

# 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-003 study visits. The checklists also specify the data collection forms that must be completed at each visit.

## 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 of this manual 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 screening visits, enter the screening attempt number in the top section of the checklist.
- For follow-up visits, enter the visit code 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 CORE (FHI), 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. Screening procedures are listed in protocol Sections 7.2 and 7.3.
- Informed consent for enrollment must be obtained before any study enrollment or follow-up procedures are performed. Enrollment procedures are listed in protocol Section 7.4. Follow-up procedures are listed in protocol Section 7.5. Note that informed consent for enrollment may be obtained before eligibility criteria are reassessed as part of final screening procedures (protocol section 7.4.1). This will limit venipuncture to a single blood draw during the Enrollment visit for purposes of HIV serology and plasma archive.
- On the day of enrollment, random assignment must take place after administration of the Baseline Behavior Assessment form, Baseline Audio Computer Assisted Self-Interview (ACASI) Questionnaire, collection of blood for plasma archive, and administration of Hepatitis B vaccine, if applicable.
- Pelvic exam procedures must be performed in the sequence shown on the pelvic exam checklists.
- At follow-up visits, behavioral assessment forms and ACASI questionnaires must be administered prior to the delivery of HIV and adherence counseling.

<b>PTID:</b>		<b>Visit Date:</b>																		
<b>Screening Attempt:</b>		<b>Visit Code: 1.0</b>																		
<b>Initials</b>		<b>Procedures</b>																		
	1. Confirm identity per site SOPs and determine whether a VOICE PTID has previously been assigned to participant.																			
	2. Determine screening attempt number: <input type="checkbox"/> First attempt ⇒ determine recruitment source and document per site SOPs. <input type="checkbox"/> Second or other attempt ⇒ CONTINUE.																			
	3. Check for co-enrollment in other studies per site SOPs: <input type="checkbox"/> NOT enrolled in another study ⇒ CONTINUE. <input type="checkbox"/> Enrolled in another study ⇒ STOP. NOT ELIGIBLE.																			
	4. Determine whether participant is of legal age to provide informed consent for research per site SOPs: <input type="checkbox"/> Of legal age ⇒ CONTINUE. <input type="checkbox"/> NOT of legal age ⇒ STOP. NOT ELIGIBLE.																			
	5. Explain, conduct, and document screening informed consent process per site SOPs: <input type="checkbox"/> Willing and able to provide written informed consent ⇒ CONTINUE. <input type="checkbox"/> NOT willing and able to provide written informed consent ⇒ STOP. NOT ELIGIBLE.																			
	6. Assign a VOICE PTID (if not done during a previous screening attempt).																			
	7. Determine last possible enrollment date for this screening attempt:  <div style="text-align: center;"> <table style="border-collapse: collapse; margin: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="width: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="width: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> </tr> <tr> <td colspan="2" style="text-align: center;">DD</td> <td></td> <td colspan="2" style="text-align: center;">MON</td> <td></td> <td colspan="2" style="text-align: center;">YY</td> </tr> </table> </div>												DD			MON			YY	
DD			MON			YY														
	8. Explain procedures to be performed at today's visit.																			
	9. Administer Demographics form.																			
	10. Administer Screening Part 1 Eligibility form: <input type="checkbox"/> ELIGIBLE thus far ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE ⇒ STOP.																			
	11. If applicable, refer participant for site medical officer review of tuberculosis status.																			
These items are structured for sites that perform urine testing in-clinic. Sites that perform testing in the lab should modify this item as needed.	12. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <input type="checkbox"/> NOT pregnant ⇒ CONTINUE. <input type="checkbox"/> Pregnant ⇒ STOP. NOT ELIGIBLE.																			
	13. Perform dipstick urinalysis for protein, glucose, nitrites and LE; complete testing logs; transcribe results onto Safety Laboratory Results form: <input type="checkbox"/> If 2+ or greater for protein OR glucose ⇒ STOP. NOT ELIGIBLE. <input type="checkbox"/> If 1+ for protein OR glucose, dipstick must be repeated at Screening Part 2 ⇒ CONTINUE. <input type="checkbox"/> If positive for nitrites and LE, treat for UTI per site SOPs only if participant has urinary symptoms. Document in chart notes. Participant must complete treatment and be free of symptoms prior to enrollment ⇒ CONTINUE. <input type="checkbox"/> Otherwise ⇒ CONTINUE.																			

<b>PTID:</b>	<b>Visit Date:</b>
<b>Screening Attempt:</b>	<b>Visit Code: 1.0</b>
<b>Initials</b>	<b>Procedures</b>
	14. Refrigerate remaining urine for gonorrhea and chlamydia SDA.
This item is structured for sites that perform HIV testing in clinic. Sites that perform in-lab testing should modify this item as needed.	15. Provide and document HIV counseling and testing per site SOPs: <ul style="list-style-type: none"> <li><input type="checkbox"/> Provide HIV pre-test counseling</li> <li><input type="checkbox"/> Provide HIV/STI risk reduction counseling and condoms</li> <li><input type="checkbox"/> Collect blood:                         <ul style="list-style-type: none"> <li><input type="checkbox"/> 1 x 6 mL lavender top (EDTA) tube</li> <li><input type="checkbox"/> 1 x 5 mL red top (no additive) tube</li> <li><input type="checkbox"/> 1 x 10 mL red top (no additive) tube</li> </ul> </li> </ul> <div style="background-color: #ffff00; padding: 5px; margin-left: 150px; width: fit-content;">                     Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes.                 </div> <ul style="list-style-type: none"> <li><input type="checkbox"/> Perform and document two rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off of both results.</li> <li><input type="checkbox"/> Provide test results and post-test counseling:                         <ul style="list-style-type: none"> <li><input type="checkbox"/> If both tests negative ⇒ UNINFECTED ⇒ ELIGIBLE ⇒ CONTINUE.</li> <li><input type="checkbox"/> If both tests positive ⇒ INFECTED ⇒ STOP. NOT ELIGIBLE.</li> <li><input type="checkbox"/> If one test positive and one test negative ⇒ DISCORDANT ⇒ PAUSE ⇒ WB is required ⇒ continue OR defer screening until HIV status is clarified.</li> </ul> </li> <li><input type="checkbox"/> Provide referrals if needed/requested.</li> <li><input type="checkbox"/> Offer HIV counseling and testing for partner(s).</li> <li><input type="checkbox"/> Transcribe results onto Screening and Enrollment HIV Test Results form.</li> </ul>
	17. Measure and document participant weight per site SOPs. Transcribe onto Safety Laboratory Results form.
	18. Determine whether participant has current RTI/STI symptoms: <ul style="list-style-type: none"> <li><input type="checkbox"/> No symptoms ⇒ CONTINUE.</li> <li><input type="checkbox"/> Symptom(s) present ⇒ evaluate per site SOPs and document in chart notes ⇒ CONTINUE.</li> </ul>
	19. Provide and explain all available findings and results.
	20. If RTI/STI is diagnosed, provide treatment and offer testing and/or treatment for partners if indicated; document in chart notes. Participant must complete treatment and be free of symptoms prior to enrollment. CONTINUE.
	21. Determine current contraceptive method, review study contraception requirements, and provide contraceptive counseling; document per site SOPs.
	22. [Prescribe/provide/refer for] contraception if indicated per site SOP; document in chart notes.

<b>PTID:</b>	<b>Visit Date:</b>
<b>Screening Attempt:</b>	<b>Visit Code: 1.0</b>
<b>Initials</b>	<b>Procedures</b>
	23. Obtain locator information and determine adequacy per site SOPs: <input type="checkbox"/> Adequate locator information ⇒ CONTINUE. <input type="checkbox"/> Inadequate locator information ⇒ PAUSE and re-assess: <input type="checkbox"/> Adequate information likely to be available prior to enrollment ⇒ CONTINUE. <input type="checkbox"/> Adequate information NOT likely to be available ⇒ STOP. NOT ELIGIBLE.
	24. Provide study informational material: [add site-specific list if desired]
	25. Provide contact information and instructions to contact the site for additional information and/or counseling if needed before the next visit.
	26. Schedule next visit.
	27. Provide reimbursement.
	28. Ensure chart notes, Screening Consent DataFax form, and all other required visit documentation is completed (hold all DataFax forms until enrollment).
	29. Review all visit documentation.
	30. Enter participant in co-enrollment database.

## Between Screening Part 1 and Screening Part 2 Worksheet

<b>PTID:</b>	<b>Screening Attempt:</b>
<b>Initials &amp; Date</b>	<b>Procedures</b>
	<p>1. Review, grade, and assess clinical significance of Screening Part 1 lab results:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Complete blood count</li> <li><input type="checkbox"/> Liver function tests (AST, ALT)</li> <li><input type="checkbox"/> Renal function tests (phosphate, creatinine)</li> <li><input type="checkbox"/> Calculated creatinine clearance rate</li> <li><input type="checkbox"/> Syphilis serology</li> <li><input type="checkbox"/> Gonorrhea SDA</li> <li><input type="checkbox"/> Chlamydia SDA</li>   <li><input type="checkbox"/> If indicated, HIV WB</li> </ul>
	<p>2. Hepatitis B test results may not be available before Screening Part 2. If results are received, review, grade, and assess clinical significance and clinical status:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> HBsAg+ and HBsAb- ⇒ not eligible for study ⇒ counsel and refer</li> <li><input type="checkbox"/> HBsAg- and HBsAb- ⇒ Hep B susceptible ⇒ offer vaccine if enroll</li> <li><input type="checkbox"/> HBsAg- and HBsAb+ ⇒ not Hep B susceptible ⇒ vaccine not indicated</li> </ul>
	<p>3. Complete laboratory test result case report forms (hold forms until enrollment):</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Safety Laboratory Results</li> <li><input type="checkbox"/> STI Laboratory Results</li> </ul> <p>If indicated:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Screening and Enrollment HIV Test Results (if HIV WB was done)</li> </ul>
	<p>4. Assess eligibility based on lab results:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Eligible</li> <li><input type="checkbox"/> Not Eligible ⇒ specify:</li> </ul>
	<p>5. Assess clinical management and referral needs:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> No action needed</li> <li><input type="checkbox"/> Action needed ⇒ specify:</li> </ul>
	<p>6. Complete additional QC/QA review of Screening Part 1 and subsequent documentation per site SOPs.</p>
	<p>7. Perform eligibility review of all Screening Part 1 data per site SOPs:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Eligible</li> <li><input type="checkbox"/> Not Eligible ⇒ specify:</li> </ul>

<b>PTID:</b>	<b>Visit Date:</b>																	
<b>Screening Attempt:</b>	<b>Visit Code: 2.0</b>																	
<b>Initials</b>	<b>Procedures</b>																	
	1. Confirm participant identity and PTID per site SOPs.																	
	2. Check for co-enrollment in other studies per site SOPs: <input type="checkbox"/> NOT enrolled in another study ⇒ CONTINUE. <input type="checkbox"/> Enrolled in another study ⇒ STOP. NOT ELIGIBLE.																	
	3. Review previous visit documentation.																	
	4. Verify current screening attempt number and confirm last possible enrollment date for this attempt:  <div style="text-align: center;"> <table style="border: none; margin: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="width: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="width: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> </tr> <tr> <td colspan="2" style="text-align: center;">DD</td> <td></td> <td colspan="2" style="text-align: center;">MON</td> <td></td> <td colspan="2" style="text-align: center;">YY</td> </tr> </table> </div>										DD			MON			YY	
DD			MON			YY												
	5. Provide and explain all prior screening test results. Provide post-test counseling if HIV WB was performed at Screening Part 1.																	
	6. Explain current eligibility status and procedures to be performed at today's visit: <input type="checkbox"/> ELIGIBLE thus far ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP. Provide clinical management as needed. Document in chart notes.																	
	7. Review/update locator information and re-assess adequacy per site SOPs: <input type="checkbox"/> Adequate locator information ⇒ CONTINUE. <input type="checkbox"/> Inadequate locator information ⇒ PAUSE and re-assess: <input type="checkbox"/> Adequate information likely to be available prior to enrollment ⇒ CONTINUE. <input type="checkbox"/> Adequate information NOT likely to be available ⇒ STOP. NOT ELIGIBLE.																	
This item is structured for sites that perform urine testing in-clinic. Sites that perform in-lab testing should modify this item as needed.	8. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <input type="checkbox"/> NOT pregnant ⇒ CONTINUE. <input type="checkbox"/> Pregnant ⇒ STOP. NOT ELIGIBLE.																	
	9. Retain aliquot of urine used for pregnancy testing for possible dipstick urinalysis (see #10-12). Refrigerate remaining urine for possible additional testing (e.g., SDA).																	
	10. Review participant's Screening Part 1 dipstick urinalysis results and determine if participant has current urinary symptoms.																	
	11. If 1+ for protein or glucose was identified at Screening Part 1, perform dipstick urinalysis for these analytes; complete testing logs; transcribe results onto Safety Laboratory Results form: <input type="checkbox"/> If 2+ or greater for protein OR glucose ⇒ STOP. NOT ELIGIBLE. <input type="checkbox"/> If 1+ for protein at this visit and 1+ for protein at Screening Part 1 ⇒ STOP. NOT ELIGIBLE. <input type="checkbox"/> If 1+ for glucose at this visit and 1+ for glucose at Screening Part 1 ⇒ STOP. NOT ELIGIBLE. <input type="checkbox"/> Otherwise ⇒ ELIGIBLE ⇒ CONTINUE.																	

