

Product Use End Visit (PUEV)**Visit Month:** _____

- Visit Summary (VS-1)
- Monthly Laboratory Results (MLR-1)
- Specimen Storage (SS-1)
- Ring Adherence (RA-1)
- Family Planning (FP-1)
- Ring Collection/Insertion (RCI-1)
- Quarterly Lab Results (QLR-1)
- Abbreviated Physical Exam (APX-1)
- Pelvic Exam (PE-1)
- STI Test Results (STI-1)
- PUEV Laboratory Results (PLR-1)
- Follow-up ACASI Tracking (FAT-1)
- Pelvic Exam Diagrams (non-DataFax)

Site to add:

- Behavior Assessment (BA-1, -2) – *local-language version*
- Vaginal Practices (VP-1) – *local-language version*
- Ring Worries (RW-1) – *local-language version*
- Social Influences Assessment (SOC-1) – *local-language version*
- Follow-up Visit LDMS Specimen Tracking Sheet

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Visit Month .

1

MTN-020 ASPIRE (192)

VS-1 (121)

Participant ID <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> - <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> - <input style="width: 20px;" type="text"/> <small>Site Number Participant Number Chk</small>	Visit Date <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <small>dd MMM yy</small>
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Visit Summary									
1. Location of study visit	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>clinic</i></td> <td style="text-align: center;"><i>home</i></td> <td style="text-align: center;"><i>other, specify:</i></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/> _____</td> </tr> </table>	<i>clinic</i>	<i>home</i>	<i>other, specify:</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____		
<i>clinic</i>	<i>home</i>	<i>other, specify:</i>							
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____							
2. Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">If yes and currently using PEP, complete Product Hold/Discontinuation Log. Record on Concomitant Medications Log.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>yes</i>	<i>no</i>	If yes and currently using PEP, complete Product Hold/Discontinuation Log. Record on Concomitant Medications Log.	<input type="checkbox"/>	<input type="checkbox"/>			
<i>yes</i>	<i>no</i>	If yes and currently using PEP, complete Product Hold/Discontinuation Log. Record on Concomitant Medications Log.							
<input type="checkbox"/>	<input type="checkbox"/>								
3. Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">If no, go to item 4.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>yes</i>	<i>no</i>	If no, go to item 4.	<input type="checkbox"/>	<input type="checkbox"/>			
<i>yes</i>	<i>no</i>	If no, go to item 4.							
<input type="checkbox"/>	<input type="checkbox"/>								
3a. Was oral or topical PrEP used?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>oral</i></td> <td style="text-align: center;"><i>topical</i></td> <td style="text-align: center;"><i>both</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">Record on Concomitant Medications Log.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>oral</i>	<i>topical</i>	<i>both</i>	Record on Concomitant Medications Log.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>oral</i>	<i>topical</i>	<i>both</i>	Record on Concomitant Medications Log.						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>							
4. Is this a PUEV, early termination, or scheduled study termination visit?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">If no, go to item 5.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>yes</i>	<i>no</i>	If no, go to item 5.	<input type="checkbox"/>	<input type="checkbox"/>			
<i>yes</i>	<i>no</i>	If no, go to item 5.							
<input type="checkbox"/>	<input type="checkbox"/>								
4a. Visit Type <i>Mark only one.</i>	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>PUEV</i></td> <td style="text-align: center;"><i>scheduled termination</i></td> <td style="text-align: center;"><i>early termination</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">Go to item 6.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>PUEV</i>	<i>scheduled termination</i>	<i>early termination</i>	Go to item 6.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>PUEV</i>	<i>scheduled termination</i>	<i>early termination</i>	Go to item 6.						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>							
5. Is this an interim visit?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">If no, go to item 6.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>yes</i>	<i>no</i>	If no, go to item 6.	<input type="checkbox"/>	<input type="checkbox"/>			
<i>yes</i>	<i>no</i>	If no, go to item 6.							
<input type="checkbox"/>	<input type="checkbox"/>								
5a. Reason for interim visit <i>Mark all that apply.</i>	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>AE report or follow-up</i></td> <td style="text-align: center;"><i>return of ring or need for a new ring</i></td> <td style="text-align: center;"><i>other, specify:</i></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/> _____</td> </tr> </table>	<i>AE report or follow-up</i>	<i>return of ring or need for a new ring</i>	<i>other, specify:</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____		
<i>AE report or follow-up</i>	<i>return of ring or need for a new ring</i>	<i>other, specify:</i>							
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____							
5b. Which forms, besides this form, were newly completed for this interim visit? <i>Mark "none" or all that apply.</i>	<table style="width:100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 5b1. None ———▶ End of form. <input type="checkbox"/> 5b2. Adverse Experience Log <input type="checkbox"/> 5b3. Product Hold/Discontinuation Log <input type="checkbox"/> 5b4. Ring Collection/Insertion <input type="checkbox"/> 5b5. Monthly Laboratory Results </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 5b6. Quarterly Laboratory Results <input type="checkbox"/> 5b7. STI Test Results <input type="checkbox"/> 5b8. Pelvic Exam <input type="checkbox"/> 5b9. other, specify: _____ </td> </tr> </table>	<input type="checkbox"/> 5b1. None ———▶ End of form. <input type="checkbox"/> 5b2. Adverse Experience Log <input type="checkbox"/> 5b3. Product Hold/Discontinuation Log <input type="checkbox"/> 5b4. Ring Collection/Insertion <input type="checkbox"/> 5b5. Monthly Laboratory Results	<input type="checkbox"/> 5b6. Quarterly Laboratory Results <input type="checkbox"/> 5b7. STI Test Results <input type="checkbox"/> 5b8. Pelvic Exam <input type="checkbox"/> 5b9. other, specify: _____						
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After completing item 5b, end of form.									
6. Were any new Adverse Experience Log forms completed for this visit?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	<i>yes</i>	<i>no</i>	<input type="checkbox"/>	<input type="checkbox"/>				
<i>yes</i>	<i>no</i>								
<input type="checkbox"/>	<input type="checkbox"/>								
7. Were any new Product Hold/Discontinuation Log forms completed for this visit?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	<i>yes</i>	<i>no</i>	<input type="checkbox"/>	<input type="checkbox"/>				
<i>yes</i>	<i>no</i>								
<input type="checkbox"/>	<input type="checkbox"/>								

