

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

Subject Case Report Forms

MTN038_Version_1.0_PROD_15OCT2018 - 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: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Screening Date of Visit

Generated On: 23 Oct 2018 18:11:14

Screening visit date

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Follow-Up YN

Generated On: 23 Oct 2018 18:11:14

Did the participant complete this visit?

Yes

No

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Follow-up Visit Summary
Generated On: 23 Oct 2018 18:11:14

Visit date _____

Was study product permanently discontinued (scheduled or early) at this visit? Yes No

Was study product held 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

Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV? Yes No

Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV? 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 Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Interim Visit Summary
Generated On: 23 Oct 2018 18:11:14

Visit date _____

Interim visit code _____

Was study product held at this visit? Yes
No

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

Were any protocol deviations reported at this visit? Yes
No

Reason for interim visit (Select all that apply.)

AE report or follow-up

Return of product or need new product

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
Visit 8
Visit 9
Visit 10
Visit 11

Other

If other, specify _____

What study procedures were completed at this visit? Select all that apply.

Vital signs

Physical exam

Pelvic exam

Specimen storage

Timed Specimen Storage

Cervical Specimen Storage

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Interim Visit Summary
Generated On: 23 Oct 2018 18:11:14

Timed Cervical Specimen Storage	<input type="checkbox"/>
Pregnancy Test Results	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
Chemistry Panel	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
STI Test Results	<input type="checkbox"/>
Behavioral Summary	<input type="checkbox"/>
Ring Insertion or Removal	<input type="checkbox"/>
Ring Adherence YN	<input type="checkbox"/>
Source Document Upload	<input type="checkbox"/>

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Missed Visit

Generated On: 23 Oct 2018 18:11:14

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) _____

Source Document Upload _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Randomization

Generated On: 23 Oct 2018 18:11:14

Is the participant ready to be randomized?

Yes

No

Randomization Date and Time _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Enrollment

Generated On: 23 Oct 2018 18:11:14

Did the participant consent to long-term specimen storage and future testing? Yes
No

Treatment arm TFV Ring
Placebo Ring

Was the participant randomized to participate in IDI (In Depth Interview)? Yes
No

Was the participant invited to participate in IDIs? Yes
No

Will this participant participate in IDIs? Yes
No

Biopsy schedule assignment Day 14 and Day 56
Day 28 and Day 91

What is the CASI ID assigned to this participant? _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Additional Study Procedures
Generated On: 23 Oct 2018 18:11:14

What study procedures were completed at this visit:

CASI and/or IDI	<input type="checkbox"/>
Vital Signs	<input type="checkbox"/>
Physical Exam	<input type="checkbox"/>
Pelvic Exam	<input type="checkbox"/>
Pregnancy Test Results	<input type="checkbox"/>
STI Test results	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
Chemistry Panel	<input type="checkbox"/>
Timed Specimen Storage	<input type="checkbox"/>
Cervical Specimen Storage	<input type="checkbox"/>
Timed Cervical Specimen Storage	<input type="checkbox"/>
Ring Insertion and Removal	<input type="checkbox"/>
Specimen Storage	<input type="checkbox"/>
Ring Adherence	<input type="checkbox"/>
Source Document Upload	<input type="checkbox"/>

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Adverse Event Y/N

Generated On: 23 Oct 2018 18:11:14

Has the participant experienced an adverse event during the study? Yes

No

If "Yes", complete the Adverse Event log.

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Adverse Event

Generated On: 23 Oct 2018 18:11:14

Date AE reported to site _____

Adverse event (AE) _____

Onset date _____

Is the AE still ongoing? Yes
No

If "No", outcome date _____

Severity grade _____
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Grade 5 (Death)

Relationship to study product _____
Related
Not related

Action taken with study product _____
Dose not changed
Dose reduced
Dose increased
Drug withdrawn
Drug interrupted
Not applicable

Other actions _____
Mark "None" or all that apply.
None

Medication(s) _____

Therapeutic procedure/surgery _____

Diagnostic procedure _____

Referral _____

Other _____

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

Status/outcome _____
Recovered/resolved
Recovering/resolving
Recovered/resolved with sequelae
Not recovered/not resolved
Fatal
Severity/frequency increased

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Adverse Event

Generated On: 23 Oct 2018 18:11:14

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

No

If "No", go to "Has or will this AE be reported as an EAE?".

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", provide EAE number below.

EAE number.

Begin number with 4-digit year, followed by 6-digit EAE number (no dashes or spaces).

Was this AE a worsening of a baseline medical condition? Yes

No

Comments (max. 450 characters) _____

Source Document Upload _____

Participant ID: _____ - _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Concomitant Medications Y/N
Generated On: 23 Oct 2018 18:11:14

Were any concomitant medications taken?

Yes

No

If "Yes", complete the Concomitant Medications log.

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Concomitant Medications
Generated On: 23 Oct 2018 18:11:14

Medication name _____

Indication _____

Date started _____

Date stopped _____

OR

Ongoing _____

Dose _____

Dose units _____

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

If "Other", specify _____

Frequency _____

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

If "Other", specify _____

Route _____

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

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Demographics

Generated On: 23 Oct 2018 18:11:14

Date of birth _____

Age _____ Fixed Unit: Years

Sex at birth? _____ Male

Female

Ethnicity _____ Hispanic or Latino

Not Hispanic or Latino

Race

Mark all that apply.

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or other Pacific Islander

White

Other

If "Other", specify _____

Gender

Mark all that apply.

