

## Section 14. Data Collection

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The purpose of this document is to provide site staff with the information they need to successfully complete and submit MTN 004 case report forms. For questions about this section or about general data collection policies, procedures, or materials, please contact Missy Cianciola (see e-mail addresses listed below).

For this study, the SDMC (Statistical and Data Management Center) is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, USA, and is in the US Pacific Time (PT) time zone. The SCHARP MTN 004 team members, along with their job role and e-mail addresses, are listed in Section 16 of this manual.

### 14.1 DataFAX Overview

DataFAX is the data management system used by SCHARP to receive and manage data collected at study sites. The site faxes an electronic image of each case report form (CRF) to SCHARP DataFAX, and the original hard copy CRF is retained by the site.

#### CRF Transmission

Case report forms can be transmitted to SCHARP in one of two ways: faxed using a fax machine connected to a land phone line (fax to phone number 206.667.4805); or faxed using a fax machine connected to the internet (fax to e-mail <datafax@scharp.org>).

SCHARP's Information Systems Technology (IST) group is available to consult with the site to determine the best method for data transmission. The SCHARP IST group can be contacted via e-mail at support@scharp.org. The SCHARP IST group should also be contacted anytime the site has technical questions or problems with their fax equipment.

#### Data Entry/Quality Control

Once a CRF image is received by SCHARP DataFAX, the following occurs:

- DataFAX identifies the study to which each CRF belongs using the barcode at the top of the form. It reads and enters the data into the study database and stores each CRF on a computer disk.
- Next, each CRF is reviewed by at least two members of SCHARP's Data Operations Group. Problems such as missing or potentially incorrect data are identified and marked with Quality Control notes (QCs).
- QCs are compiled into QC reports that are sent via e-mail to the study site on a regular basis. Sites are asked to correct or clarify any problems identified on the QC reports and refax the corrected CRFs to SCHARP DataFAX.
- When the re-faxed pages are received, SCHARP staff review the corrected pages and resolve the QCs

If a change is made to a CRF but the updated page is not re-faxed to SCHARP DataFAX, the change will not be entered and the study database will continue to contain incomplete or incorrect data. Additionally, if the change was prompted by a QC, the QC will continue to appear on subsequent QC reports until the modified CRF is received at SCHARP. Therefore, it is very important that the site refax updated CRF pages to SCHARP DataFAX **any time** a change is made to a CRF, regardless of whether or not the change was made in response to a QC report.

## 14.2 DataFax Form Completion

### 14.2.1 Guidelines

Based on the use of fax technology and Good Clinical Practices (GCPs), the following guidelines should be used for completing DataFax CRFs:

- Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool. Use only one color per form. That is, do not begin completing a form using a blue pen and then switch to a black pen during the same form completion session.
- Press firmly when recording data or writing comments.
- Print all data and comments legibly by hand. Entries that cannot be read will result in QC notes.
- Do not type data onto CRFs. Do not use cursive/script handwriting, as it can be difficult to read.
- Write numbers as large as possible while staying within the boundaries of the boxes.
- Record data on the front of CRFs only. DataFax cannot read the back of CRFs.
- Do not record data or make marks in the 0.5-inch/1.5-cm margins at the top, bottom, or sides of the CRF.
- If the lines provided for written responses are not long enough, continue in another blank area of the form (within the page margins).
- Mark only one answer except when given the instruction “Mark all that apply.”
- A response is required for every item unless instructed otherwise by a skip pattern.
- **Never** obscure, mark over, or punch holes through the barcode at the top of each CRF. DataFax requires the barcode to identify the CRF.
- **Never** use correction fluid (“white-out”) or correction tape on CRFs.
- Remove any paper clips, staples, or other attachments before faxing CRFs.
- The site staff person who initially completes the form **must** record his/her initials **and** the date in the space provided in the bottom right-hand corner of each CRF page.
- Fax forms as soon as possible after they have been completed and reviewed. Ideally, completed forms will be faxed to SCHARP within 1–2 days of completing the visit, though up to 5 days is allowed.

### 14.2.2 How to Mark Response Boxes

Many items on DataFax CRFs have a box or series of boxes for recording a response. Mark the box clearly with an **X**. Do not fill in the box with shading or mark it with a slash or other character.

**Correct:**



**Incorrect:**



Mark only one response box for each item unless the “Mark all that apply” instruction is present.

### 14.2.3 How to Record Numbers

Some questions on DataFax CRFs include boxes for recording a numeric response. DataFax can only read the numbers in these boxes if they are recorded clearly. The following instructions should be followed when recording numeric responses:

- Right justify **all** numbers and fill in any blank leading boxes with zeroes. If boxes are left blank, a QC note will be applied asking for the boxes to be filled in.

The following example shows how a value of 7 is recorded when three response boxes are provided:

**Correct:**

0 0 7

**Incorrect:**

□ □ 7

→ This example would result in a QC note.

- Write the number(s) as large as possible while staying within the boundaries of the box; try not to stray outside the boundaries of the box.

In the following example, the 4 could be misinterpreted as a 7 or a 1 because DataFax can only read what is *inside* the box:

**Correct:**

4

**Incorrect:**

4

- Write the number(s) simply, with few loops.

The following example shows the format in which numbers will be most easily read by DataFax. Also included are some commonly used formats that may be difficult for DataFax to identify.

**Easily Identified:**

0 1 2 3 4 5 6 7 8 9

**Difficult to Identify:**

ø 1 2 3 4 7

### 14.2.4 How to Record Dates

Dates are recorded using the “dd MMM yy” format, where “dd” represents the two-digit day, “MMM” represents the three-letter abbreviation of the month (in capital letters), and “yy” represents the last two digits of the year.

The month field must be filled in with the three-letter abbreviation *in English* for the date to be read in DataFax. Abbreviations are shown below:

Month	Abbreviation	Month	Abbreviation
January	JAN	July	JUL

Month	Abbreviation	Month	Abbreviation
February	<b>FEB</b>	August	<b>AUG</b>
March	<b>MAR</b>	September	<b>SEP</b>
April	<b>APR</b>	October	<b>OCT</b>
May	<b>MAY</b>	November	<b>NOV</b>
June	<b>JUN</b>	December	<b>DEC</b>

For example, June 6, 2008 is recorded as:

0	6	J	U	N	0	8
<i>dd</i>		<i>MMM</i>			<i>yy</i>	

Sometimes, only a month and a year are required (e.g., diagnosis date for a pre-existing condition), in which case the response boxes will look like this:

<i>MMM</i>			<i>yy</i>	

A diagnosis date of October, 2008 would be recorded as follows:

O	C	T	0	8
<i>MMM</i>			<i>yy</i>	

### 14.2.5 How to Record Time

Time is recorded on DataFax CRFs using the 24-hour clock (00:00-23:59), in which hours are designated from 0–23. For example, in the 24-hour clock 2:25 p.m. translates to 14:25 (2 p.m. = 14), which would be recorded as follows:

1	4	:	2	5
<i>hr</i>			<i>min</i>	

Midnight is recorded as 00:00, not 24:00.

