Subject Case Report Forms

MTN034_Version_10.0_PROD_TP_30NOV2021 - All

Signature Prompt: I certify that I have ensured the accuracy and completeness of the data reported in the Case Report Forms.

Screening visit date _____

Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Eligibility Status	Ineligible ☐ Eligible, but participant declined enrollment ☐ Eligible and enrolled ☐ Incomplete screening ☐
Date participant was found "Eligible/Not Enrolled" or "Ineligible" or "Incomplete screening".	
If eligible, but participant declined enrollment, specify reason:	

If 'eligible and enrolled', "Eligible, but participant declined enrollment" or "Incomplete screening", end of form.

Was the participant enrolled into MTN-034?	Yes ☐ No ☐
Select reason(s) why participant is ineligible	I1. Age 16 through 21 years (inclusive) at Enrollment, verified per site standard operating procedures (SOPs). ☐ I2. Able and willing to provide informed consent, and if under the legal age of consent be able to provide informed assent and obtain parental or guardian permission/consent, to be screened for and to enroll in MTN-034 ☐ I3. Able and willing to provide adequate locator information, as defined in site SOPs. ☐ I4. Able and willing to comply with all study procedural requirements. ☐ I5. Per participant report at Screening, post-menarche. ☐ I6. HIV-uninfected based on testing performed at Screening and Enrollment (per protocol algorithms in Appendices II and III). ☐ I7. Per participant report at Screening, history of at least one episode of sexual intercourse in participant's lifetime. ☐ I8. Negative pregnancy test at Screening and Enrollment. ☐ I9. Per participant report, use of an effective method of contraception for at least two months prior to Enrollment, and intending to continue use of an effective method during study participation ☐

- [ ] I10. Per participant report at Screening, willing to abstain from inserting anything into the vagina for 72 hours prior to each study visit, including receptive intercourse
- [ ] I11. At Screening/Enrollment, agrees not to participate in other research studies involving drugs, medical devices, vaginal products, or vaccines during study participation unless approved by PSRT
- [ ] E1a. Per participant report at Screening and Enrollment, intends to become pregnant during the study participation period
- [ ] E1b. Per participant report at Screening and Enrollment, intends to access and/or use oral PrEP outside the context of study participation during the study participation period
- [ ] E1c. Per participant report at Screening and Enrollment, intends to relocate away from the study site.
- [ ] E1d. Per participant report at Screening and Enrollment, intends to travel away from the study site for a time period that would interfere with product resupply and study participation.
- [ ] E2. At Screening or Enrollment, has a positive HIV test.
- [ ] E3 Diagnosed with UTI, PID, STI or reproductive tract infection (RTI) requiring treatment per WHO guidelines at Screening or Enrollment.
- [ ] E4. At Enrollment, has a clinically apparent Grade 2 or higher pelvic exam finding.
- [ ] E5a. Participant report and/or clinical evidence of known adverse reaction to any of the study products (ever).
- [ ] E5b. Participant report and/or clinical evidence of known adverse reaction to latex and polyurethane (ever).
- [ ] E5c. Participant report and/or clinical evidence of symptoms suggestive of acute HIV infection at Screening or Enrollment.
- [ ] E5d. Participant report and/or clinical evidence of non-therapeutic injection drug use in the 12 months prior to Enrollment.

	E5e. Participant report and/or clinical evidence of use of HIV PEP and/or PrEP within the 3 months prior to Enrollment. ☐
	E5f. Participant report and/or clinical evidence of currently breastfeeding. ☐
	E5g. Participant report and/or clinical evidence of last pregnancy outcome within 8 weeks or less of Enrollment. ☐
	E5h. Participant report and/or clinical evidence of participation in any other research study involving drugs, medical devices, vaginal products or vaccines within 60 days of Enrollment. ☐
	E5i. At Enrollment has significant uncontrolled active or chronic cardiovascular/renal/liver/hematologic/neurologic/GI/psychiatric/endocrine/respiratory/immunologic disorder or infectious disease. ☐
	E6a. Positive for hepatitis B surface antigen (HBsAG) at Screening Visit. ☐
	E6b. Hemoglobin Grade 2 or higher at Screenining Visit ☐
	E6c. Calculated creatinine clearance less than 60 mL/min by the Schwartz Equation at Screening Visit. ☐
	E7. Has a condition that, per IoR/designee, preclude informed assent/consent, make study participation unsafe, complicate interpretation of outcome data or interfere with achieving study objectives ☐
If "Investigator decision", specify (max. 200 characters):	
Source Data Upload	

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Screening Menstrual History
Generated On: 30 Nov 2021 19:52:11

Date of assessment	
First day of last menstrual period	
First day of last menstrual period	
OR	
Amenorrheic for past 6 months	☐
Last day of last menstrual period	
Last day of last menstrual period	
OR	
Ongoing	☐
Provide additional details to describe the participant's baseline menstrual bleeding pattern. (Max. 400 characters)	
Source Data Upload	

Was this visit completed?	Yes ☐ No ☐

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Follow-up Visit Summary
Generated On: 30 Nov 2021 19:52:11

Visit date	
Was study product held at this visit? If yes, complete a Product Hold form.	Yes ☐ No ☐
Was study product permanently discontinued (scheduled or early) at this visit? If yes, complete a Product Discontinuation form.	Yes ☐ No ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit? If yes, complete the AE Log.	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported? If yes, complete the Concomitant Medications Log.	Yes ☐ No ☐
Have any protocol deviations been reported at this visit? If yes, complete the Protocol Deviation Log.	Yes ☐ No ☐
Were any additional study procedures or forms completed outside of the scheduled study visit per protocol? If yes, complete the Additional Study Procedures form.	Yes ☐ No ☐
Complete at Visit 16 Only:	
What study product will the participant initiate at the start of Period 3 (Visit 16)?	Tablets ☐ Vaginal Ring ☐ Neither ☐
Source Data Upload	

Is the participant ready to be randomized?	Yes ☐ No ☐
Randomization Date and Time	
Randomization ID	

Was an ACASI questionnaire completed at this visit?	Yes ☐ No ☐
If "No", please explain:	

ACASI collection date	_____
Which questionnaire was completed?	☐ Visit 2 (Enrollment) ☐ Visit 6/13/20 Ring ☐ Visit 6/13/20 Tablet ☐ Visit 9 Ring ☐ Visit 9 Tablet ☐ Visit 16 Ring ☐ Visit 16 Tablet ☐ Visit 20 No product ☐ Visit 23 Ring ☐ Visit 23 Tablet ☐ Visit 23 No product ☐ Early PUEV/Discontinuer Ring ☐ Early PUEV/Discontinuer Tablet ☐ Early PUEV/Discontinuer No product
Reason Early PUEV/Discontinuers ACASI questionnaire was completed:	☐ Early Termination ☐ Permanent product discontinuation prior to PUEV/Early Termination
Were there any problems or issues related to the administration or completion of the questionnaire?	☐ Yes ☐ No
If "Yes", please describe:	_____
Source Data Upload	_____

Was a physical exam performed? Yes ☐ No ☐

Exam date _____

For each organ system or body part evaluated, indicate whether the finding(s) were normal or abnormal. If abnormal, describe the finding(s) in the text field provided. If an organ system or body part is not evaluated, select “Not Done".

General Appearance Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Head, Eye, Ear, Nose, and Throat Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Neck Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Lymph Nodes Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Heart/Cardiovascular Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Lungs/Respiratory Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Abdomen Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Extremities Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Neurological	Not Done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	
Skin	Not Done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	
Other	Not Done ☐ Normal ☐ Abnormal ☐
If "Other" is "Normal" or "Abnormal", specify:	
Source Data Upload	

Were vital signs done?	Yes ☐ No ☐
Date of assessment	
Height	Fixed Unit: centimeters
Not done	☐
Weight	Fixed Unit: kilograms
Not done	☐
Body Temperature	Fixed Unit: Celsius
Systolic BP	Fixed Unit: mmHg
Diastolic BP	Fixed Unit: mmHg
Blood Pressure Severity Grade	Not gradable ☐ Mild ☐ Moderate ☐ Severe ☐ Potentially Life-threatening ☐
Blood Pressure adverse event, if applicable	
Not reportable as an adverse event	☐
Pulse	Fixed Unit: beats per minute
Rate of respiration	Fixed Unit: breaths per minute
Source Data Upload	

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Pregnancy Test Results
Generated On: 30 Nov 2021 19:52:11

Was a pregnancy test done?	Yes ☐ No ☐
Date of Pregnancy Test	_____
Test result	Positive ☐ Negative ☐
If pregnancy test result is "Positive", complete the Pregnancy Report and Pregnancy History forms.	
First day of last menstrual period	_____
OR	
No menses	No menses since participant's last visit ☐ Amenorrheic for past 6 months ☐
If "Amenorrheic for past 6 months" or "No menses since participant's last visit" is marked, end of form.	
Last day of last menstrual period	_____
OR	
Ongoing	☐
Source Data Upload	_____

Date of study exit	_____
Did the participant complete the study?	Yes ☐ No ☐
If participant completed the study, end of form.	
Primary reason for non-completion	Death ☐ Withdrawal of consent by participant ☐ Lost to follow-up ☐ Investigator decision ☐ Study terminated by sponsor ☐ Pregnancy ☐ Other ☐
If "Withdrawal of consent by participant", "Investigator decision", or "Other", specify:	_____
If "Death", enter date of death.	_____
Was termination associated with an adverse event?	Yes ☐ No ☐ Don't know ☐
If "Yes", select applicable Adverse Event.	_____
Source Data Upload	_____

Has the participant experienced an Adverse Event during the study?	Yes ☐ No ☐

If Yes, please complete the Adverse Event Log.

