

V2 – Enrollment Visit

- Participant Date of Visit
- Enrollment
- Baseline Vaginal Practices Y/N
- Baseline Behavior Assessment Y/N
- Pregnancy Test Result
- Family Planning
- ACASI Tracking Y/N
- ACASI Tracking
- Ring Collection and Insertion
- Specimen Storage
- Concomitant Medications Y/N
- Additional Study Procedures Y/N

Site to add:

- Baseline Behavior Assessment – local language version
- Baseline Vaginal Practices – local language version
- Concomitant Medications, as indicated

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MTN-025 Participant Date of Visit

Date of Visit	<table><tr><td data-bbox="829 310 878 338">dd</td><td data-bbox="971 310 1040 338">MMM</td><td data-bbox="1117 310 1154 338">yy</td></tr><tr><td data-bbox="829 338 878 380"><input type="text"/></td><td data-bbox="878 338 927 380"><input type="text"/></td><td data-bbox="927 338 976 380"><input type="text"/></td></tr><tr><td data-bbox="976 338 1024 380"><input type="text"/></td><td data-bbox="1024 338 1073 380"><input type="text"/></td><td data-bbox="1073 338 1122 380"><input type="text"/></td></tr><tr><td data-bbox="1122 338 1170 380"><input type="text"/></td><td data-bbox="1170 338 1219 380"><input type="text"/></td><td data-bbox="1219 338 1268 380"><input type="text"/></td></tr></table>	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="text"/>
dd	MMM	yy											
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MTN-025 Enrollment

1. Date the participant marked or signed the study screening consent form	dd MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
2. Date the participant marked or signed the study enrollment consent form	dd MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
3. Did the participant agree to biological specimen and health data storage?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Pending
4. HIV status	<input type="checkbox"/> Negative <input type="checkbox"/> Positive → <i>If Positive, do not enroll. End of form.</i>
5. Enrollment 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"/>

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MTN-025 Baseline Vaginal Practices Y/N

Was a Baseline Vaginal Practices questionnaire done?	<input type="checkbox"/> Yes → <i>If Yes, complete the Baseline Vaginal Practices form.</i> <input type="checkbox"/> No
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MTN-025 Baseline Behavior Assessment Y/N

Was a Baseline Behavior Assessment Questionnaire completed?	<input type="checkbox"/> Yes → <i>If Yes, complete the Baseline Behavior Assessment form.</i> <input type="checkbox"/> No
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MTN-025 Pregnancy Test Result

hCG for pregnancy	Not done/not collected <input type="checkbox"/>	Specimen Collection date dd MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> 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="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> amenorrheic for past 6 months OR <input type="checkbox"/> no menses since participant's last visit } <i>End of form</i>
Last day of last menstrual period		dd MMM yy <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"/> Ongoing

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MTN-025 Family Planning

Note : This form is a log form. Complete a separate form for each method of contraception/family planning that the participant is currently using.

Date of completion		dd	MMM	yy
		<input type="text"/>	<input type="text"/>	<input type="text"/>
What method(s) of contraception/family planning is the participant currently using?				
Family Planning/Contraception Method	Date Regimen Started	Date Regimen Stopped	COMPLETE AT ENROLLMENT ONLY	
			Is this the same family planning method that the participant used at her last visit in ASPIRE?	Reason(s) for changing or stopping the family planning method the participant used at her last ASPIRE visit: (mark all that apply)
<input type="checkbox"/> Spermicide <input type="checkbox"/> Sponge <input type="checkbox"/> Oral contraceptive birth control pills (Ortho Evra) – The Patch <input type="checkbox"/> Implants <input type="checkbox"/> Female Condoms <input type="checkbox"/> Male Condoms <input type="checkbox"/> Sterilization (tubal ligation/hysterectomy/laparoscopy/other surgical procedure that causes sterilization) <input type="checkbox"/> Diaphragm <input type="checkbox"/> Intrauterine Device (IUD) <input type="checkbox"/> Injectable contraceptive - Depo <input type="checkbox"/> Injectable contraceptive – NET-EN <input type="checkbox"/> Injectable contraceptive – Cycloferm <input type="checkbox"/> Injectable contraceptive - Other <input type="checkbox"/> Natural methods such as the withdrawal or rhythm method <input type="checkbox"/> Sex with partner who had vasectomy <input type="checkbox"/> Emergency contraception <input type="checkbox"/> Other, specify: _____	____/____/____ dd MMM yy	____/____/____ dd MMM yy If date stopped provided, complete the “Reason(s) for changing or stopping the family planning method” item below. or <input type="checkbox"/> Ongoing	<input type="checkbox"/> Yes → <input type="checkbox"/> No → <i>If no, skip to ‘Reason(s) for changing or stopping the family planning method the participant used at her last ASPIRE visit.’</i>	<input type="checkbox"/> Interested in long-acting reversible contraception (LARC) <input type="checkbox"/> Bleeding concerns <i>Specify the type of vaginal bleeding (select all that apply)</i> <input type="checkbox"/> Heavy bleeding <input type="checkbox"/> Prolonged bleeding <input type="checkbox"/> Intermittent bleeding (e.g., spotting) <input type="checkbox"/> Less bleeding/no bleeding (e.g., no menses) <input type="checkbox"/> Break from hormones <input type="checkbox"/> Difficulty with adherence <input type="checkbox"/> Weight gain <input type="checkbox"/> Interested in getting pregnant <input type="checkbox"/> Became pregnant <input type="checkbox"/> Contraceptive choice not available <input type="checkbox"/> Bothered by pain <input type="checkbox"/> Partner objection <input type="checkbox"/> Medical contraindication: Specify: _____ <input type="checkbox"/> Other reason: Specify: _____ <input type="checkbox"/> No reason provided
	Reason(s) for changing or stopping the family planning method <input type="checkbox"/> Interested in long-acting reversible contraception (LARC) <input type="checkbox"/> Bleeding concerns <i>Specify the type of vaginal bleeding (select all that apply)</i> <input type="checkbox"/> Heavy bleeding <input type="checkbox"/> Prolonged bleeding <input type="checkbox"/> Intermittent bleeding (e.g., spotting) <input type="checkbox"/> Less bleeding/no bleeding (e.g., no menses)	<input type="checkbox"/> Break from hormones <input type="checkbox"/> Difficulty with adherence <input type="checkbox"/> Weight gain <input type="checkbox"/> Interested in getting pregnant <input type="checkbox"/> Became pregnant <input type="checkbox"/> Contraceptive choice not available <input type="checkbox"/> Bothered by pain <input type="checkbox"/> Partner objection <input type="checkbox"/> Medical contraindication Specify: _____ <input type="checkbox"/> Other reason: Specify: _____ <input type="checkbox"/> No reason provided	If yes, was there a break in use of this method for more than 1 month? <input type="checkbox"/> Yes <input type="checkbox"/> No → <i>End of form.</i>	

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MTN-025 ACASI Tracking Y/N

<p>Was an ACASI questionnaire completed at this visit?</p>	<p><input type="checkbox"/> Yes → <i>If Yes, complete the ACASI Tracking form.</i> <input type="checkbox"/> No → <i>If No, please explain:</i> _____ _____ _____</p>
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MTN-025 ACASI Tracking

ACASI collection date	dd MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Which questionnaire was completed?	<input type="checkbox"/> Baseline <input type="checkbox"/> Month 3 <input type="checkbox"/> PUEV/Discontinuers → <i>If baseline or Month 3 is marked, skip to "Were there any problems or issues related to the administration or completion of the questionnaire?"</i>
Reason PUEV/Discontinuers ACASI questionnaire was completed:	<input type="checkbox"/> scheduled PUEV <input type="checkbox"/> early termination <input type="checkbox"/> permanent product discontinuation prior to PUEV/early termination
Were there any problems or issues related to the administration or completion of the questionnaire?	<input type="checkbox"/> Yes <input type="checkbox"/> No → <i>If no, end of form.</i>
If Yes, please describe:	

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Visit : _____

Visit Date: _____

MTN-025 Ring Collection and Insertion

RING COLLECTION	
<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"/> OR 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
RING CHOICE	
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? [COMPLETE AT MONTHS 3-9 ONLY]	<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 not use the ring at this visit? Mark all that apply and then end of form.	<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: _____ END OF FORM.

Participant ID: _____ - _____

Visit : _____

Visit Date: _____

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: _____

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MTN-025 Specimen Storage

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

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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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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