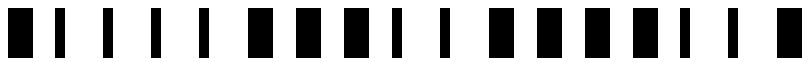


GROUP 1

Visit 5a **Visit Code 05.0**

- Visit Summary (VS-1)
- Physical Exam (PX-1)
- STI Test Results (STI-1)
- Study Product Accountability (SPA-1)
- Male Practices–Group 1 (MPI-1)
- Physical Exam–Male (non-DataFax)

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MTN-011 (135)

VS-1 (121)

Visit Code

Participant ID

- - - 0

Protocol PTID Chk Cohort

Visit Summary

Visit Date

dd MMM yy

1. What was the participant's last day of previous menses?	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<i>amenorrheic for past 6 months</i>
2. hCG for pregnancy:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>OR</i> <input type="checkbox"/>
3. Has participant's method of contraception/family planning changed since her last visit?	<input type="checkbox"/> <input type="checkbox"/>	<i>If positive, complete Pregnancy Report form and Product Hold/Discontinuation Log.</i>
4. How many new AE Log pages were completed for the female participant at this visit?	<input type="text"/> <input type="text"/>	<i>If yes, complete Family Planning form.</i>
5. How many new Product Hold/Discontinuation Log pages were completed for this visit?	<input type="text"/> <input type="text"/>	
6. Did the female participant complete the CASI Behavioral Questionnaire (BEH)?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
7. Time during visit of study product insertion:	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<i>OR</i> <input type="checkbox"/>
8. Did the couple complete coitus?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<i>If no or not required, go to instructions above item 9.</i>
8a. Time of completion of coitus:	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
Complete item 9 for Group 1 participants only, and only at Visit Code 09.0. For all other visits, leave item 9 blank.		
9. Time of post-coital study product insertion:	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<i>OR</i> <input type="checkbox"/>

Visit Summary (VS-1)	
Purpose:	This form is used to document completion of all Follow-up Visits (required and interim) completed by female participants once enrolled.
Item-specific Instructions:	
Item 1:	If the participant is unable to recall the complete date, obtain participant's best estimate. At a minimum, the month and year are required. Only record dates of menstrual period bleeding. Do not record dates of episodes of expected breakthrough bleeding experienced while a participant is on Depo, Mirena, or other continuous contraceptive method where a woman does not experience a monthly menstrual period.
Item 4:	Record in item 4 how many new AE Log pages were completed for the female participant at this visit. For example, if two new AEs were reported, record "02." Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
Item 5:	Record how many new Product Hold/Discontinuation Log pages were completed for this visit. For example, if two new product holds/discontinuations were reported, record "02." Note that the Visit Code recorded in item 1 of the Product Hold/Discontinuation Log pages should be the same as the Visit Code recorded on this form.
Items 8 and 8a:	Completion of coitus is defined as when the male partner ejaculates into the female partner's vagina.
Item 9:	When recording time, use a 24-hour clock (e.g., 8:12pm is recorded as 20:12).



MTN-011 (135)

PX-1 (036)

Visit Code

Participant ID

- - -
 Protocol PTID Chk Cohort

Physical Exam

Visit Date

dd MMM yy

VITAL SIGNS				
1. Weight	<input type="text"/> <input type="text"/> <input type="text"/> kg	OR	<input type="text"/>	<i>not done</i>
2. Body Temp	<input type="text"/> <input type="text"/> . <input type="text"/> °C			
3. BP	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> mmHg			
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 done</i>
FINDINGS				
	<i>not done</i>	<i>normal</i>	<i>abnormal</i>	<i>Notes:</i>
7. General appearance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
8. Genitourinary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
9. Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
10. Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
11. Heart/ Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
12. Lungs/ Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
13. Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
14. Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
15. Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
16. Eyes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
17. Ears, Nose, Throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
18. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Record abnormal findings on Pre-existing Conditions form or Adverse Experience Log, as applicable.

Physical Exam (PX-1)	
Purpose:	This form is used to document the female participant's vital signs and physical exam findings during screening, enrollment, and follow-up.
General Information/ Instructions:	If abnormal findings are found in items 7–18 transcribe information onto the Pre-existing Conditions form or Adverse Experience Log form, as applicable.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed.
Items 7–17:	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings on the Notes line. If not evaluated, mark the “not done” box.
Item 18:	If no other abnormal findings are identified, mark the “normal” box. If abnormal, specify the body system being referenced and describe the findings on the Notes line.



MTN-011 (135)

STI-1 (190)

Visit Code

Participant ID

- - - 0

Protocol PTID Chk Cohort

STI Test Results

Initial Specimen Collection Date

dd MMM yy

1. Vaginal Wet Prep	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
	negative				positive	
<input type="checkbox"/> 1a. Homogeneous vaginal discharge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not done		Alternate Collection Date				
<input type="checkbox"/> 1b. pH <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>		dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
					negative	positive
<input type="checkbox"/> 1c. Whiff test	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not done		Alternate Collection Date				
<input type="checkbox"/> 1d. Clue cells \geq 20%	<input type="checkbox"/>	dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
					negative	positive
Not done		Alternate Collection Date				
<input type="checkbox"/> 1e. <i>Trichomonas vaginalis</i>	<input type="checkbox"/>	dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
					negative	positive
Not done		Alternate Collection Date				
<input type="checkbox"/> 1f. Buds and/or hyphae (yeast)	<input type="checkbox"/>	dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
					negative	positive
2. Trichomonas Rapid Test	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
					negative	positive
3. <i>N. gonorrhoeae</i>	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
					negative	positive
4. <i>C. trachomatis</i>	Not done/Not collected	Alternate Collection Date				
	<input type="checkbox"/>	dd	MMM	yy	<input type="checkbox"/>	<input type="checkbox"/>
					negative	positive
5. Pre-coital pH:	Not done	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>			
6. Post-coital pH:	Not done	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>			

Complete or update Pre-existing Conditions or Adverse Experience Log, as applicable.

Comments: _____

01-AUG-12

STI Test Results (STI-1)	
Purpose:	This form is used to document Vaginal Wet Prep and STI Test Results during screening, enrollment, and follow-up for female participants.
General Information/ Instructions:	<ul style="list-style-type: none"> • Initial Specimen Collection Date: Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form). A complete date is required. • Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. A complete date is required. • Not done/Not collected: Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments lines.
Item-specific Instructions:	
Items 1–4:	If a test result(s) recorded on this form indicates that the participant has a new (or increased severity) laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse experience on an Adverse Experience (AE) Log.
Item 1:	If a vaginal wet prep was performed but not all assays were completed, mark the “Not done/Not collected” box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason on the Comments lines.
Item 1a:	Mark the “positive” box if homogeneous vaginal discharge was observed.
Item 1d:	Mark the “positive” box if 20% or more of the cells were clue cells.
Item 1e:	Mark the “positive” box if trichomonads were observed.
Item 1f:	Mark the “positive” box if yeast buds and/or hyphae were observed.
Item 5:	Record the result of the pre-coital vaginal fluid pH.
Item 6:	Record the result of the post-coital vaginal fluid pH.



MTN-011 (135)

SPA-1 (415)

Visit Code

1

Participant ID

- - - 0

Protocol PTID Chk Cohort

Study Product Accountability

Form Completion Date

dd MMM yy

1. Was study product given to the participant for clinic and/or home use? *yes* *no* → *If no, go to item 2.*

1a. Date dispensed:

dd MMM yy

1b. Number of study product applicators dispensed at this visit: 1 2 7 8 *other, specify:* _____

2. Was study product returned by the participant? *yes* *no, specify:* _____ → *If no, end of form.*

2a. Date study product was returned by participant:

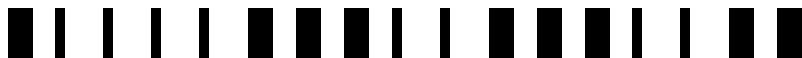
dd MMM yy

2b. Number of **used** applicators returned: *used applicators returned*

2c. Number of **unused** applicators returned: *unused applicators returned*

Comments: _____

Study Product Accountability (SPA-1)	
Purpose:	This form is used to document all study product dispensation, and used and unused product returns.
General Information/ Instructions:	This form should be completed at each visit when product is dispensed.
Item-specific Instructions:	
Item 1b:	Mark the box corresponding to the total number of applicators dispensed at this visit. For example, for Group 2 female participants at Visit 6 (26.0), the "8" box should be marked (1 applicator for clinic use, 6 applicators for home use, 1 applicator extra).
Item 2:	This item must be completed when participant returns product from the previous dispensation. For some visits, dispensation and returns will occur on the same day (e.g., Group 1, Visits 3a and 3b; Group 2, Visits 3a and 3b). For other visits, product returns will be several days after dispensation (e.g., Group 1, Visits 6a and 6b; Group 2, Visits 2 and 3a). Always record product returns on the SPA-1 form which documents that dispensation. If study product was not returned, record the reason on the line provided.
Item 2a:	Record the exact day, month, and year study product was returned by the participant.



MTN-011 (135)

MPI-1 (115)

Visit Code

Participant ID

- - -
 Protocol PTID Chk Cohort

Male Practices—Group 1

Visit Date

.
 dd MMM yy

1. Did the male participant complete the self-administered MTN-011 Male Practices questionnaire?	yes <input type="checkbox"/>	no <input type="checkbox"/>	<i>If no, end of form.</i>
2. In the past 3 full days (72 hours),	2a. did your partner perform oral sex on you?	yes <input type="checkbox"/>	no <input type="checkbox"/>
	2b. have you had anal sexual intercourse with your partner?	yes <input type="checkbox"/>	no <input type="checkbox"/>
	2c. have you had penile-vaginal sexual intercourse with your partner?	yes <input type="checkbox"/>	no <input type="checkbox"/>
	2d. have you masturbated?	yes <input type="checkbox"/>	no <input type="checkbox"/>
3. For any activity in item 2 marked "yes," did you ejaculate/come?	yes <input type="checkbox"/>	no <input type="checkbox"/>	N/A <input type="checkbox"/>
4. In the past 3 full days (72 hours),	4a. have you had any nocturnal emissions (wet dreams)?	yes <input type="checkbox"/>	no <input type="checkbox"/>
	4b. have you applied lubricants, spermicides, or any other products to your genital area?	yes <input type="checkbox"/>	no <input type="checkbox"/>

Comments: _____

Male Practices—Group 1 (MPI-1)	
Purpose:	This form is used to collect data on male behavior practices that could affect interpretation of key study data.
General Information/ Instructions:	This form is completed by transcribing responses present on the participant self-administered Male Practices Questionnaire onto this form. For Group 1 male participants, this form is required at visits 2a (02.0), 3a (03.0), 5a (05.0), and 7a (09.0).
Visit Date:	If the couple misses the visit, record the Target Visit Date recorded on the Missed Visit form for the female participant.
Item-specific Instructions:	
Item 1:	Complete for all Group 1 participants to indicate whether the required MTN-011 Male Practices Questionnaire was completed at the visit. Mark the “no” box if the questionnaire was not completed at a required visit. Record the reason(s) in Comments, leaving all other items blank.
Items 2–4:	Transcribe responses as they appear on the questionnaire document completed by the participant.

Not a DataFax form. Do not fax to DataFax.

MTN-011 (135)

Page 1 of 1

Participant ID

Protocol

PTID

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Chk

Cohort

Physical Exam—Male

Exam Date

dd

MMM

yy

VITAL SIGNS

1. Weight	<input type="text"/> <input type="text"/> <input type="text"/> kg	OR	<input type="checkbox"/>	4. Pulse	<input type="text"/> <input type="text"/> <input type="text"/> beats per minute
2. Body Temp	<input type="text"/> <input type="text"/> . <input type="text"/> °C			5. Respirations	<input type="text"/> <input type="text"/> breaths per minute
3. BP	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> mmHg			6. Height	<input type="text"/> <input type="text"/> <input type="text"/> cm OR <input type="checkbox"/>

FINDINGS

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

Record abnormal findings on Adverse Experience Log as applicable.

Physical Exam—Male (Non-DataFax)	
Purpose:	This form is used to document the male participant's vital signs and physical exam findings.
General Information/Instructions:	This form is completed each time a physical exam is performed. Because this is a non-DataFax form, do NOT fax to SCHARP DataFax.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed. The staff member who completes these items should initial and date in the space provided.
Findings:	The staff member who completes these items should initial and date in the space provided.
Item 18:	If no other abnormal findings are identified, mark the "normal" box. If abnormal, specify the body system being referenced and describe the findings on the Notes line.