

Subject Case Report Forms

MTN035_Version 4.0_PROD_BK_09JUNE2020 - All

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

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Screening Date of Visit

Generated On: 29 Jun 2020 17:43:31

Screening visit date

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Follow-up Visit Y/N

Generated On: 29 Jun 2020 17:43:31

Was this visit completed?

Yes

No

MTN035_Version 4.0_PROD_BK_09JUNE2020: All
Form: Follow-up Visit Summary
Generated On: 29 Jun 2020 17:43:31

Visit date _____

Was study product held at this visit? Yes

No

If yes, complete a Product Hold form.

Was study product permanently discontinued (scheduled or early) at this visit? Yes

No

If yes, complete a Discontinuation of Study Product form.

Did the participant exit/terminate the study at this visit? Yes

No

Were any new adverse events (AEs) reported at this visit? Yes

No

If yes, complete the AE Log.

Is the participant taking any concomitant medications that have not been previously reported? Yes

No

If yes, complete the Concomitant Medications Log.

Have any protocol deviations been reported at this visit? Yes

No

If yes, complete the Protocol Deviation Log.

Were any additional study procedures or forms completed outside of the scheduled study visit per protocol? Yes

No

If yes, complete the Additional Study Procedures form.

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Randomization

Generated On: 29 Jun 2020 17:43:31

Is the participant ready to be randomized?

Yes

No

Randomization Date and Time _____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Adverse Event

Generated On: 29 Jun 2020 17:43:31

Date AE reported to site _____

Adverse event (AE) _____

Onset date _____

Is the AE still ongoing? Yes

No

If "No", outcome date _____

Severity grade Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Grade 5 (Death)

Relationship to study product Related

Not related

Action taken with study product Dose not changed

Dose reduced

Dose increased

Drug withdrawn

Drug interrupted

Not applicable

Other actions

Mark "None" or all that apply.

None

Medication(s)

Therapeutic procedure/surgery

Diagnostic procedure

Referral

Other

If "Other", specify (max. 200 characters): _____

Status/outcome Recovered/resolved

Recovering/resolving

Recovered/resolved with
sequelae

Not recovered/not resolved

Fatal

Severity/frequency increased

Is this a serious adverse event according to ICH/GCP or protocol
guidelines? Yes

No

If "No", go to "Was this AE a worsening of a baseline medical
condition?" If "Yes", check all that apply.

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Adverse Event

Generated On: 29 Jun 2020 17:43:31

Results in death	<input type="checkbox"/>
Is life-threatening	<input type="checkbox"/>
Requires inpatient hospitalization or prolongation of existing hospitalization	<input type="checkbox"/>
Results in persistent or significant disability/incapacity	<input type="checkbox"/>
Is a congenital anomaly/birth defect	<input type="checkbox"/>
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	<input type="checkbox"/>
Was this AE a worsening of a baseline medical condition?	Yes <input type="radio"/>
	No <input type="radio"/>
Comments: (max. 200 characters)	

Medication name _____

Indication _____

Date started _____

Date stopped _____

OR

Ongoing _____

Dose _____

Dose units _____

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

If "Other", specify: _____

Frequency _____

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

If "Other", specify: _____

Route _____

- Oral
- Intramuscular
- Intravenous
- Topical
- Inhalation
- Vaginal
- Rectal
- Subcutaneous

Other

If "Other", specify: _____

Taken for a reported AE? Yes

No

If "Yes", select adverse event _____

If "Yes", select adverse event _____

If "Yes", select adverse event _____

Date of birth _____

Age _____ Fixed Unit: Years

Sex at birth _____ Male

Female

The following item should only be completed for US sites.
International sites, skip to "Ethnic group or tribe".

Race

Mark all that apply.

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or other Pacific Islander

White

Other

If "Other", specify: _____

Ethnicity _____ Hispanic or Latino

Not Hispanic or Latino

The following item should only be completed for international sites.

Ethnic group or tribe: _____ Acholi

Asian

Baganda

Basoga

Banyaruanda

Bakiga

Bagisu

Banyoro

Batoro

Chinese

Colored

Indian

Indigenous

Iteso

Karamojong

Lango

Lugbara

Mixed

Ndebele

- Shona
- Thai
- White
- Xhosa
- Zulu
- Other African Tribe
- Other

Current gender
Mark all that apply.

