Participant ID: ___ ___ ___ - ___ ___ ___ ___ ___ - ___

Visit: _____ Visit Date: _____

Subject Case Report Forms

MTN033_version 3.0_2MAY2018 - ALL

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

MTN033_version 3.0_2MAY2018: ALL
Form: Scr Date of Visit
Generated On: 07 May 2018 17:16:55

Screening visit date	

MTN033_version 3.0_2MAY2018: ALL
Form: Follow-up Visit Y/N
Generated On: 07 May 2018 17:16:55

Did the participant complete this visit?	Yes ☐
	No ☐

MTN033_version 3.0_2MAY2018: ALL
Form: Follow-up Visit Summary
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Demographics
Generated On: 07 May 2018 17:16:55

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	

MTN033_version 3.0_2MAY2018: ALL
Form: Vital Signs
Generated On: 07 May 2018 17:16:55

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	

MTN033_version 3.0_2MAY2018: ALL
Form: Physical Exam
Generated On: 07 May 2018 17:16:55

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: _____

MTN033_version 3.0_2MAY2018: ALL
Form: Physical Exam
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Genital Exam
Generated On: 07 May 2018 17:16:55

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	☐

MTN033_version 3.0_2MAY2018: ALL
Form: Genital Exam
Generated On: 07 May 2018 17:16:55

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	☐

MTN033_version 3.0_2MAY2018: ALL
Form: Genital Exam
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Anorectal Exam
Generated On: 07 May 2018 17:16:55

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 ☐

MTN033_version 3.0_2MAY2018: ALL
Form: Anorectal Exam
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Hematology
Generated On: 07 May 2018 17:16:55
Lab Name: _____

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 _____

MTN033_version 3.0_2MAY2018: ALL
Form: Hematology
Generated On: 07 May 2018 17:16:55
Lab Name:

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	

MTN033_version 3.0_2MAY2018: ALL
Form: HIV Test Results
Generated On: 07 May 2018 17:16:55

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 _____

MTN033_version 3.0_2MAY2018: ALL
Form: HIV Confirmatory Test Results
Generated On: 07 May 2018 17:16:55

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 3.0_2MAY2018: ALL
Form: Local Laboratory Results
Generated On: 07 May 2018 17:16:55
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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: STI Test Results
Generated On: 07 May 2018 17:16:55

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 ☐

MTN033_version 3.0_2MAY2018: ALL
Form: STI Test Results
Generated On: 07 May 2018 17:16:55

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

MTN033_version 3.0_2MAY2018: ALL
Form: Inclusion Exclusion Criteria
Generated On: 07 May 2018 17:16:55

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	Men or transgender women ☐ 18 years or older at Screening ☐ Able and willing to provide written informed consent ☐ HIV-1/2 uninfected at Screening and Enrollment and willing to receive HIV test results ☐ Able and willing to provide adequate locator information ☐ Available to return for all study visits and willing to comply with study participation requirements ☐ In general good health at Screening and Enrollment, as determined by the site IoR or designee ☐ At Screening, history of consensual RAI at least once in the past year per participant report ☐ At Enrollment, if currently using mild/moderate CYP3A inducer(s)/inhibitors, willing to consistently use the inducer(s)/inhibitors for the duration of study participation ☐ 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 (including the time between Screening and Enrollment) ☐ Willing to abstain from receptive anal intercourse (RAI), receptive oral anal stimulation (i.e., rimming), rectal stimulation via fingers, as well as the insertion of any non-study products into the rectum for 72 hours before and after each study visit. ☐ Hemoglobin Grade 1 or higher* ☐ Platelet count Grade 1 or higher* ☐

MTN033_version 3.0_2MAY2018: ALL
Form: Inclusion Exclusion Criteria
Generated On: 07 May 2018 17:16:55

White blood count Grade 2 or higher* ☐
Aspartate aminotransferase (AST) or alanine transaminase (ALT) Grade 1 or higher* ☐
Serum creatinine >1.3× the site laboratory upper limit of normal (ULN) ☐
International normalized ratio (INR) >1.5× the site laboratory ULN ☐
Positive for hepatitis C antibody ☐
Positive for hepatitis B surface antigen ☐
History of inflammatory bowel disease by participant report ☐
Known adverse reaction to latex or polyurethane (ever) ☐
Anticipated use of and/or unwillingness to abstain from the following medications during study participation:
a) Anticoagulant medications ☐
b) Aspirin (greater than 81 mg/day) ☐
c) Non-steroidal anti-inflammatory drugs (NSAIDS) ☐
d) Any other drugs that are associated with increased likelihood of bleeding ☐
e) Rectally-administered medications or products containing N-9 or corticosteroids ☐
f) Strong CYP3A inducer(s) and/or inhibitor(s) as specified in the MTN-033 Study Specific Procedures (SSP) Manual ☐
Known adverse reaction to any of the components of the study product, applicator or coital simulation device ☐
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 ☐
Use of post-exposure prophylaxis (PEP) for potential HIV exposure within the 6 months prior to Enrollment Use of systemic immunomodulatory medications within the 6 months prior to Enrollment, and/or anticipated use during trial participation ☐