The following chart shows equivalencies between the 12- and 24-hour clocks:

12-hour clock (a.m.)	24-hour clock	12-hour clock (p.m.)	24-hour clock
Midnight	00:00	Noon	12:00
1:00 a.m.	01:00	1:00 p.m.	13:00
2:00 a.m.	02:00	2:00 p.m.	14:00
3:00 a.m.	03:00	3:00 p.m.	15:00
4:00 a.m.	04:00	4:00 p.m.	16:00
5:00 a.m.	05:00	5:00 p.m.	17:00
6:00 a.m.	06:00	6:00 p.m.	18:00
7:00 a.m.	07:00	7:00 p.m.	19:00
8:00 a.m.	08:00	8:00 p.m.	20:00
9:00 a.m.	09:00	9:00 p.m.	21:00
10:00 a.m.	10:00	10:00 p.m.	22:00
11:00 a.m.	11:00	11:00 p.m.	23:00

## 14.2.6 Data Corrections and Additions

Sometimes, data on a DataFax CRF may need to be changed, clarified, or amended. There are many reasons why data may need to be changed, such as in response to a QC report or as a result of site review of the CRF before faxing.

It is important to make these changes to the original CRF—*never* copy data onto a new form. After making the change, the CRF *must* be re-faxed to SCHARP DataFax.

**Note:** If a correction or addition is made to one page of a multiple-page CRF, only refax the page that was changed.

**Note:** Never write over an entry once it is recorded. Use the standards outlined in the following paragraphs when changing, clarifying, or amending data.

Whenever an entry on a DataFax CRF is changed, do the following:

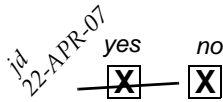
- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it unreadable with multiple cross-outs)

- place the correct or clarified answer near the box, and initial and date the correction as shown below:



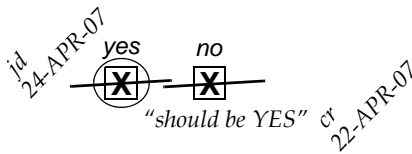
If an **X** is marked in the wrong response box, correct it by doing the following:

- draw a single horizontal line through the incorrectly marked box
- mark the correct box, and
- initial and date the correction as shown below:



If the correct answer has previously been crossed out, do the following:

- circle the correct item
- write an explanation in the white space near the item, and
- initial and date all corrections as shown below:

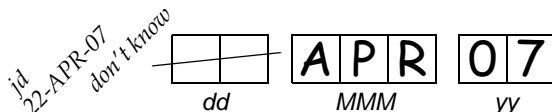


The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is faxed to SCHARP for the first time.

### 14.2.7 How to Handle Missing and Unknown Data

If the answer to an item is not known, is not available, or if the participant refuses to answer, draw a single horizontal line through the blank boxes and initial and date the item. It is helpful to write “don’t know,” “refuses to answer,” “UNK” (unknown), “N/A” (not applicable), or “REF” (refused) near the blank boxes.

For example, when recording a date, if the exact day is not known, draw a single horizontal line through the “dd” boxes and write “don’t know” next to the response boxes, as shown below:



A skip pattern is the **only** valid reason to leave a response blank. Initials and date are required for any data item that is refused, missing, unknown, or not applicable, regardless of whether it is marked as such during the initial form completion, or as an update to the form.

## 14.3 MTN 004 Study-Specific Data Collection Information

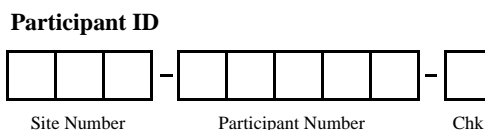
### 14.3.1 Participant ID numbers (PTIDs)

DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. SCHARP provides each site with a list of PTIDs prior to study start-up. The site should assign one PTID to each participant enrolled in the study. The PTIDs are assigned in sequential order as participants screen for the study. The site should ensure that each PTID is assigned only once. Once a participant has received a PTID, she maintains that same PTID throughout the entire study.

PTID boxes are located near the upper left corner of each CRF page.

Site staff are responsible for maintaining a log linking PTIDs to participant names (PTID-Name Link log) in accordance with Section 3 of this manual.

The PTIDs used for this study are nine digits and formatted as “XXX-YYYYY-Z.” The PTID consists of three parts: the site number (XXX), the participant number (YYYYY), and a numerical check digit (Z). The check digit (Z) is a number generated by SCHARP with the participant number, and helps ensure that the correct PTID is recorded. Below is an example of the PTID structure used in MTN 004.



### 14.3.2 Study Visit Timing

#### Screening Attempt

Each time a participant screens (each time she provides written informed consent for screening), it is called a *screening attempt*. Because sites have 36 calendar days to complete screening and enrollment procedures, the visit dates/specimen collection dates on forms completed as part of the same screening attempt may be different from each other. The 36-day screening attempt “clock” starts on and includes the day the consent form for screening is signed or marked by the participant.

#### Multiple Screening Attempts (Re-screens)

If a participant’s screening attempt is unsuccessful, she may re-screen for the study if she chooses. If she does re-screen, ALL screening procedures (except PTID assignment), evaluations, and forms must be repeated, including signing of the written informed consent for screening.

#### Completion of Required Follow-Up Visits

Required follow-up visits are regularly scheduled every week throughout the three-week study follow-up period. Per protocol, study visits should be completed within the protocol-specified visit windows. However, there may be cases when a regularly scheduled visit is made up outside of the visit window. A regularly scheduled follow-up visit is considered “missed” when a participant does not complete any of the required visit evaluations, and the next visit window has opened. For example, a participant has a One-Week Clinic Visit target date of 17-APR-07 (visit window 16-APR-07 to 18-APR-07). Her Two-Week Clinic Visit window opens 23-APR-07, and the participant does not come into the clinic until 24-APR-07 for her scheduled Two-Week Clinic Visit. Since the participant did not complete the One-Week Clinic Visit within the visit window AND did not make up the missed One-Week Clinic Visit before the Two-

Week Clinic Visit window opened (23-APR-07), the One-Week Clinic Visit is considered “missed.” A Missed Visit form is completed and faxed to SCHARP to document the “missed” visit.

### Interim Visits

A clinic visit is considered an Interim Visit when a participant presents at the site for additional clinical/laboratory/pharmacy assessments and/or procedures *outside* of the required evaluations for a scheduled study visit. The following are examples of interim visits for MTN 004:

1. A participant completes all required evaluations for a scheduled study visit within the visit window. She then returns to the site clinic within the same visit window to request replacement study gel cartons for lost study gel.
2. A participant completes all required evaluations for a scheduled study visit within the visit window. She then returns to the clinic outside the visit window to request a pregnancy test.
3. A participant completes all required evaluations for a scheduled study visit outside the visit window (the visit is made up late, after the visit window has closed). She then returns to the clinic 48-72 hours after the visit (still outside the visit window) for a repeat pelvic exam and clinical follow-up of superficial epithelial disruption (abrasion/peeling) noted during the visit pelvic exam.
4. A participant completes all required evaluations for a scheduled study visit outside the visit window (the visit is completed early, before the window has opened, due to participant travel during the visit window). She then returns to the clinic after the visit window has closed (and before the next visit window has opened) to report intermenstrual bleeding.

Phone contact with a participant is also considered an Interim Visit if the phone contact results in reporting of a new Adverse Experience (AE).

