GROUP 2

Visit 5
Visit Code 25.0

- Visit Summary (VS-1)
- Pelvic Exam (PE-1)
- STI Test Results (STI-1)
- Pharmacokinetics (PK-1)
- Study Product Accountability (SPA-1)
- Group 2–Participant-reported Dosing (PDC-1)
- Pelvic Exam Diagrams (non-DataFax)

Site to print and add:

- LDMS Specimen Tracking Sheet

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Visit Code ☐☐.☐ 1

MTN-011 (135) VS-1 (121)

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? ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy* OR ☐ *amenorrheic for past 6 months*

2. hCG for pregnancy: *not required* ☐ *negative* ☐ *positive* ☐ → *If positive, complete Pregnancy Report form and Product Hold/ Discontinuation Log.*

3. Has participant's method of contraception/family planning changed since her last visit? *yes* ☐ *no* ☐ → *If yes, complete Family Planning form.*

4. How many **new** AE Log pages were completed for the female participant at this visit? *# of pages* ☐☐

5. How many **new** Product Hold/Discontinuation Log pages were completed for this visit? *# of pages* ☐☐

6. Did the female participant complete the CASI Behavioral Questionnaire (BEH)? *yes* ☐ *no* ☐ OR *not required* ☐

7. Time during visit of study product insertion: *24-hour clock* ☐☐ (*hr*) : ☐☐ (*min*) OR *not required* ☐

8. Did the couple complete coitus? *yes* ☐ *no* ☐ *not required* ☐ → *If no or not required, go to instructions above item 9.*

   8a. Time of completion of coitus: *24-hour clock* ☐☐ (*hr*) : ☐☐ (*min*)

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: *24-hour clock* ☐☐ (*hr*) : ☐☐ (*min*) OR *not inserted* ☐

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).

Visit Code ☐☐.☐ 1

MTN-011 (135) PE-1 (138)

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 0 (Protocol / PTID / Chk / Cohort)

Pelvic Exam

Exam Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

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

1a. 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		

☐ 1b. Other abnormal findings, specify (include anatomical location): _____

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

2. Were any new pelvic finding AEs reported at this visit? ☐ *yes* ☐ *no* → *If no, go to item 3.*

2a. AE Log page (#)s: ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

3. Cervical ectopy: ☐ *0%* ☐ *1–25%* ☐ *26–50%* ☐ *51–75%* ☐ *76–100%*

☐☐☐☒ 01-AUG-12

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01 English

Staff Initials / Date

Pelvic Exam (PE-1)	
Purpose:	This form is used to document the participant's required pelvic exam assessments.
General Information/ Instructions:	Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to SCHARP DataFax.
Item-specific Instructions:	
Item 1:	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 the "abnormal findings" box and in item 1a, mark the "observed blood or bleeding; describe" box and describe on the lines provided.
Item 1a:	Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark the "other abnormal findings, specify" box 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 1a 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 10.6, 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 10.6 for more information/guidance as needed.

Visit Code ☐☐.☐ 1

MTN-011 (135) STI-1 (190)

Participant ID ☐☐☐ (Protocol) ☐☐☐☐-☐-0 (PTID, Chk, Cohort)

STI Test Results

Initial Specimen Collection Date ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

1. Vaginal Wet Prep	*Go to item 2.*	Not done/ Not collected ☐	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	
Not done ☐ 1a. Homogeneous vaginal discharge		*negative* ☐	*positive* ☐	
Not done ☐ 1b. pH ☐.☐	*If > 4.5, mark as positive.*		*positive* ☐	
Not done ☐ 1c. Whiff test		*negative* ☐	*positive* ☐	
Not done ☐ 1d. Clue cells ≥ 20%		*negative* ☐	*positive* ☐	
Not done ☐ 1e. *Trichomonas vaginalis*		*negative* ☐	*positive* ☐	
Not done ☐ 1f. Buds and/or hyphae (yeast)		*negative* ☐	*positive* ☐	
2. Trichomonas Rapid Test		Not done/ Not collected ☐	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*negative* ☐ *positive* ☐
3. *N. gonorrhoeae*		Not done/ Not collected ☐	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*negative* ☐ *positive* ☐
4. *C. trachomatis*		Not done/ Not collected ☐	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*negative* ☐ *positive* ☐
5. Pre-coital pH:		Not done ☐	☐.☐	
6. Post-coital pH:		Not done ☐	☐.☐	

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

Comments: _____

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Staff Initials / Date

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:	• 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.