<b>PTID:</b>	<b>Visit Date:</b>
<b>Screening Attempt:</b>	<b>Visit Code: 2.0</b>
<b>Initials</b>	<b>Procedures</b>
	12. If 1+ proteinuria detected at today’s visit, or if participant has urinary symptoms, perform dipstick urinalysis for nitrites and LE; complete testing logs; transcribe results onto Safety Laboratory Results form: <input type="checkbox"/> If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs. Participant must complete treatment and be free of symptoms prior to enrollment ⇒ CONTINUE. <input type="checkbox"/> Otherwise ⇒ CONTINUE.
	13. Collect baseline medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs.
	14. Perform physical exam with measurement of height and weight; document per site SOPs.
	15. Perform and document pelvic exam per Screening Pelvic Exam Checklist.
Items 16-20 could be done while awaiting pelvic lab test results.	16. If indicated, collect and prepare blood for syphilis serology.
	17. If indicated, collect and prepare blood for other testing needed to determine eligibility (specify):
	18. If indicated, prepare urine for gonorrhea and chlamydia SDA.
	19. Verify current contraceptive method, review study contraception requirements, and provide contraceptive counseling; document per site SOPs.
	20. [Prescribe/provide] contraception if indicated per site SOPs. Update baseline reproductive history documentation and Contraceptives Log form if applicable.
	21. Provide and explain available exam findings and lab test results.
	22. If STI/RTI is diagnosed, provide treatment and offer testing and/or treatment for partners if applicable; document per site SOPs. Participant must complete treatment and be free of symptoms prior to enrollment. CONTINUE.
	24. Administer Screening Part 2/Enrollment Behavioral Eligibility form.
	25. Assess participant’s current eligibility status: <input type="checkbox"/> ELIGIBLE thus far ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ⇒ PAUSE ⇒ perform and document all clinically indicated procedures. Schedule Enrollment Visit when participant is likely to be eligible. <input type="checkbox"/> NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP. Provide clinical management as needed. Document in chart notes.
	26. Provide HIV/STI risk reduction counseling and condoms. Offer HIV counseling and testing for partner(s).



<b>PTID:</b>	<b>Visit Date:</b>
<b>Screening Attempt:</b>	<b>Visit Code: 2.0</b>
<b>Initials</b>	<b>Procedures</b>
	27. Provide study informational material: [add site-specific list if desired]
	28. Provide contact information and instructions to contact the site for information and/or counseling if needed before the next visit.
	29. Schedule next visit.
	30. Provide reimbursement.
	31. Ensure chart notes and all other required visit documentation is completed (hold all DataFax forms until enrollment)
	32. Review all visit documentation.
	33. If applicable, update participant record in co-enrollment database.

<b>PTID:</b>		<b>Exam Date:</b>	
<b>Screening Attempt:</b>		<b>Visit Code:</b>	
<b>Initials</b>	<b>Procedures</b>		
	Review relevant documentation from previous and current visits.		
	Prepare exam equipment and specimen collection supplies; label as needed.		
	Explain exam procedures to participant and answer any questions.		
	Position and drape participant comfortably.		
	Palpate inguinal lymph nodes; identify all normal and abnormal findings.		
	Inspect external genitalia; identify all normal and abnormal findings.		
	Insert speculum, using warm water as lubricant if needed.		
	Inspect cervix and vagina; identify all normal and abnormal findings.		
	<b>If clinically indicated</b> , collect vaginal fluid for rapid BV test. Using the cotton swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube.		
	Collect vaginal fluid for rapid trichomonas test. Using the rayon swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube.		
	Collect vaginal fluid (1 swab) from lateral vaginal wall for Gram stain at MTN NL. Roll swab across two labeled slides and air dry.		
	<b>If clinically indicated</b> , collect vaginal fluid (1 swab) from lateral vaginal wall for KOH wet mount for candidiasis. Place swab in labeled tube (saline) and cap tube.		
	Collect vaginal fluid (1 dacron swab) from posterior fornix for biomarker analyses at MTN NL. After tip of swab is saturated, place in labeled cryovial (PBS) and cap vial.		
	Collect vaginal fluid (1 swab) from lateral vaginal wall for pH assessment. Swab fluid onto pH strip. Record pH on Vaginal Test Results form.		
	Collect endocervical cells for biomarker analyses at MTN NL: <ul style="list-style-type: none"> <li>• Remove cervical mucus with large cotton swab to expose cell layer (discard swab).</li> <li>• Insert dacron swab ~1 cm into endocervical canal and rotate two full turns.</li> <li>• Withdraw swab, place in labeled cryovial (PBS), and cap vial.</li> </ul>		
	Collect ecto- and endocervical cells for Pap smear per site SOPs. ⇒ NOT required if documented normal Pap within 12 months prior to enrollment		
	Remove speculum and perform bimanual exam.		
	Document exam per site SOPs: <ul style="list-style-type: none"> <li>• Record all exam findings on Pelvic Exam Diagrams form.</li> <li>• Record abnormal exam findings on Screening and Enrollment Pelvic Exam form.</li> <li>• Record all pelvic specimen test results on Vaginal Test Results form.</li> </ul>		
	Record slides and swabs collected for assessment at the MTN NL on LDMS Specimen Tracking Sheet and Specimen Storage/PK form.		

## Between Screening Part 2 and Enrollment Worksheet

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<b>PTID:</b>	<b>Screening Attempt:</b>
<b>Initials &amp; Date</b>	<b>Procedures</b>
	1. If applicable per site SOPs, verify participant's locator information and re-assess adequacy based on verifiable information; document per site SOPs.
	2. Based on the Screening Part 2/Enrollment Behavioral Eligibility form, and other associated documentation, review participant eligibility re: locator information, last pregnancy outcome, breastfeeding, and contraception: <input type="checkbox"/> Eligible <input type="checkbox"/> Not Eligible ⇒ specify:
	2. If Hepatitis B test results were not available before Screening Part 2, review, grade, and assess clinical significance and clinical status: <input type="checkbox"/> HBsAg+ and HBsAb- ⇒ not eligible for study ⇒ counsel and refer <input type="checkbox"/> HBsAg- and HBsAb- ⇒ Hep B susceptible ⇒ offer vaccine if enroll <input type="checkbox"/> HBsAg- and HBsAb+ ⇒ not Hep B susceptible ⇒ vaccine not indicated
Items related to Pap smears may be deleted at sites not doing these tests.	3. Review, grade, and assess the clinical significance of Pap test result (either result report from Pap collected at Screening Part 2 or documented Pap within 12 months prior to enrollment).
	4. Review, grade, and assess the clinical significance of the results of any clinically indicated lab tests performed at Screening Part 2: <input type="checkbox"/> No clinically indicated lab tests performed <input type="checkbox"/> Clinically indicated lab tests performed ⇒ specify:
	5. Complete laboratory test result case report forms (hold forms until enrollment): <input type="checkbox"/> Pap Test Result If indicated: <input type="checkbox"/> Safety Laboratory Results <input type="checkbox"/> STI Laboratory Results
	6. Complete Screening Part 2 Medical Eligibility form and assess eligibility based on all available clinical and laboratory findings and results: <input type="checkbox"/> Eligible <input type="checkbox"/> Not Eligible ⇒ specify:

**Between Screening Part 2 and Enrollment Worksheet**  
**Page 2 of 2**

<b>PTID:</b>		<b>Screening Attempt:</b>	
<b>Initials &amp; Date</b>		<b>Procedures</b>	
		7. Assess clinical management and referral needs: <input type="checkbox"/> No action needed <input type="checkbox"/> Action needed ⇒ specify:	
		8. Complete additional QC/QA review of Screening Part 2 and subsequent documentation per site SOPs.	
		9. Perform eligibility review of all Screening Part 1 and Screening Part 2 data per site SOPs: <input type="checkbox"/> Eligible <input type="checkbox"/> Not Eligible ⇒ specify:	

<b>PTID:</b>	<b>Visit Date:</b>																		
<b>Screening Attempt:</b>	<b>Visit Code: 3.0</b>																		
<b>Initials</b>	<b>Procedures</b>																		
	1. Confirm participant identity and PTID per site SOPs																		
	2. Check for co-enrollment in other studies per site SOPs: <input type="checkbox"/> NOT enrolled in another study ⇒ CONTINUE. <input type="checkbox"/> Enrolled in another study ⇒ STOP. NOT ELIGIBLE.																		
	3. Review previous visit documentation.																		
	4. Verify current screening attempt number and confirm last possible enrollment date for this attempt:  <div style="text-align: center;"> <table style="border: none; margin: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="width: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="width: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> <td style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></td> </tr> <tr> <td style="text-align: center;">DD</td> <td></td> <td style="text-align: center;">MON</td> <td></td> <td></td> <td style="text-align: center;">YY</td> <td></td> <td></td> <td></td> </tr> </table> </div>										DD		MON			YY			
DD		MON			YY														
	5. Provide and explain all prior screening test results.																		
	6. Explain current eligibility status and procedures to be performed at today's visit: <input type="checkbox"/> ELIGIBLE thus far ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ⇒ PAUSE ⇒ perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible. <input type="checkbox"/> NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP. Provide clinical management as needed. Document in chart notes.																		
	7. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <input type="checkbox"/> NOT pregnant ⇒ CONTINUE. <input type="checkbox"/> Pregnant ⇒ STOP. NOT ELIGIBLE.																		
These items are structured for sites that perform urine testing in-clinic. Sites that perform in-lab testing should modify these items as needed.	8. Retain aliquot of urine used for pregnancy testing for possible dipstick urinalysis (see #9-11). Refrigerate remaining urine for possible additional testing (e.g., SDA).																		
	9. Review participant's Screening Part 1 and Screening Part 2 dipstick urinalysis results and determine if participant has current urinary symptoms.																		
	10. If 1+ for protein or glucose was identified at Screening Part 1, repeat testing should have been done at Screening Part 2. If repeat testing was not done at Screening Part 2, or if 1+ for protein or glucose was newly identified at Screening Part 2, perform dipstick urinalysis for these analytes; complete testing logs and transcribe results onto Safety Laboratory Results form: <input type="checkbox"/> If 2+ or greater for protein OR glucose ⇒ STOP. NOT ELIGIBLE. <input type="checkbox"/> If 1+ for protein at this visit and 1+ for protein at either Screening Part 1 OR Screening Part 2 ⇒ STOP. NOT ELIGIBLE. <input type="checkbox"/> If 1+ for glucose at this visit and 1+ for glucose at either Screening Part 1 OR Screening Part 2 ⇒ STOP. NOT ELIGIBLE. <input type="checkbox"/> Otherwise ⇒ ELIGIBLE ⇒ CONTINUE.																		

