

As Needed CRFs *(does not include interviewer-administered CRFs)*

- Abbreviated Physical Exam (APX-1)
- Adverse Experience Log (AE-1)
- Baseline Family Planning (BFP-1)
- Concomitant Medications Log (CM-1)
- Demographics (DEM-1)
- Eligibility Criteria (ECI-1)
- End of Study Inventory (ESI-1)
- Enrollment (ENR-1)
- Enrollment Abbreviated Physical Exam (EPX-1)
- Family Planning (FP-1)
- Follow-up ACASI Tracking (FAT-1)
- Grade 1 Adverse Experience Log (GAE-1)
- HIV Confirmatory Results (HCR-1)
- Missed Visit (MV-1)
- Monthly Laboratory Results (MLR-1)
- Participant Receipt (PRC-1)
- Participant Transfer (PT-1)
- Pelvic Exam (PE-1)
- Pelvic Exam Diagrams (non-DataFax)
- Pre-existing Conditions (PRE-1)
- Pregnancy Outcome (PO-1, -2)
- Pregnancy Report and History (PR-1)
- Prior Trial Participation (PTP-1)
- Product Hold/Discontinuation Log (PH-1)
- Protocol Deviations Log (PDL-1)
- PUEV Laboratory Results (PLR-1)
- Quarterly Laboratory Results (QLR-1)
- Ring Adherence (RA-1)
- Ring Collection/Insertion (RCI-1)
- Screening Laboratory Results (SLR-1)
- Screening Menstrual History (SMH-1)
- Screening Pelvic Exam (SPE-1)
- Screening Specimen Storage (SSS-1)
- Screening STI Test Results (SST-1)
- Screening Visit Physical Exam (SPX-1)
- Seroconverter Laboratory Results (SCR-1)
- Social Impact Log (SIL-1)
- Specimen Storage (SS-1)
- STI Test Results (STI-1)
- Termination (TM-1)
- Visit Summary (VS-1)
- Screening Visit LDMS Specimen Tracking Sheet
- Enrollment Visit LDMS Specimen Tracking Sheet
- Follow-up Visit LDMS Specimen Tracking Sheet

This page intentionally left blank.



MTN-020 ASPIRE (192)

APX-1 (136)

Visit Month .

1

Participant ID <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"/> <small style="display: flex; justify-content: space-around; width: 100%;"> Site Number Participant Number Chk </small>	Visit Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small style="display: flex; justify-content: space-around; width: 100%;"> dd MMM yy </small>
--	--

Abbreviated Physical Exam

VITAL SIGNS

1. Weight <input type="text"/> <input type="text"/> <input type="text"/> kg	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	

SYMPTOM-DIRECTED FINDINGS *Items 6 and 7 are required assessments. Other items assessed if clinically indicated.*

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

Record abnormal findings on the Adverse Experience Log or Grade 1 Adverse Experience Log, if applicable.

26-APR-12

N:\hivnet\forms\MTN_020\forms\m020_APX.fm

0 1

English

Staff Initials / Date

Abbreviated Physical Exam (APX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings at study follow-up visits as specified in the protocol.
General Information/ Instructions:	Complete this form at quarterly, semi-annual, the Product Use End Visit (PUEV), and at an early termination visit, as applicable.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed.
Items 6-7:	These items are required to be assessed at each quarterly, semi-annual, and the PUEV or early termination visit.
Items 8-17:	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 17:	If abnormal, specify the body system being referenced and describe the findings on the Notes line.



MTN-020 ASPIRE (192)

AE-1 (460)

Note: Number pages sequentially (001, 002, 003) for each participant.

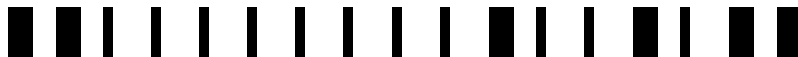
Page

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small>Site Number Participant Number Chk</small>	Date Reported to Site <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>dd MMM yy</small>
---	---

Adverse Experience Log	
1. Adverse Experience (AE) _____ <i>Record diagnosis, if available. Include anatomical location, if applicable.</i>	
2. Onset Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>dd MMM yy</small>	
3. Severity Grade <input type="checkbox"/> <i>Grade 1 (Mild)</i> <input type="checkbox"/> <i>Grade 2 (Moderate)</i> <input type="checkbox"/> <i>Grade 3 (Severe)</i> <input type="checkbox"/> <i>Grade 4 (Potentially life-threatening)</i> <input type="checkbox"/> <i>Grade 5 (Death)</i>	
4. Relationship to Study Product <input type="checkbox"/> <i>related</i> <input type="checkbox"/> <i>not related</i> <i>Record rationale:</i> _____	
5. Study Product Administration <input type="checkbox"/> <i>no change</i> <input type="checkbox"/> <i>held</i> <input type="checkbox"/> <i>permanently discontinued</i> <input type="checkbox"/> <i>N/A</i>	
6. Status/Outcome <input type="checkbox"/> continuing <input type="checkbox"/> resolved <input type="checkbox"/> death <input type="checkbox"/> severity/frequency increased (<i>Report as a new AE.</i>) <input type="checkbox"/> continuing at end of study participation	
6a. Status/Outcome Date (<i>Leave blank if Status/Outcome is "continuing."</i>) <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>dd MMM yy</small>	
7. Treatment <input type="checkbox"/> none <input type="checkbox"/> medication(s) <input type="checkbox"/> new/prolonged hospitalization <input type="checkbox"/> procedure/Surgery <input type="checkbox"/> other, specify: _____ <i>Mark "none" or all that apply. Report on Concomitant Medications Log. Comment: _____</i>	
8. Is this an SAE according to ICH guidelines? <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	
9. Has/will this AE be reported as an EAE? <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	
10. At which visit month was this AE first reported? <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <i>Visit month required (regular or interim)</i>	
11. Was this AE a worsening of a pre-existing condition? <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	

Comments: _____

Adverse Experience Log (AE-1)	
Purpose:	To document all MTN-020 Adverse Experiences (AEs) required to be reported on Log per protocol. This includes all genital, genitourinary, reproductive system, and laboratory AEs as well as all other Grade 2 or higher AEs, SAEs, and all AEs that result in clinical product hold or permanent product discontinuation.
General Information/Instructions:	Whenever possible, report a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate AE on separate AE/GAE Log pages as applicable. If a cluster of symptoms reported on separate AE/GAE Log page is later attributed to a single diagnosis, change the earliest reported symptom page to the diagnosis. In addition, mark the AE/GAE Log pages for the other symptoms with the words "Delete due to diagnosis on AE Log pages (insert page #s) and/or GAE Log pages (insert page #s)."
Item-specific Instructions:	
Page:	Number pages for this Log sequentially throughout the study for each PTID, starting with 001. Do not repeat page numbers on this log. If an AE Log page is marked for deletion, do not change the page number or re-assign that page number to another AE Log page.
Date Reported to Site:	Record the date the site became aware of the AE. For lab AEs, record the date the lab result was received.
Item 1:	Use medical terminology to describe the AE. Do not include text on the relationship to study product or timing of AE onset with regard to product use. For lab abnormalities, record the lab name with the direction (i.e., increased or decreased). For example, "increased ALT."
Item 2:	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE (onset of first symptom if diagnosis has multiple associated symptoms); date of the study visit/study exam (for physical or pelvic exam findings); specimen collection date (for lab abnormality AEs).
Item 3:	Record the severity grade using the current version of the <i>Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events</i> (including relevant appendices/addendums).
Item 4:	Mark "related" if there is a reasonable possibility that the AE may be related to the study agent. Mark "not related" if there is not a reasonable possibility that the AE is related to the study agent. In the space provided, record the clinical rationale (the reason) the AE is judged to be "related" or "not related." Complete the "Record rationale" field for each AE. This is a required field.
Item 5:	<ul style="list-style-type: none"> no change: Mark if there is no change in the participant's planned use of study product as a result of the AE. That is, the participant is still in the product use period and the AE does not result in a clinician initiated product hold or permanent discontinuation of study product. held: Mark if the AE results in a clinician initiated product hold. If multiple AEs are reported at the same visit, mark "held" for each AE contributing to the hold. A Product Hold/Discontinuation (PH) Log should be completed for each AE page with "held" marked. If an AE results in a hold, then a permanent discontinuation, update this item to "permanently discontinued" at the time of permanent discontinuation. permanently discontinued: Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, mark "permanently discontinued" for each AE contributing to the permanent discontinuation. For each AE page with this box marked, there should be a PH Log page with item 4 marked "no-permanently discontinued." N/A (not applicable): Mark if the AE's onset date (item 2) is on or after the participant's PUEV/early termination visit date. Also mark this box if the AE's onset date is on or after the date of permanent discontinuation.
Item 6:	<ul style="list-style-type: none"> continuing: AE is continuing at the time it is first reported. resolved: AE is no longer present or has returned to baseline severity/frequency. Note that if a participant started taking medication once enrolled to control an AE, the AE is not considered resolved while the medication is still indicated. death: Mark only if the severity of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation." severity/frequency increased: If an AE increases in severity or frequency after it has been first reported on this form, line through the "continuing" box and mark "severity/frequency increased." Record the date of increase as the "Status/Outcome Date." Report the increase in severity/frequency as a new AE on a new AE Log page. For this new AE, the "Onset Date" (item 2) will be the same as the "Status/Outcome Date" (item 6a) of the AE Log page used to first report the AE. Note that decreases in severity (AE improvements) are not recorded as new AEs. continuing at end of study participation: Mark this box whenever an AE is continuing at the time of participant termination.
Item 6a:	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports no longer experiencing the AE or associated symptoms; or the date of the study visit or specimen collection at which it is first noted the AE has resolved or returned to baseline status.
Item 7:	Mark "medication(s)" only if participant reports taking the medication. If medication indicated but not yet used, mark "other" and describe the medication indicated; mark "medication(s)" once the medication has been used.
Items 8 and 9:	For questions about ICH guidelines and EAE reporting, refer to the current <i>Manual for Expedited Reporting of Adverse Events</i> to DAIDS. If item 9 is "yes," be sure to make any subsequent updates made to this form on the applicable EAE form.
Item 10:	Record the Visit Month/visit code that corresponds to the "Date Reported to Site." For lab AEs, record the Visit Month that matches the "Onset Date." Note that the Visit Summary form with this visit month should have item 6 = "yes" or (for interim visits) the AE Log page marked in item 5b.



MTN-020 ASPIRE (192)

BFP-1 (075)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">Site Number Participant Number Chk</p>	Visit Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">dd MMM yy</p>
--	---

Baseline Family Planning

1. What method(s) of contraception/family planning is the participant currently using? *Mark "none" or all that apply.*

1a. none

1b. spermicide

1c. diaphragm

1d. sponge

1e. intrauterine device (IUD) → Date regimen started

1f. oral contraceptives/birth control pills → Date regimen started

1g. injectable contraceptives (such as Depo-Provera) → Date regimen started

1g1. Type: Depo Depo subq NET-EN Cyclofem other

1h. (Ortho Evra) The Patch → Date regimen started

1i. implants → Date regimen started

1j. female condoms

1k. natural methods such as the withdrawal or rhythm method

1l. male condoms

1m. sterilization (tubal ligation/hysterectomy/laparoscopy/other surgical procedure that causes sterilization)

1n. sex with partner who had a vasectomy

1o. other, specify: _____

Record on Concomitant Medications Log.

2. First day of last menstrual period OR *amenorrheic for past 6 months* → *If amenorrheic, go to item 4.*

dd MMM yy

3. Last day of last menstrual period OR *ongoing*

dd MMM yy

4. How many times has the participant been pregnant? → *If 00, end of form.*

4a. How many live births has the participant had?

Comments: _____

Baseline Family Planning (BFP-1)	
Purpose:	This form is used to document the methods of contraception/family planning used by the participant at baseline.
General Information/ Instructions:	Complete this form only at the Enrollment Visit. Only fax this form to SCHARP DataFax if the participant enrolls in the study.
Item-specific Instructions:	
Item 1:	Mark the method(s) of contraception/family planning the participant reports currently using.
Item 1e-1i:	<p>If marked, record the date the participant started using the current contraceptive regimen under "Date Regimen Started." For injectables and implants, do not record the date of the most recent injection or implant—this will be captured on the Concomitant Medications Log. Rather, record here the date the participant started using that particular contraceptive method.</p> <p>If the day portion of the date cannot be obtained, line through the "dd" boxes write "UNK" in the white space. At a minimum, a month and year are required.</p> <p>For example:</p> <ul style="list-style-type: none"> For item 1f, for a participant on oral contraceptives starting on 13-MAR-11, record this as the date regimen started (even if she has missed pills or an occasional pill pack during that time). Do not record the start date of her most recent/current pill pack. For item 1g, a participant who has regularly been getting Petogen/Depo Provera injections every 3 months starting on 01-OCT-10, record "01-OCT-10" for date regimen started. Use this as the start date even if the participant missed an occasional injection. Do not record the date of her last injection as date regimen started. For item 1i, for a participant with implants inserted most recently 3 months ago, and has had implants inserted starting 3 years prior (January 2009), record "JAN-09" as the date regimen started, lining through the "dd" boxes and writing "UNK" in the white space.
Item 1g1.:	<p>Mark the specific type of injectable contraception used by the participant.</p> <ul style="list-style-type: none"> Depo for Depo Provera (DMPA, also known as Petogen) injected into the muscle. Depo subq: mark when the sub-cutaneous route of Depo is used. NET-EN: also known as Mesigyna. Cyclofem: also known as Lunelle.
Item 2:	The first day of the last menstrual period is the first day of bleeding.
Item 3:	The last day of the last menstrual period is the last day of bleeding.
Item 4:	Use leading zeros when needed.



MTN-020 ASPIRE (192)

CM-1 (423)

Note: Number pages sequentially (001, 002, 003) for each participant.

Page

Participant ID - -

Site Number Participant Number Chk

No medications taken at Screening/Enrollment. Staff Initials/Date: _____

No medications taken throughout study. Staff Initials/Date: _____

▶ End of form. Fax to SCHARP DataFax.

1. Concomitant Medications Log		Staff Initials/Log Entry Date
Trade Name		
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no
Date Started <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>	Date Stopped <input type="text"/> <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"/> Continuing at end of study <i>dd MMM yy</i>	AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Frequency <i>Mark only one.</i> <i>prn</i> <i>qd</i> <i>tid</i> <i>qhs</i> <i>once</i> <i>bid</i> <i>qid</i> <i>other, specify:</i> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____		
Dose/Units	Route <i>Mark only one.</i> <i>PO</i> <i>IM</i> <i>IV</i> <i>TOP</i> <i>IHL</i> <i>VAG</i> <i>REC</i> <i>SC</i> <i>other, specify:</i> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____	
If contraceptive, was it dispensed at research center? <input type="checkbox"/> yes <input type="checkbox"/> no		

2. Trade Name		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no
Date Started <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>	Date Stopped <input type="text"/> <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"/> Continuing at end of study <i>dd MMM yy</i>	AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Frequency <i>Mark only one.</i> <i>prn</i> <i>qd</i> <i>tid</i> <i>qhs</i> <i>once</i> <i>bid</i> <i>qid</i> <i>other, specify:</i> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____		
Dose/Units	Route <i>Mark only one.</i> <i>PO</i> <i>IM</i> <i>IV</i> <i>TOP</i> <i>IHL</i> <i>VAG</i> <i>REC</i> <i>SC</i> <i>other, specify:</i> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____	
If contraceptive, was it dispensed at research center? <input type="checkbox"/> yes <input type="checkbox"/> no		

Concomitant Medications Log (CM-1)	
Purpose:	This form is used to document all medications taken by the participant starting at the Screening Visit. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, contraceptive medications, intrauterine contraceptive devices, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.
General Information/ Instructions:	When to fax this form: <ul style="list-style-type: none"> once the participant has enrolled in the study; when pages have been updated or additional Log pages have been completed (only fax updated or new pages); when the participant has completed study participation; and/or when instructed by SCHARP.
Item-specific Instructions:	
Page:	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.
No medications taken at Screening/ Enrollment:	Mark this box if no medications were taken by the participant from Screening through the Enrollment Visit. This box should only be marked on Page 01.
No medications taken throughout study:	Mark this box at the Termination/Study Exit Visit if no medications were taken by the participant throughout the entire study.
Trade Name:	Record the trade name of the medication (not the generic name) whenever possible.
Indication:	For health supplements, such as multivitamins, record "general health." For preventive medications, record "prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza"). For recreational drugs, record "recreation."
Start Date:	If the participant is unable to recall the exact date of medication initiation, obtain participant's best estimate. At a minimum, the year is required. For injections, record each injection as a separate entry, with the same date used for start and stop date. For oral contraceptives, record the start date (and stop date) for each pill pack.
Stop Date:	At the participant's Termination/Study Exit Visit, the "Date Stopped" must be recorded for each medication OR the "Continuing at end of study" box must be marked. At a minimum, the month and year are required.
Frequency:	Below is a list of common frequency abbreviations: prn: as needed qd: every day tid: three times daily qhs: at bedtime once: one time bid: twice daily qid: four times daily other, specify: alternative dosing schedules
Dose/Units:	If the participant does not know the exact dose or units (for example, "250 mg"), you may record an estimate (such as "1 tablet"). If no information on dose or units is known, draw a single line through the blank response box and initial and date. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).
Route:	Below is a list of common route abbreviations: PO: oral IV: intravenous IHL: inhaled REC: rectal other, specify: alternative routes IM: intramuscular TOP: topical VAG: vaginal SC: subcutaneous
If contraceptive, was it dispensed at research center?	Mark the "yes" box if the medication is a contraceptive and it was dispensed by the study site pharmacy. If a supplier of contraceptive changes, record a new entry rather than updating this item. For example, if at the Screening Visit the participant is taking contraceptive pills dispensed by a local health clinic, then starts receiving oral contraceptives dispensed by the site pharmacy at Month 3, record a new entry for the pills at Month 3 with this item marked "yes" (keep the original "no" response for the pills entry made at the Screening Visit, and add a stop date to this entry as needed).