Visit Code ☐☐.☐ 1

MTN-011 (135) PK-1 (061)

Participant ID ☐☐☐ ☐☐☐☐-☐-0
Protocol PTID Chk Cohort

Pharmacokinetics

Specimen Collection Date ☐☐ ☐☐☐ ☐☐
dd MMM yy

Not done/ Not collected

☐ 1. Participant height ☐☐☐ *cm*

☐ 2. Participant weight ☐☐☐ *kg*

SPECIMEN COLLECTION TIMES

Not done/ Not collected

hr *min*

☐ 3. Cervicovaginal lavage ☐☐ : ☐☐ *24-hour clock*

stored *not stored* *Reason not stored:*

Go to item 4.

3a. Supernatant ☐ ☐ → _____

3b. Cell pellet ☐ ☐ → _____

☐ 4. Vaginal tissue biopsy ☐☐ : ☐☐ *24-hour clock*

☐ 5. Cervical tissue biopsy ☐☐ : ☐☐ *24-hour clock*

☐ 6. Cervical cytobrush ☐☐ : ☐☐ *24-hour clock*

☐ 7. Blood draw ☐☐ : ☐☐ *24-hour clock*

☐ 8. Rectal sponge ☐☐ : ☐☐ *24-hour clock*

NO LONGER RECORDED ON THIS CRF. ☐☐☐.☐☐ *weight (grams)*

NO LONGER RECORDED ON THIS CRF. ☐☐☐.☐☐ *weight (grams)*

NO LONGER RECORDED ON THIS CRF. ☐☐☐.☐☐ *weight (grams)*

BIOPSY WEIGHTS

PRE-COLLECTION *Note: Weight includes empty cryovial and screw lid*

Not done/ Not collected

NO LONGER RECORDED ON THIS CRF.

☐ 9. Vaginal biopsy for PK: Pre-collection ☐☐☐☐.☐ *weight (mg)*

☐ 10. Cervical biopsy for PK: Pre-collection ☐☐☐☐.☐ *weight (mg)*

POST-COLLECTION *Note: Weight includes cryovial, tissue biopsy, and screw lid*

Not done/ Not collected

NO LONGER RECORDED ON THIS CRF.

☐ 11. Vaginal biopsy for PK: Post-collection ☐☐☐☐.☐ *weight (mg)*

☐ 12. Cervical biopsy for PK: Post-collection ☐☐☐☐.☐ *weight (mg)*

Comments: _____

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English

Staff Initials / Date

Pharmacokinetics (PK-1)	
Purpose:	This form is used to document pharmacokinetics, stored specimen collection, as well as pre- and post-collection weights of vaginal tissue (biopsy) pharmacokinetic (PK) specimens for female participants.
	• Visit Code: Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes. • 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. • 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.
Items 3a and 3b:	• These items must be completed after the lab has processed the primary specimen. If these specimens are not stored, mark the "not stored" box and record the reason why on the line provided.
Items 3–8:	• When recording time, use a 24-hour clock (e.g., 8:12pm is recorded as 20:12.

Visit Code ☐☐.☐ 1

MTN-011 (135) SPA-1 (415)

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: _____

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0 1 English

Staff Initials / Date

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.

Visit Code ☐☐.☐ 1

MTN-011 (135) PDC-1 (260)

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 0

Protocol PTID Chk Cohort

Group 2—Participant-reported Dosing

Form Completion Date ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

HOME DOSING (*Any dosing given during clinic visit captured on the Visit Summary form.)*

Study Gel Not Inserted	Dose #	Dosing Date	Dosing Time *(24-hour clock)*	Was this dosing time provided from the source document?
☐	Dose # 2	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐
☐	Dose # 3	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐
☐	Dose # 4	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐
☐	Dose # 5	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐
☐	Dose # 6	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐
☐	Dose # 7	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐

Comments: _____

Group 2—Participant-reported Dosing (PDC-1)	
Purpose:	This form is used to document home dosing dates and times for Group 2 participants.
General Information/ Instructions:	This form is completed for female participants in Group 2 only. Clinic staff will transcribe all relevant information from the participant's Home Dosing Log.
Item-specific Instructions:	
Dose # 2–7:	• Transcribe the date and time of each daily dosing recorded on the participant's Home Dosing Log form. The date must be transcribed using the SCHARP DataFax standard, dd MMM yy. The time must be transcribed using the 24-hour clock. • If the participant marked the "I did not insert study gel today" box on her log, mark the "Study Gel Not Inserted" box, and leave all other items for that specific day blank. • For each day that dosing information is recorded, mark "yes" if the time of dosing is provided on the source documentation (i.e., the Home Dosing Log form). If the source documentation is blank or not available, but the participant is able to report an estimated dosing date and time, record the estimated date and time, and mark the "no" box.
Dose #7:	• The "Study Gel Not Inserted" box should be marked for the first and second home dosing periods.
Comments:	• Any relevant information from the participant's log(s) may be transcribed here (e.g., partial doses). You may leave this space blank if there are no additional relevant comments.

