Subject Case Report Forms

MTN033_version 6.0_PROD_10AUG2018 - 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 complete this visit?	Yes ☐ No ☐

MTN033_version 6.0_PROD_10AUG2018: ALL
Form: Follow-up Visit Summary
Generated On: 10 Aug 2018 20:31:20

Visit date	
Was this a PK/PD Sampling Visit?	Yes ☐ No ☐
Was study product permanently discontinued (scheduled or early) at this visit?	Yes ☐ No ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit?	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported?	Yes ☐ No ☐
Were any protocol deviations reported at this visit?	Yes ☐ No ☐
Were any additional study procedures or forms completed outside of the scheduled study visit per protocol?	Yes ☐ No ☐
Source Data Upload	

What is the participant's date of birth?	
Age	Fixed Unit: Years
What was the participant's sex at birth?	Male ☐ Female ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☐
Race	
American Indian or Alaska Native	☐
Asian	☐
Black or African American	☐
Native Hawaiian or other Pacific Islander	☐
White	☐
Other	☐
Specify other:	
How do you identify your gender?	Male ☐ Female ☐ Transgender male (female to male) ☐ Transgender female (male to female) ☐ Additional category ☐ Decline to state ☐
Additional category, specify	
Source Data Upload	

Were vital signs done?	Yes ☐ No ☐
Date of Assessment	
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
Source Data Upload	

Was a physical exam performed? Yes ☐ No ☐

Date of exam _____

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: _____

Oral mucosa 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: _____

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:	_____
Source Data Upload	_____

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

Genital exam assessment

- Not done ☐
- No abnormal findings ☐
- 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)	☐
Erythema (without induration)	☐
Other, specify:	_____

Scrotum

Vesiculation	☐
Bullous reaction	☐
Ulceration	☐
Bruising, petechiae or ecchymoses	☐
Peeling	☐
Erythema (with induration)	☐
Erythema (without induration)	☐
Other, specify:	_____

Inguinal lymph node (right)	Normal ☐ Enlarged and painless ☐ Enlarged and painful ☐
Inguinal lymph node (left)	Normal ☐ Enlarged and painless ☐ Enlarged and painful ☐

VAGINAL

Was a vaginoplasty performed?	Yes ☐ No ☐
Date of most recent dilation	_____
Frequency of dilations	_____
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 blood or bleeding	☐
Abnormal blood or bleeding; describe:	
Other abnormal findings	
If other abnormal findings, specify (include anatomical location)	
Were any new genital finding AEs reported at this visit?	Yes ☐ No ☐
Adverse event #1	
Adverse event #2	
Adverse event #3	
Source Data Upload	

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

Exam date _____

PERIANAL EXAMINATION

Findings from the perianal examination
- ☐ Not done
- ☐ No abnormal findings
- ☐ Abnormal findings

Abnormal perianal findings:
select all that apply.

- ☐ Warts
- ☐ Fissure
- ☐ Ulceration
- ☐ Pigmentation
- ☐ Hemorrhoids
- ☐ Skin tags
- ☐ Leukoplakia
- ☐ Fistula
- ☐ Petechiae (less than 3 mm)
- ☐ Purpura (0.3 to 1 cm)
- ☐ Ecchymosis (greater than 1 cm)
- ☐ Discharge
- ☐ Erythema
- ☐ Bleeding
- ☐ Other abnormal findings

If other abnormal findings, specify _____

DIGITAL RECTAL EXAMINATION

Findings from the digital rectal examination
- ☐ Not done
- ☐ No abnormal findings
- ☐ Abnormal findings

If abnormal findings, specify _____

ANOSCOPY

Rectal mucosa findings from anoscopy
- ☐ Not done
- ☐ No abnormal findings
- ☐ Abnormal findings

Abnormal anoscopy findings: select all that apply.

- ☐ Erythema
- ☐ Abnormal vessels

Ulceration	☐
Friability	☐
Bleeding	☐
Discharge	☐
Polyps	☐
Hemorrhoids	☐
Other abnormal findings	☐
If other abnormal findings, specify	_____

SIGMOIDOSCOPY

Sigmoidoscopy findings	Not done ☐
	No abnormal findings ☐
	Abnormal findings ☐

Abnormal sigmoidoscopy findings: select all that apply.

