

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

## MTN-025 Follow-up Visit Summary

Location of study visit:	<input type="checkbox"/> Clinic <input type="checkbox"/> Home <input type="checkbox"/> Other If other, specify: _____
Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV?	<input type="checkbox"/> Yes → <i>If yes and currently using PEP, complete Product Hold/Discontinuation Log. Record on Concomitant Medication Log.</i> <input type="checkbox"/> No
Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, skip to "Is this an interim visit?"</i>
Was oral or topical PrEP used?	<input type="checkbox"/> Oral <input type="checkbox"/> Topical <input type="checkbox"/> Both <i>Record on Concomitant Medications Log.</i>
Is this an interim visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, skip to "Is this visit an PUEV, scheduled Study Exit Visit or an early termination?"</i>
Reason for interim visit ( <i>Mark all that apply</i> ):	<input type="checkbox"/> AE report or follow-up <input type="checkbox"/> Return of ring or need for a new ring <input type="checkbox"/> Other Other, specify: _____
Is this visit a PUEV, scheduled Study Exit Visit or an early termination?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, end of form.</i>
Visit Type:	<input type="checkbox"/> PUEV <input type="checkbox"/> Scheduled Termination <input type="checkbox"/> Early Termination

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## MTN-025 Interim Visit Procedures

Interim Visit Number	_____ . _____
Follow-up Visit Summary	<input type="checkbox"/> Yes <input type="checkbox"/> No
ACASI Tracking	<input type="checkbox"/> Yes <input type="checkbox"/> No
Pelvic Exam	<input type="checkbox"/> Yes <input type="checkbox"/> No
Physical Exam	<input type="checkbox"/> Yes <input type="checkbox"/> No
Vital Signs	<input type="checkbox"/> Yes <input type="checkbox"/> No
STI Test Results	<input type="checkbox"/> Yes <input type="checkbox"/> No
Seroconverter Laboratory Results	<input type="checkbox"/> Yes <input type="checkbox"/> No
HIV Test Results	<input type="checkbox"/> Yes <input type="checkbox"/> No
Specimen Storage	<input type="checkbox"/> Yes <input type="checkbox"/> No
Ring Collection and Insertion	<input type="checkbox"/> Yes <input type="checkbox"/> No
Pregnancy Report and History	<input type="checkbox"/> Yes <input type="checkbox"/> No
Participant Receipt	<input type="checkbox"/> Yes <input type="checkbox"/> No
Participant Transfer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Pharmacy Ring Dispensation	<input type="checkbox"/> Yes <input type="checkbox"/> No
Pregnancy Outcome	<input type="checkbox"/> Yes <input type="checkbox"/> No
Laboratory Results	<input type="checkbox"/> Yes <input type="checkbox"/> No
Pregnancy Test Result	<input type="checkbox"/> Yes <input type="checkbox"/> No
Behavior Assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No
Vaginal Practices	<input type="checkbox"/> Yes <input type="checkbox"/> No
Social Influences Assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No
Study Exit Assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No
Social Influences Assessment Supplement	<input type="checkbox"/> Yes <input type="checkbox"/> No

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MTN-025 HIV Test Results (Page 1 of 2)

<p>Rapid HIV test 1 (<i>Alere HIV Combo or backup</i>)</p>	<p>Not done/not collected <input type="checkbox"/></p>	<p>Kit Type  <input type="checkbox"/> Alere™ HIV Combo  <input type="checkbox"/> Oraquick ADVANCE HIV-1/2  <input type="checkbox"/> Uni-Gold™ Recombigen® HIV-1/2  <input type="checkbox"/> Not applicable                  If not applicable, Specify: _____</p>	<p><b>Rapid HIV test 1 collection date</b>                  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="text"/></p> <p><input type="checkbox"/> Antibody positive  <input type="checkbox"/> Antigen positive  <input type="checkbox"/> Antibody and antigen positive  <input type="checkbox"/> Negative</p> <p><i>If antibody positive, antigen positive, or antibody and antigen positive, complete Clinical Product Hold/Discontinuation Log.</i></p>
<p>Rapid HIV test 2</p>	<p>Not done/not collected <input type="checkbox"/></p>	<p>Kit Type  <input type="checkbox"/> Alere™ HIV Combo  <input type="checkbox"/> Oraquick ADVANCE HIV -1/2  <input type="checkbox"/> Uni-Gold™ Recombigen® HIV-1/2  <input type="checkbox"/> Not applicable                  If not applicable, Specify: _____</p>	<p><b>Rapid HIV test 2 collection date</b>                  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="text"/></p> <p><input type="checkbox"/> Negative  <input type="checkbox"/> Positive → <i>If positive, complete Clinical Product Hold/Discontinuation Log.</i></p>
<p>Geenius HIV-1/2 Confirmatory test</p>	<p>Not done/not collected <input type="checkbox"/></p>	<p><b>Geenius HIV-1/2 confirmatory test collection date</b>                  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="text"/></p> <p><input type="checkbox"/> HIV negative  <input type="checkbox"/> HIV-1 indeterminate  <input type="checkbox"/> HIV-2 indeterminate  <input type="checkbox"/> HIV-1 positive  <input type="checkbox"/> HIV-2 positive  <input type="checkbox"/> HIV-2 positive with HIV-1 cross-reactivity  <input type="checkbox"/> HIV positive undifferentiated (untypeable)</p>	
<p>Was plasma stored for HIV confirmatory testing?</p>		<p><input type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> Not required → <i>If 'no' or 'not required', skip to "HIV RNA PCR"</i></p>	
<p>Plasma for HIV confirmatory testing collection date</p>		<p><b>Plasma for HIV confirmatory testing collection date</b>                  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="text"/></p>	

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### MTN-025 HIV Test Results (Page 2 of 2)

<p>HIV RNA PCR</p>	<p>Not done/not collected <input type="checkbox"/></p> <p><i>If Not done/not collected, skip to "Absolute CD4+".</i></p>	<p><b>HIV RNA PCR collection date</b></p> <p>dd      MMM      yy</p> <p><input type="text"/><input type="text"/> <input type="text"/><input type="text"/><input type="text"/> <input type="text"/><input type="text"/></p> <p>&gt; = &lt;      viral copies/mL      Target not detected</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <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"/> OR <input type="checkbox"/></p>
<p>HIV RNA PCR kit lower limit of detection</p>	<p>Kit Type</p> <p><input type="checkbox"/> Abbott M2000</p> <p><input type="checkbox"/> Roche Taqman 1/2</p> <p><input type="checkbox"/> Gene Xpert</p>	<p>20      40      viral copies/mL</p> <p><input type="checkbox"/>      <input type="checkbox"/> OR <input type="text"/><input type="text"/><input type="text"/></p>
<p>Absolute CD4+</p>	<p>Not done/not collected <input type="checkbox"/></p> <p><i>If Not done/not collected, skip to "Final HIV Status".</i></p>	<p><b>Absolute CD4+ collection date</b></p> <p>dd      MMM      yy</p> <p><input type="text"/><input type="text"/> <input type="text"/><input type="text"/><input type="text"/> <input type="text"/><input type="text"/></p> <p>Unable to analyze <input type="checkbox"/> OR <input type="text"/><input type="text"/><input type="text"/><input type="text"/> cells/mm3</p>
<p>CD4 %</p>	<p>Not available</p> <p><input type="checkbox"/> OR <input type="text"/><input type="text"/>.<input type="text"/> %</p>	
<p>Final HIV Status</p>	<p><input type="checkbox"/> HIV-1 and HIV-2 uninfected</p> <p><input type="checkbox"/> HIV-1 infected</p> <p><input type="checkbox"/> HIV-2 infected</p> <p><input type="checkbox"/> HIV-1 and HIV-2 infected</p> <p><input type="checkbox"/> Pending</p>	