MTN-020 ASPIRE (192)

DEM-1 (001)

Participant ID <input style="width: 30px; height: 20px;" type="text"/> - <input style="width: 30px; height: 20px;" type="text"/> - <input style="width: 30px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> Site Number Participant Number Chk </small>	Visit Date <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy </small>
--	---

Demographics				
1. Date of birth	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	<input style="width: 30px; height: 20px;" type="text"/>	→ <i>If unknown, record age:</i> <input style="width: 30px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy years </small>
2. Is the participant currently married?	<input type="checkbox"/> <i>yes</i>	<input type="checkbox"/> <i>no</i>		
3. Highest level of education	<input type="checkbox"/> no schooling	<input type="checkbox"/> primary school, not complete	<input type="checkbox"/> secondary school, not complete	<input type="checkbox"/> secondary school, complete
	<input type="checkbox"/> primary school, complete	<input type="checkbox"/> attended college or university		
4. Ethnic group or tribe	<input style="width: 30px; height: 20px;" type="text"/>	<i>ethnic tribe code</i> <i>If other, specify:</i> _____		
5. Number of alcohol drinks per week	<input style="width: 30px; height: 20px;" type="text"/>	<i># of drinks</i>	OR	<input type="checkbox"/> <i>none</i>
6. Number of cigarettes per day	<input style="width: 30px; height: 20px;" type="text"/>	<i># of cigarettes</i>	OR	<input type="checkbox"/> <i>none</i>
7. Does the participant own a mobile phone?	<input type="checkbox"/> <i>yes</i>	<input type="checkbox"/> <i>no</i>	→ <i>If no, go to item 8.</i>	
7a. Does she have her phone with her?	<input type="checkbox"/> <i>yes - phone present</i>	<input type="checkbox"/> <i>no - phone not present</i>		
8. How long did it take the participant to travel from home to the clinic today?	<input type="checkbox"/> <i>less than 30 minutes</i>	<input type="checkbox"/> <i>30-60 minutes</i>	<input type="checkbox"/> <i>1-2 hours</i>	<input type="checkbox"/> <i>greater than 2 hours</i>
9. Does the participant earn an income of her own?	<input type="checkbox"/> <i>yes</i>	<input type="checkbox"/> <i>no</i>	→ <i>If no, end of form.</i>	
9a. How does she earn her income?	<input type="checkbox"/> <i>formal employment</i>	<input type="checkbox"/> <i>self-employment</i>	<input type="checkbox"/> <i>other</i>	

Comments: _____

Demographics (DEM-1)																																												
Purpose: This form is used to collect participants' demographic and socioeconomic information.																																												
General Information/ Instructions: This form is faxed to SCHARP DataFax only if the participant enrolls in the study. This form is completed at the Screening Visit.																																												
Item-specific Instructions:																																												
Item 1: If any portion of the date of birth is unknown, record age at time of Screening. If age is unknown, record the participant's best estimate of her age. Do not complete both answers.																																												
Item 3: If the participant attended or completed a post-secondary diploma or certificate program, mark the "attended college or university" box.																																												
<p>Item 4: This item asks about ethnic group or tribe. Record the 2-digit country-specific code below that is associated with the participant's ethnic group or tribe. If the participant identifies as "other," record, "99" and the participant's response.</p> <table border="1" data-bbox="263 779 1428 1249"> <thead> <tr> <th>MALAWI</th> <th>SOUTH AFRICA</th> <th>UGANDA</th> <th>ZAMBIA</th> <th>ZIMBABWE</th> </tr> </thead> <tbody> <tr> <td>01 - Chewa</td> <td>07 - Zulu</td> <td>11 - Black</td> <td>12 - Bemba</td> <td>16 - Shona</td> </tr> <tr> <td>02 - Lomwe</td> <td>08 - Xhosa</td> <td>06 - White</td> <td>13 - Chewa</td> <td>17 - Ndebele</td> </tr> <tr> <td>03 - Yao</td> <td>09 - Indian</td> <td>99 - Other</td> <td>14 - Tonga</td> <td>05 - Other African tribe</td> </tr> <tr> <td>04 - Tumbuka</td> <td>10 - Colored</td> <td></td> <td>15 - Lozi</td> <td>06 - White</td> </tr> <tr> <td>05 - Other African tribe</td> <td>05 - Other African tribe</td> <td></td> <td>05 - Other African tribe</td> <td>99 - Other</td> </tr> <tr> <td>06 - White</td> <td>06 - White</td> <td></td> <td>06 - White</td> <td></td> </tr> <tr> <td>99 - Other</td> <td>99 - Other</td> <td></td> <td>99 - Other</td> <td></td> </tr> </tbody> </table>					MALAWI	SOUTH AFRICA	UGANDA	ZAMBIA	ZIMBABWE	01 - Chewa	07 - Zulu	11 - Black	12 - Bemba	16 - Shona	02 - Lomwe	08 - Xhosa	06 - White	13 - Chewa	17 - Ndebele	03 - Yao	09 - Indian	99 - Other	14 - Tonga	05 - Other African tribe	04 - Tumbuka	10 - Colored		15 - Lozi	06 - White	05 - Other African tribe	05 - Other African tribe		05 - Other African tribe	99 - Other	06 - White	06 - White		06 - White		99 - Other	99 - Other		99 - Other	
MALAWI	SOUTH AFRICA	UGANDA	ZAMBIA	ZIMBABWE																																								
01 - Chewa	07 - Zulu	11 - Black	12 - Bemba	16 - Shona																																								
02 - Lomwe	08 - Xhosa	06 - White	13 - Chewa	17 - Ndebele																																								
03 - Yao	09 - Indian	99 - Other	14 - Tonga	05 - Other African tribe																																								
04 - Tumbuka	10 - Colored		15 - Lozi	06 - White																																								
05 - Other African tribe	05 - Other African tribe		05 - Other African tribe	99 - Other																																								
06 - White	06 - White		06 - White																																									
99 - Other	99 - Other		99 - Other																																									
Item 5: Record the number of alcohol drinks the participant reports drinking, on average, per week. Mark the "none" box if the participant does not drink alcohol or has less than one drink per week.																																												
Item 6: Record the number of cigarettes the participant reports smoking, on average, per day. Mark the "none" box if the participant does not smoke cigarettes or smokes less than one cigarette per day.																																												
Item 7a: Mark the "yes" box if the phone is seen by the interviewer.																																												
Item 8: If the participant did not travel from home for this visit, ask her to estimate the travel time it will take her to get to the clinic.																																												



MTN-020 ASPIRE (192)

ECI-1 (023)

Participant ID <input style="width: 30px; height: 20px;" type="text"/> - <input style="width: 60px; height: 20px;" type="text"/> - <input style="width: 30px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; width: 100%;"> Site Number Participant Number Chk </small>	Form Completion Date <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; width: 100%;"> dd MMM yy </small>
---	--

Eligibility Criteria	
1. Does this participant meet all eligibility criteria?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i> → <i>If no, go to item 2</i>
1a. Obtain signature _____ <i>Signature of Principal Investigator (or designee)</i> <i>Date</i>	
1b. Obtain signature _____ <i>Signature of second staff member verifying eligibility</i> <i>Date</i>	
2. Was the participant enrolled?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i> → <i>If yes, end of form.</i>
3. Why was the participant not enrolled? <input type="checkbox"/> participant did not complete all screening procedures → <i>End of form.</i> <input type="checkbox"/> eligible but declined enrollment → <i>End of form.</i> <input type="checkbox"/> not eligible	
4. Reason(s) for ineligibility <i>Mark all that apply.</i>	
<input type="checkbox"/> 4a. participant < 18 or > 45 years old	<input type="checkbox"/> 4h. PEP exposure in the last 6 months
<input type="checkbox"/> 4b. plans for relocation/travel	<input type="checkbox"/> 4i. participant is HIV-positive
<input type="checkbox"/> 4c. participant is pregnant or planning to become pregnant	<input type="checkbox"/> 4j. participant declines effective method of contraception
<input type="checkbox"/> 4d. participant is breastfeeding	<input type="checkbox"/> 4k. participant has a grade 2 or higher pelvic exam finding
<input type="checkbox"/> 4e. participant has not had vaginal sex in the last 3 months	<input type="checkbox"/> 4l. participant does not meet laboratory eligibility criteria
<input type="checkbox"/> 4f. participant has enrolled in another research study in the last 60 days	<input type="checkbox"/> 4m. participant does not meet other clinical eligibility criteria
<input type="checkbox"/> 4g. participant has participated in VOICE or other HIV prevention trial in the past 12 months	<input type="checkbox"/> 4n. other reason, including investigator decision. Specify: _____

Comments: _____

Eligibility Criteria (ECI-1)	
Purpose:	This form is used to document participant eligibility for enrollment in this study or reasons for participant ineligibility.
General Information/ Instructions:	<p>Complete this form for each participant screened for this study. Complete and fax this form once it is determined whether the participant will enroll in the study. If not enrolled, this is the only form that is faxed for the participant.</p> <p>If the participant has a second screening attempt, update this form with data from the second screening attempt and refax. Do not complete a new form for the second attempt.</p>
Item-specific Instructions:	
Items 1a and 1b:	Local site Standard Operating Procedures (SOPs) must specify staff members designated to affirm eligibility.
Item 3:	Mark "participant did not complete all screening procedures" when a participant begins the screening process and is eligible, but does not return to the clinic to complete screening procedures within the 28-day screening window.
Item 4:	Mark all reasons for participant ineligibility. Refer to the Eligibility Checklist for the Screening and Enrollment Visit. If the reason for ineligibility is not listed, mark the "other reason, including investigator decision" box and specify ineligibility reason on the line provided.



MTN-020 ASPIRE (192)

ESI-1 (489)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">Site Number Participant Number Chk</p>	Form Completion Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">dd MMM yy</p>
--	---

End of Study Inventory	
1. Did the participant complete her scheduled study exit (4-week post-product use) visit?	yes <input type="checkbox"/> no <input type="checkbox"/>
2. What is the highest visit month (scheduled or interim) for this participant, recorded on a form submitted via DataFax?	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <i>visit month</i>
3. How many interim visits were conducted for this participant during the study and recorded on a form submitted via DataFax?	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i># of interim visits</i>
4. Indicate the highest page number submitted for this participant for each of the following forms:	
4a. Adverse Experience Log (AE)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i> OR <input type="checkbox"/> <i>no pages submitted</i>
4b. Concomitant Medications Log (CM)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i>
4c. Pre-existing Conditions (PRE)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i>
4d. Product Hold/Discontinuation Log (PH)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i> OR <input type="checkbox"/> <i>no pages submitted</i>
4e. Social Impact Log (SIL)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i> OR <input type="checkbox"/> <i>no pages submitted</i>
4f. Protocol Deviations Log (PDL)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i> OR <input type="checkbox"/> <i>no pages submitted</i>
4g. Grade 1 Adverse Experience Log (GAE) <i>Record highest page number completed.</i>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>page #</i> OR <input type="checkbox"/> <i>no pages completed</i>

Comments: _____

End of Study Inventory (ESI-1)	
Purpose:	This form is used to confirm that SCHARP has received all study data for a given participant.
General Information/ Instructions:	Complete this form once for each enrolled participant after the participant has terminated from the study (as documented by a Termination form).
Item-specific Instructions:	
Form Completion Date:	A complete date is required.
Item 2:	Record the highest visit month (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit month of the missed visit.
Item 3:	Record the total number of interim visits documented on the Visit Summary DataFax forms submitted for this participant. If no interim visits were completed for the participant, record "000" in the boxes.
Item 4a, 4d, and 4e:	Record the highest page number of the Adverse Experience Log, Product Hold/Discontinuation Log, Protocol Deviations Log, and Social Impact Log submitted for this participant, even if that page was marked for deletion.
Item 4g:	Record the highest page number completed for the Grade 1 Adverse Experience Log. Complete this item even though these forms are not faxed to SCHARP.



MTN-020 ASPIRE (192)

ENR-1 (070)

<p>Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/></p> <p style="text-align: center; font-size: small;">Site Number Participant Number Chk</p>	
--	--

Enrollment	
1. Date the participant marked or signed the study screening consent form	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <i>dd MMM yy</i>
2. Date the participant marked or signed the study enrollment consent form	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <i>dd MMM yy</i>
3. Did the participant agree to biological specimen and health data storage?	<i>yes no pending</i> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4. HIV status	<i>negative positive</i> <input type="checkbox"/> <input type="checkbox"/>
5. Pregnancy status	<i>negative positive</i> <input type="checkbox"/> <input type="checkbox"/>
6. Randomization number assigned	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <i>randomization number</i>
7. Date prescription assigned	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <i>dd MMM yy</i>
8. Time prescription assigned	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> : <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <i>24-hour clock</i> <i>hr min</i>
9. Was the Baseline ACASI questionnaire completed?	<i>yes no</i> <input type="checkbox"/> <input type="checkbox"/>
10. Was plasma for archive collected?	<i>yes no</i> <input type="checkbox"/> <input type="checkbox"/>
11. Was self-collected vaginal fluid swab collected?	<i>yes no</i> <input type="checkbox"/> <input type="checkbox"/>
12. Was vaginal ring inserted?	<i>yes no</i> <input type="checkbox"/> <input type="checkbox"/>

Comments: _____

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 participants randomized.
General Information/ Instructions:	Fax this form to SCHARP DataFax only if the participant is enrolled (that is, she is assigned a randomization number).
Item-specific Instructions:	
Item 3:	Consent for left-over specimen and health data storage 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 4:	Record the participant's HIV status as determined by testing performed on the day of enrollment. If "positive," do not randomize/enroll the participant.
Item 5:	Record the participant's pregnancy status based on testing done on the day of enrollment. If "positive," do not randomize/enroll the participant.
Item 7:	This item must match the "date assigned" recorded for this prescription on the MTN-020 Prescription Tracking Record.
Item 8:	This item must match the "time assigned" recorded for this prescription on the MTN-020 Prescription Tracking Record.
Items 9-12:	Mark the "no" box if the procedure was not completed on the day of enrollment/randomization (date in item 7). Add the reason the item was not completed on the Comments lines. If any procedures are not completed, bring the participant back to the clinic for procedure completion as soon as possible.



MTN-020 ASPIRE (192)

EPX-1 (080)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">Site Number Participant Number Chk</p>	Visit Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">dd MMM yy</p>
--	---

Enrollment Abbreviated Physical Exam

VITAL SIGNS

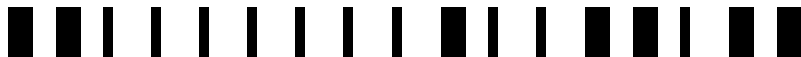
1. Weight <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> kg	4. Pulse <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> beats per minute
2. Body Temp <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> °C	5. Respirations <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> breaths per minute
3. BP <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> mmHg	

SYMPTOM-DIRECTED FINDINGS *Items 6 and 7 are required assessments. Other items assessed if clinically indicated.*

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

Record abnormal findings on Pre-existing Conditions form as applicable.

Enrollment Abbreviated Physical Exam (EPX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings at the Enrollment Visit. Only fax this form to SCHARP DataFax if the participant enrolls in the study.
General Information/ Instructions:	If abnormal findings are identified, transcribe information onto the Pre-existing Conditions form, as applicable.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed.
Items 6-7:	These items are required to be assessed at the Enrollment Visit.
Items 8-17:	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 17:	If abnormal, specify the body system being referenced and describe the findings on the Notes line.



MTN-020 ASPIRE (192)

FP-1 (155)

Visit Month .

1

Participant ID - -

Site Number Participant Number Chk

Visit Date

dd MMM yy

Family Planning

1. What method(s) of contraception/family planning has the participant used since her last visit? *Mark "none" or all that apply.*

1a. none

1b. spermicide

1c. diaphragm

1d. sponge

1e. intrauterine device (IUD)

1f. oral contraceptives/birth control pills

1g. injectable contraceptives (such as Depo-Provera)

1g1. Type: *Depo* *Depo subq* *NET-EN* *Cyclofem* *other*

1h. (Ortho Evra) The Patch

1i. implants

1j. female condoms

1k. natural methods such as the withdrawal or rhythm method

1l. male condoms

1m. sterilization (tubal ligation/hysterectomy/laparoscopy/other surgical procedure that causes sterilization)

1n. sex with partner who had a vasectomy

1o. other, specify: _____

↓

*Update
Concomitant
Medications
Log, as
needed.*

2. Has the participant had or started her menstrual period since her last visit? *yes* *no*

 → *If no, end of form.*

2a. First day of last menstrual period

dd MMM yy

2b. Last day of last menstrual period OR *ongoing*

dd MMM yy

Comments: _____

Family Planning (FP-1)	
Purpose:	This form is used to document the methods of contraception/family planning used by the participant during study follow-up. It is completed at each monthly, quarterly, and semi-annual follow-up visits, as well as at the Product Use End Visit (PUEV), and at an early termination visit, as applicable.
Item-specific Instructions:	
Item 1:	Mark any method(s) of contraception/family planning the participant reports using since her last monthly study visit. If any response boxes for items 1e–1i are marked, update the Concomitant Medications (CM) Log as needed.
Item 1g1.:	Mark the specific type of injectable contraception used by the participant. <ul style="list-style-type: none"> • Depo for Depo Provera (DMPA, also known as Petogen) injected into the muscle. • Depo subq: mark when the sub-cutaneous route of Depo is used. • NET-EN: also known as Mesigyna. • Cyclofem: also known as Lunelle.
Item 2a:	The first day of the last menstrual period is the first day of bleeding.
Item 2b:	The last day of the last menstrual period is the last day of bleeding.



MTN-020 ASPIRE (192)

FAT-1 (153)

Visit Month .

