Enrollment Visit
Visit 02.0

Required forms

- Enrollment (ENR-1)
- Vaginal Practices (VP-1)
- Physical Exam (PX-1)
- Pelvic Exam (PE-1)
- Specimen Storage (SS-1)
- Ring Collection and Insertion (RCI-1)
- Pelvic Exam Diagrams (non-DataFax)

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MTN-024/IPM 031 (203) ENR-1 (070)

Participant ID

Site Number – Participant Number – Chk

Enrollment

1. Date the participant marked or signed the consent form for study participation: dd MMM yy

2. Did the participant consent to:

   2a. long-term specimen storage and future testing? *yes* ☐ *no* ☐

   2b. participate in the PK Subset? *yes* ☐ *no* ☐

   2c. participate in the Intensive PK Subset? *yes* ☐ *no* ☐

3. Plasma for archive: Collection Date dd MMM yy ☐ *stored* ☐ *not stored* → *Reason:* _____

4. Randomization envelope number assigned: ☐☐☐

5. Randomization date and time: dd MMM yy hr : min *24-hr clock*

6. Was the participant randomized to the in-depth interview? *yes* ☐ *no* ☐

7. Was a Baseline CASI questionnaire completed at this visit? *yes* ☐ *no* ☐

8. Were there any problems or QC issues related to the administration or completion of the CASI questionnaire? *yes* ☐ *no* ☐ → *If no, end of form.*

   8a. Describe: _____

Enrollment (ENR-1)	
Purpose:	This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for the randomized participant.
General Information/Instructions:	
	Fax this form to SCHARP DataFax only if the participant is enrolled (that is, she is assigned a randomization envelope).
Item-specific Instructions:	
Item 2:	Consent for long-term specimen storage, participation in the PK Subset or Intensive PK Subset can be changed if the participant changes her consent decision after enrollment. Update as needed if the participant changes her consent during the study.
Item 3:	If the specimen is required to be stored, but for some reason it is not stored, mark "not stored" and record the reason on the line provided.
Item 4:	This item must match the randomization envelope number printed on the label of this participant's randomization envelope, and on the Randomization document contained inside the envelope. It must also match the randomization envelope number recorded for this participant on the Randomization Envelope Tracking Record.
Item 5:	These items must match the "date assigned" and "time assigned" recorded for this randomization envelope on the Randomization Envelope Tracking Record.
Item 6:	Record whether the participant has been randomized to complete the in-depth interview that takes place at the 12-Week Final Clinic Visit.
Items 7–8:	The Baseline CASI questionnaire is required at the Enrollment Visit. If it was not done, mark item 8 "yes" and provide a brief explanation in item 8a.

MTN-024/IPM 031 (203) VP-1 (185)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number Participant Number Chk

Vaginal Practices

Visit Date

dd ☐☐ MMM ☐☐☐ yy ☐☐

1. Since her last visit, has the participant inserted anything inside her vagina other than study-approved lubricant? *yes* ☐ *no* ☐ → *If no, go to item 2.*

   What has the participant inserted vaginally? *Mark all that apply.*

   - ☐ 1a. spermicides
   - ☐ 1b. female condoms
   - ☐ 1c. diaphragm
   - ☐ 1d. topical or systemic hormone replacement therapy, e.g., estrogen cream
   - ☐ 1e. vaginal medications
   - ☐ 1f. menstrual cup
   - ☐ 1g. cervical cap *(or any other vaginal barrier method)*
   - ☐ 1h. douche
   - ☐ 1i. non-study-approved lubricants
   - ☐ 1j. sex toys *(vibrators, dildos, etc.)*
   - ☐ 1k. other, specify: _____

2. Has the participant abstained from inserting anything into the vagina for 72 hours prior to this visit, including the use of study-approved lubricant and having vaginal intercourse? *yes* ☐ *no* ☐ → *If yes, end of form.*

   2a. Has the participant used study-approved lubricant within the 72 hours prior to the visit? *yes* ☐ *no* ☐ → *If no, go to item 2b.*

   2a1. Total amount used per day:

	dd	MMM	yy	*grams*
	☐☐	☐☐☐	☐☐	☐☐
n/a ☐	☐☐	☐☐☐	☐☐	☐☐
☐	☐☐	☐☐☐	☐☐	☐☐

   2b. Has the participant had vaginal intercourse within 72 hours prior to this visit? *yes* ☐ *no* ☐

