

## Section 7. Visit Checklists

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This section contains examples of checklists detailing the protocol-specified procedures that must be completed at MTN 001 study visits. The checklists also specify the data collection forms that must be completed at each visit. Detailed procedural guidance for performing clinical and laboratory procedures is provided in Sections 10 and 12, respectively. Detailed forms completion instructions are provided in Section 13.

### 7.1 Use of Checklists

The visit checklists included in this section are designed to guide site staff in proper study procedures as well as to serve as source documentation of procedures performed at study visits. Note, however, that checklists alone may not be sufficient for documenting all procedures. For example, chart notes may be required to:

- Explain why procedures in addition to those listed on a checklist were performed
- Explain why procedures listed on a checklist were not performed
- Document procedures performed at interim visits
- Document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements)

See Section 3 for detailed information on source documentation requirements. Tips for completing visit checklists in accordance with these requirements are as follows:

- Enter the participant identification number (PTID) and visit date in the top section of each checklist. If information is written on the front and back of the checklist, enter the PTID and visit date on both sides.
- For follow-up visits, mark the applicable visit in the top section of each checklist
- Enter your initials only beside the procedures that you perform. Do not enter your initials beside procedures performed by other staff members. If other staff members are not available to initial checklist items themselves, enter, initial, and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by lab staff.”
- If all procedures listed on a checklist are performed on the date entered in the top section of the form, the date need not be entered beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item.
- If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why on the checklist (if not self-explanatory); initial and date this entry.

## 7.2 Sequence of Procedures

The sequence of procedures presented on the visit checklists is a suggested ordering. In consultation with the MTN (FHI) CORE, site staff may modify the checklists included in this section to maximize the efficiency of site-specific study operations. Sites may alter the sequence of procedures to suit local staffing and logistical requirements, with the following exceptions:

- Informed consent for screening must be obtained before any screening procedures are performed.
- Informed consent for enrollment must be obtained before conduct of any study enrollment or follow-up procedures are performed. Enrollment procedures are listed in the Enrollment sub-sections of protocol Section 7.
- Behavioral assessments must be administered prior to HIV/STI risk reduction, male condom counseling and study product adherence counseling.
- Pelvic procedures must be performed in the sequence shown on the pelvic exam checklists.

## Screening Visit: Page 1 of 3

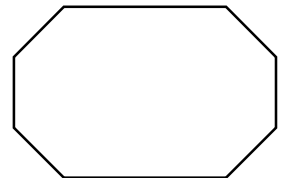
<b>PTID:</b>	<b>Visit Date:</b>
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1. \_\_\_\_\_ Confirm participant identity. Cross-check with the MTN 001 Participant Name-PTID Link Log to determine whether a MTN 001 Participant ID number has previously been assigned to the participant.
2. \_\_\_\_\_ Confirm whether the participant is between the ages of 18 and 45 (inclusive) per site SOP.
3. \_\_\_\_\_ Explain the two-step (screening and enrollment) informed consent process.
4. \_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the visit.
5. \_\_\_\_\_ Administer and obtain screening informed consent with participant according to site SOPs. Complete Consent Process Worksheet.

➤ *If the participant does not consent to screening, STOP. Do not fax any forms to SCHARP.*

6. \_\_\_\_\_ Complete the **Screening Consent** form.

Based on the 30-day screening and enrollment window, beginning on the day informed consent is obtained for screening; enter the participant's last possible enrollment date for this screening attempt



7. \_\_\_\_\_ Assign an MTN 001 PTID (if not done during a previous screening attempt) by completing a new row in the MTN 001 Name-PTID Link Log.
8. \_\_\_\_\_ Collect approximately 20-60 mL urine and:
  - 8a. \_\_\_\_\_ Aliquot approximately 5-10 mL and perform qualitative pregnancy test.
  - 8b. \_\_\_\_\_ Complete testing logs and record result on the **Screening Eligibility** form (non-DataFax).

*If the participant is pregnant, STOP. Inform the participant that she is ineligible. Retain documentation completed thus far, and complete the **Screening Summary** form, but do not fax any forms to SCHARP.*

- 8c. \_\_\_\_\_ Prepare urine for SDA for Gonorrhea and Chlamydia.

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- 8d. \_\_\_\_\_ Complete dipstick urinalysis using same aliquot as pregnancy test; record results for protein, leukocytes, and nitrites on the **Safety Laboratory Results** form. Document other results (e.g., blood, glucose), if any, in visit chart note, or in other designated site-specific document, if applicable. If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site SOP. Document additional work-up in chart notes. Document treatment on the **Concomitant Medications Log**.
9. \_\_\_\_\_ Assess behavioral eligibility on the **Screening Eligibility and Clinical Eligibility** (non- DataFax) forms.
10. \_\_\_\_\_ Provide HIV pre-test, HIV/STI risk reduction and condom counseling. Provide male condoms. *(Sites may chose to provide condoms at the end of the visit)*
11. \_\_\_\_\_ Collect blood: *(Sites to specify their site-specific volume for each tube)*
- Plain tube (no additive)
  - EDTA
12. \_\_\_\_\_ Explain to study participant that eligibility is based on results as determined by the study HIV algorithm (Protocol Appendix II).
13. \_\_\_\_\_ Prepare blood for testing at the local lab:
- HIV serology
  - Syphilis serology
  - CBC (hemoglobin, hematocrit, WBC, PLT)
  - Serum Chemistries (Phosphorous, Creatinine)
  - Liver Function Tests (AST, ALT)
  - Hepatitis B Surface Antigen
14. \_\_\_\_\_ Obtain contact information and record on site specific form.
- *If the participant does not provide adequate contact information, per site-specific definition of adequate contact information and is determined not to be a good candidate for the study (investigator decision) STOP. Inform the participant that she is ineligible. Retain documentation completed thus far, and complete the form, but do not fax any forms to SCHARP.*
15. \_\_\_\_\_ Administer the **Demographics** DataFax CRF.
16. \_\_\_\_\_ Conduct the Physical Exam and record results on the **Physical Exam** non-Data Fax form.

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17. \_\_\_\_\_ Obtain medical, menstrual, and genitourinary history with documentation of current medications. Record on **Baseline Medical and Menstrual History** form (non-Data Fax) and **Concomitant Medications Log** Data Fax CRF.
18. \_\_\_\_\_ Perform and document pelvic exam using Pelvic Exam Checklist. Complete the Pelvic Exam Diagrams (non-Data Fax), **Screening and Enrollment Pelvic Exam** and **Pelvic Laboratory Results** DataFax CRFs. Treat or refer for treatment, if applicable.
19. \_\_\_\_\_ Provide contraceptive counseling. Provide and/or refer for contraception, if applicable.
20. \_\_\_\_\_ Provide study informational material. Provide site contact information and instructions to contact the site for additional information and/or HIV/STI counseling, if needed, prior to the next visit.
21. \_\_\_\_\_ Schedule the Enrollment visit, taking into account the timing for receipt of lab results, the participant's menstrual cycle, and the 30-day screening period.
22. \_\_\_\_\_ Provide reimbursement.
23. \_\_\_\_\_ Document the visit in signed and dated chart notes. Complete the **Screening Summary** form and review all other participant chart contents for the visit, but do not fax any forms to SCHARP.

