Dec2023 V2.1 07Mar2024
Follow-up behavioral and acceptability (FU4) CRF	Socio-behavioral	V2.0 22Dec2023 V2.1 07Mar2024
PRN CRFs	Type of CRF	Version # & Date
PRN Hematology and Chemistry Results	Clinical	V1.0, 05Jan2024
PRN Symptom-directed Physical Exam	Clinical	V1.0, 05Jan2024
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 05Jan2024
Pre-existing Conditions Log	Clinical	V1.0, 05Jan2024
Protocol Deviation Log	Clinical	V1.1, 12Apr2024
Adverse Event Log	Clinical	V1.0, 05Jan2024
Social Harms and Benefits Assessment Log	Clinical	V1.0, 05Jan2024

Interim Visit		
Required CRFs	Type of CRF	Version # & Date
Updated Medical and Menstrual History	Clinical	V1.0, 05Jan2024
Visit Summary	Clinical	V1.0, 05Jan2024
PRN CRFs	Type of CRF	Version # & Date
Pelvic Exam	Clinical	V1.0, 05Jan2024
HIV, STI and Urine Test Results	Clinical	V1.0, 05Jan2024
Specimen Storage	Clinical	V1.0, 05Jan2024
PRN Hematology and Chemistry Results	Clinical	V1.0, 05Jan2024
PRN Symptom-directed Physical Exam	Clinical	V1.0, 05Jan2024
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 05Jan2024
Pre-existing Conditions Log	Clinical	V1.0, 05Jan2024
Protocol Deviation Log	Clinical	V1.1, 12Apr2024
Adverse Event Log	Clinical	V1.0, 05Jan2024
Social Harms and Benefits Assessment Log	Clinical	V1.0, 05Jan2024
PRN Interim Report of Expulsion (Phone Call)	Type of CRF	Version # & Date
PRN Expulsion Log (EXP) CRF	Socio-behavioral	V1.0, 27Feb2024
Sexual Partner Events Log (SPE) CRF	Socio-behavioral	V1.0, 07Mar2024

Missed Visit		
PRN CRFs	Type of CRF	Version # & Date
PRN Missed Visit	Clinical	V1.0, 05Jan2024

Product Hold/Discontinuation		
Required CRFs when PTID exits Study	Type of CRF	Version # & Date
Participant Disposition	Clinical	V1.0, 05Jan2024
PRN CRFs	Type of CRF	Version # & Date
Study Product Hold/Discontinuation of Log	Clinical	V1.0, 05Jan2024
HIV Confirmatory	Clinical	V1.0, 05Jan2024
Pregnancy Report and Outcome	Clinical	V1.0, 05Jan2024

MATRIX-003 Sexual Partner Visit		
Required CRFs	Type of CRF	Version # & Date
Establish Sexual Partner PTID	MATRIX-003 Sexual Partner Database	V1.0, 27Feb2024
Sexual Partner ICF	MATRIX-003 Sexual Partner Database	V1.0, 27Feb2024
Sexual Partner Demographic and Acceptability (SPDEM) CRF	MATRIX-003 Sexual Partner Database	V2.0, 22Dec2023 V2.1 07Mar2024
PRN CRFs	Type of CRF	Version # & Date
Sexual Partner Protocol Deviations	MATRIX-003 Sexual Partner Database	V1.0, 27Feb2024
Sexual Partner Social Benefits	MATRIX-003 Sexual Partner Database	V1.0, 27Feb2024

Current MATRIX-003 IDI Materials

MATRIX-003 Clinical Trial Participants (IDI Subset)		
Name of material	Type of form	Version # & Date
Participant IDI Guide (IDI)	Paper	V2.0, 22Dec2023
Participant IDI Debriefing Report	REDCap	V1.0, 14Feb2024

MATRIX-003 Sexual Partner IDI Participants		
Name of material	Type of form	Version # & Date
Sexual Partner IDI Guide (SP IDI)	Paper	V2.0, 22Dec2023
Sexual Partner Debriefing Report	REDCap	V1.0, 14Feb2024