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	<p>11. If 1+ proteinuria detected at today's visit, or if participant has urinary symptoms, perform dipstick urinalysis for nitrites and LE; complete testing logs; transcribe results onto Safety Laboratory Results form:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Participant must complete treatment and be free of symptoms prior to enrollment ⇒ PAUSE. NOT ELIGIBLE. ⇒ Schedule another Enrollment Visit when participant is likely to be eligible.</li> <li><input type="checkbox"/> Otherwise ⇒ CONTINUE.</li> </ul>
<p>This item is structured for sites that perform HIV testing in clinic. Sites that perform in-lab testing should modify this item as needed.</p>	<p>12. Provide and document HIV counseling and testing per site SOPs:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Provide HIV pre-test counseling</li> <li><input type="checkbox"/> Provide HIV/STI risk reduction counseling and condoms</li> <li><input type="checkbox"/> Collect 4 mL blood in lavender top (EDTA) tube <span style="float: right; font-size: small;">4 mL is approximate. Tailor to reflect site-specific volume.</span></li> <li><input type="checkbox"/> Perform and document two rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off of both results.</li> <li><input type="checkbox"/> Provide test results and post-test counseling: <ul style="list-style-type: none"> <li><input type="checkbox"/> If both tests negative ⇒ UNINFECTED ⇒ ELIGIBLE ⇒ CONTINUE.</li> <li><input type="checkbox"/> If both tests positive ⇒ INFECTED ⇒ STOP. NOT ELIGIBLE.</li> <li><input type="checkbox"/> If one test positive and one test negative ⇒ DISCORDANT ⇒ PAUSE ⇒ WB is required ⇒ defer further screening until HIV status is clarified.</li> </ul> </li> <li><input type="checkbox"/> Provide referrals if needed/requested.</li> <li><input type="checkbox"/> Offer HIV counseling and testing for partner(s).</li> <li><input type="checkbox"/> Transcribe results onto Screening and Enrollment HIV Test Results form.</li> </ul>
	<p>13. Review/update locator information and re-assess adequacy per site SOPs:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Adequate locator information ⇒ CONTINUE.</li> <li><input type="checkbox"/> Inadequate locator information ⇒ STOP. NOT ELIGIBLE.</li> </ul>
	<p>14. Actively review participant's baseline medical and menstrual history, current medications, and current contraceptives to verify and/or update all information recorded at Screening Part 2. Document all updates on relevant source documents and case report forms.</p>
	<p>15. If clinically indicated or otherwise required to confirm eligibility, perform pelvic exam and associated lab tests:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> No exclusionary findings identified ⇒ CONTINUE.</li> <li><input type="checkbox"/> Exclusionary finding(s) identified but likely to resolve within this screening attempt ⇒ PAUSE. NOT ELIGIBLE. ⇒ Perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible.</li> <li><input type="checkbox"/> Exclusionary finding(s) identified and NOT likely to resolve within this screening attempt ⇒ NOT ELIGIBLE. STOP. Provide clinical management as needed. Document in chart notes.</li> </ul>
	<p>16. Provide and explain available exam and lab test results.</p>

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	17. Provide any clinically indicated treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.
	18. Review study contraception requirements and provide contraceptive counseling; document per site SOPs.
	19. [Prescribe/provide] contraception if indicated per site SOPs. Update baseline reproductive history documentation and Contraceptives Log form if applicable.
	20. Administer Screening Part 2/Enrollment Behavioral Eligibility form: <input type="checkbox"/> ELIGIBLE ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE ⇒ STOP.
	21. Reinforce co-enrollment guidelines and provide associated information and counseling as needed; document in chart notes.
	22. Review all screening documentation, complete Enrollment Medical Eligibility form, and determine eligibility: <input type="checkbox"/> ELIGIBLE ⇒ CONTINUE ⇒ proceed to eligibility verification per site SOPs. <input type="checkbox"/> NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ⇒ PAUSE ⇒ perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible. <input type="checkbox"/> NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP. Provide clinical management as needed. Document in chart notes.
This item refers to verification of eligibility and should be completed by a staff member other than the person who determines eligibility per the previous item.	23. Verify participant eligibility per site SOPs: <input type="checkbox"/> ELIGIBLE ⇒ CONTINUE ⇒ proceed to enrollment informed consent process. <input type="checkbox"/> NOT ELIGIBLE ⇒ STOP. Provide clinical management as needed. Document in chart notes.
	24. Explain, conduct, and document enrollment informed consent process per site SOPs: <input type="checkbox"/> Willing and able to provide written informed consent ⇒ CONTINUE. <input type="checkbox"/> NOT willing and able to provide written informed consent ⇒ STOP. NOT ELIGIBLE.  <i>The Enrollment Informed Consent may be administered early in the visit to allow for one blood draw. If this is done, it must clearly be explained to the participant that eligibility will be determined after signing the Enrollment ICF and this does not guarantee enrollment into the study. Sites should only include this process early in the enrollment visit if they intend to move to one blood draw at enrollment.</i>
	25. Explain, conduct, and document specimen storage informed consent process per site SOPs.
	26. Administer Baseline Behavior Assessment form.
	27. Administer Enrollment ACASI Questionnaire.
	28. Collect 10 mL blood in lavender top (EDTA) tube; refrigerate pending delivery to lab for plasma archive. <i>Note: This blood collection may be collected earlier in the visit if the Enrollment ICF is administered earlier in the visit. See note in item #24.</i>
	29. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.

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	30. If participant is susceptible (HBsAg- and HBsAb-), offer Hepatitis B vaccine: <input type="checkbox"/> Participant accepted; vaccine was administered; document per site SOPs and record on Concomitant Medications Log form. <input type="checkbox"/> Participant refused; refusal was documented.
	31. Verify documentation of enrollment informed consent and assign next sequential Clinic Randomization Envelope to participant per site SOPs. <b>PARTICIPANT IS NOW ENROLLED IN THE STUDY.</b>
	32. Open the assigned envelope and confirm that the envelope number printed on the prescription contained in the envelope corresponds with the number on the outside of the envelope. Inform participant of her assignment (gel or tablets).
	33. Complete prescription.
	34. Give completed white original prescription to participant to bring to pharmacy to obtain study product. Retain envelope and yellow copy of prescription in participant's study notebook.
	35. Verify participant received study product. Review product use instructions with participant in detail, using visual aids as needed.
	36. Ask participant if she has any questions about the product use instructions. If so, address each question.
	37. Ask participant if she is ready to [insert her gel] / [take her tablets] now. <input type="checkbox"/> If yes, proceed. <input type="checkbox"/> If no, note and address all questions and concerns, then proceed.  _____ _____ _____ _____
	38. First product use: <input type="checkbox"/> For participants assigned to gel, provide a private space for gel insertion, while standing by in case participant needs assistance; remind participant to discard the wrapper and applicator in the bin provided. <input type="checkbox"/> For participants assigned to tablets, a private space is not required; remind participant to discard the bottle seals and cotton wool in the bin provided.



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	<p>39. De-brief with participant about her first study product use experience:</p> <ul style="list-style-type: none"> <li>• Was she able to [insert gel] / [take the lighter tablet and the darker tablet]?</li> <li>• Did she have any difficulties?</li> <li>• Does she have any questions about how to use her product at home?</li> <li>• Does she have any concerns about using her product at home?</li> <li>• Would she like any additional information or instructions?</li> </ul> <p><input type="checkbox"/> If no problems or questions or concerns, proceed.</p> <p><input type="checkbox"/> If yes, note and address all questions and concerns, then proceed.</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
	40. Provide adherence counseling per Enrollment Adherence Counseling checklist; document per site SOPs.
	<p>41. Schedule next visit and remind participant to:</p> <ul style="list-style-type: none"> <li>• Record menstrual bleeding days on appointment card</li> <li>• Record date and time of last product use on appointment card</li> <li>• Bring appointment card to next visit</li> <li>• Bring all unused study product to next visit</li> <li>• Bring any other medication she is taking to next visit</li> </ul>
	42. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.
	43. Provide reimbursement.
	44. Ensure that chart notes, Enrollment form, Pre-Existing Conditions form, Baseline Family Planning form, and all other required visit documentation is completed.
	45. Review all visit documentation.
	46. Update participant entries in co-enrollment database.

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	47. Fax all required DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <li><input type="checkbox"/> Screening Consent</li> <li><input type="checkbox"/> Demographics</li> <li><input type="checkbox"/> Screening and Enrollment HIV Test Results (completed at Screening Part 1)</li> <li><input type="checkbox"/> Screening and Enrollment HIV Test Results (completed at Enrollment)</li> <li><input type="checkbox"/> Safety Laboratory Results</li> <li><input type="checkbox"/> STI Laboratory Results</li> <li><input type="checkbox"/> Screening and Enrollment Pelvic Exam</li> <li><input type="checkbox"/> Vaginal Test Results</li> <li><input type="checkbox"/> Pap Test Results</li> <li><input type="checkbox"/> Specimen Storage/PK (completed at Screening Part 2)</li> <li><input type="checkbox"/> Specimen Storage/PK (completed at Enrollment)</li> <li><input type="checkbox"/> Enrollment</li> <li><input type="checkbox"/> Pre-Existing Conditions</li> <li><input type="checkbox"/> Concomitant Medications Log</li> <li><input type="checkbox"/> Contraceptives Log</li> <li><input type="checkbox"/> Baseline Family Planning</li> <li><input type="checkbox"/> Baseline Behavior Assessment</li> </ul>
	48. Back-up ACASI questionnaire data.
	49. Upload ACASI questionnaire data to SCHARP.

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	1. Confirm participant identity and PTID per site SOPs.	
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: <input type="checkbox"/> NOT enrolled in another study. <input type="checkbox"/> Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.	
	3. Instruct participant to return unused study product to pharmacy.	
	4. Review previous visit documentation.	
	5. Review elements of informed consent as needed.	
	6. Explain procedures to be performed at today’s visit.	
	7. Review/update locator information.	
	8. Administer Monthly Product Adherence and Behavior Assessment form.	
	9. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <input type="checkbox"/> NOT pregnant. <input type="checkbox"/> Pregnant, pregnancy first identified at a previous visit: <input type="checkbox"/> Continue to HOLD study product (complete #25 accordingly). <input type="checkbox"/> If applicable, refer to MTN-016; document in chart notes. <input type="checkbox"/> Pregnant, pregnancy newly identified at today’s visit: <input type="checkbox"/> HOLD study product (complete #25 accordingly). If applicable, arrange to collect product not returned today within 5 working days. <input type="checkbox"/> Initiate Pregnancy Management Worksheet <input type="checkbox"/> Complete Pregnancy Report and History form.	
	10. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #15). Refrigerate remaining urine for possible additional testing (e.g., SDA).	
	11. Administer Monthly Symptoms form.	
	12. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs.	
	13. Provide contraceptive counseling; document per site SOPs.	
	14. [Prescribe/provide] contraception if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.	

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	<p>15. Perform dipstick urinalysis:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only.</li> <li><input type="checkbox"/> If participant has urinary symptoms, test for protein, glucose, nitrites, and LE.                             <ul style="list-style-type: none"> <li>⇒ If 1+ or greater for protein, nitrites and LE also should be tested.</li> <li>⇒ If 1+ or greater for protein or glucose, product HOLD may be required; see protocol Sections 9.6 and 9.7.</li> <li>⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.</li> </ul> </li> </ul>	
	16. Perform physical exam including weight measurement; document per site SOPs.	
	17. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic Exam Checklist.	
	18. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #23-24).	
	19. Provide and explain all available findings and results.	
	20. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.	
	21. If indicated, administer Hepatitis B vaccine; document per site SOPs.	
	22. If required based on all available information, complete AE Log form(s).	
	<p>23. Provide and document HIV counseling and testing per site SOPs:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Provide HIV pre-test counseling</li> <li><input type="checkbox"/> Provide HIV/STI risk reduction counseling and condoms</li> <li><input type="checkbox"/> Collect blood:                             <ul style="list-style-type: none"> <li><input type="checkbox"/> 1 x 5 mL lavender top (EDTA) tube</li> <li><input type="checkbox"/> 1 x 5 mL red top (no additive) tube</li> </ul>                             [additional blood needed for clinically indicated testing also may be collected at this time]                         </li> <li><input type="checkbox"/> Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off.</li> <li><input type="checkbox"/> Provide test results and post-test counseling:                             <ul style="list-style-type: none"> <li><input type="checkbox"/> All tests negative.</li> <li><input type="checkbox"/> At least one test positive ⇒ HOLD study product (complete #25 accordingly). If applicable, arrange to collect product not returned today within 24 hours.</li> </ul> </li> <li><input type="checkbox"/> Provide referrals if needed/requested.</li> <li><input type="checkbox"/> Offer HIV counseling and testing for partner(s).</li> <li><input type="checkbox"/> Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.</li> </ul>	

Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes.