➤ *Note: The **Screening and Enrollment STI Laboratory Results, Pelvic Laboratory Results, Safety Laboratory Results** forms (and **HIV Test Results** form, when applicable) should be completed when all required test results are available, prior to the Enrollment Visit. Do not fax any forms to SCHARP until the participant is randomized. If the participant's lab results indicate that she is HIV-positive per protocol Appendix II, or has an active RTI and/or UTI – with the exception of asymptomatic BV and asymptomatic vulvovaginal candidiasis — she is ineligible for enrollment; retain all of these DataFax forms on site but do not fax any of them to SCHARP.*

## Enrollment Visit: Page 1 of 6

<b>PTID:</b>	<b>Visit Date:</b>
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1. \_\_\_\_\_ Complete participant registration, confirm the participant's identity, and verify her PTID.
2. \_\_\_\_\_ Review/update locator information
3. \_\_\_\_\_ Confirm that the 30-day window has not been exceeded for the current screening attempt.
4. \_\_\_\_\_ Review chart notes and other relevant documentation from previous visit(s). Confirm the participant's current eligibility status based on all screening documentation.
5. \_\_\_\_\_ Confirm behavioral eligibility and record results on **Enrollment Eligibility** form
6. \_\_\_\_\_ Explain again the two-step informed consent process and obtain written informed consent for the study. Document the informed consent process in a chart note and on any other documents per site SOP.  
*☞ If the participant does not consent to the study, complete the **Screening Summary** form and then STOP. Retain documentation completed thus far, but do not fax any forms to SCHARP.*
7. \_\_\_\_\_ Obtain written informed consent for specimen storage and possible future research testing. Document the informed consent process in a chart note and on any other documents per site SOP. Complete Consent Process Worksheet.  
*☞ Consent for specimen storage and possible future research testing is optional. If the participant does not consent, she may still take part in the study.*
8. \_\_\_\_\_ Administer assessment of informed consent comprehension, utilizing comprehension checklist, according to local SOPs.
9. \_\_\_\_\_ Complete the **Screening Summary** form and items 1-2 of the **Enrollment** form.
10. \_\_\_\_\_ Provide HIV test results in the context of post-test counseling. [Before disclosing result(s) to participant, obtain independent review, verification, and sign-off of results(s)]. Provide referrals if needed/requested. Explain the participant's current study eligibility status.  
*☞ If the participant is HIV-positive per protocol Appendix II, STOP. Retain documentation completed thus far, but do not fax any forms to SCHARP.*

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☞ *If the participant requires Sample 2 collection for WB testing: \_\_\_\_\_*

10a. \_\_\_\_\_ Provide pre-test counseling, if applicable.

10b. \_\_\_\_\_ Collect blood (plain tube or EDTA).

10c. \_\_\_\_\_ Schedule Enrollment Visit when WB test result is available, up to 30-days after written consent for screening was obtained for the current screening attempt.

11. \_\_\_\_\_ Collect 20-60 mL first void urine and:

11a. \_\_\_\_\_ Aliquot ~5 mL and perform pregnancy test.

11b. \_\_\_\_\_ Complete testing logs and transcribe result here:

negative

positive

☞ *If the participant is pregnant, STOP. Inform the participant that she is ineligible. Retain documentation completed thus far, record results in the participant's chart notes, and complete the **Screening Summary** form. Do not fax any forms to SCHARP.*

11c. \_\_\_\_\_ If clinically indicated, prepare urine for SDA for Gonorrhea and Chlamydia

12. \_\_\_\_\_ Administer the **Baseline Genital Symptoms** form.

13. \_\_\_\_\_ Review/update the **Baseline Medical and Menstrual History and Concomitant Medications Log**. Document review with a signed and dated note on each document reviewed. Initial and date updated entries.

14. \_\_\_\_\_ Complete the **Family Planning Methods** form by transcribing (from the Baseline Medical and Menstrual History form) the participant's current contraceptive/family planning methods.

15. \_\_\_\_\_ Provide contraceptive counseling. Provide and/or refer for contraception, if applicable.

16. \_\_\_\_\_ If indicated, complete dipstick urinalysis using same aliquot as pregnancy test; record results for protein, leukocytes, and nitrites on **Safety Laboratory Results** form. Document other results (e.g., blood, glucose), if any, in visit chart note, or in other designated site-specific document, if applicable. If dipstick urinalysis is positive for leukocytes or nitrites, provide/refer for treatment and/or additional UTI work-up per site SOP. Document additional work-up in chart notes. Provide treatment and document on the **Concomitant Medications Log**.

17. \_\_\_\_\_ Conduct physical exam as per Protocol Appendix III. Complete the **Physical Exam** (non-DataFax) form.

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18. \_\_\_\_\_ Perform and document pelvic exam and CVL using Pelvic Exam checklist. Complete the Pelvic Exam Diagrams (non-Data Fax), **Screening and Enrollment Pelvic Exam and Pelvic Laboratory Results** Data Fax forms.
19. \_\_\_\_\_ Complete the **Clinical Eligibility** form
20. \_\_\_\_\_ Collect blood: : (*Sites to include site-specific blood volume*)
- Plain tube (no additive)
  - EDTA
21. \_\_\_\_\_ Prepare blood for testing at the local lab:
- CBC (hemoglobin, hematocrit, WBC, PLT)
  - Serum Chemistries (Phosphorous, Creatinine)
  - Liver Function Tests (AST, ALT)
  - Plasma storage
  - Syphilis serology, if indicated
  - HIV serology if determined by site SOP
  - HIV-1 Western Blot, if indicated and determined by site SOP
22. \_\_\_\_\_ Complete an **LDMS Specimen Tracking Sheet** for stored samples.
23. \_\_\_\_\_ Administer the **Enrollment Behavior Assessment**  
*☞ This form must be administered prior to random assignment.*
24. \_\_\_\_\_ Provide HIV/STI risk reduction and male condom counseling.
25. \_\_\_\_\_ **For non-replacement participants only:** obtain the next sequential Randomization Envelope and assign it to the participant by completing the row of the MTN 001 Randomization Envelope Tracking Record that corresponds to the next sequential envelope.
26. \_\_\_\_\_ **For non-replacement participants only:** open the assigned envelope and confirm that the envelope number printed on the MTN 001 Randomization Document contained inside the envelope corresponds with the envelope number on the outside of the envelope (envelope label). Complete the Randomization Document.
27. \_\_\_\_\_ **For replacement participants only:** obtain a blank Replacement Randomization Document and the completed Randomization Document (yellow copy) of the participant being replaced. Transcribe all of the randomization information from the Randomization Document of the participant being replaced onto the Replacement Randomization Document. Complete the remainder of the Replacement Randomization Document.

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28. \_\_\_\_\_ Complete the MTN 001 prescription(s) that correspond to the participant's first study period (vaginal, oral, or dual use) per her study randomization. Deliver the Randomization Document (or Replacement Randomization Document, for replacement participants) and prescription(s) to the pharmacy according to Option A or B below. While waiting for product supplies to be delivered, continue with the remainder of this checklist.

**OPTION A:**

- \_\_\_\_\_ Give the completed white original Randomization Document (or Replacement Randomization Document) and prescription(s) to the participant to deliver to the pharmacy (where she will obtain product supplies herself). Retain the envelope (for non-replacement participants) and the yellow clinic copy of both the Randomization Document (or Replacement Randomization Document) and the prescription(s) in the participant's study notebook.
- \_\_\_\_\_ Document the amount of product the participant received here ⇒   
[or in chart notes].

**OPTION B:**

- \_\_\_\_\_ Optional: Fax a copy of the Randomization Document (or Replacement Randomization Document) and prescription(s) to the pharmacy
- \_\_\_\_\_ Deliver the completed white original Randomization Document (or Replacement Randomization Document) and prescription(s) to the pharmacy. Retain the envelope (for non-replacement participants) and the yellow clinic copy of both the Randomization Document (or Replacement Randomization Document) and the prescription(s) in the participant's study notebook.
- \_\_\_\_\_ Receive requested product supplies.
- \_\_\_\_\_ Provide product supplies to the participant.
- \_\_\_\_\_ Document the amount of product provided to the participant here ⇒   
[or in chart notes]

29. \_\_\_\_\_ Provide counseling related to the importance of participant's study participation and product use. For participants randomized to the study gel only or dual use regimen for the first study period, provide demonstration of gel applicator, instructions for gel use, and adherence counseling. Emphasize the unknown effectiveness of the study products and the importance of condom use for protection against HIV.

