

Study Exit/Termination Visit

Visit Month: _____

- Visit Summary (VS-1)
- Monthly Laboratory Results (MLR-1)
- Specimen Storage (SS-1)
- Termination (TM-1)
- End of Study Inventory (ESI-1)

Site to add:

- Study Exit Assessment (SEV-1~5) – *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: 30px;" type="text"/> <input style="width: 30px;" type="text"/> - <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> - <input style="width: 30px;" type="text"/> <small>Site Number Participant Number Chk</small>	Visit Date <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> / <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> / <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <small>dd MMM yy</small>
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Visit Summary	
1. Location of study visit	clinic <input type="checkbox"/> home <input type="checkbox"/> other, specify: <input type="text"/>
2. Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV?	yes <input type="checkbox"/> no <input type="checkbox"/> ▶ If yes and currently using PEP, complete Product Hold/Discontinuation Log. Record on Concomitant Medications Log.
3. Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV?	yes <input type="checkbox"/> no <input type="checkbox"/> ▶ If no, go to item 4.
3a. Was oral or topical PrEP used?	oral <input type="checkbox"/> topical <input type="checkbox"/> both <input type="checkbox"/> ▶ Record on Concomitant Medications Log.
4. Is this a PUEV, early termination, or scheduled study termination visit?	yes <input type="checkbox"/> no <input type="checkbox"/> ▶ If no, go to item 5.
4a. Visit Type <i>Mark only one.</i>	PUEV <input type="checkbox"/> scheduled termination <input type="checkbox"/> early termination <input type="checkbox"/> ▶ Go to item 6.
5. Is this an interim visit?	yes <input type="checkbox"/> no <input type="checkbox"/> ▶ If no, go to item 6.
5a. Reason for interim visit <i>Mark all that apply.</i>	AE report or follow-up <input type="checkbox"/> return of ring or need for a new ring <input type="checkbox"/> other, specify: <input type="text"/>
5b. Which forms, besides this form, were newly completed for this interim visit? <i>Mark "none" or all that apply.</i>	
<input type="checkbox"/> 5b1. None ▶ End of form.	<input type="checkbox"/> 5b6. Quarterly Laboratory Results
<input type="checkbox"/> 5b2. Adverse Experience Log	<input type="checkbox"/> 5b7. STI Test Results
<input type="checkbox"/> 5b3. Product Hold/Discontinuation Log	<input type="checkbox"/> 5b8. Pelvic Exam
<input type="checkbox"/> 5b4. Ring Collection/Insertion	<input type="checkbox"/> 5b9. other, specify: <input type="text"/>
<input type="checkbox"/> 5b5. Monthly Laboratory Results	
After completing item 5b, end of form.	
6. Were any new Adverse Experience Log forms completed for this visit?	yes <input type="checkbox"/> no <input type="checkbox"/>
7. Were any new Product Hold/Discontinuation Log forms completed for this visit?	yes <input type="checkbox"/> no <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>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"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>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: 15%;">Not done/ Not collected</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="width: 15%; text-align: center;">Alternate Collection Date</td> <td style="width: 15%; text-align: center;"><small>dd</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 15%; text-align: center;"><small>MMM</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 15%; text-align: center;"><small>yy</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 10%; text-align: center;"><small>negative</small> <input type="checkbox"/></td> <td style="width: 10%; text-align: center;"><small>positive</small> <input type="checkbox"/></td> </tr> </table> <p style="text-align: right; font-size: small;"><i>If newly positive, complete Product Hold/Discontinuation Log and Pregnancy Report.</i></p>	Not done/ Not collected	<input type="checkbox"/>	Alternate Collection Date	<small>dd</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>MMM</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>yy</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>negative</small> <input type="checkbox"/>	<small>positive</small> <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: 15%;">Not done/ Not collected</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="width: 15%; text-align: center;">Alternate Collection Date</td> <td style="width: 15%; text-align: center;"><small>dd</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 15%; text-align: center;"><small>MMM</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 15%; text-align: center;"><small>yy</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 10%; text-align: center;"><small>negative</small> <input type="checkbox"/></td> <td style="width: 10%; text-align: center;"><small>positive</small> <input type="checkbox"/></td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;">Kit code</td> <td colspan="5"></td> </tr> <tr> <td></td> <td></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td colspan="5"></td> </tr> </table>	Not done/ Not collected	<input type="checkbox"/>	Alternate Collection Date	<small>dd</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>MMM</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>yy</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>negative</small> <input type="checkbox"/>	<small>positive</small> <input type="checkbox"/>			Kit code								<input style="width: 20px; height: 20px;" type="text"/>					
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		Kit code																							
		<input style="width: 20px; height: 20px;" type="text"/>																							