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	24. Prepare remaining blood for required testing: <ul style="list-style-type: none"> <li>• Liver and renal function tests (AST, ALT, phosphate, creatinine)</li> </ul> If clinically indicated: <ul style="list-style-type: none"> <li>• Complete blood count</li> <li>• Syphilis serology</li> <li>• Hepatitis B surface antigen</li> <li>• Hepatitis B surface antibody</li> <li>• Plasma archive (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)</li> </ul>	
	25. Assess eligibility to continue product use: <ul style="list-style-type: none"> <li><input type="checkbox"/> ELIGIBLE:                         <ul style="list-style-type: none"> <li><input type="checkbox"/> Review Unused Product Returns slip completed by pharmacy staff.</li> <li><input type="checkbox"/> Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs.</li> <li><input type="checkbox"/> Schedule next visit.</li> <li><input type="checkbox"/> Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED.</li> <li><input type="checkbox"/> Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant’s study notebook.</li> </ul> </li> <li><input type="checkbox"/> NOT ELIGIBLE:                         <ul style="list-style-type: none"> <li><input type="checkbox"/> Schedule next visit</li> <li><input type="checkbox"/> Complete Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow copy in participant’s study notebook (<i>NA if hold initiated at previous visit</i>).</li> <li><input type="checkbox"/> Complete Product/Hold Discontinuation Log form (<i>NA if hold initiated at previous visit</i>).</li> </ul> </li> </ul>	
	26. Reinforce scheduling of next visit and remind participant to: <ul style="list-style-type: none"> <li>• Record menstrual bleeding days on appointment card</li> <li>• Record date and time of last product use on appointment card</li> <li>• Bring appointment card to next visit</li> <li>• Bring all unused study product to next visit</li> <li>• Bring any other medication she is taking to next visit</li> </ul>	
	27. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.	
	28. Provide reimbursement.	
	29. Ensure that chart notes and all other required visit documentation is completed.	

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	<p>30. Fax all required DataFax forms to SCHARP DataFax:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Follow-up Visit</li> <li><input type="checkbox"/> Monthly Product Adherence and Behavior Assessment</li> <li><input type="checkbox"/> Monthly Symptoms</li> <li><input type="checkbox"/> Follow-up HIV Rapid Test Results</li> <li><input type="checkbox"/> Follow-up Family Planning</li> <li><input type="checkbox"/> Product Returns</li> <li><input type="checkbox"/> Product Re-supply and Re-issues</li> <li><input type="checkbox"/> Safety Laboratory Results</li> </ul> <p>If Applicable:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Concomitant Medications Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Contraceptives Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Follow-up Pelvic Exam</li> <li><input type="checkbox"/> Vaginal Test Results</li> <li><input type="checkbox"/> Pap Test Results</li> <li><input type="checkbox"/> STI Laboratory Results</li> <li><input type="checkbox"/> HIV Western Blot Test Results</li> <li><input type="checkbox"/> Specimen Storage/PK</li> <li><input type="checkbox"/> Seroconverter Laboratory Test Results</li> <li><input type="checkbox"/> Product Hold/Discontinuation Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Adverse Experience Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Pregnancy Report and History</li> <li><input type="checkbox"/> Pregnancy Outcome</li> </ul>	

PTID:	Visit Date:	Visit Code:
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	1. Confirm participant identity and PTID per site SOPs.	
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: <input type="checkbox"/> NOT enrolled in another study. <input type="checkbox"/> Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.	
	3. Instruct participant to return unused study product to pharmacy.	
	4. Review previous visit documentation.	
	5. Review elements of informed consent as needed.	
	6. Explain procedures to be performed at today’s visit.	
	7. Review/update locator information.	
	8. Administer Monthly Product Adherence and Behavior Assessment form.	
	9. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <input type="checkbox"/> NOT pregnant. <input type="checkbox"/> Pregnant, pregnancy first identified at a previous visit: <input type="checkbox"/> Continue to HOLD study product. <input type="checkbox"/> If applicable, refer to MTN-016; document in chart notes. <input type="checkbox"/> Pregnant, pregnancy newly identified at today’s visit: <input type="checkbox"/> HOLD study product (complete #26 accordingly). If applicable, arrange to collect product not returned today within 5 working days. <input type="checkbox"/> Initiate Pregnancy Management Worksheet. <input type="checkbox"/> Complete Pregnancy Report and History form.	
	10. Retain aliquot of urine used for pregnancy testing for possible dipstick urinalysis (see #15). Refrigerate remaining urine for possible additional testing (e.g., SDA).	
	11. Administer Monthly Symptoms form.	
	12. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs.	
	13. Provide contraceptive counseling; document per site SOPs.	
	14. [Prescribe/provide] contraception if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.	
	15. If clinically indicated, perform dipstick urinalysis for protein, glucose, nitrites, and/or LE: ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If 1+ or greater for protein or glucose, product HOLD may be required; see protocol Sections 9.6 and 9.7. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.	

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	16. If clinically indicated, measure weight; document per site SOPs.	
	17. If clinically indicated, perform physical exam; document per site SOPs.	
	18. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic Exam Checklist.	
	19. Determine if any other clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #24-25).	
	20. Provide and explain all available findings and results.	
	21. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.	
	22. If indicated, administer Hepatitis B vaccine; document per site SOPs.	
	23. If required based on all available information, complete AE Log form(s).	
	24. Provide and document HIV counseling and testing per site SOPs: <ul style="list-style-type: none"> <li><input type="checkbox"/> Provide HIV pre-test counseling</li> <li><input type="checkbox"/> Provide HIV/STI risk reduction counseling and condoms</li> <li><input type="checkbox"/> Collect 5 mL blood in lavender top (EDTA) tube [additional blood needed for clinically indicated testing also may be collected at this time]</li> <li><input type="checkbox"/> Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off.</li> <li><input type="checkbox"/> Provide test results and post-test counseling:                             <ul style="list-style-type: none"> <li><input type="checkbox"/> All tests negative.</li> <li><input type="checkbox"/> At least one test positive ⇒ HOLD study product (complete #26 accordingly). If applicable, arrange to collect product not returned today within 24 hours.</li> </ul> </li> <li><input type="checkbox"/> Provide referrals if needed/requested.</li> <li><input type="checkbox"/> Offer HIV counseling and testing for partner(s).</li> <li><input type="checkbox"/> Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.</li> </ul>	
	25. If clinically indicated, prepare blood for additional testing; tests that may be clinically indicated include: <ul style="list-style-type: none"> <li>• Liver function tests (AST, ALT)</li> <li>• Renal function tests (phosphate, creatinine)</li> <li>• Complete blood count</li> <li>• Syphilis serology</li> <li>• Hepatitis B surface antigen</li> <li>• Hepatitis B surface antibody</li> <li>• Plasma archive (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)</li> </ul>	





<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code:</b>
<b>Initials</b>	<b>Procedures</b>	
	<p>31. Fax all required DataFax forms to SCHARP DataFax:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Follow-up Visit</li> <li><input type="checkbox"/> Monthly Product Adherence and Behavior Assessment</li> <li><input type="checkbox"/> Monthly Symptoms</li> <li><input type="checkbox"/> Follow-up HIV Rapid Test Results</li> <li><input type="checkbox"/> Follow-up Family Planning</li> <li><input type="checkbox"/> Product Returns</li> <li><input type="checkbox"/> Product Re-supply and Re-issues</li> </ul> <p>If Applicable:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Concomitant Medications Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Contraceptives Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Follow-up Pelvic Exam</li> <li><input type="checkbox"/> Vaginal Test Results</li> <li><input type="checkbox"/> Pap Test Results</li> <li><input type="checkbox"/> STI Laboratory Results</li> <li><input type="checkbox"/> Safety Laboratory Results</li> <li><input type="checkbox"/> HIV Western Blot Test Results</li> <li><input type="checkbox"/> Specimen Storage/PK</li> <li><input type="checkbox"/> Seroconverter Laboratory Test Results</li> <li><input type="checkbox"/> Product Hold/Discontinuation Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Adverse Experience Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Pregnancy Report and History</li> <li><input type="checkbox"/> Pregnancy Outcome</li> </ul>	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>		
<b>Procedures</b>		
	1. Confirm participant identity and PTID per site SOPs.	
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: <input type="checkbox"/> NOT enrolled in another study. <input type="checkbox"/> Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.	
	3. Instruct participant to return unused study product to pharmacy.	
	4. Review previous visit documentation.	
	5. Review elements of informed consent as needed.	
	6. Explain procedures to be performed at today’s visit.	
	7. Review/update locator information.	
	8. Administer the appropriate (Oral <u>or</u> Vaginal) Product Adherence and Behavior Assessment form.	
	9. Determine date and time of last study product use and record on Specimen Storage/PK form. Collect and file participant source document if available.	
	10. Administer the appropriate follow-up ACASI Questionnaire.	
	11. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <input type="checkbox"/> NOT pregnant. <input type="checkbox"/> Pregnant, pregnancy first identified at a previous visit: <input type="checkbox"/> Continue to HOLD study product. <input type="checkbox"/> If applicable, refer to MTN-016; document in chart notes. <input type="checkbox"/> Pregnant, pregnancy newly identified at today’s visit: <input type="checkbox"/> HOLD study product (complete #28 accordingly). If applicable, arrange to collect product not returned today within 5 working days. <input type="checkbox"/> Initiate Pregnancy Management Worksheet. <input type="checkbox"/> Complete Pregnancy Report and History form.	
	12. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #17). Refrigerate remaining urine for possible additional testing (e.g., SDA).	
	13. Administer Monthly Symptoms form.	
	14. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs.	
	15. Provide contraceptive counseling; document per site SOPs.	
	16. [Prescribe/provide] contraception if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.	

PTID:	Visit Date:	Visit Code:
Initials	Procedures	
	17. Perform dipstick urinalysis: <input type="checkbox"/> If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only. <input type="checkbox"/> If participant has urinary symptoms, test for protein, glucose, nitrites, and LE. ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If 1+ or greater for protein or glucose, product HOLD may be required; see protocol Sections 9.6 and 9.7. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.	
	18. Perform physical exam including weight measurement; document per site SOPs.	
	19. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic Exam Checklist.	
	20. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #25-26).	
	21. Provide and explain all available findings and results.	
	22. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.	
	23. If indicated, administer Hepatitis B vaccine; document per site SOPs.	
	24. If required based on all available information, complete AE Log form(s).	
	25. Provide and document HIV counseling and testing per site SOPs:  <input type="checkbox"/> Provide HIV pre-test counseling <input type="checkbox"/> Provide HIV/STI risk reduction counseling and condoms  <input type="checkbox"/> Collect blood: <input type="checkbox"/> 1 x 10 mL lavender top (EDTA) tube <input type="checkbox"/> 1 x 5 mL lavender top (EDTA) tube <input type="checkbox"/> 1 x 5 mL red top (no additive) tube [additional blood needed for clinically indicated testing also may be collected at this time]  <input type="checkbox"/> Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off.  <input type="checkbox"/> Provide test results and post-test counseling: <input type="checkbox"/> All tests negative. <input type="checkbox"/> At least one test positive ⇒ HOLD study product (complete #28 accordingly). If applicable, arrange to collect product not returned today within 24 hours.  <input type="checkbox"/> Provide referrals if needed/requested. <input type="checkbox"/> Offer HIV counseling and testing for partner(s). <input type="checkbox"/> Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.	

Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes.