Visit Summary (VS-1)	
Purpose:	This form is used to summarize information from each follow-up study visit performed for a participant.
General Information/ Instructions:	This form is completed for each scheduled visit. This form is also completed for interim visits/contacts where a new form (other than the Visit Summary) is completed. Note that there is no Interim Visit form for this study—instead, this form is completed to document interim visits
Item-specific Instructions:	
Visit Month:	<p>Record the visit code assigned to the visit. For required visits (Month 1, Month 2, Month 3, etc.), simply record the visit month during which the visit falls (Month 1 = 01.0, Month 2 = 02.0, etc.). For required monthly, quarterly, and semi-annual visits, the Visit Month will end in 0 (XX.0). If the visit is an interim visit/contact, use an interim code for the Visit Month. Start with the Visit Month of the last required visit and add "1" to the right of the decimal point for each interim visit conducted. For example, if the participant's last required visit was Month 8, the interim visit would be assigned a visit code (Visit Month) of 08.1. If the participant has a second interim visit, this would be assigned a code of 08.2.</p> <p>If procedures for a required visit are split over 2 or more days, and all days are within the same visit window, assign all forms completed for the split visit the same Visit Month (ending in .0). For example, if a participant completes all Month 12 procedures exam pelvic exam procedures on 08-SEP-12, and completes the pelvic procedures on 10-SEP-12, assign a Visit Month of 12.0 to all forms.</p>
Item 1:	If this contact with a participant is over the phone and results in new forms that need to be completed, mark the "other, specify" box and record "phone contact" on the line provided.
Item 2:	If the participant has taken post-exposure prophylaxis (PEP) since her last visit, mark the "yes" box. If the participant is currently using PEP, a Product Hold/Discontinuation (PH) Log must be completed.
Item 3:	Record if the participant has used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV and indicate whether oral or topical PrEP was used. If either or both were used, update the Concomitant Medications (CM) Log.
Item 4:	If the visit completed was a Product Use End Visit (PUEV), early termination, or scheduled study termination visit, mark the "yes" box. If the visit was a typical monthly, quarterly, or semi-annual visit, mark the "no" box. Note that visits where a participant is permanently discontinued from study product for clinical or protocol requirements (HIV seroconversion, for example), this is not a PUEV.
Item 4a:	Mark only one response. If the participant is terminating from the study early (she withdraws consent, for example), this is considered an early termination visit, not a PUEV. Mark scheduled study termination when the visit is the termination/study exit visit, and is being conducted after the completion of a PUEV. Once item 4a is completed, go to item 6 (it is not necessary to complete items 5 or 5a, even if the PUEV/early termination/scheduled study termination visit has an interim visit code).
Item 5b:	Mark the newly-completed forms (in addition to this form) that are being submitted for the interim visit/contact. If "other, specify" is marked, record the form acronyms in the space provided. End the form after completing this item. Leave items 6 and 7 blank for interim visits.
Item 6:	Mark the "yes" box if at least one Adverse Experience (AE) Log was newly-completed for this visit (Visit Month in item 10 of the AE Log is the same as the Visit Month recorded on this form).
Item 7:	Mark the "yes" box if at least one Product Hold/Discontinuation (PH) Log was newly completed for this visit (Visit Month in item 1 of the PH Log is the same as the Visit Month recorded on this form).



Visit Month .

1

MTN-020 ASPIRE (192)

MLR-1 (140)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 40px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> Site Number Participant Number Chk </small>	Initial Specimen Collection Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy </small>
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Monthly Laboratory Results																											
1. hCG for pregnancy	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>Not done/ Not collected</i></td> <td style="text-align: center; width: 15%;"><i>Alternate Collection Date</i></td> <td style="text-align: center; width: 15%;"><i>dd</i></td> <td style="text-align: center; width: 15%;"><i>MMM</i></td> <td style="text-align: center; width: 15%;"><i>yy</i></td> <td style="text-align: center; width: 10%;"><i>negative</i></td> <td style="text-align: center; width: 10%;"><i>positive</i></td> </tr> <tr> <td></td> <td></td> <td></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table> <p style="text-align: right; font-size: 8px; margin-top: 5px;"><i>If newly positive, complete Product Hold/Discontinuation Log and Pregnancy Report.</i></p>	<input type="checkbox"/>	<i>Not done/ Not collected</i>	<i>Alternate Collection Date</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>negative</i>	<i>positive</i>				<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>										
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2. Rapid HIV test 1	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>Not done/ Not collected</i></td> <td style="text-align: center; width: 15%;"><i>Kit code</i></td> <td style="text-align: center; width: 15%;"><i>Alternate Collection Date</i></td> <td style="text-align: center; width: 15%;"><i>dd</i></td> <td style="text-align: center; width: 15%;"><i>MMM</i></td> <td style="text-align: center; width: 15%;"><i>yy</i></td> <td style="text-align: center; width: 10%;"><i>negative</i></td> <td style="text-align: center; width: 10%;"><i>positive</i></td> </tr> <tr> <td></td> <td></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<i>Not done/ Not collected</i>	<i>Kit code</i>	<i>Alternate Collection Date</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>negative</i>	<i>positive</i>			<input style="width: 20px; height: 20px;" type="text"/>		<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>								
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3. Rapid HIV test 2	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>Not done/ Not collected</i></td> <td style="text-align: center; width: 15%;"><i>Kit code</i></td> <td style="text-align: center; width: 15%;"><i>Alternate Collection Date</i></td> <td style="text-align: center; width: 15%;"><i>dd</i></td> <td style="text-align: center; width: 15%;"><i>MMM</i></td> <td style="text-align: center; width: 15%;"><i>yy</i></td> <td style="text-align: center; width: 10%;"><i>negative</i></td> <td style="text-align: center; width: 10%;"><i>positive</i></td> </tr> <tr> <td></td> <td></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table> <p style="text-align: center; font-size: 8px; margin-top: 5px;"><i>If positive to either, complete HIV Confirmatory Results and Product Hold/Discontinuation Log.</i></p>	<input type="checkbox"/>	<i>Not done/ Not collected</i>	<i>Kit code</i>	<i>Alternate Collection Date</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>negative</i>	<i>positive</i>			<input style="width: 20px; height: 20px;" type="text"/>		<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>								
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4. Was plasma stored for HIV confirmatory testing?	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>yes</i></td> <td style="text-align: center; width: 15%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>no</i></td> <td style="text-align: center; width: 15%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>not required</i></td> <td style="width: 20%;"></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="font-size: 8px;"><i>If no or not required, go to item 5.</i></td> </tr> </table> <p style="margin-top: 10px;">4a. Plasma for HIV confirmatory testing collection date</p> <table style="width:100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="text-align: center; width: 20%;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; width: 15%;"><i>dd</i></td> <td style="text-align: center; width: 15%;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; width: 15%;"><i>MMM</i></td> <td style="text-align: center; width: 15%;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; width: 15%;"><i>yy</i></td> </tr> </table>	<input type="checkbox"/>	<i>yes</i>	<input type="checkbox"/>	<i>no</i>	<input type="checkbox"/>	<i>not required</i>								<i>If no or not required, go to item 5.</i>	<input style="width: 20px; height: 20px;" type="text"/>	<i>dd</i>	<input style="width: 20px; height: 20px;" type="text"/>	<i>MMM</i>	<input style="width: 20px; height: 20px;" type="text"/>	<i>yy</i>						
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5. Self-collected Vaginal fluid swab collection	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; width: 15%;"><i>dd</i></td> <td style="text-align: center; width: 15%;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; width: 15%;"><i>MMM</i></td> <td style="text-align: center; width: 15%;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; width: 15%;"><i>yy</i></td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 10%;"><i>not required</i></td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 10%;"><i>stored</i></td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 10%;"><i>not stored</i></td> <td style="width: 20%;"><i>Reason:</i></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="border-bottom: 1px solid black;"></td> </tr> </table>	<input style="width: 20px; height: 20px;" type="text"/>	<i>dd</i>	<input style="width: 20px; height: 20px;" type="text"/>	<i>MMM</i>	<input style="width: 20px; height: 20px;" type="text"/>	<i>yy</i>	<input type="checkbox"/>	<i>not required</i>	<input type="checkbox"/>	<i>stored</i>	<input type="checkbox"/>	<i>not stored</i>	<i>Reason:</i>													
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5a. Was blood visible on the swab?	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>yes</i></td> <td style="text-align: center; width: 15%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>no</i></td> <td style="width: 50%;"></td> </tr> </table> <p style="text-align: right; font-size: 8px; margin-top: 5px;"><i>If not required or not stored, end of form.</i></p>	<input type="checkbox"/>	<i>yes</i>	<input type="checkbox"/>	<i>no</i>																						
<input type="checkbox"/>	<i>yes</i>	<input type="checkbox"/>	<i>no</i>																								
5b. Was a used ring in place at the time of swab collection?	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>yes</i></td> <td style="text-align: center; width: 15%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>no – ring removed prior to swab collection</i></td> <td style="text-align: center; width: 15%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>no – ring not in place at start of visit</i></td> <td style="text-align: center; width: 15%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><i>no – new ring inserted prior to swab collection</i></td> <td style="text-align: center; width: 15%;"><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<i>yes</i>	<input type="checkbox"/>	<i>no – ring removed prior to swab collection</i>	<input type="checkbox"/>	<i>no – ring not in place at start of visit</i>	<input type="checkbox"/>	<i>no – new ring inserted prior to swab collection</i>	<input type="checkbox"/>																	
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Comments: _____