3. Rapid HIV test 2	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 15%;">Not done/ Not collected</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="width: 15%; text-align: center;">Alternate Collection Date</td> <td style="width: 15%; text-align: center;"><small>dd</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 15%; text-align: center;"><small>MMM</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 15%; text-align: center;"><small>yy</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 10%; text-align: center;"><small>negative</small> <input type="checkbox"/></td> <td style="width: 10%; text-align: center;"><small>positive</small> <input type="checkbox"/></td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;">Kit code</td> <td colspan="5"></td> </tr> <tr> <td></td> <td></td> <td><input style="width: 20px; height: 20px;" type="text"/></td> <td colspan="5"></td> </tr> </table> <p style="text-align: center; font-size: small;"><i>If positive to either, complete HIV Confirmatory Results and Product Hold/Discontinuation Log.</i></p>	Not done/ Not collected	<input type="checkbox"/>	Alternate Collection Date	<small>dd</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>MMM</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>yy</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>negative</small> <input type="checkbox"/>	<small>positive</small> <input type="checkbox"/>			Kit code								<input style="width: 20px; height: 20px;" type="text"/>					
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		<input style="width: 20px; height: 20px;" type="text"/>																							
4. Was plasma stored for HIV confirmatory testing?	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 15%;">yes</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;">no</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;">not required</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="width: 25%;"></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="font-size: small;"><i>If no or not required, go to item 5.</i></td> </tr> </table> <p style="padding-left: 20px;">4a. Plasma for HIV confirmatory testing collection date</p> <table style="width:100%; border-collapse: collapse; margin-left: 20px;"> <tr> <td style="text-align: center; width: 15%;"><small>dd</small></td> <td style="width: 15%; text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; width: 15%;"><small>MMM</small></td> <td style="width: 15%; text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; width: 15%;"><small>yy</small></td> <td style="width: 15%; text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> </tr> </table>	yes	<input type="checkbox"/>	no	<input type="checkbox"/>	not required	<input type="checkbox"/>								<i>If no or not required, go to item 5.</i>	<small>dd</small>	<input style="width: 20px; height: 20px;" type="text"/>	<small>MMM</small>	<input style="width: 20px; height: 20px;" type="text"/>	<small>yy</small>	<input style="width: 20px; height: 20px;" type="text"/>				
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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: 15%;">Alternate Collection Date</td> <td style="width: 15%; text-align: center;"><small>dd</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 15%; text-align: center;"><small>MMM</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 15%; text-align: center;"><small>yy</small> <input style="width: 20px; height: 20px;" type="text"/></td> <td style="width: 10%; text-align: center;"><small>not required</small> <input type="checkbox"/></td> <td style="width: 10%; text-align: center;"><small>stored</small> <input type="checkbox"/></td> <td style="width: 10%; text-align: center;"><small>not stored</small> <input type="checkbox"/></td> <td style="width: 20%;"><small>Reason:</small> _____</td> </tr> </table> <p style="font-size: small;"><i>If not required or not stored, end of form.</i></p>	Alternate Collection Date	<small>dd</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>MMM</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>yy</small> <input style="width: 20px; height: 20px;" type="text"/>	<small>not required</small> <input type="checkbox"/>	<small>stored</small> <input type="checkbox"/>	<small>not stored</small> <input type="checkbox"/>	<small>Reason:</small> _____																
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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: 15%;">yes</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;">no</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> </tr> </table>	yes	<input type="checkbox"/>	no	<input type="checkbox"/>																				
yes	<input type="checkbox"/>	no	<input type="checkbox"/>																						
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: 15%;">yes</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><small>no – ring removed prior to swab collection</small></td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><small>no – ring not in place at start of visit</small></td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;"><small>no – new ring inserted prior to swab collection</small></td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> </tr> </table>	yes	<input type="checkbox"/>	<small>no – ring removed prior to swab collection</small>	<input type="checkbox"/>	<small>no – ring not in place at start of visit</small>	<input type="checkbox"/>	<small>no – new ring inserted prior to swab collection</small>	<input type="checkbox"/>																
yes	<input type="checkbox"/>	<small>no – ring removed prior to swab collection</small>	<input type="checkbox"/>	<small>no – ring not in place at start of visit</small>	<input type="checkbox"/>	<small>no – new ring inserted prior to swab collection</small>	<input type="checkbox"/>																		