Date reported to site	_____
Adverse Event (AE)	_____
Onset date	_____
At which visit was this AE first reported?	V1 - Screening ☐ V2 - Enrollment: Period 1 Study Product Initiation ☐ V3 - Week 1 ☐ V4 - Week 4 ☐ V5 - Week 8 ☐ V6 - Week 12 ☐ V7 - Week 16 ☐ V8 - Week 20 ☐ V9 - Week 24: Period 1 Study Product Use End/Period 2 Study Product Intiation ☐ V10 - Week 25 ☐ V11 - Week 28 ☐ V12 - Week 32 ☐ V13 - Week 36 ☐ V14 - Week 40 ☐ V15 - Week 44 ☐ V16 - Week 48: Period 2 Study Product Use End/Period 3 Study Product Initiation ☐ V17 - Week 49 ☐ V18 - Week 52 ☐ V19 - Week 56 ☐ V20 - Week 60 ☐ V21 - Week 64 ☐ V22 - Week 68 ☐ V23 - Week 72: PUEV ☐ V24 - Week 73: Study Exit/Termination ☐ Interim Visit ☐
If "Interim visit" is chosen, provide interim visit code	_____
Is the AE still ongoing?	Yes ☐ No ☐
If no, outcome date	_____
Toxicity (Severity) Grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐

	Grade 5 (Death) ☐
Relationship to study product Record rationale or alternative etiology in Comments text field below.If "not related" go to, "Action Taken with Study Product".	Related ☐ Not Related ☐
If "related", which product is the AE thought to be related to? If "Oral Truvada", go to "Action Taken with Study Product".	DPV vaginal ring ☐ Oral Truvada ☐
If “related” to the DPV vaginal ring, is the AE related to the drug (dapivirine) or device (ring itself or ring insertion)?	Drug (dapivirine) ☐ Device (ring) ☐ Cannot distinguish between drug-device components ☐
Action taken with Study product	dose not changed ☐ dose reduced ☐ dose increased ☐ drug withdrawn ☐ drug interrupted ☐ not applicable ☐
Other treatment(s) taken Mark all that apply. None	☐
Medication	☐
Therapeutic procedure/surgery	☐
Diagnostic procedure	☐
Other	☐
If "Other", specify:	_____
Status/Outcome	Recovered/resolved ☐ Recovering/resolving ☐ Recovered/resolved with sequelae ☐ Not recovered/not resolved ☐ Fatal ☐ Severity/frequency increased ☐
Is this a Serious Adverse Event? If an SAE, respond to the following items. If "No", go to "Has or will this AE be reported as an EAE".	Yes ☐ No ☐
Results in death	☐
Is life-threatening	☐
Requires inpatient hospitalization or prolongation of existing hospitalization	☐

Results in persistent or significant disability/incapacity	☐
Is a congenital anomaly/birth defect	☐
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	☐
SAE/EAE onset date	
Has or will this AE be reported as an EAE?	Yes ☐ No ☐
If yes, EAE number	
Was this AE a worsening of a baseline medical condition?	Yes ☐ No ☐
Comments (Max. 400 characters)	
Source Data Upload	

Does the participant have any baseline medical history to report? Yes ☐ No ☐

If yes, complete the Baseline Medical History Log. Please remember to include any abnormal Screening or Enrollment pelvic or physical exam findings, and any Screening or Enrollment lab abnormalities.

Date medical history collected	
Description of medical condition/event	
Is condition/event gradable?	Yes ☐ No ☐
Toxicity (Severity) Grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Date medical condition/event started	
Is the condition ongoing?	Yes ☐ No ☐
Date medical condition/event ended/resolved	
Source Data Upload	

Were any concomitant medications taken by the participant?	Yes ☐ No ☐

If Yes, complete the Concomitant Medications Log.

Medication Name _____

Indication _____

Date Started _____

Date Stopped _____

Or, Ongoing ☐

Frequency

- QD ☐
- BID ☐
- TID ☐
- QID ☐
- QM ☐
- QH ☐
- ONCE ☐
- Other ☐

If "Other" Frequency, specify: _____

Route

- Oral ☐
- Intramuscular ☐
- Intravenious ☐
- Topical ☐
- Vaginal ☐
- Rectal ☐
- Subcutaneous ☐
- Other ☐

If "Other" Route, specify: _____

Dose _____

Dose Unknown ☐

Dose Units

- Grams ☐
- Micrograms ☐
- Milligrams ☐
- Milliliters ☐
- Capsules ☐
- Drops ☐
- Puffs ☐
- Sachets ☐
- Suppository ☐
- Tablets ☐
- Units ☐
- Unknown ☐
- Other ☐

If "Other" Dose Units, specify:	
Taken for a reported AE?	Yes ☐ No ☐
Applicable Adverse Event #1	
Applicable Adverse Event #2	
Applicable Adverse Event #3	
Applicable Adverse Event #4	
Source Data Upload	

Have any protocol deviations occurred?	Yes ☐ No ☐

If yes, complete the Protocol Deviation Log.

Site awareness date	
Deviation date	
Has or will this deviation be reported to local IRB/EC?	Yes ☐ No ☐
Has or will this deviation be reported to DAIDS as a critical event?	Yes ☐ No ☐
Type of deviation	Inappropriate enrollment ☐ Failure to follow randomization or blinding procedures ☐ Study product management deviation ☐ Study product dispensing error ☐ Study product use/non-use deviation ☐ Study product sharing ☐ Study product not returned ☐ Conduct of non-protocol procedure ☐ Improper AE/EAE follow-up ☐ Unreported AE ☐ Unreported EAE ☐ Breach of confidentiality ☐ Physical assessment deviation ☐ Lab assessment deviation ☐ Mishandled lab specimen ☐ Staff performing duties that they are not qualified to perform ☐ Questionnaire administration deviation ☐ Counseling deviation ☐ Use of non-IRB/EC-approved materials ☐ Use of excluded concomitant medications, devices, or non-study products. ☐ Informed consent process deviation ☐ Visit completed outside of window ☐ Other ☐
Description of deviation	
Plans and/or action taken to address the deviation	
Plans and/or action taken to prevent future occurrences of the deviation	
Deviation reported by	Fixed Unit: Staff code
Source Data Upload	

Has the participant reported a social impact during the study?	Yes ☐ No ☐

If yes, complete the Social Impact Log.

Date reported to site	
Concisely describe social impact:	
Onset Date	
Reported at visit:	V1 - Screening ☐
	V2 - Enrollment: Period 1 Study Product Initiation ☐
	V3 - Week 1 ☐
	V4 - Week 4 ☐
	V5 - Week 8 ☐
	V6 - Week 12 ☐
	V7 - Week 16 ☐
	V8 - Week 20 ☐
	V9 - Week 24: Period 1 Study Product Use End/Period 2 Study Product Intiation ☐
	V10 - Week 25 ☐
	V11 - Week 28 ☐
	V12 - Week 32 ☐
	V13 - Week 36 ☐
	V14 - Week 40 ☐
	V15 - Week 44 ☐
	V16 - Week 48: Period 2 Study Product Use End/Period 3 Study Product Initiation ☐
	V17 - Week 49 ☐
	V18 - Week 52 ☐
	V19 - Week 56 ☐
	V20 - Week 60 ☐
	V21 - Week 64 ☐
	V22 - Week 68 ☐
	V23 - Week 72: PUEV ☐
	V24 - Week 73: Study Exit/Termination ☐
	Interim Visit ☐
If Interim visit, specify Interim visit code	
Social impact type	Education - Been turned down by an educational program, told to leave an educational program, study visits interfering with school attendance/performance, or experienced other problems at school ☐

	Employment - Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work ☐
	Housing - Had trouble getting or keeping housing, had negative experience with landlord, or had other problems to housing ☐
	Medical/Dental - Been refused medical or dental treatment, or treated negatively by a health care provider ☐
	Personal Relationships - Had negative experiences with family (excluding partner) ☐
	Personal Relationships - Had negative experiences with significant other, spouse, or sex partner ☐
	Personal Relationships (Other) - Had negative experiences with friends, neighbors or other community members ☐
	Travel/Immigration - Had problems obtaining fomal permission to travel or enter another country, such as being denied a visa, or had a problem with immigration/naturalization ☐
	Other - Had other problems not covered in the list above ☐
Did this involve physical harm to the participant?	Yes ☐
	No ☐
Did this involve physical or other harm to participant's child(ren)?	Yes ☐
	No ☐
What impact did this situation have on the participant's quality of life?	Minimal disturbance ☐
	Moderate disturbance; no significant impact ☐
	Major disturbance with significant impact ☐
Describe what was done by staff and participant to address social impact	
Participant:	_____
Staff:	_____
Record current status:	Unresolved ☐
If either Unable to resolve or resolved, please enter closure date:	Unresolved at end of study ☐
	Unable to resolve; no further action taken ☐
	Resolved ☐

If either "unable to resolve; no further action" or "resolved" is marked, enter closure date:	
Source Data Upload	

Does the participant have any clinical product holds to be applied?	Yes ☐ No ☐

If "Yes", complete the Product Hold Log.

Date when study product hold was initiated _____

Visit when study product hold was initiated

- ☐ V1 - Screening
- ☐ V2 - Enrollment: Period 1 Study Product Initiation
- ☐ V3 - Week 1
- ☐ V4 - Week 4
- ☐ V5 - Week 8
- ☐ V6 - Week 12
- ☐ V7 - Week 16
- ☐ V8 - Week 20
- ☐ V9 - Week 24: Period 1 Study Product Use End/Period 2 Study Product Intiation
- ☐ V10 - Week 25
- ☐ V11 - Week 28
- ☐ V12 - Week 32
- ☐ V13 - Week 36
- ☐ V14 - Week 40
- ☐ V15 - Week 44
- ☐ V16 - Week 48: Period 2 Study Product Use End/Period 3 Study Product Initiation
- ☐ V17 - Week 49
- ☐ V18 - Week 52
- ☐ V19 - Week 56
- ☐ V20 - Week 60
- ☐ V21 - Week 64
- ☐ V22 - Week 68
- ☐ V23 - Week 72: PUEV
- ☐ V24 - Week 73: Study Exit/Termination
- ☐ Interim Visit

If 'Interim visit' is chosen, provide interim visit code: _____

Why is study product being held?