- Male
- Female
- Transgender Male
- Transgender Female
- Gender Nonconforming/Gender Variant
- Self-identify
- If "Self-identify", specify: _____
- Prefer not to answer

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Inclusion/Exclusion Criteria

Generated On: 29 Jun 2020 17:43:31

Did the participant meet all eligibility criteria? Yes
No

Informed consent date

Eligibility Status Eligible and Enrolled
Eligible/Not enrolled
Ineligible
Incomplete Screening

Was the participant enrolled into MTN-035? Yes
No

If "Eligible and enrolled" or "Incomplete Screening", end of form.

If Eligible/Not enrolled, specify reason:

End of form.

Select reason(s) why participant is ineligible.

- I1. Men (cis or transgender) and TGW who are 18-35 years old at Screening, verified per site SOP
- I2. Able and willing to provide written informed consent
- I3. HIV-1/2 uninfected at Screening and Enrollment, per applicable algorithm in Appendix II and willing to receive HIV test results
- I4. Able and willing to provide adequate locator information, as defined in site SOP
- I5. Available to return for all study visits and willing to comply with study participation requirements
- I6. In general good health at Screening and Enrollment, as determined by the site Investigator of Record (IoR) or designee
- I7. At Screening, has a history of consensual RAI at least three times in the past three months and expecting to maintain at least this frequency during study participation
- I8. Willing to not take part in other research studies involving drugs, medical devices, genital or rectal products, or vaccines during study participation (including between Screening and Enrollment)
- I9. For individuals who can get pregnant (i.e., TGM with a female reproductive system): a negative pregnancy test at Screening and Enrollment

- I10. Individuals who can get pregnant: Per participant report at Enrollment, using effective contraceptive method for 30 days (inclusive) prior to Enrollment and intending to use effective method during study
- E1a. At Screening, history of inflammatory bowel disease
- E1b. At Screening, current anorectal condition that would impede product placement or assessment of tolerability by participant report or exam
- E2. Anticipated use and/or unwillingness to abstain from using non-study rectally-administered medications/products during study participation, including personal lubricants containing N-9
- E3. Known adverse reaction to any of the components of the study products
- E4. Participation in research studies involving drugs, medical devices, genital products, or vaccines within 30 days of the Enrollment Visit
- E5. Participation in research studies involving rectal products (ever)
- E6. Per participant report, use of post-exposure prophylaxis (PEP) for potential HIV exposure within the 3 months prior to Enrollment
- E7. In the 3 months prior to Enrollment, participant engagement in condomless RAI or RVI while not on PrEP with a HIV-positive partner and either not on ART or of unknown ART use status (by self-report)
- E8. In the month prior to Enrollment, participant engagement in condomless RAI or RVI while not on PrEP with a partner who is of unknown HIV status and unknown PrEP/ART use status (by self-report)
- E9. Non-therapeutic injection drug use in the 12 months prior to Enrollment

- E10. At either Screening or Enrollment, participant-reported symptoms and/or clinical or laboratory diagnosis of active anorectal or reproductive tract infection requiring treatment per WHO Guidelines or symptomatic UTI.
- E11. For individuals who can get pregnant: Pregnant or breastfeeding at either Screening or Enrollment or planning to become pregnant during study participation
- E12. For individuals who can get pregnant: Last pregnancy outcome 90 days or less prior to Screening
- E13. Has a condition that, per IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data or interfere with achieving study objectives

If investigator decision, specify (max. 200 characters): _____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Pregnancy Test Results

Generated On: 29 Jun 2020 17:43:31

Was a pregnancy test done? Yes

No

Collection date _____

Collection time _____

Pregnancy test result Positive

Negative

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Medical History

Generated On: 29 Jun 2020 17:43:31

Date medical history collected _____

Description of medical history condition/event _____

Is condition/event gradable? Yes
No

Severity grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

Start date of medical history condition/event _____

Is the condition ongoing? Yes
No

Date medical history/condition ended/resolved _____

Was a physical exam performed? Yes
No

Date of exam _____

Body System

General Appearance Not Done
Normal
Abnormal

If "Abnormal", specify: _____

HEENT 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: _____

Lung/Respiratory Not Done
Normal
Abnormal

If "Abnormal", specify: _____

Oral Mucosa 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 system finding Not Done
Normal
Abnormal

Other system, specify: _____

If "Abnormal", specify: _____

Was a Genital Exam performed at this visit? Yes
No

If yes, complete the Genital Exam form.

