

# MTN-003 Post-seroconversion Visit Checklist

Visit Date: \_\_\_\_\_

PTID:		Visit Code:		
Visit:	Monthly	Quarterly	Semi-Annual	Annual
<b>Initials</b>	<b>Procedures</b>			<b>Required VOICE Visit</b>
	1. Confirm participant identity and PTID per site SOPs.			All visits
	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 ⇒ Obtain as much information as possible about the co-enrollment			All visits
	3. Review previous visit documentation.			All visits
	4. Review elements of informed consent as needed.			All visits
	5. Explain procedures to be performed at today's visit.			All visits
	6. Review/update locator information.			All visits
	7. Administer the Monthly Product Adherence and Behavior Assessment form. Note: Follow tailored guidance on CRF to reflect non-use of study product.			All visits
	8. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test (label with PTID): <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.			All visits
	9. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #20).			Performed once, 8 weeks after initiation of product hold
	10. Refrigerate remaining urine for gonorrhea and Chlamydia SDA testing.			Annual
	11. Administer Monthly Symptoms form.			All visits
	12. Collect interval medical and menstrual history and Concomitant Medications form.			All visits
	13. Provide contraceptive counseling; document per site SOPs.			All visits
	14. [Prescribe/provide] contraception if indicated;			As indicated at all visits

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	15. 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.		Performed once, 8 weeks after initiation of product hold	
	16. Perform physical exam per MTN-003 requirements, including weight; document per site SOPs.		Month 1, Quarterly, Semi-Annual, Annual visits (NOTE: height is measured at Semi-Annual visits)	
	17. Perform and document pelvic exam per Pelvic Exam Checklist and site SOPs. Note: Gram stains not performed for any visit		Semi-Annual, Annual visits	
	18. Provide and explain all available findings and results.		All visits	
	19. 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. <input type="checkbox"/> Complete/update AE Log as needed		All visits	
	20. Provide counseling and condoms <input type="checkbox"/> HIV-related (including secondary prevention) <input type="checkbox"/> STI risk reduction <input type="checkbox"/> Follow-up on previous referrals (if applicable) <input type="checkbox"/> New referrals (if applicable)		All visits	
	21. If indicated, administer Hepatitis B vaccine; document per site SOPs.		If indicated	
	22. If required based on all available information, complete AE Log form(s).		All visits	

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	23. Determine amounts required and collect blood (review items #24-29 to determine total amounts):  <input type="checkbox"/> _ x 10 mL lavender top (EDTA) tubes <input type="checkbox"/> _ x 5 mL lavender top (EDTA) tube <input type="checkbox"/> _ x 5 mL red top (no additive) tube  [additional blood needed for clinically indicated testing also may be collected at this time]		All visits  <div style="background-color: #ffff00; padding: 5px; border: 1px solid black;">                         Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes.                     </div>	
	24. Prepare blood for liver and renal function tests <input type="checkbox"/> AST, ALT, phosphate, creatinine		Performed once, 8 weeks after initiation of product hold	
	25. Prepare blood for plasma archive <input type="checkbox"/> Collect ~15 mL EDTA whole blood to yield at least 6 mL plasma <input type="checkbox"/> If indicated, collect additional 10 ml EDTA whole blood for resistance testing		1 <sup>st</sup> , 3 <sup>rd</sup> , and 6 <sup>th</sup> month post-seroconversion, and every 6 months thereafter	
	26. Prepare blood for complete blood count (~2mL)		Performed once, 8 weeks after initiation of product hold	
	27. Prepare blood for syphilis serology (~2mL)		Annual	
	28. Prepare blood for CD4+ T cell count (~2mL)		1 <sup>st</sup> , 3 <sup>rd</sup> , and 6 <sup>th</sup> month post-seroconversion, and every 6 months thereafter	
	29. Prepare blood for HIV RNA Viral Load (~2mL)		1 <sup>st</sup> , 3 <sup>rd</sup> , and 6 <sup>th</sup> month post-seroconversion, and every 6 months thereafter	
	30. Complete <ul style="list-style-type: none"> <li>• Specimen Storage/PK form</li> <li>• LDMS Tracking Sheet</li> </ul>		Quarterly; Semi-Annual, Annual visits	
	31. 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>		All visits	
	32. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.		All visits	

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	33. Provide reimbursement.		All visits	
	34. Ensure that chart notes and all other required visit documentation is completed.		All visits	
	35. Fax all required DataFax forms to SCHARP DataFax per the Schedule of Forms in SSP Manual Section 14.		All visits	