Not a DataFax form. Do not fax to DataFax.

MTN-011 (135)

Participant ID

Protocol | PTID | Chk | Cohort (0)

Pelvic Exam Diagrams

Exam Date

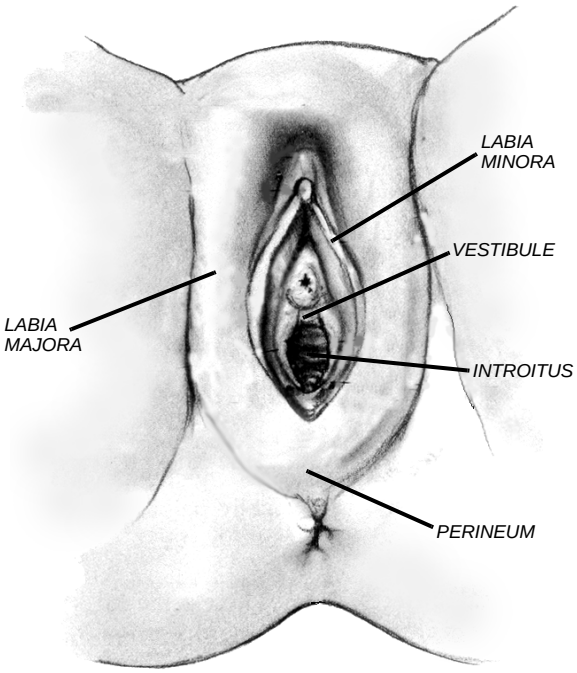
dd | MMM | yy

☐ no normal variants or abnormal findings observed

Speculum Type (screening only): Pederson ☐ Graves ☐ Cusco ☐

Speculum Size (screening only): small ☐ medium ☐ large ☐

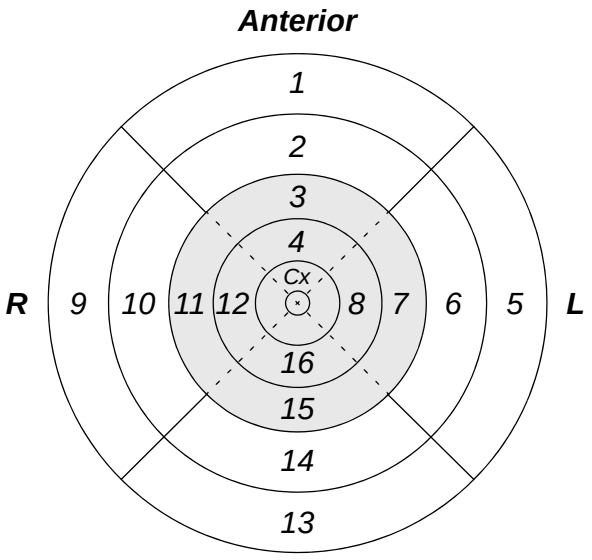
External Genitalia



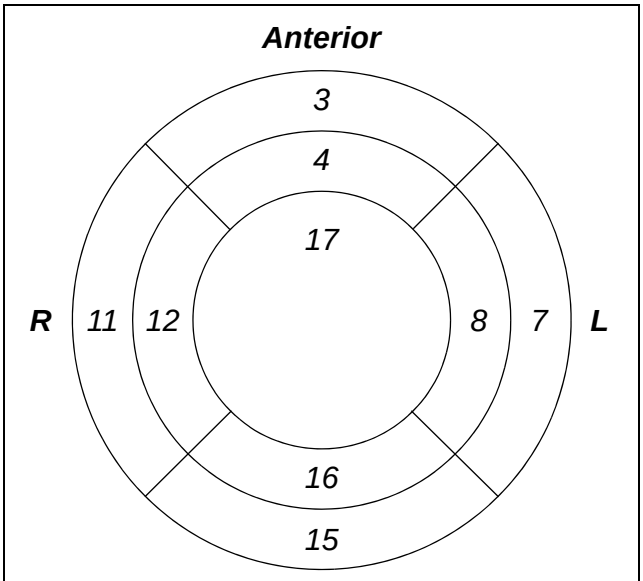
Legend for Vagina/Cervix

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



☐ ☐ ☐ ☒ 01-AUG-12

0 1 English

Staff Initials / Date

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 with each required pelvic exam, 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: • anatomic variants • gland openings • Nabothian cysts • mucus retention cysts • Gartner's duct cysts • blood vessel changes other than disruption • skin tags • scars 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).