PTID:	Visit Date:	Visit Code:
Initials	Procedures	
	26. Prepare remaining blood for required testing: <ul style="list-style-type: none"> <li>• Liver and renal function tests (AST, ALT, phosphate, creatinine)</li> <li>• Plasma archive</li> </ul> If clinically indicated: <ul style="list-style-type: none"> <li>• Complete blood count</li> <li>• Syphilis serology</li> <li>• Hepatitis B surface antigen</li> <li>• Hepatitis B surface antibody</li> <li>• Plasma archive (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)</li> </ul>	
	27. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.	
	28. Assess eligibility to continue product use: <ul style="list-style-type: none"> <li><input type="checkbox"/> ELIGIBLE:                             <ul style="list-style-type: none"> <li><input type="checkbox"/> Review Unused Product Returns slip completed by pharmacy staff.</li> <li><input type="checkbox"/> Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs.</li> <li><input type="checkbox"/> Schedule next visit.</li> <li><input type="checkbox"/> Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED.</li> <li><input type="checkbox"/> Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant’s study notebook.</li> </ul> </li> <li><input type="checkbox"/> NOT ELIGIBLE:                             <ul style="list-style-type: none"> <li><input type="checkbox"/> Schedule next visit</li> <li><input type="checkbox"/> Complete Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow copy in participant’s study notebook (<i>NA if hold initiated at previous visit</i>).</li> <li><input type="checkbox"/> Complete Product/Hold Discontinuation Log form (<i>NA if hold initiated at previous visit</i>).</li> </ul> </li> </ul>	
	29. Reinforce scheduling of next visit and remind participant to: <ul style="list-style-type: none"> <li>• Record menstrual bleeding days on appointment card</li> <li>• Bring appointment card to next visit</li> <li>• Bring all unused study product to next visit</li> <li>• Bring any other medication she is taking to next visit</li> </ul>	
	30. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.	
	31. Provide reimbursement.	
	32. Ensure that chart notes and all other required visit documentation is completed.	

PTID:	Visit Date:	Visit Code:
<b>Procedures</b>		
<b>Initials</b>		
	33. Fax all required DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <li><input type="checkbox"/> Follow-up Visit</li> <li><input type="checkbox"/> Oral <u>or</u> Vaginal Product Adherence and Behavior Assessment</li> <li><input type="checkbox"/> Monthly Symptoms</li> <li><input type="checkbox"/> Follow-up HIV Rapid Test Results</li> <li><input type="checkbox"/> Follow-up Family Planning</li> <li><input type="checkbox"/> Product Returns</li> <li><input type="checkbox"/> Product Re-supply and Re-issues</li> <li><input type="checkbox"/> Safety Laboratory Results</li> <li><input type="checkbox"/> Specimen Storage/PK</li> </ul> If Applicable: <ul style="list-style-type: none"> <li><input type="checkbox"/> Concomitant Medications Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Contraceptives Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Follow-up Pelvic Exam</li> <li><input type="checkbox"/> Vaginal Test Results</li> <li><input type="checkbox"/> Pap Test Results</li> <li><input type="checkbox"/> STI Laboratory Results</li> <li><input type="checkbox"/> HIV Western Blot Test Results</li> <li><input type="checkbox"/> Seroconverter Laboratory Test Results</li> <li><input type="checkbox"/> Product Hold/Discontinuation Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Adverse Experience Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Pregnancy Report and History</li> <li><input type="checkbox"/> Pregnancy Outcome</li> </ul>	
	34. Back-up ACASI questionnaire data.	
	35. Upload ACASI questionnaire data to SCHARP.	

# Follow-up Pelvic Exam

conducted semiannually, at PUEV, and when clinically indicated

PTID:	Exam Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	Review relevant documentation from previous and current visits.	
	Prepare exam equipment and specimen collection supplies; label as needed.	
	Explain exam procedures to participant and answer any questions.	
	Position and drape participant comfortably.	
	Palpate inguinal lymph nodes; identify all normal and abnormal findings.	
	Inspect external genitalia; identify all normal and abnormal findings.	
	Insert speculum, using warm water as lubricant if needed.	
	Inspect cervix and vagina; identify all normal and abnormal findings.	
	<b>If clinically indicated</b> , collect vaginal fluid for rapid BV test. Using the cotton swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube.	
	<b>Annually, at PUEV, and when clinically indicated</b> , collect vaginal fluid for rapid trichomonas test. Using the rayon swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube.	
	<b>Semi-Annually, Annually, and at PUEV</b> , collect vaginal fluid (1 swab) from lateral vaginal wall for Gram stain at MTN NL. Roll swab across two labeled slides and air dry.	
	<b>If clinically indicated</b> , collect vaginal fluid (1 swab) from lateral vaginal wall for KOH wet mount for candidiasis. Place swab in labeled tube (saline) and cap tube.	
	<b>At all exams</b> , collect vaginal fluid (1 dacron swab) from posterior fornix for biomarker analyses at MTN NL. After tip of swab is saturated, place in labeled cryovial (PBS) and cap vial.	
	<b>At all exams</b> , collect vaginal fluid (1 swab) from lateral vaginal wall for pH assessment. Swab fluid onto pH strip. Record pH on Vaginal Test Results form.	
	<b>At all exams</b> , collect endocervical cells for biomarker analyses at MTN NL: <ul style="list-style-type: none"> <li>• Remove cervical mucus with large cotton swab to expose cell layer (discard swab).</li> <li>• Insert dacron swab ~1 cm into endocervical canal and rotate two full turns.</li> <li>• Withdraw swab, place in labeled cryovial (PBS), and cap vial.</li> </ul>	
	<b>At PUEV and when clinically indicated</b> , collect ecto- and endocervical cells for Pap smear per site SOPs.	
	Remove speculum and perform bimanual exam.	
	Document exam per site SOPs: <ul style="list-style-type: none"> <li>• Record all exam findings on Pelvic Exam Diagrams form.</li> <li>• Record abnormal exam findings on Follow-Up Pelvic Exam form.</li> <li>• Record all pelvic specimen test results on Vaginal Test Results form.</li> </ul>	
	Record slides and swabs collected for assessment at the MTN NL on LDMS Specimen Tracking Sheet and Specimen Storage/PK form.	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	1. Confirm participant identity and PTID per site SOPs.	
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: <input type="checkbox"/> NOT enrolled in another study. <input type="checkbox"/> Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.	
	3. Instruct participant to return unused study product to pharmacy.	
	4. Review previous visit documentation.	
	5. Review elements of informed consent as needed.	
	6. Explain procedures to be performed at today's visit.	
	7. Review/update locator information.	
	8. Administer the appropriate (Oral <u>or</u> Vaginal) Product Adherence and Behavior Assessment form.	
	9. Determine date and time of last study product use and record on Specimen Storage/PK form. Collect and file participant source document if available.	
	10. Administer the appropriate follow-up ACASI Questionnaire.	
	11. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <input type="checkbox"/> NOT pregnant. <input type="checkbox"/> Pregnant, pregnancy first identified at a previous visit: <input type="checkbox"/> Continue to HOLD study product. <input type="checkbox"/> If applicable, refer to MTN-016; document in chart notes. <input type="checkbox"/> Pregnant, pregnancy newly identified at today's visit: <input type="checkbox"/> HOLD study product (complete #28 accordingly). If applicable, arrange to collect product not returned today within 5 working days. <input type="checkbox"/> Initiate Pregnancy Management Worksheet. <input type="checkbox"/> Complete Pregnancy Report and History form.	
	12. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #17). Refrigerate remaining urine for possible additional testing (e.g., SDA).	
	13. Administer Monthly Symptoms form.	
	14. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs. Update Concomitant Medications Log and/or Contraceptives Log if applicable.	
	15. Provide contraceptive counseling; document per site SOPs.	
	16. [Prescribe/provide] contraceptives if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.	



PTID:	Visit Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	17. Perform dipstick urinalysis: <input type="checkbox"/> If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only. <input type="checkbox"/> If participant has urinary symptoms, test for protein, glucose, nitrites, and LE. ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If 1+ or greater for protein or glucose, product HOLD may be required; see protocol Sections 9.6 and 9.7. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.	
	18. Perform physical exam including weight and height measurements; document per site SOPs.	
	19. Perform and document pelvic exam per Follow-Up Pelvic Exam Checklist and site SOPs.	
	20. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #25-26).	
	21. Provide and explain all available findings and results.	
	22. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.	
	23. If indicated, administer Hepatitis B vaccine; document per site SOPs. Record the vaccination as a separate entry on the Concomitant Medications Log form, and indicate that the vaccine was given on the Follow-up Visit form.	
	24. If required based on all available information, complete AE Log form(s).	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>		
<b>Procedures</b>		
	<p>25. Provide and document HIV counseling and testing per site SOPs:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Provide HIV pre-test counseling</li> <li><input type="checkbox"/> Provide HIV/STI risk reduction counseling and condoms</li> <li><input type="checkbox"/> Collect blood:                             <ul style="list-style-type: none"> <li><input type="checkbox"/> 1 x 10 mL lavender top (EDTA) tube</li> <li><input type="checkbox"/> 1 x 5 mL lavender top (EDTA) tube</li> <li><input type="checkbox"/> 1 x 5 mL red top (no additive) tube</li> </ul> <div style="border: 1px solid black; background-color: #90EE90; padding: 5px; width: fit-content; margin-left: 100px;">                                 Volumes shown are approximate.                                  Tailor this item to reflect site-specific tube types and volumes.                             </div> <p>[additional blood needed for clinically indicated testing also may be collected at this time]</p> </li> <li><input type="checkbox"/> Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off.</li> <li><input type="checkbox"/> Provide test results and post-test counseling:                             <ul style="list-style-type: none"> <li><input type="checkbox"/> All tests negative.</li> <li><input type="checkbox"/> At least one test positive ⇒ HOLD study product (complete #28 accordingly). If applicable, arrange to collect product not returned today within 24 hours.</li> </ul> </li> <li><input type="checkbox"/> Provide referrals if needed/requested.</li> <li><input type="checkbox"/> Offer HIV counseling and testing for partner(s).</li> <li><input type="checkbox"/> Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.</li> </ul>	
	<p>26. Prepare remaining blood for required testing:</p> <ul style="list-style-type: none"> <li>• Complete blood count</li> <li>• Liver and renal function tests (AST, ALT, phosphate, creatinine)</li> <li>• Plasma archive</li> </ul> <p>If clinically indicated:</p> <ul style="list-style-type: none"> <li>• Syphilis serology</li> <li>• Hepatitis B surface antigen</li> <li>• Hepatitis B surface antibody</li> <li>• Plasma archive (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)</li> </ul>	
	<p>27. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.</p>	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	28. Assess eligibility to continue product use: <ul style="list-style-type: none"> <li><input type="checkbox"/> ELIGIBLE:               <ul style="list-style-type: none"> <li><input type="checkbox"/> Review Unused Product Returns Slip completed by pharmacy staff.</li> <li><input type="checkbox"/> Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs.</li> <li><input type="checkbox"/> Schedule next visit.</li> <li><input type="checkbox"/> Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED.</li> <li><input type="checkbox"/> Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant's study notebook.</li> </ul> </li> <li><input type="checkbox"/> NOT ELIGIBLE:               <ul style="list-style-type: none"> <li><input type="checkbox"/> Schedule next visit</li> <li><input type="checkbox"/> Complete Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow copy in participant's study notebook (<i>NA if hold is continuing from a previous visit</i>).</li> <li><input type="checkbox"/> Complete Product/Hold Discontinuation Log form (<i>NA if hold is continuing from a previous visit</i>).</li> </ul> </li> </ul>	
	29. Reinforce scheduling of next visit and remind participant to: <ul style="list-style-type: none"> <li>• Record menstrual bleeding days on appointment card</li> <li>• Bring appointment card to next visit</li> <li>• Bring all unused study product to next visit</li> <li>• Bring any other medication she is taking to next visit</li> </ul>	
	30. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.	
	31. Provide reimbursement.	
	32. Ensure that chart notes and all other required visit documentation is completed.	