Monthly Laboratory Results (MLR-1)

Purpose: This form is used to document the participant's pregnancy, HIV rapid test results, and self-collected vaginal swab collection at study follow-up visits as specified in the protocol.

General Information/ Instructions: Record test results on this form as they become available. Fax this form into SCHARP DataFax once results for **all** collected specimens are recorded on the form.

- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form). A complete date is required.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen (e.g., swab) was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form.
- **Not done/Not collected:** Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments lines.

Item-specific Instructions:

Items 2 and 3: Record the assigned two-digit rapid test kit code. *Note: More test kit codes may be added to the list as the study proceeds.*

Kit Code	Rapid Test
01	Determine
02	OraQuick
03	Uni-Gold Recombigen
04	StatPak

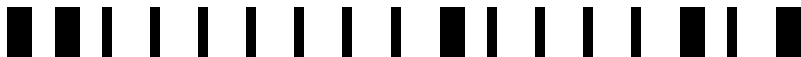
If item 2 or item 3 is positive (meaning the participant had at least one positive rapid HIV test), complete a new HIV Confirmatory Results form and a Product Hold/Discontinuation (PH) Log.

Item 4: If plasma was required but not stored for HIV confirmatory testing, record the reason on the Comments line.

Item 4a: Record the date the plasma was collected for storage for confirmatory testing.

Item 5: Record whether the vaginal fluid swab required at each monthly/quarterly/semi-annual/Product Use End Visit (PUEV) was collected. If required but not collected or stored, record reason on the line provided.

Specimen Storage (SS-1)	
Purpose:	This form is used to document collection and storage of vaginal, cervical and PK specimens and used vaginal rings by the local site laboratory during follow-up.
General Information/ Instructions:	<p>Complete this form at each quarterly, semi-annual, the Product Use End Visit (PUEV), early termination (as applicable), and Termination/Study Exit visits.</p> <ul style="list-style-type: none"> • Initial Specimen Collection Date: Record the date that the first specimen(s) was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required. • Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. A complete date is required.
Item-specific Instructions:	
Items 1–4:	If the specimen is not required to be collected at this visit, mark the “not required” box. If the specimen is required to be stored, but for some reason it is not stored, mark the “not stored” box and record the reason on the line provided.



MTN-020 ASPIRE (192)

RA-1 (133)

Visit Month .

1

Participant ID	<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>	Visit Date	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Site Number Participant Number Chk		dd MMM yy

Ring Adherence

1. Did the participant have access to a vaginal ring during the past month? *yes* *no* → *If no, end of form.*

2. How many times in the past month has the participant had the vaginal ring out, in total? *times* → *If 00, end of form.*

3. How many of these times was the vaginal ring out for more than 12 hours continuously? *times* → *If 00, go to item 5.*

4. In the past month, what is the longest number of days in a row the vaginal ring was out? *days*

5. In the past month, why was the vaginal ring out? *Record all codes that apply. See back of form for code listing.*

Reason Code

5a.

5b.

5c.

5d.

5e.

5f.

5g.

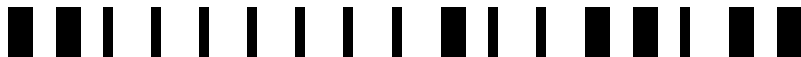
If there is a reason that is not represented in the Reason Code list, mark item 5h or 5i, as applicable, and record the reason on the adjacent specify lines. Otherwise, leave items 5h and 5i blank.