- ☐ Reactive rapid HIV test
- ☐ Adverse Event
- ☐ Reported use of PEP
- ☐ Pregnancy
- ☐ Breastfeeding

	Participant unable/unwilling to comply with required study procedures, or o/w might be put at undue risk to their safety and well-being by continuing product use according to judgment of IoR/designee ☐
	Other ☐
If "Other", specify:	
Adverse Event:	
Concomitant Medication:	
Concomitant Medication:	
Concomitant Medication:	
Concomitant Medication:	
Date of last study product use:	
Was the participant instructed to resume study product use?	Yes ☐
	No - permanently discontinued ☐
	No - early termination ☐
If 'no - permanently discontinued', 'no - early termination' or 'no - hold continuing at scheduled PUEV', complete the Product Discontinuation form.	No - Hold continuing at scheduled PUEV ☐
	No - hold continuing for another reason ☐
Date study product resumed	
Date study product hold continuing for another reason	
Source Data Upload	

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Participant Transfer
Generated On: 30 Nov 2021 19:52:11

Name of transferring study site	Emavundleni CRS ☐ Kisumu CRS ☐ MU-JHU CRS ☐ Spilhaus CRS ☐ Wits RHI CRS ☐
Name of receiving study site	Emavundleni CRS ☐ Kisumu CRS ☐ MU-JHU CRS ☐ Spilhaus CRS ☐ Wits RHI CRS ☐
Date participant records were sent to receiving study site	_____
Source Data Upload	_____

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Participant Receipt
Generated On: 30 Nov 2021 19:52:11

Name of receiving study site	Emavundleni CRS ☐ Kisumu CRS ☐ MU-JHU CRS ☐ Spilhaus CRS ☐ Wits RHI CRS ☐
Name of transferring study site	Emavundleni CRS ☐ Kisumu CRS ☐ MU-JHU CRS ☐ Spilhaus CRS ☐ Wits RHI CRS ☐
Date informed consent signed at receiving site	_____
Did the participant provide informed consent for specimen storage at receiving study site?	Yes ☐ No ☐
Date informed consent for specimen storage was signed at receiving site	_____
Source Data Upload	_____

Specimen Type	Plasma ■
	Dried Blood Spot for PK ☐
	HSV-2 Antibody ☐
	Gram Stain of Vaginal Smear ☐
	Vaginal Swab for Biomarkers ☐
	Cervical Swabs for Biomarkers ☐
	Vaginal Swabs for qPCR (microbiota) ☐
	CVL Supernatant for Biomarkers ☐
	CVL Pellet for Biomarkers ☐
	Cervical Cytobrush ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Plasma ☐
	Dried Blood Spot for PK ■
	HSV-2 Antibody ☐
	Gram Stain of Vaginal Smear ☐
	Vaginal Swab for Biomarkers ☐
	Cervical Swabs for Biomarkers ☐
	Vaginal Swabs for qPCR (microbiota) ☐
	CVL Supernatant for Biomarkers ☐
	CVL Pellet for Biomarkers ☐
	Cervical Cytobrush ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Plasma ☐
	Dried Blood Spot for PK ☐
	HSV-2 Antibody ■

	Gram Stain of Vaginal Smear ☐
	Vaginal Swab for Biomarkers ☐
	Cervical Swabs for Biomarkers ☐
	Vaginal Swabs for qPCR (microbiota) ☐
	CVL Supernatant for Biomarkers ☐
	CVL Pellet for Biomarkers ☐
	Cervical Cytobrush ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Plasma ☐
	Dried Blood Spot for PK ☐
	HSV-2 Antibody ☐
	Gram Stain of Vaginal Smear ■
	Vaginal Swab for Biomarkers ☐
	Cervical Swabs for Biomarkers ☐
	Vaginal Swabs for qPCR (microbiota) ☐
	CVL Supernatant for Biomarkers ☐
	CVL Pellet for Biomarkers ☐
	Cervical Cytobrush ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Plasma ☐
	Dried Blood Spot for PK ☐
	HSV-2 Antibody ☐
	Gram Stain of Vaginal Smear ☐
	Vaginal Swab for Biomarkers ■
	Cervical Swabs for Biomarkers ☐

	Vaginal Swabs for qPCR (microbiota) ☐
	CVL Supernatant for Biomarkers ☐
	CVL Pellet for Biomarkers ☐
	Cervical Cytobrush ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Plasma ☐
	Dried Blood Spot for PK ☐
	HSV-2 Antibody ☐
	Gram Stain of Vaginal Smear ☐
	Vaginal Swab for Biomarkers ☐
	Cervical Swabs for Biomarkers ■
	Vaginal Swabs for qPCR (microbiota) ☐
	CVL Supernatant for Biomarkers ☐
	CVL Pellet for Biomarkers ☐
	Cervical Cytobrush ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Plasma ☐
	Dried Blood Spot for PK ☐
	HSV-2 Antibody ☐
	Gram Stain of Vaginal Smear ☐
	Vaginal Swab for Biomarkers ☐
	Cervical Swabs for Biomarkers ☐
	Vaginal Swabs for qPCR (microbiota) ■
	CVL Supernatant for Biomarkers ☐
	CVL Pellet for Biomarkers ☐

	Cervical Cytobrush ☐
Was sample collected?	Yes ☐ No ☐
Specimen Collection Date	
Was sample stored?	Stored ☐ Not stored ☐
If no, record reason why sample was not stored.	
Source Data Upload	
Specimen Type	Plasma ☐ Dried Blood Spot for PK ☐ HSV-2 Antibody ☐ Gram Stain of Vaginal Smear ☐ Vaginal Swab for Biomarkers ☐ Cervical Swabs for Biomarkers ☐ Vaginal Swabs for qPCR (microbiota) ☐ CVL Supernatant for Biomarkers ■ CVL Pellet for Biomarkers ☐ Cervical Cytobrush ☐
Was sample collected?	Yes ☐ No ☐
Specimen Collection Date	
Was sample stored?	Stored ☐ Not stored ☐
If no, record reason why sample was not stored.	
Source Data Upload	
Specimen Type	Plasma ☐ Dried Blood Spot for PK ☐ HSV-2 Antibody ☐ Gram Stain of Vaginal Smear ☐ Vaginal Swab for Biomarkers ☐ Cervical Swabs for Biomarkers ☐ Vaginal Swabs for qPCR (microbiota) ☐ CVL Supernatant for Biomarkers ☐ CVL Pellet for Biomarkers ■ Cervical Cytobrush ☐
Was sample collected?	Yes ☐ No ☐

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Specimen Storage
Generated On: 30 Nov 2021 19:52:11

Specimen Collection Date	
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	
Source Data Upload	
Specimen Type	Plasma ☐
	Dried Blood Spot for PK ☐
	HSV-2 Antibody ☐
	Gram Stain of Vaginal Smear ☐
	Vaginal Swab for Biomarkers ☐
	Cervical Swabs for Biomarkers ☐
	Vaginal Swabs for qPCR (microbiota) ☐
	CVL Supernatant for Biomarkers ☐
	CVL Pellet for Biomarkers ☐
	Cervical Cytobrush ■
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	
Source Data Upload	

Rapid HIV test 1

Was Rapid HIV test sample 1 collected for testing?	Yes ☐
	No ☐

If "No", skip to Rapid HIV test 2.

Rapid HIV test 1 Kit	Alere/Abbot HIV Combo/Ultra ☐
	Oraquick ADVANCE HIV-1/2 ☐
	Uni-Gold Recombigen HIV-1/2 ☐
	Alere/Abbot Determine ☐
	Other ☐
If "Other", specify:	_____
Rapid HIV test 1 collection date	_____
Rapid HIV test 1	Antibody positive ☐
	Antigen positive ☐
	Antibody and antigen positive ☐
	Negative ☐

Rapid HIV test 2

Was Rapid HIV test sample 2 collected for testing?	Yes ☐
	No ☐

If "No", end of form.

Rapid HIV test 2 Kit	Alere/Abbot HIV Combo/Ultra ☐
	Oraquick ADVANCE HIV-1/2 ☐
	Uni-Gold Recombigen HIV-1/2 ☐
	Alere/Abbot Determine ☐
	Other ☐
If "Other", specify:	_____
Rapid HIV test 2 collection date	_____
Rapid HIV test 2	Antibody positive ☐
	Antigen positive ☐
	Antibody and antigen positive ☐
	Negative ☐

If at least one Rapid HIV tests is positive, complete the HIV Confirmatory Test Result form.

Source Data Upload _____

1. - What is the participant's date of birth? _____

2. - Age Fixed Unit: Years _____

3. - What was the participant's sex at birth?
- [ ] Male
- [x] Female

4. - Ethnic group or tribe:
- [ ] Acholi
- [ ] Baganda
- [ ] Bagisu
- [ ] Bakiga
- [ ] Banyankore
- [ ] Banyaruanda
- [ ] Banyoro
- [ ] Basoga
- [ ] Batoro
- [ ] Colored
- [ ] Indian
- [ ] Iteso
- [ ] Kalenjin
- [ ] Karamojong
- [ ] Kisii
- [ ] Lango
- [ ] Lugbara
- [ ] Luhya
- [ ] Luo
- [ ] Ndebele
- [ ] Shona
- [ ] White
- [ ] Xhosa
- [ ] Zulu
- [ ] Other African tribe
- [ ] Other

4a. - If "other", specify: _____

5. - What is the participant's marital status?
- [ ] Single
- [ ] Married legally
- [ ] Married traditionally
- [ ] Cohabitating
- [ ] Separated or divorced
- [ ] Other, specify

5a. - If "other", specify: _____

If "Single", or "Cohabiting", go to item 7.

6. - Age at first marriage — Fixed Unit: years _____

7. - Is the participant currently attending school?
- ☐ Yes
- ☐ No

If "Yes", go to item 10.

8. - Has the participant ever attended school?
- ☐ Yes
- ☐ No

If "No", go to item 13.

9. - What age did she leave school? — Fixed Unit: years _____

10. - What is the highest level of school attended
- ☐ Primary
- ☐ Secondary
- ☐ Higher (e.g., college or university)

11. - What is the highest (class/form/standard/grade/year) she completed at that level?
Instruction: for participants currently in school, record the year she is currently attending. _____

12. - How many grades has she repeated? _____

13. - What is the participant's religion?
- ☐ Anglican
- ☐ Apostolic
- ☐ Baptist
- ☐ Church of Christ
- ☐ Dutch Reformed
- ☐ Hindu
- ☐ Jehovah's Witness
- ☐ Roman Catholic
- ☐ Methodist
- ☐ Muslim
- ☐ Nomiya
- ☐ Non-Denominational
- ☐ Orthodox Christian
- ☐ Pentecostal
- ☐ Presbyterian
- ☐ Protestant
- ☐ Shembe
- ☐ Seventh-Day Adventist
- ☐ St. John Apostolic Faith Mission
- ☐ Zionist