Was a Pelvic Exam performed at this visit? Yes
No

If yes, complete the Pelvic Exam form.

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Vital Signs

Generated On: 29 Jun 2020 17:43:31

Were vital signs done? Yes

No

Date of assessment _____ Fixed Unit: cm

Height _____ Fixed Unit: cm

Weight _____ Fixed Unit: kg

Body temperature _____ Fixed Unit: C

Systolic BP _____ Fixed Unit: mmHg

Diastolic BP _____ Fixed Unit: mmHg

Pulse _____ Fixed Unit: beats/min

Rate of respiration _____ Fixed Unit: breaths/min

Rate of respiration unit _____ breaths/min

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Discontinuation of Study Product

Generated On: 29 Jun 2020 17:43:31

Date that study product use ended _____

Primary reason for ending study product use

Scheduled study product use period completed	<input type="checkbox"/>
Death	<input type="checkbox"/>
Participant refused further participation	<input type="checkbox"/>
Participant is unwilling or unable to comply with required study procedures	<input type="checkbox"/>
Lost to follow-up	<input type="checkbox"/>
Investigator decision	<input type="checkbox"/>
Participant refused further study product use	<input type="checkbox"/>
HIV infection	<input type="checkbox"/>
Early study closure	<input type="checkbox"/>
Protocol deviation	<input type="checkbox"/>
Adverse event	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Withdrawal of consent by participant	<input type="checkbox"/>
Study terminated by sponsor	<input type="checkbox"/>
One or more reactive HIV test results or acute HIV infection suspected	<input type="checkbox"/>
Reported use of non-study rectal medications or products	<input type="checkbox"/>
Other, specify	<input type="checkbox"/>

If "Reported use of non-study rectal medications or products", select applicable concomitant medication

If "Other", specify:

Visit at which study product was discontinued

V3 - Day 28/Week 4	<input type="checkbox"/>
V5 - Day 63/Week 9	<input type="checkbox"/>
V7 - Day 98/Week 14	<input type="checkbox"/>
V8 - Day 105/Week 15	<input type="checkbox"/>
Interim Visit	<input type="checkbox"/>

If "Interim visit", specify interim visit code

Type of study product discontinued

Placebo rectal inserts	<input type="checkbox"/>
Placebo rectal suppositories	<input type="checkbox"/>
Placebo rectal douche	<input type="checkbox"/>

If "Adverse event", select applicable adverse event

Date of study exit _____

Primary reason for completion/discontinuation

Scheduled exit visit/end of study	<input type="radio"/>
Death	<input type="radio"/>
Participant refused further participation	<input type="radio"/>
Participant is unwilling or unable to comply with required study procedures	<input type="radio"/>
Lost to follow-up	<input type="radio"/>
Investigator decision	<input type="radio"/>
Participant refused further study product use	<input type="radio"/>
Unable to contact participant	<input type="radio"/>
HIV infection	<input type="radio"/>
Early study closure	<input type="radio"/>
Protocol deviation	<input type="radio"/>
Adverse event	<input type="radio"/>
Pregnancy	<input type="radio"/>
Withdrawal of consent by participant	<input type="radio"/>
Study terminated by sponsor	<input type="radio"/>
Other, specify	<input type="radio"/>

If "Other", specify: _____

If "Death", enter date of death _____

If "Adverse event", select applicable adverse event _____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Social Impact

Generated On: 29 Jun 2020 17:43:31

Date reported to site _____

Concisely describe social impact _____

Onset date _____

Reported at visit code

V1 - Screening Visit

V2 - Enrollment Visit

V3 - Day 28/Week 4

V4 - Day 35/Week 5

V5 - Day 63/Week 9

V6 - Day 70/Week 10

V7 - Day 98/Week 14

V8 - Day 105/Week 15

Interim Visit

Interim visit code _____

Social impact

Personal Relationships

Travel/Immigration

Employment

Education

Medical/Dental

Health Insurance/Medical Aid/Hospital plan

Life Insurance/Funeral coverage

Housing

Military/Other Government Agency

Other

What impact has this situation had 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

Unresolved at end of study

Unable to resolve; no further action taken

Resolved

If social impact status "Unable to resolve; no further action taken" or "Resolved" is marked, record closure date _____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Participant Identifier

Generated On: 29 Jun 2020 17:43:31

Participant ID: _____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Pregnancy History

Generated On: 29 Jun 2020 17:43:31

Date pregnancy history collected _____

Has the participant ever been pregnant before? Yes

No

If "No", end of form.

