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

Visit: _____ Visit Date: _____

Subject Case Report Forms

MTN037_Version_3.0_PROD_29June2018 - CRF ALL

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

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Participant Identifier
Generated On: 29 Jun 2018 16:48:26

Participant ID: _____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Participant Replacement Assessment
Generated On: 29 Jun 2018 16:48:26

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 9 (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	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Randomization
Generated On: 29 Jun 2018 16:48:26

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

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Screening Date of Visit
Generated On: 29 Jun 2018 16:48:26

Screening visit date	

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Eligibility Criteria
Generated On: 29 Jun 2018 16:48:26

Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Eligibility Status	Ineligible ☐ Eligible, but participant did not enroll ☐ Eligible and enrolled ☐ Incomplete Screening ☐
If eligible and enrolled, end of form.	
If eligible, but participant did not enroll, specify reason	_____
Select inclusion and/or exclusion criteria that contributed to participant's study ineligibility	I1. Men and women (cis or transgender) who are 18 years or older at Screening ☐ 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 ☐ I7. At Screening, history of consensual RAI at least once in their lifetime per participant report ☐ I8. Willing to not 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 follow abstinence requirements for the duration of the study participation ☐ I10. For participants of childbearing potential: a negative pregnancy test at Screening and Enrollment ☐ I11. For participants of childbearing potential: at Enrollment, using an effective method of contraception and intending to continue use of effective method for duration of study participation ☐ E1a. Grade 1 or higher Hemoglobin at Screening ☐ E1b. Grade 1 or higher Platelet at Screening ☐ E1c. Grade 2 or higher White blood count at Screening ☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Eligibility Criteria
Generated On: 29 Jun 2018 16:48:26

E1d. Aspartate aminotransferase (AST) or alanine transaminase (ALT) Grade 1 or higher at Screening ☐

E1e. Serum creatinine > 1.3x site ULN ☐

E1f. INR >1.5 x site ULN ☐

E1g. History of inflammatory bowel disease per participant report ☐

E2. Known adverse reaction to latex or polyurethane (ever) ☐

E3a. Anticipated use of and/or unwillingness to abstain from Anticoagulant medications during study participation ☐

E3b. Anticipated use of and/or unwillingness to abstain from Rectally-administered medications during study participation ☐

E4. Known adverse reaction to any of the components of the study product ☐

E5. Use of 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 PEP for potential HIV exposure within 3 months prior to Enrollment ☐

E7. Condomless RAI and/or penile-vaginal intercourse with a partner who is known to be HIV-positive or whose status is unknown in the 6 months prior to Enrollment ☐

E8. Non-therapeutic injection drug use in the 12 months prior to Enrollment ☐

E9. Participation in research studies involving drugs, medical devices, genital or rectal products, or vaccines within 30 days of the Enrollment Visit ☐

E10. Gynecologic, genital, or rectal procedure 60 days or less prior to Enrollment, or rectal biopsy, 7 days or less prior to Enrollment ☐

E11a. At Screening or Enrollment, per participant report, medical records, clinical diagnosis and/or diagnostic testing, diagnosis or treatment of any anogenital STI within past 3 months ☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Eligibility Criteria
Generated On: 29 Jun 2018 16:48:26

	E11b. At screening or enrollment, active pharyngeal, anorectal infection or RTI requiring treatment per current CDC guidelines ☐
	E11c. At Screening or Enrollment, current symptomatic UTI ☐
	E12a. Pregnant or breastfeeding at either Screening or Enrollment or intends to become pregnant or start breastfeeding during study participation ☐
	E12b. Last pregnancy outcome 90 days or less prior to Screening ☐
	E13. Has a condition that, per IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or interfere with achieving study objectives ☐
If other reason, including investigator decision, specify	_____
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Demographics
Generated On: 29 Jun 2018 16:48:26

Date of Birth	
Derived age	Fixed Unit: Years
Sex at Birth	Male ☐
	Female ☐
Ethnicity	Hispanic or Latino ☐
	Not Hispanic or Latino ☐
US Race	
American Indian or Alaska Native	☐
Asian	☐
Black or African American	☐
Native Hawaiian or other Pacific Islander	☐
White	☐
Other	☐
If other, specify:	
Source Data Upload	

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Follow-up Visit Y/N
Generated On: 29 Jun 2018 16:48:26

Did the participant complete this visit?	Yes ☐
	No ☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Follow-up Visit Summary
Generated On: 29 Jun 2018 16:48:26

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 ☐
Have any protocol deviations been 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	

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Concomitant Medications Summary
Generated On: 29 Jun 2018 16:48:26

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

If Yes, complete the Concomitant Medications Log.