	No religion ☐
	Other ☐
13a. - If "other", specify:	_____
If "No religion", go to item 15.	
14. - How many times a week does she attend religious services?	Never ☐
	More than once a week ☐
	Once a week ☐
	Less than once a week ☐
15. - Does the participant earn an income of her own?	Yes ☐
	No ☐
16. - What were her sources of income or other financial or material support in the past month? Mark all that apply.	
16a. - Formal employment	☐
16b. - Self-employment	☐
16c. - Government or social grant	☐
16d. - Family members	☐
16e. - Partners	☐
16f. - Other	☐
16f1. - If "Other", specify:	_____
17. - How many times has the participant been pregnant?	_____
If "0", go to item 20.	
18. - Specify outcome of last pregnancy	Full term live birth (greater than or equal to 37 weeks) ☐
	Premature live birth (less than 37 weeks) ☐
	Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks) ☐
	Spontaneous abortion (less than 20 weeks) ☐
	Ectopic pregnancy ☐
	Therapeutic/elective abortion ☐
	Other ☐
18a. - If "Other", specify:	_____
19. - Date of last pregnancy outcome	_____
20. - For how many children is she the primary caregiver? Instruction: Can be biological or otherwise.	_____
21. - Does the participant's household have…	
21a. - electricity or solar panels?	Yes ☐
	No ☐
21b. - a radio?	Yes ☐

	No ☐
21c. - a television?	Yes ☐
	No ☐
21d. - a mobile telephone?	Yes ☐
	No ☐
21e. - a refrigerator?	Yes ☐
	No ☐
21f. - a table?	Yes ☐
	No ☐
21g. - a sofa?	Yes ☐
	No ☐
21h. - a CD or digital music player?	Yes ☐
	No ☐
21i. - VCR/DVD player?	Yes ☐
	No ☐
21j. - a computer/tablet?	Yes ☐
	No ☐
21k. - a car?	Yes ☐
	No ☐
21l. - a motorcycle?	Yes ☐
	No ☐
21m. - a bicycle?	Yes ☐
	No ☐
22. - Does the participant have a mobile phone?	Yes ☐
	No ☐
If "No", go to item 24.	
23. - Does the participant share her mobile phone with anyone else?	Yes ☐
	No ☐
24. - How long did it take the participant to travel from home to the clinic today?	Less than 30 minutes ☐
	30-60 minutes ☐
	1-2 hours ☐
	Greater than 2 hours ☐
Read the following items and responses aloud word for word.	
25. - .How worried are you that you may get infected with HIV in the next year?	Very worried. ☐
	Somewhat worried. ☐

	A little worried. ☐
	Not at all worried. ☐

26. - .I am going to read aloud a list of reasons why women may choose to participate in REACH. Please tell me all of the reason(s) that apply to you.
Read each response aloud.

26a. - .To get tested for HIV	Yes. ☐
	No. ☐
26b. - .To get counseling on reducing risk of HIV and STIs	Yes. ☐
	No. ☐
26c. - .To help the community fight the HIV epidemic	Yes. ☐
	No. ☐
26d. - .Because the ring and/or tablets can protect you against HIV	Yes. ☐
	No. ☐
26e. - .To make it safer for you to have sex without condoms	Yes. ☐
	No. ☐
26f. - .Because this is the only or best way for you to get health care	Yes. ☐
	No. ☐
26g. - .Because your friends are participating in REACH	Yes. ☐
	No. ☐
26h. - .Because you feel taken care of by the study staff	Yes. ☐
	No. ☐
26i. - .Because being in the study allows you to join social events at the clinic	Yes. ☐
	No. ☐
26j. - .Because of the study visit reimbursement money	Yes. ☐
	No. ☐
26k. - .Other	Yes. ☐
	No. ☐
26k1. - .If "Other", specify:	_____
Source Data Upload	_____

Were any family planning methods used by the participant during study participation?	Yes ☐ No ☐

If yes, complete the Family Planning form. Please remember to include any hormonal contraceptives taken on the Concomitant Medications Log.

Date of completion _____

What method(s) of contraception/family planning is the participant currently using?

Family Planning/Contraception Method

- ☐ Spermicide
- ☐ Sponge
- ☐ Oral contraceptive birth control pills
- ☐ (Ortho Evra) – The Patch
- ☐ Implants
- ☐ Female condoms
- ☐ Male condoms
- ☐ Sterilization (tubal ligation/hysterectomy/laparoscopy/ other surgical procedure that causes sterilization)
- ☐ Diaphragm
- ☐ Copper IUD
- ☐ Hormonal IUD (e.g., Mirena, Lilette, Skyla)
- ☐ Injectable contraceptive – Depo
- ☐ Injectable contraceptive – NET-EN
- ☐ Injectable contraceptive – Cyclofem
- ☐ Injectable contraceptive – Other
- ☐ Natural methods such as the withdrawal or rhythm method
- ☐ Sex with partner who had vasectomy
- ☐ Emergency contraception
- ☐ Other

If "Other", specify: _____

Date Regimen Started _____

Date Regimen Stopped:

OR _____

Ongoing ☐

Reason(s) for changing or stopping the family planning method ☐

Interested in long-acting reversible contraception (LARC)

Bleeding concerns ☐

Specify the type of vaginal bleeding (select all that apply):

Heavy bleeding ☐

Prolonged bleeding ☐

Intermittent bleeding (e.g., spotting)	☐
Less bleeding/no bleeding (e.g., no menses)	☐
Break from hormones	☐
Difficulty with adherence	☐
Interested in a forgettable method of contraception	☐
Weight gain	☐
Interested in getting pregnant	☐
Became pregnant	☐
Contraceptive choice not available	☐
Bothered by pain	☐
Partner objection	☐
Medical contraindication	☐
If "Medical contraindication", specify:	_____
Other reason	☐
If "Other reason", specify:	_____
No reason provided	☐
Source Data Upload	_____

Date of completion	
Age of sexual debut	
Age at which the participant first used a contraceptive method	
Did the participant use any contraceptive method(s) prior to the screening visit?	Yes ☐ No ☐

If "No", end of form.

Any family planning /contraceptive method(s) started at screening should be recorded on the Family Planning Log.

Did the participant discontinue use of at least one contraceptive method prior to the screening visit?	Yes ☐ No ☐

If "No", end of form.

Any family planning /contraceptive method(s) that are ongoing at screening should be recorded on the Family Planning Log.

Of the family planning/contraceptive method(s) used prior to screening, which method(s) has the participant discontinued?	Spermicide ☐ Sponge ☐ Oral contraceptive birth control pills (Ortho Evra) – The Patch ☐ Implants ☐ Female condoms ☐ Male condoms ☐ Sterilization (tubal ligation/hysterectomy/laparoscopy/ other surgical procedure that causes sterilization) ☐ Diaphragm ☐ Copper IUD ☐ Hormonal IUD (e.g., Mirena, Lilette, Skyla) ☐ Injectable contraceptive – Depo ☐ Injectable contraceptive – NET-EN ☐ Injectable contraceptive – Cyclofem ☐ Injectable contraceptive – Other ☐ Natural methods such as the withdrawal or rhythm method ☐ Sex with partner who had vasectomy ☐ Emergency contraception ☐ Other ☐
Family Planning/Contraception Method	
If "Other", specify:	
Date Regimen Started:	
Date Regimen Stopped:	

Reason(s) for changing or stopping the family planning method prior to Screening ☐

Interested in long-acting reversible contraception (LARC)"

Bleeding concerns ☐

Specify the type of vaginal bleeding (select all that apply):

- Heavy bleeding ☐
- Prolonged bleeding ☐
- Intermittent bleeding (e.g., spotting) ☐
- Less bleeding/no bleeding (e.g., no menses) ☐

Break from hormones ☐

Difficulty with adherence ☐

Interested in a forgettable method of contraception ☐

Weight gain ☐

Interested in getting pregnant ☐

Became pregnant ☐

Contraceptive choice not available ☐

Bothered by pain ☐

Partner objection ☐

Medical contraindication ☐

- If "Medical contraindication", specify: _____

Other reason ☐

- If "Other reason", specify: _____

No reason provided ☐

Source Data Upload _____

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Enrollment Menstrual History
Generated On: 30 Nov 2021 19:52:11

Date of assessment	
Since the Screening Visit, has the participant had her menses?	Yes ☐ No ☐
If no, end of form.	
First day of last menstrual period	
Last day of last menstrual period	
OR	
Ongoing	☐
Have there been any changes to the participant's baseline menstrual bleeding pattern since her Screening Visit?	Yes ☐ No ☐
If "Yes", how acceptable is the new pattern to the participant? Provide additional details as needed. (Max. 200 characters)	
Source Data Upload	

Date Pregnancy Reported to Site	_____
Visit at which this pregnancy was reported	V1 - Screening ☐ V2 - Enrollment: Period 1 Study Product Initiation ☐ V3 - Week 1 ☐ V4 - Week 4 ☐ V5 - Week 8 ☐ V6 - Week 12 ☐ V7 - Week 16 ☐ V8 - Week 20 ☐ V9 - Week 24: Period 1 Study Product Use End/Period 2 Study Product Intiation ☐ V10 - Week 25 ☐ V11 - Week 28 ☐ V12 - Week 32 ☐ V13 - Week 36 ☐ V14 - Week 40 ☐ V15 - Week 44 ☐ V16 - Week 48: Period 2 Study Product Use End/Period 3 Study Product Initiation ☐ V17 - Week 49 ☐ V18 - Week 52 ☐ V19 - Week 56 ☐ V20 - Week 60 ☐ V21 - Week 64 ☐ V22 - Week 68 ☐ V23 - Week 72: PUEV ☐ V24 - Week 73: Study Exit/Termination ☐ Interim Visit ☐
If "Interim visit", specify Interim visit code	_____
First day of last menstrual period	_____
Or	
Amenorrheic for past 6 months	☐
Estimated date of delivery	_____
What primary information was used to estimate the date of delivery?	Last menstrual period ☐ Initial ultrasound less than 20 weeks ☐ Initial ultrasound greater than or equal to 20 weeks ☐ Physical examination ☐

	Conception date by assisted reproduction ☐ Other ☐
If "Other", specify:	
Is this the participant's first pregnancy since enrollment in this study?	Yes ☐ No ☐
If "Yes", complete the Pregnancy History form.	
Source Data Upload	

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Pregnancy History
Generated On: 30 Nov 2021 19:52:11

Date pregnancy history collected	
Has the participant ever been pregnant before?	Yes ☐ No ☐
If no, end of form.	
Number of full term live births (greater than or equal to 37 weeks)	
Number of premature live births (less than 37 weeks)	
Number of spontaneous fetal deaths and/or still births (greater than or equal to 20 weeks)	
Number of spontaneous abortions (less than 20 weeks)	
Number of therapeutic/elective abortions	
Number of ectopic pregnancies	
Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	Yes ☐ No ☐
If "Yes", specify:	
Source Data Upload	

Is the outcome of this pregnancy obtainable?
- Yes
- No

If no, end of form.

How many pregnancy outcomes resulted from this reported pregnancy?