Number of full term live births (≥ 37 weeks) _____

Number of premature live births (less than 37 weeks) _____

Number of spontaneous fetal deaths and/or still births (≥ 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(max. 200 characters): _____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Pregnancy Report

Generated On: 29 Jun 2020 17:43:31

Date pregnancy reported to site _____

Visit at which this pregnancy was reported _____

- V1 - Screening Visit
- V2 - Enrollment Visit
- V3 - Day 28/Week 4
- V4 - Day 35/Week 5
- V5 - Day 63/Week 9
- V6 - Day 70/Week 10
- V7 - Day 98/Week 14
- V8 - Day 105/Week 15
- Interim Visit

If "Interim visit", specify Interim visit code. _____

Date of onset 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 <20 weeks
- Initial ultrasound >= 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 Pregnancy History form. _____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Participant Transfer

Generated On: 29 Jun 2020 17:43:31

Name of transferring study site	Alabama CRS	<input type="checkbox"/>
	Blantyre CRS	<input type="checkbox"/>
	Bridge HIV CRS	<input type="checkbox"/>
	Chang Mai University HIV	<input type="checkbox"/>
	Prevention CRS	<input type="checkbox"/>
	San Miguel CRS	<input type="checkbox"/>
	University of Pittsburgh CRS	<input type="checkbox"/>
	Wits RHI CRS	<input type="checkbox"/>

Name of receiving study site	Alabama CRS	<input type="checkbox"/>
	Blantyre CRS	<input type="checkbox"/>
	Bridge HIV CRS	<input type="checkbox"/>
	Chang Mai University HIV	<input type="checkbox"/>
	Prevention CRS	<input type="checkbox"/>
	San Miguel CRS	<input type="checkbox"/>
	University of Pittsburgh CRS	<input type="checkbox"/>
	Wits RHI CRS	<input type="checkbox"/>

Visit of last completed contact with participant	V1 - Screening Visit	<input type="checkbox"/>
	V2 - Enrollment Visit	<input type="checkbox"/>
	V3 - Day 28/Week 4	<input type="checkbox"/>
	V4 - Day 35/Week 5	<input type="checkbox"/>
	V5 - Day 63/Week 9	<input type="checkbox"/>
	V6 - Day 70/Week 10	<input type="checkbox"/>
	V7 - Day 98/Week 14	<input type="checkbox"/>
	V8 - Day 105/Week 15	<input type="checkbox"/>
	Interim Visit	<input type="checkbox"/>

Interim visit code	_____
Date participant's records were sent to receiving study site	_____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All
Form: Participant Receipt
Generated On: 29 Jun 2020 17:43:31

Name of receiving study site	Alabama CRS <input type="checkbox"/>
	Blantyre CRS <input type="checkbox"/>
	Bridge HIV CRS <input type="checkbox"/>
	Chang Mai University HIV <input type="checkbox"/>
	Prevention CRS <input type="checkbox"/>
	San Miguel CRS <input type="checkbox"/>
	University of Pittsburgh CRS <input type="checkbox"/>
	Wits RHI CRS <input type="checkbox"/>

Name of transferring study site	Alabama CRS <input type="checkbox"/>
	Blantyre CRS <input type="checkbox"/>
	Bridge HIV CRS <input type="checkbox"/>
	Chang Mai University HIV <input type="checkbox"/>
	Prevention CRS <input type="checkbox"/>
	San Miguel CRS <input type="checkbox"/>
	University of Pittsburgh CRS <input type="checkbox"/>
	Wits RHI CRS <input type="checkbox"/>