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## MTN-025 Seroconverter Laboratory Results YN

Is the participant enrolled in MTN-015?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, complete the Seroconverter Laboratory Results form.</i>
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## MTN-025 Seroconverter Laboratory Results

<b>T CELL SUBSETS</b>	Not done/not collected <input type="checkbox"/> → Go to HIV RNA.	<b>Specimen collection date</b> 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="text"/>	
Absolute CD4+	Unable to analyze <input type="checkbox"/> OR	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cells/mm <sup>3</sup>	
CD4 %	Not available <input type="checkbox"/>	<input type="text"/> <input type="text"/> . <input type="text"/> %	
<b>HIV RNA</b>			
HIV RNA PCR	Not done/not collected <input type="checkbox"/> → Go to Seroconverter Plasma Storage.	<b>Specimen collection date</b> 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="text"/> > = <                  viral copies/mL <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"/> OR <input type="checkbox"/>	
HIV RNA PCR Kit Lower limit of detection	<b>Kit Type</b> <input type="checkbox"/> Abbott M2000 <input type="checkbox"/> Roche Taqman <input type="checkbox"/> Gene Xpert	20                  40 <input type="checkbox"/> <input type="checkbox"/> OR	viral copies/mL <input type="text"/> <input type="text"/> <input type="text"/>
<b>Seroconverter Plasma Storage</b>	<b>Specimen collection date</b> 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="text"/> <input type="checkbox"/> Stored <input type="checkbox"/> Not stored → Reason not stored: _____		

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## MTN-025 Pregnancy Test Result

hCG for pregnancy	Not done/not collected <input type="checkbox"/>	<b>Specimen Collection date</b> dd      MMM      yy <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Negative <input type="checkbox"/> Positive → <i>If newly positive, complete a Clinical Product Hold/Discontinuation Log and Pregnancy Report CRF.</i>
First day of last menstrual period	dd      MMM      yy <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> OR <input type="checkbox"/> amenorrheic for past 6 months OR <input type="checkbox"/> no menses since participant's last visit <input type="checkbox"/> End of form	
Last day of last menstrual period	dd      MMM      yy <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> OR <input type="checkbox"/> Ongoing	

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## MTN-025 Pregnancy Report and History

<b>Pregnancy Report</b>	
1a. First day of last menstrual period	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <b>OR</b> <i>dd MMM yy</i> <input type="checkbox"/> Amenorrheic for past 6 months
2. Estimated date of delivery	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <i>dd MMM yy</i>
What information was used to estimate the date of delivery?	
3a. Last menstrual period	<input type="checkbox"/> Yes <input type="checkbox"/> No
3b. Initial ultrasound less than 20 weeks	<input type="checkbox"/> Yes <input type="checkbox"/> No
3c. Initial ultrasound is greater than or equal to 20 weeks	<input type="checkbox"/> Yes <input type="checkbox"/> No
3d. Physical Examination	<input type="checkbox"/> Yes <input type="checkbox"/> No
3e. Conception date by assisted reproduction	<input type="checkbox"/> Yes <input type="checkbox"/> No
3f. Other	<input type="checkbox"/> Yes <input type="checkbox"/> No
3f1. Other, specify: _____	
<b>Pregnancy History</b>	
4. Has the participant ever been pregnant before?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, end of form.</i>
4a. Is this the participant's first pregnancy since enrollment in this study?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, skip to "Does the participant have a history pregnancy complications or fetal/infant congenital anomalies?"</i>
4b. Number of full term live births( ≥37 weeks)	<input type="checkbox"/> <input type="checkbox"/>
4c. Number of premature live births (less than 37 weeks)	<input type="checkbox"/> <input type="checkbox"/>
4d. Number of spontaneous fetal deaths and/or still births (≥20 weeks)	<input type="checkbox"/> <input type="checkbox"/>
4e. Number of spontaneous abortions (less than 20 weeks)	<input type="checkbox"/> <input type="checkbox"/>
4f. Number of therapeutic/elective abortions	<input type="checkbox"/> <input type="checkbox"/>
4g. Number of ectopic pregnancies	<input type="checkbox"/> <input type="checkbox"/>
5. Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, end of form.</i>
5a. If yes, specify:	

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## MTN-025 Pregnancy Outcome YN

Did this pregnancy have an obtainable outcome?	<input type="checkbox"/> Yes → <i>Complete a Pregnancy Outcome form.</i> <input type="checkbox"/> No
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## MTN-025 Pregnancy Outcome (page 1 of 2)

Outcome Number:	_____
	<i>If Outcome Number recorded is 2 or greater, skip to "Outcome Date".</i>
1. How many pregnancy outcomes resulted from this reported pregnancy?	<input type="checkbox"/>
2. Outcome Date	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <i>dd                  MMM                  yy</i>
3. Place of delivery/outcome	<input type="checkbox"/> Home <input type="checkbox"/> Hospital <input type="checkbox"/> Clinic <input type="checkbox"/> Unknown <input type="checkbox"/> Other 3a. Other, specify: _____
4. Specify outcome. <i>Mark only one.</i>	<input type="checkbox"/> Full term live birth ( $\geq 37$ weeks) <input type="checkbox"/> Premature term live birth ( $<37$ weeks) <input type="checkbox"/> Stillbirth/intrauterine fetal demise ( $\geq 20$ weeks) <input type="checkbox"/> Spontaneous abortion ( $< 20$ weeks) <input type="checkbox"/> Ectopic pregnancy <input type="checkbox"/> Therapeutic/elective abortion <input type="checkbox"/> Other Other, specify: _____ <div style="border: 1px solid black; padding: 5px; width: fit-content; margin-left: auto; margin-right: auto;"><i>Skip to "Provide a brief narrative of the circumstances."</i></div> <b><i>If the pregnancy or outcome was associated with maternal complications or symptoms that would otherwise be reported as an AE, report these on an AE Log. Complete an EAE Reporting form, if applicable.</i></b>
4a1. Method	<input type="checkbox"/> C-section <input type="checkbox"/> Standard vaginal <input type="checkbox"/> Operative Vaginal <b><i>If full term live birth, go to "Were there any complications related to the pregnancy outcome?"</i></b>
5. Provide a brief narrative of the circumstances:	
6. Were there any complications related to the pregnancy outcome?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <b><i>If no, skip to "Were any fetal/infant congenital anomalies identified?"</i></b>
6a. Delivery-related complications <i>Mark "none" or all that apply.</i>	<input type="checkbox"/> none <input type="checkbox"/> intrapartum hemorrhage <input type="checkbox"/> postpartum hemorrhage <input type="checkbox"/> non-reassuring fetal status <input type="checkbox"/> chorioamnionitis <input type="checkbox"/> Other Other, specify: _____

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## MTN-025 Pregnancy Outcome (page 2 of 2)