- Example: A participant’s One-Week target visit date is 17-APR-07. She completes all required evaluations for the visit on 16-APR-07. On 18-APR-07 she calls the clinic to report new symptoms, which result in the reporting of a new adverse experience. Although she is still within the visit window (16-APR-07 to 18-APR-07), she has already completed all the required One-Week Visit evaluations. Thus, the 18-APR-07 phone contact is assigned an Interim Visit code.
- Example: A participant’s Two-Week target visit date is 24-APR-07. She completes all required evaluations for the visit on 25-APR-07. On 28-APR-07 she calls the clinic to report new symptoms which result in the reporting of a new adverse experience. Since she already completed all the required visit evaluations, and since the Three-Week Visit window has not yet opened, the 28-APR-07 phone contact is assigned an Interim Visit code.

**Note:** Study visits conducted early, before a visit window opens (e.g., due to anticipated travel by the participant during the visit window), or made up late, after a visit window has closed, are not considered Interim Visits. Such visits should be coded using the scheduled study visit code (One-Week=03.0, Two-Week=04.0, etc.). All forms that document required evaluations for a given study visit should be coded using the scheduled study visit code, regardless of whether the visit takes place within the visit window or outside the visit window (early or late). For example, forms documenting all required One-Week Clinic Visit procedures should be coded “03.0,” regardless of whether the required procedures are conducted within or outside the visit window. Consequently, additional visits required to complete scheduled study visit procedures (e.g., because a participant must leave the site before all procedures can be performed) are not considered Interim Visits. Such “split” visits also should be coded using the same scheduled study visit code.

For questions about phone contacts and assignment of visit codes to such contacts, please contact the SCHARP MTN 004 Project Manager.



### 14.3.3 Visit Codes and Page Numbers

Some DataFax CRFs will include boxes in the upper right corner for a visit code. DataFax uses the visit code to identify the visit at which a CRF is completed. However, not all DataFax CRFs include boxes for visit codes. If a form is only completed once during a study (for example, the Enrollment form, the Termination form), the visit code will be automatically assigned in DataFax.

MTN 004 has six scheduled study visits. When visit code boxes are provided, site staff are responsible for entering the visit code in the boxes provided in the upper right corner of each page.

The following table lists visit type, timing, and DataFax visit codes for each visit.

**Table 14-1: Visit Timing and Visit Codes**

Visit Type	Timing	Visit Code
Screening 1	Up to Day -36	01.0
Screening 2	Up to Day -36	01.0
Enrollment	Day 0	02.0
One-Week Visit	Day 6-8	03.0
Two-Week Visit	Day 13-15	04.0
Three-Week Visit	Day 20-24	05.0

#### Visit Codes for visits that occur over more than one calendar day

In cases when a participant absolutely cannot complete all required visit evaluations in one day (for example, she is menstruating and a pelvic/colposcopy exam cannot be performed), complete as many of the required evaluations as possible. Schedule the participant for another visit to conduct the remaining required evaluations as soon as possible, and preferably within the visit window. Note that when the participant returns to complete the remaining required evaluations, these are still considered part of her regular visit (regardless of whether or not they occur within visit window); therefore, the forms completed for these remaining evaluations should be assigned the same regular visit code as the previous visit.

- Example: A participant's Two-Week Clinic Visit target date is 24-APR-07 (visit window is 23-APR-07 to 25-APR-07). The participant comes to the clinic on 23-APR-07 for her Two-Week Clinic Visit and is on her menses. On 23-APR-07 (Visit Code = 04.0), complete all study visit evaluations except the pelvic exam and pelvic laboratory assays. Instruct the participant to come back to the clinic on 26-APR-07 (when menses is expected to have ended) to complete the required pelvic exam and pelvic laboratory assays. The forms completed at the 26-APR-07 visit are assigned the same Two-Week Visit Code as the 23-APR-07 forms (Visit Code = 04.0), since the required evaluations for the Two-Week Clinic Visit were conducted on both dates.

#### Visit codes for interim visits

In addition to the scheduled, protocol-required visits listed in Table 14-1, interim visits may occur once the participant is enrolled (see Section 14.3.2 for a definition and examples of interim visits). Interim visit codes are assigned using the following guidelines:

- In the boxes to the left of the decimal point, record the two-digit visit code for the most recent scheduled visit (whether that visit was completed or missed).
- Use the guide below to complete the box to the right of the decimal point:
  - ##.1 = the first interim visit after the most recent scheduled visit,
  - ##.2 = the second interim visit after the most recent scheduled visit,
  - ##.3 = the third interim visit after the most recent scheduled visit, and so on.

Example #1: A participant returns to the site clinic two days after she has completed her One-Week Clinic Visit (Visit Code = 03.0). The visit window of her Two-Week Clinic Visit has not yet opened. For this interim visit, record the following visit code:

**Visit Code for this Interim Visit:**

Visit Code   .

Example #2: A participant returns to the site clinic again two days after her 03.1 interim visit (described in Example #1). The visit window for her Two-Week Clinic Visit has not yet opened. Record the following visit code:

**Visit Code for this Interim Visit:**

Visit Code   .

### Page numbers

Other CRFs, such as log forms (e.g., Adverse Experience Log or Concomitant Medications Log), may include boxes in the upper right corner for page numbers, as shown below:

Page

In the example of the Adverse Experience Log, the participant's first adverse experience would be reported as page 01, the second would be 02, and so on.

### 14.3.4 Staff Initials/Date

Most forms include a line in the lower-right corner for a staff member's initials and the date on which the form was completed. When more than one staff member records data on a CRF, the site should designate the staff member who has primary responsibility for the form. This individual completes the staff initials/date field. The individual not identified in the staff initials/date field writes his/her initials and date next to each data element for which he/she is responsible.

### 14.3.5 Case Report Form Completion Schedule

The SCHARP-provided case report forms for this study include DataFax forms (forms that are completed and faxed to SCHARP DataFax) and non-DataFax forms (forms that are completed but **not** faxed to SCHARP DataFax).

Some SCHARP-provided forms are required to be completed at each visit, while other forms are required only at one visit or only when specifically indicated. The following table (Table 14-3) lists the DataFax and non-DataFax forms that are **required** to be completed at each study visit.

**Table 14-2: MTN 004 Case Report Form Completion Schedule**

Visit	Visit Code	Forms	Form Acronym
Screening 1	1.0	Screening Consent Demographics Screening 1 and Enrollment Pelvic Exam Pelvic Laboratory Results Safety Laboratory Results STI Laboratory Results Concomitant Medications Log (non-DataFax) Baseline Medical History (non-DataFax) History of Genital Symptoms (non-DataFax) Physical Exam (non-DataFax) Pelvic Exam Diagrams (non-DataFax) Screening 1 Visit Eligibility (non-DataFax) Clinical Eligibility (non-DataFax) Screening Summary (non-DataFax) LDMS Specimen Tracking Sheet	SC-1 DEM-1 SPE-1 thru SPE-2 PLR-1 SL-1 thru SL-2 SLR-1 thru SLR-2 CM-1 N/A 2 pages N/A N/A N/A N/A 4 pages N/A N/A 2 pages N/A
Screening 2	1.0	(non-DataFax) Screening 2 Visit/Enrollment Eligibility	N/A 2 pages
Enrollment	2.0	Family Planning Methods Baseline Genital Symptoms Screening 1 and Enrollment Pelvic Exam Pelvic Laboratory Results Safety Laboratory Results Pre-existing Conditions Enrollment Pharmacokinetics (non-DataFax) Physical Exam (non-DataFax) Pelvic Exam Diagrams (non-DataFax) Clinical Eligibility (non-DataFax) LDMS Specimen Tracking Sheet	FPM-1 BGS-1 SPE-1 thru SPE-2 PLR-1 SL-1 thru SL-2 PRE-1 ENR-1 PK-1 N/A N/A N/A N/A