Date informed consent signed at receiving site	_____
--	-------

MTN035_Version 4.0_PROD_BK_09JUNE2020: All
Form: Participant Replacement Assessment
Generated On: 29 Jun 2020 17:43:31

Date of assessment _____

Does this participant meet protocol-specified criteria for replacement? Yes
No

Why is this participant being replaced? None of the doses administered (e.g., due to non-adherence or permanent discontinuation)
Early termination before visit 7 (e.g., due to participant voluntarily withdrawing from the study, death, lost to follow-up, relocation, or permanent discontinuation)
Other

If other, specify _____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All
Form: Protocol Deviations Log
Generated On: 29 Jun 2020 17:43:31

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
 - 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 _____

Perianal examination findings Not done
No abnormal findings
Abnormal findings

Anorectal exam date _____

PERIANAL EXAMINATION

If "Abnormal findings", select all that apply:

Warts	<input type="checkbox"/>
Fissure	<input type="checkbox"/>
Ulceration	<input type="checkbox"/>
Pigmentation	<input type="checkbox"/>
Hemorrhoids	<input type="checkbox"/>
Skin tags	<input type="checkbox"/>
Leukoplakia	<input type="checkbox"/>
Fistula	<input type="checkbox"/>
Petechiae (less than 3 mm)	<input type="checkbox"/>
Purpura (0.3 to 1 cm)	<input type="checkbox"/>
Ecchymosis (greater than 1 cm)	<input type="checkbox"/>
Discharge	<input type="checkbox"/>
Erythema	<input type="checkbox"/>
Bleeding	<input type="checkbox"/>
Other abnormal findings	<input type="checkbox"/>

If "Other abnormal findings", specify: _____

DIGITAL RECTAL EXAMINATION

Digital rectal examination findings Not done
No abnormal findings
Abnormal findings

If "Abnormal findings", specify: _____

ANOSCOPY

Rectal mucosa findings Not done
No abnormal findings
Abnormal findings

If "Abnormal findings", select all that apply:

Erythema	<input type="checkbox"/>
Abnormal vessels	<input type="checkbox"/>
Ulceration	<input type="checkbox"/>

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Anorectal Exam

Generated On: 29 Jun 2020 17:43:31

Friability	<input type="checkbox"/>
Bleeding	<input type="checkbox"/>
Discharge	<input type="checkbox"/>
Polyps	<input type="checkbox"/>
Hemorrhoids	<input type="checkbox"/>
Other abnormal findings	<input type="checkbox"/>

If "Other abnormal findings", specify: _____

Were any new anorectal finding AEs reported at this visit? Yes
No

Adverse event #1 _____

Adverse event #2 _____

Adverse event #3 _____

At Screening or Enrollment, evaluate any abnormalities for eligibility. Update the Medical History log when applicable. During follow-up, complete or update the Adverse Event Log, when applicable.

Pelvic exam assessment Abnormal Findings
No abnormal findings

Exam date _____
If "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	<input type="checkbox"/>
Cervical ulcer	<input type="checkbox"/>
Cervical blister	<input type="checkbox"/>
Cervical pustule	<input type="checkbox"/>
Cervical peeling	<input type="checkbox"/>
Cervical ecchymosis	<input type="checkbox"/>
GENERAL/OTHER	
Odor (vaginal)	<input type="checkbox"/>
Condyloma	<input type="checkbox"/>
If condyloma, specify location: _____	
Adnexal masses (based on bimanual exam; not pregnancy or infection-related)	<input type="checkbox"/>
Uterine masses (based on bimanual exam)	<input type="checkbox"/>
Uterine tenderness	<input type="checkbox"/>
Adnexal tenderness	<input type="checkbox"/>
Abnormal blood or bleeding	<input type="checkbox"/>
If "Abnormal blood or bleeding", specify: _____	
Other abnormal findings	<input type="checkbox"/>
If "Other abnormal findings", specify (include anatomical location): _____	
At Screening or Enrollment, evaluate any abnormalities for eligibility. Update the Medical History log when applicable. During follow-up, complete or update the Adverse Event Log, when applicable.	
Were any new pelvic finding AEs reported at this visit?	Yes <input type="radio"/>
	No <input type="radio"/>
Adverse event #1	_____
Adverse event #2	_____
Adverse event #3	_____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Specimen Storage

Generated On: 29 Jun 2020 17:43:31

Specimen type Plasma for archive

Was specimen collected? Yes

No

Specimen collection date

Was sample stored? Stored

Not stored

If "No", record reason why sample was not stored (max. 200 characters).