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Concomitant Medications Log
Generated On: 29 Jun 2018 16:48:26

Medication Name _____

Indication _____

Date Started _____

Date Stopped

Or _____

Continuing at end of study ☐

Frequency

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

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Concomitant Medications Log
Generated On: 29 Jun 2018 16:48:26

	Unknown ☐
	Other ☐
If other dose units, please 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	

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Adverse Event Summary
Generated On: 29 Jun 2018 16:48:26

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

If Yes, complete the Adverse Event form.

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Adverse Event
Generated On: 29 Jun 2018 16:48:26

Date reported to site	_____
Adverse Event (AE)	_____
Onset date	_____
At which visit was this AE first reported?	Visit 3.0 ☐ Visit 4.0 ☐ Visit 4.0a ☐ Visit 5.0 ☐ Visit 6.0 ☐ Visit 6.0a ☐ Visit 7.0 ☐ Visit 8.0 ☐ Visit 8.0a ☐ Visit 9.0 ☐ 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 ☐
Action Taken with Study Product	dose not changed ☐ dose reduced ☐ dose increased ☐ drug withdrawn ☐ drug interrupted ☐ not applicable ☐
Other action(s) taken	☐
None	
Medication	☐
New/prolonged hospitalization	☐
Therapeutic procedure/surgery	☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Adverse Event
Generated On: 29 Jun 2018 16:48:26

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 following question.	Yes ☐ No ☐

If "Yes", check all that apply.

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?	Yes ☐ No ☐
Comments	_____
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Behavioral Assessment
Generated On: 29 Jun 2018 16:48:26

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

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Interim Visit Summary
Generated On: 29 Jun 2018 16:48:26

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 4a ☐ Visit 5 ☐ Visit 6 ☐ Visit 6a ☐ Visit 7 ☐ Visit 8 ☐ Visit 8a ☐ Visit 9 - Final Contact ☐
Other	☐
If other, specify	_____
What study procedures were completed at this visit? Select all that apply.	
Vital signs	☐
Physical exam	☐
Pelvic exam	☐
Anorectal exam	☐
Specimen storage for PK, PD and mucosal safety	☐
Pelvic specimen collection	☐
Anorectal specimen storage for PK, PD, and mucosal safety	☐
Pregnancy test	☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Interim Visit Summary
Generated On: 29 Jun 2018 16:48:26

CBC testing (includes platelets and differential)	☐
Serum creatinine, AST, or ALT	☐
HIV test(s)	☐
HIV confirmatory test(s)	☐
STI test(s) (other than HIV)	☐
Web-based Self-Interview	☐
Pregnancy report	☐
Pregnancy history	☐
Participant Replacement	☐
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: WSI Tracking
Generated On: 29 Jun 2018 16:48:26

WSI collection date	_____
WSI ID	_____
Which questionnaire was completed?	Visit 2 Baseline WSI ☐ Visit 3 Follow-Up WSI ☐ Visit 5 Follow-Up WSI ☐ Visit 7 Follow-Up WSI ☐ Visit 8 In-Depth Interview ☐
Were there any problems or issues related to the administration or completion of the questionnaire?	Yes ☐ No ☐
If yes, please describe	_____
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Study Discontinuation
Generated On: 29 Jun 2018 16:48:26

Date of study exit	_____
Did the participant complete the study?	Yes ☐ No ☐
If participant completed the study, end of form.	
Primary reason for non-completion	Death ☐ Withdrawal of consent by participant ☐ Lost to follow-up ☐ Investigator decision ☐ Study terminated by sponsor ☐ Pregnancy ☐ 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	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Medical History Summary
Generated On: 29 Jun 2018 16:48:26

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 Screening or Enrollment anorectal, pelvic or physical exam findings, and any Screening or Enrollment lab abnormalities.