5h. Other reason ring removed by participant or clinician, specify: _____

5i. Other reason ring came out on its own, specify: _____

Comments: _____

Ring Adherence (RA-1)																																																													
Purpose:	This form is used to document the participant's self-reported study ring use during follow-up.																																																												
General Information/ Instructions:	<p>Complete this form at each monthly, quarterly and semi-annual follow-up visits, as well as the Product Use End Visit (PUEV), and at an early termination visit, as applicable. Complete at these visits even if the participant has been on product hold or has been permanently discontinued from ring use.</p> <p>All items on this form refer to ring access and use during the past month only, regardless of whether or not the participant missed her last monthly visit.</p>																																																												
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Item 1:	Mark "no" if the participant did not have a ring in her possession during the past month. Mark "yes" if the participant had access to a vaginal ring, regardless of how long ago the ring was dispensed, and regardless of whether or not the participant used the ring. For example, a participant is dispensed a ring at her Month 1 Visit. She misses her Month 2 Visit, but returns for her Month 3 Visit. At her Month 3 Visit, mark "yes" since the participant had in her possession for the past month the ring that was dispensed at her Month 1 Visit.																																																												
Item 2:	The purpose of this question is to capture all instances in the past month when the ring was expelled, or was removed other than at regularly scheduled study visits. Do not count instances when the ring was removed at a regularly scheduled visit to insert a new ring.																																																												
Item 4:	When determining the longest number of days in a row, include partial days as a day. For example, if a participant reports she removed the ring on a Wednesday and re-inserted it on a Friday, count this as 3 days (Wednesday, Thursday, Friday). This item should be an over-estimate rather than an exact or under-estimate.																																																												
Item 5:	Refer to the list of Reason Codes below. Record the two-digit code that corresponds to each reason the vaginal ring was out during the past month (because the participant or clinician removed the ring, or ring expulsion occurred). Up to seven Reason Codes may be recorded (items 5a-5g). A Reason Code is required for item 5a. Record any additional reason codes in items 5b-5g; leave any unused items blank. For example, if three Reason Codes apply, record the codes in items 5a-5c and leave items 5d-5g blank.																																																												
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MTN-020 ASPIRE (192)

FP-1 (155)

Visit Month .

1

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">Site Number Participant Number Chk</p>	Visit Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">dd MMM yy</p>
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Family Planning

1. What method(s) of contraception/family planning has the participant used since her last visit? *Mark "none" or all that apply.*

1a. none

1b. spermicide

1c. diaphragm

1d. sponge

1e. intrauterine device (IUD)

1f. oral contraceptives/birth control pills

1g. injectable contraceptives (such as Depo-Provera)

1g1. Type: *Depo* *Depo subq* *NET-EN* *Cyclofem* *other*

1h. (Ortho Evra) The Patch

1i. implants

1j. female condoms

1k. natural methods such as the withdrawal or rhythm method

1l. male condoms

1m. sterilization (tubal ligation/hysterectomy/laparoscopy/other surgical procedure that causes sterilization)

1n. sex with partner who had a vasectomy

1o. other, specify: _____

↓

Update Concomitant Medications Log, as needed.

2. Has the participant had or started her menstrual period since her last visit?

yes *no* → *If no, end of form.*

2a. First day of last menstrual period

dd MMM yy

2b. Last day of last menstrual period

OR *ongoing*

dd MMM yy

Comments: _____

Family Planning (FP-1)	
Purpose:	This form is used to document the methods of contraception/family planning used by the participant during study follow-up. It is completed at each monthly, quarterly, and semi-annual follow-up visits, as well as at the Product Use End Visit (PUEV), and at an early termination visit, as applicable.
Item-specific Instructions:	
Item 1:	Mark any method(s) of contraception/family planning the participant reports using since her last monthly study visit. If any response boxes for items 1e–1i are marked, update the Concomitant Medications (CM) Log as needed.
Item 1g1.:	Mark the specific type of injectable contraception used by the participant. <ul style="list-style-type: none"> • Depo for Depo Provera (DMPA, also known as Petogen) injected into the muscle. • Depo subq: mark when the sub-cutaneous route of Depo is used. • NET-EN: also known as Mesigyna. • Cyclofem: also known as Lunelle.
Item 2a:	The first day of the last menstrual period is the first day of bleeding.
Item 2b:	The last day of the last menstrual period is the last day of bleeding.



MTN-020 ASPIRE (192)

RCI-1 (135)

Visit Month .

1

Participant ID - -

Site Number Participant Number Chk

Visit Date

dd *MMM* *yy*

Ring Collection/Insertion

1. Did the participant have a ring in place at the start of the visit? *yes* *no*

If yes, go to item 2.

1a. When was the ring last in place? *dd* *MMM* *yy* OR *not applicable*
(ring not in place since last visit)

2. Number of **used** rings collected *none* *1* *2* *3*

If "1," go to item 3.

2a. If none, 2, or 3, specify reason: _____

3. Number of **unused (never inserted)** rings collected *none* *1* *2* *3*

4. Number of **new rings** dispensed to participant: *none* *1* *2* *3*

Go to item 5.

4a. Reason ring not dispensed

participant on clinical hold

participant has been permanently discontinued from product

participant declined study ring, specify: _____

scheduled PUEV

early termination

other, specify: _____

Go to item 7.

5. Was a new ring inserted at this visit? *yes* *no*

If no, go to item 6.

5a. Who inserted the new ring? *participant* *study staff*

6. Was a ring in place at the end of the visit? *yes* *no*

If yes, go to item 7.

6a. Reason ring not in place at end of visit

participant declined to have ring inserted

participant had to leave before ring could be inserted

other, specify: _____

7. **Appearance of most recently-used ring:** *used* *not used* *not sure* *no ring*

Ring Collection/Insertion (RCI-1)	
Purpose:	This form is used to document rings that are inserted and collected for each participant for the duration of the study.
General Information/ Instructions:	<p>Complete this form at each monthly, quarterly, and semi-annual follow-up visits, as well as at the Product Use End Visit (PUEV), and at early termination visit, as applicable. Complete at interim visits as needed.</p> <p>If the participant has been permanently discontinued from study product, this form is not required to be completed at visits following the permanent discontinuation.</p>
Item-specific Instructions:	
Item 1a:	If the vaginal ring was not in place at the start of the visit, record the date the vaginal ring was last in place over the past month. If the participant is unable to recall the exact date, obtain the participant's best estimate. At a minimum, the month and year are required. If the ring was not in place at any time since this form was last completed, mark the "not applicable" box.
Item 2a:	If no rings were collected (returned), specify the reason why (for example, participant forgot, or participant had no dispensed rings to return). If two or three rings were collected, specify reason why (specify why examples include: two rings were dispensed at last visit, or participant returned one recently-dispensed ring along with a ring dispensed at 3 months, but never returned).
Item 4:	Only document ring(s) dispensed and given to the participant.
Item 4a:	If participant declined to have a ring dispensed to her, record a brief reason for her decline on the line provided. If the reason for her decline is due to or associated with an adverse event, document the adverse event on an Adverse Experience (AE) Log and note in the AE Log Comments that the participant declined the ring because of the AE.
Item 7:	Document the clinic staff's assessment of the appearance of the participant's most recently-used ring. Base this assessment only on the appearance of the ring, do not factor in the participant's reported use of the ring or other information when marking a response. If no ring was returned (item 2 of this form is "none"), mark "no ring" to indicate no ring was available for this assessment at this visit. If 2 or more rings are collected, record the appearance of the ring most recently-used by the participant.