1

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> Site Number Participant Number Chk </small>	Visit Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy </small>
--	---

Follow-up ACASI Tracking

1. Was an ACASI questionnaire completed at this visit? yes no ➔ *If no, record reasons in Comments. End the form.*

1a. Which questionnaire was completed? Month 3 PUEV/Discontinuers ➔ *If Month 3, go to item 2.*

1b. Reason PUEV/Discontinuers ACASI questionnaire was completed: scheduled PUEV early termination permanent product discontinuation prior to PUEV/early termination

2. Were there any problems or issues related to the administration or completion of the questionnaire? yes no ➔ *If no, end of form.*

2a. Describe:

Comments: _____

Follow-up ACASI Tracking (FAT-1)	
Purpose:	This form is used to document participant completion of the Audio Computer-assisted Self Interview (ACASI) computerized questionnaires during follow-up.
General Information/ Instructions:	<p>Complete this form at the Month 3 Visit. Also complete this form at the participant's Product Use End Visit (PUEV) or early termination visit.</p> <p>Additionally, complete this form (and the PUEV/Discontinuers ACASI questionnaire) if participant is permanently discontinued from study product (as documented by a Product Hold/Discontinuation Log).</p>
Item-specific Instructions:	
Item 2a:	Use this space to describe when and why multiple ACASI questionnaires are completed for a participant at a visit. If there were any unusual details related to the ACASI questionnaire administration or completion, describe them here.

Grade 1 Adverse Experience Log (GAE-1)	
Purpose:	To document MTN-020 Grade 1 non-genital, non-laboratory Adverse Experiences (AEs). All genital, genitourinary, reproductive system, and laboratory value AEs, all other AEs grade 2 and higher, all SAEs, and any AE resulting in a clinical product hold or permanent product discontinuation are reported using the Adverse Experience (AE) Log.
General Information/Instructions:	<p>**THIS FORM IS NOT FAXED TO SCHARP DATAFAX**</p> <p>Because this form documents AEs not required to be in the study database, do not fax GAE Log pages to SCHARP DataFax. If the AEs documented on Grade 1 Adverse Experience (GAE) Log pages are needed in the study database, SCHARP will provide specific faxing instructions at that time.</p> <p>Whenever possible, report a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate AE on separate GAE/AE Log pages as applicable. If a cluster of symptoms reported on separate GAE/AE Log pages is later attributed to a single diagnosis, change the earliest reported symptom page to the diagnosis. In addition, mark the GAE/AE Log pages for the other symptoms with the words "Delete due to diagnosis on GAE Log pages (insert page #s) and/or AE Log pages (insert page #s)."</p>
Item-specific Instructions:	
Page:	Number pages for this Log sequentially throughout the study for each PTID, starting with 001. Do not repeat page numbers on this Log. If a GAE Log page is marked for deletion, do not change the page number or re-assign that page number to another GAE Log page.
Item 1:	Use medical terminology to describe the AE. Do not include text on the relationship to study product or timing of AE onset with regard to product use.
Item 2:	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE (onset of first symptom if diagnosis has multiple associated symptoms); date of the study visit/study exam (for physical or pelvic exam findings).
Item 3:	The severity grade item has been hard-coded as Grade 1. No action required for this item. If the AE is Grade 2 or higher, mark this form for delete and report using an AE Log page.
Item 4:	Mark "related" if there is a reasonable possibility that the AE may be related to the study agent. Mark "not related" if there is not a reasonable possibility that the AE is related to the study agent. In the space provided, record the clinical rationale (the reason) the AE is judged to be "related" or "not related." Complete the "Record rationale" field for each AE. This is a required field.
Item 5:	<ul style="list-style-type: none"> no change: Mark if there is no change in the participant's planned use of study product as a result of the AE. That is, the participant is still in the product use period and the AE does not result in a clinician initiated product hold or permanent discontinuation of study product. held: If the AE results in a clinical product hold, stop completion of this form and record the AE on an AE Log page. Mark this form for delete. permanently discontinued: If the AE results in permanent discontinuation of study product, stop completion of this form and record the AE on an AE Log page. Mark this form for delete. N/A (not applicable): Mark if the AE's onset date (item 2) is on or after the participant's PUEV/early termination visit date. Also mark this box if the AE's onset date is on or after the date of permanent product discontinuation.
Item 6:	<ul style="list-style-type: none"> continuing: AE is continuing at the time it is first reported. resolved: AE is no longer present or has returned to baseline severity/frequency. Note that if a participant started taking medication once enrolled to control an AE, the AE is not considered resolved while the medication is still indicated. severity/frequency increased: If an AE increases in severity or frequency after it has been first reported on this form, line through the "Continuing" box and mark "Severity/frequency increased." Record the date of increase as the "Status/Outcome Date." Report the increase in severity/frequency as a new AE on a new AE Log page. For this new AE, the "Onset Date" (item 2) will be the same as the "Status/Outcome Date" (item 6a) of the GAE Log page used to first report the AE. Note that decreases in severity (AE improvements) are not recorded as new AEs. continuing at end of study participation: Mark this box whenever an AE is continuing at the time of participant study termination.
Item 6a:	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports no longer experiencing the AE or associated symptoms; or the date of the study visit at which it is first noted the AE has resolved or returned to baseline status.
Item 7:	Mark "medication(s)" only if participant reports taking the medication. If medication indicated but not yet used, mark "other" and describe the medication indicated; mark "medication(s)" once the medication has been used.
Items 8 and 9:	These items are hard-coded as "no." If the AE meets criteria for SAE and/or EAE reporting, mark this form for "delete" and complete a new AE Log page for the AE.
Item 10:	Record the Visit Month/visit code that corresponds to the "Date Reported to Site."

HIV Confirmatory Results (HCR-1)	
Purpose:	This form is used to document results from local lab confirmatory HIV testing once a participant has a positive rapid HIV test result. This form also documents the HIV RNA viral load and CD4+ count obtained on the day the participant has a positive rapid HIV test.
General Information/ Instructions:	<p>Complete this form for each visit where the participant has at least one positive rapid HIV test. As a reminder, the MTN-020 Follow-up HIV Testing Algorithm is as follows:</p> <ul style="list-style-type: none"> • STEP 1: Perform two rapid HIV tests. If at least one result is positive, go to STEP 2. • STEP 2: Collect blood on same day as positive rapid HIV result and perform the following: <ul style="list-style-type: none"> • Western Blot testing and record results in items 1 and 2. • Viral load and CD4+ testing. Record results in items 3 and 4. • Store plasma. Document date stored plasma was collected on the Monthly Laboratory Results CRF (item 4a). <p>Fax this form to SCHARP DataFax as soon as any results are available, leaving all pending items blank. Do not wait for all results before faxing. Faxing this form with items blank will not generate a QC.</p>
Item-specific Instructions:	
	<ul style="list-style-type: none"> • Visit Month: The visit month recorded on this form should be the same visit month recorded on the Monthly Laboratory Results form documenting the positive HIV rapid test result. • Specimen Collection Date: Record the date the specimen was collected (NOT the date results were reported or recorded on the form). The Specimen Collection Date should be the same date as the collection date of the plasma for HIV seroconversion confirmation (Monthly Laboratory Results, item 4a).
Items 3 and 4:	If, based on the results for RNA/DNA testing, the Network Lab requests Western Blot testing to be repeated, complete a new Monthly Laboratory Results form (items 4 and 4a) to document the WB specimen collection. Also complete a new HIV Confirmatory Results form for the repeat WB results.
Item 3:	Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation, regardless of whether the result is more or less than the limit of detection for the assay.
Item 4a:	If automatically calculated, record the CD4+ percentage that was reported for the specimen in item "4." If the CD4+ percentage is not available (was not reported and would have to be manually calculated), mark the "not available" box.
Item 5:	Once a participant's HIV status has been determined, record the final HIV status. If the final HIV status is not clearly negative or clearly positive or once all results are available, mark the "pending" box. If the participant's final HIV status is determined to be positive (according to the protocol testing algorithm), update the Product Hold/Discontinuation Log to reflect permanent discontinuation of study product.



MTN-020 ASPIRE (192)

MV-1 (463)

Visit Month . 0

1

Participant ID	<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"/> - <input type="text"/>	Form Completion 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"/>
	Site Number Participant Number Chk		dd MMM yy

Missed Visit

1. Target Visit Date:

2. Reason visit was missed. *Mark only one.*

2a. unable to contact participant

2b. unable to schedule appointment(s) within allowable window

2c. participant refused visit

2d. participant incarcerated

2e. participant admitted to a health care facility

2f. participant withdrew from study → *Complete a Termination form.*

2g. participant deceased → *Complete a Termination form. Complete an Adverse Experience Log.*

2h. other, specify: _____

3. Steps taken to address the missed visit (corrective action plan): _____

Comments: _____

Missed Visit (MV-1)	
Purpose:	Complete this form whenever an enrolled participant misses a required visit according to the visit window outlined in the protocol or Study-specific Procedures (SSP) manual.
General Information/ Instructions:	If the QC Report indicates that a visit is overdue, confirm that the visit was missed before completing a Missed Visit form. Fax this form when it is determined that a visit has been missed and cannot be completed within the visit window. Record the Visit Month of the visit that was missed. Record the date that the form was completed. This will not necessarily be the target date of the missed visit. A complete date is required.
Item-specific Instructions:	
Item 1:	Record the target date of the visit. A complete date is required.
Item 2:	Record the reason the participant missed the visit.



Visit Month .

1

MTN-020 ASPIRE (192)

MLR-1 (140)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 40px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; width: 100%;"> Site Number Participant Number Chk </small>	Initial Specimen Collection Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; width: 100%;"> dd MMM yy </small>
---	--

Monthly Laboratory Results																	
1. hCG for pregnancy	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;">Not done/ Not collected</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;">Alternate Collection Date</td> <td style="text-align: center; width: 10%;">dd</td> <td style="text-align: center; width: 15%;">MMM</td> <td style="text-align: center; width: 10%;">yy</td> <td style="text-align: center; width: 10%;">negative</td> <td style="text-align: center; width: 10%;">positive</td> </tr> <tr> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table> <p style="text-align: right; font-size: small; margin-top: 5px;"><i>If newly positive, complete Product Hold/Discontinuation Log and Pregnancy Report.</i></p>	Not done/ Not collected	<input type="checkbox"/>	Alternate Collection Date	dd	MMM	yy	negative	positive		<input type="checkbox"/>		<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not done/ Not collected	<input type="checkbox"/>	Alternate Collection Date	dd	MMM	yy	negative	positive										
	<input type="checkbox"/>		<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>										
2. Rapid HIV test 1	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;">Not done/ Not collected</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;">Alternate Collection Date</td> <td style="text-align: center; width: 10%;">dd</td> <td style="text-align: center; width: 15%;">MMM</td> <td style="text-align: center; width: 10%;">yy</td> <td style="text-align: center; width: 10%;">negative</td> <td style="text-align: center; width: 10%;">positive</td> </tr> <tr> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Kit code</td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	Not done/ Not collected	<input type="checkbox"/>	Alternate Collection Date	dd	MMM	yy	negative	positive		<input type="checkbox"/>	Kit code	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not done/ Not collected	<input type="checkbox"/>	Alternate Collection Date	dd	MMM	yy	negative	positive										
	<input type="checkbox"/>	Kit code	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>										
3. Rapid HIV test 2	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;">Not done/ Not collected</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;">Alternate Collection Date</td> <td style="text-align: center; width: 10%;">dd</td> <td style="text-align: center; width: 15%;">MMM</td> <td style="text-align: center; width: 10%;">yy</td> <td style="text-align: center; width: 10%;">negative</td> <td style="text-align: center; width: 10%;">positive</td> </tr> <tr> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Kit code</td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table> <p style="text-align: center; font-size: small; margin-top: 5px;"><i>If positive to either, complete HIV Confirmatory Results and Product Hold/Discontinuation Log.</i></p>	Not done/ Not collected	<input type="checkbox"/>	Alternate Collection Date	dd	MMM	yy	negative	positive		<input type="checkbox"/>	Kit code	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not done/ Not collected	<input type="checkbox"/>	Alternate Collection Date	dd	MMM	yy	negative	positive										
	<input type="checkbox"/>	Kit code	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>										
4. Was plasma stored for HIV confirmatory testing?	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;">yes</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 10%;">no</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 10%;">not required</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> </tr> <tr> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table> <p style="text-align: right; font-size: small; margin-top: 5px;"><i>If no or not required, go to item 5.</i></p>	yes	<input type="checkbox"/>	no	<input type="checkbox"/>	not required	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>				
yes	<input type="checkbox"/>	no	<input type="checkbox"/>	not required	<input type="checkbox"/>												
	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>												
4a. Plasma for HIV confirmatory testing collection date	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 15%;">Alternate Collection Date</td> <td style="text-align: center; width: 10%;">dd</td> <td style="text-align: center; width: 15%;">MMM</td> <td style="text-align: center; width: 10%;">yy</td> </tr> <tr> <td></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> </tr> </table>	Alternate Collection Date	dd	MMM	yy		<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>								
Alternate Collection Date	dd	MMM	yy														
	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>														
5. Self-collected Vaginal fluid swab collection	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 15%;">Alternate Collection Date</td> <td style="text-align: center; width: 10%;">dd</td> <td style="text-align: center; width: 15%;">MMM</td> <td style="text-align: center; width: 10%;">yy</td> <td style="text-align: center; width: 10%;">not required</td> <td style="text-align: center; width: 10%;">stored</td> <td style="text-align: center; width: 10%;">not stored</td> <td style="text-align: center; width: 10%;">Reason:</td> </tr> <tr> <td></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">_____</td> </tr> </table>	Alternate Collection Date	dd	MMM	yy	not required	stored	not stored	Reason:		<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Alternate Collection Date	dd	MMM	yy	not required	stored	not stored	Reason:										
	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____										
5a. Was blood visible on the swab?	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;">yes</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 10%;">no</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> </tr> <tr> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table> <p style="text-align: right; font-size: small; margin-top: 5px;"><i>If not required or not stored, end of form.</i></p>	yes	<input type="checkbox"/>	no	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>								
yes	<input type="checkbox"/>	no	<input type="checkbox"/>														
	<input type="checkbox"/>		<input type="checkbox"/>														
5b. Was a used ring in place at the time of swab collection?	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20%;">yes</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;">no – ring removed prior to swab collection</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;">no – ring not in place at start of visit</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> <td style="text-align: center; width: 15%;">no – new ring inserted prior to swab collection</td> <td style="text-align: center; width: 10%;"><input type="checkbox"/></td> </tr> <tr> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	yes	<input type="checkbox"/>	no – ring removed prior to swab collection	<input type="checkbox"/>	no – ring not in place at start of visit	<input type="checkbox"/>	no – new ring inserted prior to swab collection	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
yes	<input type="checkbox"/>	no – ring removed prior to swab collection	<input type="checkbox"/>	no – ring not in place at start of visit	<input type="checkbox"/>	no – new ring inserted prior to swab collection	<input type="checkbox"/>										
	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>										

Comments: _____

Monthly Laboratory Results (MLR-1)

Purpose: This form is used to document the participant's pregnancy, HIV rapid test results, and self-collected vaginal swab collection at study follow-up visits as specified in the protocol.

General Information/ Instructions: Record test results on this form as they become available. Fax this form into SCHARP DataFax once results for **all** collected specimens are recorded on the form.

- **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 (e.g., swab) 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.
- **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 2 and 3: Record the assigned two-digit rapid test kit code. *Note: More test kit codes may be added to the list as the study proceeds.*

Kit Code	Rapid Test
01	Determine
02	OraQuick
03	Uni-Gold Recombigen
04	StatPak

If item 2 or item 3 is positive (meaning the participant had at least one positive rapid HIV test), complete a new HIV Confirmatory Results form and a Product Hold/Discontinuation (PH) Log.

Item 4: If plasma was required but not stored for HIV confirmatory testing, record the reason on the Comments line.

Item 4a: Record the date the plasma was collected for storage for confirmatory testing.

Item 5: Record whether the vaginal fluid swab required at each monthly/quarterly/semi-annual/Product Use End Visit (PUEV) was collected. If required but not collected or stored, record reason on the line provided.



MTN-020 ASPIRE (192)

PRC-1 (466)

Participant ID <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"/> <small>Site Number Participant Number Chk</small>	Form Completion Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small>
--	--

Participant Receipt	
<i>Note: Do not assign a new Participant ID. Record the Participant ID assigned by the original study site.</i>	
1. Name of receiving study site	_____
2. Name of transferring study site	_____
3. Date informed consent signed at receiving site	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small>
4. Did participant provide informed consent for specimen storage at receiving study site?	<small>yes</small> <input type="checkbox"/> <small>no</small> <input type="checkbox"/> → <i>If no, end of form.</i>
4a. Date informed consent for specimen storage was signed	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small>

Comments: _____

26-APR-12

N:\hivnet\forms\MTN_020\forms\m020_PRC.fm

English

Staff Initials / Date

Participant Receipt (PRC-1)	
Purpose:	Complete this form when a transferred participant has provided informed consent at the receiving study clinic/site.
General Information/ Instructions:	<p>The Participant Receipt form is completed by the receiving site (the site at which the participant will be continuing his or her study visits).</p> <p>For more information on Participant Transfer and Receipt, refer to the protocol, Study-specific Procedures (SSP) manual, and/or Manual of Operations (MOP).</p>
Item-specific Instructions:	
Participant ID:	Do not assign a new Participant ID. Record the Participant ID assigned by the original study site.
Item 3:	A complete date is required.
Item 4a:	A complete date is required.



MTN-020 ASPIRE (192)

PT-1 (465)

Participant ID <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"/> <small>Site Number Participant Number Chk</small>	Form Completion Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small>
--	--

Participant Transfer	
1. Name of transferring study site	_____
2. Name of receiving study site	_____
3. Visit Month of last completed contact with participant	<input type="text"/> <input type="text"/> . <input type="text"/>
4. Date participant records were sent to receiving study site	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small>

Comments: _____

26-APR-12

N:\hivnet\forms\MTN_020\forms\m020_PT.fm

English

Staff Initials / Date

Participant Transfer (PT-1)	
Purpose:	Complete this form when a participant is transferring to another study clinic/site.
General Information/ Instructions:	The Participant Transfer form is completed by the transferring site (the site that the participant is leaving). For more information on Participant Transfer and Receipt, refer to the protocol, Study-specific Procedures (SSP) manual, and/or Manual of Operations (MOP).
Item-specific Instructions:	
Item 4:	A complete date is required.