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Baseline Medical History Log
Generated On: 29 Jun 2018 16:48:26

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

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Physical Exam
Generated On: 29 Jun 2018 16:48:26

Exam date _____

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

General Appearance
- Not Done ☐
- Normal ☐
- Abnormal ☐

If abnormal, specify: _____

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

If abnormal, specify: _____

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: _____

Lungs/Respiratory
- Not Done ☐
- Normal ☐
- Abnormal ☐

If abnormal, specify: _____

Abdomen
- Not Done ☐
- Normal ☐
- Abnormal ☐

If abnormal, specify: _____

Extremities
- Not Done ☐
- Normal ☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Physical Exam
Generated On: 29 Jun 2018 16:48:26

	Abnormal ☐
If abnormal, specify:	_____
Neurological	Not Done ☐
	Normal ☐
	Abnormal ☐
If abnormal, specify:	_____
Skin	Not Done ☐
	Normal ☐
	Abnormal ☐
If abnormal, specify:	_____
Other	Not Done ☐
	Normal ☐
	Abnormal ☐
Other system, specify	_____
If other is abnormal, specify:	_____
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Vital Signs
Generated On: 29 Jun 2018 16:48:26

Date of assessment	
Height	Fixed Unit: cm
Weight	
Body Temperature	Fixed Unit: C
Systolic BP	Fixed Unit: mmHg
Diastolic BP	Fixed Unit: mmHg
Pulse	Fixed Unit: beats per minute
Rate of respiration	Fixed Unit: breaths per minute
Source Data Upload	

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Pregnancy Test Result
Generated On: 29 Jun 2018 16:48:26

Was a pregnancy test done?	Yes ☐ No ☐
Date of Pregnancy Test	_____
Test result	Positive ☐ Negative ☐
If positive, complete Pregnancy Report, Pregnancy History, Product Discontinuation, and Study Discontinuation forms.	
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Pregnancy Report
Generated On: 29 Jun 2018 16:48:26

Date Pregnancy Reported to Site	_____
Visit at which this pregnancy was reported	Visit 3.0 ☐ Visit 4.0 ☐ Visit 4.0a ☐ Visit 5.0 ☐ Visit 6.0 ☐ Visit 6.0a ☐ Visit 7.0 ☐ Visit 8.0 ☐ Visit 8.0a ☐ Visit 9.0 ☐ Interim Visit ☐
If Interim visit, specify Interim visit code	_____
First day of last menstrual period	_____
Or	
Amenorrheic for past 6 months	☐
Estimated date of delivery	_____
What primary information was used to estimate the date of delivery?	Last menstrual period ☐ Initial ultrasound less than 20 weeks ☐ Initial ultrasound greater than or equal to 20 weeks ☐ Physical examination ☐ Conception date by assisted reproduction ☐ Other ☐
If "Other", specify:	_____
Is this the participant's first pregnancy since enrollment in this study?	Yes ☐ No ☐
If "Yes", complete the Pregnancy History form.	
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Pregnancy History
Generated On: 29 Jun 2018 16:48:26

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

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Pregnancy Outcome Log
Generated On: 29 Jun 2018 16:48:26

Is the outcome of this pregnancy obtainable?	Yes ☐ No ☐
If no, end the form.	
How many pregnancy outcomes resulted from this reported pregnancy?	_____
Outcome date	_____
Place of delivery/outcome	home ☐ hospital ☐ clinic ☐ unknown ☐ other ☐
Other, specify	_____
Specify outcome	Full term live birth (>= 37 weeks) ☐ Premature live birth (<37 weeks) ☐ Stillbirth/intrauterine fetal demise (>=20 weeks) ☐ Spontaneous abortion (<20 weeks) ☐ Ectopic pregnancy ☐ Therapeutic/elective abortion ☐ Other ☐
If Other, specify	_____
Method	C-section ☐ Standard vaginal ☐ Operative vaginal ☐
Provide a brief narrative of the circumstances:	_____
Was the Infant enrolled into MTN-016?	Yes ☐ No ☐ Pending ☐
If yes, what is the infant's participant ID?	_____
Were there any complications related to the pregnancy outcome?	Yes ☐ No ☐
Delivery-related complications: Mark “None” or all that apply.	☐
None	
Intrapartum hemorrhage	☐
Postpartum hemorrhage	☐
Non-reassuring fetal status	☐
Chorioamnionitis	☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Pregnancy Outcome Log
Generated On: 29 Jun 2018 16:48:26