- 29a. \_\_\_\_\_ Counsel participants to abstain from sex 24 hours prior to the End-of-the-Study Visit, if possible.

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30. \_\_\_\_\_ Once product supplies arrive, complete the remainder of the **Enrollment** form.
31. \_\_\_\_\_ Reinforce the instructions to contact the site to request additional product, if needed, prior to the next visit and remind the participant that she will be asked to return unused study product that she has remaining at her next visit.
32. \_\_\_\_\_ Provide male condoms and offer panty liners.
33. \_\_\_\_\_ Provide watch device and remind participant to record on her appointment card (or other designated site-specific document) the date and time of the last 3 doses of study product she takes prior to her next study visit.
34. \_\_\_\_\_ Reinforce site contact information and instructions to contact the site to report symptoms — *especially genital symptoms* — and/or to request for additional information, HIV/STI counseling, and/or condoms, if needed, prior to the next visit.
35. \_\_\_\_\_ Explain the follow-up visit schedule to the participant and schedule her Week 3 Clinic Visit.
36. \_\_\_\_\_ Inform the participant of tests to be performed at the next visit. Also inform the participant of availability of HIV/STI counseling, testing, and STI treatment for partners.
37. \_\_\_\_\_ Treat or refer for findings as needed.
38. \_\_\_\_\_ Provide reimbursement for study visit.
39. \_\_\_\_\_ Complete the **Pre-Existing Conditions** form. Record all medical conditions that are ongoing at the time of participant randomization, based on source data collected throughout the screening process. Whenever possible, record a diagnosis rather than individual signs and symptoms. When this is not possible, record each individual sign or symptom. Do not record STIs or other infections that were fully treated prior to randomization. In the "comments" box for each condition, record as much information as possible on the severity and/or frequency of the condition at the time of participant randomization.
40. \_\_\_\_\_ Document the visit in a signed and dated chart note. Complete and review all participant chart contents from both the screening and enrollment visits.

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41. \_\_\_\_\_ Non-Data Fax forms:
- Screening Eligibility
  - Enrollment Eligibility
  - Baseline Medical and Menstrual History
  - Physical Exam (x2)
  - Pelvic Exam Diagrams (x2)
  - Clinical Eligibility (x2)
  - Screening Summary
  - LDMS Specimen Tracking Sheet
42. \_\_\_\_\_ Complete and fax all required DataFax forms to SCHARP:
- Screening Consent
  - Demographics
  - Screening and Enrollment Pelvic Exam (x2)
  - Baseline Genital Symptoms
  - Screening and Enrollment STI Laboratory Results
  - Pelvic Laboratory Results\* (x2)
  - Safety Laboratory Results\* (x2)
  - Concomitant Medications Log
  - Family Planning Methods
  - Enrollment
  - Pre-Existing Conditions
  - Enrollment Behavior Assessment

☞ ***Pelvic Laboratory and Safety Laboratory Results forms are required for enrolled participants and MUST be completed, reviewed, and faxed to SCHARP once enrollment visit lab results are available. If HIV and/or other STI lab testing are conducted on samples collected at this visit, complete the **Screening and Enrollment STI Laboratory Results** form and the **HIV Test Results** form, if applicable.***

## Follow-up Clinic Visits, Mid-Study Period Visit: Page 1 of 5

<b>PTID:</b>	<b>Visit Date:</b>
<p><b>Please indicate to which follow-up visit this checklist applies:</b></p> <p><b>3-Week:</b> _____ <b>10-Week:</b> _____ <b>17-Week:</b> _____</p>	

1. \_\_\_\_\_ Complete participant registration, confirm the participant's identity, and verify her PTID.
  
2. \_\_\_\_\_ Review/update locator information.
  
3. \_\_\_\_\_ Review chart notes and other relevant documentation from previous visit(s).
  
4. \_\_\_\_\_ Explain the content and sequence of procedures for today's visit.
  
5. \_\_\_\_\_ Review elements of informed consent as needed.
  
6. \_\_\_\_\_ Collect 20-60 mL urine and:
  - 6a. \_\_\_\_\_ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
  - 6b. \_\_\_\_\_ Complete testing logs and transcribe result onto the form.

If the participant is pregnant:

  - 6c. \_\_\_\_\_ Inform the participant that she must discontinue product use; arrange to collect her unused study product.
  - 6d. \_\_\_\_\_ Complete an MTN 001 Pregnancy Management Worksheet.
  - 6e. \_\_\_\_\_ Complete Product Hold/Discontinuation Tracking Sheet(s), if applicable.
  - 6f. \_\_\_\_\_ Complete a **Study Product Hold/Resume/pK Supply/Re-Supply Slip**, marked "Permanent Discontinuation." Deliver the completed white original to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.
  
7. \_\_\_\_\_ Collect unused study product to return to pharmacy. Document product collection in the chart notes. If participant did not bring the unused product at this visit, remind her to bring it for her next scheduled visit or make arrangements to collect the product.
  
8. \_\_\_\_\_ Provide and explain available exam and lab test results. Before disclosing HIV test results to participant, obtain independent review, verification, and sign-off of both results. Provide post-test counseling. Provide referrals if needed/requested. Provide treatment for RTIs/STIs if needed. Document treatment on the **Concomitant Medications Log**.
  
9. \_\_\_\_\_ Record/transcribe the date and time of the participant's last 3 doses of study product onto the **Study Product Adherence and Behavior Assessment** form.

## Follow-up Clinic Visits, Mid-Study Period Visit: Page 2 of 5

<b>PTID:</b>	<b>Visit Date:</b>
<p><b>Please indicate to which follow-up visit this checklist applies:</b></p> <p><b>3-Week:</b> _____ <b>10-Week:</b> _____ <b>17-Week:</b> _____</p> <p><i>Note: Any protocol-specified studies or exams that were not completed on the assigned visit date must be completed at the next scheduled visit or at an interim visit.</i></p>	

10. \_\_\_\_\_ Administer the **Study Product Adherence and Behavior Assessment** form.
11. \_\_\_\_\_ Administer the **Follow-up Genital Symptoms** form
12. \_\_\_\_\_ Perform interval medical/menstrual history; record findings on the **Follow-up Medical History Log** form. Record interval contraceptive/family planning method use and menstrual history in the visit chart note.
  - 12a. \_\_\_\_\_ Complete a **Genital Bleeding Assessment** form for unexpected genital bleeding.
13. \_\_\_\_\_ Review and update the **Concomitant Medications Log** form.
14. \_\_\_\_\_ Complete the **Family Planning Methods** form by transcribing (from the visit chart note) the participant's current contraceptive/family planning methods.
15. \_\_\_\_\_ Provide contraceptive counseling. Provide and/or refer for contraception, if applicable.
16. \_\_\_\_\_ Collect blood as follows. Complete a **Pharmacokinetics – Intensive** form. (*Sites to include site-specific blood volume*)
  - Plain tube (no additive)
  - EDTA
17. \_\_\_\_\_ Complete an **LDMS Specimen Tracking Sheet** for stored samples.
18. \_\_\_\_\_ Prepare blood for testing/storage at the local lab.
  - Serum Chemistries (Phosphorous, Creatinine)
  - Liver Function Tests (AST, ALT)
  - Tenofovir levels
19. \_\_\_\_\_ Perform physical exam per Protocol Appendix III and record on the **Physical Exam** (non-DataFax) form.
20. \_\_\_\_\_ Perform pelvic exam using the Pelvic Exam Checklist and complete the Pelvic Exam Diagrams, **Follow-up Pelvic Exam** and **Pelvic Laboratory Results** (if indicated) forms.
  - 20a. \_\_\_\_\_ During the exam, if applicable, assess genital symptoms reported during administration of the **Follow-up Genital Symptoms** form. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