<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code:</b>
<b>Initials</b>	<b>Procedures</b>	
	<p>33. Fax all required DataFax forms to SCHARP DataFax:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Follow-up Visit</li> <li><input type="checkbox"/> Oral <u>or</u> Vaginal Product Adherence and Behavior Assessment</li> <li><input type="checkbox"/> Monthly Symptoms</li> <li><input type="checkbox"/> Follow-up HIV Rapid Test Results</li> <li><input type="checkbox"/> Follow-up Family Planning</li> <li><input type="checkbox"/> Follow-up Pelvic Exam</li> <li><input type="checkbox"/> Product Returns and Dispensations</li> <li><input type="checkbox"/> Safety Laboratory Results</li> <li><input type="checkbox"/> Specimen Storage/PK</li> <li><input type="checkbox"/> Vaginal Test Results</li> </ul> <p>If Applicable:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Concomitant Medications Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Contraceptives Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Pap Test Result</li> <li><input type="checkbox"/> STI Laboratory Results</li> <li><input type="checkbox"/> HIV Western Blot Test Results</li> <li><input type="checkbox"/> Seroconverter Laboratory Test Results</li> <li><input type="checkbox"/> Product Hold/Discontinuation Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Adverse Experience Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Pregnancy Report and History</li> <li><input type="checkbox"/> Pregnancy Outcome</li> <li><input type="checkbox"/> Missed Visit</li> </ul>	
	34. Back-up ACASI questionnaire data.	
	35. Upload ACASI questionnaire data to SCHARP.	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	1. Confirm participant identity and PTID per site SOPs.	
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: <input type="checkbox"/> NOT enrolled in another study. <input type="checkbox"/> Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.	
	3. Instruct participant to return unused study product to pharmacy.	
	4. Review previous visit documentation.	
	5. Review elements of informed consent as needed.	
	6. Explain procedures to be performed at today's visit.	
	7. Review/update locator information.	
	8. Administer the Menstrual Practices and Study Disclosure Assessment form	
	9. Administer the appropriate (Oral <u>or</u> Vaginal) Product Adherence and Behavior Assessment form.	
	10. Determine date and time of last study product use and record on Specimen Storage/PK form. Collect and file participant source document if available.	
	11. Administer the appropriate follow-up ACASI Questionnaire.	
	12. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <input type="checkbox"/> NOT pregnant. <input type="checkbox"/> Pregnant, pregnancy first identified at a previous visit: <input type="checkbox"/> Continue to HOLD study product. <input type="checkbox"/> If applicable, refer to MTN-016; document in chart notes. <input type="checkbox"/> Pregnant, pregnancy newly identified at today's visit: <input type="checkbox"/> HOLD study product (complete #30 accordingly). If applicable, arrange to collect product not returned today within 5 working days. <input type="checkbox"/> Initiate Pregnancy Management Worksheet. <input type="checkbox"/> Complete Pregnancy Report and History form.	
	13. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #19).	
	14. Refrigerate remaining urine for gonorrhea and Chlamydia SDA testing.	
	15. Administer Monthly Symptoms form.	
	16. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs. Update Concomitant Medications Log and/or Contraceptives Log if applicable.	
	17. Provide contraceptive counseling; document per site SOPs.	
	18. [Prescribe/provide] contraceptives if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	19. Perform dipstick urinalysis: <input type="checkbox"/> If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only. <input type="checkbox"/> If participant has urinary symptoms, test for protein, glucose, nitrites, and LE. ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If 1+ or greater for protein or glucose, product HOLD may be required; see protocol Sections 9.6 and 9.7. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.	
	20. Perform physical exam including weight and height measurements; document per site SOPs.	
	21. Perform and document pelvic exam per Follow-Up Pelvic Exam Checklist and site SOPs.	
	22. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #27-28).	
	23. Provide and explain all available findings and results.	
	24. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.	
	25. If indicated, administer Hepatitis B vaccine; document per site SOPs. Record the vaccination as a separate entry on the Concomitant Medications Log form, and indicate that the vaccine was given on the Follow-up Visit form.	
	26. If required based on all available information, complete AE Log form(s).	

<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code:</b>
<b>Initials</b>	<b>Procedures</b>	
	<p>27. Provide and document HIV counseling and testing per site SOPs:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Provide HIV pre-test counseling</li> <li><input type="checkbox"/> Provide HIV/STI risk reduction counseling and condoms</li> <li><input type="checkbox"/> Collect blood:             <ul style="list-style-type: none"> <li><input type="checkbox"/> 1 x 10 mL lavender top (EDTA) tube</li> <li><input type="checkbox"/> 2 x 5 mL lavender top (EDTA) tube</li> <li><input type="checkbox"/> 2 x 5 mL red top (no additive) tube</li> </ul> <div style="border: 1px solid black; background-color: #90EE90; padding: 2px; margin-left: 20px;">                     Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes.                 </div> <p>[additional blood needed for clinically indicated testing also may be collected at this time]</p> </li> <li><input type="checkbox"/> Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off.</li> <li><input type="checkbox"/> Provide test results and post-test counseling:             <ul style="list-style-type: none"> <li><input type="checkbox"/> All tests negative.</li> <li><input type="checkbox"/> At least one test positive ⇒ HOLD study product (complete #30 accordingly). If applicable, arrange to collect product not returned today within 24 hours.</li> </ul> </li> <li><input type="checkbox"/> Provide referrals if needed/requested.</li> <li><input type="checkbox"/> Offer HIV counseling and testing for partner(s).</li> <li><input type="checkbox"/> Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.</li> </ul>	
	<p>28. Prepare remaining blood for required testing:</p> <ul style="list-style-type: none"> <li>• Complete blood count</li> <li>• Liver and renal function tests (AST, ALT, phosphate, creatinine)</li> <li>• Plasma archive</li> <li>• Syphilis serology</li> </ul> <p>If clinically indicated:</p> <ul style="list-style-type: none"> <li>• Hepatitis B surface antigen (required if susceptible but not vaccinated)</li> <li>• Hepatitis B surface antibody</li> <li>• Plasma archive (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)</li> </ul>	
	<p>29. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.</p>	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	<p>30. Assess eligibility to continue product use:</p> <p><input type="checkbox"/> ELIGIBLE:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Review Unused Product Returns Slip completed by pharmacy staff.</li> <li><input type="checkbox"/> Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs.</li> <li><input type="checkbox"/> Schedule next visit.</li> <li><input type="checkbox"/> Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED.</li> <li><input type="checkbox"/> Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant's study notebook.</li> </ul> <p><input type="checkbox"/> NOT ELIGIBLE:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Schedule next visit</li> <li><input type="checkbox"/> Complete Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow copy in participant's study notebook (<i>NA if hold is continuing from a previous visit</i>).</li> <li><input type="checkbox"/> Complete Product/Hold Discontinuation Log form (<i>NA if hold is continuing from a previous visit</i>).</li> </ul>	
	<p>31. Reinforce scheduling of next visit and remind participant to:</p> <ul style="list-style-type: none"> <li>• Record menstrual bleeding days on appointment card</li> <li>• Bring appointment card to next visit</li> <li>• Bring all unused study product to next visit</li> <li>• Bring any other medication she is taking to next visit</li> </ul>	
	<p>32. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.</p>	
	<p>33. Provide reimbursement.</p>	
	<p>34. Ensure that chart notes and all other required visit documentation is completed.</p>	



<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code:</b>
<b>Initials</b>	<b>Procedures</b>	
	<p>35. Fax all required DataFax forms to SCHARP DataFax:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Follow-up Visit</li> <li><input type="checkbox"/> Oral <u>or</u> Vaginal Product Adherence and Behavior Assessment</li> <li><input type="checkbox"/> Menstrual Practices and Study Disclosure Assessment</li> <li><input type="checkbox"/> Monthly Symptoms</li> <li><input type="checkbox"/> Follow-up HIV Rapid Test Results</li> <li><input type="checkbox"/> Follow-up Family Planning</li> <li><input type="checkbox"/> Follow-up Pelvic Exam</li> <li><input type="checkbox"/> Product Returns and Dispensations</li> <li><input type="checkbox"/> Safety Laboratory Results</li> <li><input type="checkbox"/> STI Laboratory Results</li> <li><input type="checkbox"/> Specimen Storage/PK</li> <li><input type="checkbox"/> Vaginal Test Results</li> </ul> <p>If Applicable:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Concomitant Medications Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Contraceptives Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Pap Test Result</li> <li><input type="checkbox"/> HIV Western Blot Test Results</li> <li><input type="checkbox"/> Seroconverter Laboratory Test Results</li> <li><input type="checkbox"/> Product Hold/Discontinuation Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Adverse Experience Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Pregnancy Report and History</li> <li><input type="checkbox"/> Pregnancy Outcome</li> <li><input type="checkbox"/> Missed Visit</li> </ul>	
	36. Back-up ACASI questionnaire data.	
	37. Upload ACASI questionnaire data to SCHARP.	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	1. Confirm participant identity and PTID per site SOPs.	
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: <input type="checkbox"/> NOT enrolled in another study. <input type="checkbox"/> Enrolled in another study ⇒ Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT.	
	3. Instruct participant to return unused study product to pharmacy.	
	4. Review previous visit documentation.	
	5. Review elements of informed consent as needed.	
	6. Explain procedures to be performed at today’s visit.	
	7. Review/update locator information.	
	8. Administer the Menstrual Practices and Study Disclosure Assessment form	
	9. Administer the appropriate (Oral <u>or</u> Vaginal) Product Adherence and Behavior Assessment form.	
	10. Determine date and time of last study product use and record on Specimen Storage/PK form. Collect and file participant source document if available.	
	11. Administer Perceived Product Assessment form. <ul style="list-style-type: none"> <li>• Clinician to complete item 1 or 2</li> </ul>	
	12. Administer the appropriate follow-up ACASI Questionnaire.	
	13. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <input type="checkbox"/> NOT pregnant. <input type="checkbox"/> Pregnant, pregnancy first identified at a previous visit: <input type="checkbox"/> If applicable, refer to MTN-016; document in chart notes. <input type="checkbox"/> Pregnant, pregnancy newly identified at today’s visit: <input type="checkbox"/> Initiate Pregnancy Management Worksheet. <input type="checkbox"/> Complete Pregnancy Report and History form.	
	14. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #20).	
	15. Refrigerate remaining urine for gonorrhea and Chlamydia SDA testing.	
	16. Administer Monthly Symptoms form.	
	17. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs. Update Concomitant Medications Log and/or Contraceptives Log if applicable.	
	18. Provide contraceptive counseling; document per site SOPs.	
	19. [Prescribe/provide] contraceptives if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	20. Perform dipstick urinalysis: <input type="checkbox"/> If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only. <input type="checkbox"/> If participant has urinary symptoms, test for protein, glucose, nitrites, and LE. ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.	
	21. Perform physical exam including weight and height measurements; document per site SOPs.	
	22. Perform and document pelvic exam per Follow-Up Pelvic Exam Checklist and site SOPs.	
	23. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #28-29).	
	24. Provide and explain all available findings and results.	
	25. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.	
	26. If indicated, administer Hepatitis B vaccine; document per site SOPs. Record the vaccination as a separate entry on the Concomitant Medications Log, and indicate that the vaccine was given on the Follow-up Visit form.	
	27. If required based on all available information, complete AE Log form(s).	
	28. Provide and document HIV counseling and testing per site SOPs:  <input type="checkbox"/> Provide HIV pre-test counseling <input type="checkbox"/> Provide HIV/STI risk reduction counseling and condoms  <input type="checkbox"/> Collect blood: <input type="checkbox"/> 1 x 10 mL lavender top (EDTA) tube <input type="checkbox"/> 2 x 5 mL lavender top (EDTA) tube <input type="checkbox"/> 3 x 5 mL red top (no additive) tube [additional blood needed for clinically indicated testing also may be collected at this time]  <input type="checkbox"/> Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off. <input type="checkbox"/> Provide test results and post-test counseling <input type="checkbox"/> Provide referrals if needed/requested. <input type="checkbox"/> Offer HIV counseling and testing for partner(s). <input type="checkbox"/> Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.	

Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes.