Erythema	☐
Abnormal vessels	☐
Ulceration	☐
Friability	☐
Bleeding	☐
Discharge	☐
Polyps	☐
Hemorrhoids	☐
Other abnormal findings	☐
If other abnormal findings, specify	_____
Source Data Upload	_____

HEMOGRAM

Was a hematology sample collected? ☐ Yes ☐ No

Hematology collection date _____

Hemoglobin _____

Hemoglobin severity grade ☐ 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 Adverse event _____

WBC _____

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

WBC Adverse event _____

Was a differential done? ☐ Yes ☐ No

Differential collection date _____

Neutrophils _____

Neutrophils severity grade ☐ 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 Adverse event	
Monocytes	
Eosinophils	
Basophils	
Source Data Upload	

Was sample 1 collected for HIV testing?	Yes ☐ No ☐
Date of collection	_____
Sample 1 HIV test result	Positive ☐ Negative ☐ Indeterminate ☐

If the Rapid test is positive or indeterminate, complete the HIV Confirmatory Results Form and alert the MTN Laboratory Core.

Source Data Upload _____

Sample 1 Confirmatory Tests

Was sample 1 collected for HIV Confirmatory testing? Yes ☐ No ☐

Collection date _____

Sample 1 HIV Confirmatory test result Positive ☐ Negative ☐ Indeterminate ☐ Invalid ☐

If negative, indeterminate, or invalid, contact the MTN LC.
If positive, collect sample 2.

Sample 2 Collection

Was sample 2 collected for HIV Confirmatory testing? Yes ☐ No ☐

Collection date _____

Sample 2 HIV Confirmatory test result Positive ☐ Negative ☐ Indeterminate ☐ Invalid ☐

Was sample 2 stored? Stored ☐ Not stored ☐

Final HIV status

Final HIV status HIV uninfected ☐ HIV infected ☐ pending ☐

Source Data Upload _____

MTN033_version 6.0_PROD_10AUG2018: ALL
Form: Local Laboratory Results
Generated On: 10 Aug 2018 20:31:20
Lab Name:

Was a sample collected for blood chemistries?	Yes ☐ No ☐
Collection date	
AST (SGOT)	
AST (SGOT) severity grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ not gradable ☐
AST (SGOT) adverse event	
ALT (SGPT)	
ALT (SGPT) severity grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ not gradable ☐
ALT (SGPT) Adverse event	
Creatinine	
Creatinine severity grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ not gradable ☐
Creatinine Adverse event	
Source Data Upload	

Was a pharyngeal sample collected for N. gonorrhea and C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - Pharyngeal test result	Negative ☐ Positive ☐
C. trachomatis - Pharyngeal test result	Negative ☐ Positive ☐
Was a sample collected for Syphilis testing?	Yes ☐ No ☐
Collection date	_____
Syphilis screening test result	Non-reactive ☐ Reactive ☐ Not reported ☐
Syphilis titer	_____
Syphilis confirmatory test	Postive ☐ Negative ☐ Indeterminate ☐ Not done ☐
Was a urine sample collected for N. gonorrhea and C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - URINE test result	Negative ☐ Positive ☐
C. trachomatis - URINE test result	Negative ☐ Positive ☐
Was a rectal swab sample collected for N. gonorrhea and C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - RECTAL SWAB test result	Negative ☐ Positive ☐
C. trachomatis RECTAL SWAB test result	Negative ☐ Positive ☐
Was a rectal swab collected for HSV-1 and HSV-2 testing?	Yes ☐ No ☐
Collection date	_____
HSV-1 test result	Negative ☐

	Positive ☐
HSV-2 test result	Negative ☐
	Positive ☐
Source Data Upload	

Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Informed Consent Date	_____
Eligibility Status	Ineligible ☐ Eligible, but participant did not enroll ☐ Eligible, enrolled ☐ Incomplete Screening ☐
If eligible, but participant did not enroll, specify reason	_____
If eligible and enrolled or incomplete screening, end of form	
Select inclusion and/or exclusion criteria that contributed to participant's study ineligibility	I1. Men or transgender women who are 18 years or older at Screening, verified per site SOP ☐ I2. Able and willing to provide written informed consent ☐ I3. HIV-1/2 uninfected at Screening and Enrollment and willing to receive HIV test results ☐ I4. Able and willing to provide adequate locator information ☐ 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 IoR or designee ☐ I7. At Screening, history of consensual RAI at least once in the past year per participant report ☐ I8. Willing not to take part in other research studies involving drugs, medical devices, genital or rectal products, or vaccines for the duration of study participation ☐ I9. Willing to abstain from receptive anal intercourse, oral anal stimulation, rectal stimulation via fingers, and insertion of any non-study products into rectum for 72 hours before and after each visit ☐ E1a. Hemoglobin Grade 1 or higher ☐ E1b. Platelet count Grade 1 or higher ☐ E1c. White blood count Grade 2 or higher ☐ E1d. Aspartate aminotransferase (AST) or alanine transaminase (ALT) Grade 1 or higher ☐