## Follow-up Clinic Visits, Mid-Study Period Visit: Page 3 of 5

<b>PTID:</b>	<b>Visit Date:</b>
<p><b>Please indicate to which follow-up visit this checklist applies:</b></p> <p><b>3-Week:</b> _____ <b>10-Week:</b> _____ <b>17-Week:</b> _____</p> <p><i>Note: Any protocol-specified studies or exams that were not completed on the assigned visit date must be completed at the next scheduled visit or at an interim visit.</i></p>	

21. \_\_\_\_\_ If applicable, assess any non-genital symptoms reported in the participant’s interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.
22. \_\_\_\_\_ If applicable, complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests when available.
23. \_\_\_\_\_ If product use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents, and on the Product Hold/Discontinuation Tracking Sheet(s), if applicable. Inform the site’s study pharmacist of the product hold/discontinuation or resumption by completing a **Study Product Hold/Resume/pK Supply/Re-Supply Slip** and delivering the white original to the pharmacy. Retain the yellow clinic copy in the participant’s study notebook. If the hold, discontinuation, or resumption affects product use in the CURRENT study period, complete/update the **Product Hold/Discontinuation Log** form (for holds/discontinuations, complete one form per reason). Refer to Protocol Section 9.4 and the SSP Manual, Section 10, for guidelines on holding, discontinuing or continuing with study product. Contact PSRT if there are any questions about study product or clinical management.
24. \_\_\_\_\_ For all participants (unless product is held):
- 24a. \_\_\_\_\_ Complete a **Prescription or Study Product Hold/Resume/pK Supply/Re-Supply Slip**.
- 24b. \_\_\_\_\_ Follow your site-specific procedure for product re-supply.
- 24c. \_\_\_\_\_ Provide panty liners and watch device as needed
- 24d. \_\_\_\_\_ After product supplies are received, document the number of product provided here →
25. \_\_\_\_\_ Provide HIV/STI risk reduction, protocol and product use adherence, and male condom counseling. Provide condoms and offer panty liners.
26. \_\_\_\_\_ Schedule the next visit and inform the participant of what to expect. Remind the participant to abstain from having sex 24 hours prior to the next visit.
27. \_\_\_\_\_ Inform the participant of availability of HIV/STI counseling, testing, and STI treatment for partners.

## Follow-up Clinic Visits, Mid-Study Period Visit: Page 4 of 5

<b>PTID:</b>	<b>Visit Date:</b>
<b>Please indicate to which follow-up visit this checklist applies:</b> <b>3-Week:</b> _____ <b>10-Week:</b> _____ <b>17-Week:</b> _____ <i>Note: Any protocol-specified studies or exams that were not completed on the assigned visit date must be completed at the next scheduled visit or at an interim visit.</i>	

28. \_\_\_\_\_ Reinforce the instructions to contact the site to request additional product, if needed, prior to the next visit and remind the participant that she will be asked to return all unused study product at her next visit.
29. \_\_\_\_\_ Reinforce site contact information and instructions to contact the site to report symptoms — especially genital symptoms — and/or to request for additional information, HIV/STI counseling, contraceptive counseling, and/or condoms, if needed, prior to the next visit.
30. \_\_\_\_\_ Provide study reimbursement

### Additionally and Only If Clinically Indicated (C1-C4):

- C1. \_\_\_\_\_ Perform dipstick urinalysis on aliquot of used for pregnancy testing. Complete testing logs and transcribe protein, leukocyte, and nitrites results onto the **Safety Laboratory Results** form. Document other results (e.g., blood, glucose), if any, in visit chart note, or in other designated site-specific document, if applicable.
- C2. \_\_\_\_\_ Perform culture if positive for leukocyte esterase or nitrites; may omit if culture not standard of care for UTI diagnosis. Document additional work-up in visit chart note. If applicable, provide treatment and record on the **Concomitant Medications Log** form.
- C3. \_\_\_\_\_ Prepare urine for SDA for Gonorrhea and Chlamydia. Transcribe results onto the **STI Laboratory Results** form.
- C4. \_\_\_\_\_ Collect blood for Syphilis Serology, and/or HBsAg. Transcribe results onto the **STI Laboratory Results** form.

31. \_\_\_\_\_ Remind participant to record on her appointment card (or other designated site-specific document) the date and time of the last three doses of study product she takes prior to her next study visit.
32. \_\_\_\_\_ Complete the **Follow-up Visit** form.

## Follow-up Clinic Visits, Mid-Study Period Visit: Page 5 of 5

<b>PTID:</b>	<b>Visit Date:</b>
<b>Please indicate to which follow-up visit this checklist applies:</b>	
<b>3-Week:</b> _____ <b>10-Week:</b> _____ <b>17-Week:</b> _____	

33. \_\_\_\_\_ Complete and review all participant chart contents for the visit, including the following non-Data Fax forms:

Physical Exam Form  
Pelvic Exam Diagram  
LDMS Tracking Sheet

34. \_\_\_\_\_ Complete and fax all required Data Fax forms to SCHARP:

Follow-up Visit  
Follow-up Genital Symptoms  
Follow-up Pelvic Exam  
Family Planning Methods  
Safety Laboratory Results (when all results available)  
Study Product Adherence and Behavior Assessment  
Pharmacokinetics - Intensive

As Needed:

Follow-up Medical History Log (update/add entries as applicable)  
Pelvic Laboratory Results  
HIV Test Results  
Genital Bleeding Assessment  
Concomitant Medications Log (required for updated or new pages)  
Adverse Experience Log (required if any AEs identified or updated at this visit)  
Product Hold/Discontinuation Log (required if product use *in current study period* is held/discontinued or resumed at this visit)  
Pregnancy Report and History (required if pregnancy identified at this visit)  
Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)  
STI Laboratory Results

Early Termination:

Termination  
End of Study Inventory

## Follow-up Clinic Visits, End of Study Period Visit: Page 1 of 5

PTID:	Visit Date:
<p>Please indicate to which follow-up visit this checklist applies:</p> <p>6-Week: _____ 13-Week: _____ 20-Week: _____</p> <p><i>Note: Any protocol-specified studies or exams that were not completed on the assigned visit date must be completed at the next scheduled visit or at an interim visit.</i></p>	

1. \_\_\_\_\_ Complete participant registration, confirm the participant's identity, and verify her PTID.
2. \_\_\_\_\_ Review/update locator information.
3. \_\_\_\_\_ Review chart notes and other relevant documentation from previous visit(s).
4. \_\_\_\_\_ Review elements of informed consent as needed.
5. \_\_\_\_\_ Explain the content and sequence of procedures for today's visit.
6. \_\_\_\_\_ Collect 20-60 mL urine and:
  - 6a. \_\_\_\_\_ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
  - 6b. \_\_\_\_\_ Complete testing logs and transcribe result onto the form.