Visit Month .

1

MTN-020 ASPIRE (192)

QLR-1 (144)

Page 1 of 1

Participant ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> Site Number Participant Number Chk </small>	Initial Specimen Collection Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy </small>
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Quarterly Laboratory Results					
1. Hemogram	<input type="checkbox"/> Not done/Not collected <i>Go to item 2.</i> ←	Alternate Collection Date dd <input type="text"/> <input type="text"/>	MMM <input type="text"/> <input type="text"/>	yy <input type="text"/> <input type="text"/>	
Not reported <input type="checkbox"/> 1a. Hemoglobin	<input type="text"/> <input type="text"/> . <input type="text"/> g/dL	Severity Grade (if applicable) <input type="text"/>	AE Log page # <input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	not reportable as an AE
Not reported <input type="checkbox"/> 1b. Hematocrit	<input type="text"/> <input type="text"/> . <input type="text"/> %				
Not reported <input type="checkbox"/> 1c. MCV	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> fL				
Not reported <input type="checkbox"/> 1d. Platelets	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> x10 ³ /mm ³	Severity Grade (if applicable) <input type="text"/>	AE Log page # <input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	not reportable as an AE
Not reported <input type="checkbox"/> 1e. WBC	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> x10 ³ /mm ³	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	
Differential <input type="checkbox"/> Not done → <i>Go to item 2.</i>					
Not reported <input type="checkbox"/> 1f. Neutrophils	Absolute Count <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cells/mm ³	Severity Grade (if applicable) <input type="text"/>	AE Log page # <input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	not reportable as an AE
Not reported <input type="checkbox"/> 1g. Lymphocytes	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cells/mm ³	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	
Not reported <input type="checkbox"/> 1h. Monocytes	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cells/mm ³				
Not reported <input type="checkbox"/> 1i. Eosinophils	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cells/mm ³				
Not reported <input type="checkbox"/> 1j. Basophils	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cells/mm ³				
2. Chemistries	<input type="checkbox"/> Not done/Not collected <i>End of form.</i> ←	Alternate Collection Date dd <input type="text"/> <input type="text"/>	MMM <input type="text"/> <input type="text"/>	yy <input type="text"/> <input type="text"/>	
Not reported <input type="checkbox"/> 2a. AST (SGOT)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> U/L	Severity Grade (if applicable) <input type="text"/>	AE Log page # <input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	not reportable as an AE
Not reported <input type="checkbox"/> 2b. ALT (SGPT)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> U/L	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	
Not reported <input type="checkbox"/> 2c. Creatinine	OR <input type="text"/> <input type="text"/> . <input type="text"/> mg/dL <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> μmol/L	Severity Grade (if applicable) <input type="text"/>	AE Log page # <input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	not reportable as an AE

Quarterly Laboratory Results (QLR-1)

Purpose: This form is used to provide data on the participant's quarterly laboratory test results.

General Information/ Instructions: Use this form to report the hematology, differential, and liver and renal function test results obtained from specimens collected at quarterly and semi-annual, the Product Use End Visit (PUEV), and early termination (as applicable) visits as they become available.

- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form). A complete date is required.
- **Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. A complete date is required.
- **Not done/Not collected:** Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage.

Results Reporting:

- Results should be documented on the form using the units present on the source laboratory results document. If the units present on the form do not match your source results report, contact the MTN-020 Management Team. Note that the following units are equivalent:

$$\text{IU/L} = \text{U/L} \qquad \text{I/I} \times 100 = \% \qquad 10^9/\text{L} = 10^3/\text{mm}^3 = 10^3/\mu\text{L}$$

For creatinine, only record the result in the units listed on the source document.

- If the site lab does not report results to the same level of precision allowed on the form, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the form. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
 - If the site lab does not produce test results in the units used on this form, first perform the conversion, then round the converted result if necessary.

Severity Grade:

- If any values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results. If a value is below severity grade 1, leave the "Severity Grade," "AE Log page #," and "not reportable as an AE" boxes blank.
- Always compare the severity grade range to the value that was recorded on the form (not the lab-reported value).
- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
 - Treat all missing digits in the lab value as zeros.
 - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
- Record any Grade 1 or higher lab values on the Adverse Experience (AE) Log as applicable.



MTN-020 ASPIRE (192)

APX-1 (136)

Visit Month .

1

Participant ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> Site Number Participant Number Chk </small>	Visit Date <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy </small>
---	---

Abbreviated Physical Exam

VITAL SIGNS

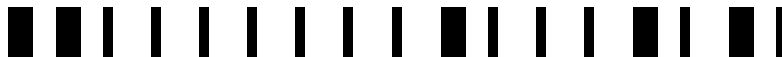
1. Weight <input type="text"/> <input type="text"/> <input type="text"/> kg	4. Pulse <input type="text"/> <input type="text"/> <input type="text"/> beats per minute
2. Body Temp <input type="text"/> <input type="text"/> . <input type="text"/> °C	5. Respirations <input type="text"/> <input type="text"/> breaths per minute
3. BP <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> mmHg	

SYMPTOM-DIRECTED FINDINGS *Items 6 and 7 are required assessments. Other items assessed if clinically indicated.*

	<i>not done</i>	<i>normal</i>	<i>abnormal</i>	<i>Notes:</i>
6. General appearance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
7. Abdomen/ Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
8. Neck	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
9. Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
10. Heart/ Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
11. Lungs/ Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
12. Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
13. Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
14. Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
15. Eyes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
16. Ears, Nose, Throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
17. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Record abnormal findings on the Adverse Experience Log or Grade 1 Adverse Experience Log, if applicable.