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Product Hold Y/N

Generated On: 29 Jun 2020 17:43:31

Does the participant have any clinical product holds to be applied?

Yes

No

If "Yes", complete the Product Hold Log.

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Product Hold Log

Generated On: 29 Jun 2020 17:43:31

Date study product hold was initiated _____

Visit study product hold was initiated _____

V1 - Screening Visit

V2 - Enrollment Visit

V3 - Day 28/Week 4

V4 - Day 35/Week 5

V5 - Day 63/Week 9

V6 - Day 70/Week 10

V7 - Day 98/Week 14

V8 - Day 105/Week 15

Interim Visit

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

Why is study product being held? _____

Positive HIV test

Adverse Event

Acquisition of an anorectal STI

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 - hold continuing for another reason

No - early termination

If 'no - permanently discontinued', 'no - early termination' or 'no - hold continuing at scheduled PUEV', complete the Discontinuation of Study Product form.

No - hold continuing at scheduled PUEV

No - permanently discontinued

Date study product resumed _____

Date study product hold continuing for another reason _____

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 Full term live birth (greater than or equal to 37 weeks)
If "Stillbirth/intrauterine fetal demise", "Spontaneous abortion", "Ectopic pregnancy" or "Therapeutic/elective abortion" is chosen, go to "Provide a brief narrative of the circumstances:" 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: _____

Method C-section
Standard vaginal
Operative vaginal

If "Full term live birth", go to "Were there any complications related to the pregnancy outcome?".

Provide a brief narrative of the circumstances (max. 400 characters). _____

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

If "No", skip to "Were any fetal/infant congenital anomalies identified?".

Delivery-related complications. Mark "None" or all that apply.

None

Intrapartum hemorrhage

Postpartum hemorrhage

Non-reassuring fetal status

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Pregnancy Outcome Log

Generated On: 29 Jun 2020 17:43:31

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? Yes

Mark all that apply. If "No" or "Unknown", go to statement above No

"Infant gender". Complete AE Log. Unknown

Central nervous system, cranio-facial

Central nervous system, spinal

Cardiovascular

Renal

Gastrointestinal

Pulmonary

Musculoskeletal/extremities

Physical defect

Skin

Genitourinary

Chromosomal

Cranio-facial (structural)

Hematologic

Infectious

Endocrine/metabolic

Other

Describe congenital anomaly/defect _____

Specify congenital anomaly/defect AE.

Complete AE Log. _____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Pregnancy Outcome Log

Generated On: 29 Jun 2020 17:43:31

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

Female

Infant gender

Infant birth weight Or Fixed Unit: kg

Infant birth weight unavailable

Infant birth length Or Fixed Unit: centimeters

Infant birth length unavailable

Infant birth head circumference Or Fixed Unit: cm

Infant birth head circumference unavailable

Infant birth abdominal circumference Or Fixed Unit: centimeters

Infant birth abdominal circumference unavailable

Infant gestational age by examination in weeks Fixed Unit: Weeks

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

Infant gestational age by examination unavailable

Method used to determine gestational age Ballard

Dubowitz

Other

If other, specify:

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: HIV Test Results

Generated On: 29 Jun 2020 17:43:31

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

AlereTM HIV Combo
Oraquick ADVANCE HIV-1/2
Uni-Gold Recombigen HIV-1/2
Alere Determine
Alere Determine HIV-1/2 AG-AB
Combo
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", go to Was an HIV-EIA test done?

Rapid HIV test 2 Kit

AlereTM HIV Combo
Oraquick ADVANCE HIV-1/2
Uni-Gold Recombigen HIV-1/2
Alere Determine
Alere Determine HIV-1/2 AG-AB
Combo
Other

If "Other", specify: _____

Rapid HIV test 2 collection date _____

Rapid HIV test 2

Antibody positive
Antigen positive
Antibody and antigen positive
Negative

Was an HIV-EIA test done? Yes
No

HIV-EIA collection date _____

HIV-EIA test result

Positive
Negative
Indeterminate

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: HIV Test Results

Generated On: 29 Jun 2020 17:43:31

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

MTN035_Version 4.0_PROD_BK_09JUNE2020: All
Form: HIV Confirmatory Results
Generated On: 29 Jun 2020 17:43:31

Sample 1 Confirmatory Tests

Was sample 1 collected for HIV Confirmatory testing? Yes
No

If "No", go to Was sample 2 collected for HIV Confirmatory testing?

