

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

Subject Case Report Forms

MTN033_version 2.0_5MAR2018 - ALL

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Scr Date of Visit

Generated On: 06 Mar 2018 00:57:34

Screening visit date _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Follow-up Visit Y/N

Generated On: 06 Mar 2018 00:57:34

Did the participant complete this visit?

Yes

No

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Follow-up Visit Summary
Generated On: 06 Mar 2018 00:57:34

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Demographics

Generated On: 06 Mar 2018 00:57:34

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Vital Signs

Generated On: 06 Mar 2018 00:57:34

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Physical Exam

Generated On: 06 Mar 2018 00:57:34

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: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Physical Exam
Generated On: 06 Mar 2018 00:57:34

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: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Genital Exam

Generated On: 06 Mar 2018 00:57:34

At Screening or Enrollment, evaluate any abnormalities 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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Genital Exam

Generated On: 06 Mar 2018 00:57:34

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Genital Exam

Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Anorectal Exam

Generated On: 06 Mar 2018 00:57:34

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Anorectal Exam

Generated On: 06 Mar 2018 00:57:34

Ulceration	<input type="checkbox"/>
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 _____

SIGMOIDOSCOPY

Sigmoidoscopy findings	Not done <input type="radio"/>
	No abnormal findings <input type="radio"/>
	Abnormal findings <input type="radio"/>

Abnormal sigmoidoscopy findings: select all that apply.

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Hematology

Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Hematology

Generated On: 06 Mar 2018 00:57:34

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: HIV Test Results

Generated On: 06 Mar 2018 00:57:34

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.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: HIV Confirmatory Test Results
Generated On: 06 Mar 2018 00:57:34

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Local Laboratory Results

Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: STI Test Results

Generated On: 06 Mar 2018 00:57:34

Was a pharyngeal sample collected for N. gonorrhoea and C. trachomatis testing? Yes
No

Collection date _____
N. gonorrhoea - 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. gonorrhoea and C. trachomatis testing? Yes
No

Collection date _____
N. gonorrhoea - URINE test result Negative
Positive

C. trachomatis - URINE test result Negative
Positive

Was a rectal swab sample collected for N. gonorrhoea and C. trachomatis testing? Yes
No

Collection date _____
N. gonorrhoea - 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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: STI Test Results

Generated On: 06 Mar 2018 00:57:34

	Positive <input type="checkbox"/>
HSV-2 test result	Negative <input type="checkbox"/>
	Positive <input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Inclusion Exclusion Criteria
Generated On: 06 Mar 2018 00:57:34

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 2.0_5MAR2018: ALL
Form: Inclusion Exclusion Criteria
Generated On: 06 Mar 2018 00:57:34

- 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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Inclusion Exclusion Criteria
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- 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 Enrollment
- 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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Enrollment

Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Randomization

Generated On: 06 Mar 2018 00:57:34

Is the participant ready to be randomized?

Yes

No

Randomization Date and Time _____

Randomization ID _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Adverse Event Summary

Generated On: 06 Mar 2018 00:57:34

Has the participant experienced an Adverse Event during the study?

Yes

No

If yes, please complete the Adverse Event Log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Adverse Event Log
Generated On: 06 Mar 2018 00:57:34

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.

dose not changed

dose reduced

dose increased

drug withdrawn

drug interrupted

not applicable

Action taken with Study product

None

Medication

New/prolonged hospitalization

Therapeutic procedure/surgery

Diagnostic procedure

Other

Other, specify _____

Status/Outcome recovered/resolved

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Adverse Event Log
Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Concomitant Medications Summary
Generated On: 06 Mar 2018 00:57:34

Is the participant taking any concomitant medications?

Yes

No

If yes, please complete the Concomitant Medications Log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Concomitant Medications Log
Generated On: 06 Mar 2018 00:57:34

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
Intravenous
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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Concomitant Medications Log
Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Baseline Medical History Y/N

Generated On: 06 Mar 2018 00:57:34

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.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Baseline Medical History Log
Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Product Hold Summary
Generated On: 06 Mar 2018 00:57:34

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Product Hold Log

Generated On: 06 Mar 2018 00:57:34

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Protocol Deviations Summary
Generated On: 06 Mar 2018 00:57:34

Have any protocol deviations occurred?

Yes

No

If yes, please complete the Protocol Deviation Log.

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Protocol Deviations Log
Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Specimen Storage
Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Anorectal Specimen Storage
Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Anorectal Specimen Storage
Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Timed Anorectal Specimen Storage
Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Missed Visit

Generated On: 06 Mar 2018 00:57:34

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) _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: CASI Summary

Generated On: 06 Mar 2018 00:57:34

Was a CASI questionnaire and/or an in-depth interview completed
at this visit?

Yes

No

If no, please explain: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: CASI Tracking

Generated On: 06 Mar 2018 00:57:34

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Dose Administration
Generated On: 06 Mar 2018 00:57:34

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Pharmacy Dispensation
Generated On: 06 Mar 2018 00:57:34

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Participant Identifier

Generated On: 06 Mar 2018 00:57:34

Participant ID: _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL

Form: Product Discontinuation

Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Study Discontinuation
Generated On: 06 Mar 2018 00:57:34

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 _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Additional Study Procedures
Generated On: 06 Mar 2018 00:57:34

CASI	<input type="checkbox"/>
Vital Signs	<input type="checkbox"/>
Physical Exam	<input type="checkbox"/>
Genital Exam	<input type="checkbox"/>
Anorectal Exam	<input type="checkbox"/>
STI Tests	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
Local Laboratory Results	<input type="checkbox"/>
Specimen Storage	<input type="checkbox"/>
Anorectal Specimen Storage	<input type="checkbox"/>
Timed Anorectal Specimen Storage	<input type="checkbox"/>
Participant Replacement form	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Interim Visit Summary
Generated On: 06 Mar 2018 00:57:34

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

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN033_version 2.0_5MAR2018: ALL
Form: Participant Replacement Assessment
Generated On: 06 Mar 2018 00:57:34

Date of assessment _____

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

Why is this participant being replaced? Single dose was not administered at visit 3 (e.g., due to non-adherence)
 None of the 7 daily 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 _____