6b. Non-delivery related complications <i>Mark "none" or all that apply.</i>	<input type="checkbox"/> none <input type="checkbox"/> hypertensive disorders of pregnancy <input type="checkbox"/> gestational diabetes <input type="checkbox"/> other, specify: _____																
7. Were any fetal/infant congenital anomalies identified?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <b><i>If no or unknown, skip to statement above "Infant gender".</i></b>																
7a. Congenital anomalies identified. <i>Mark all that apply.</i>  <b><i>Complete AE Log and EAE Reporting form.</i></b>	<table border="0"><tr><td><input type="checkbox"/> Central nervous system, cranio-facial</td><td><input type="checkbox"/> Skin</td></tr><tr><td><input type="checkbox"/> Central nervous system, spinal</td><td><input type="checkbox"/> Genitourinary</td></tr><tr><td><input type="checkbox"/> Cardiovascular</td><td><input type="checkbox"/> Chromosomal</td></tr><tr><td><input type="checkbox"/> Renal</td><td><input type="checkbox"/> Cranio-facial (structural)</td></tr><tr><td><input type="checkbox"/> Gastrointestinal</td><td><input type="checkbox"/> Hematologic</td></tr><tr><td><input type="checkbox"/> Pulmonary</td><td><input type="checkbox"/> Infectious</td></tr><tr><td><input type="checkbox"/> Musculoskeletal/extremities</td><td><input type="checkbox"/> Endocrine/metabolic</td></tr><tr><td><input type="checkbox"/> Physical defect</td><td><input type="checkbox"/> Other, specify: _____</td></tr></table>	<input type="checkbox"/> Central nervous system, cranio-facial	<input type="checkbox"/> Skin	<input type="checkbox"/> Central nervous system, spinal	<input type="checkbox"/> Genitourinary	<input type="checkbox"/> Cardiovascular	<input type="checkbox"/> Chromosomal	<input type="checkbox"/> Renal	<input type="checkbox"/> Cranio-facial (structural)	<input type="checkbox"/> Gastrointestinal	<input type="checkbox"/> Hematologic	<input type="checkbox"/> Pulmonary	<input type="checkbox"/> Infectious	<input type="checkbox"/> Musculoskeletal/extremities	<input type="checkbox"/> Endocrine/metabolic	<input type="checkbox"/> Physical defect	<input type="checkbox"/> Other, specify: _____
<input type="checkbox"/> Central nervous system, cranio-facial	<input type="checkbox"/> Skin																
<input type="checkbox"/> Central nervous system, spinal	<input type="checkbox"/> Genitourinary																
<input type="checkbox"/> Cardiovascular	<input type="checkbox"/> Chromosomal																
<input type="checkbox"/> Renal	<input type="checkbox"/> Cranio-facial (structural)																
<input type="checkbox"/> Gastrointestinal	<input type="checkbox"/> Hematologic																
<input type="checkbox"/> Pulmonary	<input type="checkbox"/> Infectious																
<input type="checkbox"/> Musculoskeletal/extremities	<input type="checkbox"/> Endocrine/metabolic																
<input type="checkbox"/> Physical defect	<input type="checkbox"/> Other, specify: _____																
7b. Specify congenital anomaly/defect AE: ( <i>will be a drop-down menu in Rave</i> )																	
7c. Describe the congenital anomaly/defect:																	
<b><i>Complete items 8-13 below for live births only. Otherwise, end of form.</i></b>																	
8. Infant gender	<input type="checkbox"/> Male <input type="checkbox"/> Female																
9. Infant birth weight	_____ kg <b>OR</b> <input type="checkbox"/> Unavailable																
10. Infant birth length	_____ cm <b>OR</b> <input type="checkbox"/> Unavailable																
11. Infant birth head circumference	_____ cm <b>OR</b> <input type="checkbox"/> Unavailable																
12. Infant birth abdominal circumference	_____ cm <b>OR</b> <input type="checkbox"/> Unavailable																
13. Infant gestational age by examination	_____ weeks _____ days <b>OR</b> <input type="checkbox"/> Unavailable → <b><i>If unavailable, end of form.</i></b>																
13a. Method used to determine gestational age	<input type="checkbox"/> Ballard <input type="checkbox"/> Dubowitz <input type="checkbox"/> Other Other, specify: _____																

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## MTN-025 Specimen Storage

1a. and 1b. Hair collection for PK	<b>Hair for PK collection date</b> dd      MMM      yy □□ □□□□ □□  <input type="checkbox"/> Stored → If 'stored', skip to "Self-Collected Vaginal Fluid Swab". <input type="checkbox"/> Not stored
Reason hair collection/storage was not done (1c – 1g1)  <i>Mark all that apply.</i>	<input type="checkbox"/> Not required <input type="checkbox"/> Unable to obtain hair sample; specify reason: _____ <input type="checkbox"/> Insufficient quantity of hair <input type="checkbox"/> Participant declined hair collection after counseling specify reason: _____ <input type="checkbox"/> Other Other, specify reason: _____
2. Self-Collected Vaginal Fluid Swab	<b>Self-Collected Vaginal Fluid Swab collection date</b> dd      MMM      yy □□ □□□□ □□  <input type="checkbox"/> Not required <input type="checkbox"/> Stored <input type="checkbox"/> Not stored → Reason not stored: _____  <i>If not required or not stored, skip to "Plasma Storage".</i>
2b. Was blood visible on the swab?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2c. Was a used ring in place at the time of swab collection?	<input type="checkbox"/> Yes <input type="checkbox"/> No – ring removed prior to swab collection <input type="checkbox"/> No – ring not in place at the start of visit <input type="checkbox"/> No – new ring inserted prior to swab collection
3. Plasma Storage	<b>Plasma storage collection date</b> dd      MMM      yy □□ □□□□ □□  <input type="checkbox"/> Not required <input type="checkbox"/> Stored <input type="checkbox"/> Not stored → Reason not stored: _____

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## MTN-025 Pharmacy Ring Dispensation

Date Vaginal Ring(s) dispensed:	dd      MMM      yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
How many vaginal rings were dispensed at this visit?	<input type="text"/>
<b>Complete the ring code and lot number for each ring dispensed.</b>	
<i>Vaginal Ring #1</i>	
Ring code	<input type="text"/> <input type="text"/> . <input type="text"/>
Lot number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<i>Vaginal Ring #2</i>	
Ring code	<input type="text"/> <input type="text"/> . <input type="text"/>
Lot number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<i>Vaginal Ring #3</i>	
Ring code	<input type="text"/> <input type="text"/> . <input type="text"/>
Lot number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

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## MTN-025 Ring Collection and Insertion

<b>RING COLLECTION</b>	
<i>If this is the Enrollment Visit, skip to item 3.</i>	
1. Did the participant have a ring in place at the start of the visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, go to 1b.</i>
1a. Ring code for ring in place at start of visit:	_____. ____ → <i>Skip to Item 2.</i>
1b. When was a ring last in place?	dd          MMM          yy <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <b>OR</b> 1b1. <input type="checkbox"/> N/A (ring was not in place since last visit)
2. Was a used or unused ring(s) collected, or expected to be collected, at this visit?	<input type="checkbox"/> Yes → <i>Update the Vaginal Ring Tracking Log.</i> <input type="checkbox"/> No
<b>RING CHOICE</b>	
3. Did the participant choose to use a new ring at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, go to Item 5.</i> <input type="checkbox"/> Not applicable → <i>If not applicable, go to Item 6.</i>
4. Did the participant accept to receive the ring(s) on a quarterly schedule? <b>[COMPLETE AT MONTHS 3-9 ONLY]</b>	<input type="checkbox"/> Yes → <i>If yes, go to Item 5.</i> <input type="checkbox"/> No 4a. If no, specify reason: _____ → <i>Go to Item 6.</i>
5. What are the reasons that the participant opted to <b>not</b> use the ring at this visit? <b>Mark all that apply and then end of form.</b>	<input type="checkbox"/> Participant undecided/not ready <input type="checkbox"/> Participant not interested <input type="checkbox"/> Ring less effective than participant wants <input type="checkbox"/> Side effects Specify: _____ <input type="checkbox"/> Participant intends to fall pregnant <input type="checkbox"/> Partner unsupportive or dislikes ring <input type="checkbox"/> Family or relative unsupportive ring <input type="checkbox"/> Participant prefers alternative HIV prevention method <input type="checkbox"/> Other Other, specify: _____ <b>END OF FORM.</b>