Collection date _____

ARCHITECT HIV Ag/Ab Combo Non reactive
Reactive
Not done

Geenius HIV-1/2 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)
Invalid
Not done

Aptima HIV-1 RNA Qualitative assay Non reactive
Reactive
Invalid
Not done

"If negative or indeterminate consult the MTN LC.

If positive, collect sample 2."

Sample 2 Collection

Was sample 2 collected for HIV Confirmatory testing? Yes
No

If "No", go to Final HIV status.

Collection date _____

ARCHITECT HIV Ag/Ab Combo Non reactive
Reactive
Not done

Geenius HIV-1/2 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) <input type="radio"/>
	Invalid <input type="radio"/>
	Not done <input type="radio"/>

Aptima HIV-1 RNA Qualitative assay	Non reactive <input type="radio"/>
	Reactive <input type="radio"/>
	Invalid <input type="radio"/>
	Not done <input type="radio"/>

Was sample 2 stored?	Stored <input type="radio"/>
	Not stored <input type="radio"/>

Final HIV status	HIV uninfected <input type="radio"/>
Final HIV status	HIV infected <input type="radio"/>
	pending <input type="radio"/>

Genital exam assessment Abnormal Findings
No abnormal findings

Exam date _____

Abnormal findings. Select all that apply. _____

Glans

Vesiculation

Bullous reaction

Ulceration

Bruising, petechiae or ecchymoses

Peeling

Erythema (with induration)

Erythema (without induration)

Other, specify: _____

Urethral Meatus

Ulceration

Edema

Discharge

Erythema (with induration)

Erythema (without induration)

Other, specify: _____

Internal and external foreskin (if present)

Vesiculation

Bullous reaction

Ulceration

Bruising, petechiae or ecchymoses

Peeling

Erythema (with induration)

Erythema (without induration)

Other, specify: _____

Shaft

Vesiculation

Bullous reaction

Ulceration

Bruising, petechiae or ecchymoses

Peeling

Erythema (with induration)	<input type="checkbox"/>
Erythema (without induration)	<input type="checkbox"/>
Other, specify: _____	
Scrotum	
Vesiculation	<input type="checkbox"/>
Bullous reaction	<input type="checkbox"/>
Ulceration	<input type="checkbox"/>
Bruising, petechiae or ecchymoses	<input type="checkbox"/>
Peeling	<input type="checkbox"/>
Erythema (with induration)	<input type="checkbox"/>
Erythema (without induration)	<input type="checkbox"/>
Other, specify: _____	
Inguinal lymph node (right)	Normal <input type="checkbox"/>
	Enlarged and painless <input type="checkbox"/>
	Enlarged and painful <input type="checkbox"/>
Inguinal lymph node (left)	Normal <input type="checkbox"/>
	Enlarged and painless <input type="checkbox"/>
	Enlarged and painful <input type="checkbox"/>
At Screening or Enrollment, evaluate any abnormalities for eligibility. Update the Medical History log when applicable. During follow-up, complete or update the Adverse Event Log, when applicable.	
Were any new genital finding AEs reported at this visit?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Adverse event #1	_____
Adverse event #2	_____
Adverse event #3	_____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Missed Visit

Generated On: 29 Jun 2020 17:43:31

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) _____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: Enrollment

Generated On: 29 Jun 2020 17:43:31

Product Sequence participant was randomized to (auto-populated by
Medidata Balance)

Is this a replacement participant?

Yes

No

PTID of participant being replaced

Was a sample collected for syphilis testing? Yes

No

Collection date _____

Syphilis test (EIA)

Positive

Negative

Indeterminate

Not done

Syphilis test (RPR)

Non-reactive

Reactive

Not done

Syphilis titer

Syphilis confirmatory test

Positive

Negative

Indeterminate

Not done

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: STI Test Result

Generated On: 29 Jun 2020 17:43:31

Was a urine sample collected for NAAT for GC/CT/Trichomonas? Yes
No

If no, skip to "Was a pharyngeal swab collected for NAAT for GC/CT?"

