

MATRIX-002: Data Collection Materials Table of Contents

V2.2, 12APR2024

Current MATRIX-002 CRFs by Study Visit

V1: Screening		
Required CRFs	Type of CRF	Version # & Date
Establish PTID	Clinical	V1.0, 12Oct2023
Demographic (DEM) CRF	Socio-Behavioral	V2.1, 02Oct2023
ICF Summary	Clinical	V1.0, 12Oct2023
Baseline Medical and Menstrual History	Clinical	V1.0, 12Oct2023
Screening Physical Exam and Vital Signs	Clinical	V1.0, 12Oct2023
Pelvic Exam	Clinical	V1.0, 12Oct2023
Hematology and Chemistry Results	Clinical	V1.0, 12Oct2023
HIV, STI, and Urine Test Results	Clinical	V1.0, 12Oct2023
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 12Oct2023
Pre-existing Conditions Log	Clinical	V1.0, 12Oct2023
Protocol Deviation Log	Clinical	V1.1, 12Apr2024

V2: Enrollment, 1st Film		
Required CRFs	Type of CRF	Version # & Date
MATRIX-002 Randomization	Clinical	V1.0, 12Oct2023
Pelvic Exam	Clinical	V1.0, 12Oct2023
HIV, STI and Urine Test Results	Clinical	V1.0, 12Oct2023
Updated Medical and Menstrual History	Clinical	V1.0, 12Oct2023
Specimen Storage	Clinical	V1.0, 12Oct2023
Visit Summary	Clinical	V1.0, 12Oct2023
Baseline behavioral (BEH) CRF	Socio-behavioral	V2.1, 02Oct2023
Baseline acceptability (BL) CRF	Socio-behavioral	V2.1, 02Oct2023
Clinician Observation (CO) CRF	Socio-behavioral	V2.1, 02Oct2023
Post-insertion acceptability (FU1) CRF	Socio-behavioral	V2.1, 02Oct2023
PRN CRFs	Type of CRF	Version # & Date
PRN Hematology and Chemistry Results	Clinical	V1.0, 12Oct2023
PRN Targeted Physical Exam	Clinical	V1.0, 12Oct2023
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 12Oct2023
Pre-existing Conditions Log	Clinical	V1.0, 12Oct2023
Protocol Deviation Log	Clinical	V1.1, 12Apr2024
Adverse Event Log	Clinical	V1.0, 12Oct2023
Social Harms and Benefits Assessment Log	Clinical	V1.0, 12Oct2023

V3: 24-72 Hour Phone Contact		
Required CRFs	Type of CRF	Version # & Date
Visit Summary	Clinical	V1.0, 12Oct2023
Brief acceptability (FU2) CRF	Socio-behavioral	V2.1, 12Oct2023
Brief acceptability (FU2) CRF	Socio-behavioral	V3.0, 08Feb2024

V4: Week 1 Phone Contact		
Required CRFs	Type of CRF	Version # & Date
Updated Medical and Menstrual History	Clinical	V1.0, 12Oct2023
Visit Summary	Clinical	V1.0, 12Oct2023
Brief acceptability (FU2) CRF	Socio-behavioral	V2.1, 12Oct2023
Brief acceptability (FU2) CRF	Socio-behavioral	V3.0, 08Feb2024

V5: Week 2 Phone Contact		
Required CRFs	Type of CRF	Version # & Date
Updated Medical and Menstrual History	Clinical	V1.0, 12Oct2023
Visit Summary	Clinical	V1.0, 12Oct2023
Brief acceptability (FU2) CRF	Socio-behavioral	V2.1, 12Oct2023
Brief acceptability (FU2) CRF	Socio-behavioral	V3.0, 08Feb2024

V6: Week 4 Clinic Follow-up, 2nd Film		
Required CRFs	Type of CRF	Version # & Date
Pelvic Exam	Clinical	V1.0, 12Oct2023
HIV, STI and Urine Test Results	Clinical	V1.0, 12Oct2023
Updated Medical and Menstrual History	Clinical	V1.0, 12Oct2023
Specimen Storage	Clinical	V1.0, 12Oct2023
Visit Summary	Clinical	V1.0, 12Oct2023
Clinician Observation (CO) CRF	Socio-behavioral	V2.1, 02Oct2023
Post-insertion acceptability (FU1) CRF	Socio-behavioral	V2.1, 02Oct2023
Follow-up behavioral and acceptability (FU3) CRF	Socio-behavioral	V2.1, 12Oct2023
Follow-up behavioral and acceptability (FU3) CRF	Socio-behavioral	v2.2, 08Feb2024
PRN CRFs	Type of CRF	Version # & Date
PRN Hematology and Chemistry Results	Clinical	V1.0, 12Oct2023
PRN Targeted Physical Exam	Clinical	V1.0, 12Oct2023
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 12Oct2023
Pre-existing Conditions Log	Clinical	V1.0, 12Oct2023
Protocol Deviation Log	Clinical	V1.1, 12Apr2024
Adverse Event Log	Clinical	V1.0, 12Oct2023
Social Harms and Benefits Assessment Log	Clinical	V1.0, 12Oct2023