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## MTN-025 Ring Collection and Insertion

RING PROVISION	
6. Was a ring provided at this visit?	<input type="checkbox"/> Yes → <i>If yes, complete Vaginal Ring Tracking Log and go to item 7.</i> <input type="checkbox"/> No
6a. Reason ring not provided:	<input type="checkbox"/> Participant on clinical hold <input type="checkbox"/> Participant has been permanently discontinued from product <input type="checkbox"/> Participant declined study ring <input type="checkbox"/> Scheduled PUEV <input type="checkbox"/> Early Termination <input type="checkbox"/> Other Other, specify: _____ <i>END OF FORM.</i>
7. Was a new ring inserted at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, go to item 8.</i>
7a. Ring code of ring inserted:	_____.
7b. Who inserted the new ring?	<input type="checkbox"/> Participant <input type="checkbox"/> Study Staff
8. Was a ring in place at the end of the visit?	<input type="checkbox"/> Yes → <i>If yes, end of form.</i> <input type="checkbox"/> No
8a. Reason ring not in place at end of visit:	<input type="checkbox"/> Participant declined to have ring inserted at clinic visit <input type="checkbox"/> Participant had to leave before ring could be inserted <input type="checkbox"/> Other Other, specify: _____

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

### MTN-025 Laboratory Results (page 1 of 2)

<b>HEMOGRAM</b> <input type="checkbox"/> Not done/not collected → Go to Serum Chemistries.		<b>Hemogram collection date</b> dd      MMM      yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
<input type="checkbox"/> Not Reported	Hemoglobin	_____ Severity grade: <input type="checkbox"/> Grade 1 - Mild <input type="checkbox"/> Grade 2 - Moderate <input type="checkbox"/> Grade 3 - Severe <input type="checkbox"/> Grade 4 – Potentially life-threatening <input type="checkbox"/> Not gradable	Specify AE: _____ (AE term, onset date)
<input type="checkbox"/> Not Reported	Hematocrit	_____	
<input type="checkbox"/> Not Reported	MCV	_____	
<input type="checkbox"/> Not Reported	Platelets	_____ Severity grade: <input type="checkbox"/> Grade 1 - Mild <input type="checkbox"/> Grade 2 - Moderate <input type="checkbox"/> Grade 3 - Severe <input type="checkbox"/> Grade 4 – Potentially life-threatening <input type="checkbox"/> Not gradable	Specify AE: _____ (AE term, onset date)
<input type="checkbox"/> Not Reported	WBC	_____ Severity grade: <input type="checkbox"/> Grade 1 - Mild <input type="checkbox"/> Grade 2 - Moderate <input type="checkbox"/> Grade 3 - Severe <input type="checkbox"/> Grade 4 – Potentially life-threatening <input type="checkbox"/> Not gradable	Specify AE: _____ (AE term, onset date)
<b>DIFFERENTIAL</b> <input type="checkbox"/> Not done → Skip to “Serum Chemistries”			
<input type="checkbox"/> Not Reported	Neutrophils	<b>Absolute Count</b> _____ Severity grade: <input type="checkbox"/> Grade 1 - Mild <input type="checkbox"/> Grade 2 - Moderate <input type="checkbox"/> Grade 3 - Severe <input type="checkbox"/> Grade 4 – Potentially life-threatening <input type="checkbox"/> Not gradable	Specify AE: _____ (AE term, onset date)

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

### MTN-025 Laboratory Results (page 2 of 2)

<input type="checkbox"/> Not Reported	Lymphocytes	Absolute Count _____  Severity grade: <input type="checkbox"/> Grade 1 - Mild <input type="checkbox"/> Grade 2 - Moderate <input type="checkbox"/> Grade 3 - Severe <input type="checkbox"/> Grade 4 – Potentially life-threatening <input type="checkbox"/> Not gradable	Specify AE: _____ (AE term, onset date)
<input type="checkbox"/> Not Reported	Monocytes	Absolute Count _____	
<input type="checkbox"/> Not Reported	Eosinophils	Absolute Count _____	
<input type="checkbox"/> Not Reported	Basophils	Absolute Count _____	
<b>SERUM CHEMISTRIES</b>  <input type="checkbox"/> Not done/not collected → End of form.		<b>Specimen collection date</b> dd    MMM    yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
<input type="checkbox"/> Not Reported	AST (SGOT)	_____  Severity grade: <input type="checkbox"/> Grade 1 - Mild <input type="checkbox"/> Grade 2 - Moderate <input type="checkbox"/> Grade 3 - Severe <input type="checkbox"/> Grade 4 – Potentially life-threatening <input type="checkbox"/> Not gradable	Specify AE: _____ (AE term, onset date)
<input type="checkbox"/> Not Reported	ALT (SGPT)	_____  Severity grade: <input type="checkbox"/> Grade 1 - Mild <input type="checkbox"/> Grade 2 - Moderate <input type="checkbox"/> Grade 3 - Severe <input type="checkbox"/> Grade 4 – Potentially life-threatening <input type="checkbox"/> Not gradable	Specify AE: _____ (AE term, onset date)
<input type="checkbox"/> Not Reported	Creatinine	_____  Severity grade: <input type="checkbox"/> Grade 1 - Mild <input type="checkbox"/> Grade 2 - Moderate <input type="checkbox"/> Grade 3 - Severe <input type="checkbox"/> Grade 4 – Potentially life-threatening <input type="checkbox"/> Not gradable	Specify AE: _____ (AE term, onset date)

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

## MTN-025 STI Test Results

<b>Syphilis Serology</b>	<input type="checkbox"/> Not done/not collected → <i>Skip to "Trichomonas Rapid Test"</i>	<b>Specimen collection date</b> dd      MMM      yy □□ □□ □□ □□
Syphilis screening test		Non-reactive    reactive □                    □ ↓ <i>If non-reactive, go to Trichomonas Rapid Test.</i>
Syphilis titer		1: □□ □□ □□
Syphilis confirmatory test		<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Indeterminate
<b>Trichomonas Rapid Test</b>	<input type="checkbox"/> Not done/not collected	<b>Specimen collection date</b> dd      MMM      yy □□ □□ □□ □□ □□  <input type="checkbox"/> Positive <input type="checkbox"/> Negative
<b><i>N. gonorrhoeae</i></b>	<input type="checkbox"/> Not done/not collected	<b>Specimen collection date</b> dd      MMM      yy □□ □□ □□ □□ □□  <input type="checkbox"/> Positive <input type="checkbox"/> Negative
<b><i>C. trachomatis</i></b>	<input type="checkbox"/> Not done/not collected	<b>Specimen collection date</b> dd      MMM      yy □□ □□ □□ □□ □□  <input type="checkbox"/> Positive <input type="checkbox"/> Negative
<i>At Screening, record STI diagnoses in Baseline Medical Conditions Log form when applicable. Complete or update Adverse Experience Log during follow-up, if applicable.</i>		