Male

Female

Transgender Male

Transgender Female

Gender Nonconforming/Gender Variant

Self-identify

If "Self-identify", specify _____

Prefer not to answer

In the past 12 months, what was/were the biological sex(es) of the partner(s) with whom the participant had vaginal sex? Both male and female partners

Exclusively female partners

Exclusively male partners

NA (no sex partners)

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Hematology

Generated On: 23 Oct 2018 18:11:14

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 severity grade - calculated Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Hemoglobin adverse event, if applicable _____

Hematocrit _____

MCV _____

Platelets

Platelets severity grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Platelets severity grade - calculated Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Platelets adverse event, if applicable _____

WBC

WBC severity grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Hematology

Generated On: 23 Oct 2018 18:11:14

Lab Name: _____

WBC severity grade - calculated

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

WBC adverse event, if applicable _____

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 severity grade - calculated

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Neutrophils adverse event, if applicable _____

Lymphocytes

Lymphocytes severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Lymphocytes severity grade - calculated

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Lymphocytes adverse event, if applicable _____

Monocytes _____

Eosinophils _____

Basophils _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Hematology

Generated On: 23 Oct 2018 18:11:14

Lab Name: _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Inclusion/Exclusion Criteria
Generated On: 23 Oct 2018 18:11:14

Did the participant meet all eligibility criteria? Yes
No

Informed Consent Date _____

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

Was the participant enrolled in MTN-038? Yes
No

If eligible and enrolled or incomplete screening, end of form.

Select reason(s) why participant is ineligible.

- I1 - Assigned female sex at birth
- I2 - Age 18 through 45 years (inclusive) at Screening, verified per site SOPs
- I3 - Able and willing to provide written informed consent to be screened for and enrolled in MTN-038
- I4 - Able and willing to provide adequate locator information, as defined in site SOPs
- I5 - Able to communicate in spoken and written English
- I6 - Available for all visits and able and willing to comply with all study procedural requirements
- I7 - Willing to abstain from receptive vaginal or anal sexual activities for 72 hours prior to each clinical visit and for 72 hours after biopsy collection
- I8 - Willing to use male condoms for penile-vaginal and penile-rectal sexual intercourse for the duration of study participation
- I9 - Using an effective method of contraception for at least 30 days (inclusive) prior to Enrollment, and intending to continue use of an effective method for the duration of study participation
- I10 - In general good health as determined by the Investigator of Record (IoR)/designee at Screening and Enrollment
- I11 - HIV-uninfected based on testing performed at Screening and Enrollment

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Inclusion/Exclusion Criteria
Generated On: 23 Oct 2018 18:11:14

- I12 - Per participant report at Screening, regular menstrual cycles with at least 21 days between menses
- I13 - Regular menstrual cycles with at least 21 days between menses
- I14 - Participants over the age of 21 (inclusive) must have documentation of a satisfactory Pap within the past 3 years prior to Enrollment consistent with Grade 0 according to the Female Genital Grading Table for Use in Microbicide Studies Addendum 1 (Dated November 2007) to the DAIDS Table for Grading Adult and Pediatric Adverse Events, Corrected Version 2.1, JulyMarch 2017, or satisfactory evaluation with no treatment required of Grade 1 or higher Pap result
- I15 - At Screening and Enrollment, agrees not to participate in other research studies involving drugs, medical devices, vaginal or rectal products, or vaccines after the Screening Visit and for the duration of study participation
- E1 - Pregnant at Screening or Enrollment or plans to become pregnant during the study period
- E2 - Diagnosed with a urinary tract infection (UTI) or reproductive tract infection (RTI) at Screening or Enrollment
- E3 - Diagnosed with an acute sexually transmitted infection (STI) requiring treatment per current Centers for Disease Control and Prevention (CDC) guidelines at Screening or Enrollment such as gonorrhea, chlamydia, trichomonas, pelvic inflammatory disease, and/or syphilis
- E4 - Has a clinically apparent Grade 2 or higher pelvic exam finding (observed by study staff) at Screening or Enrollment, as per the current Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, and/or Addendum 1
- E5a - Known adverse reaction to any of the study products (ever), including polyurethane

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Inclusion/Exclusion Criteria
Generated On: 23 Oct 2018 18:11:14

- E5b - Chronic and/or recurrent vaginal candidiasis
- E5c - Non-therapeutic injection drug use in the 12 months prior to Enrollment
- E5d - Last pregnancy outcome less than 90 days prior to Enrollment
- E5e - Gynecologic or genital procedure (e.g., tubal ligation, dilation and curettage, piercing) 45 days or less prior to Enrollment
- E5f - Currently breastfeeding or planning to breastfeed during the study
- E5g - Participation in any other research study involving drugs, medical devices, vaginal or rectal products, or vaccines, in the 60 days prior to Enrollment
- E6 - Use of pre-exposure prophylaxis (PrEP) for HIV prevention and/or post-exposure prophylaxis (PEP) for potential HIV exposure within the 3 months prior to Enrollment, and/or anticipated use and/or unwillingness to abstain from PrEP during trial participation
- E7a - Grade 1 or higher Aspartate aminotransferase (AST) or alanine transaminase (ALT)
- E7b - Grade 1 or higher Hemoglobin
- E7c - Calculated creatinine clearance less than 60 mL/min by the Cockcroft-Gault formula
- E7d - Positive Hepatitis B surface antigen result
- E8 - Has any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate the interpretation of study outcome data, or otherwise interfere with achieving the study objectives including any significant uncontrolled active or chronic medical condition

If Eligible/Not enrolled, specify reason: _____

If not enrolled due to the decision of the Investigator of Record (IoR)/designee, specify (max. 200 characters): _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Pregnancy Test Results
Generated On: 23 Oct 2018 18:11:14

Was a pregnancy test done? Yes
No

Collection date _____

Collection time _____

Pregnancy test result Positive
Negative

If pregnancy test result is positive, complete a Pregnancy History and Pregnancy Report form.