Pelvic Exam (PE-1)	
Purpose:	This form is used to document the participant's pelvic exam assessment during study follow-up.
General Information/Instructions:	Complete this form at each semi-annual visit, the Product Use End Visit (PUEV), at early termination visit (as applicable), and when a clinically indicated pelvic exam is performed during follow-up. Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to 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:	<p>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 observations of blood or bleeding).</p> <p>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.</p> <p>Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the <i>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)</i>. Refer to SSP manual section 10.6 for more information/guidance as needed.</p>

Not a DataFax form. Do not fax to DataFax.

MTN-020 ASPIRE (192)

Pelvic Exam Diagrams

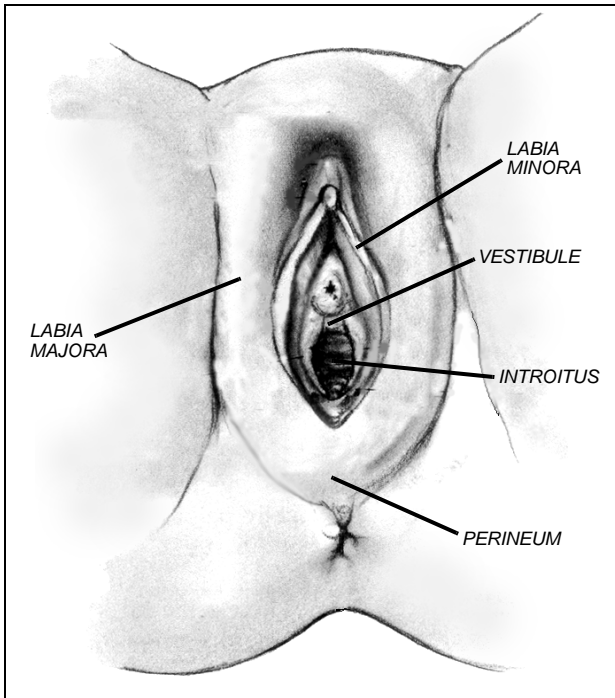
Page 1 of 1

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>	Exam Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
Site Number Participant Number Chk	dd MMM yy

no normal variants or abnormal findings observed

Speculum Type (screening only)			Speculum Size (screening only)		
<i>Pederson</i>	<i>Graves</i>	<i>Cusco</i>	<i>small</i>	<i>medium</i>	<i>large</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

External Genitalia

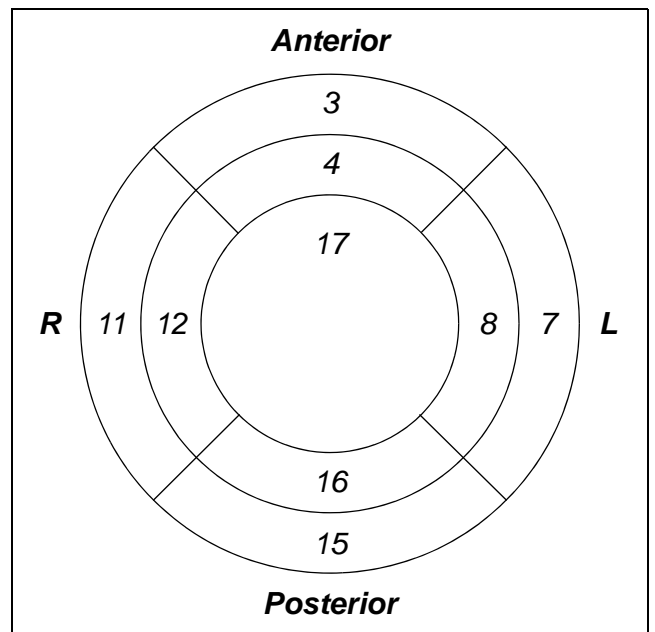
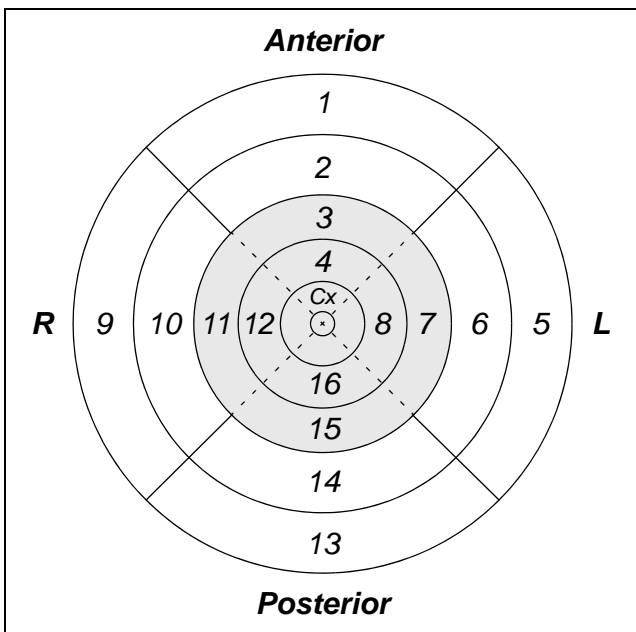


Legend for Vagina/Cervix

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



26-APR-12

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 at the Screening Visit, each semi-annual visit, at the Product Use End Visit (PUEV), 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:	<p>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:</p> <ul style="list-style-type: none"> • anatomic variants • gland openings • Nabothian cysts • mucus retention cysts • Gartner's duct cysts • blood vessel changes other than disruption • skin tags • scars <p>If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box.</p>
Documenting findings on the cervix:	If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).



MTN-020 ASPIRE (192)

PRE-1 (012)

Note: Number pages sequentially (01, 02, 03) for each participant.

Participant ID <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"/> - <input type="text"/> <small>Site Number Participant Number Chk</small>	<input type="checkbox"/> No pre-existing conditions reported or observed. Staff Initials/Date _____ ➔ End of form. Fax to SCHARP DataFax.
---	--

Pre-existing Conditions

1. Condition	Onset Date <i>MMM</i> <i>yy</i> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Staff Initials/Date
--------------	--	---------------------

Comments	Ongoing at Enrollment? <i>yes</i> <i>no</i> <input type="checkbox"/> <input type="checkbox"/>	Severity Grade <i>grade</i> <i>not gradable</i> <input type="checkbox"/> <input type="checkbox"/>
----------	---	---

2. Condition	Onset Date <i>MMM</i> <i>yy</i> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Staff Initials/Date
--------------	--	---------------------

Comments	Ongoing at Enrollment? <i>yes</i> <i>no</i> <input type="checkbox"/> <input type="checkbox"/>	Severity Grade <i>grade</i> <i>not gradable</i> <input type="checkbox"/> <input type="checkbox"/>
----------	---	---

3. Condition	Onset Date <i>MMM</i> <i>yy</i> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Staff Initials/Date
--------------	--	---------------------

Comments	Ongoing at Enrollment? <i>yes</i> <i>no</i> <input type="checkbox"/> <input type="checkbox"/>	Severity Grade <i>grade</i> <i>not gradable</i> <input type="checkbox"/> <input type="checkbox"/>
----------	---	---

4. Condition	Onset Date <i>MMM</i> <i>yy</i> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Staff Initials/Date
--------------	--	---------------------

Comments	Ongoing at Enrollment? <i>yes</i> <i>no</i> <input type="checkbox"/> <input type="checkbox"/>	Severity Grade <i>grade</i> <i>not gradable</i> <input type="checkbox"/> <input type="checkbox"/>
----------	---	---

Pre-existing Conditions (PRE-1)	
Purpose:	The Pre-existing Conditions form serves as the "starting point" or baseline from which study clinicians must determine whether conditions identified during follow-up are adverse events (AEs).
General Information/ Instructions:	<ul style="list-style-type: none"> At the Screening Visit, record relevant baseline medical history. This includes conditions and symptoms reported by the participant during the baseline medical/menstrual history as well as any conditions identified via pelvic exam, physical exam, or laboratory testing. This includes, but is not limited to, history of hospitalizations, surgeries, allergies, any condition that required prescription or chronic medication (that is, more than 2 weeks in duration), and acute conditions occurring prior to Enrollment. At the Enrollment Visit, review and update as needed. Do record pre-existing conditions if identified during follow-up. Add a chart note to explain why the PRE entry was added after Enrollment
Item-specific Instructions:	
Page:	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.
Condition:	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."
Onset Date:	If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required.
Comments:	This field is optional. Use it to record any additional relevant information about the condition, including any associated signs/symptoms.
Severity Grade:	For each condition, grade the severity according to the <i>Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events</i> and the <i>DAIDS Female Genital Grading Table for Use in Microbicide Studies</i> (as appropriate). If a condition is not gradable, mark the "not gradable" box. Review and update as needed for conditions ongoing at the Enrollment Visit.
Ongoing at Enrollment?	Mark the "yes" box for chronic conditions, as well as any other conditions, ongoing at the Enrollment Visit. If a condition resolves or increases in severity or frequency after the Enrollment Visit, document this in chart notes and/or another document other than this form.



MTN-020 ASPIRE (192)

PO-1 (442)

Visit Month

Outcome Number

Participant ID - -
 Site Number Participant Number Chk

Outcome unobtainable. → Go to page 2.

Pregnancy Outcome

If Outcome Number recorded above is 2 or greater, go to item 2.

1. How many pregnancy outcomes resulted from this reported pregnancy?

2. Outcome Date
 dd MMM yy

3. Place of delivery/outcome
 home unknown
 hospital other, specify: _____
 clinic

4. Specify outcome *Mark only one.*

Items 4a-4f: If the pregnancy or outcome was associated with maternal complications or symptoms that would otherwise be reported as an AE, report these on an AE Log. Complete an EAE Reporting form, if applicable.

4a1. Method:
 C-section
 standard vaginal
 operative vaginal
If full term live birth, go to item 6.

4a. full term live birth (≥ 37 weeks) → 4a1. Method:
 4b. premature term live birth (< 37 weeks)
 4c. stillbirth/intrauterine fetal demise (≥ 20 weeks)
 4d. spontaneous abortion (< 20 weeks)
 4e. ectopic pregnancy
 4f. therapeutic/elective abortion
 4g. other, specify: _____

5. Provide a brief narrative of the circumstances: _____

6. Were there any complications related to the pregnancy outcome? *yes* *no* → *If no, go to item 7 on page 2.*

6a. Delivery-related complications *Mark "none" or all that apply.*
 6a1. none 6a4. non-reassuring fetal status
 6a2. intrapartum hemorrhage 6a5. chorioamnionitis
 6a3. postpartum hemorrhage 6a6. other, specify: _____

6b. Non-delivery-related complications *Mark "none" or all that apply.*
 6b1. none
 6b2. hypertensive disorders of pregnancy
 6b3. gestational diabetes
 6b4. other, specify: _____

Pregnancy Outcome (PO-1)	
Purpose:	This form is used to report pregnancy outcome information for a pregnancy reported post-enrollment. Complete this form when information about a pregnancy outcome becomes available to study staff or when it is determined that pregnancy outcome is unobtainable.
General Information/ Instructions:	A Pregnancy Outcome form is required for each Pregnancy Report form that is completed for a participant.
Item-specific Instructions:	
Visit Month:	Record the visit month of the participant's corresponding Pregnancy Report form.
Outcome Number:	A pregnancy outcome can be an infant or fetus. The conception of twins, for example, will result in reporting of two outcomes. For a pregnancy resulting in one outcome, record "1" here. For a pregnancy with multiple outcomes, record the outcome number corresponding to the outcome data recorded on the form.
Outcome unobtainable:	If it is determined that an outcome is unobtainable (i.e., the participant refuses further contact), mark the "Outcome unobtainable" box at the top of the page and fax both pages of this form to SCHARP DataFax.
Item 1:	If the pregnancy results in two or more outcomes, complete a Pregnancy Outcome form for each outcome. Each Pregnancy Outcome form will have the same visit month, but different outcome numbers (for example, one Pregnancy Outcome form will have an outcome number =1 and the second form will have an outcome number =2, and so on).
Item 4:	If the outcome is spontaneous fetal death, still birth, spontaneous abortion, therapeutic/elective abortion, or ectopic pregnancy, the outcome itself is not an adverse experience (AE). If a therapeutic/elective abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Experience (AE) Log, if prior to termination, with "procedure/surgery" marked under item 7, "Treatment." If there are any maternal complications as a result of the pregnancy outcome, refer to the protocol, Study-specific Procedures (SSP) manual, and <i>Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2</i> for guidance on AE and expedited AE reporting requirements.
Item 5:	Include information on medical conditions associated with the outcome, including early contractions, rupture of membranes, and cramping, along with actions taken as a result of these conditions.



MTN-020 ASPIRE (192)

PO-2 (443)

Visit Month .

Outcome Number

Participant ID - -
 Site Number Participant Number Chk

No data recorded on this page.

Pregnancy Outcome

7. Were any fetal/infant congenital anomalies identified? *yes* *no* *unknown* **If no or unknown, go to the statement above item 8.**

7a. Congenital anomalies identified *Mark all that apply. Complete AE Log and EAE Reporting form.*

<input type="checkbox"/> central nervous system, cranio-facial	<input type="checkbox"/> musculoskeletal/extremities	<input type="checkbox"/> cranio-facial (structural)
<input type="checkbox"/> central nervous system, spinal	<input type="checkbox"/> physical defect	<input type="checkbox"/> hematologic
<input type="checkbox"/> cardiovascular	<input type="checkbox"/> skin	<input type="checkbox"/> infectious
<input type="checkbox"/> renal	<input type="checkbox"/> genitourinary	<input type="checkbox"/> endocrine/metabolic
<input type="checkbox"/> gastrointestinal	<input type="checkbox"/> chromosomal	<input type="checkbox"/> other
<input type="checkbox"/> pulmonary		

7b. Describe the congenital anomaly/defect: _____

Complete items 8-13 for live births only. Otherwise, end of form.

8. Infant gender *male* *female*

9. Infant birth weight kg OR *unavailable*

10. Infant birth length cm OR *unavailable*

11. Infant birth head circumference cm OR *unavailable*

12. Infant birth abdominal circumference cm OR *unavailable*

13. Infant gestational age by examination *weeks* *days* OR *unavailable* **If unavailable, end of form.**

13a. Method used to determine gestational age *Ballard* *Dubowitz* *other, specify:* _____

Pregnancy Outcome (PO-2)	
Item-specific Instructions:	
Visit Month:	Record the visit month that is present on page 1 of this form.
No data recorded on this page:	This box should only be marked if the "outcome unobtainable" box is marked on page 1. This box must only be marked if all items on the page are left blank.
Outcome Number:	Record the outcome number that is present on page 1 of this form.
Item 7a:	If a woman on study has a baby with a congenital anomaly, report the event on an Adverse Experience (AE) Log, if prior to termination. On the AE Log, record "Congenital Anomaly in Offspring" on Item 1, record the Outcome Date as the Onset Date, and record the specific anomaly on the Comments line. Also submit an Expedited Adverse Event (EAE) Reporting form.
Items 9-12:	Record the information as documented in medical records. If no medical record documentation of the information is available, complete this item based on participant report. Mark the "unavailable" box if no medical record documentation is available and the participant does not know the information.
Item 13:	Record the infant's gestational age at birth. If the infant's gestational age is determined using the Ballard method, please record "0" in the "days" box. Mark the "unavailable" box if no medical record documentation of the infant's gestational age is available.



MTN-020 ASPIRE (192)

PR-1 (440)

Visit Month .

1

Participant ID - -

Site Number Participant Number Chk

Pregnancy Report

1. First day of last menstrual period OR *amenorrheic for past 6 months*

dd MMM yy

2. Estimated date of delivery

dd MMM yy

3. What information was used to estimate the date of delivery?

	<i>yes</i>	<i>no</i>
3a. last menstrual period	<input type="checkbox"/>	<input type="checkbox"/>
3b. initial ultrasound < 20 weeks	<input type="checkbox"/>	<input type="checkbox"/>
3c. initial ultrasound ≥ 20 weeks	<input type="checkbox"/>	<input type="checkbox"/>
3d. physical examination	<input type="checkbox"/>	<input type="checkbox"/>
3e. conception date by assisted reproduction	<input type="checkbox"/>	<input type="checkbox"/>
3f. other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>

Pregnancy History

4. Has the participant ever been pregnant before? *yes* *no* → *If no, end of form.*

4a. Is this the participant's first pregnancy since enrollment in this study? *yes* *no* → *If no, go to item 5.*

4b. Number of full term live births (≥ 37 weeks)

4c. Number of premature live births (< 37 weeks)

4d. Number of spontaneous fetal deaths and/or still births (≥ 20 weeks)

4e. Number of spontaneous abortions (< 20 weeks)

4f. Number of therapeutic/elective abortions

4g. Number of ectopic pregnancies

5. Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies? *yes* *no* → *If no, end of form.*

5a. If yes, specify: _____

Pregnancy Report and History (PR-1)	
Purpose:	Complete this form when reporting a pregnancy of a study participant post enrollment through termination.
General Information/ Instructions:	<p>A Pregnancy Report and History form is required for each new pregnancy that the participant experiences during the study.</p> <ul style="list-style-type: none"> • Visit Month: Record the visit month of the visit at which study staff became aware that the participant is/was pregnant.
Item-specific Instructions:	
Item 1:	A complete date is required. Record best estimate if date not known.
Item 2:	A complete date is required.
Item 3d:	Physical examination includes fundal height, uterine size by pelvic exam, and/or fetal heart rate.
Item 5:	Include information on pregnancy complications and fetal/infant congenital anomalies experienced prior to enrolling in the study as well as any conditions experienced/reported during the study.