If the participant is pregnant:

  - 6c. \_\_\_\_\_ Inform the participant that she must discontinue product use; arrange to collect her unused study product.
  - 6d. \_\_\_\_\_ Complete a MTN 001 Pregnancy Management Worksheet (but do not complete a Product Hold/Discontinuation Log form at this time).
  - 6e. \_\_\_\_\_ Complete the Product Hold/Discontinuation Tracking Sheet(s), if applicable.
  - 6f. \_\_\_\_\_ Complete a **Study Product Hold/Resume/pK Supply/Re-Supply Slip**. Deliver the original to the pharmacy. Retain a copy in the participant's study notebook.
7. \_\_\_\_\_ Collect unused study product. If participant did not bring unused product at this visit, remind her to bring it at her next scheduled visit or make arrangements to collect product.
8. \_\_\_\_\_ Provide and explain available exam and lab test results. Provide post-test counseling, if appropriate. Provide treatment for RTIs/STIs if needed. Document treatment on the **Concomitant Medications Log**.
9. \_\_\_\_\_ Observe a single dose of the study drug. If participant does not bring sufficient unused study product to visit for use as observed dose, study product will be dispensed to participant during study visit.

## Follow-up Clinic Visits, End of Study Period Visit: Page 2 of 6

PTID:	Visit Date:
Please indicate to which follow-up visit this checklist applies: 6-Week: _____ 13-Week: _____ 20-Week: _____ <i>Note: Any protocol-specified studies or exams that were not completed on the assigned visit date must be completed at the next scheduled visit or at an interim visit.</i>	

10. \_\_\_\_\_ Administer the **Follow-up Genital Symptoms** form.
11. \_\_\_\_\_ Perform interval medical/menstrual history; record findings on the **Follow-up Medical History Log** form. Record interval contraceptive/family planning method use and menstrual history in visit chart note.
  - 11a. \_\_\_\_\_ If genital blood/bleeding is reported, complete a **Genital Bleeding Assessment** form for unexpected genital bleeding.
12. \_\_\_\_\_ Review and update the **Concomitant Medications Log**.
13. \_\_\_\_\_ Complete the **Family Planning Methods** form by transcribing (from the visit chart note) the participant's current contraceptive/family planning methods.
14. \_\_\_\_\_ Provide contraceptive counseling. Provide and/or refer for contraception, if applicable.
15. \_\_\_\_\_ Perform physical exam as per Protocol Appendix III and record on the **Physical Exam** (non-DataFax) form.
16. \_\_\_\_\_ Confirm participant abstained from sex for at least 24 hours prior to the study visit.
17. \_\_\_\_\_ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.
18. \_\_\_\_\_ Collect blood as follows:
  - Plain tube(s) (no additive)
  - EDTA
  - CPT Tube with Sodium Citrate
19. \_\_\_\_\_ Complete an **LDMS Specimen Tracking Sheet** for stored samples

## Follow-up Clinic Visits, End of Study Period Visit: Page 4 of 6

PTID:	Visit Date:
<p>Please indicate to which follow-up visit this checklist applies:</p> <p>6-Week: _____ 13-Week: _____ 20-Week: _____</p> <p><i>Note: Any protocol-specified studies or exams that were not completed on the assigned visit date must be completed at the next scheduled visit or at an interim visit.</i></p>	

20. \_\_\_\_\_ Prepare blood for testing/storage at the local lab. Insert lock for specimen collection:
- Pre-dose:
    - Complete Blood Count with differential (lymphocyte) for flow cytometry calculations
    - Serum Chemistries (Phosphorous, Creatinine)
    - Liver Function Tests (AST, ALT)
    - Tenofovir
    - Plasma for storage
    - PBMC for intracellular tenofovir
    - Plasma for flow cytometry
  - Post-dose blood collection at 1, 2, 4, 6, and 8 hours:
    - Tenofovir
    - PBMC for intracellular tenofovir
21. \_\_\_\_\_ Perform pelvic exam using the Pelvic Exam Checklist and complete the Pelvic Exam Diagrams, **Follow-up Pelvic Exam** and **Pelvic Laboratory Results** forms.
- 21a. \_\_\_\_\_ During the exam, if applicable, assess genital symptoms reported during administration of the **Follow-up Genital Symptoms** form. Provide or refer for follow-up care as needed. Document follow-up in chart notes.
- 21b. \_\_\_\_\_ Collect genital PK specimens at the assigned time point and record collection times on the **Pharmacokinetics -- Intensive** form.  
*NOTE: Pelvic exam should be timed such that the genital specimens may be collected at the randomly assigned time point. Make sure that genital PK specimens are collected within 15 minutes of blood collection for the assigned collection time point.*
- 21c. \_\_\_\_\_ **For Bronx site only:** collect rectal PK specimens within 15 AFTER collection of the vaginal PK specimens. Complete the **Rectal PK** form.

## Follow-up Clinic Visits, End of Study Period Visit: Page 4 of 6

PTID:	Visit Date:
<p>Please indicate to which follow-up visit this checklist applies:</p> <p>6-Week: _____ 13-Week: _____ 20-Week: _____</p> <p><i>Note: Any protocol-specified studies or exams that were not completed on the assigned visit date must be completed at the next scheduled visit or at an interim visit.</i></p>	

22. \_\_\_\_\_ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.
23. \_\_\_\_\_ If product use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents, and on the Product Hold/Discontinuation Tracking Sheet(s), if applicable. Inform the site's study pharmacist of the product hold/discontinuation or resumption by completing a **Study Product Hold/Resume/pK Supply/Re-Supply Slip** and delivering the white original to the pharmacy. Retain the yellow copy in the participant's study notebook. Refer to Protocol Section 9.4 and the SSP Manual, Section 10, for guidelines on holding, discontinuing or continuing with study product. Contact PSRT if there are any questions about study product or clinical management.
24. \_\_\_\_\_ Record/transcribe the date and time of the participant's last 3 doses of study product onto the **Study Product Adherence and Behavior Assessment** form.
25. \_\_\_\_\_ Administer the **Study Product Adherence and Behavior Assessment** form, the **Acceptability Assessment** form (Weeks 6 and 13 only), the **Final Acceptability Assessment** form (Week 20 only), and the **Product Sharing Assessment** form.
26. \_\_\_\_\_ Provide HIV/STI risk reduction, protocol and product use adherence, and male condom counseling.
27. \_\_\_\_\_ Provide condoms, offer panty liners, and provide referrals if needed/requested.
28. \_\_\_\_\_ Schedule the next visit and inform the participant of what to expect. Also inform the participant of availability of HIV/STI counseling, testing, and STI treatment for partners.
29. \_\_\_\_\_ Reinforce site contact information and instructions to contact the site to report symptoms — especially genital symptoms — and/or to request for additional information, HIV/STI counseling, and/or condoms, if needed, prior to the next visit.
30. \_\_\_\_\_ Provide study reimbursement.

## Follow-up Clinic Visits, End of Study Period Visit: Page 5 of 6

PTID:	Visit Date:
Please indicate to which follow-up visit this checklist applies: 6-Week: _____ 13-Week: _____ 20-Week: _____	

Additionally Only If Clinically Indicated (C1-C4):

C1. \_\_\_\_\_ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe protein, leukocyte, and nitrites results onto the **Safety Laboratory Results** form. Document other results (e.g., blood, glucose), if any, in visit chart note, or in other designated site-specific document, if applicable.

C2. \_\_\_\_\_ Perform culture if positive for leukocyte esterase or nitrites; may omit if culture not standard of care for UTI diagnosis. Document additional work-up in visit chart note. If applicable, provide and record treatment on the **Concomitant Medications Log** form.

C3. \_\_\_\_\_ Prepare urine for SDA for Gonorrhea and Chlamydia. Transcribe results onto the **STI Laboratory Results** form.

C4. \_\_\_\_\_ Collect blood for Syphilis Serology and/or HBsAg. Transcribe results onto the **STI Laboratory Results** form.