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Medical History Y/N

Generated On: 23 Oct 2018 18:11:14

Does the participant have any medical history to report?

Yes

No

If "Yes", complete the Medical History form.

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Medical History

Generated On: 23 Oct 2018 18:11:14

Date medical history collected _____

Description of medical history condition/event _____

Is condition/event gradable? Yes
No

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

Start date of medical history condition/event _____

Is the condition ongoing? Yes
No

Date medical history/condition ended/resolved _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Physical Exam

Generated On: 23 Oct 2018 18:11:14

Was a physical exam performed? Yes
No

Date of exam _____

BODY SYSTEM

General Appearance Not Done
Normal
Abnormal

If abnormal, specify: _____

HEENT Not Done
Normal
Abnormal

If "Abnormal", specify: _____

Neck Not Done
Normal
Abnormal

If "Abnormal", specify: _____

Lymph Nodes Not Done
Normal
Abnormal

If "Abnormal", specify: _____

Heart/Cardiovascular Not Done
Normal
Abnormal

If "Abnormal", specify: _____

Lung/Respiratory Not Done
Normal
Abnormal

If "Abnormal", specify: _____

Abdomen Not Done
Normal
Abnormal

If "Abnormal", specify: _____

Extremities Not Done
Normal
Abnormal

If "Abnormal", specify: _____

Neurological Not Done

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Physical Exam
Generated On: 23 Oct 2018 18:11:14

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 Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Vital Signs

Generated On: 23 Oct 2018 18:11:14

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 blood pressure _____ Fixed Unit: mmHg

Diastolic blood pressure _____ Fixed Unit: mmHg

Pulse _____ Fixed Unit: beats/min

Rate of respiration _____ Fixed Unit: breaths/min

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Discontinuation of Study Product
Generated On: 23 Oct 2018 18:11:14

Date that study product use ended _____

Primary reason for ending study product use

- Scheduled study product use period completed
- Death
- Participant refused further participation
- Participant is unwilling or unable to comply with required study procedures
- Investigator decision
- Lost to follow-up
- Participant refused further study product use
- Unable to contact participant
- HIV infection
- Early study closure
- Protocol deviation
- Adverse event
- Pregnancy
- Withdrawal of consent by participant
- Study terminated by sponsor
- One or more reactive HIV test results or acute HIV infection suspected
- Breastfeeding
- Allergic reaction to the IVR
- Non-therapeutic injection drug use
- Reported use of PEP
- Reported use of PrEP
- Use of anticoagulant
- Other, specify

If "Other", specify

If "Adverse event", select applicable adverse event

Source Document Upload

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Study Termination
Generated On: 23 Oct 2018 18:11:14

Date of study exit _____

Primary reason for completion/discontinuation

Scheduled exit visit/end of study	<input type="radio"/>
Death	<input type="radio"/>
Participant refused further participation	<input type="radio"/>
Participant is unwilling or unable to comply with required study procedures	<input type="radio"/>
Lost to follow-up	<input type="radio"/>
Investigator decision	<input type="radio"/>
Participant refused further study product use	<input type="radio"/>
Unable to contact participant	<input type="radio"/>
HIV infection	<input type="radio"/>
Early study closure	<input type="radio"/>
Protocol deviation	<input type="radio"/>
Adverse event	<input type="radio"/>
Pregnancy	<input type="radio"/>
Allergic reaction to the IVR	<input type="radio"/>
Breastfeeding	<input type="radio"/>
Non-therapeutic drug use	<input type="radio"/>
Other, specify	<input type="radio"/>

If "Other", specify _____

If "Death", enter date of death _____

If "Adverse event", select applicable adverse event _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Pregnancy History

Generated On: 23 Oct 2018 18:11:14

Date pregnancy history collected _____

Has the participant ever been pregnant before? Yes

No

If "No", end of form. _____

Number of full term live births (>=37 weeks) _____

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

Number of spontaneous fetal deaths and/or still births (>=20 weeks) _____

Number of spontaneous abortions (Less than 20 weeks) _____

Number of therapeutic/elective abortions _____

Number of ectopic pregnancies _____

Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies? Yes

No

If "Yes", specify: _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Pregnancy Report
Generated On: 23 Oct 2018 18:11:14

Date pregnancy reported to site _____

Visit at which this pregnancy was reported

Screening

Enrollment

V3 - Day 1

V4 - Day 7

V5 - Day 14

V6- Day 28

V7 - Day 42

V8 - Day 56

V9 - Day 91 PUEV

V10 - Day 92 Final Contact

Interim Visit

If Interim visit, specify Interim visit code _____

Date of onset of last menstrual period _____

Or

Amenorrheic for past 6 months

Estimated date of delivery _____

What primary information was used to estimate the date of delivery?