MTN-020 ASPIRE (192)

PTP-1 (077)

<p>Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/></p> <p style="text-align: center; font-size: small;">Site Number Participant Number Chk</p>	
--	--

Prior Trial Participation	
<p>1. Was the participant enrolled in VOICE (MTN-003)?</p>	<p style="text-align: right; font-size: small;">yes no</p> <p style="text-align: right;"> <input type="checkbox"/> <input type="checkbox"/> → <i>If no, go to item 2.</i> </p>
<p>1a. VOICE PTID</p>	<p style="text-align: center;"> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> </p>
<p>2. Has the participant previously enrolled in a microbicide trial other than VOICE? This includes HPTN 035, CAPRISA 004, Carraguard, MDP, and any other microbicide trial.</p>	<p style="text-align: right; font-size: small;">yes no</p> <p style="text-align: right;"> <input type="checkbox"/> <input type="checkbox"/> → <i>If no, go to item 3.</i> </p>
<p>2a. Record the short title of each study (for example, CAPRISA 004)</p> <p>_____</p> <p>_____</p>	<p>_____</p> <p>_____</p>
<p>3. Has the participant previously enrolled in an oral pre-exposure prophylaxis (PrEP) trial for HIV prevention (other than VOICE)? This includes FemPrEP, Partners in PrEP, as well as any other oral PrEP trial.</p>	<p style="text-align: right; font-size: small;">yes no</p> <p style="text-align: right;"> <input type="checkbox"/> <input type="checkbox"/> → <i>If no, go to item 4.</i> </p>
<p>3a. Record the short title of each study (for example, FemPrEP)</p> <p>_____</p> <p>_____</p>	<p>_____</p> <p>_____</p>
<p>4. Has the participant previously enrolled in any other research studies, including any HIV prevention studies (HPTN studies) or HIV vaccine trials?</p>	<p style="text-align: right; font-size: small;">yes no</p> <p style="text-align: right;"> <input type="checkbox"/> <input type="checkbox"/> → <i>If no, go to item 5.</i> </p>
<p>4a. Record the short title of each study (for example, HPTN 123)</p> <p>_____</p> <p>_____</p>	<p>_____</p> <p>_____</p>
<p>5. How did the participant hear about the ASPIRE trial? <i>Mark all that apply.</i></p> <p><input type="checkbox"/> 5a. from study staff (includes CAB members and outreach workers)</p> <p><input type="checkbox"/> 5b. from a friend or family member</p> <p><input type="checkbox"/> 5c. from someone in the community other than a CAB member</p> <p><input type="checkbox"/> 5d. from a brochure or poster</p> <p><input type="checkbox"/> 5e. other; specify: _____</p> <p>_____</p>	

Prior Trial Participation (PTP-1)	
Purpose:	This form is used to collect information on prior trial participation.
General Information/ Instructions:	This form is completed at the Enrollment Visit. Only fax this form to SCHARP DataFax if the participant enrolls in the study.
Item-specific Instructions:	
Item 1 and 1a:	If this participant was previously enrolled in VOICE (MTN-003), mark the "yes" box and record the participant's PTID.



MTN-020 ASPIRE (192)

PH-1 (410)

Note: Number pages sequentially (01, 02, 03) for each participant.

Page

Participant ID - -
 Site Number Participant Number Chk

Product Hold/Discontinuation Log

1. Date and visit month when study product hold was initiated
dd MMM yy visit month

2. Why is study product being held?
Mark only one per page.

pregnancy

positive rapid HIV test result

adverse experience → AE Log page #

breastfeeding

allergic reaction to the study product → AE Log page #

report of PEP use for HIV exposure

other, specify: _____

3. Date of last study product use
dd MMM yy

4. Was the participant instructed to resume study product use?

yes → Date ring inserted:

no – hold continuing for another reason → Date:

no – early termination → Date:

no – hold continuing at scheduled PUEV → Date:

no – permanently discontinued → Date: → *Complete Follow-up ACASI Tracking form.*

Comments: _____

Product Hold/Discontinuation Log (PH-1)

Purpose: This form is used to document temporary clinical holds and clinical permanent discontinuations of study product use as instructed by study site staff. This form is completed each time a participant is instructed by study staff to temporarily stop (hold) or permanently discontinue study product use. If, at the same visit, a product hold/discontinuation is initiated for more than one reason, complete one Product Hold/Discontinuation Log page for each reason. The same visit month should be used on each Log page.

Do not complete this form in cases where a participant has decided herself to not use the study ring.

Item-specific Instructions:

Page: Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers.

Item 2: Note that participant decline or refusal of study product is not documented as a product hold. Do not record this as a reason in "other, specify."

Item 3: Record the last date the study product was present in the vagina. Use a best estimate if the actual date cannot be determined.

***Note:** Do not wait for information about product resumption or permanent discontinuation to fax the form—fax this form to SCHARP DataFax as soon as items 1 through 3 have been completed. Refax the page once item 4 has been completed.*

Item 4: If "no - hold for another reason" is marked, record the date that the participant would have been instructed to resume study product use based on resolution of the reason indicated in item 2.

If "no – permanently discontinued" is marked, record the date the permanent discontinuation was initiated.

Also complete the Follow-up ACASI Tracking form to document whether the PUEV/Discontinuers ACASI questionnaire was completed for the participant.



MTN-020 ASPIRE (192)

PDL-1 (495)

Note: Number pages sequentially (01, 02, 03) for each participant.

Page

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">Site Number Participant Number Chk</p>	Form Completion Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">dd MMM yy</p>
--	---

Protocol Deviation Log					
1. Site awareness date:	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">dd MMM yy</p>				
2. Deviation date:	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">dd MMM yy</p>				
3. Has or will this deviation be reported to local IRB/EC?	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; font-size: small;">yes</td> <td style="text-align: center; font-size: small;">no</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	yes	no	<input type="checkbox"/>	<input type="checkbox"/>
yes	no				
<input type="checkbox"/>	<input type="checkbox"/>				
4. Has or will this deviation be reported to DAIDS as a critical event?	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; font-size: small;">yes</td> <td style="text-align: center; font-size: small;">no</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	yes	no	<input type="checkbox"/>	<input type="checkbox"/>
yes	no				
<input type="checkbox"/>	<input type="checkbox"/>				
5. Type of deviation:	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>deviation code (See back of form for code listing.)</i>				
6. Description of deviation:	<hr/> <hr/>				
7. Plans and/or action taken to address the deviation:	<hr/> <hr/>				
8. Plans and/or action taken to prevent future occurrences of the deviation:	<hr/> <hr/> <hr/>				
9. Deviation reported by:	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>staff code</i>				

Protocol Deviation Log (PDL-1)

Purpose: This form documents and reports protocol deviations identified for study participants.

General Information/ Instructions: Complete this form each time a protocol deviation is identified. Consult the MTN Regulatory Team (mtnregulatory@mtntopshiv.org) and the Study Management Team if you are unsure if an event requires reporting as a deviation.

Item-specific Instructions:

Page: Number pages sequentially for each participant, starting with 01. Do not re-assign page numbers if a form is marked for deletion.

Item 2: Record the date the event occurred (start date).

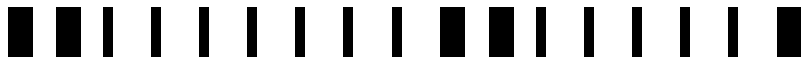
Item 5: Record the two-digit category code that best describes the type of deviation. Use "99" (other) if none of the listed categories match. Describe the specifics of the deviation in item 6.

Code	Description
01	Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.
02	Failure to follow trial randomization or blinding procedures: Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.
03	Study product management deviation: The site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.
04	Study product dispensing error: The wrong study product was dispensed to a participant, or study product was dispensed to a participant on product hold. Do not include any information related to study product assignment (product codes) on this form. Pharmacy staff must follow up with the MTN Pharmacist separately.
05	Study product use/non-use deviation: Participant did not use the study product (including product refusals) or used it incorrectly (i.e., not in accordance with protocol requirements).
06	Study product sharing: Participant has shared study product with another person or study participant.
07	Study product not returned: Study product was not returned by the participant per protocol requirements.
08	Conduct of non-protocol procedure: A clinical or administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice.
09	Improper AE/EAE follow-up: Use when an AE or EAE is not followed per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol.
10	Unreported AE: Site staff become aware of an AE, but do not report it per protocol requirements.
11	Unreported EAE: Site staff become aware of an EAE, but do not report it per protocol and DAIDS EAE Manual requirements.

Code	Description
12	Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member puts a participant's name on a case report form.
13	Physical assessment deviation: Include missed or incomplete physical/pelvic/rectal exam assessments.
14	Lab assessment deviation: Include missed, or incomplete lab specimen collection.
15	Mishandled lab specimen: Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens.
16	Staff performing duties that they are not qualified to perform: Use for any instance when any study procedure, including clinical and administrative procedures, is completed by a staff member who is not adequately qualified AND delegated to perform the procedure.
17	Questionnaire administration deviation: A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed.
18	Counseling deviation: Protocol-required counseling was not done and/or not documented correctly.
19	Use of non-IRB/EC-approved materials: Include use of ANY study-related material that requires IRB or EC approval for use per site requirements.
20	Use of excluded concomitant medications, devices or non-study products
21	Informed consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process.
22	Visit completed outside of window: Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. For example, use if Visit 3.0 procedures are done in the Visit 4.0 window.
99	Other

Item 6: Briefly describe the specific details of the deviation.

Item 9: Record staff code of the site staff person who completed the form. Sites will need to assign a four-digit staff code to each site staff person who will be completing this form. This list is created, maintained, and kept at the study site.



Visit Month .

1

MTN-020 ASPIRE (192)

PLR-1 (193)

Participant ID <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"/> - <input type="text"/>	Initial Specimen Collection Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Site Number Participant Number Chk	dd MMM yy

PUEV Laboratory Results

1. PAP SMEAR Not done/ Not collected

Alternate Collection Date dd MMM yy

Go to item 2. negative for intraepithelial lesion or cancer (malignancy) SIL-high grade (HSIL)

ASCUS AGC

ASC-H AGC-favor neoplastic

SIL-low grade (LSIL) cancer

2. SYPHILIS SEROLOGY Not done/ Not collected

Alternate Collection Date dd MMM yy

Go to item 3. non-reactive reactive

2a. Syphilis screening test If non-reactive, go to item 3.

2a1. Syphilis titer 1:

2b. Syphilis confirmatory test negative positive indeterminate

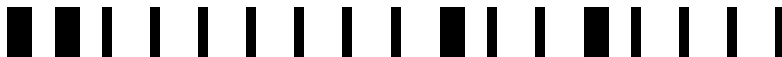
3. Were any new AE Log pages completed based on results recorded on this form? yes no

If no, end of form.

3a. AE Log page number(s)

Complete or update Adverse Experience Log, if applicable.

PUEV Laboratory Results (PLR-1)	
Purpose:	This form is used to document results of Pap specimens and Syphilis serology collected during the Product Use End Visit (PUEV).
General Information/ Instructions:	<p>This form is completed at the PUEV. It is also completed at an early termination visit, if applicable. Record test results on this form as they become available. If the Pap test result indicates that the participant has a condition requiring further evaluation, record the result on the Adverse Experience (AE) Log. Do not use this Pap smear to diagnose STIs, such as Trichomoniasis.</p> <ul style="list-style-type: none"> • Initial Specimen Collection Date: Record the date that the first specimen(s) 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.
Item-specific Instructions:	
Item 1:	<p>Record the Pap Smear result. Mark only one box.</p> <ul style="list-style-type: none"> • Negative for intraepithelial lesion or cancer (malignancy): Includes all normal findings and any findings of infection (trichomonas, candida, etc.), reactive changes/inflammation, glandular changes due to hysterectomy, or atrophic changes. • ASCUS: Mark this box when abnormal/atypical squamous cells of undetermined significance are reported. • ASC-H: Mark this box when abnormal/atypical squamous cells that cannot exclude high-grade squamous intraepithelial lesions (HSIL) are reported. • SIL-low grade (LSIL): Mark this box when low-grade squamous interepithelial lesions are reported. This category includes presence of human papillomavirus (HPV) infection, mild dysplasia, and cervical interepithelial neoplasia (CIN 1). • SIL-high grade (HSIL): Mark this box when high-grade squamous interepithelial lesions are reported. This category includes the presence of moderate to severe dysplasia, carcinoma in situ (CIS), CIN 2, and CIN 3, or changes suspicious for invasive cancer. • AGC: Mark this box when atypical/abnormal glandular cells are reported. This category includes endocervical (from cervical canal) atypical cells; endometrial atypical cells; glandular atypical cells. • AGC-favor neoplastic: Mark this box when atypical/abnormal glandular cells that favor cell growth (neoplastic changes) are reported. This category includes endocervical cells and glandular cells. • Cancer: Mark this box when cancer or adenocarcinoma is reported. This includes endocervical, endometrial, extrauterine, and other (not specified) cancers/adenocarcinomas.
Item 2:	If the syphilis screening test is reactive, items 2a1 and 2b must be completed.
Item 2a1:	Use leading zeros when recording a syphilis titer level. For example, a titer level of 1:16 would be recorded on the form as "1:0016."
Item 2b:	If a result is positive, provide treatment according to WHO guidelines, and report the relevant infection on the AE Log.



Visit Month .

1

MTN-020 ASPIRE (192)

QLR-1 (144)

Participant ID <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"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> Site Number Participant Number Chk </small>	Initial Specimen Collection Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy </small>
---	---

Quarterly Laboratory Results

1. Hemogram	Not done/Not collected <input type="checkbox"/> Go to item 2. ←	Alternate Collection Date dd <input type="text"/> <input type="text"/>	MMM <input type="text"/> <input type="text"/>	yy <input type="text"/> <input type="text"/>	
Not reported <input type="checkbox"/> 1a. Hemoglobin	<input type="text"/> <input type="text"/> . <input type="text"/> g/dL	Severity Grade (if applicable) <input type="text"/>	AE Log page # <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	not reportable as an AE
Not reported <input type="checkbox"/> 1b. Hematocrit	<input type="text"/> <input type="text"/> . <input type="text"/> %				
Not reported <input type="checkbox"/> 1c. MCV	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> fL				
Not reported <input type="checkbox"/> 1d. Platelets	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> x10 ³ /mm ³	Severity Grade (if applicable) <input type="text"/>	AE Log page # <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	not reportable as an AE
Not reported <input type="checkbox"/> 1e. WBC	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> x10 ³ /mm ³	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	
Differential <input type="checkbox"/> Not done —→ Go to item 2.					
Not reported <input type="checkbox"/> 1f. Neutrophils	Absolute Count <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cells/mm ³	Severity Grade (if applicable) <input type="text"/>	AE Log page # <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	not reportable as an AE
Not reported <input type="checkbox"/> 1g. Lymphocytes	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cells/mm ³	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	
Not reported <input type="checkbox"/> 1h. Monocytes	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cells/mm ³				
Not reported <input type="checkbox"/> 1i. Eosinophils	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cells/mm ³				
Not reported <input type="checkbox"/> 1j. Basophils	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cells/mm ³				
2. Chemistries	Not done/Not collected <input type="checkbox"/> End of form. ←	Alternate Collection Date dd <input type="text"/> <input type="text"/>	MMM <input type="text"/> <input type="text"/>	yy <input type="text"/> <input type="text"/>	
Not reported <input type="checkbox"/> 2a. AST (SGOT)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> U/L	Severity Grade (if applicable) <input type="text"/>	AE Log page # <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	not reportable as an AE
Not reported <input type="checkbox"/> 2b. ALT (SGPT)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> U/L	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	
Not reported <input type="checkbox"/> 2c. Creatinine	OR <input type="text"/> <input type="text"/> . <input type="text"/> mg/dL <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> μmol/L	Severity Grade (if applicable) <input type="text"/>	AE Log page # <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>	not reportable as an AE

Quarterly Laboratory Results (QLR-1)

Purpose: This form is used to provide data on the participant's quarterly laboratory test results.

General Information/ Instructions: Use this form to report the hematology, differential, and liver and renal function test results obtained from specimens collected at quarterly and semi-annual, the Product Use End Visit (PUEV), and early termination (as applicable) visits as they become available.

- **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.

Results Reporting:

- Results should be documented on the form using the units present on the source laboratory results document. If the units present on the form do not match your source results report, contact the MTN-020 Management Team. Note that the following units are equivalent:

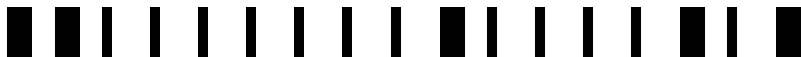
$$\text{IU/L} = \text{U/L} \qquad \text{I/I} \times 100 = \% \qquad 10^9/\text{L} = 10^3/\text{mm}^3 = 10^3/\mu\text{L}$$

For creatinine, only record the result in the units listed on the source document.

- If the site lab does not report results to the same level of precision allowed on the form, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the form. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
 - If the site lab does not produce test results in the units used on this form, first perform the conversion, then round the converted result if necessary.

Severity Grade:

- If any values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results. If a value is below severity grade 1, leave the "Severity Grade," "AE Log page #," and "not reportable as an AE" boxes blank.
- Always compare the severity grade range to the value that was recorded on the form (not the lab-reported value).
- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
 - Treat all missing digits in the lab value as zeros.
 - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
- Record any Grade 1 or higher lab values on the Adverse Experience (AE) Log as applicable.



MTN-020 ASPIRE (192)

RA-1 (133)

Visit Month .

1

Participant ID <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"/>	Visit Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Site Number Participant Number Chk	dd MMM yy

Ring Adherence

1. Did the participant have access to a vaginal ring during the past month? *yes* *no* **→ If no, end of form.**

2. How many times in the past month has the participant had the vaginal ring out, in total? *times* **→ If 00, end of form.**

3. How many of these times was the vaginal ring out for more than 12 hours continuously? *times* **→ If 00, go to item 5.**

4. In the past month, what is the longest number of days in a row the vaginal ring was out? *days*

5. In the past month, why was the vaginal ring out? *Record all codes that apply. See back of form for code listing.*

Reason Code

5a.

5b.

5c.

5d.

5e.

5f.

5g.

If there is a reason that is not represented in the Reason Code list, mark item 5h or 5i, as applicable, and record the reason on the adjacent specify lines. Otherwise, leave items 5h and 5i blank.

