

MTN036_version 7.0_PROD_30OCT2018: All

Form: Randomization

Generated On: 31 Oct 2018 15:21:17

Is the participant ready to be randomized?

Yes

No

Randomization Date and Time _____

Randomization ID _____

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Form: Screening Date of Visit

Generated On: 31 Oct 2018 15:21:17

Screening visit date

**MTN036_version 7.0_PROD_30OCT2018: All
Form: Adverse Event Summary
Generated On: 31 Oct 2018 15:21:17**

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

If yes, please complete the Adverse Event Log.

MTN036_version 7.0_PROD_30OCT2018: All**Form: Adverse Event Log****Generated On: 31 Oct 2018 15:21:17**

Date reported to site _____

Adverse Event (AE) _____

Onset date _____

At which visit was this AE first reported?

V2.0 - Enrollment

V3.0 - Day 1

V4.0 - Day 2

V5.0 - Day 3

V6.0 - Day 7

V7.0 - Day 14

V8.0 - Day 28/Week 4

V9.0 - Day 56/Week 8

V10.0 - Day 91/Week 13

V11.0 - Day 92-94

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to study product Related Not Related Action taken with Study product dose not changed dose reduced dose increased drug withdrawn drug interrupted not applicable Other action(s) taken (Select all that apply)

None

Medication Therapeutic procedure/surgery

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Diagnostic procedure	<input type="checkbox"/>
Other	<input type="checkbox"/>
Other, specify _____	
Status/Outcome	recovered/resolved <input type="radio"/>
	recovering/resolving <input type="radio"/>
	resolved with sequelae <input type="radio"/>
	not recovered/resolved <input type="radio"/>
	fatal <input type="radio"/>
Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines? If "No", go to "Has or will this AE be reported as an EAE?". If "Yes", check all that apply.	Yes <input type="radio"/>
	No <input type="radio"/>
Results in death	<input type="checkbox"/>
Is life-threatening	<input type="checkbox"/>
Requires inpatient hospitalization or prolongation of existing hospitalization	<input type="checkbox"/>
Results in persistent or significant disability/incapacity	<input type="checkbox"/>
Is a congenital anomaly/birth defect	<input type="checkbox"/>
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	<input type="checkbox"/>
Has or will this AE be reported as an EAE?	Yes <input type="radio"/>
	No <input type="radio"/>
If yes, EAE number _____	
Was this AE a worsening of a baseline medical condition?	Yes <input type="radio"/>
	No <input type="radio"/>
Comments _____	

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Form: Follow-up Visit Y/N

Generated On: 31 Oct 2018 15:21:17

Did the participant complete this visit?

Yes

No

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Form: Follow-up Visit Summary
Generated On: 31 Oct 2018 15:21:17

Visit date _____

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

Did the participant exit/terminate the study at this visit? Yes
No

Were any new adverse events (AEs) reported at this visit? Yes
No

Is the participant taking any concomitant medications that have not
been previously reported? Yes
No

Were any protocol deviations reported at this visit? Yes
No

Were any additional study procedures or forms completed outside of
the scheduled study visit per protocol? Yes
No

**MTN036_version 7.0_PROD_30OCT2018: All
Form: Concomitant Medications Summary
Generated On: 31 Oct 2018 15:21:17**

Is the participant taking any concomitant medications?

Yes

No

If yes, please complete the Concomitant Medications Log.

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Medication Name _____

Indication _____

Date Started _____

Date Stopped _____

Or _____

Continuing at end of study

Frequency _____ PRN

QD

BID

TID

QID

QHS

ONCE

Other

If other frequency, specify _____

Route _____

Oral

Intramuscular

Intravenous

Topical

Inhalation

Vaginal

Rectal

Subcutaneous

Other

If other route, specify _____

Dose _____

Dose Unknown

Dose Units _____

Grams

Micrograms

Milligrams

Milliliters

Capsules

Drops

Puffs

Sachets

Suppository

Tablets

Units

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Form: Concomitant Medications Log
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Unknown

Other

If other dose units, specify _____

Taken for a reported AE? Yes

No

Applicable Adverse Event #1 _____

Applicable Adverse Event #2 _____

Applicable Adverse Event #3 _____

Applicable Adverse Event #4 _____

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Form: Demographics

Generated On: 31 Oct 2018 15:21:17

What is the participant's date of birth?