Outcome date

Place of delivery/outcome
- Home
- Hospital
- Clinic
- Unknown
- Other

If "Other", specify:

Specify outcome

If the pregnancy or outcome was associated with maternal complications or symptoms that would otherwise be reported as an AE, report these on an AE log. Complete an EAE reporting form, if applicable.
- Full term live birth (greater than or equal to 37 weeks)
- Premature live birth (less than 37 weeks)
- Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks)
- Spontaneous abortion (less than 20 weeks)
- Ectopic pregnancy
- Therapeutic/elective abortion
- Other

If "Other", specify:
If stillbirth/intrauterine fetal demise, spontaneous abortion, ectopic pregnancy or therapeutic/elective abortion is marked, go to "provide a brief narrative of the circumstances ".

Method
If full term live birth, go to "Were there any complications related to the pregnancy outcome?".
- C-section
- Standard vaginal
- Operative vaginal

Provide a brief narrative of the circumstances

Were there any complications related to the pregnancy outcome?
- Yes
- No

If there were no complications related to the pregnancy outcome, skip to the "Were any fetal/infant congenital anomalies identified" item.

Delivery-related complications: Mark “None” or all that apply.

- ☐ None
- ☐ Intrapartum hemorrhage
- ☐ Postpartum hemorrhage
- ☐ Non-reassuring fetal status

Chorioamnionitis ☐

Other ☐

If "Other", specify: _____

Non-delivery related complications: Mark “None” or all that apply. ☐

None

Hypertensive disorders of pregnancy ☐

Gestational diabetes ☐

Other ☐

If "Other", specify: _____

Were any fetal/infant congenital anomalies identified?
Mark all that apply. If No or unknown, go to statement above "infant gender". Complete AE Log and EAE Reporting form.

Yes ☐
No ☐
Unknown ☐

Central nervous system, cranio-facial ☐

Central nervous system, spinal ☐

Cardiovascular ☐

Renal ☐

Gastrointestinal ☐

Pulmonary ☐

Muscoloskeletal/extremities ☐

Physical defect ☐

Skin ☐

Genitourinary ☐

Chromosomal ☐

Cranio-facial (structural) ☐

Hematologic ☐

Infectious ☐

Endocrine/metabolic ☐

Other ☐

Specify congenital anomaly/defect AE _____

Describe the congenital anomaly/defect: _____

Complete the infant items below for live births only. Otherwise, end of form.

Male ☐
Female ☐

Infant gender

Infant birth weight — Fixed Unit: kg

Or

Infant birth weight unavailable ☐

Infant birth length — Fixed Unit: centimeters

Or

Infant birth length unavailable ☐

Infant birth head circumference — Fixed Unit: cm

Or

Infant birth head circumference unavailable ☐

Infant birth abdominal circumference — Fixed Unit: centimeters

or

Infant birth abdominal circumference unavailable ☐

Infant gestational age by examination in weeks — Fixed Unit: Weeks

Infant gestational age by examination in days — Fixed Unit: Days

or

Infant gestational age by examination unavailable ☐

If unavailable, end of form.

Method used to determine gestational age
- Ballard ☐
- Dubowitz ☐
- Other ☐

If other, specify

Source Data Upload

Pelvic exam assessment	Not done ☐ Abnormal findings ☐ No abnormal findings ☐
Exam date	_____

Abnormal findings. Mark all that apply.

VULVAR	
Vulvar edema	☐
Vulvar erythema	☐
Vulvar rash	☐
Vulvar tenderness	☐
Bartholin's or Skene's gland abnormality	☐
Vulvar ulcer	☐
Vulvar blister	☐
Vulvar pustule	☐
Vulvar peeling	☐
Vulvar ecchymosis	☐
VAGINAL	
Vaginal edema	☐
Vaginal erythema	☐
Vaginal masses (polyps, myomas, possible malignancy)	☐
Vaginal abrasions or lacerations	☐
Vaginal tenderness	☐
Vaginal ulcer	☐
Vaginal blister	☐
Vaginal pustule	☐
Vaginal peeling	☐
Vaginal ecchymosis	☐
Abnormal vaginal discharge	Slight ☐ Moderate ☐ Pooling ☐
CERVICAL	
Cervical edema and/or friability	☐
Cervical erythema	☐
Cervical masses (polyps, myomas, possible malignancy)	☐

Cervical motion tenderness	☐
Cervical discharge	☐
Cervical ulcer	☐
Cervical blister	☐
Cervical pustule	☐
Cervical peeling	☐
Cervical ecchymosis	☐
GENERAL/OTHER	
Odor (vaginal)	☐
Condyloma	☐
If condyloma, specify location:	_____
Adnexal masses (based on bimanual exam; not pregnancy or infection-related)	☐
Uterine masses (based on bimanual exam)	☐
Uterine tenderness	☐
Adnexal tenderness	☐
Abnormal blood or bleeding	☐
Abnormal blood or bleeding; describe:	_____
Other abnormal findings	☐
If other abnormal findings, specify (include anatomical location):	_____
Complete or update Baseline Medical Conditions Log or Adverse Event Log, as applicable.	
Were any new pelvic finding AEs reported at this visit?	Yes ◯ No ◯
Adverse event #1	_____
Adverse event #2	_____
Adverse event #3	_____
Cervical ectopy	0% ◯ 1-25% ◯ 26-50% ◯ 51-75% ◯ 76-100% ◯ Not done ◯
Source Data Upload	_____

Date participant last used study product: _____

Visit when study product use ended

- ☐ V1 - Screening
- ☐ V2 - Enrollment: Period 1 Study Product Initiation
- ☐ V3 - Week 1
- ☐ V4 - Week 4
- ☐ V5 - Week 8
- ☐ V6 - Week 12
- ☐ V7 - Week 16
- ☐ V8 - Week 20
- ☐ V9 - Week 24: Period 1 Study Product Use End/Period 2 Study Product Intiation
- ☐ V10 - Week 25
- ☐ V11 - Week 28
- ☐ V12 - Week 32
- ☐ V13 - Week 36
- ☐ V14 - Week 40
- ☐ V15 - Week 44
- ☐ V16 - Week 48: Period 2 Study Product Use End/Period 3 Study Product Initiation
- ☐ V17 - Week 49
- ☐ V18 - Week 52
- ☐ V19 - Week 56
- ☐ V20 - Week 60
- ☐ V21 - Week 64
- ☐ V22 - Week 68
- ☐ V23 - Week 72: PUEV
- ☐ V24 - Week 73: Study Exit/Termination
- ☐ Interim Visit

If 'Interim visit' is chosen, provide interim visit code: _____

Primary reason for ending study product use:

- ☐ Scheduled study product use period completed
- ☐ Acquisition of HIV infection
- ☐ Adverse Event
- ☐ Allergic reaction to study product
- ☐ Reported use of PrEP for HIV prevention
- ☐ Non-therapeutic injection drug use
- ☐ Participant declined study product

	Participant requests to change product use (Period 3 only) ☐ Participant unable/unwilling to comply with required study procedures, or otherwise might be put at undue risk to their safety and well-being by continuing product use, according to judgment of IoR/designee ☐ Other ☐
If "Other", specify	
If Adverse Event, select applicable Adverse Event	
Source Data Upload	

Was vaginal pH done?
- Yes
- No

Date of collection: _____

Vaginal pH: _____

Was a vaginal wet prep sample collected?
- Yes
- No

If no, skip to "Was a sample collected for Syphilis testing?"

Date of collection: _____

Homogenous vaginal discharge
- Positive
- Negative
- Not done

Whiff test
- Positive
- Negative
- Not done

Clue cells greater or equal to 20%
- Positive
- Negative
- Not done

Trichomonas vaginalis
- Positive
- Negative
- Not done

Buds and/or hyphae (yeast)
- Positive
- Negative
- Not done

Was a sample collected for Syphilis testing?
- Yes
- No

If no, skip to "Was a sample collected for Trichomonas testing?"

Date of collection: _____

Syphilis screening test
- Non-reactive
- Reactive
- Not reported

If Syphilis screening test is 'non-reactive', skip to "Was a sample collected for Trichomonas testing?"

Syphilis titer: _____

Syphilis confirmatory test
- Postive
- Negative
- Indeterminate
- Not done

Was a sample collected for Trichomonas testing?
- Yes

	No ☐
If no, skip to "Was a vaginal sample collected for NAAT for GC/CT?"	
Date of collection	_____
Trichomonas test	Positive ☐
	Negative ☐
	Not done ☐
Was a vaginal sample collected for NAAT for GC/CT?	Yes ☐
	No ☐
If no, skip to "Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?"	
Date of collection	_____
N. gonorrhea	Positive ☐
	Negative ☐
	Not done ☐
C. trachomatis	Positive ☐
	Negative ☐
	Not done ☐
Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?	Yes ☐
	No ☐
Date of collection	_____
Hepatitis B Surface Antigen (HBsAG)	Positive ☐
	Negative ☐
Source Data Upload	_____

HEMOGRAM

Was a hematology sample collected? ☐ Yes ☐ No

Date of collection

Hemoglobin

Hemoglobin severity grade ☐ Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable

Hemoglobin Severity Grade - Calculated ☐ Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable

Hemoglobin Adverse Event

Hematocrit

MCV

Platelets

Platelets severity grade ☐ Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable

Platelets Severity Grade - Calculated ☐ Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable

Platelets Adverse Event

WBC

WBC severity grade ☐ Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable

WBC Severity Grade -Calculated	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable ☐
WBC Adverse Event	
DIFFERENTIAL	
Was a differential done?	Yes ☐ No ☐
Date of collection	
Neutrophils	
Neutrophils severity grade	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable ☐
Neutrophils Severity Grade - Calculated	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable ☐
Neutrophils Adverse Event	
Lymphocytes	
Lymphocytes severity grade	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable ☐
Lymphocytes Severity Grade - Calculated	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable ☐
Lymphocytes Adverse Event	
Monocytes	
Eosinophils	
Basophils	

Was a sample collected for blood chemistries?	Yes ☐ No ☐
Date of collection	
Creatinine	
Creatinine severity grade	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable ☐
Creatinine Severity Grade - Calculated	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable ☐
Creatinine Adverse Event	
Calculated creatinine clearance	
Calculated Creatinine Clearance Severity Grade	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable ☐
Calculated Creatinine Clearance Severity Grade - Calculated	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable ☐
Calculated Creatinine Clearance Adverse Event	
Source Data Upload	

Geenius HIV-1/2 confirmatory test

Was Geenius HIV-1/2 confirmatory test collected for testing? Yes / No

If "No", skip to "Was plasma for confirmatory testing collected?"