Abbreviated Physical Exam (APX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings at study follow-up visits as specified in the protocol.
General Information/ Instructions:	Complete this form at quarterly, semi-annual, the Product Use End Visit (PUEV), and at an early termination visit, as applicable.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed.
Items 6-7:	These items are required to be assessed at each quarterly, semi-annual, and the PUEV or early termination visit.
Items 8-17:	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings on the Notes line. If not evaluated, mark the "not done" box.
Item 17:	If abnormal, specify the body system being referenced and describe the findings on the Notes line.



Visit Month .

1

MTN-020 ASPIRE (192)

PE-1 (138)

Participant ID - -

Site Number Participant Number Chk

Exam Date

dd MMM yy

Pelvic Exam

1. Pelvic exam assessment: *not done* *abnormal findings* *no abnormal findings* → *If no abnormal findings, go to item 2.*
 ↘ *If not done, end of form.*

1a. Abnormal findings. *Mark all that apply.*

VULVAR	VAGINAL	CERVICAL	GENERAL/OTHER
<input type="checkbox"/> vulvar edema <input type="checkbox"/> vulvar erythema <input type="checkbox"/> vulvar rash <input type="checkbox"/> vulvar tenderness <input type="checkbox"/> Bartholin's or Skene's gland abnormality <u>Vulvar lesions</u> <input type="checkbox"/> ulcer <input type="checkbox"/> blister <input type="checkbox"/> pustule <input type="checkbox"/> peeling <input type="checkbox"/> ecchymosis	<input type="checkbox"/> vaginal edema <input type="checkbox"/> vaginal erythema <input type="checkbox"/> vaginal masses (polyps, myomas, possible malignancy) <input type="checkbox"/> vaginal abrasions or lacerations <input type="checkbox"/> vaginal tenderness <u>Abnormal vaginal discharge</u> <input type="checkbox"/> slight <input type="checkbox"/> moderate <input type="checkbox"/> pooling <u>Vaginal lesions</u> <input type="checkbox"/> ulcer <input type="checkbox"/> blister <input type="checkbox"/> pustule <input type="checkbox"/> peeling <input type="checkbox"/> ecchymosis	<input type="checkbox"/> cervical edema and/or friability <input type="checkbox"/> cervical erythema <input type="checkbox"/> cervical masses (polyps, myomas, possible malignancy) <input type="checkbox"/> cervical motion tenderness <input type="checkbox"/> cervical discharge <u>Cervical lesions</u> <input type="checkbox"/> ulcer <input type="checkbox"/> blister <input type="checkbox"/> pustule <input type="checkbox"/> peeling <input type="checkbox"/> ecchymosis	<input type="checkbox"/> odor (vaginal) <input type="checkbox"/> condyloma, specify location: <hr/> <input type="checkbox"/> adnexal masses (based on bimanual exam; not pregnancy or infection-related) <input type="checkbox"/> uterine masses (based on bimanual exam) <input type="checkbox"/> uterine tenderness <input type="checkbox"/> adnexal tenderness <input type="checkbox"/> observed blood or bleeding; describe: <hr/> <hr/> <hr/> <hr/>

1b. Other abnormal findings, specify (include anatomical location): _____

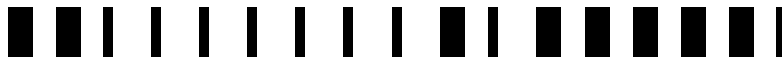
Complete or update Adverse Experience Log as applicable.

2. Were any new pelvic finding AEs reported at this visit? *yes* *no* → *If no, go to item 3.*

2a. AE Log page (#)s:

3. Cervical ectopy: 0% 1-25% 26-50% 51-75% 76-100%

Pelvic Exam (PE-1)	
Purpose:	This form is used to document the participant's pelvic exam assessment during study follow-up.
General Information/Instructions:	Complete this form at each semi-annual visit, the Product Use End Visit (PUEV), at early termination visit (as applicable), and when a clinically indicated pelvic exam is performed during follow-up. Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to DataFax.
Item-specific Instructions:	
Item 1:	Note that observation of any genital blood or bleeding is considered an abnormal finding, regardless of whether the blood is expected (menstrual blood, for example). If blood or bleeding is observed, mark the "abnormal findings" box and in item 1a, mark the "observed blood or bleeding; describe" box and describe on the lines provided.
Item 1a:	<p>Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark the "other abnormal findings, specify" box and describe the abnormal finding on the line provided, including anatomical location. In general, for abnormal findings reported as adverse events on an AE Log, use text from item 1a as AE descriptive text finding (this does not apply to observations of blood or bleeding).</p> <p>Observed blood or bleeding; describe: If blood or bleeding is observed, mark this item and in the space provided, briefly describe the color, amount, and location of the blood/bleeding. If known, specify if the blood was menstrual or non-menstrual. Assess the blood/bleeding for AE reporting purposes. Per Study-specific Procedures (SSP) manual section 10.6, all bleeding occurring during follow-up that is different from the participant's baseline bleeding pattern is an AE. This may include unusually heavy or prolonged menses, as well as non-menstrual bleeding different from baseline.</p> <p>Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the <i>Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Addendum 1: Female Genital Grading Table for Use in Microbicide Studies (FGGT)</i>. Refer to SSP manual section 10.6 for more information/guidance as needed.</p>



Visit Month .

1

MTN-020 ASPIRE (192)

STI-1 (190)

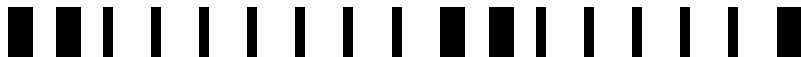
Participant ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> Site Number Participant Number Chk </small>	Initial Specimen Collection Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy </small>
---	---

STI Test Results					
1. Vaginal Wet Prep	<input type="checkbox"/>	Not done/ Not collected ←	Alternate Collection Date dd MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
<input type="checkbox"/> 1a. Homogeneous vaginal discharge	<input type="checkbox"/>	negative	<input type="checkbox"/>	positive	<input type="checkbox"/>
<input type="checkbox"/> 1b. pH <input type="text"/> . <input type="text"/>	<input type="checkbox"/>	If > 4.5, mark as positive. →	positive	<input type="checkbox"/>	
<input type="checkbox"/> 1c. Whiff test	<input type="checkbox"/>	negative	<input type="checkbox"/>	positive	<input type="checkbox"/>
<input type="checkbox"/> 1d. Clue cells ≥ 20%	<input type="checkbox"/>	negative	<input type="checkbox"/>	positive	<input type="checkbox"/>
<input type="checkbox"/> 1e. <i>Trichomonas vaginalis</i>	<input type="checkbox"/>	negative	<input type="checkbox"/>	positive	<input type="checkbox"/>
<input type="checkbox"/> 1f. Buds and/or hyphae (yeast)	<input type="checkbox"/>	negative	<input type="checkbox"/>	positive	<input type="checkbox"/>
2. <i>Trichomonas</i> Rapid Test	<input type="checkbox"/>	Not done/ Not collected	Alternate Collection Date dd MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	negative	positive
<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
3. <i>N. gonorrhoeae</i>	<input type="checkbox"/>	Not done/ Not collected	Alternate Collection Date dd MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	negative	positive
<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
4. <i>C. trachomatis</i>	<input type="checkbox"/>	Not done/ Not collected	Alternate Collection Date dd MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	negative	positive
<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Complete or update Adverse Experience Log, if applicable.