Age

Fixed Unit: Years

What was the participant's sex at birth?

Male

Female

What is the participant's current gender identity?

Male

Female

Transgender

Does not identify as female,
male, or transgender

Ethnicity

Hispanic or Latino

Not Hispanic or Latino

Race

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or other Pacific Islander

White

Other

Specify other:

In the past 12 months, with whom did the participant have vaginal sex:

Both male and female partners

Exclusively female partners

Exclusively male partners

NA (no sex partners)

MTN036_version 7.0_PROD_30OCT2018: All
Form: Study Discontinuation
Generated On: 31 Oct 2018 15:21:17

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
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 _____

**MTN036_version 7.0_PROD_30OCT2018: All
Form: Baseline Medical History Summary
Generated On: 31 Oct 2018 15:21:17**

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 pelvic or physical exam findings, abnormal bleeding patterns, and any Screening or Enrollment lab abnormalities.

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Form: Baseline Medical History Log
Generated On: 31 Oct 2018 15:21:17

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 _____

MTN036_version 7.0_PROD_30OCT2018: All**Form: Pregnancy Report****Generated On: 31 Oct 2018 15:21:17**

Date pregnancy reported to site _____

Visit at which this pregnancy was reported
V3.0 - Day 1
V4.0 - Day 2
V5.0 - Day 3
V6.0 - Day 7
V7.0 - Day 14
V8.0 - Day 28/Week 4
V9.0 - Day 56/Week 8
V10.0 - Day 91/Week 13
V11.0 - Day 92-94
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

Complete the Pregnancy History CRF _____

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Form: Pregnancy History

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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: _____

MTN036_version 7.0_PROD_30OCT2018: All**Form: Physical Exam****Generated On: 31 Oct 2018 15:21:17**

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

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Form: Physical Exam
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_____ 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

_____ If Other is abnormal or normal, specify: _____

MTN036_version 7.0_PROD_30OCT2018: All**Form: Pelvic Exam****Generated On: 31 Oct 2018 15:21:17**

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

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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 Baseline Medical Conditions Log or Adverse Event Log, as applicable.	
Were any new pelvic finding AEs reported at this visit?	Yes <input type="radio"/>
	No <input type="radio"/>
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"/>

MTN036_version 7.0_PROD_30OCT2018: All**Form: Pregnancy Outcome Log****Generated On: 31 Oct 2018 15:21:17**

Is the outcome of this pregnancy obtainable? Yes

If no, end the form. No

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 (≥ 37 weeks)

Premature term 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 _____

Were there any complications related to the pregnancy outcome? Yes

No

Delivery-related complications Select "none" or all that apply.

None

Intrapartum hemorrhage

Postpartum hemorrhage

Non-reassuring fetal status

Chorioamnionitis

Other

If other, specify _____

MTN036_version 7.0_PROD_30OCT2018: All**Form: Pregnancy Outcome Log****Generated On: 31 Oct 2018 15:21:17**

Non-delivery related complications
 Select "none" or all that apply.

None

Hypertensive disorders of pregnancy Gestational diabetes Other

If other, specify _____

Were any fetal/infant congenital anomalies identified? Yes No

Congenital anomalies identified. Select all that apply. Complete AE
 Log and EAE Reporting form. 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.

Infant gender Male Female

Infant birth weight Fixed Unit: kg

Or

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Form: Pregnancy Outcome Log
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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

Method used to determine gestational age Ballard
Dubowitz
Other

If other, specify _____

**MTN036_version 7.0_PROD_30OCT2018: All
Form: Behavioral Summary
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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

If no, please explain: _____

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Form: CASI Tracking

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CASI collection date _____

Which questionnaire was completed? Baseline CASI
Visit 8 Follow-Up CASI
Visit 9 Follow-Up CASI
Exit CASI

Were there any problems or issues related to the administration or completion of the questionnaire? Yes
No

If yes, please describe _____

MTN036_version 7.0_PROD_30OCT2018: All
Form: Product Discontinuation
Generated On: 31 Oct 2018 15:21:17

Date study product use was permanently discontinued _____

Primary reason for ending study product use

Scheduled study product use period completed	<input type="radio"/>
Acquisition of HIV infection	<input type="radio"/>
Allergic reaction to the VR	<input type="radio"/>
Adverse Event	<input type="radio"/>
Pregnancy	<input type="radio"/>
Breastfeeding	<input type="radio"/>
Non-therapeutic injection drug use	<input type="radio"/>
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.	<input type="radio"/>
Other	<input type="radio"/>

If other, specify _____

If adverse event, select applicable adverse event _____

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Form: Product Hold Summary
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Does the participant have any clinical product holds to be applied? Yes

No

If Yes, complete the Product Hold Log.

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Date when study product hold was initiated: _____

Why is study product being held? _____

Adverse Event Reported use of PEP for HIV exposure Reported use of PrEP for HIV prevention Use of heparin, Lovenox, warfarin, Plavix (clopidogrel bisulfate), or other 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

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 - hold continuing for another reason No - early termination

If 'no - permanently discontinued', 'no - early termination' or 'no - hold continuing at Visit 10)', complete the Product Discontinuation form. _____

No - hold continuing at Visit 10 No - permanently discontinued

Date study product resumed _____

Date study product hold continuing for another reason _____

MTN036_version 7.0_PROD_30OCT2018: All
Form: Pregnancy Test Results
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Was a pregnancy test done? Yes
No

Date of Pregnancy Test _____
Time _____

Test result Positive
Negative

If pregnancy test result is positive, add the Pregnancy folder.

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Form: Hematology

Generated On: 31 Oct 2018 15:21:17

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 _____

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Form: Hematology

Generated On: 31 Oct 2018 15:21:17

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

**MTN036_version 7.0_PROD_30OCT2018: All
Form: Protocol Deviations Summary
Generated On: 31 Oct 2018 15:21:17**

Have any protocol deviations occurred?

Yes

No

If yes, please complete the Protocol Deviation Log.

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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 _____

MTN036_version 7.0_PROD_30OCT2018: All**Form: Eligibility Criteria****Generated On: 31 Oct 2018 15:21:17**

Did the participant meet all eligibility criteria? Yes

No

Eligibility Status Ineligible

Eligible, but participant did not enroll

Eligible, enrolled

Incomplete Screening

If eligible and enrolled or incomplete screening, 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. 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
- I4. Able and willing to provide adequate locator information
- 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 comply with abstinence and other protocol requirements as outlined in Sections 6.6 and 6.7
- I8. Willing to use male condoms for penile-vaginal intercourse (PVI) and penile-rectal 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 at Screening and Enrollment
- I11. HIV-uninfected based on testing performed at Screening and Enrollment (per protocol algorithm in Appendix II)
- I12. Regular menstrual cycles with at least 21 days between menses at Screening
- I13. States a willingness to refrain from inserting any non-study vaginal products or objects into the vagina for the 24 hours preceding the Enrollment Visit and for the duration of study participation.

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-
- 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, Version 2.1, March 2017, or satisfactory evaluation with no treatment required of Grade 1 or higher Pap result
- I15. Agrees not to participate in other research studies involving drugs, medical devices, vaginal 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 UTI or reproductive tract infection (RTI) at Screening or Enrollment
- E3. Diagnosed with an acute STI requiring treatment per current Centers for Disease Control and Prevention (CDC) guidelines at Screening or Enrollment such as gonorrhea (GC), CT, trichomonas, PID, 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 DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events
- E5a. Known adverse reaction to any of the study products (ever)
- 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 period

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- E5g. Participation in any other research study involving drugs, medical devices, vaginal 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 AST or ALT laboratory abnormalities at Screening Visit
- E7b. Grade 1 or higher hemoglobin laboratory abnormalities at Screening Visit
- E8. Has any other condition that 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 other reason, including investigator decision, specify _____

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Form: HIV Test Results

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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.