5h. Other reason ring removed by participant or clinician, specify: _____

5i. Other reason ring came out on its own, specify: _____

Comments: _____

Ring Adherence (RA-1)																																																													
Purpose:	This form is used to document the participant's self-reported study ring use during follow-up.																																																												
General Information/ Instructions:	<p>Complete this form at each monthly, quarterly and semi-annual follow-up visits, as well as the Product Use End Visit (PUEV), and at an early termination visit, as applicable. Complete at these visits even if the participant has been on product hold or has been permanently discontinued from ring use.</p> <p>All items on this form refer to ring access and use during the past month only, regardless of whether or not the participant missed her last monthly visit.</p>																																																												
Item-specific Instructions:																																																													
Item 1:	Mark "no" if the participant did not have a ring in her possession during the past month. Mark "yes" if the participant had access to a vaginal ring, regardless of how long ago the ring was dispensed, and regardless of whether or not the participant used the ring. For example, a participant is dispensed a ring at her Month 1 Visit. She misses her Month 2 Visit, but returns for her Month 3 Visit. At her Month 3 Visit, mark "yes" since the participant had in her possession for the past month the ring that was dispensed at her Month 1 Visit.																																																												
Item 2:	The purpose of this question is to capture all instances in the past month when the ring was expelled, or was removed other than at regularly scheduled study visits. Do not count instances when the ring was removed at a regularly scheduled visit to insert a new ring.																																																												
Item 4:	When determining the longest number of days in a row, include partial days as a day. For example, if a participant reports she removed the ring on a Wednesday and re-inserted it on a Friday, count this as 3 days (Wednesday, Thursday, Friday). This item should be an over-estimate rather than an exact or under-estimate.																																																												
Item 5:	Refer to the list of Reason Codes below. Record the two-digit code that corresponds to each reason the vaginal ring was out during the past month (because the participant or clinician removed the ring, or ring expulsion occurred). Up to seven Reason Codes may be recorded (items 5a-5g). A Reason Code is required for item 5a. Record any additional reason codes in items 5b-5g; leave any unused items blank. For example, if three Reason Codes apply, record the codes in items 5a-5c and leave items 5d-5g blank.																																																												
REASONS RING REMOVED BY PARTICIPANT OR CLINICIAN																																																													
<table border="1"> <thead> <tr> <th colspan="2">Hygienic or Physical Reasons</th> <th colspan="2">Social or Sexual Reasons</th> </tr> <tr> <th>Code</th> <th>Description</th> <th>Code</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>10</td> <td>Discomfort/symptoms: Ring caused discomfort/ participant experienced genital or other symptoms</td> <td>20</td> <td>Partner ring knowledge: Did not want husband or primary sex partner to know about ring</td> </tr> <tr> <td>11</td> <td>Ring falling out: Ring was partially falling out</td> <td>21</td> <td>Partner concerns/objections: Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring</td> </tr> <tr> <td>12</td> <td>Ring placement: Didn't feel the ring was correctly placed</td> <td>22</td> <td>Family concerns/objections: Family member (other than husband/primary sex partner) did not like the ring and/or wanted her to remove/stop using the ring</td> </tr> <tr> <td>13</td> <td>Ring presence: Wanted to look at the ring or see if the ring was still in place</td> <td>23</td> <td>Friend or peer concerns/objections: Friend or peer did not like the ring and/or wanted her to remove/stop using the ring</td> </tr> <tr> <td>14</td> <td>Menses/Bleeding: Had or was expecting menses/ any type of genital bleeding or spotting</td> <td>24</td> <td>Removal for sex: Participant or partner did not want to have vaginal sex with the ring in place</td> </tr> <tr> <td>15</td> <td>Cleaned ring: Removed ring to clean it</td> <td>25</td> <td>Discomfort during sex: The ring feeling uncomfortable or painful during vaginal sex</td> </tr> <tr> <td>16</td> <td>Cleaned vagina: Removed ring to clean vagina</td> <td>26</td> <td>Partner felt ring during sex: The sex partner feeling the ring during sex</td> </tr> <tr> <td colspan="2">Study-related or Procedural Reasons</td> <td>27</td> <td>Showed ring: Removed ring to show it to someone</td> </tr> <tr> <td>30</td> <td>Product hold: Participant placed on product hold; includes ring removals at Day 35</td> <td>28</td> <td>Not having sex: Participant was not having sex so she decided to remove/stop using the ring</td> </tr> <tr> <td>31</td> <td>Product permanently discontinued: Participant permanently discontinued from product</td> <td></td> <td></td> </tr> <tr> <td>32</td> <td>Procedure: Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam) that was <i>not</i> conducted at a regularly scheduled study visit</td> <td></td> <td></td> </tr> <tr> <td>33</td> <td>Inserted new ring: Ring removed to insert new ring between study visits or at an interim visit</td> <td></td> <td></td> </tr> <tr> <td>34</td> <td>Missed visit: Participant removed ring due to missed scheduled visit</td> <td></td> <td></td> </tr> </tbody> </table>		Hygienic or Physical Reasons		Social or Sexual Reasons		Code	Description	Code	Description	10	Discomfort/symptoms: Ring caused discomfort/ participant experienced genital or other symptoms	20	Partner ring knowledge: Did not want husband or primary sex partner to know about ring	11	Ring falling out: Ring was partially falling out	21	Partner concerns/objections: Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring	12	Ring placement: Didn't feel the ring was correctly placed	22	Family concerns/objections: Family member (other than husband/primary sex partner) did not like the ring and/or wanted her to remove/stop using the ring	13	Ring presence: Wanted to look at the ring or see if the ring was still in place	23	Friend or peer concerns/objections: Friend or peer did not like the ring and/or wanted her to remove/stop using the ring	14	Menses/Bleeding: Had or was expecting menses/ any type of genital bleeding or spotting	24	Removal for sex: Participant or partner did not want to have vaginal sex with the ring in place	15	Cleaned ring: Removed ring to clean it	25	Discomfort during sex: The ring feeling uncomfortable or painful during vaginal sex	16	Cleaned vagina: Removed ring to clean vagina	26	Partner felt ring during sex: The sex partner feeling the ring during sex	Study-related or Procedural Reasons		27	Showed ring: Removed ring to show it to someone	30	Product hold: Participant placed on product hold; includes ring removals at Day 35	28	Not having sex: Participant was not having sex so she decided to remove/stop using the ring	31	Product permanently discontinued: Participant permanently discontinued from product			32	Procedure: Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam) that was <i>not</i> conducted at a regularly scheduled study visit			33	Inserted new ring: Ring removed to insert new ring between study visits or at an interim visit			34	Missed visit: Participant removed ring due to missed scheduled visit		
Hygienic or Physical Reasons		Social or Sexual Reasons																																																											
Code	Description	Code	Description																																																										
10	Discomfort/symptoms: Ring caused discomfort/ participant experienced genital or other symptoms	20	Partner ring knowledge: Did not want husband or primary sex partner to know about ring																																																										
11	Ring falling out: Ring was partially falling out	21	Partner concerns/objections: Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring																																																										
12	Ring placement: Didn't feel the ring was correctly placed	22	Family concerns/objections: Family member (other than husband/primary sex partner) did not like the ring and/or wanted her to remove/stop using the ring																																																										
13	Ring presence: Wanted to look at the ring or see if the ring was still in place	23	Friend or peer concerns/objections: Friend or peer did not like the ring and/or wanted her to remove/stop using the ring																																																										
14	Menses/Bleeding: Had or was expecting menses/ any type of genital bleeding or spotting	24	Removal for sex: Participant or partner did not want to have vaginal sex with the ring in place																																																										
15	Cleaned ring: Removed ring to clean it	25	Discomfort during sex: The ring feeling uncomfortable or painful during vaginal sex																																																										
16	Cleaned vagina: Removed ring to clean vagina	26	Partner felt ring during sex: The sex partner feeling the ring during sex																																																										
Study-related or Procedural Reasons		27	Showed ring: Removed ring to show it to someone																																																										
30	Product hold: Participant placed on product hold; includes ring removals at Day 35	28	Not having sex: Participant was not having sex so she decided to remove/stop using the ring																																																										
31	Product permanently discontinued: Participant permanently discontinued from product																																																												
32	Procedure: Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam) that was <i>not</i> conducted at a regularly scheduled study visit																																																												
33	Inserted new ring: Ring removed to insert new ring between study visits or at an interim visit																																																												
34	Missed visit: Participant removed ring due to missed scheduled visit																																																												
REASONS RING CAME OUT ON ITS OWN																																																													
<table border="1"> <thead> <tr> <th>Code</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>40</td> <td>Urination</td> </tr> <tr> <td>41</td> <td>Bowel movement: Having a bowel movement</td> </tr> <tr> <td>42</td> <td>Sex: Having sex or just finished sex</td> </tr> <tr> <td>43</td> <td>Physical activity: Physical activity (other than sex), including lifting heavy objects</td> </tr> <tr> <td>44</td> <td>Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up)</td> </tr> <tr> <td>45</td> <td>Menses: Had her menses</td> </tr> </tbody> </table>		Code	Description	40	Urination	41	Bowel movement: Having a bowel movement	42	Sex: Having sex or just finished sex	43	Physical activity: Physical activity (other than sex), including lifting heavy objects	44	Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up)	45	Menses: Had her menses																																														
Code	Description																																																												
40	Urination																																																												
41	Bowel movement: Having a bowel movement																																																												
42	Sex: Having sex or just finished sex																																																												
43	Physical activity: Physical activity (other than sex), including lifting heavy objects																																																												
44	Body position: Was squatting or sitting or changing body position (i.e., move from lying down to standing up)																																																												
45	Menses: Had her menses																																																												



MTN-020 ASPIRE (192)

RCI-1 (135)

Visit Month .

1

Participant ID - -

Site Number Participant Number Chk

Visit Date

dd *MMM* *yy*

Ring Collection/Insertion

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* *2* *3*

If "1," go to item 3.

2a. If none, 2, or 3, specify reason: _____

3. Number of **unused (never inserted)** rings collected *none* *1* *2* *3*

4. Number of **new rings** dispensed to participant: *none* *1* *2* *3*

Go to item 5.

4a. Reason ring not dispensed

participant on clinical hold

participant has been permanently discontinued from product

participant declined study ring, specify: _____

scheduled PUEV

early termination

other, specify: _____

Go to item 7.

5. Was a new ring inserted at this visit? *yes* *no*

If no, go to item 6.

5a. Who inserted the new ring? *participant* *study staff*

6. Was a ring in place at the end of the visit? *yes* *no*

If yes, go to item 7.

6a. Reason ring not in place at end of visit

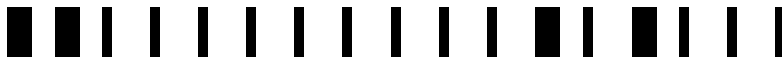
participant declined to have ring inserted

participant had to leave before ring could be inserted

other, specify: _____

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

Ring Collection/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:	<p>Complete this form at each monthly, quarterly, and semi-annual follow-up visits, as well as at the Product Use End Visit (PUEV), and at early termination visit, as applicable. Complete at interim visits as needed.</p> <p>If the participant has been permanently discontinued from study product, this form is not required to be completed at visits following the permanent discontinuation.</p>
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 the "not applicable" box.
Item 2a:	If no rings were collected (returned), specify the reason why (for example, participant forgot, or participant had no dispensed rings to return). If two or three rings were collected, specify reason why (specify why examples include: two rings were dispensed at last visit, or participant returned one recently-dispensed ring along with a ring dispensed at 3 months, but never returned).
Item 4:	Only document ring(s) dispensed and given to the participant.
Item 4a:	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 7:	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. If 2 or more rings are collected, record the appearance of the ring most recently-used by the participant.



MTN-020 ASPIRE (192)

SLR-1 (040)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small>Site Number Participant Number Chk</small>	Initial Specimen Collection Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>dd MMM yy</small>
---	--

Screening Laboratory Results

	Alternate Collection Date <small>dd MMM yy</small> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
1. Hemogram	
1a. Hemoglobin	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> g/dL Severity Grade (if applicable) <input type="checkbox"/> <i>Note: Grade 2 or higher is exclusionary.</i>
1b. Hematocrit	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> %
1c. MCV	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> fL
1d. Platelets	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> x10 ³ /mm ³ Severity Grade (if applicable) <input type="checkbox"/> <i>Note: Grade 1 or higher is exclusionary.</i>
1e. WBC	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> x10 ³ /mm ³ Severity Grade (if applicable) <input type="checkbox"/>
Differential	Absolute Count
1f. Neutrophils	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> cells/mm ³ Severity Grade (if applicable) <input type="checkbox"/>
1g. Lymphocytes	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> cells/mm ³ Severity Grade (if applicable) <input type="checkbox"/>
1h. Monocytes	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> cells/mm ³
1i. Eosinophils	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> cells/mm ³
1j. Basophils	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> cells/mm ³
	Alternate Collection Date <small>dd MMM yy</small> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
2. Chemistries	
2a. AST (SGOT)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> U/L Severity Grade (if applicable) <input type="checkbox"/> <i>Note: Grade 1 or higher is exclusionary.</i>
2b. ALT (SGPT)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> U/L Severity Grade (if applicable) <input type="checkbox"/> <i>Note: Grade 1 or higher is exclusionary.</i>
2c. Creatinine	OR <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> mg/dL <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> μmol/L Severity Grade (if applicable) <input type="checkbox"/> <i>Note: Grade 2 or higher is exclusionary.</i>

Screening Laboratory Results (SLR-1)	
Purpose:	This form is used to provide data on the participant's baseline laboratory test results (the results obtained closest to and before the date of enrollment).
General Information/ Instructions:	<p>Use this form to report the hematology, differential, and liver and renal function test results obtained from specimens collected at the Screening Visit as they become available. Do not fax the form to SCHARP DataFax until all results are available and the participant has enrolled in the study.</p> <ul style="list-style-type: none"> • Initial Specimen Collection Date: Record the date that the first specimen(s) 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.
If a participant has any laboratory results reported on this form repeated (re-drawn) between the Screening and Enrollment Visit:	<p>If any or all of the labs listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated lab results on a new SLR-1 form, and only fax this SLR-1 form to SCHARP (the form completed closest to the time of enrollment). SCHARP can only receive one SLR-1 form per enrolled participant.</p> <ul style="list-style-type: none"> • Example 1: Participant has Screening Visit on 22-May-12 and has a grade 2 hemoglobin and grade 2 ALT. All labs are re-drawn on 27-May-12. All results from 27-May-12 are normal (below grade 1). SCHARP will require an SLR-1 with Initial Specimen Collection Date of 27-May-12 (no Alternate Collection Date should be listed). If enrolled, only fax the SLR-1 dated 27-May-12 to SCHARP DataFax. If a SLR-1 was completed for the 22-May-12 results, keep this form in the participant's file but do not fax to SCHARP DataFax. • Example 2: A participant has Screening Visit on 22-May-12 and all labs are normal except for ALT, which is grade 2. On 27-May-12, a re-draw is performed for ALT, AST, and creatinine only. These results come back normal. SCHARP will require an SLR-1 with the Initial Collection Date of 22-May-12, and results from this day will be recorded for items 1a–1j. For item 2, record an Alternate Collection Date of 27-May-12 and the results from this day in items 2a–2c. If a SLR-1 was completed for the 22-May-12 results (all results from this day), keep this form in the participant's file but do not fax to SCHARP DataFax.
Results Reporting:	<ul style="list-style-type: none"> • Results should be documented on the form using the units present on the source laboratory results document. If the units present on the form do not match your source results report, contact the MTN-020 Management Team. Note that the following units are equivalent: $IU/L = U/L$ $I/I \times 100 = \%$ $10^9/L = 10^3/mm^3 = 10^3/\mu L$ For creatinine, only record the result in the units listed on the source document. • If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the form. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL. <ul style="list-style-type: none"> - If the site lab does not produce test results in the units used on this form, first perform the conversion, then round the converted result if necessary.
Severity Grade:	<ul style="list-style-type: none"> • If any values meet the criteria for severity grade 1 or greater, according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i>, record the grade in the appropriate box next to the result. If value is below Grade 1, leave severity grade box blank. • Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. <ul style="list-style-type: none"> - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade. • Record any Grade 1 or higher lab values on the Pre-existing Conditions form.



MTN-020 ASPIRE (192)

SMH-1 (051)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small>Site Number Participant Number Chk</small>	Visit Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>dd MMM yy</small>
---	--

Screening Menstrual History	
1. Age of first menses (menarche)	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> years
2. Usual menstrual cycle	regular <input type="checkbox"/> irregular <input type="checkbox"/> amenorrheic for past 6 months <input type="checkbox"/> → Specify: _____
3. Usual number of days between menses (1 st day to 1 st day)	minimum <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> # of days TO maximum <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> # of days
4. Usual number of bleeding days (record range)	minimum <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> # of days TO maximum <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> # of days
5. First day of last menstrual period	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>dd MMM yy</small>
6. Last day of last menstrual period	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> OR <input type="checkbox"/> ongoing
7. Usual type of menstrual flow (at heaviest day of menses)	light <input type="checkbox"/> moderate <input type="checkbox"/> heavy <input type="checkbox"/>
8. Provide additional details as needed to describe the participant's baseline menstrual bleeding pattern.	
_____ _____ _____ _____ _____ _____ _____	

Record usual menstrual symptoms and any irregular bleeding on the Pre-existing Conditions form.

Screening Menstrual History (SMH-1)	
Purpose:	This form is used to document information on the participant's menstrual history at the Screening Visit. This form is faxed to SCHARP only if the participant enrolls in the study.
Item-specific Instructions:	
Item 3:	Record the usual number of days that the participant experiences between menses starting on the first day of her menstrual period up to and including the day before the first day of her next menstrual period.
Item 4:	Record the range (minimum and maximum) of the usual number of bleeding days of the participant's menses. For example, if a participant reports that she has experienced menses that have lasted for a minimum of 3 days and a maximum of 6 days, record "03" for minimum of days and "06" for maximum number of days.
Item 5:	Record the first day of the participant's most recent menstrual period.
Item 7:	This item is based on how the participant describes her heaviest flow day during menses.
Item 8:	During follow-up, occurrences of genital bleeding will be compared to the participant's baseline bleeding pattern (as documented on this form) in order to determine if the episode requires reporting as an AE. With this mind, use this space to describe as best possible the participant's usual genital bleeding pattern. Include details such as number of sanitary pads typically used, any spotting that is experienced, and any additional details on amount/heaviness of flow. Update with additional details as needed at the Enrollment Visit.