Last menstrual period

Initial ultrasound <20 weeks

Initial ultrasound >= 20 weeks

Physical examination

Conception date by assisted reproduction

Other

If "Other", specify: _____

Is this the participant's first pregnancy since enrollment in this study? Yes

No

If "Yes", complete Pregnancy History form. _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Chemistry Panel - LFT, RFT, Other

Generated On: 23 Oct 2018 18:11:14

Lab Name: _____

Was a sample collected for serum chemistries? Yes
No

Specimen Collection Date _____

LIVER FUNCTION TESTS

AST (SGOT) Result _____

AST (SGOT) Severity Grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

AST (SGOT) severity grade - calculated Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

AST (SGOT) Adverse Event _____

ALT (SGPT) Result _____

ALT (SGPT) Severity Grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

ALT (SGPT) severity grade - calculated Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

ALT (SGPT) Adverse Event _____

RENAL FUNCTION TESTS

Creatinine Result _____

Creatinine Severity Grade Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)
Not gradable

Creatinine severity grade - calculated Grade 1 (Mild)

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Chemistry Panel - LFT, RFT, Other

Generated On: 23 Oct 2018 18:11:14

Lab Name:

_____	Grade 2 (Moderate) <input type="radio"/>
_____	Grade 3 (Severe) <input type="radio"/>
_____	Grade 4 (Potentially life-threatening) <input type="radio"/>
_____	Not gradable <input type="radio"/>

Creatinine Adverse Event _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Protocol Deviations Y/N
Generated On: 23 Oct 2018 18:11:14

Have any protocol deviations been reported?

Yes

No

If "Yes", complete the Protocol Deviations Log.

If "Yes", complete the Protocol Deviations Log.

Source Document Upload _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Protocol Deviations Log
Generated On: 23 Oct 2018 18:11:14

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Pelvic Exam

Generated On: 23 Oct 2018 18:11:14

Pelvic exam assessment Not done
No abnormal findings
Abnormal findings

Exam date _____
Was the Vaginal Ring in place at the start of the pelvic exam? Yes
No

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

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Pelvic Exam

Generated On: 23 Oct 2018 18:11:14

Cervical erythema	<input type="checkbox"/>
Cervical masses (polyps, myomas, possible malignancy)	<input type="checkbox"/>
Cervical motion tenderness	<input type="checkbox"/>
Cervical discharge	<input type="checkbox"/>
Cervical ulcer	<input type="checkbox"/>
Cervical blister	<input type="checkbox"/>
Cervical pustule	<input type="checkbox"/>
Cervical peeling	<input type="checkbox"/>
Cervical ecchymosis	<input type="checkbox"/>

GENERAL/OTHER

Odor (vaginal)	<input type="checkbox"/>
Condyloma	<input type="checkbox"/>
If condyloma, specify location	_____
Adnexal masses (based on bimanual exam; not pregnancy or infection-related)	<input type="checkbox"/>
Uterine masses (based on bimanual exam)	<input type="checkbox"/>
Uterine tenderness	<input type="checkbox"/>
Adnexal tenderness	<input type="checkbox"/>
Abnormal blood or bleeding	<input type="checkbox"/>
Abnormal blood or bleeding; describe	_____
Other abnormal findings	<input type="checkbox"/>
If other abnormal findings, specify (include anatomical location)	_____

Complete or update 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 _____

Cervical ectopy

0%	<input type="radio"/>
1-25%	<input type="radio"/>
26-50%	<input type="radio"/>
51-75%	<input type="radio"/>
76-100%	<input type="radio"/>
Not done	<input type="radio"/>

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Behavioral Summary
Generated On: 23 Oct 2018 18:11:14

Was a CASI questionnaire completed at this visit? Yes
No

If no, please explain: _____
Was an in-depth interview completed at this visit? Yes
No
Not applicable

If no, please explain: _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: CASI Tracking

Generated On: 23 Oct 2018 18:11:14

CASI collection date _____

Which questionnaire was completed?

Enrollment CASI

Visit 6 (Day 28/Week 4)

Follow-Up CASI

Visit 8 (Day 56/Week 8)

Follow-Up CASI

PUEV CASI

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

Yes

No

If yes, please describe _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: HIV Test Results

Generated On: 23 Oct 2018 18:11:14

Was sample 1 collected for HIV testing? Yes
No

Collection date _____
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 Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: STI Test Results

Generated On: 23 Oct 2018 18:11:14

Was a sample collected for Syphilis testing? Yes
No

Collection date _____
Syphilis screening test Non-reactive
Reactive
Not reported

Syphilis titer _____
Syphilis confirmatory test Positive
Negative
Indeterminate
Not done

Was a vaginal wet prep sample collected? Yes
No

Collection date _____
Vaginal pH _____
Homogenous vaginal discharge Positive
Negative
Not done

Whiff test Positive
Negative
Not done

Clue cells \geq 20% Positive
Negative
Not done

Trichomonas vaginalis Positive
Negative
Not done

Buds and/or hyphae (yeast) Positive
Negative
Not done

Was a sample collected for NAAT for GC/CT and trichomonas? Yes
No

Collection date _____
N. gonorrhea Positive
Negative
Not done

C. trachomatis Positive

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: STI Test Results
Generated On: 23 Oct 2018 18:11:14

	Negative <input type="radio"/>
	Not done <input type="radio"/>
Trichomonas	Positive <input type="radio"/>
	Negative <input type="radio"/>
	Not done <input type="radio"/>
Was a sample collected for dipstick urinalysis tests?	Yes <input type="radio"/>
	No <input type="radio"/>
Collection date	
Leukocyte esterase (LE)	Positive <input type="radio"/>
	Negative <input type="radio"/>
	Not done <input type="radio"/>
Nitrates	Positive <input type="radio"/>
	Negative <input type="radio"/>
	Not done <input type="radio"/>
Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?	Yes <input type="radio"/>
	No <input type="radio"/>
Date of collection	
Hepatitis B Surface Antigen (HBsAG)	Positive <input type="radio"/>
	Negative <input type="radio"/>
	Not done <input type="radio"/>
Source Document Upload	

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Specimen Storage
Generated On: 23 Oct 2018 18:11:14