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

## MTN-025 Vital Signs

Exam 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"/>
		<i>dd</i> <i>MMM</i> <i>yy</i>
1	Weight	<input type="text"/> <input type="text"/> <input type="text"/> <i>kg</i>
2	Body Temperature	<input type="text"/> <input type="text"/> . <input type="text"/> °C
3	Systolic BP	<input type="text"/> <input type="text"/> <input type="text"/> <i>mmHg</i>
4	Diastolic BP	<input type="text"/> <input type="text"/> <input type="text"/> <i>mmHg</i>
4	Pulse	<input type="text"/> <input type="text"/> <input type="text"/> <i>beats per minute</i>
5	Respirations	<input type="text"/> <input type="text"/> <i>breaths per minute</i>
6	Height	<input type="text"/> <input type="text"/> <input type="text"/> cm OR <input type="text"/> <i>not required</i>

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

## MTN-025 Physical Exam

Exam 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"/>	
<b>FINDINGS</b>					
<i>For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings in the text field provided. If not evaluated, select "Not done".</i>					
		<b>Not done</b>	<b>Normal</b>	<b>Abnormal</b>	<b>If abnormal, specify:</b>
1	General appearance	<input type="text"/>	<input type="text"/>	<input type="text"/>	
2	Abdomen/ Gastrointestinal	<input type="text"/>	<input type="text"/>	<input type="text"/>	
3	Neck	<input type="text"/>	<input type="text"/>	<input type="text"/>	
4	Lymph Nodes	<input type="text"/>	<input type="text"/>	<input type="text"/>	
5	Heart/Cardiovascular	<input type="text"/>	<input type="text"/>	<input type="text"/>	
6	Lungs/Respiratory	<input type="text"/>	<input type="text"/>	<input type="text"/>	
7	Extremities	<input type="text"/>	<input type="text"/>	<input type="text"/>	
8	Neurological	<input type="text"/>	<input type="text"/>	<input type="text"/>	
9	Skin	<input type="text"/>	<input type="text"/>	<input type="text"/>	
10	Eyes	<input type="text"/>	<input type="text"/>	<input type="text"/>	
11	Ears, Nose, Throat	<input type="text"/>	<input type="text"/>	<input type="text"/>	
12	Other	<input type="text"/>	<input type="text"/>	<input type="text"/>	
<b>Record abnormal findings on Baseline Medical History Log or Adverse Experience Log as applicable.</b>					

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

### MTN-025 Pelvic Exam

Exam 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"/> <i>dd          MMM          yy</i>		
Pelvic exam assessment	<input type="checkbox"/> Not done → <i>If not done, end of form.</i> <input type="checkbox"/> Abnormal findings <input type="checkbox"/> No abnormal findings → <i>If no abnormal findings, skip to "Were any new pelvic finding AEs reported at the visit?"</i>		
<b>Abnormal findings. Mark all that apply.</b>			
<b>VULVAR</b>	<b>VAGINAL</b>	<b>CERVICAL</b>	<b>GENERAL/OTHER</b>
<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: _____ <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"/> abnexal tenderness <input type="checkbox"/> abnormal blood or bleeding; describe: _____ _____
<input type="checkbox"/> Other abnormal findings, specify (include anatomical location): _____			
<b>Complete or update Baseline Medical Conditions Log or Adverse Experience Log, as applicable.</b>			
Were any new pelvic finding AEs reported at this visit?	<input type="checkbox"/> Yes → Specify AE: _____ (AE term and onset date) Specify AE: _____ (AE term and onset date) Specify AE: _____ (AE term and onset date) <input type="checkbox"/> No		
Cervical ectopy:	<input type="checkbox"/> 0% <input type="checkbox"/> 1-25% <input type="checkbox"/> 26-50% <input type="checkbox"/> 51-75% <input type="checkbox"/> 76-100%		

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

### MTN-025 Missed Visit

Target Visit 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"/>
Reason visit was missed: <i>Mark only one.</i>	<input type="checkbox"/> unable to contact participant
	<input type="checkbox"/> unable to schedule appointment(s) within allowable window
	<input type="checkbox"/> participant refused visit
	<input type="checkbox"/> participant incarcerated
	<input type="checkbox"/> participant admitted to a health care facility → <i>Complete Adverse Experience Log, as applicable.</i>
	<input type="checkbox"/> participant withdrew from study → <i>Complete a Termination form.</i>
	<input type="checkbox"/> participant deceased → <i>Complete a Termination form. Complete an Adverse Experience Log.</i>
<input type="checkbox"/> other, specify: _____	
Steps taken to address the missed visit (corrective action plan):	

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

### MTN-025 Participant Transfer

Name of transferring study site	<input type="checkbox"/> Blantyre CRS <input type="checkbox"/> Botha's Hill CRS <input type="checkbox"/> Chatsworth CRS <input type="checkbox"/> Emavundleni CRS <input type="checkbox"/> eThekweni CRS <input type="checkbox"/> Isipingo CRS <input type="checkbox"/> Malawi CRS <input type="checkbox"/> MU-JHU Research Collaboration (MUJHU CARE LTD) CRS <input type="checkbox"/> Seke South CRS <input type="checkbox"/> Spilhaus CRS <input type="checkbox"/> Tongaat CRS <input type="checkbox"/> Verulam CRS <input type="checkbox"/> Wits Reproductive Health and HIV Institute CRS (WRHI CRS) <input type="checkbox"/> Zengeza CRS
Name of receiving study site	<input type="checkbox"/> Blantyre CRS <input type="checkbox"/> Botha's Hill CRS <input type="checkbox"/> Chatsworth CRS <input type="checkbox"/> Emavundleni CRS <input type="checkbox"/> eThekweni CRS <input type="checkbox"/> Isipingo CRS <input type="checkbox"/> Malawi CRS <input type="checkbox"/> MU-JHU Research Collaboration (MUJHU CARE LTD) CRS <input type="checkbox"/> Seke South CRS <input type="checkbox"/> Spilhaus CRS <input type="checkbox"/> Tongaat CRS <input type="checkbox"/> Verulam CRS <input type="checkbox"/> Wits Reproductive Health and HIV Institute CRS (WRHI CRS) <input type="checkbox"/> Zengeza CRS
Date participant records were sent to receiving study site	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="text"/>