- [ ] E1e. Serum creatinine >1.3× the site laboratory upper limit of normal (ULN)
- [ ] E1f. International normalized ratio (INR) >1.5× the site laboratory ULN
- [ ] E1g. Positive for hepatitis C antibody
- [ ] E1h. Positive for hepatitis B surface antigen
- [ ] E1i. History of inflammatory bowel disease by participant report
- [ ] E2. Known adverse reaction to latex or polyurethane (ever)
- [ ] E3a. Anticipated use of and/or unwillingness to abstain from the following medications during study participation: Anticoagulant medications
- [ ] E3b. Aspirin (greater than 81 mg/day)
- [ ] E3c. Non-steroidal anti-inflammatory drugs (NSAIDS)
- [ ] E3d. Any other drugs that are associated with increased likelihood of bleeding
- [ ] E3e. Rectally-administered medications or products containing N-9 or corticosteroids
- [ ] E3f. CYP3A inducer(s) and/or inhibitor(s) as specified in the MTN-033 Study Specific Procedures (SSP) Manual
- [ ] E3g. Hormone-replacement therapy in tablet, injectable or gel form
- [ ] E4. Known adverse reaction to any of the components of the study product, applicator or coital simulation device
- [ ] E5. Use of pre-exposure prophylaxis (PrEP) for HIV prevention within 1 month prior to Enrollment, and/or anticipated use and/or unwillingness to abstain from PrEP during trial participation
- [ ] E6. Use of post-exposure prophylaxis (PEP) for potential HIV exposure within the 6 months prior to Enrollment
- [ ] E7. Use of systemic immunomodulatory medications within the 6 months prior to Enrollment, and/or anticipated use during trial participation

	E8. RAI without a condom and/or penile-vaginal intercourse with a partner who is known to be HIV-positive in the 6 months prior to Enrollment. ☐
	E9. Non-therapeutic injection drug use in the 12 months prior to Enrollment ☐
	E10. Participation in research studies involving drugs, medical devices, genital or rectal products, or vaccines within 30 days of the Enrollment Visit ☐
	E11. Per participant report at Screening, treatment of an anogenital STI (after diagnosis) within the past 3 months ☐
	E12. At Screening, active anorectal infection or RTI requiring treatment per current CDC guidelines ☐
	E13. At Enrollment, active anorectal infection or RTI requiring treatment per current CDC guidelines or symptomatic UTI ☐
	E14. 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 other reason, including investigator decision, specify	_____
Source Data Upload	_____

Did the participant consent to long-term specimen storage and future testing?	Yes ☐ No ☐
PK and PD Time Assignment	1 hour ☐ 4 hours ☐
Sequence Assignment	Sequence A ☐ Sequence B ☐
Is this a replacement participant?	Yes ☐ No ☐
PTID of participant being replaced	_____
Source Data Upload	_____

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

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?	V2.0 - Day 0/Enrollment ☐ V3.0 - Dosing visit ☐ V4.0 - 24 Hr sampling visit ☐ V5.0 - Dosing visit ☐ V6.0 - 24 Hr sampling visit ☐ V7.0 - Termination ☐ Interim Visit ☐
If 'Interim visit' is chosen, provide interim visit code	
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 ☐
Record rationale or alternative etiology in Comments section below.	
Action taken with Study product	dose not changed ☐ dose reduced ☐ dose increased ☐ drug withdrawn ☐ drug interrupted ☐ not applicable ☐
Other action(s) taken (Select all that apply)	☐
None	
Medication	☐
New/prolonged hospitalization	☐
Therapeutic procedure/surgery	☐
Diagnostic procedure	☐
Other	☐
Other, specify	
Status/Outcome	recovered/resolved ☐

	recovering/resolving ☐
	resolved with sequelae ☐
	not recovered/resolved ☐
	fatal ☐
Is this a serious adverse event according to ICH/GCP or protocol guidelines? If "No", go to "Has or will this AE be reported as an EAE?". If "Yes", check all that apply.	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	☐
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 ☐
Was this AE related to the flexible sigmoidoscopy procedures?	Yes ☐ No ☐
Was this AE related to applicator insertion or coital simulation device?	Yes ☐ No ☐
Comments	_____
Source Data Upload	_____

Is the participant taking any concomitant medications?	Yes ☐ No ☐

If yes, please complete the Concomitant Medications Log.