MTN033_version 3.0_2MAY2018: ALL
Form: Inclusion Exclusion Criteria
Generated On: 07 May 2018 17:16:55

	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 ☐
	Non-therapeutic injection drug use in the 12 months prior to Enrollmen ☐
	Participation in research studies involving drugs, medical devices, genital or rectal products, or vaccines within 30 days of the Enrollment Visit ☐
	Per participant report at Screening, treatment of an anogenital STI (after diagnosis) within the past 3 months ☐
	At Screening, participant-reported symptoms, and/or clinical or laboratory diagnosis of active anorectal or reproductive tract infection (RTI) requiring treatment or symptomatic urinary tract infection (UTI). ☐
	At Enrollment, active anorectal infection or RTI requiring treatment or symptomatic UTI. ☐
	Has any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives. ☐
If other reason, including investigator decision, specify	_____
Source Data Upload	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Enrollment
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Randomization
Generated On: 07 May 2018 17:16:55

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

MTN033_version 3.0_2MAY2018: ALL
Form: Adverse Event Summary
Generated On: 07 May 2018 17:16:55

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

If yes, please complete the Adverse Event Log.

MTN033_version 3.0_2MAY2018: ALL
Form: Adverse Event Log
Generated On: 07 May 2018 17:16:55

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 ☐

MTN033_version 3.0_2MAY2018: ALL
Form: Adverse Event Log
Generated On: 07 May 2018 17:16:55

	recovering/resolving ☐
	resolved with sequelae ☐
	not recovered/resolved ☐
	fatal ☐
Is this a Serious Adverse Event?	Yes ☐
	No ☐
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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Concomitant Medications Summary
Generated On: 07 May 2018 17:16:55

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

If yes, please complete the Concomitant Medications Log.

MTN033_version 3.0_2MAY2018: ALL
Form: Concomitant Medications Log
Generated On: 07 May 2018 17:16:55

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 ☐

MTN033_version 3.0_2MAY2018: ALL
Form: Concomitant Medications Log
Generated On: 07 May 2018 17:16:55

	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	

MTN033_version 3.0_2MAY2018: ALL
Form: Baseline Medical History Y/N
Generated On: 07 May 2018 17:16:55

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.

MTN033_version 3.0_2MAY2018: ALL
Form: Baseline Medical History Log
Generated On: 07 May 2018 17:16:55

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	

MTN033_version 3.0_2MAY2018: ALL
Form: Product Hold Summary
Generated On: 07 May 2018 17:16:55

MTN033_version 3.0_2MAY2018: ALL
Form: Product Hold Log
Generated On: 07 May 2018 17:16:55

MTN033_version 3.0_2MAY2018: ALL
Form: Protocol Deviations Summary
Generated On: 07 May 2018 17:16:55

Have any protocol deviations occurred?	Yes ☐
	No ☐

If yes, please complete the Protocol Deviation Log.

MTN033_version 3.0_2MAY2018: ALL
Form: Protocol Deviations Log
Generated On: 07 May 2018 17:16:55

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	

MTN033_version 3.0_2MAY2018: ALL
Form: Specimen Storage
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Anorectal Specimen Storage
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Anorectal Specimen Storage
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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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Timed Anorectal Specimen Storage
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Missed Visit
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: CASI Summary
Generated On: 07 May 2018 17:16:55

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

MTN033_version 3.0_2MAY2018: ALL
Form: CASI Tracking
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Dose Administration
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Pharmacy Dispensation
Generated On: 07 May 2018 17:16:55

Source Data Upload

MTN033_version 3.0_2MAY2018: ALL
Form: Participant Identifier
Generated On: 07 May 2018 17:16:55

Participant ID: _____

MTN033_version 3.0_2MAY2018: ALL
Form: Product Discontinuation
Generated On: 07 May 2018 17:16:55

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 3.0_2MAY2018: ALL
Form: Study Discontinuation
Generated On: 07 May 2018 17:16:55

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	_____

MTN033_version 3.0_2MAY2018: ALL
Form: Additional Study Procedures
Generated On: 07 May 2018 17:16:55

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	☐

MTN033_version 3.0_2MAY2018: ALL
Form: Interim Visit Summary
Generated On: 07 May 2018 17:16:55

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 3.0_2MAY2018: ALL
Form: Participant Replacement Assessment
Generated On: 07 May 2018 17:16:55

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	_____