Geenius HIV-1/2 confirmatory test collection date _____

Geenius HIV-1/2 confirmatory test: HIV negative / HIV-1 indeterminate / HIV-2 indeterminate / HIV-1 positive / HIV-2 positive / HIV-2 positive with HIV-1 cross-reactivity / HIV positive undifferentiated (untypeable)

Plasma

Was plasma for confirmatory testing collected? Yes / No

If "No", skip to "Was HIV RNA PCR testing completed?"

Was plasma stored for HIV confirmatory testing? Stored / Not stored

Plasma for HIV confirmatory testing collection date _____

HIV RNA PCR

Was HIV RNA PCR testing completed? Yes / No

If "No", skip to "Were Absolute CD4+ collected for testing?

HIV RNA PCR collection date _____

HIV RNA PCR: Greater than / Equal to / Less than

HIV RNA PCR: Fixed Unit: viral copies/mL _____

Or

Target not detected ☐

HIV RNA PCR kit lower limit of detection

HIV RNA PCR kit: Abbott M2000 / Roche TaqMan / Gene Xpert

HIV RNA PCR kit lower limit of detection: 20 / 40

OR

HIV RNA PCR kit lower limit of detection	Fixed Unit: viral copies/mL
Absolute CD4+	
Were Absolute CD4+ collected for testing?	Yes ☐ No ☐
If "No", skip to "Final HIV Status".	
Absolute CD4 collection date	
Absolute CD4+	Fixed Unit: cells/mm^3
Or	
Unable to analyze	☐
CD4 %	
CD4 % not available	☐
Or	
CD4 %	Fixed Unit: %
Final HIV status	
Final HIV status	HIV uninfected ☐ HIV infected ☐ pending ☐
Source Data Upload	

T CELL SUBSETS

Were T Cell Subsets collected for testing? Yes / No

If "No", skip to "Were Absolute CD4+ collected for testing?"

T CELL SUBSETS collection date

T CELL SUBSETS Positive / Negative

Absolute CD4+

Were Absolute CD4+ collected for testing? Yes / No

If "No", skip to "Was HIV RNA PCR testing completed?"

Absolute CD4 collection date

Absolute CD4+ Fixed Unit: cells/mm3

Or

Unable to analyze

CD4 %

CD4 % not available

OR

CD4 % Fixed Unit: %

HIV RNA PCR

Was HIV RNA PCR testing completed? Yes / No

If "No", skip to "Was seroconverter plasma collected for storage?"

HIV RNA PCR collection date

HIV RNA PCR Greater than / Equal to / Less than

HIV RNA PCR Fixed Unit: viral copies/mL

OR

HIV RNA PCR target not detected

HIV RNA PCR kit lower limit of detection

HIV RNA PCR Kit Abbott M2000 / Roche TaqMan / Gene Xpert

HIV RNA PCR Kit Lower limit of detection 20 / 40

OR

HIV RNA PCR Kit Lower limit of detection	Fixed Unit: viral copies/mL
Seroconverter Plasma Storage	
Was seroconverter plasma collected for storage?	Yes ☐ No ☐
Seroconverter Plasma storage collection date	
Seroconverter Plasma storage	Stored ☐ Not stored ☐
Seroconverter Plasma storage reason not stored	
Source Data Upload	

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Enrollment
Generated On: 30 Nov 2021 19:52:11

Date the participant marked or signed the study screening and enrollment consent form	
Did the participant and parent/guardian, if applicable, consent to long-term specimen storage and future testing?	Yes ☐ No ☐
HIV Status	Positive ☐ Negative ☐
Pregnancy Status	Positive ☐ Negative ☐
Has the participant received an HPV vaccination prior to enrollment?	Yes ☐ No ☐
Has the participant received an HBV vaccination prior to enrollment?	Yes ☐ No ☐
Product Sequence participant was randomized to:	Sequence A ☐ Sequence B ☐
Was the participant randomized to participate in serial IDI (In Depth Interview)?	Yes ☐ No ☐
Was the participant invited to participate in Serial IDIs?	Yes ☐ No ☐
Will this participant participate in Serial IDIs?	Yes ☐ No ☐
Source Data Upload	

Visit date	_____
Interim visit code	_____
Was study product held at this visit? If yes, complete a Product Hold form.	Yes ☐ No ☐
Was study product use permanently discontinued (scheduled or early) at this visit? If yes, complete a Product Discontinuation form.	Yes ☐ No ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit? If yes, complete the AE Log.	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported? If yes, complete the Concomitant Medications Log.	Yes ☐ No ☐
Have any protocol deviations been reported at this visit? If yes, complete the Protocol Deviation Log.	Yes ☐ No ☐
Reason for interim visit (Mark all that apply.)	
AE report or follow-up	☐
Return of product or need new product	☐
Completion of missed visit procedures	☐
If missed visit procedures are completed, for which visit are procedures being made up?	V1 - Screening ☐ V2 - Enrollment: Period 1 Study Product Initiation ☐ V3 - Week 1 ☐ V4 - Week 4 ☐ V5 - Week 8 ☐ V6 - Week 12 ☐ V7 - Week 16 ☐ V8 - Week 20 ☐ V9 - Week 24: Period 1 Study Product Use End/Period 2 Study Product Intiation ☐ V10 - Week 25 ☐ V11 - Week 28 ☐ V12 - Week 32 ☐ V13 - Week 36 ☐ V14 - Week 40 ☐ V15 - Week 44 ☐ V16 - Week 48: Period 2 Study Product Use End/Period 3 Study Product Initiation ☐ V17 - Week 49 ☐

	V18 - Week 52 ☐
	V19 - Week 56 ☐
	V20 - Week 60 ☐
	V21 - Week 64 ☐
	V22 - Week 68 ☐
	V23 - Week 72: PUEV ☐
	V24 - Week 73: Study Exit/Termination ☐
	Interim Visit ☐
Other	☐
If "Other", specify:	_____
What study procedures were completed at this visit?	
Adherence counseling?	☐
Product Change?	☐
Provision or return of study tablets?	☐
Provision or return of study ring?	☐
Tablet Assessment?	☐
Ring Assessment?	☐
ACASI?	☐
Vital signs?	☐
Physical exam?	☐
Pelvic exam?	☐
Specimen collection?	☐
Pregnancy test?	☐
CBC testing (includes platelets)?	☐
Serum creatinine?	☐
HIV test(s)?	☐
HIV confirmatory tests?	☐
HIV seroconverter tests?	☐
STI test(s) (other than HIV)?	☐
Participant transfer?	☐
Participant receipt?	☐
Product Preference and Acceptability?	☐
Social Benefits and Impacts?	☐

COVID-19 Behavioral Assessment ☐

Source Data Upload

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Additional Study Procedures
Generated On: 30 Nov 2021 19:52:11

What study procedures were completed at this visit?	
Adherence counseling?	☐
Product Change?	☐
Provision or return of study tablets?	☐
Provision or return of study ring?	☐
Tablet Assessment?	☐
Ring Assessment?	☐
ACASI?	☐
Vital signs?	☐
Physical exam?	☐
Pelvic exam?	☐
Specimen collection?	☐
Pregnancy test?	☐
CBC testing (includes platelets)?	☐
Serum creatinine?	☐
HIV test(s)?	☐
HIV confirmatory tests?	☐
HIV seroconverter tests?	☐
STI test(s) (other than HIV)?	☐
Participant transfer?	☐
Participant receipt?	☐
Product Preference and Acceptability?	☐
Social Benefits and Impacts?	☐
COVID-19 Behavioral Assessment	☐

Participant ID: _____

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Social Benefits and Impacts
Generated On: 30 Nov 2021 19:52:11

1. - Date of Completion	_____
2. - .At any time during the past 3 months, have you experienced a positive change, event, or experience in your life related to your study participation?	Yes. ☐ No. ☐
If "Yes", complete a Social Benefits Form.	
3. - .At any time during the past 3 months, have you experienced a negative change, event, or experience in your life related to your study participation?	Yes. ☐ No. ☐
If "Yes", complete a Social Impact Form.	
Source Data Upload	_____

Has the participant reported a social benefit during the study?	Yes ☐ No ☐

If "Yes", complete the Social Benefit Log.

Concisely describe social benefit: _____

Reported at visit?

- ☐ V1 - Screening
- ☐ V2 - Enrollment: Period 1 Study Product Initiation
- ☐ V3 - Week 1
- ☐ V4 - Week 4
- ☐ V5 - Week 8
- ☐ V6 - Week 12
- ☐ V7 - Week 16
- ☐ V8 - Week 20
- ☐ V9 - Week 24: Period 1 Study Product Use End/Period 2 Study Product Intiation
- ☐ V10 - Week 25
- ☐ V11 - Week 28
- ☐ V12 - Week 32
- ☐ V13 - Week 36
- ☐ V14 - Week 40
- ☐ V15 - Week 44
- ☐ V16 - Week 48: Period 2 Study Product Use End/Period 3 Study Product Initiation
- ☐ V17 - Week 49
- ☐ V18 - Week 52
- ☐ V19 - Week 56
- ☐ V20 - Week 60
- ☐ V21 - Week 64
- ☐ V22 - Week 68
- ☐ V23 - Week 72: PUEV
- ☐ V24 - Week 73: Study Exit/Termination
- ☐ Interim Visit

If Interim visit, specify Interim visit code _____

The social benefit was related to:

- ☐ Activities: Participant became involved in community activities
- ☐ Altruism: Participant helping community/others by participating in REACH
- ☐ Education: The study educated the participant or inspired /enabled participant to restart school or improve school performance.