31. \_\_\_\_\_ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including Follow-up Medical History
32. \_\_\_\_\_ Complete **Follow-up Visit** form
33. \_\_\_\_\_ Complete and review all participant chart contents for the visit, including the following non-Data Fax forms:

Physical Exam Form  
Pelvic Exam Diagram  
LDMS Specimen Tracking Sheet

## Follow-up Clinic Visits, End of Study Period Visit: Page 6 of 6

PTID:	Visit Date:
Please indicate to which follow-up visit this checklist applies: 6-Week: _____ 13-Week: _____ 20-Week: _____	

34. \_\_\_\_\_ Complete and fax all required Data Fax forms to SCHARP:

- Follow-up Visit
- Follow-up Genital Symptoms
- Family Planning Methods
- Follow-up Pelvic Exam
- Pelvic Laboratory Results
- Safety Laboratory Results (when all results available)
- Study Product Adherence and Behavior Assessment
- Product Sharing Assessment
- Acceptability Assessment (Week 6 and 13 only)
- Final Acceptability Assessment (Week 20 only)
- Pharmacokinetics – Intensive
- Rectal PK (if applicable)
- Flow Cytometry

As Needed:

- Follow-up Medical History Log (update/add entries as needed)
- Concomitant Medications Log (required for updated or new pages)
- Adverse Experience Log (required if any AEs identified or updated at this visit)
- Pregnancy Report and History (required if pregnancy identified at this visit)
- Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)
- STI Laboratory Results

Early Termination:

- Termination
- End of Study Inventory

## Follow-up Clinic Visits, Study Period 2 and 3 Start: Page 1 of 5

PTID: _____	Visit Date: _____
<p>Please indicate to which follow-up visit this checklist applies:</p> <p>7-Week: _____ 14-Week: _____</p>	

1. \_\_\_\_\_ Complete participant registration, confirm the participant's identity, and verify her PTID.
2. \_\_\_\_\_ Review/update locator information.
3. \_\_\_\_\_ Review chart notes and other relevant documentation from previous visit(s).
4. \_\_\_\_\_ If indicated, collect unused study product. If participant did not bring unused product at this visit, remind her to bring it at her next scheduled visit or make arrangements to collect product.
5. \_\_\_\_\_ Review elements of informed consent as needed.
6. \_\_\_\_\_ Explain the content and sequence of procedures for today's visit.
7. \_\_\_\_\_ Collect 20-60 mL urine and:
  - 7a. \_\_\_\_\_ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
  - 7b. \_\_\_\_\_ Complete testing logs and transcribe result onto the form.

If the participant is pregnant:

  - 7c. \_\_\_\_\_ Inform the participant that she must discontinue product use; arrange to collect her unused study product.
  - 7d. \_\_\_\_\_ Complete a MTN 001 Pregnancy Management Worksheet
  - 7e. \_\_\_\_\_ Complete/update the Product Hold/Discontinuation Log Tracking Sheet(s), if applicable.
  - 7f. \_\_\_\_\_ Complete a **Study Product Hold/Resume/PK Supply/Re-Supply Slip**. Deliver the original copy to the pharmacy. Retain a copy in the participant's study notebook.
8. \_\_\_\_\_ Provide and explain available exam and lab test results. Provide post-test counseling, if appropriate. Provide treatment for RTIs/STIs if needed. Document treatment on the **Concomitant Medications Log**.
9. \_\_\_\_\_ Administer the **Follow-up Genital Symptoms** form
10. \_\_\_\_\_ Perform interval medical/menstrual history; record findings on the **Follow-up Medical History Log** form. Record interval contraceptive/family planning method use and menstrual history in the visit chart note.
  - 10a. \_\_\_\_\_ Complete a **Genital Bleeding Assessment** form for unexpected genital bleeding.

## Follow-up Clinic Visits, Study Period 2 and 3 Start: Page 2 of 5

PTID: _____	Visit Date: _____
<p>Please indicate to which follow-up visit this checklist applies:</p> <p>7-Week: _____ 14-Week: _____</p>	

11. \_\_\_\_\_ Review and update the **Concomitant Medications Log**.
  
12. \_\_\_\_\_ Complete the **Family Planning Methods** form by transcribing (from the visit chart note) the participant's current contraceptive/family planning methods.
  
13. \_\_\_\_\_ Provide contraceptive counseling. Provide or refer for contraception, if applicable.
  
14. \_\_\_\_\_ Collect blood as follows:
  - Plain tube(s) (no additive)
  - EDTA
  
15. \_\_\_\_\_ Provide HIV pre-test, HIV/STI risk reduction and condom counseling.
  
16. \_\_\_\_\_ Prepare blood for testing at the local lab.
  - HIV Serology
  - CBC (hemoglobin, hematocrit, WBC, PLT)
  - Serum Chemistries (Phosphorous, Creatinine)
  - Liver Function Tests (AST, ALT)
  
17. \_\_\_\_\_ For all participants (unless product is held):
  - 17a. \_\_\_\_\_ Complete a **Prescription**.
  - 17b. \_\_\_\_\_ Follow your site-specific procedures for product re-supply. The white original prescription will be taken to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.
  - 17c. \_\_\_\_\_ After product supplies are received, provide the supplies to the participant and document the amount of product provided here
 

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18. \_\_\_\_\_ Perform physical exam and record on the **Physical Exam** form.
  
19. \_\_\_\_\_ Perform pelvic exam using the Follow-Up Pelvic Exam Checklist and complete the Pelvic Exam Diagrams, **Follow-up Pelvic Exam** and **Pelvic Laboratory Results** (if indicated) forms.
  - 19a. \_\_\_\_\_ During exam, if applicable, assess genital symptoms reported during administration of the **Follow-up Genital Symptoms** form. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

## Follow-up Clinic Visits, Study Period 2 and 3 Start: Page 3 of 5

PTID: _____	Visit Date: _____
<p>Please indicate to which follow-up visit this checklist applies:</p> <p>7-Week: _____ 14-Week: _____</p>	

20. \_\_\_\_\_ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.
21. \_\_\_\_\_ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.
22. \_\_\_\_\_ If product use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents, and on the Product Hold/Discontinuation Tracking Sheet(s), if applicable. Inform the site's study pharmacist of the product hold/discontinuation by completing a **Study Product Hold/Resume/PK Supply/Re-Supply Slip** and delivering the white original to him/her. Retain the yellow clinic copy in the participant's study notebook. If the hold, discontinuation, or resumption affects product use in the CURRENT study period, complete/update the Product Hold/Discontinuation Log form (for holds/discontinuations, complete one form per reason). Refer to Protocol Section 9.4 and the SSP Manual, Section 10, for guidelines on holding, discontinuing or continuing with study product. Contact PSRT if there are any questions about study product or clinical management
23. \_\_\_\_\_ Provide condoms, offer panty liners, and provide referrals if needed/requested.
24. \_\_\_\_\_ Schedule the next visit and inform the participant of what to expect at that visit. Also inform the participant of availability of HIV/STI counseling, testing, and STI treatment for partners.
25. \_\_\_\_\_ Reinforce site contact information and instructions to contact the site to report symptoms — especially genital symptoms — and/or to request for additional information, HIV/STI counseling, and/or condoms, if needed, prior to the next visit.
26. \_\_\_\_\_ Provide study reimbursement.
27. \_\_\_\_\_ Remind participant to record on her appointment card (or other designated site-specific document) the date and time of the last three doses of study product she takes prior to next study visit. Also, remind participant to bring in unused product at next study visit.
28. \_\_\_\_\_ Complete **Follow-up Visit** form

## Follow-up Clinic Visits, Study Period 2 and 3 Start: Page 5 of 5

PTID:	Visit Date:
Please indicate to which follow-up visit this checklist applies: 7-Week: _____ 14-Week: _____	

### Additionally Only If Clinically Indicated (C1-C4):

- C1. \_\_\_\_\_ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe protein, leukocyte, and nitrites onto the **Safety Laboratory Results** form. Document other results (e.g., blood, glucose), if any, in visit chart note, or in other designated site-specific document, if applicable.
- C2. \_\_\_\_\_ Perform culture if positive for leukocyte esterase or nitrites; may omit if culture not standard of care for UTI diagnosis. Document additional work-up in visit chart note. If applicable, provide treatment and record treatment on the **Concomitant Medications Log**.
- C3. \_\_\_\_\_ Prepare urine for SDA for Gonorrhea and Chlamydia. Transcribe results onto the STI Laboratory Results form.
- C4. \_\_\_\_\_ Collect blood for Syphilis Serology and/or HBsAg. Transcribe results onto the **STI Laboratory Results** form.