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.*

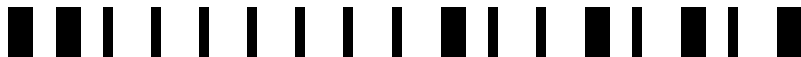
Kit Code	Rapid Test
01	Determine
02	OraQuick
03	Uni-Gold Recombigen
04	StatPak

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.



Visit Month .

1

MTN-020 ASPIRE (192)

SS-1 (149)

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"/> <p style="font-size: small; text-align: center;">Site Number Participant Number Chk</p>	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"/> <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;"><i>dd</i> <i>MMM</i> <i>yy</i></p>
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Specimen Storage																									
1. Vaginal smear for gram stain:	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;">Alternate Collection Date</td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><i>dd</i></td> <td style="text-align: center; padding: 5px;"><i>MMM</i></td> <td style="text-align: center; padding: 5px;"><i>yy</i></td> <td style="text-align: center; padding: 5px;"><i>not required</i></td> <td style="text-align: center; padding: 5px;"><i>stored</i></td> <td style="text-align: center; padding: 5px;"><i>not stored</i></td> <td style="padding: 5px;"><i>Reason:</i></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="padding: 5px;">_____</td> <td style="padding: 5px;"></td> </tr> </table>	Alternate Collection Date								<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</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"/>	<input type="checkbox"/>	_____	
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<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</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"/>	<input type="checkbox"/>	_____																			
2. Endocervical swab for biomarkers:	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;">Alternate Collection Date</td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><i>dd</i></td> <td style="text-align: center; padding: 5px;"><i>MMM</i></td> <td style="text-align: center; padding: 5px;"><i>yy</i></td> <td style="text-align: center; padding: 5px;"><i>not required</i></td> <td style="text-align: center; padding: 5px;"><i>stored</i></td> <td style="text-align: center; padding: 5px;"><i>not stored</i></td> <td style="padding: 5px;"><i>Reason:</i></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="padding: 5px;">_____</td> <td style="padding: 5px;"></td> </tr> </table> <p style="margin-left: 20px;">2a. Was blood visible on the swab?</p> <p style="margin-left: 20px;"><i>yes</i> <i>no</i></p> <p style="margin-left: 20px;"><input type="checkbox"/> <input type="checkbox"/></p> <p style="margin-left: 100px;">_____</p> <p style="margin-left: 100px;"><i>If not required or not stored, go to item 3.</i></p>	Alternate Collection Date								<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</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"/>	<input type="checkbox"/>	_____	
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3. Quarterly/ semi-annual/PUEVI/ study exit plasma for PK:	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;">Alternate Collection Date</td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><i>dd</i></td> <td style="text-align: center; padding: 5px;"><i>MMM</i></td> <td style="text-align: center; padding: 5px;"><i>yy</i></td> <td style="text-align: center; padding: 5px;"><i>not required</i></td> <td style="text-align: center; padding: 5px;"><i>stored</i></td> <td style="text-align: center; padding: 5px;"><i>not stored</i></td> <td style="padding: 5px;"><i>Reason:</i></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="padding: 5px;">_____</td> <td style="padding: 5px;"></td> </tr> </table>	Alternate Collection Date								<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</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"/>	<input type="checkbox"/>	_____	
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4. Used vaginal ring:	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;">Alternate Collection Date</td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><i>dd</i></td> <td style="text-align: center; padding: 5px;"><i>MMM</i></td> <td style="text-align: center; padding: 5px;"><i>yy</i></td> <td style="text-align: center; padding: 5px;"><i>not required</i></td> <td style="text-align: center; padding: 5px;"><i>stored</i></td> <td style="text-align: center; padding: 5px;"><i>not stored</i></td> <td style="padding: 5px;"><i>Reason:</i></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="padding: 5px;">_____</td> <td style="padding: 5px;"></td> </tr> </table>	Alternate Collection Date								<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</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"/>	<input type="checkbox"/>	_____	
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Comments: _____