Blood

1. - Was plasma for archive/storage collected? Yes
No

Collection date _____

Collection time _____

Plasma for archive/storage Stored
Not Stored

If not stored, specify reason _____

2. - Was plasma for PK collected? Yes
No

Collection date _____

Collection time _____

Plasma for PK Stored
Not Stored

If not stored, specify reason _____

Rectal PK Specimens

3. - Was a rectal swab for PK collected? Yes
No

Collection date _____

Collection time _____

Rectal Swab for PK Stored
Not Stored

If not stored, specify reason _____

Was HSV-1/2 for archive/storage collected? Yes
No

Collection date _____

Collection time _____

HSV-1/2 for archive/storage Stored
Not stored

If not stored, specify reason _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Cervical Specimen Storage

Generated On: 23 Oct 2018 18:11:14

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? _____

Cervicovaginal lavage (CVL) for PD, PK, and Biomarkers
Was CVL collected? Yes No

Collection date _____
Collection time _____
Cervicovaginal lavage (CVL) - cell pellet Stored Not Stored

If not stored, specify reason _____
Cervicovaginal lavage (CVL) - supernatant Stored Not Stored

If not stored, specify reason _____
Cervicovaginal fluid (CVF) for anti-HSV activity
Was CVF for anti-HSV activity collected? Yes No

Collection date _____
Collection time _____
Cervicovaginal fluid (CVF) for anti-HSV activity Stored Not Stored

If not stored, specify reason _____
Cervicovaginal fluid (CVF) for PK
Was CVF for PK collected? Yes No

Collection date _____
Collection time _____
Cervicovaginal fluid (CVF) for PK Stored Not stored

If not stored, specify reason _____
CVF for biomarkers
Was CVF for biomarkers collected? Yes No

Collection date _____
Collection time _____
CVF for biomarkers Stored Not stored

If not stored, specify reason _____
Cervical tissue for PK

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Cervical Specimen Storage
Generated On: 23 Oct 2018 18:11:14

Were cervical biopsies for PK collected? Yes
No

Collection date _____
Collection time _____
Cervical tissue for PK Stored
Not stored

If not stored, specify reason _____

Cervical tissue for PD
Were cervical biopsies for PD collected? Yes
No

Collection date _____
Collection time _____
Cervical tissue for PD Stored
Not stored

If not stored, specify reason _____

Vaginal swabs for Microbiota
Were vaginal swabs for microbiota culture collected? Yes
No

Collection date _____
Vaginal swabs for microbiota culture Stored
Not Stored

If not stored, specify reason _____

Vaginal Gram stain
Was a Vaginal Gram stain collected? Yes
No

Collection date _____
Vaginal Gram stain Stored
Not Stored

If not stored, specify reason _____

Source Document Upload _____

Participant ID: _____ - _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Ring Adherence YN

Generated On: 23 Oct 2018 18:11:14

Since the participant's last adherence assessment (or since the ring was inserted, if currently Visit 6/Day 28), has she ever used a vaginal ring?

Yes

No

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Ring Adherence

Generated On: 23 Oct 2018 18:11:14

Did the participant disclose her ring use to her primary partner? Yes
No
Not applicable

Since her last adherence assessment (or since the ring was inserted, if currently Visit 6/Day 28), how many times in total has the participant had a vaginal ring out? _____

How many of these times since the participant's last adherence assessment (or since the ring was inserted, if currently Visit 6/Day 28) was a vaginal ring out for more than 12 hours continuously? _____

Since the participant's last adherence assessment (or since the ring was inserted if currently Visit 6/Day 28), what is the longest number of days in a row the vaginal ring was out? _____

Was the ring removed? Yes
No

Did the ring come out on its own? Yes
No

For each instance when the ring was out since her last adherence assessment (or since the ring was inserted, if currently Visit 6/Day 28), please add a log line below. Ring removals by site staff for the purpose of clinical examination should not be recorded on this form.

Date ring was removed or came out (estimate if exact date not known): _____

Time ring was removed or came out (estimate if exact time not known): _____

Was the ring re-inserted? Yes
No

If the ring was re-inserted, date the ring was re-inserted (estimate if exact date not known): _____

If the ring was re-inserted, time the ring was re-inserted (estimate if exact time not known): _____

If removed, Reason #1 why vaginal ring was removed:

- Discomfort/symptoms: Ring caused discomfort/participant experienced genital or other symptoms
- Ring falling out: Ring was partially falling out
- Ring placement: Didn't feel the ring was correctly placed
- Ring presence: Wanted to look at the ring or see if the ring was still in place
- Menses/Bleeding: Had or was expecting menses/any type of genital bleeding or spotting
- Cleaned ring: Removed ring to clean it
- Cleaned vagina: Removed ring to clean vagina
- Felt sick: Felt sick/had non-genital side effects from the ring
- Emotional worries: Had emotional worries about the ring

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Ring Adherence
Generated On: 23 Oct 2018 18:11:14

- Partner ring knowledge: Did not want husband or primary sex partner to know about ring
- Partner concerns/objections: Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring
- Family concerns/objections: Family member (other than husband/primary sex partner) did not like the ring and/or wanted her to remove/stop using the ring
- Friend or peer concerns/objections: Friend or peer did not like the ring and/or wanted her to remove/stop using the ring
- Removal for sex: Participant or partner did not want to have vaginal sex with the ring in place
- Discomfort during sex: The ring feeling uncomfortable or painful during vaginal sex
- Partner felt ring during sex: The sex partner feeling the ring during sex
- Showed ring: Removed ring to show it to someone
- Not having sex: Participant was not having sex so she decided to remove/stop using the ring
- Interfered with sexual pleasure: The ring interfered with her sexual pleasure
- Interfered with partner's sexual pleasure: the ring interfered with her partner's sexual pleasure
- Disliked ring: Removed ring because did not like the ring
- Partner disliked ring: Removed ring because partner did not like the ring
- Participant wanted to get pregnant
- Partner wanted her to get pregnant
- Product hold: Participant placed on product hold
- Product permanently discontinued: Participant permanently discontinued from product
- Procedure: Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam)