	Family Planning/Contraception: The participant was able to access contraception and family planning services ☐
	Feeling better about oneself: Improved self-esteem or feeling of empowerment ☐
	HIV testing: The participant received regular HIV testing ☐
	Housing: The participant obtained better or improved her housing situation ☐
	Improved communication: Participant learned more effective ways of communicating with family, friends, employers or others ☐
	Income: Obtained or increased income (includes getting study reimbursement) ☐
	Nutrition/food: The participant was able to improve nutrition or amount of food intake for self or family. ☐
	New relationships: Participant created new relationships ☐
	Peer Support: Participant felt supported by or was able to provide support to peers ☐
	Preventative care services: The participant was able to receive preventative health care such as pap smears, HPV/HBV vaccine ☐
	Pride about project participation: Feels pride about participation in REACH ☐
	Staying HIV free: REACH provided more effective ways for the participant to avoid becoming infected with HIV ☐
	Treatment of other illnesses: The participant was able to treat/consult with a doctor about other illnesses (non-STIs) ☐
	Treatment of STIs: The participant was able to treat STIs ☐
	Work: Obtained or improved employment situation (includes informal work) ☐
	Other ☐
If "Other", specify:	_____
What impact did this situation have on the participant's quality of life?	Minimal ☐
	Moderate - no significant impact ☐
	Major - significant impact ☐
Did this involve social benefit to someone other than the participant?	Yes ☐

	No ☐
How many other people did this social benefit involve?	1 ☐
	2 ☐
	3 ☐
	4 ☐
Person 1 (If yes, enter type of relationship)	Partner ☐
	Adult family member ☐
	Child ☐
	Other REACH participant ☐
	Friend ☐
	Acquaintance ☐
	Employer ☐
	Other ☐
If "Other", specify:	_____
Person 2 (If more than one type of relationship)	Partner ☐
	Adult family member ☐
	Child ☐
	Other REACH participant ☐
	Friend ☐
	Acquaintance ☐
	Employer ☐
	Other ☐
If "Other", specify:	_____
Person 3 (If more than 2 types of relationship)	Partner ☐
	Adult family member ☐
	Child ☐
	Other REACH participant ☐
	Friend ☐
	Acquaintance ☐
	Employer ☐
	Other ☐
If "Other", specify:	_____
Person 4 (if more than 4 types of relationship)	Partner ☐
	Adult family member ☐
	Child ☐
	Other REACH participant ☐
	Friend ☐

	Acquaintance ☐
	Employer ☐
	Other ☐
If "Other", specify:	
Source Data Upload	

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Product Choice
Generated On: 30 Nov 2021 19:52:11

1. - Form Completion date	
Instructions: Complete this section at Month 12 visit (Visit 16), when the participant chooses a product for the first time. Text in normal font should be read out loud to the participant. Italicized text should not be read out loud.	
2. - .Now that you have tried out each product and used it for 6 months, you have the option to choose which prevention method you would like to use for the next study period. Would you like to use the tablets or the ring? (Do not read responses out loud.)	Tablets ☐ Ring ☐ Neither ☐
If neither, skip to item 4.	
3. - .Would you say you chose this product mainly because you liked the product you chose, or because you disliked the other product? (Read responses out loud.)	Liked the chosen product. ☐ Disliked the other product. ☐ Both reasons equally. ☐
4. - Ask the participant to explain her response to the previous question. For example, if she liked the chosen product, ask her to explain why she liked it. If she disliked the product not selected or does not want to use either product, ask her to explain why. Record participant's response.(Max. 800 characters)	
Source Data Upload	

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Product Change
Generated On: 30 Nov 2021 19:52:11

1. - Form Completion date	
Instructions: Complete this section at Visits 17-22 if the participant decides to switch study products or stop product use all together.	
2. - What product was the participant using prior to this visit?	Tablets ☐ Ring ☐ Neither ☐
3. - What product does the participant want to start using at this visit? (Response should be different from previous question.)	Tablets ☐ Ring ☐ Neither ☐
If neither, skip to item 5.	
Read the following question and responses aloud. Text in normal font should be read out loud to the participant. Italicized text should not be read out loud.	
4. - .Would you say you wanted to change products mainly because you disliked the product you were using before, or because you preferred the other product? (Read responses out loud.)	Disliked the product I was using. ☐ Liked the chosen product. ☐ Both reasons equally. ☐
5. - Ask the participant to explain her response to the previous question. For example, if she disliked the product she was using, ask her to explain why she disliked it. Or, if she decided she now prefers the other product or does not want to use either product, ask her to explain why. Record participant's response.	
Source Data Upload	

Form Completion Date _____

Visit of counseling session

- V1 - Screening ☐
- V2 - Enrollment: Period 1 Study Product Initiation ☐
- V3 - Week 1 ☐
- V4 - Week 4 ☐
- V5 - Week 8 ☐
- V6 - Week 12 ☐
- V7 - Week 16 ☐
- V8 - Week 20 ☐
- V9 - Week 24: Period 1 Study Product Use End/Period 2 Study Product Intiation ☐
- V10 - Week 25 ☐
- V11 - Week 28 ☐
- V12 - Week 32 ☐
- V13 - Week 36 ☐
- V14 - Week 40 ☐
- V15 - Week 44 ☐
- V16 - Week 48: Period 2 Study Product Use End/Period 3 Study Product Initiation ☐
- V17 - Week 49 ☐
- V18 - Week 52 ☐
- V19 - Week 56 ☐
- V20 - Week 60 ☐
- V21 - Week 64 ☐
- V22 - Week 68 ☐
- V23 - Week 72: PUEV ☐
- V24 - Week 73: Study Exit/Termination ☐
- Interim Visit ☐

If "Interim visit", specify Interim Visit code: _____

Is the participant currently using the ring or tablets?

- Tablets ☐
- Ring ☐
- Neither ☐

Is the participant scheduled to receive drug level feedback?

- Yes ☐
- No ☐

Are drug levels available for counseling?

- Yes ☐
- No ☐

If no drug levels are available for counseling, skip to the instruction, "Indicate which topics were covered during the session. Mark all that apply."

Which drug levels are available?	FTC/TDF ☐ DPV ☐
Date specimen collected	_____
What is the drug level concentration?	_____
Drug Level Unit	fmol/sample ☐ BLQ (Below Level of Quantification) ☐ mg ☐
For counseling, which category does the drug level correspond to?	Green ☐ Yellow ☐ Red ☐

Indicate which topics were covered during the session. Mark all that apply.

Adherence goal setting	☐
Adherence reminder strategies	☐
Barriers to adherence	☐
Communication skills	☐
Product Storage	☐
Disclosing product use to others	☐
Planning for future PrEP use	☐
PrEP or ring education	☐
Problem solving	☐
Social Support	☐
Other	☐
If "Other", specify:	_____

Indicate which barriers/challenges were explored during this session: Mark all that apply or "None could be identified."

Barriers to return for study visits (e.g., money or time)	☐
Disruption in routine (for example, travel away from home)	☐
Forgetting/no dose available	☐
Job commitments	☐
Lack of privacy	☐
Medication side effects	☐
Negative reactions (family, friends, partner)	☐
Partying/drugs/alcohol	☐
School Commitments (classes or exams)	☐

Side effects	☐
Stigma/fear of stigma	☐
Other	☐
If "Other", specify:	
None could be identified	☐

Indicate which adherence strategies/facilitators were chosen during this session: Mark all that apply or "None could be identified"

Carrying case	☐
Daily text message	☐
Weekly check-in via text	☐
Weekly check-in via phone call	☐
Peer buddy	☐
Adherence support group in person	☐
Adherence support group online	☐
Additional counseling visits	☐
Other item that participant identifies	☐
If "Other", specify:	
None could be identified	☐

Were there any unexpected problems in the session?	Yes ◯
	No ◯

If "No", end of form.

If "Yes", please explain what happened and how the participant handled the problem. (Max. 800 characters)	
Source Data Upload	

Study Product Sequence	Sequence A ☐ Sequence B ☐
Study Product Sequence (autopopulated from Medidata Balance)	_____
Was a vaginal ring or tablet bottle dispensed at this visit?	Vaginal Ring ☐ Truvada Bottle ☐
Visit study product dispensed	V1 - Screening ☐ V2 - Enrollment: Period 1 Study Product Initiation ☐ V3 - Week 1 ☐ V4 - Week 4 ☐ V5 - Week 8 ☐ V6 - Week 12 ☐ V7 - Week 16 ☐ V8 - Week 20 ☐ V9 - Week 24: Period 1 Study Product Use End/Period 2 Study Product Intiation ☐ V10 - Week 25 ☐ V11 - Week 28 ☐ V12 - Week 32 ☐ V13 - Week 36 ☐ V14 - Week 40 ☐ V15 - Week 44 ☐ V16 - Week 48: Period 2 Study Product Use End/Period 3 Study Product Initiation ☐ V17 - Week 49 ☐ V18 - Week 52 ☐ V19 - Week 56 ☐ V20 - Week 60 ☐ V21 - Week 64 ☐ V22 - Week 68 ☐ V23 - Week 72: PUEV ☐ V24 - Week 73: Study Exit/Termination ☐ Interim Visit ☐
If "Interim visit", specify visit code	_____
Date study product dispensed	_____
How many vaginal rings or tablet bottles were dispensed?	1 ☐ 2 ☐
Tablet bottle Lot Number #1	_____
Tablet bottle Lot Number #2	_____

Vaginal Ring #1 Lot Number	
Vaginal Ring #2 Lot Number	
Source Data Upload	

Tablet Bottle Return	
No tablet bottle(s) returned	☐
OR	
Date tablet bottle returned by participant	_____
Number of tablet bottles returned at this study visit	1 ☐ 2 ☐
Tablet Bottle Provision	
No Tablet bottle(s) provided	☐
OR	
Date Tablet bottle(s) provided	_____
Number of tablet bottles provided	1 ☐ 2 ☐
Source Data Upload	_____

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Tablet Assessment
Generated On: 30 Nov 2021 19:52:11

1. - Date of Assessment	
2. - Was the participant's first tablet dose directly observed at the clinic?	Yes ☐ No ☐
If "Yes", go to item 4.	
2a. - If "No", specify reason:	Participant refused to swallow tablet ☐ Participant unable to swallow tablet ☐ Other ☐
3. - . Explain the response for the reason provided why the participant's first tablet dose was not directly observed at the clinic.	
End of form.	
4. - How many attempts did the participant need to successfully swallow the tablet?	
5. - Based on your assessment and her feedback, how easy or difficult was it for the participant to swallow the tablet?	Very difficult ☐ Difficult ☐ Easy ☐ Very easy ☐
If "Easy" or "Very easy", end of form.	
6. - If difficult or very difficult, why? (Mark all that apply):	☐
a. Difficulty swallowing due to size of tablet	
b. - Difficulty swallowing due to pain of swallowing	☐
c. - Swallowing caused participant to feel nauseated	☐
d. - Swallowing caused the participant to gag	☐
e. - Other	☐
6e1. - If "Other", specify:	
Source Data Upload	

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Ring Insertion and Removal
Generated On: 30 Nov 2021 19:52:11