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

## MTN-025 Participant Receipt

Name of receiving study site:	<input type="checkbox"/> Blantyre CRS <input type="checkbox"/> Botha's Hill CRS <input type="checkbox"/> Chatsworth CRS <input type="checkbox"/> Emavundleni CRS <input type="checkbox"/> eThekweni CRS <input type="checkbox"/> Isipingo CRS <input type="checkbox"/> Malawi CRS <input type="checkbox"/> MU-JHU Research Collaboration (MUJHU CARE LTD) CRS <input type="checkbox"/> Seke South CRS <input type="checkbox"/> Spilhaus CRS <input type="checkbox"/> Tongaat CRS <input type="checkbox"/> Verulam CRS <input type="checkbox"/> Wits Reproductive Health and HIV Institute CRS (WRHI CRS) <input type="checkbox"/> Zengeza CRS
Name of transferring study site:	<input type="checkbox"/> Blantyre CRS <input type="checkbox"/> Botha's Hill CRS <input type="checkbox"/> Chatsworth CRS <input type="checkbox"/> Emavundleni CRS <input type="checkbox"/> eThekweni CRS <input type="checkbox"/> Isipingo CRS <input type="checkbox"/> Malawi CRS <input type="checkbox"/> MU-JHU Research Collaboration (MUJHU CARE LTD) CRS <input type="checkbox"/> Seke South CRS <input type="checkbox"/> Spilhaus CRS <input type="checkbox"/> Tongaat CRS <input type="checkbox"/> Verulam CRS <input type="checkbox"/> Wits Reproductive Health and HIV Institute CRS (WRHI CRS) <input type="checkbox"/> Zengeza CRS
Date informed consent signed at receiving site:	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="text"/>
Did the participant provided informed consent for specimen storage at receiving study site?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, end of form.</i>
Date informed consent for specimen storage was signed:	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="text"/>

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

### MTN-025 Vaginal Ring Tracking

RING PROVIDED			RING RETURNED					
Ring Code	Date Ring Provided (dd-MMM-yy)	Visit ring provided	Date Ring Returned (dd-MMM-yy)	Visit ring returned	Ring Storage	Mark checkbox if ring code is unknown when ring returned	If ring was stored, how did the participant rate her ability to keep the ring inserted as instructed, per participant report?	If ring was stored, how many days was the vaginal ring out for any reason, in total per participant report?
_____	--/---/---	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	--/---/--- <input type="checkbox"/> Ring not returned, specify reason: _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use
_____	--/---/---	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	--/---/--- <input type="checkbox"/> Ring not returned, specify reason: _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use
_____	--/---/---	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	--/---/--- <input type="checkbox"/> Ring not returned, specify reason: _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

_____	____/____/____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Ring not returned, specify reason: _____ _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____ _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use
_____	____/____/____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Ring not returned, specify reason: _____ _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____ _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use
_____	____/____/____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Ring not returned, specify reason: _____ _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____ _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use
_____	____/____/____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Ring not returned, specify reason: _____ _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____ _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use
_____	____/____/____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Ring not returned, specify reason: _____ _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____ _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

_____. -	---/---/---	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	---/---/--- <input type="checkbox"/> Ring not returned, specify reason: _____ _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____ _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use
_____.	---/---/---	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	---/---/--- <input type="checkbox"/> Ring not returned, specify reason: _____ _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____ _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use
_____. -	---/---/---	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	---/---/--- <input type="checkbox"/> Ring not returned, specify reason: _____ _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____ _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use
_____.	---/---/---	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	---/---/--- <input type="checkbox"/> Ring not returned, specify reason: _____ _____	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Stored <input type="checkbox"/> Not stored → If not stored, specify reason: _____ _____	<input type="checkbox"/> → End of form	<input type="checkbox"/> Very poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Very good <input type="checkbox"/> Excellent	_____ # days ring was out during use

Participant ID: \_\_\_\_\_ - \_\_\_\_\_  
Visit: \_\_\_\_\_

### MTN-025 Date of Visit

Did the participant complete this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If No, end the form.</i>
Visit 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"/>

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

## MTN-025 Ring Adherence Y/N

Since the participant's last study visit, has she ever used a vaginal ring?	<input type="checkbox"/> Yes → <i>If Yes, complete Ring Adherence form.</i> <input type="checkbox"/> No
---	--

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

### MTN-025 Ring Adherence

1.	Did the participant disclose her ring use to her primary partner?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
2.	Since her last study visit, how many times in total has the participant had a vaginal ring out, excluding expected instances when a ring was briefly removed and replaced with a new ring?	____ times <i>If 0, end of form.</i>
3.	How many of these times since the participant's last study visit was a vaginal ring out for more than 12 hours continuously?	____ times <i>If 0, go to item 5.</i>
4.	Since the participant's last study visit, what is the longest number of days in a row the vaginal ring was out?	____ days
5. What are the reason(s) why the vaginal ring(s) were out?  <i>Record all of the reasons that apply. Refer to the CRF Completion Guidelines for a listing of reasons.</i>		
Reason 1: _____		
Reason 2: _____		
Reason 3: _____		
Reason 4: _____		
Reason 5: _____		
Reason 6: _____		
Reason 7: _____		
<i>If there is a reason that is not represented in the Reason list, specify the reason on the adjacent specify lines below. Otherwise, leave remaining items blank.</i>		
Other reason ring removed by participant or clinician, specify: _____		
Other reason ring came out on its own, specify: _____		

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

## MTN-025 ACASI Tracking YN

<p>Was an ACASI questionnaire completed at this visit?</p>	<p><input type="checkbox"/> Yes → <i>If Yes, complete the ACASI Tracking form.</i></p> <p><input type="checkbox"/> No → <i>If No, please explain:</i></p> <p>_____</p> <p>_____</p> <p>_____</p>
--	--



Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

## MTN-025 Additional Study Procedures

ACASI Tracking	<input type="checkbox"/> Yes <input type="checkbox"/> No
Pelvic Exam	<input type="checkbox"/> Yes <input type="checkbox"/> No
Physical Exam	<input type="checkbox"/> Yes <input type="checkbox"/> No
Vital Signs	<input type="checkbox"/> Yes <input type="checkbox"/> No
STI Test Results	<input type="checkbox"/> Yes <input type="checkbox"/> No
Seroconverter Laboratory Results	<input type="checkbox"/> Yes <input type="checkbox"/> No
HIV Test Results	<input type="checkbox"/> Yes <input type="checkbox"/> No
Specimen Storage	<input type="checkbox"/> Yes <input type="checkbox"/> No
Pregnancy Report and History	<input type="checkbox"/> Yes <input type="checkbox"/> No
Participant Receipt	<input type="checkbox"/> Yes <input type="checkbox"/> No
Participant Transfer	<input type="checkbox"/> Yes <input type="checkbox"/> No
Pregnancy Outcome	<input type="checkbox"/> Yes <input type="checkbox"/> No
Laboratory Results	<input type="checkbox"/> Yes <input type="checkbox"/> No
Behavior Assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No
Vaginal Practices	<input type="checkbox"/> Yes <input type="checkbox"/> No
Social Influences Assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No
Study Exit Assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No

Social Influences Assessment Supplement

Yes  No

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

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

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

## MTN-025 Termination

Termination Date	<table border="1"><tr><td>dd</td><td>MMM</td><td>yy</td></tr><tr><td><input type="text"/><input type="text"/></td><td><input type="text"/><input type="text"/><input type="text"/></td><td><input type="text"/><input type="text"/></td></tr></table> <p><i>Date the site determined that the participant was no longer in the study.</i></p>	dd	MMM	yy	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
dd	MMM	yy					
<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>					
Reason for termination <i>Mark only one.</i>	<input type="checkbox"/> scheduled exit visit/end of study → <b>End of form.</b>						
	<input type="checkbox"/> death, <i>indicate date and cause if known</i>						
	Date of death: dd      MMM      yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>						
	Cause of death, specify: _____						
	<input type="checkbox"/> participant refused further participation: _____						
	<input type="checkbox"/> participant relocated, no follow-up planned						
	<input type="checkbox"/> investigator decision, specify: _____						
	<input type="checkbox"/> unable to contact participant						
	<input type="checkbox"/> inappropriate enrollment → <i>End of form.</i>						
	<input type="checkbox"/> other, specify: _____						
<input type="checkbox"/> Early study closure → <i>End of form.</i>							
Was termination associated with an adverse experience?	Yes      No      don't know <input type="checkbox"/> <input type="checkbox"/> — <input type="checkbox"/> → <i>If no or don't know, end of form.</i>  If yes, specify AE: _____ (AE term and onset date)						