PTID:	Visit Date:	Visit Code:
<b>Initials</b>		
<b>Procedures</b>		
	29. Prepare remaining blood for required testing: <ul style="list-style-type: none"> <li>• Complete blood count</li> <li>• Liver and renal function tests (AST, ALT, phosphate, creatinine)</li> <li>• Plasma archive</li> <li>• Syphilis serology</li> <li>• Hepatitis B surface antigen</li> </ul> If clinically indicated: <ul style="list-style-type: none"> <li>• Hepatitis B surface antibody</li> <li>• Plasma archive (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)</li> </ul>	
	30. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.	
	31. If applicable, arrange to collect product not returned today within 2 working days.	
	32. Reinforce scheduling of next visit and remind participant to: <ul style="list-style-type: none"> <li>• Record menstrual bleeding days on appointment card</li> <li>• Bring appointment card to next visit</li> <li>• Bring any other medication she is taking to next visit</li> </ul> If considered an early termination visit: <ul style="list-style-type: none"> <li><input type="checkbox"/> Schedule a final study contact for disclosure of all remaining exam and lab test results.</li> <li><input type="checkbox"/> If applicable, schedule contact to ascertain the participant’s pregnancy outcome.</li> <li><input type="checkbox"/> If applicable, schedule clinically indicated follow-up for unresolved SAEs/EAEs and previously reported AEs found to have increased severity at this visit.</li> <li><input type="checkbox"/> Inform the participant of planned methods and timeframes for unblinding and dissemination of study results.</li> <li><input type="checkbox"/> Determine and document whether participant is willing to be contacted about future studies for which she may be eligible.</li> <li><input type="checkbox"/> Reinforce site contact information, update participant locator information, and determine participant preference for post-study contact.</li> </ul>	
	33. Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit.	
	34. Provide reimbursement.	
	35. Ensure that chart notes and all other required visit documentation is completed.	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>		
<b>Procedures</b>		
	<p>36. Fax all required DataFax forms to SCHARP DataFax:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Follow-up Visit</li> <li><input type="checkbox"/> Oral <u>or</u> Vaginal Product Adherence and Behavior Assessment</li> <li><input type="checkbox"/> Menstrual Practices and Study Disclosure Assessment</li> <li><input type="checkbox"/> Monthly Symptoms</li> <li><input type="checkbox"/> Pap Test Result</li> <li><input type="checkbox"/> Follow-up HIV Rapid Test Results</li> <li><input type="checkbox"/> Follow-up Family Planning</li> <li><input type="checkbox"/> Follow-up Pelvic Exam</li> <li><input type="checkbox"/> Perceived Product Assessment</li> <li><input type="checkbox"/> Product Returns and Dispensations</li> <li><input type="checkbox"/> Product Use End Visit</li> <li><input type="checkbox"/> Safety Laboratory Results</li> <li><input type="checkbox"/> STI Laboratory Results</li> <li><input type="checkbox"/> Specimen Storage/PK</li> <li><input type="checkbox"/> Vaginal Test Results</li> </ul> <p>If Applicable:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Concomitant Medications Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Contraceptives Log (new and/or updated form pages)</li> <li><input type="checkbox"/> HIV Western Blot Test Results</li> <li><input type="checkbox"/> Seroconverter Laboratory Test Results</li> <li><input type="checkbox"/> Adverse Experience Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Pregnancy Report and History</li> <li><input type="checkbox"/> Pregnancy Outcome</li> </ul>	
	<div style="background-color: #90EE90; padding: 5px; border: 1px solid black;"> <p>If the PUEV is not completed, <u>only the PPA and PEV forms</u> are to be completed. Do not complete a Missed Visit form or any other VOICE CRF for this visit.</p> </div>	
	37. Back-up ACASI questionnaire data.	
	38. Upload ACASI questionnaire data to SCHARP.	

**Note:** Use this checklist only for participants who are completing a scheduled Study Exit Visit approximately 8 weeks after their PUEV. If a participant is completing an early termination visit, use the PUEV checklist instead.

<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code: 89.0</b>
<b>Initials</b>	<b>Procedures</b>	
	1. Confirm participant identity and PTID per site SOPs.	
	2. Review previous visit documentation.	
	3. Review elements of informed consent as needed.	
	4. Explain procedures to be performed at today’s visit.	
	5. Review update locator information.	
	6. Administer the Menstrual Practices and Study Disclosure Assessment form.	
	7. Administer the Study Exit Behavior Assessment form.	
	8. Administer the Product hold/Discontinuers/SEV ACASI Questionnaire.	
	9. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: <input type="checkbox"/> NOT pregnant. <input type="checkbox"/> Pregnant, pregnancy first identified at a previous visit: <input type="checkbox"/> If applicable, refer to MTN-016; document in chart notes. <input type="checkbox"/> Pregnant, pregnancy newly identified at today’s visit: <input type="checkbox"/> Initiate Pregnancy Management Worksheet. <input type="checkbox"/> Complete Pregnancy Report and History form. <input type="checkbox"/> Explain to the participant that she will continue to be followed until the outcome of her pregnancy can be ascertained.	
	10. Retain aliquot of urine used for pregnancy testing for possible dipstick urinalysis (see #15). Refrigerate remaining urine for possible additional testing (e.g., SDA).	
	11. Administer Monthly Symptoms form.	
	12. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs. Update Concomitant Medications Log and/or Contraceptives Log if applicable. For medications/contraceptives that the participant continues to use at this visit, mark the “Continuing at end of study” box in the “Date Stopped” field.	
	13. Provide contraceptive counseling; document per site SOPs.	
	14. [Prescribe/provide] contraceptives if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.	
	15. If clinically indicated, perform dipstick urinalysis: <input type="checkbox"/> If participant has urinary symptoms, test for protein, glucose, nitrites, and LE. ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.	

<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code: 89.0</b>
<b>Initials</b>	<b>Procedures</b>	
	16. If clinically indicated, measure weight and/or perform physical exam. Document per site SOPs.	
	17. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic Exam Checklist and site SOPs.	
	18. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #24-25).	
	19. Provide and explain all available findings and results.	
	20. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.	
	21. If indicated, administer Hepatitis B vaccine; document per site SOPs. Record the vaccination as a separate entry on the Concomitant Medications Log, and indicate that the vaccine was given on the Follow-up Visit form.	
	22. If required based on all available information, complete AE Log form(s).	
	<p>23. 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.”</p> <p>Any SAEs/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.</p>	
	<p>24. Provide and document HIV counseling and testing per site SOPs:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Provide HIV pre-test counseling.</li> <li><input type="checkbox"/> Provide HIV/STI risk reduction counseling and condoms.</li> <li><input type="checkbox"/> Collect blood: <ul style="list-style-type: none"> <li><input type="checkbox"/> 1 x 10 mL lavender top (EDTA) tube</li> <li><input type="checkbox"/> 1 x 5 mL lavender top (EDTA) tube</li> </ul>                     [additional blood needed for clinically indicated testing also may be collected at this time]                 </li> <li><input type="checkbox"/> Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off.</li> <li><input type="checkbox"/> Provide test results and post-test counseling: <ul style="list-style-type: none"> <li><input type="checkbox"/> At least one test positive ⇒ Advise the participant that additional visits and tests may be needed to confirm or clarify her HIV status.</li> </ul> </li> <li><input type="checkbox"/> Provide referrals if needed/requested.</li> <li><input type="checkbox"/> Offer HIV counseling and testing for partner(s).</li> <li><input type="checkbox"/> Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.</li> </ul>	

<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code: 89.0</b>
<b>Initials</b>	<b>Procedures</b>	
	<p>25. Prepare remaining blood for required testing:</p> <ul style="list-style-type: none"> <li>• Plasma archive</li> </ul> <p>If clinically indicated:</p> <ul style="list-style-type: none"> <li>• Complete blood count</li> <li>• Liver and renal function tests (AST, ALT, phosphate, creatinine)</li> <li>• Syphilis serology</li> <li>• Hepatitis B surface antigen</li> <li>• Hepatitis B surface antibody</li> <li>• HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1)</li> <li>• CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)</li> </ul>	
	26. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.	
	<p>27. If the Termination and PUEV visits are conducted during the same visit, arrange to collect product not returned today within 2 working days. If Termination visit only, all study product should have already been collected prior to termination, so no product collection necessary.</p>	
	<p>28. Reinforce site contact information and:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> If applicable, schedule a final study contact for disclosure of all remaining exam and lab test results.</li> <li><input type="checkbox"/> If applicable, schedule contact to ascertain the participant's pregnancy outcome.</li> <li><input type="checkbox"/> If applicable, schedule clinically indicated follow-up for unresolved SAEs/EAEs and previously reported AEs found to have increased in severity at this visit.</li> <li><input type="checkbox"/> Inform the participant of planned methods and timeframes for unblinding and dissemination of study results.</li> <li><input type="checkbox"/> Determine and document whether participant is willing to be contacted about future studies for which she may be eligible.</li> <li><input type="checkbox"/> Determine participant preference for post-study contact.</li> </ul>	
	29. Provide reimbursement.	
	30. Ensure that chart notes and all other required visit documentation is completed.	



<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code: 89.0</b>
<b>Initials</b>	<b>Procedures</b>	
	<p>31. Fax all required DataFax forms to SCHARP DataFax:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Menstrual Practices and Study Disclosure Assessment</li> <li><input type="checkbox"/> Study Exit Behavior Assessment</li> <li><input type="checkbox"/> Monthly Symptoms</li> <li><input type="checkbox"/> Follow-up HIV Rapid Test Results</li> <li><input type="checkbox"/> Follow-up Family Planning</li> <li><input type="checkbox"/> Specimen Storage/PK</li> <li><input type="checkbox"/> End of Study Inventory</li> <li><input type="checkbox"/> Study Exit Visit</li> <li><input type="checkbox"/> Termination</li> </ul> <p>If Applicable:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Follow-up Pelvic Exam</li> <li><input type="checkbox"/> Vaginal Test Results</li> <li><input type="checkbox"/> Pap Test Results</li> <li><input type="checkbox"/> Safety Laboratory Results</li> <li><input type="checkbox"/> STI Laboratory Results</li> <li><input type="checkbox"/> HIV Western Blot Test Results</li> <li><input type="checkbox"/> Seroconverter Laboratory Test Results</li> <li><input type="checkbox"/> Adverse Experience Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Pregnancy Report and History</li> <li><input type="checkbox"/> Pregnancy Outcome</li> <li><input type="checkbox"/> Product Returns and Dispensations</li> </ul>	
	<div style="background-color: yellow; padding: 5px; border: 1px solid black;"> <p>If the Study Exit/Termination Visit is not completed, <u>only the SEV, TM and ESI forms</u> are to be completed. Do not complete a Missed Visit form or any other VOICE CRF for this visit.</p> </div>	
	32. Back-up ACASI questionnaire data.	
	33. Upload ACASI questionnaire data to SCHARP.	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	1. Confirm participant identity and PTID per site SOPs.	
	2. Instruct participant to return unused study product, if any, to pharmacy.	
	3. Review previous visit documentation.	
	4. Review elements of informed consent as needed.	
	5. Explain procedures to be performed at today's visit.	
	6. Review/update locator information.	
	7. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs.	
	8. If clinically indicated, perform physical exam; document per site SOPs.	
	9. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic Exam Checklist.	
	10. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #18 below).	
	11. If clinically indicated, collect urine (15-60 mL) for pregnancy testing; aliquot 5 mL if dipstick urinalysis is clinically indicated.  <input type="checkbox"/> NOT pregnant <input type="checkbox"/> Pregnant, pregnancy first identified at a previous visit: <input type="checkbox"/> Continue to HOLD study product. <input type="checkbox"/> If applicable, refer to MTN-016; document in chart notes. <input type="checkbox"/> Pregnant, pregnancy newly identified at today's visit: <input type="checkbox"/> HOLD study product and complete new Product Hold/Discontinuation Log form. <input type="checkbox"/> Initiate Pregnancy Management Worksheet <input type="checkbox"/> Complete Pregnancy Report and History form.	
	12. If clinically indicated, collect urine (or use aliquot from pregnancy testing) and perform dipstick urinalysis for protein, glucose, nitrites, and/or LE: ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If 1+ or greater for protein or glucose, another reason for product HOLD may be indicated; see protocol Sections 9.6 and 9.7. Complete a new Product Hold/Discontinuation Log if indicated. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.	
	13. If clinically indicated, refrigerate remaining urine for gonorrhea and Chlamydia SDA.	
	14. Provide and explain all available findings and results.	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>		
<b>Procedures</b>		
	15. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.	
	16. If indicated, administer Hepatitis B vaccine; document per site SOPs.	
	17. If required based on all available information, complete AE Log form(s).	
	18. If Sample 2 of the protocol follow-up HIV testing algorithm is being drawn at this visit, refer to the HIV Sample 2 Visit Checklist. Otherwise, please complete the following steps if indicated: <input type="checkbox"/> Provide and document HIV counseling and testing per site SOPs. <input type="checkbox"/> Provide referrals if needed/requested. <input type="checkbox"/> Offer HIV counseling and testing for partner(s).	
	19. If clinically indicated, draw and prepare blood for additional testing; tests that may be clinically indicated include: <ul style="list-style-type: none"> <li>• HIV serology</li> <li>• Liver function tests (AST, ALT)</li> <li>• Renal function tests (phosphate, creatinine)</li> <li>• Complete blood count</li> <li>• Syphilis serology</li> <li>• Hepatitis B surface antigen</li> <li>• Hepatitis B surface antibody</li> </ul>	
	20. Schedule or reinforce scheduling of next visit and remind participant to: <ul style="list-style-type: none"> <li>• Record menstrual bleeding days on appointment card</li> <li>• Bring appointment card to next visit</li> <li>• Bring any other medication she is taking to next visit</li> </ul>	
	21. Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit.	
	22. Provide reimbursement as needed/indicated.	
	23. Ensure that chart notes and all other required visit documentation is completed.	