**Table 14-2: MTN 004 Case Report Form Completion Schedule**

<b>Visit</b>	<b>Visit Code</b>	<b>Forms</b>	<b>Form Acronym</b>
One-Week Clinic Visit	3.0	Follow-Up Visit Family Planning Methods StudyGel Adherence Follow-up Genital Symptoms Follow-up Pelvic Exam Pelvic Laboratory Results Safety Laboratory Results (non-DataFax) Follow-Up Medical History (non-DataFax) Physical Exam (non-DataFax) Pelvic Exam Diagrams (non-DataFax) LDMS Specimen Tracking Sheet	FV-1 FPM-1 SGA-1 FGS-1 FPE-1 thru FPE-3 PLR-1 SL-1 thru SL-2 N/A 2 pages N/A N/A N/A
Two-Week Clinic Visit	4.0	Follow-Up Visit Family Planning Methods Study Gel Adherence Acceptability Assessment Follow-up Genital Symptoms Follow-up Pelvic Exam Pelvic Laboratory Results Safety Laboratory Results Pharmacokinetics (non-DataFax) Follow-up Medical History (non-DataFax) Physical Exam (non-DataFax) Pelvic Exam Diagrams (non-DataFax) LDMS Specimen Tracking Sheet	FV-1 FPM-1 SGA-1 AA-1 thru AA-2 FGS-1 FPE-1 thru FPE-3 PLR-1 SL-1 thru SL-2 PK-1 N/A 2 pages N/A N/A N/A
Three-Week Clinic Visit	5.0	Follow-Up Visit Family Planning Methods Follow-up Genital Symptoms Follow-up Pelvic Exam Pelvic Laboratory Results CASI Tracking Termination End of Study Inventory (non-DataFax) Follow-up Medical History (non-DataFax) Physical Exam (non-DataFax) Pelvic Exam Diagrams (non-DataFax) LDMS Specimen Tracking Sheet	FV-1 FPM-1 FGS-1 FPE-1 thru FPE-3 PLR-1 CT-1 TM-1 ESI-1 N/A 2 pages N/A N/A N/A

**Table 14-2: MTN 004 Case Report Form Completion Schedule**

Visit	Visit Code	Forms	Form Acronym
If Indicated	Will Vary	Follow-up Pelvic Exam Pelvic Laboratory Results Safety Laboratory Results STI Laboratory Results HSV-2 Culture Adverse Experience Log Interim Visit Product Hold/Discontinuation Genital Bleeding Assessment HIV Test Results Pregnancy Report and History Pregnancy Outcome Missed Visit (non-DataFax) Physical Exam (non-DataFax) Pelvic Exam Diagrams (non-DataFax) Specimen Tracking Sheet	FPE-1 thru FPE-3 PLR-1 SL-1 thru SL-2 SLR-1 thru SLR-2 HSR-1 AE-1 IV-1 PH-1 GBA 1-3 HTR-1 PR-1 PO-1 MV-1 N/A N/A N/A

### 14.3.6 Site Review of DataFax Forms

Each form must be reviewed for completeness and legibility before being faxed to SCHARP DataFax. As part of the review, the site should check the following:

- Other than the participant ID number (PTID), there is no information on the form that could identify the participant (e.g., name, phone number, national identification number, or any other personal identifiers).
- A response has been recorded for each item, unless the item was skipped as instructed by a skip pattern or the item was marked as missing or unknown as described in 14.2.7.
- All text responses are clearly recorded.
- There are no marks on or above the DataFax barcode at the top of each DataFax page.
- There are no:
  - missing dates,
  - missing visit codes,
  - incorrect PTIDs,
  - incorrect visit codes,
  - missing data for items beginning a series of skip patterns, and/or
  - inconsistent or discrepant data.

While CRFs are being reviewed, it is important that they are stored and tracked systematically. It is also necessary to have a system to identify whether a CRF has been faxed to SCHARP DataFax. Such a system may include using a stamp to date the back of the CRF, or utilizing the SCHARP CRF Tracking System (see SSP Section 14.3.7 for more information).

**Important:** If a date stamp is used to document when the form is faxed, stamp *only* the back of the CRF, *never* the front. Be sure to date stamp the back of the CRF each time it is faxed, including refaxes.

### 14.3.7 Faxing DataFax Forms

To streamline the submission of DataFax forms, the site should identify which staff members will be responsible for faxing forms to SCHARP DataFax and receiving and responding to QC reports.

It is important that the sites fax completed DataFax CRFs to SCHARP within the time period specified in the site's MTN 004 Data Management SOP, and that they respond promptly to requests for clarifications and corrections included in QC reports. Early detection of recurrent problems provides an opportunity to reduce errors and improve data quality.

For sites wishing to confirm the receipt of faxed forms at SCHARP, the CRF Tracking System (CTS) is available. This system generates two types of e-mails listings: 1) the number of form pages received at SCHARP; and 2) which specific forms were received at SCHARP for a given PTID and visit. Please contact the MTN 004 Project Manager if you would like to use the CRF Tracking System or for more information about the CRF Tracking System.

### 14.3.8 Non-DataFax Forms

MTN 004 sites will receive non-DataFax forms from SCHARP. These forms will be easily identifiable because there will not be a DataFax barcode along the top of the CRF. In place of the barcode, the following text will appear: "NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX."

These forms should **not** be faxed to SCHARP DataFax. Instead, they should be kept in the participant's file as a record of the activities recorded on the form. The form completion guidelines described in sections 14.3.1 through 14.3.4 should be applied when completing non-DataFax CRFs as well.

## 14.4 Form Supply and Storage

### 14.4.1 Form and Specimen Label Supply

All case report forms needed for the study will be provided by SCHARP. Forms will be supplied using form visit packets, where the packet contains all of the required CRFs for the visit. For example, the Screening Visit packet will include all of the CRFs listed for this visit in the Case Report Form Completion Schedule table (table 13-3). In addition for form packets for each visit listed in Table 13-3, bulk supplies of "as needed" CRFs will be provided to the site (for example, Pregnancy Report and History, Pregnancy Outcome, Genital Bleeding Assessment, etc.).

SCHARP will also ensure sites have access to specimen labels (either printed on-site or printed by SCHARP). Specimen labels should be used for all primary specimen collection containers. Customized PK labels for use on PK specimen primary collection containers will also be provided. Please refer to the Laboratory section of the manual for more information on laboratory specimen collection and labeling.

## 14.4.2 Form Storage

Specifications for form storage will be detailed in the site's MTN 001 Data Management SOP. It is recommended that for each participant, study CRFs be stored in a hard-cover notebook. SCHARP can provide a template for use in creating notebook cover labels and spine labels. SCHARP can also provide a template that can be used to create tab dividers.

It is suggested that Concomitant Medications Log forms, Adverse Experience Log forms, and Product Hold/Discontinuation forms be kept in their own tabbed sections within the participant study notebook. This makes page numbering and updating of these forms easier than if these forms are stored by visit within the participant's study notebook.

## 14.5 How to Complete Interviewer-administered Forms

In order to standardize interviewer-administered data collection from site to site and to maximize quality, it is critical that participant interviews be conducted with a non-biased, non-judgmental approach. Study staff should help a participant feel comfortable sharing personal information and opinions while asking the study questions in a consistent manner from participant to participant.