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Ring Adherence
Generated On: 23 Oct 2018 18:11:14

Delay in insertion of new ring:
Ring removed between study visits and there was a delay in new ring insertion
Missed visit: Participant removed ring due to missed scheduled visit
Other

If removed, Reason #2 why vaginal ring was removed:

Discomfort/symptoms: Ring caused discomfort/participant experienced genital or other symptoms
Ring falling out: Ring was partially falling out
Ring placement: Didn't feel the ring was correctly placed
Ring presence: Wanted to look at the ring or see if the ring was still in place
Menses/Bleeding: Had or was expecting menses/any type of genital bleeding or spotting
Cleaned ring: Removed ring to clean it
Cleaned vagina: Removed ring to clean vagina
Felt sick: Felt sick/had non-genital side effects from the ring
Emotional worries: Had emotional worries about the ring
Partner ring knowledge: Did not want husband or primary sex partner to know about ring
Partner concerns/objections: Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring
Family concerns/objections: Family member (other than husband/primary sex partner) did not like the ring and/or wanted her to remove/stop using the ring
Friend or peer concerns/objections: Friend or peer did not like the ring and/or wanted her to remove/stop using the ring
Removal for sex: Participant or partner did not want to have vaginal sex with the ring in place
Discomfort during sex: The ring feeling uncomfortable or painful during vaginal sex
Partner felt ring during sex: The sex partner feeling the ring during sex

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Ring Adherence
Generated On: 23 Oct 2018 18:11:14

- Shown ring: Removed ring to show it to someone
- Not having sex: Participant was not having sex so she decided to remove/stop using the ring
- Interfered with sexual pleasure: The ring interfered with her sexual pleasure
- Interfered with partner's sexual pleasure: the ring interfered with her partner's sexual pleasure
- Disliked ring: Removed ring because did not like the ring
- Partner disliked ring: Removed ring because partner did not like the ring
- Participant wanted to get pregnant
- Partner wanted her to get pregnant
- Product hold: Participant placed on product hold
- Product permanently discontinued: Participant permanently discontinued from product
- Procedure: Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam)
- Delay in insertion of new ring: Ring removed between study visits and there was a delay in new ring insertion
- Missed visit: Participant removed ring due to missed scheduled visit
- Other

If removed, Reason #3 why vaginal ring was removed:

- Discomfort/symptoms: Ring caused discomfort/participant experienced genital or other symptoms
- Ring falling out: Ring was partially falling out
- Ring placement: Didn't feel the ring was correctly placed
- Ring presence: Wanted to look at the ring or see if the ring was still in place
- Menses/Bleeding: Had or was expecting menses/any type of genital bleeding or spotting
- Cleaned ring: Removed ring to clean it
- Cleaned vagina: Removed ring to clean vagina
- Felt sick: Felt sick/had non-genital side effects from the ring

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Ring Adherence
Generated On: 23 Oct 2018 18:11:14

- Emotional worries: Had emotional worries about the ring
- Partner ring knowledge: Did not want husband or primary sex partner to know about ring
- Partner concerns/objections: Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring
- Family concerns/objections: Family member (other than husband/primary sex partner) did not like the ring and/or wanted her to remove/stop using the ring
- Friend or peer concerns/objections: Friend or peer did not like the ring and/or wanted her to remove/stop using the ring
- Removal for sex: Participant or partner did not want to have vaginal sex with the ring in place
- Discomfort during sex: The ring feeling uncomfortable or painful during vaginal sex
- Partner felt ring during sex: The sex partner feeling the ring during sex
- Showed ring: Removed ring to show it to someone
- Not having sex: Participant was not having sex so she decided to remove/stop using the ring
- Interfered with sexual pleasure: The ring interfered with her sexual pleasure
- Interfered with partner's sexual pleasure: the ring interfered with her partner's sexual pleasure
- Disliked ring: Removed ring because did not like the ring
- Partner disliked ring: Removed ring because partner did not like the ring
- Participant wanted to get pregnant
- Partner wanted her to get pregnant
- Product hold: Participant placed on product hold
- Product permanently discontinued: Participant permanently discontinued from product
- Procedure: Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam)

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Ring Adherence
Generated On: 23 Oct 2018 18:11:14

	Delay in insertion of new ring: <input type="checkbox"/>
	Ring removed between study visits and there was a delay in new ring insertion
	Missed visit: Participant removed ring due to missed scheduled visit <input type="checkbox"/>
	Other <input type="checkbox"/>

Other reason ring was removed, please specify: _____

If the vaginal ring came out on its own, Reason #1:

	Urination <input type="checkbox"/>
	Bowel movement: Having a bowel movement <input type="checkbox"/>
	Sex: Having sex or just finished sex <input type="checkbox"/>
	Physical activity: Physical activity (other than sex), including lifting heavy objects <input type="checkbox"/>
	Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up) <input type="checkbox"/>
	Menses related <input type="checkbox"/>
	Other <input type="checkbox"/>

If the vaginal ring came out on its own, Reason #2:

	Urination <input type="checkbox"/>
	Bowel movement: Having a bowel movement <input type="checkbox"/>
	Sex: Having sex or just finished sex <input type="checkbox"/>
	Physical activity: Physical activity (other than sex), including lifting heavy objects <input type="checkbox"/>
	Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up) <input type="checkbox"/>
	Menses related <input type="checkbox"/>
	Other <input type="checkbox"/>

If the vaginal ring came out on its own, Reason #3:

	Urination <input type="checkbox"/>
	Bowel movement: Having a bowel movement <input type="checkbox"/>
	Sex: Having sex or just finished sex <input type="checkbox"/>
	Physical activity: Physical activity (other than sex), including lifting heavy objects <input type="checkbox"/>
	Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up) <input type="checkbox"/>
	Menses related <input type="checkbox"/>
	Other <input type="checkbox"/>

Other reason ring came out on its own, please specify: _____

Source Document Upload _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Product Hold YN

Generated On: 23 Oct 2018 18:11:14

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

Yes

No

If "Yes", complete the Product Hold Log.