Medication Name _____

Indication _____

Date Started _____

Date Stopped

Or _____

Ongoing ☐

Frequency

- PRN ☐
- QD ☐
- BID ☐
- TID ☐
- QID ☐
- QHS ☐
- ONCE ☐
- Other ☐

If other frequency, specify _____

Route

- Oral ☐
- Intramuscular ☐
- Intravenious ☐
- Topical ☐
- Inhalation ☐
- 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	

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

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

Date medical history collected	
Description of medical history condition/event	
Medical History Event Gradable	Yes ☐ No ☐
Medical History Event Severity/Intensity	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Not gradable ☐
Date of medical history condition/event	
Is the condition ongoing?	Yes ☐ No ☐
End Date of Medical History Event	
Source Data Upload	

Have any protocol deviations occurred?	Yes ☐ No ☐

If yes, please 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	

Was Plasma for PK collected?	Yes ☐ No ☐
Date of collection	_____
Time Point	Baseline ☐ 0.5 hour ☐ 1.0 hour ☐ 1.5 hours ☐ 2.0 hours ☐ 2.5 hours ☐ 3.0 hours ☐ 4.0 hours ☐ N/A ☐
Collection time	_____
Plasma for PK	Stored ☐ Not stored ☐
If not stored, specify reason	_____
Was plasma collected for archive?	Yes ☐ No ☐
Date of collection	_____
Plasma for archive	Stored ☐ Not stored ☐
If not stored, specify reason	_____
Source Data Upload	_____

Were rectal fluid specimens collected for PK?	Yes ☐ No ☐
Collection Date	
Collection time	
Rectal swab for PK stored?	Stored ☐ Not stored ☐
If not stored, specify reason	
Were rectal fluid specimens collected for microbiome?	Yes ☐ No ☐
Collection Date	
Collection time (microbiome)	
Rectal swab for microbiome stored?	Stored ☐ Not stored ☐
If not stored, specify reason	
Were specimens collected for rectal enema effluent for PK?	Yes ☐ No ☐
Collection Date	
Collection time	
Fluid from rectal enema stored?	Stored ☐ Not stored ☐
If not stored, specify reason	
Non-viable cells stored?	Stored ☐ Not stored ☐
If not stored, specify reason	
Were rectal biopsies collected for PK?	Yes ☐ No ☐
Collection Date	
Collection time (biopsy PK)	
Rectal biopsies for PK stored?	Stored ☐ Not stored ☐
If not stored, specify reason	
Were rectal biopsies collected for ex vivo challenge?	Yes ☐ No ☐
Collection Date	
Collection time (ex vivo)	
Rectal biopsies for ex vivo stored?	Stored ☐ Not stored ☐
If not stored, specify reason	

Were rectal biopsies collected for histology, transcriptomics, and proteomics?	Yes ☐ No ☐
Collection Date	_____
Collection time (histology)	_____
Rectal biopsies for histology stored?	Stored ☐ Not stored ☐
If not stored, specify reason	_____
Collection time (transcriptomics)	_____
Rectal biopsies for transcriptomics stored?	Stored ☐ Not stored ☐
If not stored, specify reason	_____
Collection time (proteomics)	_____
Rectal biopsies for proteomics stored?	Stored ☐ Not stored ☐
If not stored, specify reason	_____
Source Data Upload	_____