### Interviewing Techniques

An interviewer uses both verbal and non-verbal techniques to obtain the most honest, accurate, and thorough responses from participants. These techniques are discussed in the sections below.

### Welcoming the Participant

- When a new participant arrives at the clinic, everything about the study is new. Help make the participant feel comfortable.
- Perhaps offer the participant a glass of water or other beverage.
- Introduce yourself, and try to create rapport (connection) between yourself and the participant to help her feel comfortable during the interview.
- Some DataFax forms include introduction statements before certain items to help prepare the participant for sensitive questions. Read each of these introductions as they appear on the forms.

### Asking Sensitive Questions

This study is about a very sensitive subject: HIV. Gaining an understanding of sexual behavior patterns can affect the transmission of HIV and the development of prevention methods.

Your level of comfort with asking sensitive questions will affect the participant's comfort and answers. If you ask the questions in a confident and supportive manner, the participant will feel more confident and comfortable answering the questions. Make eye contact with the participant to let her know that you are listening to her and aware that she is being asked difficult questions. Avoid apologizing for questions or making facial gestures that might show you feel any way but neutral about a question or the participant's response. If the participant feels judged for her behavior, she will be less likely to share honestly with you.

### Recording Participants' Responses Verbatim

Often, interviewer-administered questions will have a list of response categories provided to capture the participant's response. Almost always, an "other, specify" box is included as one of the response categories in order to capture participant responses that do not fit into one of the categories already listed. When a

participant's response does not match or fit into one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "Local Language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, go back and translate the text recorded on the "Local Language" line into English, and record the English translation of the response on the "English" line. If the participant's response was in English originally, leave the "English" line blank.

### **Pacing the Interview**

Every participant is different. Some will know or say the answer to questions very quickly. Others may have to think longer to come up with answers, or may change their answers after giving more thought to the subject. Always account for this variety when doing an interview. Read items slowly. Let the participant finish thinking before you record her response and go on to the next item.

### **Reading Items Aloud**

Read all items to the participant **word-for-word**, and speak clearly. Avoid re-phrasing items because this can change the meaning of the item, making it inconsistent with another participant's interview. Provide explanation or interpretation if necessary only after reading the item word-for-word. Avoid tangential—though related—counseling and educational discussions during data collection. When applicable, acknowledge questions and concerns raised by the participant during the interview, and state that the subject can be discussed after the end of the interview.

Vary your tone of voice, so that you don't sound automated. Emphasize the important words in an item, so that the meaning of the question comes through.

When given the option, choose "clinical" versus "street" or "vernacular" language based on participant preferences/cues.

For items with multiple sub-items, read all sub-items to the participant and mark the appropriate response for each, based on participant report.

### **Probing**

One of the major goals of the study's interviews is to obtain accurate information on many HIV related behaviors. These interviews ask participants to recall many aspects of personal behaviors. However, participants may not remember or know the answer to every question. The technique for helping a participant remember an answer, clarify a response, decide between two similar but different answers, or report something more precisely is called "probing."

Effective probing helps a participant think more about a question or refine an answer that is too general, however, probing must not bias or otherwise direct participant responses. As the interviewer, you cannot offer the participant an answer. Therefore, all probes must be neutral.

The following are some probing strategies to use when a participant initially answers "don't know" to an item or cannot refine her response enough for the item to be adequately recorded.

- **Repeat Probe:** The repeat probe is used by repeating the item or response categories (if the response categories are part of the question). Although the participant might hear you the first time you ask a question, she may need to hear the question more than once to provide an answer. Instead of rephrasing a question if you notice the participant is confused, always first repeat the item as it is written. Sometimes hearing the question a second time is all that is needed.
- **Echo Probe:** The echo probe involves repeating the participant's exact response. Sometimes hearing the answer with a different voice will help her be more precise. The echo should always be repeated in a neutral, non-judgmental style.



- **Silent Probe:** The silent probe is used by pausing briefly after a participant gives what seems to be an uncertain answer. Although silence can feel awkward, sometimes it is helpful when a participant is trying to determine the most accurate answer to a question. Use a silent probe when the participant sounds unsure of her answer and may need some extra time to think more carefully about the question.
- **Non-verbal Probe:** The non-verbal probe is used by giving hand or facial gestures that may help the participant to come up with an answer. Remember that all such gestures must be neutral and non-judgemental.
- **Specification Probe:** The specification probe is used by asking the participant to give a more precise answer. Although a participant may give an answer that he or she considers accurate, it may not be specific enough. For example, if an item asks how many times the participant did something and she answers with a range (“5 to 10”). Ranges are not acceptable for this type of interviewing. In this case, the probe, “Can you be more specific?” is often enough to help the participant choose the most accurate response.
- **Historical Probe:** The historical probe is used by asking whether the event in question occurred anytime around major holidays or personal events such as a birthday or other life event. Some items require the participant to recall dates, and initially she may be unable to recall a date. Referencing a calendar can also help the participant remember dates.

### Watching for Non-verbal Cues

A participant may give you one answer verbally, but express something else using body language or facial expressions. Although you should not question a participant so as to make her feel like you don't trust her answers, be aware of whether she is giving you non-verbal cues that indicate she is not feeling comfortable, not taking the interview seriously, or not answering honestly.

### Checking Your Work

During the interview it is important to use the forms instructions (those on the front and back of each page) to guide the interview. Also, make sure the participant is understanding and responding to you, and record all reported information on the forms. **After the interview and while the participant is still there**, review the forms for accuracy and completeness so you can complete an item that might have accidentally been missed. **Once the participant has left, any items identified as missed must remain as is and will be considered “missing data”**. Because all interviewer-administered CRFs are source documents (with the participant being the source of the data), missing items cannot be completed once the participant has left the clinic. For items identified as “missed”, please line through the item and write “item missed in error” in the white space next to the item, and initial and date.

## 14.6 Form Completion Instructions

Detailed form completion instructions for each form are provided on the back of each form page. These instructions include the purpose of each form as well as how each form should be completed. Some items on forms are straightforward and do not require specific instructions. Therefore, you will not see all form items listed in the form-specific completion instructions, but rather, only those items needing detailed explanation.

Below are some additional instructions for the **Pre-existing Conditions**, **Concomitant Medications Log**, and **Adverse Experience Log** case report forms.

### Pre-existing Conditions and Concomitant Medication Log

- For the Pre-existing Conditions and Concomitant Medication Log forms, note that you should fax each page to SCHARP any time a new entry is added or modified, even if the page is not complete. You should **not** wait to complete all entries on a page before faxing to SCHARP.