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Pregnancy Outcome Log
Generated On: 23 Oct 2018 18:11:14

Is the outcome of this pregnancy obtainable? Yes
No

If no, end of form.

How many pregnancy outcomes resulted from this reported pregnancy? _____

Outcome date _____

Place of delivery/outcome Home
Hospital
Clinic
Unknown
Other

If "Other", specify: _____

Specify outcome Full term live birth (greater than or equal to 37 weeks)
If the pregnancy or outcome was associated with maternal complications or symptoms that would otherwise be reported as an AE, report these on an AE log. Complete an EAE reporting form, if applicable. Premature live birth (less than 37 weeks)
Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks)
Spontaneous abortion (less than 20 weeks)
Ectopic pregnancy
Therapeutic/elective abortion
Other

If "Other", specify: _____

If stillbirth/intrauterine fetal demise, spontaneous abortion, ectopic pregnancy or therapeutic/elective abortion is marked, go to "provide a brief narrative of the circumstances".

Method C-section
If full term live birth, go to "Were there any complications related to the pregnancy outcome?". Standard vaginal
Operative vaginal

Provide a brief narrative of the circumstances _____

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

If there were no complications related to the pregnancy outcome, skip to the "Were any fetal/infant congenital anomalies identified" item.

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

- None
- Intrapartum hemorrhage
- Postpartum hemorrhage
- Non-reassuring fetal status

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Pregnancy Outcome Log

Generated On: 23 Oct 2018 18:11:14

Chorioamnionitis

Other

If "Other", specify: _____

Non-delivery related complications: Mark "None" or all that apply.

None

Hypertensive disorders of pregnancy

Gestational diabetes

Other

If "Other", specify: _____

Were any fetal/infant congenital anomalies identified? Yes

Mark all that apply. If No or unknown, go to statement above "infant gender". Complete AE Log and EAE Reporting form. No

Unknown

Central nervous system, cranio-facial

Central nervous system, spinal

Cardiovascular

Renal

Gastrointestinal

Pulmonary

Musculoskeletal/extremities

Physical defect

Skin

Genitourinary

Chromosomal

Cranio-facial (structural)

Hematologic

Infectious

Endocrine/metabolic

Other

Specify congenital anomaly/defect AE _____

Describe the congenital anomaly/defect: _____

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

Female

Infant gender _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Pregnancy Outcome Log
Generated On: 23 Oct 2018 18:11:14

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 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

If unavailable, end of form.

Method used to determine gestational age Ballard
Dubowitz
Other

If other, specify

Source Document Upload

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Product Hold Log

Generated On: 23 Oct 2018 18:11:14

Date when study product hold was initiated _____

Visit when study product hold was initiated _____

- Enrollment
- V3 - Day 1
- V4 - Day 7
- V5 - Day 14
- V6 - Day 28
- V7 - Day 42
- V8 - Day 56
- V9 - Day 91 PUEV
- V10 - Day 92 Final Contact
- Interim Visit

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

Why is study product being held? _____

- Reactive rapid HIV test
- Adverse Event
- Reported use of PEP
- Reported use of PrEP
- Use of anticoagulant
- Participant unable/unwilling to comply with required study procedures, or o/w might be put at undue risk to their safety and well-being by continuing product use according to judgment of IoR/designee
- Other

If "Other", specify: _____

Adverse Event: _____

Concomitant Medication: _____

Concomitant Medication: _____

Concomitant Medication: _____

Concomitant Medication: _____

Date of last study product use: _____

Was the participant instructed to resume study product use? _____

- Yes
- No - permanently discontinued
- No - early termination
- No - Hold continuing at scheduled PUEV
- No - hold continuing for another reason

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

Date study product resumed _____

Date study product hold continuing for another reason _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Ring Insertion and Removal
Generated On: 23 Oct 2018 18:11:14

Date of assessment _____

Did the participant have a ring in place at the start of the visit? Yes
No

If no, skip to "Was a ring inserted at this visit?"

Was the ring removed at this visit? Yes
No

If no, skip to "Was a ring inserted at this visit?"

Date ring was removed _____

Time ring was removed _____

Who removed the ring? Participant
Study Staff

Reason ring was removed Participant on clinical hold
Participant has been permanently discontinued from product
Participant declined study ring use
Early termination
Scheduled return of ring
Scheduled PUEV
Other

If participant declined study ring use or other, specify _____

Ring Storage Stored
Not stored

If not stored, specify reason _____

Was a ring inserted at this visit? Yes
No

If no, end of form

Date ring was inserted _____

Time ring was inserted _____

Did the participant attempt to insert the ring herself? Yes
No, inserted by study staff

If "Yes", go to "Based on your assessment and her feedback, how easy or difficult was it for the participant to insert the ring?"

If "No, inserted by study staff," please describe the reason: _____

If "No, inserted by study staff," End of form.