29. \_\_\_\_\_ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-Data Fax forms:

Physical Exam  
Pelvic Exam Diagrams

30. \_\_\_\_\_ Complete and fax all required Data Fax forms to SCHARP Data Fax:

Follow-up Visit  
Follow-up Genital Symptoms  
Follow-up Pelvic Exam  
Family Planning Methods  
Safety Laboratory Results (when all results available)  
STI Laboratory Results (when all results are available)

As Needed:

## Follow-up Clinic Visits, Study Period 2 and 3 Start: Page 5 of 5

PTID:	Visit Date:
Please indicate to which follow-up visit this checklist applies: 7-Week: _____ 14-Week: _____	

Follow-up Medical History Log (update/add entries as needed)  
Pelvic Laboratory Results  
Concomitant Medications Log (required for updated or new pages)

Adverse Experience Log (required if any AEs identified or updated at this visit)  
Product Hold/Discontinuation Log (required if product use *in current study period* is held/discontinued or resumed at this visit)  
Pregnancy Report and History (required if pregnancy identified at this visit)  
Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)

Early Termination:

Termination  
End of Study Inventory

## Follow-up Clinic Visit, Study Termination Visit: Page 1 of 4

PTID: _____	Visit Date: _____
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1. \_\_\_\_\_ Complete participant registration, confirm the participant's identity, and verify her PTID.
2. \_\_\_\_\_ Review/update locator information.
3. \_\_\_\_\_ Review chart notes and other relevant documentation from previous visit(s).
4. \_\_\_\_\_ Review elements of informed consent as needed.
5. \_\_\_\_\_ Explain the content and sequence of procedures for today's visit.
6. \_\_\_\_\_ Collect 20-60 mL urine and:
  - 6a. \_\_\_\_\_ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
  - 6b. \_\_\_\_\_ Complete testing logs and transcribe result onto the form.

If the participant is pregnant:

  - 6e. \_\_\_\_\_ Complete a **Pregnancy Report and History** form.
  - 6f. \_\_\_\_\_ Explain to the participant that a post-study contact will be required to ascertain the outcome of her pregnancy.
7. \_\_\_\_\_ Collect any unused study product to return to pharmacy.
8. \_\_\_\_\_ Provide and explain available exam and lab test results from previous visit. Provide post-test counseling, if appropriate. Provide treatment for RTIs/STIs if needed. Document treatment on the **Concomitant Medications Log**.
9. \_\_\_\_\_ Administer the **Follow-up Genital Symptoms** form
10. \_\_\_\_\_ Perform interval medical/menstrual history; record findings on the **Follow-up Medical History** form. Record interval contraceptive/family planning method use and menstrual history in visit chart note.
  - 9a. \_\_\_\_\_ If genital blood/bleeding is reported, conduct a pelvic exam. Complete a **Genital Bleeding Assessment** form for unexpected genital bleeding.
11. \_\_\_\_\_ Review and update the **Concomitant Medications Log**.
12. \_\_\_\_\_ Complete the **Family Planning Methods** form by transcribing (from the visit chart note) the participant's current contraceptive/family planning methods.
13. \_\_\_\_\_ Provide contraceptive counseling. Provide/refer for contraception, if applicable.

## Follow-up Clinic Visit, Study Termination Visit: Page 2 of 4

PTID:	Visit Date:
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14. \_\_\_\_\_ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.
15. \_\_\_\_\_ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests. Contact PSRT if there are any questions about management.
16. \_\_\_\_\_ Review all **Adverse Experience Log** forms completed for the participant and update the forms as needed. For AEs that are "continuing" at this visit, update the status/outcome of the AE to "continuing at end of study participation."
- ☞ Any SAEs or EAEs identified as continuing at this visit must be re-evaluated within 30 days. Any previously reported AEs found to have increased in severity at this visit also must be re-evaluated in 30 days. Consult with the IoR/designee to establish a clinically appropriate follow-up plan for the participant and document the plan on the participant's file.*
17. \_\_\_\_\_ Provide HIV pre-test counseling; during pre-test counseling, reinforce that although this is the participant's last scheduled study visit, additional visits and tests will be done if needed to confirm or clarify her HIV status.
18. \_\_\_\_\_ Collect blood as follows:  
 plain tube(s) (no additive)  
 EDTA
19. \_\_\_\_\_ Complete an **LDMS Specimen Tracking Sheet** for stored samples.
20. \_\_\_\_\_ Prepare blood for testing/storage at the local lab.  
 HIV Serology  
 CBC (hemoglobin, hematocrit, WBC, PLT)  
 Serum Chemistries (Phosphorous, Creatinine)  
 Liver Function Tests (AST, ALT)  
 Plasma for storage
21. \_\_\_\_\_ If participant has been randomized to or selected for the In-Depth interview, is evaluable (i.e., does not meet criteria for replacement), and has given consent for participation, conduct the recorded in-depth interview.
22. \_\_\_\_\_ Provide HIV/STI risk reduction and male condom counseling. Also inform the participant of availability of HIV/STI counseling, testing, and STI treatment for partners.
23. \_\_\_\_\_ Provide condoms, and/or referrals if needed/requested.
24. \_\_\_\_\_ Complete **Follow-up Visit** form.

## Follow-up Clinic Visit, Study Termination Visit: Page 3 of 4

<b>PTID:</b>	<b>Visit Date:</b>
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25. \_\_\_\_\_ Completion **Termination** form.
26. \_\_\_\_\_ Complete **End of Study Inventory** form.
27. \_\_\_\_\_ Reinforce site contact information.
28. \_\_\_\_\_ Provide study reimbursement.

Additionally Only If Clinically Indicated (C1-C6):

- C1. \_\_\_\_\_ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe protein, leukocyte, and nitrites results onto the **Safety Laboratory Results** form. Document other results (e.g., blood, glucose), if any, in visit chart note, or in other designated site-specific document, if applicable.
- C2. \_\_\_\_\_ Perform if positive for leukocyte esterase or nitrites; may omit if culture not standard of care for UTI diagnosis. Document additional work-up in visit chart note. If applicable, provide treatment and record on the **Concomitant Medications Log** form.
- C3. \_\_\_\_\_ Prepare urine for SDA for Gonorrhea and Chlamydia. Transcribe results onto the **STI Laboratory Results** form.
- C4. \_\_\_\_\_ Collect blood for Syphilis Serology and/or HBsAg. Transcribe results onto the **STI Laboratory Results** form.
- C5. \_\_\_\_\_ Perform physical exam and complete non-DataFax **Physical Exam** form.
- C6. \_\_\_\_\_ Perform pelvic exam. Complete the **Follow-up Pelvic Exam** form and, if applicable, the Pelvic **Laboratory Results** form.