Comments: _____

STI Test Results (STI-1)	
Purpose:	This form is used to document Vaginal Wet Prep and STI Test Results by the local site laboratory.
General Information/ Instructions:	<p>Complete this form at each semi-annual visit, the Product Use End Visit (PUEV), at early termination (as applicable), and at other visits where these tests are performed during follow-up.</p> <ul style="list-style-type: none"> • Initial Specimen Collection Date: Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form). A complete date is required. • Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. A complete date is required. • Not done/Not collected: Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments lines.
Item-specific Instructions:	
Items 1–4:	If a test result(s) recorded on this form indicates that the participant has a new (or increased severity) laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse experience on an Adverse Experience (AE) Log.
Item 1:	If a vaginal wet prep was performed but not all assays were completed, mark the "Not done/Not collected" box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason on the Comments lines.
Item 1a:	Mark the "positive" box if homogeneous vaginal discharge was observed.
Item 1b:	Vaginal fluid pH is required at all semi-annual visits and the PUEV.
Item 1d:	Mark the "positive" box if 20% or more of the cells were clue cells.
Item 1e:	Mark the "positive" box if trichomonads were observed.
Item 1f:	Mark the "positive" box if yeast buds and/or hyphae were observed.



Visit Month .

1

MTN-020 ASPIRE (192)

PLR-1 (193)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 40px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> Site Number Participant Number Chk </small>	Initial Specimen Collection Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy </small>
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PUEV Laboratory Results

1. PAP SMEAR Not done/Not collected

Alternate Collection Date

negative for intraepithelial lesion or cancer (malignancy) SIL-high grade (HSIL)
 ASCUS AGC
 ASC-H AGC-favor neoplastic
 SIL-low grade (LSIL) cancer

Go to item 2. ←

2. SYPHILIS SEROLOGY Not done/Not collected

Alternate Collection Date

Go to item 3. ←

2a. Syphilis screening test non-reactive reactive

If non-reactive, go to item 3. →

2a1. Syphilis titer 1:

2b. Syphilis confirmatory test negative positive indeterminate

3. Were any new AE Log pages completed based on results recorded on this form? yes no

If no, end of form. →

3a. AE Log page number(s)

Complete or update Adverse Experience Log, if applicable.

PUEV Laboratory Results (PLR-1)	
Purpose:	This form is used to document results of Pap specimens and Syphilis serology collected during the Product Use End Visit (PUEV).
General Information/ Instructions:	<p>This form is completed at the PUEV. It is also completed at an early termination visit, if applicable. Record test results on this form as they become available. If the Pap test result indicates that the participant has a condition requiring further evaluation, record the result on the Adverse Experience (AE) Log. Do not use this Pap smear to diagnose STIs, such as Trichomoniasis.</p> <ul style="list-style-type: none"> • Initial Specimen Collection Date: Record the date that the first specimen(s) was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required. • Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. A complete date is required.
Item-specific Instructions:	
Item 1:	<p>Record the Pap Smear result. Mark only one box.</p> <ul style="list-style-type: none"> • Negative for intraepithelial lesion or cancer (malignancy): Includes all normal findings and any findings of infection (trichomonas, candida, etc.), reactive changes/inflammation, glandular changes due to hysterectomy, or atrophic changes. • ASCUS: Mark this box when abnormal/atypical squamous cells of undetermined significance are reported. • ASC-H: Mark this box when abnormal/atypical squamous cells that cannot exclude high-grade squamous intraepithelial lesions (HSIL) are reported. • SIL-low grade (LSIL): Mark this box when low-grade squamous interepithelial lesions are reported. This category includes presence of human papillomavirus (HPV) infection, mild dysplasia, and cervical interepithelial neoplasia (CIN 1). • SIL-high grade (HSIL): Mark this box when high-grade squamous interepithelial lesions are reported. This category includes the presence of moderate to severe dysplasia, carcinoma in situ (CIS), CIN 2, and CIN 3, or changes suspicious for invasive cancer. • AGC: Mark this box when atypical/abnormal glandular cells are reported. This category includes endocervical (from cervical canal) atypical cells; endometrial atypical cells; glandular atypical cells. • AGC-favor neoplastic: Mark this box when atypical/abnormal glandular cells that favor cell growth (neoplastic changes) are reported. This category includes endocervical cells and glandular cells. • Cancer: Mark this box when cancer or adenocarcinoma is reported. This includes endocervical, endometrial, extrauterine, and other (not specified) cancers/adenocarcinomas.
Item 2:	If the syphilis screening test is reactive, items 2a1 and 2b must be completed.
Item 2a1:	Use leading zeros when recording a syphilis titer level. For example, a titer level of 1:16 would be recorded on the form as "1:0016."
Item 2b:	If a result is positive, provide treatment according to WHO guidelines, and report the relevant infection on the AE Log.



MTN-020 ASPIRE (192)

FAT-1 (153)

Visit Month .

1

Participant ID <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> - <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> - <input style="width: 20px;" type="text"/>	Visit Date <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>
Site Number Participant Number Chk	dd MMM yy

Follow-up ACASI Tracking

1. Was an ACASI questionnaire completed at this visit? yes no → *If no, record reasons in Comments. End the form.*

1a. Which questionnaire was completed? Month 3 PUEV/Discontinuers → *If Month 3, go to item 2.*

1b. Reason PUEV/Discontinuers ACASI questionnaire was completed:	scheduled PUEV	early termination	permanent product discontinuation prior to PUEV/early termination
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Were there any problems or issues related to the administration or completion of the questionnaire? yes no → *If no, end of form.*

2a. Describe:

Comments: _____

Follow-up ACASI Tracking (FAT-1)	
Purpose:	This form is used to document participant completion of the Audio Computer-assisted Self Interview (ACASI) computerized questionnaires during follow-up.
General Information/ Instructions:	<p>Complete this form at the Month 3 Visit. Also complete this form at the participant's Product Use End Visit (PUEV) or early termination visit.</p> <p>Additionally, complete this form (and the PUEV/Discontinuers ACASI questionnaire) if participant is permanently discontinued from study product (as documented by a Product Hold/Discontinuation Log).</p>
Item-specific Instructions:	
Item 2a:	Use this space to describe when and why multiple ACASI questionnaires are completed for a participant at a visit. If there were any unusual details related to the ACASI questionnaire administration or completion, describe them here.