Other	☐
If "Other", specify:	_____
Non-delivery related complications: Mark “None” or all that apply.	☐
None	
Hypertensive disorders of pregnancy	☐
Gestational diabetes	☐
Other	☐
If "Other", specify:	_____
Were any fetal/infant congenital anomalies identified? Mark all that apply. Complete AE Log and EAE Reporting form.	Yes ☐ No ☐ Unknown ☐
Central nervous system, cranio-facial	☐
Central nervous system, spinal	☐
Cardiovascular	☐
Renal	☐
Gastrointestinal	☐
Pulmonary	☐
Muscoloskeletal/extremities	☐
Physical defect	☐
Skin	☐
Genitourinary	☐
Chromosomal	☐
Cranio-facial (structural)	☐
Hematologic	☐
Infectious	☐
Endocrine/metabolic	☐
Other	☐
Specify congenital anomaly/defect AE	_____
Describe the congenital anomaly/defect: Complete the infant items below for live births only. Otherwise, end of form.	_____
Infant gender	Male ☐ Female ☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Pregnancy Outcome Log
Generated On: 29 Jun 2018 16:48:26

Infant birth weight	Fixed Unit: kg
OR	
Infant birth weight unavailable	☐
Infant birth length	Fixed Unit: centimeters
OR	
Infant birth length unavailable	☐
Infant birth head circumference	Fixed Unit: cm
OR	
Infant birth head circumference unavailable	☐
Infant birth abdominal circumference	Fixed Unit: centimeters
OR	
Infant birth abdominal circumference unavailable	☐
Infant birth abdominal circumference unit	cm
Infant gestational age by examination in weeks	Fixed Unit: Weeks
Infant gestational age by examination in days	Fixed Unit: Days
OR	
Infant gestational age by examination unavailable	☐
Method used to determine gestational age	Ballard ☐ Dubowitz ☐ Other ☐
If Other, specify	
Source Data Upload	

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Anorectal Exam and Sigmoidoscopy
Generated On: 29 Jun 2018 16:48:26

At Screening and Enrollment, evaluate any abnormalities for eligibility. Update 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 findings:
select all that apply.

- Warts ☐
- Fissure ☐
- Ulceration ☐
- Pigmentation ☐
- Hemorrhoids ☐
- Skin tags ☐
- Leukoplakia ☐
- Fistula ☐
- Petechiae (less than 3 mm) ☐
- Purpura (0.3-1 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

Was an anoscopy performed at this visit?
- Yes ☐
- No ☐
- Not required ☐

If no, specify: _____

Rectal mucosa findings:
- Not done ☐
- No abnormal findings ☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Anorectal Exam and Sigmoidoscopy
Generated On: 29 Jun 2018 16:48:26

	Abnormal findings ☐
Abnormal findings: select all that apply.	
Erythema	☐
Abnormal vessels	☐
Ulceration	☐
Friability	☐
Bleeding	☐
Discharge	☐
Polyps	☐
Hemorrhoids	☐
Other abnormal findings	☐
If other abnormal findings, specify	_____
SIGMOIDOSCOPY	
Was a sigmoidoscopy performed at this visit?	Yes ☐ No ☐ Not required ☐
If no, specify:	_____
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	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Pelvic Exam
Generated On: 29 Jun 2018 16:48:26

Pelvic exam assessment	Not done ☐ Abnormal findings ☐ No abnormal findings ☐
Exam date	_____
Abnormal findings. Select all that apply.	
VULVAR	
Vulvar edema	☐
Vulvar erythema	☐
Vulvar rash	☐
Vulvar tenderness	☐
Bartholin's or Skene's gland abnormality	☐
Vulvar ulcer	☐
Vulvar blister	☐
Vulvar pustule	☐
Vulvar peeling	☐
Vulvar ecchymosis	☐
VAGINAL	
Vaginal edema	☐
Vaginal erythema	☐
Vaginal masses (polyps, myomas, possible malignancy)	☐
Vaginal abrasions or lacerations	☐
Vaginal tenderness	☐
Vaginal ulcer	☐
Vaginal blister	☐
Vaginal pustule	☐
Vaginal peeling	☐
Vaginal ecchymosis	☐
Abnormal vaginal discharge	Slight ☐ Moderate ☐ Pooling ☐
CERVICAL	
Cervical edema and/or friability	☐
Cervical erythema	☐
Cervical masses (polyps, myomas, possible malignancy)	☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Pelvic Exam
Generated On: 29 Jun 2018 16:48:26