MTN-020 ASPIRE (192)

SPE-1 (038)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 40px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> Site Number Participant Number Chk </small>	Exam Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy </small>
--	--

Screening Pelvic Exam																																							
<div style="display: flex; justify-content: space-between; align-items: center;"> <i>abnormal findings</i> <i>no abnormal findings</i> <div style="display: flex; align-items: center;"> <input style="width: 20px; height: 20px;" type="checkbox"/> → <i>If no abnormal findings, go to item 2.</i> </div> </div> <p>1. Pelvic exam assessment:</p> <p>1a. Abnormal findings. <i>Mark all that apply.</i></p> <table border="1" style="width:100%; border-collapse: collapse; font-size: 10px;"> <thead> <tr> <th style="width: 25%; text-align: center;">VULVAR</th> <th style="width: 25%; text-align: center;">VAGINAL</th> <th style="width: 25%; text-align: center;">CERVICAL</th> <th style="width: 25%; text-align: center;">GENERAL/OTHER</th> </tr> </thead> <tbody> <tr> <td style="vertical-align: top; padding: 5px;"> <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 </td> <td style="vertical-align: top; padding: 5px;"> <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 </td> <td style="vertical-align: top; padding: 5px;"> <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 </td> <td style="vertical-align: top; padding: 5px;"> <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"/> adnexal tenderness <input type="checkbox"/> observed blood or bleeding; describe: _____ _____ _____ _____ </td> </tr> <tr> <td colspan="5" style="padding: 5px;"> <input type="checkbox"/> 1b. Other abnormal findings, specify (include anatomical location): _____ </td> </tr> <tr> <td colspan="5" style="text-align: center; padding: 5px;"><i>Record all abnormal findings on Pre-existing Conditions form.</i></td> </tr> <tr> <td colspan="5" style="padding: 5px;"> <table style="width:100%; font-size: 10px;"> <tr> <td style="width: 20%;"></td> <td style="text-align: center;">0%</td> <td style="text-align: center;">1-25%</td> <td style="text-align: center;">26-50%</td> <td style="text-align: center;">51-75%</td> <td style="text-align: center;">76-100%</td> </tr> <tr> <td>2. Cervical ectopy:</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table> </td> </tr> </tbody> </table>					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"/> adnexal tenderness <input type="checkbox"/> observed blood or bleeding; describe: _____ _____ _____ _____	<input type="checkbox"/> 1b. Other abnormal findings, specify (include anatomical location): _____					<i>Record all abnormal findings on Pre-existing Conditions form.</i>					<table style="width:100%; font-size: 10px;"> <tr> <td style="width: 20%;"></td> <td style="text-align: center;">0%</td> <td style="text-align: center;">1-25%</td> <td style="text-align: center;">26-50%</td> <td style="text-align: center;">51-75%</td> <td style="text-align: center;">76-100%</td> </tr> <tr> <td>2. Cervical ectopy:</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>						0%	1-25%	26-50%	51-75%	76-100%	2. Cervical ectopy:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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"/> adnexal tenderness <input type="checkbox"/> observed blood or bleeding; describe: _____ _____ _____ _____																																				
<input type="checkbox"/> 1b. Other abnormal findings, specify (include anatomical location): _____																																							
<i>Record all abnormal findings on Pre-existing Conditions form.</i>																																							
<table style="width:100%; font-size: 10px;"> <tr> <td style="width: 20%;"></td> <td style="text-align: center;">0%</td> <td style="text-align: center;">1-25%</td> <td style="text-align: center;">26-50%</td> <td style="text-align: center;">51-75%</td> <td style="text-align: center;">76-100%</td> </tr> <tr> <td>2. Cervical ectopy:</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>						0%	1-25%	26-50%	51-75%	76-100%	2. Cervical ectopy:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																							
	0%	1-25%	26-50%	51-75%	76-100%																																		
2. Cervical ectopy:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																		

Screening Pelvic Exam (SPE-1)	
Purpose:	This form is used to provide data on the participant's baseline pelvic exam assessment (the pelvic exam performed closest to and prior to the date of enrollment).
General Information/ Instructions:	<p>Complete this form at the participant's Screening Visit pelvic exam. Transcribe information from the Pelvic Exam Diagrams (non-DataFax) source form onto this form for submission to DataFax. Do not fax the form to SCHARP DataFax until the participant has enrolled in the study.</p> <p>If a participant has a second pelvic exam prior to or on the day of Enrollment: Document the repeat screening pelvic exam on a new Pelvic Exam Diagram (non-DataFax) form and a new Screening Pelvic Exam form. If the participant enrolls, only fax the Screening Pelvic Exam form completed for the repeat exam (the exam done closest to enrollment) to SCHARP DataFax. Keep all Pelvic Exam Diagrams and Screening Pelvic Exam forms completed during screening in the participant's study file.</p>
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:	<p>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. Refer to the <i>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)</i> for more details regarding severity grading information on the abnormal findings listed. Record all abnormal findings onto the Pre-existing Conditions form. In general, use the same text on both forms to describe the abnormal finding (this does not apply to observances of blood or bleeding).</p> <p>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 baseline documentation purposes.</p> <p>Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the FGGT. Refer to Study-specific Procedures (SSP) manual section 10.6 for more information/guidance as needed.</p>



MTN-020 ASPIRE (192)

SSS-1 (049)

Participant ID	<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"/> - <input type="text"/>	Initial Specimen Collection 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"/>
	Site Number Participant Number Chk		dd MMM yy

Screening Specimen Storage

1. Vaginal smear for gram stain

Alternate Collection Date

dd MMM yy

stored not stored Reason: _____

2. Endocervical swab for biomarkers

Alternate Collection Date

dd MMM yy

stored not stored Reason: _____

2a. Was blood visible on the swab?

yes no

Go to item 3.

3. Syphilis Serology

Alternate Collection Date

dd MMM yy

3a. Syphilis screening test

non-reactive reactive

If non-reactive, end of form.

3a1. Syphilis titer

1:

3b. Syphilis confirmatory

negative positive indeterminate

Comments: _____

Screening Specimen Storage (SSS-1)	
Purpose:	This form is used to document collection and storage of specimens collected during the Screening Visit pelvic exam as well as results of syphilis testing at screening.
General Information/ Instructions:	<p>Complete this form at the Screening Visit. Record test results on this form as they become available. Only fax this form to SCHARP DataFax if the participant enrolls in the study</p> <p>If a repeat screening pelvic exam is performed (between screening and enrollment, or on the day of enrollment), do not collect a second endocervical swab or gram stain specimen during the repeat screening pelvic exam. These specimens should only be collected and stored at the first (Screening Visit) pelvic exam. If the participant does not enroll, these specimens should be destroyed/marked for destruction in LDMS.</p> <p>This form should only be completed once for each participant, even if a repeat screening pelvic exam is performed.</p> <ul style="list-style-type: none"> • Initial Specimen Collection Date: Record the date that the first specimen(s) 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.
Item-specific Instructions:	
Items 1 and 2:	If the specimen is not stored at this visit, mark the "not stored" box and record the reason why on the line provided.
Item 3:	If the syphilis screening test is reactive, items 3a1 and 3b must be completed.
Item 3a1:	Use leading zeros when recording a syphilis titer level. For example, a titer level of 1:16 would be recorded on the form as "1:0016."
Item 3b:	If a result is positive, provide treatment according to WHO guidelines, and report the relevant infection on the Pre-existing Conditions form.



MTN-020 ASPIRE (192)

SST-1 (033)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">Site Number Participant Number Chk</p>	Initial Specimen Collection Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;"><i>dd</i> <i>MMM</i> <i>yy</i></p>
--	--

Screening STI Test Results					
1. Vaginal Wet Prep	<input type="checkbox"/> Not done <input type="checkbox"/> Go to item 2.	<input type="checkbox"/> Not done/Not collected	Alternate Collection Date <i>dd</i> <i>MMM</i> <i>yy</i> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i>negative</i> <input style="width: 20px; height: 20px;" type="checkbox"/>	<i>positive</i> <input style="width: 20px; height: 20px;" type="checkbox"/>
<input type="checkbox"/> 1a. Homogeneous vaginal discharge					
<input type="checkbox"/> 1b. pH <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> → <i>If > 4.5, mark as positive.</i>		<i>positive</i> <input style="width: 20px; height: 20px;" type="checkbox"/>		
<input type="checkbox"/> 1c. Whiff test					
<input type="checkbox"/> 1d. Clue cells ≥ 20%					
<input type="checkbox"/> 1e. <i>Trichomonas vaginalis</i>					
<input type="checkbox"/> 1f. Buds and/or hyphae (yeast)					
2. <i>Trichomonas</i> Rapid Test	Alternate Collection Date <i>dd</i> <i>MMM</i> <i>yy</i> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>				
			<i>negative</i> <input style="width: 20px; height: 20px;" type="checkbox"/>	<i>positive</i> <input style="width: 20px; height: 20px;" type="checkbox"/>	
3. <i>N. gonorrhoeae</i>	Alternate Collection Date <i>dd</i> <i>MMM</i> <i>yy</i> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>				
			<i>negative</i> <input style="width: 20px; height: 20px;" type="checkbox"/>	<i>positive</i> <input style="width: 20px; height: 20px;" type="checkbox"/>	
4. <i>C. trachomatis</i>	Alternate Collection Date <i>dd</i> <i>MMM</i> <i>yy</i> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>				
			<i>negative</i> <input style="width: 20px; height: 20px;" type="checkbox"/>	<i>positive</i> <input style="width: 20px; height: 20px;" type="checkbox"/>	

Record STI diagnoses on Pre-existing Conditions form when applicable.

Comments: _____

Screening STI Test Results (SST-1)	
Purpose:	This form is used to document Vaginal Wet Prep and other STI Test Results performed at the Screening Visit.
General Information/ Instructions:	<p>Complete this form at the Screening Visit, as results become available.</p> <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:	
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 1b:	Vaginal fluid pH is required at all semi-annual visits and the PUEV.
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.



MTN-020 ASPIRE (192)

SPX-1 (035)

Participant ID <input style="width: 30px; height: 20px;" type="text"/> - <input style="width: 30px; height: 20px;" type="text"/> - <input style="width: 30px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> Site Number Participant Number Chk </small>	Visit Date <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy </small>
--	---

Screening Visit Physical Exam

VITAL SIGNS

1. Weight <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> kg	4. Pulse <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> beats per minute
2. Body Temp <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> . <input style="width: 30px; height: 20px;" type="text"/> °C	5. Respirations <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> breaths per minute
3. BP <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> / <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> mmHg	6. Height <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> cm

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. Abdomen/ Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
9. Neck	<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 as applicable.

Screening Visit Physical Exam (SPX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings at the Screening Visit. This form is faxed to SCHARP only if the participant enrolls in the study.
General Information/ Instructions:	Complete this form at the Screening Visit. If abnormal findings are found in items 7–18 transcribe information onto the Pre-existing Conditions DataFax form.
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 abnormal, specify the body system being referenced and describe the findings on the Notes line.

Seroconverter Laboratory Results (SCR-1)	
Purpose:	This form is used to document MTN-015 enrollment status as well as CD4+ and HIV RNA test results for participants who have been confirmed as HIV-1 infected.
General Information/ Instructions:	<p>Complete this form for participants with a final HIV status of "infected" per the HIV confirmatory Results form. Complete this form at the regularly scheduled MTN-020 visits occurring 1 month, 3 months, 6 months, 12 months, 18 months and 24 months after determination of HIV infection. For example, if a participant's HIV infection is determined between the Month 3 and 4 visits, complete this form at the participant's Month 4, 6, 9, 15, 21, and 27 visits. Complete this form at these timepoints regardless of enrollment into MTN-015.</p> <p>Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax when results for all collected specimens are available and recorded.</p> <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) 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: For every test, mark either the "Not done/Not collected" box or enter a test result.
Item-specific Instructions:	
Item 2a1:	If automatically calculated, record the CD4+ percentage that was reported for the specimen in item 2a. If the CD4+ percentage is not available (was not reported and would have to be manually calculated), mark the "not available" box.
Item 3a:	Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation, regardless of whether the result is more or less than the limit of detection for the assay. Note that the ">" symbol is "greater than" and the "<" symbol is "less than."

Social Impact Log (SIL-1)

Purpose: Complete this form when recording the occurrence, update, and resolution of adverse social impacts reported by participants at any time during the study.

General Information/ Instructions: This form should be completed only when a participant has a negative experience associated with study participation.

Item-specific Instructions:

Page: Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers/ Do not renumber any Social Impact Log pages after faxing, unless instructed by SCHARP.

Item 2: Record the date the negative experience first started. At minimum, a month and year are required.

Item 4: Use the Code List below to code the social impact. Use leading zeros when needed.

Item 7: This item may be updated at subsequent follow-up visits.

Code	Definition
01 Personal Relationships	Had negative experiences with family (excluding partner)
02 Partner Relationships	Had negative experiences with significant other, spouse, or sex partner
03 Personal Relationships – Other	Had negative experiences with friends, neighbors or other community members
04 Travel/Immigration	Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization
05 Employment	Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work
06 Education	Been turned down by an educational program, told to leave an educational program, study visits interfering with school attendance/performance, or experienced other problems at school
07 Medical/Dental	Been refused medical or dental treatment, or treated negatively by a health care provider
08 Housing	Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing
09 Other	Had other problems not covered in the codes above



MTN-020 ASPIRE (192)

SS-1 (149)

Visit Month .

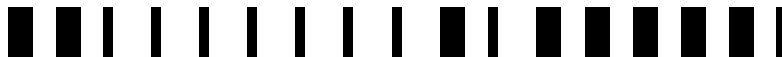
1

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">Site Number Participant Number Chk</p>	Initial Specimen Collection Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">dd MMM yy</p>
--	---

Specimen Storage																																																	
1. Vaginal smear for gram stain:	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;">Alternate Collection Date</td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><i>dd</i></td> <td style="text-align: center; padding: 5px;"><i>MMM</i></td> <td style="text-align: center; padding: 5px;"><i>yy</i></td> <td style="text-align: center; padding: 5px;"><i>not required</i></td> <td style="text-align: center; padding: 5px;"><i>stored</i></td> <td style="text-align: center; padding: 5px;"><i>not stored</i></td> <td style="text-align: center; padding: 5px;"><i>Reason:</i></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="padding: 5px;">_____</td> <td style="padding: 5px;"></td> </tr> </table>	Alternate Collection Date								<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>		<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																									
Alternate Collection Date																																																	
<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>																																											
<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																																											
2. Endocervical swab for biomarkers: 2a. Was blood visible on the swab?	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;">Alternate Collection Date</td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><i>dd</i></td> <td style="text-align: center; padding: 5px;"><i>MMM</i></td> <td style="text-align: center; padding: 5px;"><i>yy</i></td> <td style="text-align: center; padding: 5px;"><i>not required</i></td> <td style="text-align: center; padding: 5px;"><i>stored</i></td> <td style="text-align: center; padding: 5px;"><i>not stored</i></td> <td style="text-align: center; padding: 5px;"><i>Reason:</i></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="padding: 5px;">_____</td> <td style="padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;"><i>yes</i></td> <td style="padding: 5px;"><i>no</i></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"><i>If not required or not stored, go to item 3.</i></td> </tr> </table>	Alternate Collection Date								<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>		<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____		<i>yes</i>	<i>no</i>							<input type="checkbox"/>	<input type="checkbox"/>														<i>If not required or not stored, go to item 3.</i>
Alternate Collection Date																																																	
<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>																																											
<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																																											
<i>yes</i>	<i>no</i>																																																
<input type="checkbox"/>	<input type="checkbox"/>																																																
							<i>If not required or not stored, go to item 3.</i>																																										
3. Quarterly/ semi-annual/PUEVI/ study exit plasma for PK:	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;">Alternate Collection Date</td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><i>dd</i></td> <td style="text-align: center; padding: 5px;"><i>MMM</i></td> <td style="text-align: center; padding: 5px;"><i>yy</i></td> <td style="text-align: center; padding: 5px;"><i>not required</i></td> <td style="text-align: center; padding: 5px;"><i>stored</i></td> <td style="text-align: center; padding: 5px;"><i>not stored</i></td> <td style="text-align: center; padding: 5px;"><i>Reason:</i></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="padding: 5px;">_____</td> <td style="padding: 5px;"></td> </tr> </table>	Alternate Collection Date								<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>		<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																									
Alternate Collection Date																																																	
<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>																																											
<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																																											
4. Used vaginal ring:	<table style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;">Alternate Collection Date</td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><i>dd</i></td> <td style="text-align: center; padding: 5px;"><i>MMM</i></td> <td style="text-align: center; padding: 5px;"><i>yy</i></td> <td style="text-align: center; padding: 5px;"><i>not required</i></td> <td style="text-align: center; padding: 5px;"><i>stored</i></td> <td style="text-align: center; padding: 5px;"><i>not stored</i></td> <td style="text-align: center; padding: 5px;"><i>Reason:</i></td> <td style="padding: 5px;"></td> </tr> <tr> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input style="width: 20px; height: 20px;" type="text"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="text-align: center; padding: 5px;"><input type="checkbox"/></td> <td style="padding: 5px;">_____</td> <td style="padding: 5px;"></td> </tr> </table>	Alternate Collection Date								<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>		<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																									
Alternate Collection Date																																																	
<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>																																											
<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																																											

Comments: _____

Specimen Storage (SS-1)	
Purpose:	This form is used to document collection and storage of vaginal, cervical and PK specimens and used vaginal rings by the local site laboratory during follow-up.
General Information/ Instructions:	<p>Complete this form at each quarterly, semi-annual, the Product Use End Visit (PUEV), early termination (as applicable), and Termination/Study Exit visits.</p> <ul style="list-style-type: none"> • Initial Specimen Collection Date: Record the date that the first specimen(s) 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.
Item-specific Instructions:	
Items 1–4:	If the specimen is not required to be collected at this visit, mark the “not required” box. If the specimen is required to be stored, but for some reason it is not stored, mark the “not stored” box and record the reason on the line provided.