Not a DataFax form. Do not fax to DataFax.

MTN-020 ASPIRE (192)

Pelvic Exam Diagrams

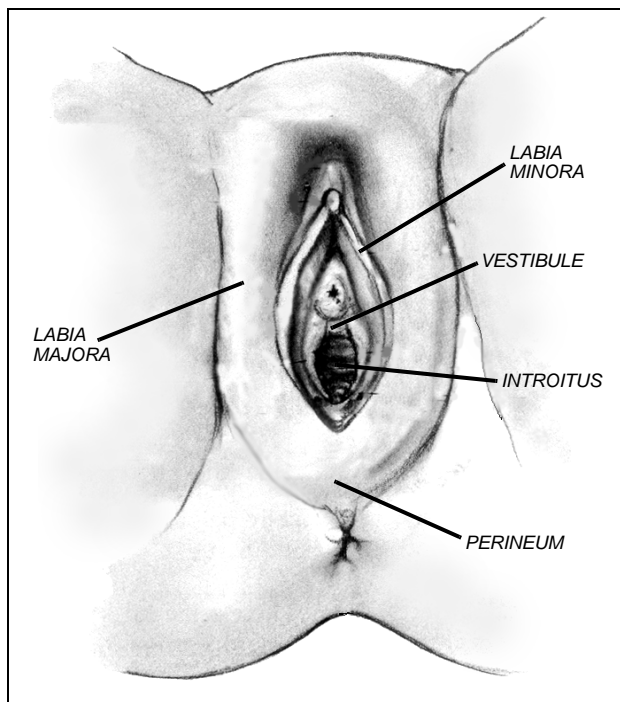
Page 1 of 1

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	Exam Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
Site Number Participant Number Chk	dd MMM yy

no normal variants or abnormal findings observed

Speculum Type (screening only)			Speculum Size (screening only)		
<i>Pederson</i>	<i>Graves</i>	<i>Cusco</i>	<i>small</i>	<i>medium</i>	<i>large</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

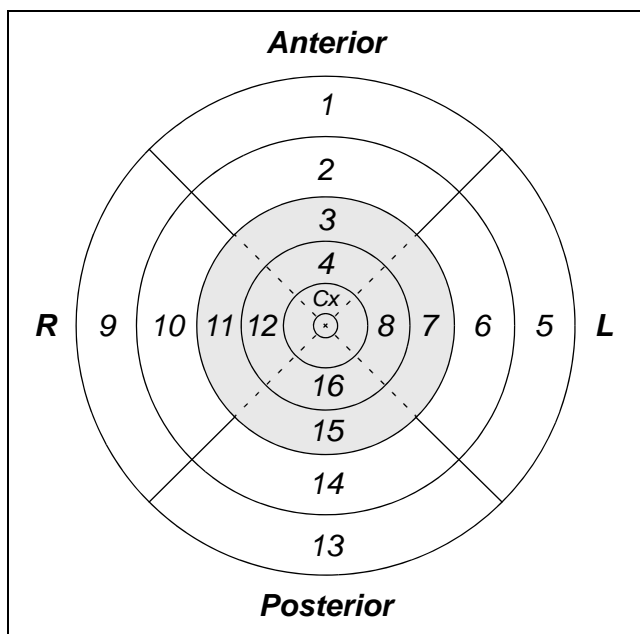
External Genitalia



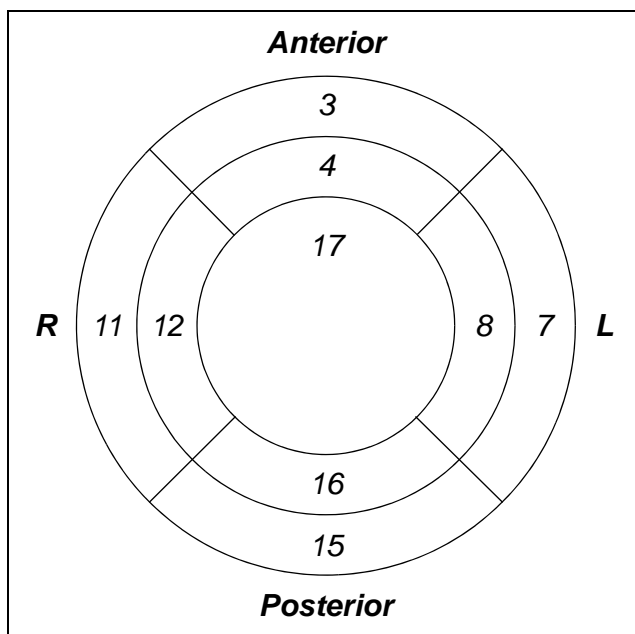
Legend for Vagina/Cervix

1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, proximal half
11. Right lateral fornix
12. Cervical trunk, right lateral
13. Posterior vagina, distal half
14. Posterior vagina, proximal half
15. Posterior fornix
16. Cervical trunk, post
17. Cervical face

Vagina



Cervix



26-APR-12

English

Staff Initials / Date

Pelvic Exam Diagrams (non-DataFax)	
Purpose:	This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through termination/study exit).
General Information/ Instructions:	This form is completed at the Screening Visit, each semi-annual visit, at the Product Use End Visit (PUEV), and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to SCHARP DataFax. Transcribe information onto the appropriate Pelvic Exam DataFax form for submission to DataFax and store this form in the participant's chart notes.
Item-specific Instructions:	
Findings:	<p>All variants of normal (normal findings) and all abnormal findings must be documented on this form. Variants of normal need only be recorded on this form, and not on any of the Pelvic Exam DataFax forms. The following findings are considered normal variants:</p> <ul style="list-style-type: none"> • anatomic variants • gland openings • Nabothian cysts • mucus retention cysts • Gartner's duct cysts • blood vessel changes other than disruption • skin tags • scars <p>If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box.</p>
Documenting findings on the cervix:	If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).