<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code:</b>
<b>Initials</b>	<b>Procedures</b>	
	24. If applicable, fax all completed DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <li><input type="checkbox"/> Interim Visit</li> <li><input type="checkbox"/> Concomitant Medications Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Contraceptives Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Follow-up Pelvic Exam</li> <li><input type="checkbox"/> Vaginal Test Results</li> <li><input type="checkbox"/> STI Laboratory Results</li> <li><input type="checkbox"/> Safety Laboratory Results</li> <li><input type="checkbox"/> Adverse Experience Log (new and/or updated form pages)</li> <li><input type="checkbox"/> Product Returns</li> <li><input type="checkbox"/> Product Re-supply and Re-issues</li> <li><input type="checkbox"/> Product Hold/Discontinuation Log</li> <li><input type="checkbox"/> Pregnancy Report and History</li> <li><input type="checkbox"/> Pregnancy Outcome</li> <li><input type="checkbox"/> HIV Western Blot Test Results</li> <li><input type="checkbox"/> Specimen Storage/PK</li> <li><input type="checkbox"/> Seroconverter Laboratory Test Results</li> </ul>	

PTID:	Visit Date:	Visit Code:
<b>Initials</b>	<b>Procedures</b>	
	1. Provide and document HIV counseling and testing per site SOPs	
	2. Provide sample 1 test result(s) and counseling	
	3. Provide HIV/STI risk reduction counseling and condoms	
	4. Collect 25 mL blood in lavender top (EDTA) tubes and perform the following: <ul style="list-style-type: none"> <li><input type="checkbox"/> Western Blot</li> <li><input type="checkbox"/> Plasma archive               <ul style="list-style-type: none"> <li>⇒ Store a minimum of 6x1 mL aliquots</li> </ul> </li> <li><input type="checkbox"/> CD4+ T cell count test</li> <li><input type="checkbox"/> HIV-1 RNA PCR test</li> </ul> [additional blood needed for clinically-indicated testing also may be collected at this time]	
	5. Provide referrals if needed/requested	
	6. Offer HIV counseling and testing for partner(s)	
	7. Inform participant of MTN-015 and her potential eligibility	
	8. If the Sample 2 results will be reported to the clinic prior to when the next monthly visit is scheduled/due, schedule an interim visit as needed.	
	9. Fax all required DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <li><input type="checkbox"/> HIV Western Blot Test Results</li> <li><input type="checkbox"/> Specimen Storage/PK</li> <li><input type="checkbox"/> Seroconverter Laboratory Test Results</li> </ul>	

Blood draw volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes.

<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code: 3.0</b>
<b>Initials</b>	<b>Procedures</b>	
	<p>1. Determine whether the participant should be approached for possible inclusion in MTN-003B by reviewing her VOICE study records and completing items 1-5 of the MTN-003B Eligibility form:</p> <p><input type="checkbox"/> Potentially eligible ⇒ CONTINUE.</p> <p><input type="checkbox"/> Not potentially eligible ⇒ STOP. Complete the MTN-003B Eligibility form and fax to SCHARP DataFax. Retain this checklist and the MTN-003B Eligibility form in the participant's VOICE study chart.</p>	
	<p>2. If today's visit is taking place on a day after the VOICE enrollment visit, confirm participant identity and VOICE PTID per site SOPs.</p>	
	<p>3. If today's visit is taking place on a day after the VOICE enrollment visit, check for co-enrollment in other (non-approved) studies per site SOPs:</p> <p><input type="checkbox"/> NOT enrolled in another study ⇒ CONTINUE.</p> <p><input type="checkbox"/> Enrolled in another study ⇒ STOP. Product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule the participant to return when a response from PSRT is expected.</p>	
	<p>4. Explain the purpose and sequence of procedures for today's visit.</p>	
	<p>5. If today's visit is taking place on a day after the VOICE enrollment visit, review/update locator information.</p>	
	<p>6. If today's visit is taking place on a day after the VOICE enrollment visit, perform and document an abbreviated interval medical history:</p> <ul style="list-style-type: none"> <li>• Ascertain the current status of conditions that were ongoing at enrollment</li> <li>• Ascertain whether the participant experienced any new symptoms or health problems since enrollment</li> <li>• Ascertain any changes in contraception or other concomitant medications since enrollment</li> </ul> <p>Follow up on reported history, if needed, as part of #26.</p>	
	<p>7. Explain, conduct, and document the MTN-003B informed consent process per site SOPs:</p> <p><input type="checkbox"/> Willing and able to provide written informed consent ⇒ CONTINUE.</p> <p><input type="checkbox"/> NOT willing and able to provide written informed consent ⇒ NOT ELIGIBLE ⇒ STOP. Complete the MTN-003B Eligibility form and fax to SCHARP DataFax. Retain this checklist and the MTN-003B Eligibility form in the participant's VOICE study chart.</p>	
	<p>8. Has the participant been tested for pregnancy today?</p> <p><input type="checkbox"/> Yes ⇒ CONTINUE.</p> <p><input type="checkbox"/> No ⇒ collect urine, aliquot ~5 mL, and perform pregnancy test:</p> <p><input type="checkbox"/> NOT pregnant ⇒ CONTINUE.</p> <p><input type="checkbox"/> Pregnant ⇒ NOT ELIGIBLE ⇒ STOP. Complete the MTN-003B Eligibility form and fax to SCHARP DataFax. Retain this checklist and the MTN-003B Eligibility form in the participant's VOICE study chart.</p>	
	<p>9. Retain remaining urine (at least 10 mL) for delivery to the local lab for subsequent storage.</p>	

<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code: 3.0</b>
<b>Initials</b>	<b>Procedures</b>	
	<p>10. Review all available information and <u>determine</u> eligibility for MTN-003B:</p> <p><input type="checkbox"/> Eligible ⇒ CONTINUE.</p> <p><input type="checkbox"/> Not eligible ⇒ STOP. Complete the MTN-003B Eligibility form and fax to SCHARP DataFax. Retain this checklist and the MTN-003B Eligibility form in the participant's VOICE study chart.</p>	
	<p>11. <u>Verify</u> eligibility for MTN-003B per site SOPs:</p> <p><input type="checkbox"/> Eligible ⇒ CONTINUE.</p> <p><input type="checkbox"/> Not eligible ⇒ STOP. Complete the MTN-003B Eligibility form and fax to SCHARP DataFax. Retain this checklist and the MTN-003B Eligibility form in the participant's VOICE study chart.</p>	
	12. Complete MTN-003B Lactation and Contraceptive History form.	
	13. Administer MTN-003B Food Frequency Questionnaire.	
	14. Administer MTN-003B Physical Activity Questionnaire.	
	<p>15. Based on review of VOICE study records, determine whether participant height and weight have been measured and documented within the past 14 days:</p> <p><input type="checkbox"/> Yes ⇒ Transcribe height and weight onto MTN-003B Visit Procedures form.</p> <p><input type="checkbox"/> No ⇒ Measure height and weight, document per VOICE SOPs, and transcribe onto MTN-003B Visit Procedures form.</p> <p>Compare current height and weight to baseline, as part of ongoing safety monitoring for VOICE. Follow up if needed as part of #26.</p>	
	16. Assess for physical signs of malnutrition; record findings in chart notes and complete item 2 on the MTN-003B Visit Procedures form.	
	17. Collect 15 mL blood in plain (no additive) tubes; prepare tubes for delivery to the local lab for subsequent storage of serum.	
	18. Verify participant's current age and record on MTN-003B DXA Scan form.	
	19. Perform DXA scans of spine and hip (two scans of each). Save scans electronically and print copies of each (four print-outs in total).	
	20. Transcribe DXA scan results onto MTN-003B DXA Scan form.	
	<p>21. Assess whether any Z-score (age 18-29) or T-score (age 30+) is less than -2.0 SD:</p> <p><input type="checkbox"/> No ⇒ CONTINUE.</p> <p><input type="checkbox"/> Yes ⇒ Obtain IoR (or designee) opinion on whether calcium supplementation should be provided; document in chart notes and mark here:</p> <p style="padding-left: 40px;"><input type="checkbox"/> No, supplementation not indicated</p> <p style="padding-left: 40px;"><input type="checkbox"/> Yes, supplementation indicated</p> <p style="padding-left: 40px;">⇒ As part of #23, discuss options for prevention or treatment of osteoporosis with participant.</p>	
	<p>22. Assess whether DXA scan results meet criteria for AE reporting; document on MTN-003B DXA Scan form and mark here:</p> <p><input type="checkbox"/> No ⇒ source document as needed and CONTINUE.</p> <p><input type="checkbox"/> Yes ⇒ source document and complete AE Log form for "bone mineral density loss."</p>	

<b>PTID:</b>	<b>Visit Date:</b>	<b>Visit Code: 3.0</b>
<b>Initials</b>	<b>Procedures</b>	
	23. Provide and explain all available results to participant. If indicated (see #21), discuss options for prevention or treatment of osteoporosis with participant.	
	24. If indicated (see #21), provide calcium supplementation; update concomitant medication documentation per site SOPs.	
	25. If malnutrition is identified, counsel the participant on locally available treatment options and sources of nutrition support; document in chart notes.	
	26. If today's visit is taking place on a day after the VOICE enrollment visit, if applicable, address any other issues, questions, or concerns related to VOICE or MTN-003B; document per site SOPs; complete VOICE case report forms if needed.	
	27. Remind participant that her next MTN-003B visit will take place in six months. Reinforce scheduling of next VOICE visit. Remind participant to bring unused study product and any medications she is taking to her next VOICE visit.	
	28. Reinforce contact information and instructions to contact the site to report symptoms and/or request additional information, counseling, study product, or condoms if needed before the next visit.	
	29. Provide reimbursement.	
	30. Ensure chart notes, required case report forms (see #32), MTN-003B LDMS Specimen Tracking Sheet, and all other required visit documentation is completed.	
	31. Review all visit documentation (including DXA scan print-outs).	
	32. Back-up DXA scan data (should be done daily on days when scans are performed).	
	33. Fax all required DataFax forms to SCHARP DataFax: <input type="checkbox"/> MTN-003B Eligibility <input type="checkbox"/> MTN-003B Visit Procedures <input type="checkbox"/> MTN-003B Lactation and Contraceptive History <input type="checkbox"/> MTN-003B Food Frequency Questionnaire <input type="checkbox"/> MTN-003B Physical Activity Questionnaire <input type="checkbox"/> MTN-003B DXA Scan  If applicable: <input type="checkbox"/> AE Log form	