Date of assessment	
RING PROVISION	
No ring provided	☐
OR	
Date ring provided	
If no rings were provided at this visit, skip to the RING RETURN section of this form.	
Number of rings provided	1 ◯ 2 ◯
Was a ring inserted at this visit?	Yes ◯ No ◯
If ring was not inserted, specify reason:	
RING RETURN	
Did the participant have a ring in place at the start of the visit?	Yes ◯ No ◯
Ring not returned	☐
If ring not returned, end of form.	
Date ring returned	
Number of rings returned at this study visit	1 ◯ 2 ◯
Date returned ring #1 was provided	
Date returned ring #1 was inserted	
OR	
Unknown	☐
Date returned ring #1 was removed	
OR	
Unknown	☐
If only one ring returned, Skip to "Was the ring(s) stored"	
Date returned ring #2 was provided	
Date returned ring #2 was inserted	
OR	
Unknown	☐
Date returned ring #2 was removed	
OR	
Unknown	☐
Was the ring(s) stored?	Stored ◯ Not stored ◯
If "Not stored", specify reason:	
Source Data Upload	

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Ring Assessment
Generated On: 30 Nov 2021 19:52:11

1. - Date of Assessment	_____
2. - Did the participant attempt to insert a ring herself?	Yes ☐ No, inserted by study staff ☐
If Yes, go to Item 3.	
2a. If “No, inserted by study staff”, please describe the reason.	_____
End of form.	
3. - Based on your assessment and her feedback, how easy or difficult was it for the participant to insert the ring?	Very difficult ☐ Difficult ☐ Easy ☐ Very easy ☐
If "Easy" or "Very easy", go to item 5.	
4. - If "Very difficult" or "Difficult", why? (Mark all that apply)	
a. - Reluctance to insert the ring herself	☐
b. - Physical discomfort while inserting the ring	☐
c. - Difficulty folding and gripping ring	☐
d. - Difficulty inserting the ring far enough	☐
e. - Required more than one attempt	☐
f. - Other	☐
4f1. - If "Other", specify:	_____
5. - Did the participant require any help from the clinician to insert the ring?	Yes ☐ No ☐
5a. - If "Yes", specify:	_____
6. - Did study staff verify that the ring was in place?	Yes ☐ No ☐
6a. - If "No", specify:	_____
7. - If "Yes", upon verifying, was the ring correctly inserted by the participant?	Yes ☐ No ☐
7a. - If "No", specify:	_____
Source Data Upload	_____

MTN034_Version_10.0_PROD_TP_30NOV2021: All
Form: Product Preference and Acceptability
Generated On: 30 Nov 2021 19:52:11

1. - Form Completion Date	_____
If Visit 23, skip to item 5.	
2. - What product did the participant use most recently?	Ring ☐ Tablets ☐
If the participant used the ring most recently:	
3. - .Please rate how much you like using the ring for HIV prevention.	Dislike very much ☐ Dislike ☐ Neither like nor dislike ☐ Like ☐ Like very much ☐
If the participant used the tablet most recently:	
4. - .Please rate how much you like using the tablets for HIV prevention.	Dislike very much ☐ Dislike ☐ Neither like nor dislike ☐ Like ☐ Like very much ☐
If Visit 9 or Visit 16, and participant has not seroconverted or is not pregnant, end of form.	
5. - .Would you prefer to use the ring or the tablets for HIV prevention?	Ring ☐ Tablets ☐ Either product equally ☐ Neither product ☐
Source Data Upload	_____

Target Visit Date	
Reason visit was missed	Unable to contact participant ☐ Unable to schedule appointment(s) within allowable window ☐ Participant refused visit ☐ Participant incarcerated ☐ Participant admitted to a health care facility ☐ Participant withdrew from study ☐ Participant deceased ☐ Other ☐
If "Other", specify:	
Steps taken to address the missed visit (corrective action plan)	
Source Data Upload	

1 - Date of assessment _____

.As you may know, there is an outbreak of a respiratory disease caused by the novel coronavirus. The disease is called COVID-19. There are millions of confirmed cases and many deaths related to COVID-19, including here in [add country & COVID-19 relevant info (I.e., lockdown started in X month)].

2 - .How many people do you know personally are (or have been) infected with COVID-19?

Please include both suspected and confirmed infections, do not count yourself, and give your best estimate if you do not know the exact number.

_____

3 - .Were you infected (or suspected to be infected) with COVID-19?

(Do not read response options)

- ☐ Yes, tested and the result was positive.
- ☐ Yes, suspected but not confirmed by a test.
- ☐ No, tested and the result was negative.
- ☐ No.
- ☐ Not sure.

4 - .How often did you follow the guidelines in your community, like staying at home, to prevent yourself from getting or transmitting COVID-19?

- ☐ Always.
- ☐ Often.
- ☐ Occasionally.
- ☐ Rarely.

5 - .Now I'm going to ask you about some worries you might currently have. Please indicate how worried or concerned you are about the following things:

a - .Having enough food to eat

- ☐ Very worried.
- ☐ A little worried.
- ☐ Not worried at all.

b - .Having a job/going to school

- ☐ Very worried.
- ☐ A little worried.
- ☐ Not worried at all.

c - .Having money to cover basic expenses

- ☐ Very worried.
- ☐ A little worried.
- ☐ Not worried at all.

d - .Getting the coronavirus (COVID-19)

- ☐ Very worried.
- ☐ A little worried.
- ☐ Not worried at all.

e - .Getting HIV

- ☐ Very worried.
- ☐ A little worried.
- ☐ Not worried at all.

f - .Unplanned pregnancy

- ☐ Very worried.
- ☐ A little worried.

	Not worried at all. ☐
6 - .Between getting COVID-19 and getting HIV, which is more concerning to you right now?	Getting COVID-19. ☐ Getting HIV. ☐ Both equally. ☐ Neither concerns me. ☐
7 - .How has COVID-19 influenced your interest in preventing HIV?	Decreased. ☐ Increased. ☐ No influence. ☐
8 - .How has COVID-19 influenced your interest in using[Ring/Tablet]?	Decreased. ☐ Increased. ☐ No influence. ☐
9 - .Do you think other people would judge you or treat you badly if you had COVID-19?	Yes. ☐ No. ☐

10 - .I'm going to ask you about several different aspects of your life that might have changed because of COVID-19 (and the plans used to manage it). For each one, please tell me if the following has decreased, increased, or not changed because of COVID-19.

a - .Your level of anxiety (nervous or on edge; not being able to stop or control worrying)	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
b - .Your feelings of depression (hopeless, little interest in doing things, feeling constantly sad)	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
c - .Your feeling of connection to family	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
d - .Your feeling of connection to friends	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
e - .How often you have sex	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
f - .The number of sexual partners you have	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐

g - .Access to your contraceptive method	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
h - .Access to condoms	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
i - .How often you use condoms when you have sex	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
j - .Violence in your household	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
k - .Your alcohol consumption	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
l - .Your access to money for necessary items	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
m - .How much food you eat	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
n - .Your access to health care	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
o - .Access to HIV testing	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
p - .The amount of support to use the [Ring/Tablets] that you receive from the study counselors or nurses	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed. ☐
q - .Your adherence to the [Ring/Tablets]	Has decreased because of COVID-19. ☐

	Has increased because of COVID-19. ☐ Has not changed. ☐
r - .Your feeling of connection to your primary partner	Has decreased because of COVID-19. ☐ Has increased because of COVID-19. ☐ Has not changed/no different because of COVID-19. ☐ N/A: No primary partner. ☐ N/A: Don't know. ☐
11 - .Due to COVID-19, did you experience a time when you were unable to get your [Ring/Tablets] as planned, and therefore could not use it/them? If "No" skip to item 14	Yes. ☐ No. ☐
12 - .During the time when you did not have study product, how worried were you about not having your [Ring/Tablets]?	Very worried. ☐ Somewhat worried. ☐ Not at all worried. ☐
13 - .During the time when you did not have your [Ring/Tablets], was there any change in your sexual behavior? Please agree or disagree with the following statements.	
a - .I stopped having vaginal sex	Agree. ☐ Disagree. ☐
b - .I had less vaginal sex	Agree. ☐ Disagree. ☐
c - .I used a condom more frequently	Agree. ☐ Disagree. ☐
d - .I switched to other types of sex (e.g. oral/anal)	Agree. ☐ Disagree. ☐
d1 - .If "Other", specify:	_____
14. - .Due to COVID-19, did you receive more than one month's supply of your [Ring/Tablets]? If "No", skip to item 18	Yes. ☐ No. ☐
15 - .When you had extra supply of [Ring/Tablets], how worried were you about being able to store it properly?	Very worried. ☐ Somewhat worried. ☐ Not at all worried. ☐
16 - .Did anyone find out you were using the [Ring/Tablets] because you had extra product to store?	Yes. ☐ No. ☐ Not sure/Don't know. ☐
17 - .Did anyone take or use any of the extra [Rings/Tablets] you had stored during the COVID-19 outbreak?	Yes. ☐ No. ☐ Not sure/Don't know. ☐

18 - .Did you experience any of the following situations, because of COVID-19 and the plans to manage the outbreak?

a - .Less privacy than usual	Yes. ☐ No. ☐
b - .Less access to clean water than usual	Yes. ☐ No. ☐
c - .Less access to toilet facilities than usual	Yes. ☐ No. ☐
d - .Being unable to conceal product use from others	Yes. ☐ No. ☐
e - .Forgetting to use your study product	Yes. ☐ No. ☐

19. - .Which types of [Ring/Tablets] adherence support have been most helpful to you during the COVID-19 outbreak?

(Do not read responses aloud, select all that apply)

- a - .Daily text message ☐
- b - .Weekly check-in via text message ☐
- c - .Weekly check in via phone call ☐
- d - .Peer buddy ☐
- e - .In-person counseling ☐
- f - .In-person adherence support groups ☐
- g - .Online adherence support groups ☐
- h - .Pill keychain ☐
- i - .Support from friends ☐
- j - .Support from family ☐
- k - .Support from husband/partner ☐
- I - .Other ☐
  - l1 - .If "Other", specify: _____
- m - .None of the above ☐

20 - .Which types of [Ring/Tablets] adherence support have you missed the most during the COVID-19 outbreak?

(Do not read responses aloud, select all that apply)

- a - .Daily text message ☐
- b - .Weekly check-in via text message ☐
- c - .Weekly check in via phone call ☐

d - .Peer buddy	☐
e - .In-person counseling	☐
f - .In-person adherence support groups	☐
g - .Online adherence support groups	☐
h - .Pill keychain	☐
i - .Support from friends	☐
j - .Support from family	☐
k - .Support from husband/partner	☐
l - . Other	☐
l1 - .If "Other", specify:	_____
m - .None of the above	☐