Time Point	1 hour ☐
	4 hours ☐
Were rectal fluid specimens collected for PK?	Yes ☐
	No ☐
Collection Date	
Collection time	
Rectal swab for PK stored?	Stored ☐
	Not stored ☐
If not stored, specify reason	
Were specimens collected for rectal enema effluent for PD/PK?	Yes ☐
	No ☐
Collection Date	
Collection time	
Fluid from rectal enema stored?	Stored ☐
	Not stored ☐
If not stored, specify reason	
Fluid from non-viable cells	Stored ☐
	Not stored ☐
If not stored, specify reason	
Were rectal biopsies collected for PK?	Yes ☐
	No ☐
Collection Date	
Collection time (biopsy PK)	
Rectal biopsies for PK stored?	Stored ☐
	Not stored ☐
If not stored, specify reason	
Were rectal biopsies collected for ex vivo challenge?	Yes ☐
	No ☐
Collection Date	
Collection time (ex vivo)	
Rectal biopsies for ex vivo stored?	Stored ☐
	Not stored ☐
If not stored, specify reason	
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	

Was a CASI questionnaire and/or an in-depth interview completed at this visit?	Yes ☐ No ☐
If no, please explain:	

MTN033_version 6.0_PROD_10AUG2018: ALL
Form: CASI Tracking
Generated On: 10 Aug 2018 20:31:20

CASI collection date	_____
CASI ID	_____
Which questionnaire was completed?	Visit 2 Baseline CASI ☐ Visit 3 Follow-Up CASI ☐ Visit 5 Follow-Up CASI ☐
Were there any problems or issues related to the administration or completion of the questionnaire?	Yes ☐ No ☐
If yes, please describe	_____
Was an in-depth interview completed?	Yes ☐ No ☐ Not required ☐
Which visit was the IDI completed on?	Visit 3 ☐ Visit 5 ☐
Source Data Upload	_____

Visit number	Visit 3 ☐ Visit 5 ☐
Date gel application administered	_____
Time gel application administered	_____
Did the participant report having a bowel movement after use of gel/coital simulation device?	Yes ☐ No ☐
If yes, did the participant report seeing gel with bowel movement or in the commode?	Yes ☐ No ☐
Complete the following fields if the coital simulation device was used at this visit.	
Time gel application completed	_____
Estimated amount of gel inserted	Fixed Unit: g _____
Source Data Upload	_____

Participant ID: _____

Date study product use discontinued for this study period:	
"Primary reason for ending study product use:"	Scheduled study product use period completed ☐ Acquisition of HIV infection ☐ Anorectal STIs ☐ 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 ☐ Reported use of strong CYP3A inducers or inhibitors ☐ Reported use of systemic immunomodulatory medications ☐ Reported use of PEP or PrEP ☐ At the discretion of the IoR/designee ☐ Adverse Event ☐ Other ☐
If Other, specify	
If Adverse Event, select applicable Adverse Event	
Source Data Upload	

MTN033_version 6.0_PROD_10AUG2018: ALL
Form: Study Discontinuation
Generated On: 10 Aug 2018 20:31:20

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 ☐ HIV infection ☐ Permanent study product discontinuation ☐ 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	

CASI	☐
Vital Signs	☐
Physical Exam	☐
Genital Exam	☐
Anorectal Exam	☐
STI Tests	☐
HIV Test Results	☐
Hematology	☐
Local Laboratory Results	☐
Specimen Storage	☐
Anorectal Specimen Storage	☐
Timed Anorectal Specimen Storage	☐
Participant Replacement form	☐

Visit date	_____
Interim visit code	_____
Was study product use permanently discontinued (scheduled or early) at this visit?	Yes ☐ No ☐
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit?	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported?	Yes ☐ No ☐
Have any protocol deviations been reported at this visit?	Yes ☐ No ☐
Reason for interim visit (Select all that apply.)	
AE report or follow-up	☐
Completion of missed visit procedures	☐
If completion of missed visit procedures, for which visit are procedures being made up?	Visit 3 ☐ Visit 4 ☐ Visit 5 ☐ Visit 6 ☐ Visit 7 - Termination ☐
Other	☐
If other, specify	_____
What study procedures were completed at this visit? Select all that apply.	
Vital signs	☐
Physical exam	☐
Genital exam	☐
Anorectal exam	☐
Specimen storage for PK, PD and mucosal safety	☐
Anorectal specimen storage for PK, PD, and mucosal safety	☐
CBC testing (includes platelets and differential)	☐
Serum creatinine, AST, or ALT	☐
HIV test(s)	☐
STI test(s) (other than HIV)	☐
CASI	☐
Participant Replacement Assessment	☐

MTN033_version 6.0_PROD_10AUG2018: ALL
Form: Participant Replacement Assessment
Generated On: 10 Aug 2018 20:31:20

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	
Source Data Upload	