### Adverse Experience Log (AE Log)

- For the Adverse Experience Log form, do **not** wait until the AE resolves before faxing the form page to SCHARP. In most cases, when you first report the AE on an AE Log form, the AE will have a “continuing” status (form item 6). Once the AE resolves (the AE resolves, the AE is grade 5 - death, or the AE increases in severity/frequency), update item 6 and 6a of the **original** AE Log form page. Initial and date all additions, and refax the form page to SCHARP.
- Always make changes, corrections, and updates to the **originally-completed** Adverse Experience Log form page. Once an AE Log form page has been started and faxed to SCHARP, the data from that page should **never** be transcribed onto another AE Log form page. All updates and corrections should be made to the originally-completed form page (regardless of how messy or crowded the form page becomes).
- For item 1, note that planned procedures or surgeries are **not** AEs. For example, a tonsillectomy is not an AE, and should not be reported as an AE. Any adverse experiences associated with the planned procedure or surgery are AEs and should be reported on an AE Log form. For example, a throat infection that resulted from the tonsillectomy is a reportable AE.
- Note that for **item 3**, the Female Genital Grading Table for Use in Microbicide Studies (Female Genital Tox Table) will be used to assign severity grades to AEs (in addition to the DAIDS “Tox Table”). The Female Genital Tox Table is Appendix V of the protocol. For **item 4**, note that if “not related” is marked, you need to record the reason the AE is determined to be “not related” in the Comments field of the form. For example, for an AE of headache that is judged “not related”, the Comments entry may be something like “#4 - not related in time to this AE onset”.
- For **item 5**, mark “no change” if the AE does not result in a product hold or discontinuation.
- For **item 7**, note that if the AE results in a new or prolonged hospitalization, the AE meets the criteria for “serious” and item 8 of the AE Log form should be marked “yes”.
- There may be a situation where an AE reported on an Adverse Experience Log form needs to be deleted (in the case where the AE is later found to actually be a pre-existing condition, for example). To indicate an AE Log page should be deleted, draw a diagonal line across the entire form page, write “delete due to \_\_\_\_\_” (include the reason the AE is being deleted), and initial and date. Refax the form to SCHARP. Do **not** reassign the page number assigned to the deleted AE to another AE, and do not renumber the other AE Log pages present for the participant.
- For **item 10**, note that the Visit Code recorded is the same visit code assigned to the visit date in the “Date Reported to Site” field.

## 14.7 Case Report Forms

This section contains each MTN 004 case report form developed for the study. Detailed form completion instructions for each form are provided on the back of each form page.

Use the Visit Checklist developed for the visit for a suggested order in which the forms should be completed at each visit.

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**SAMPLE**. DO NOT FAX  
TO DATAFAX

MTN 004 (136)



SC-1 (005)

**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"/>	
Site Number				Participant Number						Chk	

**Screening Consent**

**Visit 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"/>
dd		MMM			yy		

1. Is the participant between the ages of 18 and 24 years old? .....  *yes*     *no* → **If no, participant is ineligible. End of form.**

2. Was the participant able and willing to provide written informed consent for screening per local regulations and guidelines? .....  *yes*     *no* → **If no, participant is ineligible. End of form.**

2a. When was the informed consent form for screening marked or signed? .....

*dd*                  *MMM*                  *yy*

Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

---

## Screening Consent (SC-1)

*This form is used to document that a participant provided written informed consent for screening for this study. This form must be completed for each participant who is assigned an MTN 004 PTID.*

*This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment visit.*

***Note:** If a participant is being re-screened, a new Screening Consent form must be completed as part of the subsequent screening attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

***Note:** There is no visit code field on this form since this form is only administered during screening.*

- **Item 1:** According to the protocol, a participant must “be between the ages of 18 and 24 years-old at screening and enrollment, inclusive, and verified per site standard operating procedures (SOPs).” Participants who are under 18 years or over 24 years of age should not be screened for the study. If a participant reports that she is 24 years of age at screening, her Enrollment Visit must be conducted prior to her next birthday for her to be eligible to enroll per protocol.
- **Comments:** Record any necessary or additional information at the bottom of the form.

**SAMPLE** *Do NOT FAX*  
*TO DATAFAX*

MTN 004 (136)



DEM-1 (001)

**Participant ID**

-      -   
Site Number Participant Number Chk

**Demographics**

**Form Completion Date**

dd MMM yy

I will start by asking you some general questions about yourself.

1. What is your date of birth? .....       → If unknown, record age:    
dd MMM yy years

2. What is your gender? .....  male  female  
**NOT APPLICABLE FOR THIS PROTOCOL.**

3. Do you consider yourself to be Latina or of Hispanic origin? .....  yes  no

4. What is your race? *Read categories aloud. Mark all that apply.*

- 4a. American Indian or Alaskan Native
- 4b. Asian
- 4c. Black or African American
- 4d. Native Hawaiian or Other Pacific Islander
- 4e. White
- 4f. Mixed
- 4g. other, specify:  
\_\_\_\_\_

---

## Demographics (DEM-1)

*This interviewer-administered form is used to collect participants' demographic and socioeconomic information.*

*This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment visit.*

***Note:** If a participant is being re-screened, a new Demographics form must be completed as part of the subsequent screening attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

***If the participant refuses to give a response to any item(s), draw a line through the response boxes, write "refused," and initial and date the note in the white space next to the item.***

***If the participant is unable to give a response to any item(s), mark the "don't know" box (if provided). Otherwise, draw a line through the response boxes, write "don't know," and initial and date the note in the white space next to the item.***

### General Interviewer Tips:

*See Section 14.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

*It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.*

### Item-specific Instructions:

***Note:** There is no visit code field on this form since this form is only administered during screening.*

- **Item 1:** If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record the participant's best estimate of her age. Do not complete both answers. *NOTE: participant must be between the ages of 18 and 24 years at the time of screening and enrollment, inclusive, and verified per site SOP, to be eligible for study participation.*
- **Item 4:** This item must be self-identified by the participant. This item asks about race. Read each category aloud and mark the response(s) that apply based on the participant's response. If the participant feels that an appropriate choice is not listed mark the "other, specify" box and record her response on the line provided.

SAMPLE Do NOT FAX TO DATAFAX

Visit Code

0

1

MTN 004 (136)

SPE-1 (041)

Participant ID

Site Number Participant Number Chk

Screening 1 and Enrollment Pelvic Exam

Exam Date

dd MMM yy

1. Naked eye, speculum, and bimanual exam assessments: .....

If no abnormal findings, go to item 2.

no abnormal findings

abnormal findings

If abnormal findings are noted, consult protocol to determine participant eligibility.

1a. Abnormal non-colposcopic findings: Mark all that apply.

- 1a1. enlarged/tender inguinal lymph nodes
1a2. abnormal vaginal discharge
1a3. abnormal cervical discharge
1a4. blood-tinged discharge
1a5. blood in vagina—no identified source
1a6. blood from cervical os
1a7. bleeding from site of epithelial disruption
1a8. erythema
1a9. ulceration
1a10. laceration
1a11. abrasion
1a12. peeling
1a13. petechia
1a14. ecchymosis
1a15. vesicles
1a16. edema
1a17. abnormal cysts
1a18. grossly white finding
1a19. mass
1a20. warts—on and/or interior to labia minora
1a21. warts—exterior to labia minora
1a22. adnexal tenderness
1a23. cervical motion tenderness
1a24. uterine tenderness
1a25. other abnormal findings, specify:

If finding is present at Enrollment, record on Pre-existing Conditions form.

2. Colposcopic exam assessment: Required at Enrollment Visit. ....

not done

no abnormal findings

abnormal findings

If not done OR no abnormal findings, go to item 3 on page 2.

If abnormal findings are noted, consult protocol to determine participant eligibility.

2a. Abnormal colposcopic findings: Mark all that apply.

- 2a1. abnormal vaginal discharge
2a2. abnormal cervical discharge
2a3. blood-tinged discharge
2a4. blood in vagina—no identified source
2a5. blood from cervical os
2a6. bleeding from site of epithelial disruption
2a7. erythema
2a8. ulceration
2a9. laceration
2a10. abrasion
2a11. peeling
2a12. petechia
2a13. ecchymosis
2a14. vesicles
2a15. edema
2a16. abnormal cysts
2a17. grossly white finding
2a18. mass
2a19. warts—on and/or interior to labia minora
2a20. warts—exterior to labia minora
2a21. other abnormal findings, specify:

If finding is present at Enrollment, record on Pre-existing Conditions form.