Date of collection _____

N. gonorrhea Positive
Negative
Not done

C. trachomatis Positive
Negative
Not done

Trichomonas test Positive
Negative
Not done

Was a pharyngeal swab collected for NAAT for GC/CT? Yes
No

If no, skip to "Was a vaginal swab collected for NAAT for GC/CT?"

Date of collection _____

N. gonorrhea Positive
Negative
Not done

C. trachomatis Positive
Negative
Not done

Was a vaginal swab collected for NAAT for GC/CT? Yes
No

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

Date of collection _____

N. gonorrhea Positive
Negative
Not done

C. trachomatis Positive
Negative
Not done

Was a vaginal sample collected for NAAT for Trichomonas? Yes
No

If no, skip to "Was an anorectal swab collected for NAAT for GC/CT?"

Date of collection _____

Trichomonas test	Positive	<input type="radio"/>
	Negative	<input type="radio"/>
	Not done	<input type="radio"/>

Was an anorectal swab collected for NAAT for GC/CT?	Yes	<input type="radio"/>
	No	<input type="radio"/>

If no, skip to "Was an anorectal swab collected for HSV-1/2 detection?"

Date of collection _____

N. gonorrhoea	Positive	<input type="radio"/>
	Negative	<input type="radio"/>
	Not done	<input type="radio"/>

C. trachomatis	Positive	<input type="radio"/>
	Negative	<input type="radio"/>
	Not done	<input type="radio"/>

Was an anorectal swab collected for HSV-1/2 detection?	Yes	<input type="radio"/>
	No	<input type="radio"/>

If no, skip to "Was the participant diagnosed with asymptomatic BV?"

Date of collection _____

HSV test result	Negative	<input type="radio"/>
	Positive for HSV-1	<input type="radio"/>
	Positive for HSV-2	<input type="radio"/>
	Positive for HSV-1 and HSV-2	<input type="radio"/>
	Inconclusive	<input type="radio"/>

Was the participant diagnosed with asymptomatic BV?	Yes	<input type="radio"/>
	No	<input type="radio"/>

Was the participant diagnosed with asymptomatic candida?	Yes	<input type="radio"/>
	No	<input type="radio"/>

Study Product Sequence

Sequence A

Sequence B

Sequence C

Sequence D

Sequence E

Sequence F

Study Product Sequence (autopopulated from Medidata Balance)

Visit study product dispensed

V1 - Screening Visit

V2 - Enrollment Visit

V3 - Day 28/Week 4

V4 - Day 35/Week 5

V5 - Day 63/Week 9

V6 - Day 70/Week 10

V7 - Day 98/Week 14

V8 - Day 105/Week 15

Interim Visit

If "Interim visit", specify visit code

Date study product dispensed

Which product was dispensed at this visit?

Select all that apply.

Placebo rectal inserts

Placebo rectal suppositories

Empty enema bottles

Empty enema tips

How many of the following study products were dispensed? 20

NA

Placebo rectal inserts

Placebo rectal suppositories 20

NA

Empty enema bottles 1

2

3

4

NA

Enema bottle tips 1

2

- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- NA

Was study lubricant provided to the participant?

- Yes
 - No
-

MTN035_Version 4.0_PROD_BK_09JUNE2020: All
Form: Behavioral Assessments Summary
Generated On: 29 Jun 2020 17:43:31

Was a CASI questionnaire completed at this visit? Yes
No

If no, please explain: _____

Was an in-depth interview completed at this visit? Yes
No

If no, please explain: _____

Complete the following item at Visit 8 only.

Was a conjoint analysis assessment completed at this visit? Yes
No

If no, please explain: _____

MTN035_Version 4.0_PROD_BK_09JUNE2020: All

Form: CASI Tracking

Generated On: 29 Jun 2020 17:43:31

CASI collection date

Which questionnaire was completed?

Baseline

Rectal Insert PUEV

Rectal Suppository PUEV

Rectal Enema PUEV

CASI ID

Were there any problems or issues related to the administration or completion of the questionnaire?

Yes

No

If yes, please describe:
