MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Additional Study Procedures
Generated On: 10 Jun 2019 22:10:20

What study procedures were completed at this visit?	
Baseline Behavioral Questionnaire	☐
Hematology	☐
HIV test	☐
Hormone tests	☐
Local labs	☐
Pelvic exam	☐
Physical exam	☐
Pregnancy test	☐
PUEV Behavioral Questionnaire	☐
Ring insertion or removal	☐
Ring outage SMS	☐
STI tests	☐
Vital signs	☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Participant Identifier
Generated On: 10 Jun 2019 22:10:20

Participant ID: _____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Screening Date of Visit
Generated On: 10 Jun 2019 22:10:20

Screening visit date	_____
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Protocol Deviations Summary
Generated On: 10 Jun 2019 22:10:20

Have any protocol deviations occurred?	Yes ☐
	No ☐

If yes, complete the Protocol Deviation Log.

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Protocol Deviations Log
Generated On: 10 Jun 2019 22:10:20

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 as a critical event?	Yes ☐ No ☐
Type of deviation	Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met. ☐ Study product management deviation: The site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements. ☐ Study product dispensing error: The wrong study product was dispensed to a participant on product hold. Pharmacy staff must follow up with the MTN Pharmacist separately. ☐ Study product sharing: Participant has shared study product with another person or study participant ☐ Study product not returned: Study product was not returned by the participant per protocol requirements. ☐ Conduct of non-protocol procedure: A clinical or administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice ☐ Improper AE follow-up: use when an AE or SAE is not followed per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol ☐ Unreported AE: Site staffs become aware of an AE, but do not report it per protocol requirements. ☐ Unreported AE: Site staffs become aware of an SAE, but do not report it per protocol requirements ☐ Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member put a participant's name on a case report form. ☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Protocol Deviations Log
Generated On: 10 Jun 2019 22:10:20

	Physical assessment deviation: Include missed or incomplete physical/pelvic exam assessments. ☐
	Lab assessment deviation: Include missed, or incomplete lab specimen collection ☐
	Mishandled lab specimen: Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens. ☐
	Staff performing duties that they are not qualified to perform: use for any instance when any study procedure is completed by a staff member who is not adequately qualified AND delegated to perform ☐
	Questionnaire administration deviation: A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed the procedure ☐
	Counseling deviation: Protocol-required counseling was not done and/or not documented correctly ☐
	Use of non-IRB/EC-approved materials: Include use of ANY study-related material that requires IRB or EC approval for use per site requirements ☐
	Use of excluded concomitant medications, devices, or non-study products ☐
	Informed consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process ☐
	Visit completed outside of window: Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. ☐
	Other ☐
Description of deviation	
Plans and/or action taken to address the deviation	
Plans and/or action taken to prevent future occurrences of the deviation	
Deviation reported by	Fixed Unit: Staff code
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Product Hold Summary
Generated On: 10 Jun 2019 22:10:20

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

If "Yes", complete the Product Hold Log.

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Specimen Storage
Generated On: 10 Jun 2019 22:10:20

Source document _____

Specimen Type
- [x] Blood for DPV & LNG concentration
- [ ] Cervical biopsies for DPV concentration
- [ ] Cervical biopsies for PD
- [ ] CVF for DPV concentration
- [ ] CVF for LNG concentration
- [ ] CVF for microbiota qPCR
- [ ] CVF for microbiota culture
- [ ] CVL for biomarkers pellet
- [ ] CVL for biomarkers supernatant
- [ ] Plasma for archive
- [ ] Vaginal Gram Stain
- [ ] Used vaginal ring

Was sample collected?
- [ ] Yes
- [ ] No

Specimen Collection Date _____

Specimen Collection Time _____

Was sample stored?
- [ ] Stored
- [ ] Not stored

If no, record reason why sample was not stored. _____

Specimen Type
- [ ] Blood for DPV & LNG concentration
- [x] Cervical biopsies for DPV concentration
- [ ] Cervical biopsies for PD
- [ ] CVF for DPV concentration
- [ ] CVF for LNG concentration
- [ ] CVF for microbiota qPCR
- [ ] CVF for microbiota culture
- [ ] CVL for biomarkers pellet
- [ ] CVL for biomarkers supernatant
- [ ] Plasma for archive
- [ ] Vaginal Gram Stain
- [ ] Used vaginal ring

Was sample collected?
- [ ] Yes
- [ ] No

Specimen Collection Date _____

Specimen Collection Time _____

Was sample stored?
- [ ] Stored

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Specimen Storage
Generated On: 10 Jun 2019 22:10:20

	Not stored ☐
If no, record reason why sample was not stored.	_____
Specimen Type	Blood for DPV & LNG concentration ☐
	Cervical biopsies for DPV concentration ☐
	Cervical biopsies for PD ■
	CVF for DPV concentration ☐
	CVF for LNG concentration ☐
	CVF for microbiota qPCR ☐
	CVF for microbiota culture ☐
	CVL for biomarkers pellet ☐
	CVL for biomarkers supernatant ☐
	Plasma for archive ☐
	Vaginal Gram Stain ☐
	Used vaginal ring ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	_____
Specimen Type	Blood for DPV & LNG concentration ☐
	Cervical biopsies for DPV concentration ☐
	Cervical biopsies for PD ☐
	CVF for DPV concentration ■
	CVF for LNG concentration ☐
	CVF for microbiota qPCR ☐
	CVF for microbiota culture ☐
	CVL for biomarkers pellet ☐
	CVL for biomarkers supernatant ☐
	Plasma for archive ☐
	Vaginal Gram Stain ☐
	Used vaginal ring ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Specimen Storage
Generated On: 10 Jun 2019 22:10:20

Was sample stored?
- Stored ☐
- Not stored ☐

If no, record reason why sample was not stored. _____

Specimen Type
- Blood for DPV & LNG concentration ☐
- Cervical biopsies for DPV concentration ☐
- Cervical biopsies for PD ☐
- CVF for DPV concentration ☐
- CVF for LNG concentration ■
- CVF for microbiota qPCR ☐
- CVF for microbiota culture ☐
- CVL for biomarkers pellet ☐
- CVL for biomarkers supernatant ☐
- Plasma for archive ☐
- Vaginal Gram Stain ☐
- Used vaginal ring ☐

Was sample collected?
- Yes ☐
- No ☐

Specimen Collection Date _____

Specimen Collection Time _____

Was sample stored?
- Stored ☐
- Not stored ☐

If no, record reason why sample was not stored. _____

Specimen Type
- Blood for DPV & LNG concentration ☐
- Cervical biopsies for DPV concentration ☐
- Cervical biopsies for PD ☐
- CVF for DPV concentration ☐
- CVF for LNG concentration ☐
- CVF for microbiota qPCR ■
- CVF for microbiota culture ☐
- CVL for biomarkers pellet ☐
- CVL for biomarkers supernatant ☐
- Plasma for archive ☐
- Vaginal Gram Stain ☐
- Used vaginal ring ☐

Was sample collected?
- Yes ☐
- No ☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Specimen Storage
Generated On: 10 Jun 2019 22:10:20

Specimen Collection Date _____

Specimen Collection Time _____

Was sample stored?
- ☐ Stored
- ☐ Not stored

If no, record reason why sample was not stored. _____

Specimen Type
- ☐ Blood for DPV & LNG concentration
- ☐ Cervical biopsies for DPV concentration
- ☐ Cervical biopsies for PD
- ☐ CVF for DPV concentration
- ☐ CVF for LNG concentration
- ☐ CVF for microbiota qPCR
- ■ CVF for microbiota culture
- ☐ CVL for biomarkers pellet
- ☐ CVL for biomarkers supernatant
- ☐ Plasma for archive
- ☐ Vaginal Gram Stain
- ☐ Used vaginal ring

Was sample collected?
- ☐ Yes
- ☐ No

Specimen Collection Date _____

Specimen Collection Time _____

Was sample stored?
- ☐ Stored
- ☐ Not stored

If no, record reason why sample was not stored. _____

Specimen Type
- ☐ Blood for DPV & LNG concentration
- ☐ Cervical biopsies for DPV concentration
- ☐ Cervical biopsies for PD
- ☐ CVF for DPV concentration
- ☐ CVF for LNG concentration
- ☐ CVF for microbiota qPCR
- ☐ CVF for microbiota culture
- ■ CVL for biomarkers pellet
- ☐ CVL for biomarkers supernatant
- ☐ Plasma for archive
- ☐ Vaginal Gram Stain
- ☐ Used vaginal ring

Was sample collected?
- ☐ Yes

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Specimen Storage
Generated On: 10 Jun 2019 22:10:20

	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	_____
Specimen Type	Blood for DPV & LNG concentration ☐
	Cervical biopsies for DPV concentration ☐
	Cervical biopsies for PD ☐
	CVF for DPV concentration ☐
	CVF for LNG concentration ☐
	CVF for microbiota qPCR ☐
	CVF for microbiota culture ☐
	CVL for biomarkers pellet ☐
	CVL for biomarkers supernatant ■
	Plasma for archive ☐
	Vaginal Gram Stain ☐
	Used vaginal ring ☐
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	_____
Specimen Type	Blood for DPV & LNG concentration ☐
	Cervical biopsies for DPV concentration ☐
	Cervical biopsies for PD ☐
	CVF for DPV concentration ☐
	CVF for LNG concentration ☐
	CVF for microbiota qPCR ☐
	CVF for microbiota culture ☐
	CVL for biomarkers pellet ☐
	CVL for biomarkers supernatant ☐
	Plasma for archive ■
	Vaginal Gram Stain ☐
	Used vaginal ring ☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Specimen Storage
Generated On: 10 Jun 2019 22:10:20

Was sample collected? Yes / No

Specimen Collection Date _____

Specimen Collection Time _____

Was sample stored? Stored / Not stored

If no, record reason why sample was not stored. _____

Specimen Type
- Blood for DPV & LNG concentration
- Cervical biopsies for DPV concentration
- Cervical biopsies for PD
- CVF for DPV concentration
- CVF for LNG concentration
- CVF for microbiota qPCR
- CVF for microbiota culture
- CVL for biomarkers pellet
- CVL for biomarkers supernatant
- Plasma for archive
- Vaginal Gram Stain
- Used vaginal ring

Was sample collected? Yes / No

Specimen Collection Date _____

Specimen Collection Time _____

Was sample stored? Stored / Not stored

If no, record reason why sample was not stored. _____

Specimen Type
- Blood for DPV & LNG concentration
- Cervical biopsies for DPV concentration
- Cervical biopsies for PD
- CVF for DPV concentration
- CVF for LNG concentration
- CVF for microbiota qPCR
- CVF for microbiota culture
- CVL for biomarkers pellet
- CVL for biomarkers supernatant
- Plasma for archive
- Vaginal Gram Stain

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Specimen Storage
Generated On: 10 Jun 2019 22:10:20

	Used vaginal ring ■
Was sample collected?	Yes ☐
	No ☐
Specimen Collection Date	_____
Specimen Collection Time	_____
Was sample stored?	Stored ☐
	Not stored ☐
If no, record reason why sample was not stored.	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Pregnancy Report
Generated On: 10 Jun 2019 22:10:20

Date Pregnancy Reported to Site	
Visit at which this pregnancy was reported	Enrollment ☐ Visit 3 ☐ Visit 4 ☐ Visit 5 ☐ Visit 6 ☐ Visit 7 ☐ Visit 8 ☐ Visit 9 ☐ Visit 10 ☐ Visit 11 ☐ Visit 12 ☐ Visit 13 ☐ Visit 14 ☐ Visit 15 ☐ Interim Visit ☐
If "Interim visit", specify Interim visit code	
First day of last menstrual period	
Or	
Amenorrheic for past 6 months	☐
Estimated due date	
Method used to determine due date	Transvaginal ultrasound. ☐ Quantitative β-hCG determination. ☐ Clinical history and other information collected in the study (e.g., last menstrual period). ☐ Estimate based on pelvic and/or abdominal examination or pregnancy outcome. ☐ Investigator estimation in the absence of above criteria. ☐
If "Investigator estimation", explain:	
Estimated date of conception (based on estimated due date)	
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Pregnancy History
Generated On: 10 Jun 2019 22:10:20

Date pregnancy history collected	
Has the participant ever been pregnant before?	Yes ☐ No ☐
If no, end of form.	
How many times has the participant been pregnant?	
Date last pregnancy ended	
Number of full term live births (greater than or equal to 37 weeks)	
Number of premature live births (less than 37 weeks)	
Number of vaginal births	
Number of c-section births	
Number of spontaneous fetal deaths and/or still births (greater than or equal to 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	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Pregnancy Outcome Log
Generated On: 10 Jun 2019 22:10:20

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) ☐
- 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, therapeutic/elective abortion, or other, is marked, go to "Provide a brief narrative of the circumstances". _____

Method
- C-section ☐
- Standard vaginal ☐
- Operative vaginal ☐

If full term live birth, go to "Were there any complications related to the pregnancy outcome?".

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

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Pregnancy Outcome Log
Generated On: 10 Jun 2019 22:10:20

Intrapartum hemorrhage ☐

Postpartum hemorrhage ☐

Non-reassuring fetal status ☐

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 ☐ No ☐ Unknown ☐

If no or unknown, go to statement above "Infant gender".
Mark all that apply. Complete AE Log.

Central nervous system, cranio-facial ☐

Central nervous system, spinal ☐

Cardiovascular ☐

Renal ☐

Gastrointestinal ☐

Pulmonary ☐

Muscoloskeletal/extremities ☐

Physical defect ☐

Skin ☐

Genitourinary ☐

Chromosomal ☐

Cranio-facial (structural) ☐

Hematologic ☐

Infectious ☐

Endocrine/metabolic ☐

Other ☐

Specify congenital anomaly/defect AE _____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Pregnancy Outcome Log
Generated On: 10 Jun 2019 22:10:20

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	
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:	
1 minute apgar score	
5 minutes apgar score	
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Pelvic Exam
Generated On: 10 Jun 2019 22:10:20

Pelvic exam assessment	Not done ☐ Abnormal findings ☐ No abnormal findings ☐
Exam date	_____

Abnormal findings. Mark all that apply.

VULVAR	
Vulvar edema	☐
Vulvar erythema	☐
Vulvar rash	☐
Vulvar tenderness	☐
Bartholin's or Skene's gland abnormality	☐
Vulvar ulcer	☐
Vulvar blister	☐
Vulvar pustule	☐
Vulvar peeling	☐
Vulvar ecchymosis	☐
VAGINAL	
Vaginal edema	☐
Vaginal erythema	☐
Vaginal masses (polyps, myomas, possible malignancy)	☐
Vaginal abrasions or lacerations	☐
Vaginal tenderness	☐
Vaginal ulcer	☐
Vaginal blister	☐
Vaginal pustule	☐
Vaginal peeling	☐
Vaginal ecchymosis	☐
Abnormal vaginal discharge	Slight ☐ Moderate ☐ Pooling ☐
CERVICAL	
Cervical edema and/or friability	☐
Cervical erythema	☐
Cervical masses (polyps, myomas, possible malignancy)	☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Pelvic Exam
Generated On: 10 Jun 2019 22:10:20

Cervical motion tenderness	☐
Cervical discharge	☐
Cervical ulcer	☐
Cervical blister	☐
Cervical pustule	☐
Cervical peeling	☐
Cervical ecchymosis	☐
GENERAL/OTHER	
Odor (vaginal)	☐
Condyloma	☐
If condyloma, specify location:	_____
Adnexal masses (based on bimanual exam; not pregnancy or infection-related)	☐
Uterine masses (based on bimanual exam)	☐
Uterine tenderness	☐
Adnexal tenderness	☐
Abnormal blood or bleeding	☐
abnormal blood or bleeding; describe:	_____
Other abnormal findings	☐
If other abnormal findings, specify (include anatomical location):	_____
Complete or update Baseline Medical Conditions 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% ◯ 1-25% ◯ 26-50% ◯ 51-75% ◯ 76-100% ◯ Not done ◯
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Product Hold Log
Generated On: 10 Jun 2019 22:10:20

Date when study product hold was initiated	_____
Why is study product being held?	Adverse Event ☐ Reported use prohibited medications ☐ 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? If 'no - permanently discontinued', 'no - early termination' or 'no - hold continuing at scheduled PUEV', complete the Product Discontinuation form."	Yes ☐ No - permanently discontinued ☐ No - early termination ☐ No - Hold continuing at scheduled PUEV ☐ No - hold continuing for another reason ☐
Date study product resumed	_____
Date study product hold continuing for another reason	_____
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: STI Test Results
Generated On: 10 Jun 2019 22:10:20

Was vaginal pH done? Yes ☐ No ☐

If no, skip to "Was a vaginal wet prep sample collected?"

Date of collection _____

Vaginal pH _____

Was a vaginal wet prep sample collected? Yes ☐ No ☐

If no, skip to "Was a sample collected for Syphilis testing?"

Date of collection: _____

Homogenous vaginal discharge Positive ☐ Negative ☐ Not done ☐

Whiff test Positive ☐ Negative ☐ Not done ☐

Clue cells greater or equal to 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 Syphilis testing? Yes ☐ No ☐

If no, skip to "Was a vaginal sample collected for Trichomonas testing via NAAT?"

Date of collection _____

Syphilis screening test Non-reactive ☐ Reactive ☐ Not reported ☐

If Syphilis screening test is 'non-reactive', skip to "Was a sample collected for Trichomonas testing?"

Syphilis titer _____

Syphilis confirmatory test Positive ☐ Negative ☐ Indeterminate ☐ Not done ☐

Was a vaginal sample collected for Trichomonas testing via NAAT? Yes ☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: STI Test Results
Generated On: 10 Jun 2019 22:10:20

	No ☐
If no, skip to "Was a sample collected for NAAT for GC/CT?"	
Date of collection	_____
Trichomonas test	Positive ☐
	Negative ☐
	Not done ☐
Was a sample collected for NAAT for GC/CT?	Yes ☐
	No ☐
If no, skip to "Was a swab collected for genital lesion HSV testing?"	
Date of collection	_____
N. gonorrhea	Positive ☐
	Negative ☐
	Not done ☐
C. trachomatis	Positive ☐
	Negative ☐
	Not done ☐
Was a swab collected for genital lesion HSV testing?	Yes ☐
	No ☐
Date of collection:	_____
Herpes Simplex Virus 1 IgG Antibody Result	Negative ☐
	HSV-1 Positive ☐
	HSV-2 Positive ☐
	HSV-1 Positive AND HSV-2 Positive ☐
	HSV-1/2 Undifferentiated ☐
	Not Done ☐
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Interim Visit Summary
Generated On: 10 Jun 2019 22:10:20

Visit date	_____
Interim visit code	_____
Was study product held at this visit? If yes, complete a Product Hold form.	Yes ◯ No ◯
Was study product use permanently discontinued (scheduled or early) at this visit? If yes, complete a Product Discontinuation form.	Yes ◯ No ◯
Did the participant exit/terminate the study at this visit?	Yes ◯ No ◯
Were any new adverse events (AEs) reported at this visit? If yes, complete the AE Log.	Yes ◯ No ◯
Is the participant taking any concomitant medications that have not been previously reported? If yes, complete the Concomitant Medications Log.	Yes ◯ No ◯
Have any protocol deviations been reported at this visit? If yes, complete the Protocol Deviation Log.	Yes ◯ No ◯
Reason for interim visit (Mark all that apply.)	
AE report or follow-up	☐
Return of product or need new product	☐
Completion of missed visit procedures	Yes ◯ No ◯
If "Yes", for which visit are procedures being made up?	_____
Other	☐
If "Other", specify:	_____
What study procedures were completed at this visit?	
Baseline Behavioral Questionnaire	☐
Bleeding SMS report	☐
Hematology	☐
HIV confirmatory test	☐
HIV test	☐
Hormone tests	☐
Local labs	☐
Pelvic exam	☐
Physical exam	☐
Pregnancy test	☐
PUEV Behavioral Questionnaire	☐
Ring insertion or removal	☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Interim Visit Summary
Generated On: 10 Jun 2019 22:10:20

Ring outage SMS report	☐
Specimen storage	☐
STI test(s) (other than HIV)	☐
Vaginal bleeding assessment	☐
Vital signs	☐
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Randomization
Generated On: 10 Jun 2019 22:10:20

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

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Missed Visit
Generated On: 10 Jun 2019 22:10:20

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

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Follow-up Visit Y/N
Generated On: 10 Jun 2019 22:10:20

Did the participant complete this visit?	Yes ☐
	No ☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Follow-up Visit Summary
Generated On: 10 Jun 2019 22:10:20

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 ☐
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: HIV Test Results
Generated On: 10 Jun 2019 22:10:20

Was sample 1 collected for HIV testing?	Yes ☐
	No ☐
Date of collection	_____
Sample 1 HIV test result	Positive ☐
	Negative ☐
	Indeterminate ☐

If the test is positive or indeterminate, complete the HIV Confirmatory Results Form and alert the MTN Laboratory Core.

Source document _____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: HIV Confirmatory Test Results
Generated On: 10 Jun 2019 22:10:20

Sample 1 Confirmatory Tests

Was HIV confirmatory testing done for sample 1? Yes ☐ No ☐

Date confirmatory testing for sample 1 _____

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 (by MTN Virology core)? 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 ☐

Source document _____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Local Laboratory Results
Generated On: 10 Jun 2019 22:10:20
Lab Name: _____

Was a sample collected for blood chemistries?	Yes ☐ No ☐
Collection date	_____
AST (SGOT)	_____
AST (SGOT) severity grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ not gradable ☐
AST (SGOT) 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)	_____
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	_____
Creatinine	_____
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 ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Local Laboratory Results
Generated On: 10 Jun 2019 22:10:20
Lab Name: _____

	Grade 4 – Potentially life-threatening ☐ not gradable ☐
Creatinine Adverse event	_____
Albumin	_____
Albumin severity grade	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ not gradable ☐
Albumin Severity Grade - Calculated	Grade 1 – Mild ☐ Grade 2 – Moderate ☐ Grade 3 – Severe ☐ Grade 4 – Potentially life-threatening ☐ not gradable ☐
Albumin adverse event	_____
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Enrollment
Generated On: 10 Jun 2019 22:10:20

Did the participant consent to long-term specimen storage and future testing?	Yes ☐ No ☐
Group assignment	Continuous ring use ☐ Cyclic ring use ☐
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Screening Menstrual History
Generated On: 10 Jun 2019 22:10:20

Date of assessment	
Age of first menses (menarche)	Fixed Unit: years
In the past 3 months, has the participant had her menses?	Yes ☐ No ☐
Does the participant typically experience any premenstrual symptoms?	Yes ☐ No ☐
If yes, specify	
Usual number of days between menses (1st day to 1st day)	Fixed Unit: days
For how many days does the participant usually experience bleeding?	Fixed Unit: days
Minimum usual number of bleeding days	Fixed Unit: days
Maximum usual number of bleeding days	Fixed Unit: days
Provide additional details as needed to describe the participant's baseline menstrual bleeding pattern.	
First day of last menstrual period	
Last day of last menstrual period	
Or	
Ongoing	☐
When the participant has her menses, is the bleeding usually light, moderate or heavy? Select the response that describes the heaviest flow during menses.	Light bleeding (used panty liner, toilet paper or no protection) ☐ Moderate bleeding (used sanitary pad or tampon) ☐ Heavy bleeding (leaked) ☐
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Enrollment Menstrual History
Generated On: 10 Jun 2019 22:10:20

Date of assessment	
Since the Screening Visit, has the participant had her menses?	Yes ☐ No ☐
First date of last menstrual period:	
Last date of last menstrual period	
Or	
Ongoing	☐
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Ring Insertion and Removal
Generated On: 10 Jun 2019 22:10:20

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 use ☐ Participant declined study ring use ☐ Early termination ☐ Day 28, Day 58, or Day 90 Visit ☐ Temporarily removed by staff for clinic procedure ☐ Other ☐
If participant declined study ring use or other, specify	
Was the ring properly stored?	Yes ☐ No ☐
Was a ring inserted at this visit?	Yes – new ring inserted ☐ Yes – previous ring re-inserted ☐ No ☐
If no, end of form.	
Date ring was inserted:	
Time ring was inserted:	
Who inserted the ring?	Participant ☐ Study Staff ☐
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Hormone Tests
Generated On: 10 Jun 2019 22:10:20

Was a sample collected for sex hormone-binding globulin (SHBG)?	Yes ☐ No ☐
Date of collection:	
SHBG	Fixed Unit: nmol/L
Was a serum progesterone sample collected?	Yes ☐ No ☐
Date of collection:	
Progesterone	Fixed Unit: nmol/L
Symbol	< ☐ = ☐
Was a serum estradiol sample collected?	Yes ☐ No ☐
Date of collection:	
Estradiol	Fixed Unit: pg/mL
Symbol	< ☐ = ☐
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Pharmacy Dispensation
Generated On: 10 Jun 2019 22:10:20

Date vaginal ring dispensed:	
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Phone Follow-up
Generated On: 10 Jun 2019 22:10:20

Phone call date	_____
Was an at-home pregnancy test done?	Yes ☐ No ☐
At-home pregnancy test result	Positive ☐ Negative ☐
Is the participant taking a hormonal contraceptive?	Yes ☐ No ☐
Has the participant's menses returned?	Yes ☐ No ☐
Will the participant return for another Phone Follow-up visit?	Yes ☐ No ☐
Complete at Visit 15 Only:	
Were any new adverse events (AEs) reported at this visit? If yes, complete the AE Log.	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported? If yes, complete the Concomitant Medications Log.	Yes ☐ No ☐
Complete at Visit 18 Only:	
Was the participant referred for evaluation of secondary amenorrhea?	Yes ☐ No ☐
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Adverse Event Y/N
Generated On: 10 Jun 2019 22:10:20

Has the participant experienced an adverse event during the study?	Yes ☐ No ☐
If "Yes", complete the Adverse Event log.	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Adverse Event Log
Generated On: 10 Jun 2019 22:10:20

Date reported to site	_____
Adverse event (AE)	_____
Onset date	_____
At which visit was this AE first reported?	Enrollment ☐ Visit 3 ☐ Visit 4 ☐ Visit 5 ☐ Visit 6 ☐ Visit 7 ☐ Visit 8 ☐ Visit 9 ☐ Visit 10 ☐ Visit 11 ☐ Visit 12 ☐ Visit 13 ☐ Visit 14 ☐ Visit 15 ☐ 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 treatments Mark "None" or all that apply. None	☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Adverse Event Log
Generated On: 10 Jun 2019 22:10:20

Medication(s)	☐
New/prolonged hospitalization	☐
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 ☐
Is this a serious adverse event according to ICH/GCP or protocol guidelines?	Yes ☐ No ☐

If "No", go to "Was this AE a worsening of a baseline medical condition?"

If "Yes", complete Initial Reporter and check all that apply.

Initial reporter	
Results in death	☐
If results in death, is there an autopsy?	Yes ☐ No ☐
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	☐
Date study product temporarily interrupted	
Date study product was restarted	
Date study product permanently stopped	
SAE narrative	
Was this AE a worsening of a baseline medical condition?	Yes ☐ No ☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Adverse Event Log
Generated On: 10 Jun 2019 22:10:20

Comments (max. 450 characters):	
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Concomitant Medications Y/N
Generated On: 10 Jun 2019 22:10:20

Were any concomitant medications taken?	Yes ☐
	No ☐

If "Yes", complete the Concomitant Medications log.

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Concomitant Medications Log
Generated On: 10 Jun 2019 22:10:20

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

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Concomitant Medications Log
Generated On: 10 Jun 2019 22:10:20

	Nasal ☐
	Intraocular ☐
	Transdermal ☐
	Intraperitoneal ☐
	Other ☐
If "Other", specify:	
Taken for a reported AE?	Yes ☐
	No ☐
Adverse Event	
Adverse Event	
Adverse Event	
Adverse Event	
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Demographics
Generated On: 10 Jun 2019 22:10:20

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:	_____
Highest education level completed	Eighth grade or lower ☐ Partial high school ☐ High school graduate ☐ Partial college ☐ College graduate ☐ Partial graduate school ☐ Graduate school degree ☐
Relationship status	Single ☐ In a relationship, not married ☐ Married ☐ Widowed ☐ Divorced ☐
Do you currently have a primary sex partner? By primary sex partner, we mean a person you have sex with on a regular basis or who you consider to be your main partner.	Yes ☐ No ☐
Is your primary sex partner a man or a woman?	Man ☐ Woman ☐ Other ☐
If Other, specify	_____
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Hematology
Generated On: 10 Jun 2019 22:10:20
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

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Hematology
Generated On: 10 Jun 2019 22:10:20
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	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Hematology
Generated On: 10 Jun 2019 22:10:20
Lab Name: _____

Source document _____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Inclusion/Exclusion Criteria
Generated On: 10 Jun 2019 22:10:20

Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Informed Consent Date	_____
Eligibility Status	Eligible and Enrolled ☐ Eligible/Not enrolled ☐ Ineligible ☐ Incomplete Screening ☐
If eligible and enrolled, 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-044/IPM 053/CCN019 ☐ 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 intercourse and tampon use for 24 hours preceding Enrollment and clinical visits where samples are taken and for 1 week following each cervical biopsy visit ☐ I8. Not at risk for pregnancy at Enrollment, and intending to continue use of an effective, non-hormonal method for the duration of study participation. ☐ I9. In general good health as determined by the Investigator of Record (IoR)/designee at Screening and Enrollment ☐ I10. HIV-uninfected based on testing performed at Screening and Enrollment (per protocol algorithm in Appendix II) ☐ I11. Per participant report at Screening, current regular menstrual cycles of approximately 21 to 35 days in duration with no reported intermenstrual bleeding ☐ I12. Intact uterus with at least one ovary ☐

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Inclusion/Exclusion Criteria
Generated On: 10 Jun 2019 22:10:20

- [ ] I13. States a willingness to refrain from inserting any non-study vaginal products or objects into the vagina for the 24 hours preceding Enrollment and for the duration of study participation.
- [ ] I14. Participants over the age of 21 must have documentation of a satisfactory Pap within the past 3 years prior to Enrollment
- [ ] I15. At Screening and Enrollment, agrees not to participate in other research studies involving drugs, medical devices, vaginal products or vaccines
- [ ] E1. Body mass index greater than 40 kg/m2 at Screening
- [ ] E2. Pregnant at Screening or Enrollment or plans to become pregnant during the study period
- [ ] E3. Diagnosed with symptomatic urinary tract infection (UTI) or reproductive tract infection (RTI) at Screening or Enrollment
- [ ] E4. Diagnosed with an acute STI requiring treatment per current CDC guidelines at Screening or Enrollment such as GC, chlamydia, trichomonas, PID and/or syphilis
- [ ] E5. Has a clinically apparent Grade 2 or higher pelvic exam finding (observed by study staff) at Screening or Enrollment.
- [ ] E6a. Known adverse reaction to any component of the study product (ever)
- [ ] E6b.Chronic and/or recurrent vaginal candidiasis
- [ ] E6c. Has a contraindication to a progestin-only contraceptive method as defined by a category 3 or 4 condition according to the CDC U.S. Medical Eligibility Criteria for Contraceptive Use, 2016
- [ ] E6d. Use of hormonal contraception, including hormonal IUD and implants within the 28 days prior to Enrollment
- [ ] E6e. Current use or planned use of CYP3A inhibitors and inducers
- [ ] E6f. Current use or planned use of antibiotics and/or corticosteroids that may interact with levonorgestrel

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Inclusion/Exclusion Criteria
Generated On: 10 Jun 2019 22:10:20

	E6g. Depot medroxyprogesterone acetate (DMPA) use in the 6 months prior to Enrollment or any prior use without return of regular spontaneous menstrual cycles. ☐
	E6h. Non-therapeutic injection drug use in the 12 months prior to Enrollment ☐
	E6i. Post-exposure prophylaxis (PEP) for HIV exposure within the 3 months prior to Enrollment ☐
	E6j. Pre-exposure prophylaxis (PrEP) for HIV prevention within the 3 months prior to Enrollment ☐
	E6k. Last pregnancy outcome less than 60 days prior to Enrollment ☐
	E6l. Gynecologic or genital procedure (e.g., tubal ligation, dilation and curettage, piercing) 45 days or less prior to Enrollment ☐
	E6m. Currently breastfeeding or planning to breastfeed during the study period ☐
	E6n. Participation in any other research study involving drugs, medical devices, vaginal products or vaccines, in the 60 days prior to Enrollment ☐
	E7a. Grade 1 or higher AST or ALT laboratory abnormalities at Screening Visit ☐
	E7b. Grade 1 or higher Creatinine laboratory abnormalities at Screening Visit ☐
	E7c. 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 interpretation of study outcome data, or o/w interfere with achieving the study objectives ☐
Additional details about why subject did not qualify	_____
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Pregnancy Test Results
Generated On: 10 Jun 2019 22:10:20

Was a pregnancy test done?	Yes ☐
	No ☐
Collection date	_____
Collection time	_____
Pregnancy test result	Positive ☐
	Negative ☐
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Physical Exam
Generated On: 10 Jun 2019 22:10:20

Was a physical exam performed? Yes ☐ No ☐

Date of exam _____

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

General Appearance Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

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: _____

Breast Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Abdomen Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

Extremities Not Done ☐ Normal ☐ Abnormal ☐

If "Abnormal", specify: _____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Physical Exam
Generated On: 10 Jun 2019 22:10:20

Neurological	Not Done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Skin	Not Done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Other system finding	Not Done ☐ Normal ☐ Abnormal ☐
Other system, specify:	_____
If "Abnormal", specify:	_____
Source document	_____

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Vital Signs
Generated On: 10 Jun 2019 22:10:20

Were vital signs done?	Yes ☐ No ☐
Date of assessment	
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	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Product Discontinuation
Generated On: 10 Jun 2019 22:10:20

Date that study product use ended	
Primary reason for ending study product use	☐ Scheduled study product use period completed ☐ Adverse Event ☐ Acquisition of HIV-1 infection ☐ Allergic reaction to the vaginal ring ☐ Pregnancy ☐ Breastfeeding ☐ Non-therapeutic injection drug use ☐ Reported use of PEP for HIV exposure ☐ Reported use of PrEP for HIV prevention ☐ Participant is unable or unwilling to comply with required study procedures, or otherwise might be put at undue risk according to the judgment of the IoR/designee ☐ Other
If "Other", specify:	
If "Adverse event", select applicable adverse event	
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Study Discontinuation
Generated On: 10 Jun 2019 22:10:20

Date of study exit	
Primary reason for completion/discontinuation	Scheduled exit visit/end of study ☐ Death ☐ Lost to follow-up ☐ Investigator decision ☐ Early study closure ☐ Adverse event ☐ Permanent Study Product Termination ☐ Withdrawal of consent by participant ☐ Other, specify ☐
If "withdrawal of consent by participant", "investigator decision", or "Other", specify:	
If "Death", enter date of death	
If "Adverse event", select applicable Adverse event	
Source document	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Baseline Medical History Y/N
Generated On: 10 Jun 2019 22:10:20

Does the participant have any medical history to report?	Yes ☐ No ☐

If "Yes", complete the Medical History log.

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Baseline Medical History Log
Generated On: 10 Jun 2019 22:10:20

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	

MTN044_Version_4.0_PROD_10JUN2019: ALL
Form: Baseline Behavioral Questionnaire
Generated On: 10 Jun 2019 22:10:20

Date of assessment _____

PREGNANCY PREVENTION

A1 - In your lifetime, have you ever used any of the following contraceptive methods? "[Interviewer: read items a - q aloud.]

a - Male condom	Yes ☐ No ☐
b - Female or internal condom	Yes ☐ No ☐
c - Oral contraception ("The Pill")	Yes ☐ No ☐
d - Emergency contraception (Ella, Plan B One-Step, Next Choice, My Way, Yuzpe regimen, or Paragard IUD specifically for emergency contraception)	Yes ☐ No ☐
e - The Patch (such as Ortho Evra or Xulane)	Yes ☐ No ☐
f - Depo-Provera ("The Shot")	Yes ☐ No ☐
g - Contraceptive/hormonal vaginal ring (such as NuvaRing, Estring, or Femring)	Yes ☐ No ☐
If yes, specify _____	
h - Spermicidal sponge, foam, cream, or jelly	Yes ☐ No ☐
i - Cervical barrier (such as diaphragm, cervical cap, etc.)	Yes ☐ No ☐
j - Intra-uterine device or IUD (such as Mirena, Paragard, Skyla)	Yes ☐ No ☐
k - Implant (such as Implanon, Nexplanon, Norplant)	Yes ☐ No ☐
l - Withdrawal or "pull-out" method	Yes ☐ No ☐
m - Fertility awareness-based methods (such as menstrual cycle tracking, periodic abstinence)	Yes ☐ No ☐
n - Female Sterilization	Yes ☐ No ☐
o - Male Sterilization	Yes ☐ No ☐
p - Other	Yes ☐

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	No ☐
If Other, please specify	_____
q - None – I have never used any contraception (birth control)	Yes ☐ No ☐

IF “No” TO ANY OF QUESTIONS A1a-p, SKIP THE CORRESPONDING A2a-p ITEMS.

A2 - In the past 30 days, have you used any of the following contraceptive methods?

[Interviewer: read applicable items a-p aloud and check all that apply]

a - Male condom	☐
b - Female or internal condom	☐
c - Oral contraception (“The Pill”)	☐
d - Emergency contraception (Ella, Plan B One-Step, Next Choice, My Way, Yuzpe regimen, or Paragard IUD specifically for emergency contraception)	☐
e - The Patch (such as Ortho Evra or Xulane)	☐
f - Depo-Provera (“The Shot”)	☐
g - Vaginal ring (such as Nuva Ring)	☐
h - Spermicidal sponge, foam, cream, or jelly	☐
i - Cervical barrier (diaphragm, cervical cap, etc.)	☐
j - Intra-uterine device or IUD (such as Mirena, Paragard, Skyla)	☐
k - Implant (such Implanon, Nexplanon, Norplant)	☐
l - Withdrawal or “pull-out” method	☐
m - Fertility awareness-based methods or menstrual cycle tracking	☐
n - Female Sterilization	☐
o - Male Sterilization	☐
p - Other	☐
If Other, please specify	_____

For the next questions, we will ask you about items that women sometimes insert into their vaginas.This may be for personal hygiene or other reasons, and some women may not insert any of these items. Please note that these questions are about putting items inside your vagina and not about using them outside your vagina. You should feel free to tell us anything you have used. Your answers will not affect your participation in the study.

B1 - Have you ever in your life used/inserted any of the following? [Interviewer: read items a-l aloud]

a - Male condom	Yes ☐ No ☐
b - Female or internal condom	Yes ☐ No ☐

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c - Non-contraceptive vaginal ring (such as dapivirine ring or other investigational vaginal ring)	Yes ☐ No ☐
If yes, specify	_____
d - Spermicidal sponge, cream or jelly	Yes ☐ No ☐
e - Cervical barrier (diaphragm, cervical cap, etc.) or menstrual cup	Yes ☐ No ☐
f - Douche or other personal hygiene product that is inserted inside the vagina	Yes ☐ No ☐
g - Tampon	Yes ☐ No ☐
h - Personal or sexual lubricant	Yes ☐ No ☐
i - Vaginal medication in cream or gel form	Yes ☐ No ☐
j - Sex toys	Yes ☐ No ☐
k - Menstrual cup	Yes ☐ No ☐
l - Other	Yes ☐ No ☐
If Other, please specify	_____
B2 - How many times did you douche vaginally in the past 3 months?	_____

Now, I would like to ask you some questions about your sexual behavior. There are no right or wrong answers to the questions, and every answer is important. Please feel free to be completely honest.

C1 - In your lifetime, what type(s) of sexual activity have you had? [Interviewer: read items a-b aloud]

a - Vaginal sex By "vaginal sex", I mean when a man inserts his penis into your vagina.	Yes ☐ No ☐
b - Anal sex By "anal sex", I mean when a man puts his penis into your anus/butt.	Yes ☐ No ☐
C2 - During the last act of vaginal sex that you had, was a condom used?	Yes, male condom ☐ Yes, female condom ☐ No ☐ Not applicable ☐
C3 - How many sex partners have you had in your life? Please only count persons with whom you have had vaginal sex or anal sex, including your primary sex partner.	_____

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C4 - How many sex partners have you had in the past 30 days? Please only count persons with whom you have had vaginal sex or anal sex, including your primary sex partner.	

Ring acceptability and Concerns

D1 - How worried are you about using one vaginal ring for 3 months? [Interviewer: read response categories aloud]	Very worried ☐ Somewhat worried ☐ A little worried ☐ Not at all worried ☐
D2 - Overall, how much do you like the ring? [Interviewer: read response categories aloud]	Dislike very much ☐ Dislike ☐ Like ☐ Like very much ☐

ADDITIONAL COMMENTS

We are close to the end of the interview. Is there anything that we haven't asked that you think we should have?	

This is the end of the interview. Thank you for answering these questions.

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Date of assessment _____

RING ACCEPTABILITY

The following questions are about your overall experience with the ring.
[Interviewer: read all response categories aloud].

Overall, how much do you like the ring?	Dislike very much ☐ Dislike ☐ Like ☐ Like very much ☐
What are your preferences about wearing the ring?	I prefer wearing it every day ☐ I prefer removing the ring for two days each month ☐ I don't have a preference ☐
Overall, how easy or difficult was it to use the ring?	Very difficult ☐ Difficult ☐ Easy ☐ Very easy ☐
The first time you inserted the ring in your vagina, was it difficult or easy to insert?	Very difficult ☐ Difficult ☐ Easy ☐ Very easy ☐ I never inserted the ring ☐
The last time you inserted the ring in your vagina, was it difficult or easy to insert?	Very difficult ☐ Difficult ☐ Easy ☐ Very easy ☐ I did not insert the ring since the beginning of the study ☐
The first time you took the ring out, was it difficult or easy to take out?	Very difficult ☐ Difficult ☐ Easy ☐ Very easy ☐ I did not take the ring out at all during the study ☐
The last time you took the ring out, was it difficult or easy to take out?	Very difficult ☐ Difficult ☐ Easy ☐ Very easy ☐ I did not take the ring out at all during the study ☐
Overall, how often did you think about the ring being inside your body?	Never ☐

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	Some of the time ☐
	Most of the time ☐
	All of the time ☐
Overall, were you aware of the ring during your normal daily activities?	Never ☐
	Some of the time ☐
	Most of the time ☐
	All of the time ☐
Overall, how did it feel to have the ring inside you every day?	Very comfortable ☐
	Comfortable ☐
	Uncomfortable ☐
	Very uncomfortable ☐
Overall, how acceptable were any changes in your bleeding pattern while using the ring?	Very acceptable ☐
	Somewhat acceptable ☐
	Somewhat unacceptable ☐
	Very unacceptable ☐
	I did not have any changes in my bleeding pattern while using the ring ☐
Have you ever checked to see if the ring was still inside you?	Yes ☐
	No ☐

If "No", skip to the instruction above the question "Overall, did you notice that your vagina was wetter?"

How often did you check to see if it was still inside you?	Hardly ever ☐
	Occasionally ☐
	Frequently ☐
	All of the time ☐
How did you typically check to see if the ring was still inside you?	I used my fingers ☐
	had my partner check with his/her fingers ☐
	Other ☐

If Other, specify _____

The following questions are about changes in your vagina that you may have experienced while wearing the ring.

Overall, did you notice that your vagina was wetter?	Yes ☐
	No ☐
How much has your vagina being wetter bothered you?	Not at all ☐
	A little ☐
	Somewhat ☐
	Very much ☐

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Overall, did you notice that your vagina was drier?	Yes ☐ No ☐
How much has your vagina being drier bothered you?	Not at all ☐ A little ☐ Somewhat ☐ Very much ☐
Overall have you experienced any other changes in your vagina while wearing the ring?	Yes ☐ No ☐
If Yes, specify	_____
How much has this change bothered you?	Not at all ☐ A little ☐ Somewhat ☐ Very much ☐

PRODUCT PREFERENCE

Now we would like to ask you about your experience with both the male condom and the vaginal ring.

[Interviewer: read all response categories aloud in Section E.]

As a method to prevent HIV, which do you prefer to use—the ring or the male condom?	Ring ☐ Condom ☐ Neither–I dislike both study products ☐ Both–I like both study products equally ☐
As a method OF CONTRACEPTION, which do you prefer to use—the ring or the male condom?	Ring ☐ Condom ☐ Neither–I dislike both study products ☐ Both–I like both study products equally ☐
Would you prefer to use separate methods for contraception and HIV prevention or a combined method?	Separate methods ☐ A combined method ☐ Don't care ☐ Don't know ☐
We're getting close to the end of the interview.	
Is there anything that we haven't asked that you think we should have?	_____
Is there anything else you would like to tell us about your experience with the ring?	_____
This is the end of the interview. Thank you for answering these questions.	
Source document	_____

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Date of assessment	_____
Did the participant continue ring use during any spotting/bleeding episodes?	Yes ☐ No ☐
Did the participant use tampons during any spotting/bleeding episodes?	Yes ☐ No ☐
According to the participant, did any spotting/bleeding occur within 2 days after:	
Vaginal sex?	Yes ☐ No ☐
If yes, record any relevant details.	_____
Painful vaginal sex?	Yes ☐ No ☐
If yes, record any relevant details.	_____
Painful or uncomfortable insertion or removal of the ring?	Yes ☐ No ☐
If yes, record any relevant details.	_____
Painful or uncomfortable insertion or removal of any other vaginal product/preparation?	Yes ☐ No ☐
If yes, record any relevant details.	_____
A pelvic exam?	Yes ☐ No ☐
If yes, record any relevant details.	_____
Condom use?	Yes ☐ No ☐
If yes, record any relevant details.	_____
Based on all information available, is this bleeding menstrual or non-menstrual?	Menstrual ☐ Non-menstrual ☐ Unknown ☐ Both ☐
Is any of this bleeding/spotting an SAE?	Yes ☐ No ☐
If yes, select applicable Adverse Event:	_____
Source document	_____

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Form: Bleeding SMS
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Date of assessment	_____
Did the participant report any vaginal spotting or bleeding via SMS?	Yes ☐ No ☐ No SMS data available ☐
Did the participant report any vaginal spotting or bleeding at this visit (that was not reported by SMS)?	Yes ☐ No ☐
On how many days did the participant experience vaginal spotting or bleeding?	_____
Date of spotting/bleeding?	_____
Was the report made by SMS or at the study visit?	SMS ☐ Visit ☐
Description of spotting/bleeding	None ☐ Light bleeding/spotting (used panty liner, toilet paper, or no protection) ☐ Moderate bleeding (used sanitary pad or tampon) ☐ Heavy bleeding (soaked multiple sanitary pads or tampons) ☐
How bothersome was the spotting/bleeding?	Not at all ☐ A little ☐ Somewhat ☐ Very much ☐
Source document	_____

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Form: Ring Outage SMS
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Date of assessment	_____
Did the participant report any partial or full ring outages via SMS?	Yes ☐ No ☐ No SMS data available ☐
Did the participant report any partial or full ring outages at this visit (that were not reported by SMS)?	Yes ☐ No ☐
How many times did the participant report a full ring outage?	_____
Date ring outage reported by participant	_____
Was the ring outage reported by SMS or at the clinic visit?	SMS ☐ Participant report at visit ☐
Did the ring ever partially fall out?	Yes ☐ No ☐
Did the ring ever fully fall out?	Yes ☐ No ☐
Number of times ring fell out fully	_____
Did the participant ever remove the ring?	Yes ☐ No ☐
Number of times ring was removed	_____
Was the ring out for more than 24 hours?	Yes ☐ No ☐
Was the ring out for more than 3 hours?	Yes ☐ No ☐
Ring was out of place/moved	Yes ☐ No ☐
Physical discomfort with the ring	Yes ☐ No ☐
During menses	Yes ☐ No ☐
Before, during or after sex	Yes ☐ No ☐
Bathroom event /toilet (bowel movement or urination)	Yes ☐ No ☐
Exercising or other Activities (eg. Running, jumping, straining, bending, crouching etc..)	Yes ☐ No ☐
Other	Yes ☐ No ☐

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Was the ring re-inserted?	Never ☐
	Sometimes ☐
	Often ☐
	Always ☐
If yes, was the ring rinsed before it was re-inserted?	Never ☐
	Sometimes ☐
	Often ☐
	Always ☐
Source document	_____