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

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: STI Test Results
Generated On: 29 Jun 2018 16:48:26

Was a pharyngeal sample collected for N. gonorrhea and C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - Pharyngeal test result	Positive ☐ Negative ☐
C. trachomatis - Pharyngeal test result	Positive ☐ Negative ☐
Was a vaginal sample collected for N. gonorrhea and C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - vaginal test result	Positive ☐ Negative ☐
C. trachomatis - Vaginal test result	Positive ☐ Negative ☐
Was a sample collected for Syphilis testing?	Yes ☐ No ☐
Collection date	_____
Syphilis screening test	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	Positive ☐ Negative ☐
C. trachomatis - URINE test result	Positive ☐ Negative ☐
Was a rectal swab sample collected for N. gonorrhea and C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - RECTAL SWAB test result	Positive ☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: STI Test Results
Generated On: 29 Jun 2018 16:48:26

	Negative ☐
C. trachomatis - RECTAL SWAB test result	Positive ☐
	Negative ☐
Was a rectal swab collected for HSV-1 and HSV-2 testing?	Yes ☐
	No ☐
Collection date	_____
HSV-1 test result	Positive ☐
	Negative ☐
HSV-2 test result	Positive ☐
	Negative ☐
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Hematology
Generated On: 29 Jun 2018 16:48:26
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	_____

DIFFERENTIAL

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	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Hematology
Generated On: 29 Jun 2018 16:48:26
Lab Name:

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	

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Local Laboratory Results
Generated On: 29 Jun 2018 16:48:26
Lab Name: _____

Was a sample collected for serum 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	_____
OR	
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	_____
OR	
Creatinine	_____
Creatinine severity grade	Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Potentially life-threatening ☐ Not gradable ☐
Creatinine Adverse event	_____
OR	
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: HIV Tests Results
Generated On: 29 Jun 2018 16:48:26

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 Test Result form and alert the MTN Laboratory Core.

Source Data Upload _____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: HIV Confirmatory Tests
Generated On: 29 Jun 2018 16:48:26

Sample 1 Confirmatory Tests

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

Date of collection _____

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

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

Sample 2 Collection

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

Date of collection _____

Was sample 2 stored? Stored ☐ Not stored ☐

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

Final HIV status

Final HIV status HIV uninfected ☐ HIV infected ☐ Pending ☐

Source Data Upload _____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Specimen Storage
Generated On: 29 Jun 2018 16:48:26

Was Plasma for PK collected?	Yes ☐ No ☐
Date of collection	_____
Time Point	Pre-dose ☐ 1 hour ☐ 2 hours ☐ 3 hours ☐ 4 hours ☐ 5-6 hours ☐ 24 hours ☐ 48 hours ☐
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	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Anorectal Specimen Storage
Generated On: 29 Jun 2018 16:48:26

Time Point	0.5-1 hour ☐
	1.5-3 hours ☐
	3.5-5 hours ☐
	24 hours ☐
	48 hours ☐
Specimen Type	Fluid from rectal enema ■
	Non-viable cells ☐
	Rectal sponge for PD ☐
	Rectal sponge for PK ☐
	Rectal biopsies for PK ☐
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ☐
	Anal swab for HPV ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Fluid from rectal enema ☐
	Non-viable cells ■
	Rectal sponge for PD ☐
	Rectal sponge for PK ☐
	Rectal biopsies for PK ☐
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ☐
	Anal swab for HPV ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Anorectal Specimen Storage
Generated On: 29 Jun 2018 16:48:26

Source Data Upload

Specimen Type
- Fluid from rectal enema
- Non-viable cells
- Rectal sponge for PD
- Rectal sponge for PK
- Rectal biopsies for PK
- Rectal biopsies for PD
- Rectal biopsy for archive
- Rectal biopsy for histology
- Anal swab for HPV

Was sample collected?
- Yes
- No

Specimen Collection Date

Specimen Collection Time

Was sample stored?
- Stored
- Not Stored

If no, record reason why sample was not stored.