26-MAR-07

01

14-24

Language

Staff Initials / Date



---

## Screening 1 and Enrollment Pelvic Exam (SPE-1)

*This form, along with the non-DataFax Pelvic Exam Diagrams, is used to document the pelvic (and, when applicable, colposcopy) exams conducted during the Screening 1 and Enrollment Visits. This form should be completed once to document the Screening 1 Pelvic Exam, and once to document the Enrollment pelvic/colposcopy exam.*

*This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment Visit.*

**Note:** *If a participant screens more than once for the study (i.e., has multiple screening attempts), and eventually enrolls in the study, only the Screening 1 and Enrollment Pelvic Exam form from the successful screening attempt that led to enrollment should be faxed to SCHARP. For each enrolled participant, only one Screening 1 and Enrollment Pelvic Exam form for the Screening 1 Visit (assigned visit code 1.0), and one Screening 1 and Enrollment Pelvic Exam form for the Enrollment Visit (assigned visit code 2.0) should be faxed to SCHARP DataFax.*

### Item-specific Instructions:

- **Item 1:** Document only those abnormal findings observed during naked eye, speculum, and bimanual examinations. If no abnormal findings are observed, mark the “no abnormal findings” box, leave item 1a blank and go to item 2. If one or more abnormal findings are observed, mark the “abnormal findings” box and continue to item 1a.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed via naked eye, speculum, and bimanual examination **only**. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.
- **Item 2:** Colposcopy is required at the Enrollment Visit. Document any abnormal findings observed during colposcopic examination **only**. If the exam did not include colposcopy, mark the “not done” box, leave item 2a blank and go to item 3. If colposcopy was required but not done, also record the reason it was not done in the Comments section at the bottom of page 2. If no abnormal findings are observed on colposcopy, mark the “no abnormal findings” box, leave item 2a blank and go to item 3. If one or more abnormal findings are observed, mark the “abnormal findings” box and continue to item 2a.
- **Item 2a:** Mark the box to the left of **each** abnormal finding observed on colposcopy **only**. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.

**SAMPLE**. Do NOT FAX  
TO DATAFAX

MTN 004 (136)



SPE-2 (042)

Visit Code   .  0

1

**Participant ID**

-      -   
Site Number Participant Number Chk

**Screening 1 and Enrollment Pelvic Exam**

3. Do any of these exam findings involve deep epithelial disruption? .....  yes  no  
*If yes, participant is ineligible at this time. Complete remainder of form.* **If no, go to item 4.**

3a. Was the deep epithelial disruption observed in more than one distinct area? .....  yes  no

4. Cervical Ectopy: Percentage of cervical surface area.  
0% 1-25% 26-50% 51-75% > 75%

4a. Cervical ectopy assessed by: .....  naked eye  colposcopy

**Alternate Collection Date**

dd	MMM	yy		not required	stored	not stored	Reason:
<input type="text"/>	<input type="text"/>	<input type="text"/>	5. Gram stain (vaginal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<input type="text"/>	<input type="text"/>	<input type="text"/>	6. Cervical swabs.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<input type="text"/>	<input type="text"/>	<input type="text"/>	7. Vaginal swab .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

---

## Screening 1 and Enrollment Pelvic Exam (SPE-2)

- **Items 4 and 4a:** When colposcopy is performed, cervical ectopy must be assessed by colposcopy and not by naked eye. If colposcopy was performed, item 4a should be marked “colposcopy.” If colposcopy was not performed, item 4a should be marked “naked eye.”
- **Items 5–7:** Record the alternate collection date when the specimen(s) was *collected* for this visit if the date is not the same as the Exam Date (NOT the date results were reported or recorded on the form). Complete date required.
- **Item 5:** Collection of a vaginal Gram Stain smear (duplicate slides) is required as part of the Screening 1 and Enrollment Visit pelvic exams. If a vaginal Gram Stain smear was not collected, mark the “not stored” box and record the reason.
- **Item 6:** Collection of cervical swabs for cytokine and innate factor testing is required as part of the Enrollment Visit pelvic exam. If cervical swabs were not collected at the Enrollment Visit, mark the “not stored” box and record the reason. If this is the Screening 1 Visit pelvic exam, mark the “not required” box.
- **Item 7:** Collection of a vaginal swab for quantitative culture is required as part of the Enrollment Visit pelvic exam. If a vaginal swab was not collected at the Enrollment Visit, mark the “not stored” box and record the reason. If this is the Screening 1 Visit pelvic exam, mark the “not required” box.
- **Comments:** Record any necessary or additional information at the bottom of the form.

**SAMPLE**. Do NOT FAX  
TO DATAFAX

Visit Code

□□□.□□

1

MTN 004 (136)

PLR-1 (143)

**Participant ID**

□□□-□□□□□□-□  
Site Number Participant Number Chk

**Pelvic Laboratory Results**

Initial Specimen Collection Date  
□□ □□□□ □□  
dd MMM yy

**Alternate Collection Date**

Not done/ Not collected dd MMM yy  
□ □□□ □□□□ □□  
Not done

**1. VAGINAL WET PREP STUDIES**

- 1a. Homogeneous vaginal discharge ..... *negative*  *positive*
- 1b. pH..... □□ → *If > 4.5 mark as positive.* →
- 1c. Whiff test .....
- 1d. Clue cells > 20%.....
- 1e. *Trichomonas vaginalis*.....
- 1f. Buds and/or hyphae (yeast) .....

**Alternate Collection Date**

Not done/ Not collected dd MMM yy  
□ □□□ □□□□ □□

**2. PAP SMEAR**

- negative for intraepithelial lesion or cancer (malignancy)
- ASC-US
- ASC-H
- SIL-low grade (LSIL)
- SIL-high grade (HSIL)
- AGC
- AGC-favor neoplastic
- cancer

Comments: \_\_\_\_\_

---

## Pelvic Laboratory Results (PLR-1)

This form is used to document results of specimens collected during the Screening, Enrollment, and follow-up pelvic exams. Record test results on this form as they become available. Fax this form to SCHARP DataFax once results for **all** collected specimens are recorded on this form.

If a test result(s) recorded on this form indicates that the participant has a laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as either a pre-existing condition on the Pre-existing Conditions form (for Enrollment test result(s) only), or an adverse experience on the Adverse Experience (AE) Log (for follow-up visit test result(s) only).