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)

TM-1 (490)

Participant ID - -

Site Number Participant Number Chk

Termination

1. Termination date *Date the site determined that the participant was no longer in the study.*

dd MMM yy

2. Reason for termination *Mark only one.*

2a. scheduled exit visit/end of study \longrightarrow **End of form.**

2b. death, *indicate date and cause if known*

2b1. date of death: *date unknown* OR

dd MMM yy

2b2. cause of death: _____ *cause unknown* OR \longrightarrow **Complete or update Adverse Experience Log.**

2c. participant refused further participation, specify: _____

2d. ~~NOT APPLICABLE FOR THIS PROTOCOL~~ schedule

2e. participant relocated, no follow-up planned

2f. investigator decision, specify: _____

2g. unable to contact participant

2h. ~~NOT APPLICABLE FOR THIS PROTOCOL.~~

2i. inappropriate enrollment \longrightarrow **End of form.**

2j. invalid ID due to duplicate screening/enrollment \longrightarrow **End of form.**

2k. other, specify: _____

2l. early study closure

3. Was termination associated with an adverse experience? *yes* *no* *don't know* \longrightarrow **If no or don't know, end of form.**

AE Log page #

3a. Record AE Log page number OR Specify: _____

Comments: _____

Termination (TM-1)	
Purpose:	This form should be completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.
Item-specific Instructions:	
Item 1:	A complete date is required.
Item 2:	Mark only the primary reason for termination.
Item 2a:	Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.
Item 2b1:	At a minimum, the month and year are required.
Item 2l:	Early study closure: Only mark 2l when instructed by SCHARP.
Item 3a:	Record the page number of the Adverse Experience Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the "specify" line.



MTN-020 ASPIRE (192)

ESI-1 (489)

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>	Form Completion 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>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

End of Study Inventory	
1. Did the participant complete her scheduled study exit (4-week post-product use) visit?	yes <input type="checkbox"/> no <input type="checkbox"/>
2. What is the highest visit month (scheduled or interim) for this participant, recorded on a form submitted via DataFax?	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <i>visit month</i>
3. How many interim visits were conducted for this participant during the study and recorded on a form submitted via DataFax?	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i># of interim visits</i>
4. Indicate the highest page number submitted for this participant for each of the following forms:	
4a. Adverse Experience Log (AE)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i> OR <input type="checkbox"/> <i>no pages submitted</i>
4b. Concomitant Medications Log (CM)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i>
4c. Pre-existing Conditions (PRE)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i>
4d. Product Hold/Discontinuation Log (PH)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i> OR <input type="checkbox"/> <i>no pages submitted</i>
4e. Social Impact Log (SIL)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i> OR <input type="checkbox"/> <i>no pages submitted</i>
4f. Protocol Deviations Log (PDL)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i> OR <input type="checkbox"/> <i>no pages submitted</i>
4g. Grade 1 Adverse Experience Log (GAE) <i>Record highest page number completed.</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"/> <i>page #</i> OR <input type="checkbox"/> <i>no pages completed</i>

Comments: _____

End of Study Inventory (ESI-1)	
Purpose:	This form is used to confirm that SCHARP has received all study data for a given participant.
General Information/ Instructions:	Complete this form once for each enrolled participant after the participant has terminated from the study (as documented by a Termination form).
Item-specific Instructions:	
Form Completion Date:	A complete date is required.
Item 2:	Record the highest visit month (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit month of the missed visit.
Item 3:	Record the total number of interim visits documented on the Visit Summary DataFax forms submitted for this participant. If no interim visits were completed for the participant, record "000" in the boxes.
Item 4a, 4d, and 4e:	Record the highest page number of the Adverse Experience Log, Product Hold/Discontinuation Log, Protocol Deviations Log, and Social Impact Log submitted for this participant, even if that page was marked for deletion.
Item 4g:	Record the highest page number completed for the Grade 1 Adverse Experience Log. Complete this item even though these forms are not faxed to SCHARP.