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

## MTN-025 Adverse Experience Y/N

Has the participant experienced any new adverse events or are there any updates to previously reported AEs?	<input type="checkbox"/> Yes → <i>If Yes, complete or update the Adverse Experience log.</i> <input type="checkbox"/> No
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## MTN-025 Adverse Experience Log

Date reported to site	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	<i>dd</i> <i>MMM</i> <i>yy</i>
1. Adverse Experience (AE)	
<i>Record diagnosis, if available. Include anatomical location, if applicable.</i>	
2. Onset 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"/>
	<i>dd</i> <i>MMM</i> <i>yy</i>
3. Severity Grade	<input type="checkbox"/> Grade 1 (Mild) <input type="checkbox"/> Grade 2 (Moderate) <input type="checkbox"/> Grade 3 (Severe) <input type="checkbox"/> Grade 4 (Potentially life-threatening) <input type="checkbox"/> Grade 5 (Death)
4. Relationship to Study Product	<input type="checkbox"/> Related <input type="checkbox"/> Not related <i>Record rationale or alternative etiology in Comments.</i>
5. Study Product Administration	<input type="checkbox"/> No change <input type="checkbox"/> Held <input type="checkbox"/> Permanently discontinued <input type="checkbox"/> N/A
6. Status/Outcome	<input type="checkbox"/> Continuing <input type="checkbox"/> Resolved <input type="checkbox"/> Death <input type="checkbox"/> Severity/frequency increased ( <i>Report as a new AE</i> ) <input type="checkbox"/> Continuing at end of study participation
6a. Status/Outcome Date <i>Leave blank if item 6 is "continuing" or "continuing at end of study participation"</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	<i>dd</i> <i>MMM</i> <i>yy</i>
7. Treatment <i>Mark "none" or all that apply.</i>	<input type="checkbox"/> None <input type="checkbox"/> Medication(s) <i>Report on Concomitant Medications Log.</i> <input type="checkbox"/> New/prolonged hospitalization <i>Comment:</i> _____ <input type="checkbox"/> Procedure/Surgery <i>Comment:</i> _____ <input type="checkbox"/> Other Other, specify: _____
8. Is this an SAE according to ICH guidelines?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. Has/will this AE be reported as an EAE?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If 'No', go to item 11.</i>
10. EAE Number	_____
11. Was this AE a worsening of a baseline medical condition?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

## Concomitant Medications Y/N

Is the participant taking any new concomitant medications that have not been previously reported or are there any updates to existing concomitant medications?	<input type="checkbox"/> Yes → <i>If Yes, please review or update the Concomitant Medications Log.</i> <input type="checkbox"/> No
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Participant ID: \_\_\_\_\_ - \_\_\_\_\_

## MTN-025 Clinical Product Hold/Discontinuation Y/N

Does the participant have any clinical product holds/discontinuations to be applied?	<input type="checkbox"/> Yes → <i>If Yes, complete the Clinical Product Hold/Discontinuation Log.</i> <input type="checkbox"/> No
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### MTN-025 Clinical Product Hold/Discontinuation Log

<p>Date when study product hold was initiated:</p>	<table border="1"> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td colspan="2"><i>dd</i></td> <td colspan="3"><i>MMM</i></td> <td colspan="3"><i>yy</i></td> </tr> </table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<i>dd</i>		<i>MMM</i>			<i>yy</i>								
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>																
<i>dd</i>		<i>MMM</i>			<i>yy</i>																		
<p>Why is study product being held? <i>Mark only one per page.</i></p>	<p><input type="checkbox"/> Pregnancy</p> <p><input type="checkbox"/> Reactive rapid HIV test result</p> <p><input type="checkbox"/> Adverse Experience Adverse Experience: _____ <i>Specify Adverse Experience and Onset Date</i></p> <p><input type="checkbox"/> Breastfeeding</p> <p><input type="checkbox"/> Allergic reaction to the study product Adverse Experience: _____ <i>Specify Adverse Experience and Onset Date</i></p> <p><input type="checkbox"/> Report of PEP use for HIV exposure Concomitant medication: _____ <i>Specify Concomitant medication name and Date started</i></p> <p><input type="checkbox"/> Participant unable/unwilling to comply with the required study procedures, or otherwise might be put at undue risk by continuing product use per judgment of IoR/designee</p> <p><input type="checkbox"/> Other Other, specify: _____</p>																						
<p>Date of last study product use</p>	<table border="1"> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td>OR</td> <td><input type="checkbox"/></td> <td><i>participant never used ring</i></td> </tr> <tr> <td colspan="2"><i>dd</i></td> <td colspan="3"><i>MMM</i></td> <td colspan="3"><i>yy</i></td> <td></td> <td></td> <td></td> </tr> </table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>	<i>participant never used ring</i>	<i>dd</i>		<i>MMM</i>			<i>yy</i>					
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>	<i>participant never used ring</i>													
<i>dd</i>		<i>MMM</i>			<i>yy</i>																		
<p>Was the participant instructed to resume study product use?</p>	<table border="1"> <tr> <td rowspan="2" style="text-align: center; vertical-align: middle;"> </td> <td><input type="checkbox"/> Yes</td> </tr> <tr> <td> <input type="checkbox"/> No – hold continuing for another reason  <input type="checkbox"/> No – early termination  <input type="checkbox"/> No – hold continuing at scheduled PUEV  <input type="checkbox"/> No – permanently discontinued → <i>Complete ACASI Tracking form.</i> </td> </tr> <tr> <td colspan="2"> <p><b>Date:</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center;"><i>dd MMM yy</i></p> </td> </tr> </table>		<input type="checkbox"/> Yes	<input type="checkbox"/> No – hold continuing for another reason <input type="checkbox"/> No – early termination <input type="checkbox"/> No – hold continuing at scheduled PUEV <input type="checkbox"/> No – permanently discontinued → <i>Complete ACASI Tracking form.</i>	<p><b>Date:</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center;"><i>dd MMM yy</i></p>																		
	<input type="checkbox"/> Yes																						
	<input type="checkbox"/> No – hold continuing for another reason <input type="checkbox"/> No – early termination <input type="checkbox"/> No – hold continuing at scheduled PUEV <input type="checkbox"/> No – permanently discontinued → <i>Complete ACASI Tracking form.</i>																						
<p><b>Date:</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center;"><i>dd MMM yy</i></p>																							

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

## MTN-025 Protocol Deviation YN

Have any protocol deviations occurred?	<input type="checkbox"/> Yes → <i>If Yes, complete the Protocol Deviation Log.</i> <input type="checkbox"/> No
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## MTN-025 Protocol Deviation (page 1 of 2)