Source Data Upload

Specimen Type
- Fluid from rectal enema
- Non-viable cells
- Rectal sponge for PD
- Rectal sponge for PK
- Rectal biopsies for PK
- Rectal biopsies for PD
- Rectal biopsy for archive
- Rectal biopsy for histology
- Anal swab for HPV

Was sample collected?
- Yes
- No

Specimen Collection Date

Specimen Collection Time

Was sample stored?
- Stored
- Not Stored

If no, record reason why sample was not stored.

Source Data Upload

Specimen Type
- Fluid from rectal enema
- Non-viable cells
- Rectal sponge for PD

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Anorectal Specimen Storage
Generated On: 29 Jun 2018 16:48:26

	Rectal sponge for PK ☐
	Rectal biopsies for PK ■
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ☐
	Anal swab for HPV ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Fluid from rectal enema ☐
	Non-viable cells ☐
	Rectal sponge for PD ☐
	Rectal sponge for PK ☐
	Rectal biopsies for PK ☐
	Rectal biopsies for PD ■
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ☐
	Anal swab for HPV ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Fluid from rectal enema ☐
	Non-viable cells ☐
	Rectal sponge for PD ☐
	Rectal sponge for PK ☐
	Rectal biopsies for PK ☐
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ■

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Anorectal Specimen Storage
Generated On: 29 Jun 2018 16:48:26

	Rectal biopsy for histology ☐
	Anal swab for HPV ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Fluid from rectal enema ☐
	Non-viable cells ☐
	Rectal sponge for PD ☐
	Rectal sponge for PK ☐
	Rectal biopsies for PK ☐
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ■
	Anal swab for HPV ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Fluid from rectal enema ☐
	Non-viable cells ☐
	Rectal sponge for PD ☐
	Rectal sponge for PK ☐
	Rectal biopsies for PK ☐
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ☐
	Anal swab for HPV ■
Was sample collected?	Yes ☐
	No ☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Anorectal Specimen Storage
Generated On: 29 Jun 2018 16:48:26

Specimen Collection Date	
Specimen Collection Time	
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	
Source Data Upload	

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Pelvic Specimen Storage
Generated On: 29 Jun 2018 16:48:26

Was vaginal fluid for PK collect	Yes ☐ No ☐
Collection date	_____
Time period	0.5-1 hour ☐ 1.5-3 hours ☐ 3.5-5 hours ☐ 24 hours ☐ 48 hours ☐
Collection time	_____
Vaginal Fluid for PK	Stored ☐ Not stored ☐
If not stored, specify reason	_____
Was blood visible on the swab?	Yes ☐ No ☐
Did the participant experience any vaginal spotting or bleeding in the past seven days?	Yes ☐ No ☐
On how many of these days did the participant experience heavy bleeding?	_____
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Enrollment
Generated On: 29 Jun 2018 16:48:26

Date the participant marked or signed the study screening and enrollment consent form	
Did the participant consent to long-term specimen storage and future testing?	Yes ☐ No ☐
PK, PD, and Mucosal Safety Time Assignment	0.5-1 hour ☐ 1.5-3 hours ☐ 3.5-5 hours ☐ 24 hours ☐
48 Hr visit sampling assignment	Visit 4.0a ☐ Visit 6.0a ☐ Visit 8.0a ☐
Is this a replacement participant?	Yes ☐ No ☐
PTID of participant being replaced	
Source Data Upload	

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Additional Study Procedures
Generated On: 29 Jun 2018 16:48:26

Web-based Self-Interview	☐
Vital Signs	☐
Physical Exam	☐
Pelvic Exam	☐
Anorectal Exam	☐
Pregnancy Test	☐
STI Test Results	☐
HIV Test Results	☐
Hematology	☐
Local Laboratory Results	☐
Specimen Storage	☐
Anorectal Specimen Storage	☐
Pelvic Specimen Storage	☐
Participant Replacement	☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Protocol Deviations Summary
Generated On: 29 Jun 2018 16:48:26

Have any protocol deviations occurred?	Yes ☐
	No ☐

If yes, please complete the Protocol Deviation Log.