Visit Month .

1

MTN-020 ASPIRE (192)

STI-1 (190)

Participant ID <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"/> <small style="display: flex; justify-content: space-between; font-size: 8px;"> Site Number Participant Number Chk </small>	Initial Specimen Collection Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> dd MMM yy </small>
--	---

STI Test Results					
1. Vaginal Wet Prep	Not done/ Not collected <input type="checkbox"/>	Go to item 2. ←	Alternate Collection Date dd <input type="text"/> <input type="text"/>	MMM <input type="text"/> <input type="text"/> <input type="text"/>	yy <input type="text"/> <input type="text"/>
Not done <input type="checkbox"/> 1a. Homogeneous vaginal discharge	negative <input type="checkbox"/>	positive <input type="checkbox"/>			
Not done <input type="checkbox"/> 1b. pH <input type="text"/> . <input type="text"/> →	If > 4.5, mark as positive.	positive <input type="checkbox"/>			
Not done <input type="checkbox"/> 1c. Whiff test	negative <input type="checkbox"/>	positive <input type="checkbox"/>			
Not done <input type="checkbox"/> 1d. Clue cells ≥ 20%	negative <input type="checkbox"/>	positive <input type="checkbox"/>			
Not done <input type="checkbox"/> 1e. <i>Trichomonas vaginalis</i>	negative <input type="checkbox"/>	positive <input type="checkbox"/>			
Not done <input type="checkbox"/> 1f. Buds and/or hyphae (yeast)	negative <input type="checkbox"/>	positive <input type="checkbox"/>			
2. Trichomonas Rapid Test	Not done/ Not collected <input type="checkbox"/>				Alternate Collection Date dd <input type="text"/> <input type="text"/>
			MMM <input type="text"/> <input type="text"/> <input type="text"/>	yy <input type="text"/> <input type="text"/>	negative <input type="checkbox"/>
			positive <input type="checkbox"/>		
3. <i>N. gonorrhoeae</i>	Not done/ Not collected <input type="checkbox"/>				Alternate Collection Date dd <input type="text"/> <input type="text"/>
			MMM <input type="text"/> <input type="text"/> <input type="text"/>	yy <input type="text"/> <input type="text"/>	negative <input type="checkbox"/>
			positive <input type="checkbox"/>		
4. <i>C. trachomatis</i>	Not done/ Not collected <input type="checkbox"/>				Alternate Collection Date dd <input type="text"/> <input type="text"/>
			MMM <input type="text"/> <input type="text"/> <input type="text"/>	yy <input type="text"/> <input type="text"/>	negative <input type="checkbox"/>
			positive <input type="checkbox"/>		

Complete or update Adverse Experience Log, if applicable.

Comments: _____

STI Test Results (STI-1)	
Purpose:	This form is used to document Vaginal Wet Prep and STI Test Results by the local site laboratory.
General Information/ Instructions:	<p>Complete this form at each semi-annual visit, the Product Use End Visit (PUEV), at early termination (as applicable), and at other visits where these tests are performed during follow-up.</p> <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 1b:	Vaginal fluid pH is required at all semi-annual visits and the PUEV.
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.

Termination (TM-1)	
Purpose:	This form should be completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.
Item-specific Instructions:	
Item 1:	A complete date is required.
Item 2:	Mark only the primary reason for termination.
Item 2a:	Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.
Item 2b1:	At a minimum, the month and year are required.
Item 2l:	Early study closure: Only mark 2l when instructed by SCHARP.
Item 3a:	Record the page number of the Adverse Experience Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the "specify" line.



MTN-020 ASPIRE (192)

VS-1 (121)

Visit Month .

1

Participant ID <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> - <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> - <input style="width: 30px;" type="text"/> <small>Site Number Participant Number Chk</small>	Visit Date <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> / <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> / <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <small>dd MMM yy</small>
---	--

Visit Summary									
1. Location of study visit	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>clinic</i></td> <td style="text-align: center;"><i>home</i></td> <td style="text-align: center;"><i>other, specify:</i></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/> _____</td> </tr> </table>	<i>clinic</i>	<i>home</i>	<i>other, specify:</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____		
<i>clinic</i>	<i>home</i>	<i>other, specify:</i>							
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____							
2. Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">If yes and currently using PEP, complete Product Hold/Discontinuation Log. Record on Concomitant Medications Log.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>yes</i>	<i>no</i>	If yes and currently using PEP, complete Product Hold/Discontinuation Log. Record on Concomitant Medications Log.	<input type="checkbox"/>	<input type="checkbox"/>			
<i>yes</i>	<i>no</i>	If yes and currently using PEP, complete Product Hold/Discontinuation Log. Record on Concomitant Medications Log.							
<input type="checkbox"/>	<input type="checkbox"/>								
3. Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">If no, go to item 4.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>yes</i>	<i>no</i>	If no, go to item 4.	<input type="checkbox"/>	<input type="checkbox"/>			
<i>yes</i>	<i>no</i>	If no, go to item 4.							
<input type="checkbox"/>	<input type="checkbox"/>								
3a. Was oral or topical PrEP used?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>oral</i></td> <td style="text-align: center;"><i>topical</i></td> <td style="text-align: center;"><i>both</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">Record on Concomitant Medications Log.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>oral</i>	<i>topical</i>	<i>both</i>	Record on Concomitant Medications Log.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>oral</i>	<i>topical</i>	<i>both</i>	Record on Concomitant Medications Log.						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>							
4. Is this a PUEV, early termination, or scheduled study termination visit?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">If no, go to item 5.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>yes</i>	<i>no</i>	If no, go to item 5.	<input type="checkbox"/>	<input type="checkbox"/>			
<i>yes</i>	<i>no</i>	If no, go to item 5.							
<input type="checkbox"/>	<input type="checkbox"/>								
4a. Visit Type <i>Mark only one.</i>	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>PUEV</i></td> <td style="text-align: center;"><i>scheduled termination</i></td> <td style="text-align: center;"><i>early termination</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">Go to item 6.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>PUEV</i>	<i>scheduled termination</i>	<i>early termination</i>	Go to item 6.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>PUEV</i>	<i>scheduled termination</i>	<i>early termination</i>	Go to item 6.						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>							
5. Is this an interim visit?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> <td style="border-left: 1px solid black; padding-left: 10px;">If no, go to item 6.</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </table>	<i>yes</i>	<i>no</i>	If no, go to item 6.	<input type="checkbox"/>	<input type="checkbox"/>			
<i>yes</i>	<i>no</i>	If no, go to item 6.							
<input type="checkbox"/>	<input type="checkbox"/>								
5a. Reason for interim visit <i>Mark all that apply.</i>	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>AE report or follow-up</i></td> <td style="text-align: center;"><i>return of ring or need for a new ring</i></td> <td style="text-align: center;"><i>other, specify:</i></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/> _____</td> </tr> </table>	<i>AE report or follow-up</i>	<i>return of ring or need for a new ring</i>	<i>other, specify:</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____		
<i>AE report or follow-up</i>	<i>return of ring or need for a new ring</i>	<i>other, specify:</i>							
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____							
5b. Which forms, besides this form, were newly completed for this interim visit? <i>Mark "none" or all that apply.</i>	<table style="width:100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 5b1. None → End of form. <input type="checkbox"/> 5b2. Adverse Experience Log <input type="checkbox"/> 5b3. Product Hold/Discontinuation Log <input type="checkbox"/> 5b4. Ring Collection/Insertion <input type="checkbox"/> 5b5. Monthly Laboratory Results </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 5b6. Quarterly Laboratory Results <input type="checkbox"/> 5b7. STI Test Results <input type="checkbox"/> 5b8. Pelvic Exam <input type="checkbox"/> 5b9. other, specify: _____ </td> </tr> </table>	<input type="checkbox"/> 5b1. None → End of form. <input type="checkbox"/> 5b2. Adverse Experience Log <input type="checkbox"/> 5b3. Product Hold/Discontinuation Log <input type="checkbox"/> 5b4. Ring Collection/Insertion <input type="checkbox"/> 5b5. Monthly Laboratory Results	<input type="checkbox"/> 5b6. Quarterly Laboratory Results <input type="checkbox"/> 5b7. STI Test Results <input type="checkbox"/> 5b8. Pelvic Exam <input type="checkbox"/> 5b9. other, specify: _____						
<input type="checkbox"/> 5b1. None → End of form. <input type="checkbox"/> 5b2. Adverse Experience Log <input type="checkbox"/> 5b3. Product Hold/Discontinuation Log <input type="checkbox"/> 5b4. Ring Collection/Insertion <input type="checkbox"/> 5b5. Monthly Laboratory Results	<input type="checkbox"/> 5b6. Quarterly Laboratory Results <input type="checkbox"/> 5b7. STI Test Results <input type="checkbox"/> 5b8. Pelvic Exam <input type="checkbox"/> 5b9. other, specify: _____								
After completing item 5b, end of form.									
6. Were any new Adverse Experience Log forms completed for this visit?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	<i>yes</i>	<i>no</i>	<input type="checkbox"/>	<input type="checkbox"/>				
<i>yes</i>	<i>no</i>								
<input type="checkbox"/>	<input type="checkbox"/>								
7. Were any new Product Hold/Discontinuation Log forms completed for this visit?	<table style="width:100%; border: none;"> <tr> <td style="text-align: center;"><i>yes</i></td> <td style="text-align: center;"><i>no</i></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	<i>yes</i>	<i>no</i>	<input type="checkbox"/>	<input type="checkbox"/>				
<i>yes</i>	<i>no</i>								
<input type="checkbox"/>	<input type="checkbox"/>								

Visit Summary (VS-1)	
Purpose:	This form is used to summarize information from each follow-up study visit performed for a participant.
General Information/ Instructions:	This form is completed for each scheduled visit. This form is also completed for interim visits/contacts where a new form (other than the Visit Summary) is completed. Note that there is no Interim Visit form for this study—instead, this form is completed to document interim visits
Item-specific Instructions:	
Visit Month:	<p>Record the visit code assigned to the visit. For required visits (Month 1, Month 2, Month 3, etc.), simply record the visit month during which the visit falls (Month 1 = 01.0, Month 2 = 02.0, etc.). For required monthly, quarterly, and semi-annual visits, the Visit Month will end in 0 (XX.0). If the visit is an interim visit/contact, use an interim code for the Visit Month. Start with the Visit Month of the last required visit and add "1" to the right of the decimal point for each interim visit conducted. For example, if the participant's last required visit was Month 8, the interim visit would be assigned a visit code (Visit Month) of 08.1. If the participant has a second interim visit, this would be assigned a code of 08.2.</p> <p>If procedures for a required visit are split over 2 or more days, and all days are within the same visit window, assign all forms completed for the split visit the same Visit Month (ending in .0). For example, if a participant completes all Month 12 procedures exam pelvic exam procedures on 08-SEP-12, and completes the pelvic procedures on 10-SEP-12, assign a Visit Month of 12.0 to all forms.</p>
Item 1:	If this contact with a participant is over the phone and results in new forms that need to be completed, mark the "other, specify" box and record "phone contact" on the line provided.
Item 2:	If the participant has taken post-exposure prophylaxis (PEP) since her last visit, mark the "yes" box. If the participant is currently using PEP, a Product Hold/Discontinuation (PH) Log must be completed.
Item 3:	Record if the participant has used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV and indicate whether oral or topical PrEP was used. If either or both were used, update the Concomitant Medications (CM) Log.
Item 4:	If the visit completed was a Product Use End Visit (PUEV), early termination, or scheduled study termination visit, mark the "yes" box. If the visit was a typical monthly, quarterly, or semi-annual visit, mark the "no" box. Note that visits where a participant is permanently discontinued from study product for clinical or protocol requirements (HIV seroconversion, for example), this is not a PUEV.
Item 4a:	Mark only one response. If the participant is terminating from the study early (she withdraws consent, for example), this is considered an early termination visit, not a PUEV. Mark scheduled study termination when the visit is the termination/study exit visit, and is being conducted after the completion of a PUEV. Once item 4a is completed, go to item 6 (it is not necessary to complete items 5 or 5a, even if the PUEV/early termination/scheduled study termination visit has an interim visit code).
Item 5b:	Mark the newly-completed forms (in addition to this form) that are being submitted for the interim visit/contact. If "other, specify" is marked, record the form acronyms in the space provided. End the form after completing this item. Leave items 6 and 7 blank for interim visits.
Item 6:	Mark the "yes" box if at least one Adverse Experience (AE) Log was newly-completed for this visit (Visit Month in item 10 of the AE Log is the same as the Visit Month recorded on this form).
Item 7:	Mark the "yes" box if at least one Product Hold/Discontinuation (PH) Log was newly completed for this visit (Visit Month in item 1 of the PH Log is the same as the Visit Month recorded on this form).

MTN-020 Screening Visit LDMS Specimen Tracking Sheet

For login of stored specimens into LDMS

Page 1 of 1

Participant ID <div style="display: flex; align-items: center; gap: 10px;"> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> - <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> - <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 10px; margin-top: 5px;"> Site Number Participant Number Chk </div>			Visit Code 97.0		Specimen Collection Date <div style="display: flex; justify-content: space-around; align-items: center; gap: 10px;"> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 12px; margin-top: 5px;"> <i>dd</i> <i>MMM</i> <i>yy</i> </div>		
# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB ADD/DER	INSTRUCTIONS FOR PROCESSING LAB		
<input type="checkbox"/>	Vaginal Smear for Gram Stain (VAG)	NON	SLD	GRS	Re-label with LDMS label. Make 2 slides. Ship one slide to MTN NL and store other slide on-site.		
<input type="checkbox"/>	Endocervical Swab (CXS)	PBS (400 µL)	CXS	N/A	Place tissue in a cryovial with 400 µL PBS and store at ≤-70°C within 8 hours.		

Comments: _____

Initials: _____ **LDMS Data Entry Date:** / _____
Sending Staff Receiving Staff
dd *MMM* *yy*
LDMS Staff

MTN-020 Screening Visit LDMS Specimen Tracking Sheet

For login of stored specimens into LDMS

Page 1 of 1

Purpose: This non-DataFax form is used to document collection and entry of study specimens into the Laboratory Data Management System (LDMS).

General Information/Instructions: A copy of this form accompanies specimens for storage (in their original specimen collection containers) to the LDMS entry laboratory. Once the specimens have been entered into LDMS, this form is kept on file at the LDMS entry laboratory. If the site chooses, a copy of this completed form may be made once the specimens have been entered into LDMS and the copy kept in the participant's study notebook. This is not required, however. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the specimens were collected.
- **TUBES or SPECIMENS COLLECTED:** In the box provided, record the total number of tubes or specimens collected for that primary specimen type. If no LDMS specimens of the primary specimen type were collected, record "0."
- **Primary Specimen, Primary Additive, and Aliquot Derivative Codes:** See table below for a listing of the codes.

VAG: Vaginal Swab	NON: No Additive
CXS: Cervical Swab	PL1/2: Single or double spun plasma
SLD: Slide	PBS: Phosphate buffered saline
	GRS: Gram Stain Slide

- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials – Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
- **LDMS Data Entry Date – LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.

MTN-020 Enrollment Visit LDMS Specimen Tracking Sheet

For login of stored specimens into LDMS

Page 1 of 1

Purpose: This non-DataFax form is used to document collection and entry of study specimens into the Laboratory Data Management System (LDMS).

General Information/Instructions: A copy of this form accompanies specimens for storage (in their original specimen collection containers) to the LDMS entry laboratory. Once the specimens have been entered into LDMS, this form is kept on file at the LDMS entry laboratory. If the site chooses, a copy of this completed form may be made once the specimens have been entered into LDMS and the copy kept in the participant's study notebook. This is not required, however. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the specimens were collected.
- **TUBES or SPECIMENS COLLECTED:** In the box provided, record the total number of tubes or specimens collected for that primary specimen type. If no LDMS specimens of the primary specimen type were collected, record "0."
- **Primary Specimen, Primary Additive, and Aliquot Derivative Codes:** See table below for a listing of the codes.

BLD: Whole Blood	PL1/2: Single or double spun plasma
EDT: EDTA	VAG: Vaginal Swab
SWB: Swab	NON: No Additive

- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials – Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
- **LDMS Data Entry Date – LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.

MTN-020 Follow-up Visit LDMS Specimen Tracking Sheet

For login of stored specimens into LDMS

Page 1 of 1

Purpose: This non-DataFax form is used to document collection and entry of study specimens into the Laboratory Data Management System (LDMS).

General Information/Instructions: A copy of this form accompanies specimens for storage (in their original specimen collection containers) to the LDMS entry laboratory. Once the specimens have been entered into LDMS, this form is kept on file at the LDMS entry laboratory. If the site chooses, a copy of this completed form may be made once the specimens have been entered into LDMS and the copy kept in the participant's study notebook. This is not required, however. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Note: Cell Pellets will only be rarely collected in ASPIRE. Refer to the SSP for current codes and indicate these on this sheet if sending a Cell Pellet.

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the specimens were collected.
- **TUBES or SPECIMENS COLLECTED:** In the box provided, record the total number of tubes or specimens collected for that primary specimen type. If no LDMS specimens of the primary specimen type were collected, record "0."
- **Primary Specimen, Primary Additive, and Aliquot Derivative Codes:** See table below for a listing of the codes.

BLD: Whole Blood	NON: No Additive	IVR: Intravaginal ring
VAG: Vaginal Swab	SLD: Slide	SWB: Swab
CXS: Cervical Swab	PBS: Phosphate buffered saline	GRS: Gram Stain Slide
EDT: EDTA	PL1/2: Single or double spun plasma	

- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials – Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
- **LDMS Data Entry Date – LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.