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Form: HIV Confirmatory Test Results

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Sample 1 Confirmatory Tests

Was sample 1 collected for HIV Confirmatory testing? Yes
No

Collection date _____

Sample 1 HIV Confirmatory test result Positive
Negative
Indeterminate
Invalid

If negative, indeterminate, or invalid, contact the MTN LC.

If positive, collect sample 2.

Sample 2 Collection

Was sample 2 collected for HIV Confirmatory testing? Yes
No

Collection date _____

Sample 2 HIV Confirmatory test result Positive
Negative
Indeterminate

Was a sample for testing by the MTN Virology core stored? Stored
Not stored

Final HIV status

Final HIV status HIV uninfected
HIV infected
pending

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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 _____

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 _____

Was a sample collected for dipstick urinalysis tests? Yes
No

Collection date _____

Leukocyte esterase (LE) Positive
Negative
Not done

Nitrates Positive
Negative
Not done

MTN036_version 7.0_PROD_30OCT2018: All**Form: STI Test Results****Generated On: 31 Oct 2018 15:21:17**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

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Form: STI Test Results

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	Negative	<input type="checkbox"/>
	Not done	<input type="checkbox"/>

Trichomonas	Positive	<input type="checkbox"/>
	Negative	<input type="checkbox"/>
	Not done	<input type="checkbox"/>

MTN036_version 7.0_PROD_30OCT2018: All**Form: Specimen Storage****Generated On: 31 Oct 2018 15:21:17****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 _____

Time relative to ring insertion or removal Not applicable
1 hour following ring insertion
2 hours following ring insertion
4 hours following ring insertion
Prior to ring removal
1 hour following ring removal
2 hours following ring removal
4 hours following ring removal

Collection time _____

Plasma for PK Stored
Not Stored

If not stored, specify reason _____

Rectal PK/PD 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 _____

MTN036_version 7.0_PROD_30OCT2018: All**Form: Cervical Specimen Storage****Generated On: 31 Oct 2018 15:21:17**

Did the participant experience any vaginal spotting or bleeding in the past seven days? Yes

No

Don't know

On how many of these days did the participant experience heavy bleeding? _____

Cervicovaginal lavage (CVL) for PD, PK, or Biomarkers

Was CVL for PD collected? Yes

No

Collection date _____

Collection time _____

Cervicovaginal lavage (CVL) for PD - Supernatant Stored

Not Stored

If not stored, specify reason _____

Cervicovaginal lavage (CVL) for PD - Cell Pellet Stored

Not Stored

If not stored, specify reason _____

Cervicovaginal fluid (CVF) for PK

Was CVF for PK collected? Yes

No

Collection date _____

Time point of CVF collection Not applicable

1 hour following ring insertion

2 hours following ring insertion

4 hours following ring insertion

Prior to ring removal

1 hour following ring removal

2 hours following ring removal

4 hours following ring removal

Collection time _____

Was blood visible on the swab? Yes

No

Cervicovaginal fluid (CVF) for PK Stored

Not Stored

If not stored, specify reason _____

Cervical tissue for PK

Were cervical biopsies for PK collected? Yes

No

Collection date _____

Collection time _____

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Form: Cervical Specimen Storage
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Cervical biopsies for PK 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 _____

Were vaginal swabs for microbiota qPCR collected? Yes
No

Collection date _____

Vaginal swabs for microbiota qPCR 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 _____