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Protocol Deviations Log
Generated On: 29 Jun 2018 16:48:26

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	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Missed Visit
Generated On: 29 Jun 2018 16:48:26

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

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Dose Administration
Generated On: 29 Jun 2018 16:48:26

Dose number	Visit 3 ☐ Visit 5 ☐ Visit 7 ☐
Date gel application administered	_____
Time gel application administered	_____
Dosage Administered	Fixed Unit: mL 4 ☐ 16 ☐ 32 ☐
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Pharmacy Dispensation
Generated On: 29 Jun 2018 16:48:26

Which visit was study product (PC-1005) dispensed:	Visit 3 ☐ Visit 5 ☐ Visit 7 ☐
Date study product (PC-1005) dispensed:	_____
Dosage dispensed	4 ☐ 16 ☐ 32 ☐
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Product Discontinuation
Generated On: 29 Jun 2018 16:48:26

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 ☐ Adverse Event ☐ Allergic reaction to study product ☐ Anogenital STIs ☐ Anticoagulant use ☐ Pregnancy or Breastfeeding ☐ Reported use of PEP or PrEP for HIV prevention ☐ 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 ☐ Use of CYP3A inhibitors ☐ Non-therapeutic injection drug use ☐ Participant declined study product ☐ Other ☐
If Other, specify	
If Adverse Event, select applicable Adverse Event	
Source Data Upload	

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Product Hold Summary
Generated On: 29 Jun 2018 16:48:26

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

If Yes, complete the Product Hold form

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Product Hold Log
Generated On: 29 Jun 2018 16:48:26

Date when study product hold was initiated:	_____
Why is study product being held?	☐ Reactive rapid HIV test ☐ Adverse Event ☐ Reported use of PEP ☐ Pregnancy ☐ Breastfeeding ☐ Participant unable/unwilling to comply with the required study procedures, or otherwise might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee ☐ Other
Other, specify:	_____
Adverse Event:	_____
Concomitant Medication:	_____
Concomitant Medication:	_____
Concomitant Medication:	_____
Concomitant Medication:	_____
Date of last study product use:	_____
Was the participant instructed to resume study product use? If 'no - permanently discontinued', 'no - early termination' or 'no - hold continuing at scheduled PUEV', complete the Product Discontinuation form.	☐ Yes ☐ No - hold continuing for another reason ☐ No - early termination ☐ No - hold continuing at scheduled PUEV ☐ No - permanently discontinued
Date study product resumed	_____
Date study product hold continuing for another reason	_____
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Anorectal Specimen Storage Enr
Generated On: 29 Jun 2018 16:48:26

Specimen Type	Fluid from rectal enema ■
	Non-viable cells ☐
	Rectal sponge for PD ☐
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ☐
	Anal swab for HPV ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____

Specimen Type	Fluid from rectal enema ☐
	Non-viable cells ■
	Rectal sponge for PD ☐
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ☐
	Anal swab for HPV ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____

Specimen Type	Fluid from rectal enema ☐
	Non-viable cells ☐
	Rectal sponge for PD ■
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ☐
	Anal swab for HPV ☐

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Anorectal Specimen Storage Enr
Generated On: 29 Jun 2018 16:48:26

Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Fluid from rectal enema ☐
	Non-viable cells ☐
	Rectal sponge for PD ☐
	Rectal biopsies for PD ■
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ☐
	Anal swab for HPV ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____
Specimen Type	Fluid from rectal enema ☐
	Non-viable cells ☐
	Rectal sponge for PD ☐
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ■
	Rectal biopsy for histology ☐
	Anal swab for HPV ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____

MTN037_Version_3.0_PROD_29June2018: CRF ALL
Form: Anorectal Specimen Storage Enr
Generated On: 29 Jun 2018 16:48:26

Specimen Type	Fluid from rectal enema ☐
	Non-viable cells ☐
	Rectal sponge for PD ☐
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ■
	Anal swab for HPV ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____

Specimen Type	Fluid from rectal enema ☐
	Non-viable cells ☐
	Rectal sponge for PD ☐
	Rectal biopsies for PD ☐
	Rectal biopsy for archive ☐
	Rectal biopsy for histology ☐
	Anal swab for HPV ■
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not Stored ☐
If no, record reason why sample was not stored.	_____
Source Data Upload	_____