Comments:

Vaginal Practices (VP-1)	
Purpose:	This form is used to collect participant vaginal practices.
General Information/Instructions:	
	Complete this form at the 4-Week, 8-Week and the 12-Week Final Clinic Visit, and at early termination visit, if applicable.
Item-specific Instructions:	
Item 1k:	If the participant reports inserting anything other than what is listed on this form, mark “other” and specify the practice on the line provided. Study vaginal rings do not apply.
Item 2a1:	Record the total amount per day of study-approved lubricant the participant has indicated using within the 72 hours prior to the clinic visit.

MTN-024/IPM 031 (203) PX-1 (036)

Visit Code . 1

Participant ID

Site Number – Participant Number – Chk

Physical Exam

Visit Date dd MMM yy

VITAL SIGNS	
1. Height *not required* ☐ OR ___ *cm*	4. BP ___ / ___ *mmHg*
2. Weight ___ *kg*	5. Pulse ___ *beats per minute*
3. Body Temp ___ . ___ *°C*	6. Respirations ___ *breaths per minute*

FINDINGS *Items 9–15 may be omitted from assessment after the Enrollment Visit.*

	not done	*normal*	*abnormal*	*Notes*
7. General appearance	☐	☐	☐	
8. Abdomen/Gastrointestinal	☐	☐	☐	
9. Neck	☐	☐	☐	
10. Lymph Nodes	☐	☐	☐	
11. Heart/Cardiovascular	☐	☐	☐	
12. Lungs/Respiratory	☐	☐	☐	
13. Extremities	☐	☐	☐	
14. Neurological	☐	☐	☐	
15. Skin	☐	☐	☐	
16. Other	☐	☐	☐	

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

Comments:

Physical Exam (PX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings.
General Information/Instructions:	
	Complete this form at the Screening, Enrollment, and the 4-Week and 8-Week Visits and the 12-Week Final Clinic Visit. If abnormal findings are found, for items 7–16, transcribe the information onto the Pre-existing Conditions or Adverse Experience form(s).
Item-specific Instructions:	
Vital Signs:	Use leading zeros as applicable.
Item 1:	This item is required at Screening only.
Items 7–15:	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings in Notes. If not evaluated, mark "not done" and record the reason in Notes. Normal findings may also be described in Notes, but is not required.
Item 16:	If no other abnormal findings are identified, mark "not done."

MTN-024/IPM 031 (203) PE-1 (138)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Pelvic Exam

Visit Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

1. Vaginal pH — *not done* ☐ ☐☐.☐ *If > 4.5, mark positive.* → *positive* ☐

2. Pelvic exam assessment: *not done* ☐ *abnormal findings* ☐ *no abnormal findings* ☐ → *If no abnormal findings, go to item 3.*
   → *If not done, end of form.*

2a. Abnormal findings. *Mark all that apply.*

VULVAR	VAGINAL	CERVICAL	GENERAL/OTHER
☐ vulvar edema	☐ vaginal edema	☐ cervical edema and/or friability	☐ odor *(vaginal)*
☐ vulvar erythema	☐ vaginal erythema	☐ cervical erythema	☐ condyloma, specify location: _____
☐ vulvar rash	☐ vaginal masses *(polyps, myomas, possible malignancy)*	☐ cervical masses *(polyps, myomas, possible malignancy)*	☐ adnexal masses *(based on bimanual exam; not pregnancy or infection-related)*
☐ vulvar tenderness	☐ vaginal abrasions or lacerations	☐ cervical motion tenderness	☐ uterine masses *(based on bimanual exam)*
☐ Bartholin's or Skene's gland abnormality	☐ vaginal tenderness	☐ cervical discharge	☐ uterine tenderness
Vulvar lesions	Abnormal vaginal discharge	Cervical lesions	☐ adnexal tenderness
☐ ulcer	☐ slight	☐ ulcer	☐ observed blood or bleeding; describe:
☐ blister	☐ moderate	☐ blister	_____
☐ pustule	☐ pooling	☐ pustule	_____
☐ peeling	Vaginal lesions	☐ peeling	_____
☐ ecchymosis	☐ ulcer	☐ ecchymosis	_____
	☐ blister		_____
	☐ pustule		
	☐ peeling		
	☐ ecchymosis		

☐ 2b. Other abnormal findings, specify (include anatomical location): _____

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

3. Were any new pelvic finding AEs reported at this visit? *yes* ☐ *no* ☐ → *If no, end of form.*

3a. AE Log page (#)s: ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

Pelvic Exam (PE-1)

Purpose:	This form is used to document the participant's pelvic exam assessment.
General Information/Instructions:	
	Complete this form at Screening, Enrollment, and the 4-Week and 8-Week visits, the 12-Week Final Clinic Visit, and early termination visit (as applicable), and when a clinically indicated pelvic exam is performed during interim visits. Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to DataFax.
Item-specific Instructions:	
Item 1:	Vaginal fluid pH is required at Enrollment Visit, 4-Week and 8-Week Visit and the 12-Week Final Clinic Visit.
Item 2:	Note that observation of any genital blood or bleeding is considered an abnormal finding, regardless of whether the blood is expected (menstrual blood, for example). If blood or bleeding is observed, mark "abnormal findings" and in item 2a, mark "observed blood or bleeding; describe" and describe on the lines provided.
Item 2a:	• Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark "other abnormal findings, specify" and describe the abnormal finding on the line provided, including anatomical location. In general, for abnormal findings reported as adverse events on an AE Log, use text from item 2a as AE descriptive text finding (this does not apply to observances of blood or bleeding). • Observed blood or bleeding; describe: If blood or bleeding is observed, mark this item and in the space provided, briefly describe the color, amount, and location of the blood/bleeding. If known, specify if the blood was menstrual or non-menstrual. Assess the blood/bleeding for AE reporting purposes. Per Study-specific Procedures (SSP) manual section 7, all bleeding occurring during follow-up that is different from the participant's baseline bleeding pattern is an AE. This may include unusually heavy or prolonged menses, as well as non-menstrual bleeding different from baseline. • Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the *Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Addendum 1: Female Genital Grading Table for Use in Microbicide Studies (FGGT)*. Refer to SSP manual section 7 for more information/guidance as needed.

MTN-024/IPM 031 (203) SS-1 (149)

Visit Code . 1

Participant ID

Site Number – Participant Number – Chk

Specimen Storage

Initial Specimen Collection Date: dd MMM yy

Not done/ Not collected		Alternate Collection Date (dd MMM yy)	stored	not stored	Reason not stored
☐	1. Vaginal smear for gram stain		☐	☐	
☐	2. Quantitative vaginal culture		☐	☐	
☐	3. Vaginal swab for biomarkers:	not required ☐	☐	☐	
	3a. Was blood visible on the swab?	yes ☐ no ☐			
☐	4. Cervicovaginal lavage:	not required ☐	☐	☐	
	4a. Cell pellet	stored ☐ not stored ☐			
☐	5. Cervical cytobrush	not required ☐	☐	☐	
☐	6. Used vaginal ring	not required ☐	☐	☐	

Comments:

Specimen Storage (SS-1)	
Purpose:	This form is used to document collection and storage of vaginal and cervical specimens by the local site laboratory.
General Information/Instructions:	
	Complete this form at Enrollment, 4-Week and 8-Week Visits, and the 12-Week Final Clinic Visits as applicable.
Visit Code:	Record the visit code assigned to this visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
Initial Specimen Collection Date:	Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. A complete date is required.
Not done/Not collected:	Mark this box in the event that a specimen was not collected or not required.
Stored/Not Stored:	Mark “stored” for specimens that are collected and sent to the lab for processing. If specimens are not stored, mark “not stored” and record the reason why on the line provided.
Item-specific Instructions:	
Items 3–6:	If the specimen is not required to be collected at this visit, mark “not required.”

MTN-024/IPM 031 (203) RCI-1 (135)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Ring Collection and Insertion

Visit Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

1. Did the participant have a ring in place at the start of the visit? *yes* ☐ *no* ☐ → *If yes, go to item 2.*

   1a. When was the ring last in place? dd ☐☐ MMM ☐☐☐ yy ☐☐ OR ☐ *not applicable (ring not in place since last visit)*

2. Number of **used** rings collected: *none* ☐ *1* ☐ → *If "1," go to item 3.*

   2a. If none, specify reason: _____

3. Number of **new rings** dispensed to participant: *none* ☐ *1* ☐ → *If "1," go to item 4.*

   3a. Reason ring not dispensed:

   - ☐ participant on clinical hold
   - ☐ participant has been permanently discontinued from product
   - ☐ participant declined study ring, specify: _____
   - ☐ early termination
   - ☐ 12-Week Final Clinic Visit
   - ☐ other, specify: _____

   → *Go to item 6.*

4. Was a new ring inserted at this visit? *yes* ☐ *no* ☐ → *If no, go to item 5.*

   4a. Who inserted the new ring? *participant* ☐ *study staff* ☐

5. Was a ring in place at the end of the visit? *yes* ☐ *no* ☐ → *If yes, go to item 6.*

   5a. Reason ring not in place at end of visit:

   - ☐ participant declined to have ring inserted
   - ☐ participant had to leave before ring could be inserted
   - ☐ other, specify: _____

6. Appearance of most recently-used ring: ☐ *used* ☐ *not used* ☐ *not sure* ☐ *no ring*

Ring Collection and Insertion (RCI-1)

Purpose:	This form is used to document rings that are inserted and collected for each participant for the duration of the study.

General Information/Instructions:

- Complete this form at the 4-Week and 8-Week Visits and the 12-Week Final Clinic Visit, and at early termination visit, as applicable. Complete at interim visits as needed.
- If the participant has been permanently discontinued from study product, this form is not required to be completed at visits following the permanent discontinuation.

Item-specific Instructions:

Item 1a:	If the vaginal ring was not in place at the start of the visit, record the date the vaginal ring was last in place over the past month. If the participant is unable to recall the exact date, obtain the participant's best estimate. At a minimum, the month and year are required. If the ring was not in place at any time since this form was last completed, mark “not applicable.”
Item 2a:	If no rings were collected (returned), specify the reason why (for example, participant forgot, or participant had no dispensed rings to return).
Item 3:	Only document ring(s) dispensed and given to the participant.
Item 3a:	If participant declined to have a ring dispensed to her, record a brief reason for her decline on the line provided. If the reason for her decline is due to or associated with an adverse event, document the adverse event on an Adverse Experience (AE) Log and note in the AE Log comments that the participant declined the ring because of the AE.
Item 6:	Document the clinic staff’s assessment of the appearance of the participant’s most recently-used ring. Base this assessment only on the appearance of the ring, do not factor in the participant’s reported use of the ring or other information when marking a response. If no ring was returned (item 2 of this form is “none”), mark “no ring” to indicate no ring was available for this assessment at this visit. Record the appearance of the ring most recently used by the participant.

THIS IS NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.

MTN-024/IPM 031 (203)

Participant ID

Site Number – Participant Number – Chk

Pelvic Exam Diagrams

Exam Date

dd MMM yy

☐ no normal variants or abnormal findings observed

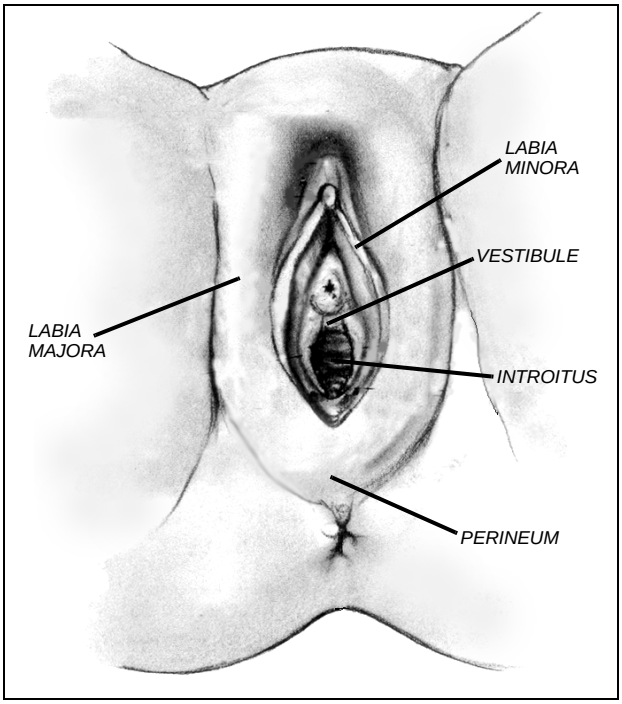
Speculum Type (screening only)

Pederson ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only)

small ☐ *medium* ☐ *large* ☐

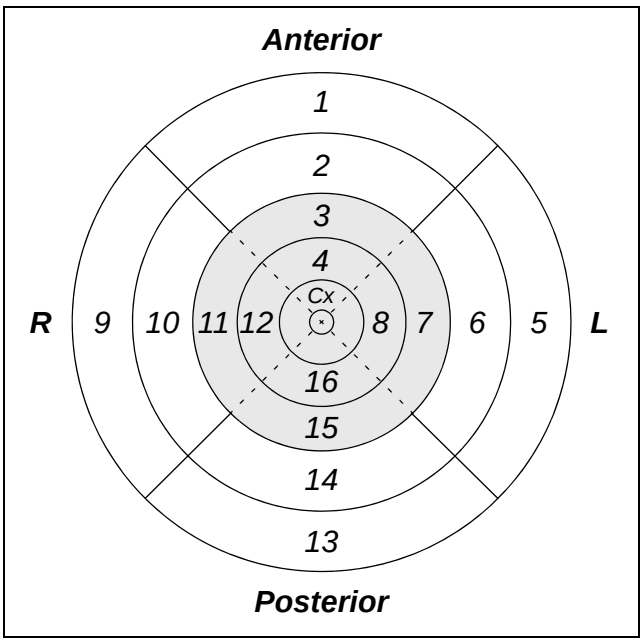
External Genitalia



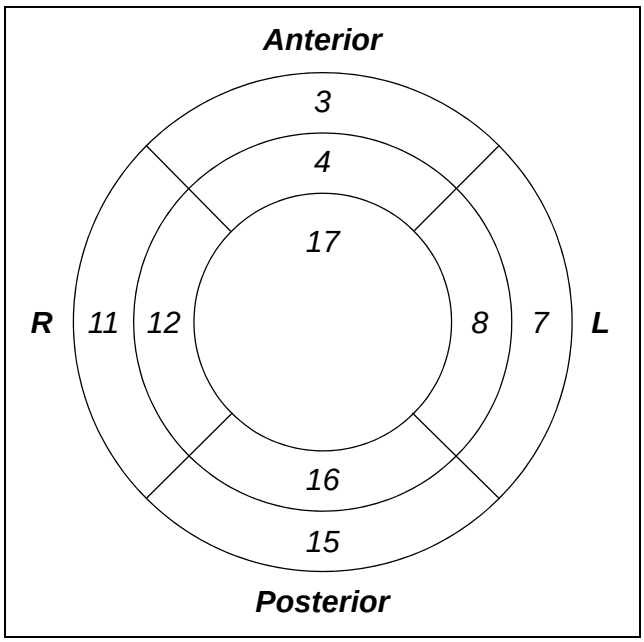
Legend for Vagina/Cervix

1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, proximal half
11. Right lateral fornix
12. Cervical trunk, right lateral
13. Posterior vagina, distal half
14. Posterior vagina, proximal half
15. Posterior fornix
16. Cervical trunk, post
17. Cervical face

Vagina



Cervix



Pelvic Exam Diagrams (non-DataFax)

Purpose: This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through termination/study exit).

General Information/Instructions:

This form is completed at the Screening Visit, the Enrollment Visit, the 4-Week and 8-Week Visits, the 12-Week Final Clinic Visit, and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to SCHARP DataFax. Transcribe information onto the appropriate Pelvic Exam DataFax form for submission to DataFax and store this form in the participant's chart notes.

Item-specific Instructions:

Findings: All variants of normal (normal findings) and all abnormal findings must be documented on this form. Variants of normal need only be recorded on this form, and not on any of the Pelvic Exam DataFax forms. The following findings are considered normal variants:

- expected menstrual and non-menstrual bleeding
- anatomic variants
- gland openings
- Nabothian cysts
- mucus retention cysts
- Gartner's duct cysts
- blood vessel changes other than disruption
- skin tags
- scars
- cervical ectopy

If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box.

Documenting findings on the cervix: If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).