

V1 – Screening Visit

- Participant Date of Visit
- Eligibility Criteria
Complete at Screening Visit only if it is determined the participant will not enroll in HOPE. If Enrollment Visit is scheduled, move blank form to Enrollment Visit forms and complete at the Enrollment Visit.
- Demographics
- Baseline Medical History Y/N
- Baseline Medical History
- Pelvic Exam
- Physical Exam
- Vital Signs
- STI Test Results
- Laboratory Results
- Concomitant Medications Y/N

Site to add:

- Pelvic Exam Diagrams (non Medidata Rave)
- Concomitant Medications, as indicated

Participant ID: _____ - _____
Folder: V1 - Screening

MTN-025 Participant Date of Visit

Date of Visit	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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Participant ID: _____ - _____

Folder: V1 - Screening

MTN-025 Eligibility Criteria

Does this participant meet all eligibility criteria?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was the participant enrolled into HOPE?	<input type="checkbox"/> Yes → <i>If yes, end of form.</i> <input type="checkbox"/> No
Why was the participant not enrolled?	<input type="checkbox"/> eligible, but participant did not complete all screening procedures → <i>End of Form.</i> <input type="checkbox"/> eligible, but participant declined enrollment Specify reason: _____ → <i>End of Form.</i> <input type="checkbox"/> not eligible
Reasons for ineligibility. <i>Record all that apply.</i>	<input type="checkbox"/> Not previously enrolled in MTN-020 (ASPIRE) <input type="checkbox"/> Unable/unwilling to provide written informed consent <input type="checkbox"/> Unable/unwilling to provide adequate locator information <input type="checkbox"/> HIV infected at Screening or Enrollment <input type="checkbox"/> Declines effective method of contraception at Enrollment and for duration of study participation <input type="checkbox"/> Does not agree to not participate in other research studies for duration of study participation <input type="checkbox"/> Study product use permanently discontinued in response to AE or safety related concern with taking part in MTN-020 (ASPIRE) trial <input type="checkbox"/> Plans for relocation/travel per participant report at Screening <input type="checkbox"/> Grade 3 or higher Hemoglobin at Screening <input type="checkbox"/> Grade 3 or high Pap results at Screening <input type="checkbox"/> Currently taking PEP at Enrollment <input type="checkbox"/> Participated in other research study involving drugs, medical devices, vaginal products, or vaccines within 60 days of Enrollment with the exception of MTN-020 (ASPIRE) <input type="checkbox"/> Pregnant at Screening/Enrollment or plans to become pregnant during study participation period <input type="checkbox"/> Currently breastfeeding <input type="checkbox"/> Diagnosed with UTI, PID, STI, or RTI which has not resolved or undergone complete treatment <input type="checkbox"/> Grade 3 pelvic exam finding at Screening or has not improved to non-exclusionary grading or resolved within 56 days of Screening <input type="checkbox"/> Grade 3 or higher AST/ALT at Screening <input type="checkbox"/> Grade 3 or high Creatinine at Screening <input type="checkbox"/> Grade 3 or higher Platelet Count at Screening <input type="checkbox"/> Other, including IoR discretion Specify: _____

Participant ID: _____ - _____

Folder: V1 - Screening

MTN-025 Demographics (Page 1 of 2)

Is this participant enrolled in MTN-025 or part of the Decliner Population?	<input type="checkbox"/> MTN-025 main study <input type="checkbox"/> Decliner Population
Gender:	<input checked="" type="checkbox"/> Female <input type="checkbox"/> Male
Date of Birth	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"/> If date of birth unknown, record age: <input type="checkbox"/> <input type="checkbox"/> years
Is the participant currently married?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Highest level of education?	<input type="checkbox"/> no schooling <input type="checkbox"/> primary school, not complete <input type="checkbox"/> primary school, complete <input type="checkbox"/> secondary school, not complete <input type="checkbox"/> secondary school, complete <input type="checkbox"/> attended college or university
Ethnic group or tribe	<input type="checkbox"/> Chewa <input type="checkbox"/> Lomwe <input type="checkbox"/> Yao <input type="checkbox"/> Tumbuka <input type="checkbox"/> Other African tribe <input type="checkbox"/> White <input type="checkbox"/> Zulu <input type="checkbox"/> Xhosa <input type="checkbox"/> Indian <input type="checkbox"/> Colored <input type="checkbox"/> Black <input type="checkbox"/> Shona <input type="checkbox"/> Ndebele <input type="checkbox"/> Other If other, specify: _____
Number of alcohol drinks per week	_____ # of drinks
Number of cigarettes per day	_____ # of cigarettes
How long did it take the participant to travel from home to the clinic today?	<input type="checkbox"/> less than 30 minutes <input type="checkbox"/> 30-60 minutes <input type="checkbox"/> 1-2 hours <input type="checkbox"/> greater than 2 hours <input type="checkbox"/> N/A
Does the participant earn an income of her own?	<input type="checkbox"/> Yes <input type="checkbox"/> No → If no, skip to "How many times has the participant been pregnant?"

Participant ID: _____ - _____

Folder: V1 - Screening

MTN-025 Baseline Medical History Y/N

Does the participant have any medical history to report?	<input type="checkbox"/> Yes → <i>If 'Yes', complete the Baseline Medical History Log.</i> <input type="checkbox"/> No
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Participant ID: _____ - _____

Folder: V1 - Screening

MTN-025 Baseline Medical History

Date medical history collected	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"/>
Description of medical history condition/event	<hr/> <hr/> <hr/> <hr/> <hr/>
Is condition/event gradable?	<input type="checkbox"/> Yes <input type="checkbox"/> No → If 'No', skip to "Date medical condition/event started".
Toxicity (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)
Date medical condition/event started	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"/>
Is the condition ongoing?	<input type="checkbox"/> Yes → If 'Yes', end of form. <input type="checkbox"/> No
Date medical condition/event ended/resolved	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: _____ - _____

Folder: V1 - Screening

MTN-025 Pelvic Exam

Exam date	<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>			
Abnormal findings. Mark all that apply.				
VULVAR	VAGINAL	CERVICAL	GENERAL/OTHER	
<input type="checkbox"/> vulvar edema <input type="checkbox"/> vulvar erythema <input type="checkbox"/> vulvar rash <input type="checkbox"/> vulvar tenderness <input type="checkbox"/> Bartholin's or Skene's gland abnormality <u>Vulvar lesions</u> <input type="checkbox"/> ulcer <input type="checkbox"/> blister <input type="checkbox"/> pustule <input type="checkbox"/> peeling <input type="checkbox"/> ecchymosis	<input type="checkbox"/> vaginal edema <input type="checkbox"/> vaginal erythema <input type="checkbox"/> vaginal masses (polyps, myomas, possible malignancy) <input type="checkbox"/> vaginal abrasions or lacerations <input type="checkbox"/> vaginal tenderness <u>Abnormal vaginal discharge</u> <input type="checkbox"/> slight <input type="checkbox"/> moderate <input type="checkbox"/> pooling <u>Vaginal lesions</u> <input type="checkbox"/> ulcer <input type="checkbox"/> blister <input type="checkbox"/> pustule <input type="checkbox"/> peeling <input type="checkbox"/> ecchymosis	<input type="checkbox"/> cervical edema and/or friability <input type="checkbox"/> cervical erythema <input type="checkbox"/> cervical masses (polyps, myomas, possible malignancy) <input type="checkbox"/> cervical motion tenderness <input type="checkbox"/> cervical discharge <u>Cervical lesions</u> <input type="checkbox"/> ulcer <input type="checkbox"/> blister <input type="checkbox"/> pustule <input type="checkbox"/> peeling <input type="checkbox"/> ecchymosis	<input type="checkbox"/> odor (vaginal) <input type="checkbox"/> condyloma, specify location: _____ <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): _____				
<i>Complete or update Baseline Medical Conditions Log as applicable.</i>				
Were any new pelvic finding AEs reported at this visit?	<input type="checkbox"/> Yes <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: _____ - _____

Folder: V1 - Screening

MTN-025 Physical Exam

Exam Date:		dd	MMM	yy	
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
FINDINGS					
<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>					
		Not done	Normal	Abnormal	If abnormal, specify:
1	General appearance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2	Abdomen/ Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3	Neck	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4	Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5	Heart/Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6	Lungs/Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7	Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8	Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9	Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10	Eyes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11	Ears, Nose, Throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12	Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Record abnormal findings on Baseline Medical History Log as applicable.					

Participant ID: _____ - _____

Folder: V1 - Screening

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 MMM 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>
5. Pulse	<input type="text"/> <input type="text"/> <input type="text"/> <i>beats per minute</i>
6. Respirations	<input type="text"/> <input type="text"/> <i>breaths per minute</i>
7. Height	<input type="text"/> <input type="text"/> <input type="text"/> cm OR <input type="checkbox"/> <i>not required</i>

Participant ID: _____ - _____

Folder: V1 - Screening

MTN-025 STI Test Results

Syphilis Serology	<input type="checkbox"/> Not done/not collected → <i>Skip to "Trichomonas Rapid Test"</i>	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"/>
Syphilis screening test		Non-reactive reactive <input type="checkbox"/> <input type="checkbox"/> ↓ If non-reactive, go to <i>Trichomonas Rapid Test</i> .
Syphilis titer		1: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Syphilis confirmatory test		<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Indeterminate
Trichomonas Rapid Test	<input type="checkbox"/> Not done/not collected	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"/> Positive <input type="checkbox"/> Negative
<i>N. gonorrhoeae</i>	<input type="checkbox"/> Not done/not collected	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"/> Positive <input type="checkbox"/> Negative
<i>C. trachomatis</i>	<input type="checkbox"/> Not done/not collected	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"/> Positive <input type="checkbox"/> Negative
At Screening, record STI diagnoses in <i>Baseline Medical Conditions Log form</i> when applicable.		

Participant ID: _____ - _____

Folder: V1 - Screening

MTN-025 Laboratory Results (Page 1 of 2)

HEMOGRAM <input type="checkbox"/> Not done/not collected → Go to Serum Chemistries.		Hemogram 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"/> 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
<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
<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
DIFFERENTIAL <input type="checkbox"/> Not done → Skip to "Serum Chemistries"		
<input type="checkbox"/> Not Reported	Neutrophils	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

Participant ID: _____ - _____

Folder: V1 - Screening

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
<input type="checkbox"/> Not Reported	Monocytes	Absolute Count _____
<input type="checkbox"/> Not Reported	Eosinophils	Absolute Count _____
<input type="checkbox"/> Not Reported	Basophils	Absolute Count _____
SERUM CHEMISTRIES <input type="checkbox"/> Not done/not collected → <i>End of form.</i>		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="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
<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
<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

Participant ID: _____ - _____

Folder: V1 - Screening

MTN-025 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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