Site awareness 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"/>
Deviation 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"/>
Has or will this deviation be reported to local IRB/EC?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has or will this deviation be reported to DAIDS as a critical event?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Type of Deviation:	<input type="checkbox"/> Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met. <input type="checkbox"/> Study product management deviation: The site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements. <input type="checkbox"/> Study product dispensing error: The wrong study product was dispensed to a participant on product hold. Pharmacy staff must follow up with the MTN Pharmacist separately. <input type="checkbox"/> Study product sharing: Participant has shared study product with another person or study participant <input type="checkbox"/> Study product not returned: Study product was not returned by the participant per protocol requirements. <input type="checkbox"/> Conduct of non-protocol procedure: A clinical or administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice <input type="checkbox"/> Improper AE/EAE follow-up: use when an AE or EAE is not followed per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol <input type="checkbox"/> Unreported AE: Site staffs become aware of an AE, but do not report it per protocol requirements. <input type="checkbox"/> Unreported EAE: Site staffs become aware of an EAE, but do not report it per protocol and DAIDS EAE Manual requirements. <input type="checkbox"/> Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member put a participant's name on a case report form. <input type="checkbox"/> Physical assessment deviation: Include missed or incomplete physical/pelvic exam assessments. <input type="checkbox"/> Lab assessment deviation: Include missed, or incomplete lab specimen collection <input type="checkbox"/> Mishandled lab specimen: Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens. <input type="checkbox"/> Staff performing duties that they are not qualified to perform: use for any instance when any study procedure, including clinical and administrative procedures, is completed by a staff member who is not adequately qualified AND delegated to perform the procedure <input type="checkbox"/> Questionnaire administration deviation: A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed <input type="checkbox"/> Counseling deviation: Protocol-required counseling was not done and/or not documented correctly <input type="checkbox"/> Use of non-IRB/EC-approved materials: Include use of ANY study-related material that requires IRB or EC approval for use per site requirements <input type="checkbox"/> Use of excluded concomitant medications, devices, or non-study products <input type="checkbox"/> Informed consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process <input type="checkbox"/> Visit completed outside of window: Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. For example, if visit 3.0 procedures are done in the visit 4.0 window <input type="checkbox"/> Other

## MTN-025 Protocol Deviation (page 2 of 2)

Description of deviation:	
Plans and/or action taken to address the deviation:	
Plans and/or action taken to prevent future occurrences of the deviation:	
Deviation reported by:	_____ staff code

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

## MTN-025 Social Benefit Y/N

Did a social benefit occur?	<input type="checkbox"/> Yes → <i>If Yes, complete Social Benefit Log.</i> <input type="checkbox"/> No
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## MTN-025 Social Benefit Log (page 1 of 2)

Concisely describe social benefit:		
Reported at visit:		<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>
The social benefit was related to:	<input type="checkbox"/> Pride about project participation: Feels pride about participation in HOPE <input type="checkbox"/> Feeling better about oneself: Improved self-esteem or feeling of empowerment <input type="checkbox"/> Education: The study educated the participant or inspired /enabled participant to restart school or improve school performance <input type="checkbox"/> Housing: The participant obtained better or improved her housing situation <input type="checkbox"/> Nutrition/food: The participant was able to improve nutrition or amount of food intake for self or family. <input type="checkbox"/> Improved communication: Participant learned more effective ways of communicating with family, friends, employers or others <input type="checkbox"/> Work: Obtained or improved employment situation (includes informal work) <input type="checkbox"/> Income: Obtained or increased income (includes getting study reimbursement) <input type="checkbox"/> HIV testing: The participant received regular HIV testing <input type="checkbox"/> Treatment of STIs: The participant was able to treat STIs <input type="checkbox"/> Treatment of other illnesses: The participant was able to treat/consult with a doctor about other illnesses (non-STIs) <input type="checkbox"/> Family Planning/Contraception: The participant was able to access contraception and family planning services <input type="checkbox"/> Preventative care services: The participant was able to receive preventative health care such as pap smears. <input type="checkbox"/> Staying HIV free: HOPE provided more effective ways for the participant to avoid becoming infected with HIV <input type="checkbox"/> Altruism: Participant helping community/others by participating in HOPE <input type="checkbox"/> Activities: Participant became involved in community activities <input type="checkbox"/> Peer Support: Participant felt supported by or was able to provide support to peers <input type="checkbox"/> New relationships: Participant created new relationships <input type="checkbox"/> Other Other, specify: _____	
What impact did this situation have on the participant's quality of life?	<input type="checkbox"/> Minimal <input type="checkbox"/> Moderate – no significant impact <input type="checkbox"/> Major – significant impact	
Did this involve social benefit to someone other than the participant?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Person 1 (If yes, enter type of relationship)	<input type="checkbox"/> Partner <input type="checkbox"/> Adult family member <input type="checkbox"/> Child <input type="checkbox"/> Other HOPE participant	<input type="checkbox"/> Friend <input type="checkbox"/> Acquaintance <input type="checkbox"/> Employer <input type="checkbox"/> Other, specify: _____

MTN-025 Social Benefit Log (page 2 of 2)

Person 2 (If more than one type of relationship)	<input type="checkbox"/> Partner <input type="checkbox"/> Adult family member <input type="checkbox"/> Child <input type="checkbox"/> Other HOPE participant	<input type="checkbox"/> Friend <input type="checkbox"/> Acquaintance <input type="checkbox"/> Employer <input type="checkbox"/> Other, specify: _____
Person 3 (If more than two types of relationship)	<input type="checkbox"/> Partner <input type="checkbox"/> Adult family member <input type="checkbox"/> Child <input type="checkbox"/> Other HOPE participant	<input type="checkbox"/> Friend <input type="checkbox"/> Acquaintance <input type="checkbox"/> Employer <input type="checkbox"/> Other, specify: _____

Participant ID: \_\_\_\_\_ - \_\_\_\_\_

## MTN-025 Social Impact Y/N

Did a social impact occur?	<input type="checkbox"/> Yes → <i>If Yes, complete Social Impact Log.</i> <input type="checkbox"/> No
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## MTN-025 Social Impact Log

Concisely describe social impact:	
Onset 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"/>
Reported at visit:	<input type="text"/> . <input type="text"/> <input type="text"/>
Social impact type:	<input type="checkbox"/> Personal Relationships – Had negative experiences with family (excluding partner) <input type="checkbox"/> Personal Relationships – Had negative experiences with significant other, spouse, or sex partner <input type="checkbox"/> Personal Relationships – Other – Had negative experiences with friends, neighbors, or other community members <input type="checkbox"/> Travel/Immigration – Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization <input type="checkbox"/> Employment – Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work <input type="checkbox"/> Education – Been turned down by an educational program, told to leave an educational program, study visits interfering with school attendance/performance, or experienced other problems at school <input type="checkbox"/> Medical/Dental – Been refused medical or dental treatment, or treated negatively by a health care provider <input type="checkbox"/> Housing – Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing <input type="checkbox"/> Other – Had other problems not covered above
Did this involve physical harm to the participant?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did this involve physical or other harm to participant's child(ren)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
What impact did this situation have on the participant's quality of life?	<input type="checkbox"/> Minimal disturbance <input type="checkbox"/> Moderate disturbance; no significant impact <input type="checkbox"/> Major disturbance with significant impact
Describe what was done by staff and participant to address social impact:	
Participant: _____ _____ _____	
Staff: _____ _____ _____	
Record current status:	<input type="checkbox"/> Unresolved <input type="checkbox"/> Unresolved at end of study <input type="checkbox"/> Unable to resolve; no further action taken <input type="checkbox"/> Resolved
<p style="text-align: center;">If either is marked, enter closure date:</p> <p style="text-align: center;">dd      MMM      yy  <input type="text"/> <input type="text"/>    <input type="text"/> <input type="text"/> <input type="text"/>    <input type="text"/> <input type="text"/></p>	