MTN036_version 7.0_PROD_30OCT2018: All

Form: Enrollment

Generated On: 31 Oct 2018 15:21:17

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

Ring strength participant was randomized to _____

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

Was the participant invited to participate in IDI? Invited
Not invited

Will this participant participate in IDI? Yes
No

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Form: Missed Visit

Generated On: 31 Oct 2018 15:21:17

Target Visit Date _____

- Reason visit was missed
- unable to contact participant
 - unable to schedule
 - appointment(s) within allowable
 - window
 - participant refused visit
 - participant incarcerated
 - participant admitted to a health
 - care facility
 - participant withdrew from study
 - participant deceased
 - other

If other, specify _____

Steps taken to address the missed visit (corrective action plan) _____

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Form: Pharmacy Dispensation
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MTN036_version 7.0_PROD_30OCT2018: All
Form: Ring Insertion and Removal
Generated On: 31 Oct 2018 15:21:17

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 monthly
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 no, 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 Physical discomfort while
inserting

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Form: Ring Insertion and Removal
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	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 clinican 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 _____

MTN036_version 7.0_PROD_30OCT2018: All

Form: Ring Adherence Summary

Generated On: 31 Oct 2018 15:21:17

Since the participant's last study visit (or since the ring was inserted if Visit 8/Day 28), has she ever used a vaginal ring?

Yes

No

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Did the participant disclose her ring use to her primary partner? Yes

No

Not applicable

Since her last study visit (or since the ring was inserted if Visit 8/Day 28), how many times in total has the participant had a vaginal ring out, excluding expected instances when a ring was briefly removed and replaced with a new ring? _____

How many of these times since the participant's last study visit (or since the ring was inserted if Visit 8/Day 28) was a vaginal ring out for more than 12 hours continuously? _____

Since the participant's last study visit (or since the ring was inserted if Visit 8/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

If the ring was removed, please add a log line below for each reason the ring was removed. If the ring came out on its own, please add a log line below for each reason the ring came out on its own.

What are the reason(s) why the 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

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Form: Ring Adherence

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- 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:
- 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) that was not conducted at a regularly scheduled study visit
- 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:

 What are the reason(s) why the vaginal ring came out on its own?

 Urination

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Form: Ring Adherence
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Bowel movement: Having a bowel movement

Sex: Having sex or just finished sex

Physical activity: Physical activity (other than sex), including lifting heavy objects

Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up)

Menses related

Other

Other reason ring removed by participant or clinician, specify: _____

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

MTN036_version 7.0_PROD_30OCT2018: All**Form: Interim Visit Summary****Generated On: 31 Oct 2018 15:21:17**

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 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 collection Cervical Specimen Collection Pregnancy test CBC testing (includes platelets and differential)

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Form: Interim Visit Summary
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AST or ALT	<input type="checkbox"/>
Plasma for archive/storage	<input type="checkbox"/>
HIV test(s)	<input type="checkbox"/>
HIV confirmatory test(s)	<input type="checkbox"/>
STI test(s) (other than HIV)	<input type="checkbox"/>
CASI and/or IDI	<input type="checkbox"/>
Ring Insertion or Removal	<input type="checkbox"/>

MTN036_version 7.0_PROD_30OCT2018: All**Form: Vital Signs****Generated On: 31 Oct 2018 15:21:17**

Date of assessment	
Height	Fixed Unit: centimeters
Weight	Fixed Unit: kilograms
Body Temperature	Fixed Unit: Celsius
Systolic BP	Fixed Unit: mmHg
Diastolic BP	Fixed Unit: mmHg
Pulse	Fixed Unit: beats per minute
Rate of respiration	Fixed Unit: breaths per minute

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Form: Additional Study Procedures
Generated On: 31 Oct 2018 15:21:17

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	<input type="checkbox"/>
STI Tests	<input type="checkbox"/>
HIV Tests	<input type="checkbox"/>
CBC with differential and platelets	<input type="checkbox"/>
AST or ALT	<input type="checkbox"/>
Specimen collection	<input type="checkbox"/>
Ring Insertion or Removal	<input type="checkbox"/>
HIV Confirmatory Test Results	<input type="checkbox"/>