29. \_\_\_\_\_ If indicated, treat or refer any findings.
30. \_\_\_\_\_ Schedule next visit to provide the participant with any remaining lab test results, to provide counseling if indicated, and to follow-up on any AEs, if indicated.
31. \_\_\_\_\_ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-Data Fax form:

LDMS Specimen Tracking Sheet

## Follow-up Clinic Visit, Study Termination Visit: Page 4 of 4

PTID:	Visit Date:
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32. \_\_\_\_\_ Complete and fax all required Data Fax forms to SCHARP Data Fax:

Termination  
Follow-up Visit  
Family Planning Methods  
STI Laboratory Results  
End of Study Inventory  
Follow-up Genital Symptoms  
Safety Laboratory Results (when all results available)

As Needed:

Follow-up Medical History Log (update/add new entries as needed)  
Concomitant Medications Log (required for updated or new pages)  
Adverse Experience Log (required if any AEs identified or updated at this visit)  
Pregnancy Report and History (required if pregnancy identified at this visit)  
Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)

➤ *Note: Once the Study Termination Visit is completed, complete the MTN 001 Study Exit worksheet.*

**Pelvic Exam**  
**Screening, Enrollment, 6-week, 13-week, 20-week**  
**Page 1 of 2**

<b>PTID:</b>	<b>Visit Date:</b>
<b>Please indicate to which visit this checklist applies:</b>	
<b>Screening :</b> _____ <b>Enrollment:</b> _____ <b>6-week:</b> _____ <b>13-week:</b> _____ <b>20-week:</b> _____	

1. \_\_\_\_\_ Explain the exam procedures to the participant and answer any participant questions.
2. \_\_\_\_\_ Using a pencil, write the PTID and specimen collection date on the frosted side of two microscope slides for vaginal wet mount. Then affix a SCHARP-provided PTID label to the other side of each slide (under the pencil markings) and write the specimen collection date in ink on each label.
3. \_\_\_\_\_ Affix a SCHARP-provided PTID label to a glass or plastic tube containing approximately six drops (100 µL) of saline. Write the specimen collection date in ink on the label.
4. \_\_\_\_\_ Position and drape the participant comfortably.
5. \_\_\_\_\_ Palpate inguinal lymph nodes. Document abnormal findings on the **Screening and Enrollment Pelvic Exam** form or the **Follow-up Pelvic Exam** form at follow-up visits.
6. \_\_\_\_\_ Inspect external genitalia: Note all findings on the Pelvic Exam Diagrams. Document abnormal findings on the **Screening and Enrollment Pelvic Exam** form or the **Follow-up Pelvic Exam** form at follow-up visits.
7. \_\_\_\_\_ Insert speculum, using warm water as lubricant if needed. Observe general state and note the position of the cervix.
8. \_\_\_\_\_ Assess for homogenous discharge. Record observation on the **Pelvic Laboratory Results** form.
9. \_\_\_\_\_ Inspect cervix and vagina: Note all findings on the **Pelvic Exam Diagrams** form. Document abnormal findings on the **Screening and Enrollment Pelvic Exam** form or the **Follow-up Pelvic Exam** form at follow-up visits.
10. \_\_\_\_\_ **Screening Visit only:** If indicated, perform Pap smear per site SOP.
11. \_\_\_\_\_ **Screening Visit only:** Record the size of speculum used and position of the participant's cervix on the **Pelvic Exam Diagrams** (non-DataFax) form.
12. \_\_\_\_\_ Collect vaginal fluids from the lateral vaginal wall via swab and swab fluids onto the pH strip. Record pH on the **Pelvic Laboratory Results** form.

**Pelvic Exam**  
**Screening, Enrollment, 6-week, 13-week, 20-week**  
**Page 2 of 2**

PTID:	Visit Date:
Please indicate to which visit this checklist applies:	
Screening : _____ Enrollment: _____ 6-week: _____ 13-week: _____ 20-week: _____	

13. \_\_\_\_\_ Swab vaginal fluids from the lateral vaginal wall for wet prep; proceed immediately to Step 13a or place the swab in a labeled glass or plastic tube containing approximately six drops (100 µL) of saline to allow for non-immediate slide preparation and evaluation, as follows (see also SSP Section 12):
- 13a. \_\_\_\_\_ Smear vaginal fluids from the swab onto two labeled slides.
  - 13b. \_\_\_\_\_ Apply KOH to one slide, perform whiff test, then apply cover slip.
  - 13c. \_\_\_\_\_ Apply saline to the second slide, emulsify, then apply cover slip. Immediately evaluate for trichomonads, yeast buds, pseudohyphae, and clue cells.
  - 13d. \_\_\_\_\_ Evaluate KOH slide for yeast buds and pseudohyphae.
  - 13e. \_\_\_\_\_ If slides are read in-clinic by clinical staff, record results directly onto the **Pelvic Laboratory Results** form. If slides are read by lab staff (either in the local lab or a designated in-clinic lab area) complete testing logs and then transcribe results onto the **Pelvic Laboratory Results** form.

*For screening and enrollment visits: If lab results are positive for trichomonads, yeast buds, pseudohyphae and/or clue cells, the participant is ineligible, with the exception of asymptomatic BV and asymptomatic vulvovaginal candidiasis. STOP. Inform the participant that she is ineligible. Otherwise eligible participants diagnosed with RTI and/or UTI may be enrolled after completing treatment and all symptoms have resolved. Retain documentation completed thus far, and complete the form, but do not fax any forms to SCHARP.*

14. \_\_\_\_\_ Perform bimanual exam, if indicated. Document abnormal findings on the **Screening and Enrollment Pelvic Exam** form or the **Follow-up Pelvic Exam** form at follow-up visits.
15. \_\_\_\_\_ **6- week, 13-week and 20-week visits only:**
- 15a. \_\_\_\_\_ Collect CVL sample, cytologic brush specimens, and vaginal biopsies for pK analysis. Genital samples should be collected within 15 minutes of blood collection for pK analysis.
- NOTE: Blood may be collected prior to or following genital sample collection; genital sample collection must follow all other pelvic exam/lab procedures. CVL samples need to be placed on ice immediately and then frozen.*
16. \_\_\_\_\_ **For Bronx site only at 6- week, 13-week and 20-week visits only:**
- 16a. \_\_\_\_\_ Collect rectal samples for pK analysis within 15 minutes *after* vaginal pK sample collection; put on ice for up to 4 hours, then freeze.
17. \_\_\_\_\_ At **Enrollment visit only**: collect CVL sample.

**Pelvic Exam**  
**3-week, 7-week, 10-week, 14-week, 17-week**  
**Page 1 of 1**

<b>PTID:</b>	<b>Visit Date:</b>
<b>Please indicate to which visit this checklist applies:</b>	
<b>3-Week :</b> _____ <b>7-Week:</b> _____ <b>10-week:</b> _____ <b>14-week:</b> _____ <b>17-week:</b> _____	

1. \_\_\_\_\_ Explain the exam procedures to the participant and answer any participant questions.
2. \_\_\_\_\_ Position and drape the participant comfortably.
3. \_\_\_\_\_ Palpate inguinal lymph nodes. Document abnormal findings on the **Follow-up Pelvic Exam** form.
4. \_\_\_\_\_ Inspect external genitalia: Note all findings on the **Pelvic Exam Diagrams** form. Document abnormal findings on the **Follow-up Pelvic Exam** form.
5. \_\_\_\_\_ Insert speculum, using warm water as lubricant if needed. Observe general state and note the position of the cervix.
6. \_\_\_\_\_ Assess for homogenous discharge. If indicated, perform wet mount and complete the **Pelvic Laboratory Results** form.
7. \_\_\_\_\_ Inspect cervix and vagina: Note all findings on the **Pelvic Exam Diagrams** (non-DataFax) **form**. Document abnormal findings on the **Follow-up Pelvic Exam** form.
8. \_\_\_\_\_ If indicated, perform Herpes culture (at sites where standard of care for diagnosis)
9. \_\_\_\_\_ Perform bimanual exam, if indicated. Document abnormal findings on the **Follow-up Pelvic Exam** form.