Based on your assessment and her feedback, how easy or difficult was it for the participant to insert the ring? Very difficult
Difficult
Easy
Very easy

If very difficult or difficult, why? (Choose all that apply) Reluctance to insert herself

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Ring Insertion and Removal
Generated On: 23 Oct 2018 18:11:14

	Physical discomfort while inserting	<input type="checkbox"/>
	Difficulty folding and gripping ring	<input type="checkbox"/>
	Difficulty inserting far enough	<input type="checkbox"/>
	Required more than 1 attempt	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If other, specify _____

Did the participant require any help from the clinician to insert the ring?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If yes, specify _____

Did study staff verify that the ring was in place?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If no, explain _____

If yes, upon verifying, was the ring correctly inserted by the participant?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If no, explain _____

Source Document Upload _____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: HIV Confirmatory Results

Generated On: 23 Oct 2018 18:11:14

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 _____

Was sample 2 stored? Stored
Not stored

Final HIV status

Final HIV status HIV uninfected
HIV infected
pending

Source Document Upload _____

Participant ID: _____ - _____ - _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Pharmacy Dispensation
Generated On: 23 Oct 2018 18:11:14

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Timed Specimen Storage
Generated On: 23 Oct 2018 18:11:14

Blood
Was plasma for archive/storage collected? Yes
No

Collection date _____
Collection time _____
Plasma for archive/storage Stored
Not Stored

If not stored, specify reason _____

Plasma for PK
Was plasma for PK collected prior to ring removal? Yes
No

Collection date _____
Collection time _____
Plasma for PK Stored
Not Stored

If not stored, specify reason _____

Was plasma for PK collected 4 hours following ring removal? Yes
No

Collection date _____
Collection time _____
Plasma for PK Stored
Not stored

If not stored, specify reason _____

Rectal PK Specimens
Was a rectal swab for PK collected prior to ring removal? Yes
No

Collection date _____
Collection time _____
Rectal Swab for PK Stored
Not Stored

If not stored, specify reason _____

Was a rectal swab for PK collected 4 hours following ring removal? Yes
No

Collection date _____
Collection time _____
Rectal Swab for PK Stored
Not stored

If not stored, specify reason _____

Was HSV-1/2 for archive/storage collected? Yes

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Timed Specimen Storage
Generated On: 23 Oct 2018 18:11:14

	No <input type="radio"/>
Collection date	_____
Collection time	_____
HSV-1/2 for archive/storage	Stored <input type="radio"/>
	Not stored <input type="radio"/>
If not stored, specify reason	_____
Source Document Upload	_____

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL

Form: Timed Cervical Specimen Storage

Generated On: 23 Oct 2018 18:11:14

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? _____

Cervicovaginal lavage (CVL) for PD, PK, and Biomarkers
Was CVL collected? Yes No

If Visit 2, was sample taken prior to ring insertion? Yes No Not applicable

Collection date _____
Collection time _____
Cervicovaginal lavage (CVL) - cell pellet Stored Not Stored

If not stored, specify reason _____
Cervicovaginal lavage (CVL) - supernatant Stored Not Stored

If not stored, specify reason _____
Cervicovaginal fluid (CVF) for anti-HSV activity
Was CVF for anti-HSV activity collected? Yes No

Collection date _____
Collection time _____
Cervicovaginal fluid (CVF) for anti-HSV activity Stored Not Stored

If not stored, specify reason _____
Cervicovaginal fluid (CVF) for PK
Was CVF for PK collected one hour following ring insertion? Yes No

Collection date _____
Collection time _____
Cervicovaginal fluid (CVF) for PK Stored Not stored

If not stored, specify reason _____
Was CVF for PK collected 4 hours following ring insertion? Yes No

Collection date _____
Collection time _____
Cervicovaginal fluid (CVF) for PK Stored

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Timed Cervical Specimen Storage
Generated On: 23 Oct 2018 18:11:14

_____ Not stored

If not stored, specify reason _____

Was CVF for PK collected immediately prior to ring removal? Yes

No

Collection date _____

Collection time _____

Cervicovaginal fluid (CVF) for PK Stored

Not stored

If not stored, specify reason _____

Was CVF for PK collected 4 hours following ring removal? Yes

No

Collection date _____

Collection time _____

Cervicovaginal fluid (CVF) for PK Stored

Not stored

If not stored, specify reason _____

CVF for biomarkers

Was CVF for biomarkers collected? Yes

No

Collection date _____

Collection time _____

CVF for biomarkers Stored

Not stored

If not stored, specify reason _____

Cervical tissue for PK

Were cervical biopsies for PK collected? Yes

No

Collection date _____

Collection time _____

Cervical tissue for PK Stored

Not stored

If not stored, specify reason _____

Cervical tissue for PD

Were cervical biopsies for PD collected? Yes

No

Collection date _____

Collection time _____

Cervical tissue for PD Stored

Not stored

Participant ID: _____

Visit: _____

Visit Date: _____

MTN038_Version_1.0_PROD_15OCT2018: ALL
Form: Timed Cervical Specimen Storage
Generated On: 23 Oct 2018 18:11:14

If not stored, specify reason _____

Vaginal swabs for Microbiota

Were vaginal swabs for microbiota culture collected? Yes
No

Collection date _____

Was blood visible on the swab? Yes
No

Vaginal swabs for microbiota culture Stored
Not Stored

If not stored, specify reason _____

Vaginal Gram stain

Was a Vaginal Gram stain collected? Yes
No

Collection date _____

Vaginal Gram stain Stored
Not Stored

If not stored, specify reason _____

Source Document Upload _____