V7: 24-72 Hour Phone Contact		
Required CRFs	Type of CRF	Version # & Date
Visit Summary	Clinical	V1.0, 12Oct2023
Brief acceptability (FU2) CRF	Socio-behavioral	V2.1, 12Oct2023
Brief acceptability (FU2) CRF	Socio-behavioral	V3.0, 08Feb2024

V8: Week 6 Phone Contact		
Required CRFs	Type of CRF	Version # & Date
Updated Medical and Menstrual History	Clinical	V1.0, 12Oct2023
Visit Summary	Clinical	V1.0, 12Oct2023

Brief acceptability (FU2) CRF	Socio-behavioral	V2.1, 12Oct2023
Brief acceptability (FU2) CRF	Socio-behavioral	V3.0, 08Feb2024

V9: Week 8 Clinic Follow-up

Required CRFs	Type of CRF	Version # & Date
Pelvic Exam	Clinical	V1.0, 12Oct2023
Hematology and Chemistry Results	Clinical	V1.0, 12Oct2023
HIV, STI and Urine Test Results	Clinical	V1.0, 12Oct2023
Updated Medical and Menstrual History	Clinical	V1.0, 12Oct2023
Specimen Storage	Clinical	V1.0, 12Oct2023
Visit Summary	Clinical	V1.0, 12Oct2023
Final behavior and acceptability (FU4) CRF	Socio-behavioral	V2.1, 12Oct2023
Final behavior and acceptability (FU4) CRF	Socio-behavioral	v2.2, 08Feb2024
PRN CRFs	Type of CRF	Version # & Date
PRN Targeted Physical Exam	Clinical	V1.0, 12Oct2023
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 12Oct2023
Pre-existing Conditions Log	Clinical	V1.0, 12Oct2023
Protocol Deviation Log	Clinical	V1.1, 12Apr2024
Adverse Event Log	Clinical	V1.0, 12Oct2023
Social Harms and Benefits Assessment Log	Clinical	V1.0, 12Oct2023

V10: Week 9 Final Phone Contact

Required CRFs	Type of CRF	Version # & Date
Updated Medical and Menstrual History	Clinical	V1.0, 12Oct2023
Visit Summary	Clinical	V1.0, 12Oct2023

Interim Visit

Required CRFs	Type of CRF	Version # & Date
Updated Medical and Menstrual History	Clinical	V1.0, 12Oct2023
Visit Summary	Clinical	V1.0, 12Oct2023
PRN CRFs	Type of CRF	Version # & Date
Pelvic Exam	Clinical	V1.0, 12Oct2023
HIV, STI and Urine Test Results	Clinical	V1.0, 12Oct2023
Specimen Storage	Clinical	V1.0, 12Oct2023
PRN Hematology and Chemistry Results	Clinical	V1.0, 12Oct2023
PRN Targeted Physical Exam	Clinical	V1.0, 12Oct2023
PRN Ongoing Logs	Type of CRF	Version # & Date
Concomitant Medications Log	Clinical	V1.0, 12Oct2023
Pre-existing Conditions Log	Clinical	V1.0, 12Oct2023
Protocol Deviation Log	Clinical	V1.1, 12Apr2024
Adverse Event Log	Clinical	V1.0, 12Oct2023
Social Harms and Benefits Assessment Log	Clinical	V1.0, 12Oct2023
PRN Interim Report of Expulsion (Phone Call)	Type of CRF	Version # & Date
PRN Expulsion Log (EXP)	Socio-behavioral	V1.0, 19Feb2024

Missed Visit		
PRN CRFs	Type of CRF	Version # & Date
PRN Missed Visit	Clinical	V1.0, 12Oct2023

Product Hold/Discontinuation		
Required CRFs when PTID exits Study	Type of CRF	Version # & Date
Participant Disposition	Clinical	V1.0, 12Oct2023
PRN CRFs	Type of CRF	Version # & Date
Study Product Hold/Discontinuation of Log	Clinical	V1.0, 12Oct2023
HIV Confirmatory	Clinical	V1.0, 12Oct2023
Pregnancy Report and Outcome	Clinical	V1.0, 12Oct2023

MATRIX-002 Sexual Partner Visit		
Required CRFs	Type of CRF	Version # & Date
Establish Sexual Partner PTID	MATRIX-002 Sexual Partner Database	V1.1, 26Feb2024
Sexual Partner ICF	MATRIX-002 Sexual Partner Database	V1.0, 12Oct2023
Sexual Partner Demographic (SPDEM) form	MATRIX-002 Sexual Partner Database	V2.1, 02Oct2023
PRN CRFs	Type of CRF	Version # & Date
Sexual Partner Protocol Deviations	MATRIX-002 Sexual Partner Database	V1.0, 12Oct2023
Sexual Partner Social Benefits	MATRIX-002 Sexual Partner Database	V1.0, 12Oct2023

Current MATRIX-002 IDI Materials

MATRIX-002 Clinical Trial Participants (IDI Subset)		
Name of material	Type of form	Version # & Date
Participant IDI Guide	Paper	V1.0, 02Jun2023
Participant IDI Debriefing Report	REDCap	V1.0, 19Oct2023

MATRIX-002 Sexual Partner IDI Participants		
Name of material	Type of form	Version # & Date
Sexual Partner IDI Guide	Paper	V1.0, 05Jun2023
Sexual Partner Debriefing Report	REDCap	V1.0, 20Oct2023