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 14.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the week on study plus 2.0. For example, the One-week Clinic Visit is assigned a visit code of “03.0,” the Two-week Clinic Visit is assigned a visit code of “04.0,” etc.
- **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. Complete date required.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form. Complete date required.
- **Results Reporting**
  - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
  - If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
- **Item 1:** A vaginal wet prep is required at the One-week, Two-week, and Three-week Clinic Visits, and when clinically indicated. If a vaginal wet prep was performed but not all assays were completed, mark the “Not done” box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason in the Comments section.
- **Item 1a:** Mark the “positive” box if homogeneous vaginal discharge was observed. If positive, mark “abnormal vaginal discharge” in item 1a of the Screening and Enrollment, Repeat Screening, or Follow-up Pelvic Exam form completed for this pelvic exam.
- **Item 1d:** Mark the “positive” box if more than 20% of cells were clue cells.
- **Item 1e:** Mark the “positive” box if trichomonads were observed.
- **Item 1f:** Mark the “positive” box if yeast buds and/or hyphae were observed.
- **Item 2:** Record the Pap Smear result. Mark only one box. **Note:** *A Pap Smear result is required at the Screening Visit only, and only for those participants who do not have documentation of a normal Pap test result in the 12 calendar months prior to Screening. Only participants with a negative or ASC-US Pap Smear result will be eligible to enroll in the study; participants with an ASC-H, LSIL, HSIL, AGC, AGC-favor neoplastic, or cancer result should not be enrolled in the study.*
  - **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.
  - **ASC-US:** 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 lesion (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.

SAMPLE: DO NOT FAX  
TO DATAFAX

Visit Code

□□□.□□

1

MTN 004 (136)

SL-1 (151)

Participant ID

□□□-□□□□□□-□  
Site Number Participant Number Chk

Safety Laboratory Results

Initial Specimen Collection Date

□□ □□□□ □□  
dd MMM yy

Not done/ Not collected Alternate Collection Date  
dd MMM yy  
 □□ □□□□ □□

1. HEMOGRAM

Not reported

1a. WBC..... □□□.□ x10<sup>3</sup>/mm<sup>3</sup> .....  □□□ OR   
1b. Hemoglobin ..... □□.□ g/dL .....  □□□ OR   
1c. Hematocrit..... □□.□ % .....  □□□ OR   
1d. Platelets □□□□□□□□ cells/mm<sup>3</sup> .....  □□□ OR   
1e. RBC..... □.□□ x10<sup>6</sup>/mm<sup>3</sup> .....  □□□ OR

Not done/ Not collected Alternate Collection Date  
dd MMM yy  
 □□ □□□□ □□

2. DIFFERENTIAL

Not reported

2a. Neutrophils..... □□.□ OR □□□□□□ Severity Grade If applicable  AE Log Page # □□□ Not reportable as an AE OR   
2b. Lymphocytes..... □□.□ OR □□□□□□  □□□ OR   
2c. Monocytes ..... □□.□ OR □□□□□□  □□□ OR   
2d. Eosinophils ..... □□.□ OR □□□□□□  □□□ OR   
2e. Basophils ..... □□.□ OR □□□□□□  □□□ OR   
2f. Bands..... □□.□ OR □□□□□□  □□□ OR   
2g. Atypical lymphocytes.. □□.□ OR □□□□□□  □□□ OR   
2h. other, specify: ..... □□.□ OR □□□□□□  □□□ OR

□□□ x 26-MAR-07

01  
Language

14-30

Staff Initials / Date

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## Safety Laboratory Results (SL-1)

This form is used to document local safety laboratory results of specimens collected during screening, enrollment, and study follow-up. Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax once results for **all** collected specimens are recorded on the form.

If a test result(s) recorded on this form indicates that the participant has a laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as either a pre-existing condition on the Pre-existing Conditions form (for Enrollment Visit test result(s) only), or an adverse experience on an Adverse Experience (AE) Log (for follow-up visit test result(s) only).

**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. Complete date required.

**Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. Complete date required.

### Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
- If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. 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.
  - If the result reported by the lab has less digits than on the form, fill in “0” for each missing digit. For example a hematocrit value of “42%” would be recorded as “42.0%.”

### Severity Grade:

- If any abnormal laboratory 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.
- 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.
  - 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.
- There may be situations in which a lab value falls within a site’s lab normal ranges and also within a gradable range per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table*.

**AE Log Page #:** If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.

**Not Reportable as an AE:** Mark if the lab value is gradable per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-Existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.

**Item 2:** If a differential specimen was collected but results were not reported for all items, mark the “Not reported” box for each result that was not reported. If lab results are available in both percentage and absolute count, absolute count should be recorded on the form.

SAMPLE-DO NOT FAX  
TO DATAFAX

MTN 004 (136)



SL-2 (152)

Visit Code [ ][ ] . [ ]

[ 1 ]

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]  
Site Number Participant Number Chk

Safety Laboratory Results

BLOOD CHEMISTRIES

Not done/ Not collected  Alternate Collection Date dd MMM yy [ ][ ] [ ][ ][ ][ ] [ ][ ][ ]

3. LIVER FUNCTION TESTS

3a. Alkaline phosphatase [ ][ ][ ][ ] U/L Severity Grade [ ] AE Log Page # [ ][ ][ ] Not reportable as an AE [ ] OR [ ]

Not done/ Not collected  Alternate Collection Date dd MMM yy [ ][ ] [ ][ ][ ][ ] [ ][ ][ ]

4. RENAL FUNCTION TESTS

4a. Creatinine [ ][ ] . [ ] mg/dL Severity Grade [ ] AE Log Page # [ ][ ][ ] Not reportable as an AE [ ] OR [ ]

Not done/ Not collected  Alternate Collection Date dd MMM yy [ ][ ] [ ][ ][ ][ ] [ ][ ][ ]

5. COAGULATION STUDIES

5a. INR..... [ ][ ] . [ ][ ] ..... Severity Grade [ ] AE Log Page # [ ][ ][ ] Not reportable as an AE [ ] OR [ ]

Alternate Collection Date

dd MMM yy [ ][ ] [ ][ ][ ][ ] [ ][ ][ ]

6. Plasma ..... not required [ ] stored [ ] not stored [ ] Reason: \_\_\_\_\_

Comments: \_\_\_\_\_



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## Safety Laboratory Results (SL-2)

**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. Complete date required.

**Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. Complete date required.

### Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
- If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. 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.
  - If the result reported by the lab has less digits than on the form, fill in “0” for each missing digit. For example a hematocrit value of “42%” would be recorded as “42.0%.”

### Severity Grade:

- If any abnormal laboratory 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.
- 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.
  - 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.
- There may be situations in which a lab value falls within a site’s lab normal ranges and also within a gradable range per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table*.

**AE Log Page #:** If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.

**Not Reportable as an AE:** Mark if the lab value is gradable per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-Existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.

- **Item 6:** Plasma archive is required at the Enrollment and Two-week visits. If a plasma specimen was not collected, mark the “not stored” box and record the reason.

**SAMPLE**. DO NOT FAX  
TO DATAFAX



Visit Code

□□□.□□

1

MTN 004 (136)

SLR-1 (131)

**Participant ID**

□□□-□□□□□□-□  
Site Number Participant Number Chk

**STI Laboratory Results**

**Initial Specimen Collection Date**

□□ □□□□ □□  
dd MMM yy

Not done/ Not collected  Alternat Collection Date dd MMM yy □□□□ □□□□ □□□□

**1. URINE TESTS**

Not done  1a. Protein .....  negative or trace  1+  2+  3+  4+  Severity Grade If applicable  AE Log Page # □□□ OR  Not reportable as an AE

1b. Glucose .....  negative  positive  
 1c. Blood .....  negative  positive  
 1d. Leukocyte esterase (LE) .....  negative  positive  
 1e. Nitrites .....  negative  positive

**If clinically indicated, perform culture and sensitivity.**

1f. Culture.....  negative  positive

**If positive during follow-up, complete Adverse Experience Log.**

Not done/ Not collected  Alternat Collection Date dd MMM yy □□□□ □□□□ □□□□

**HIV TEST RESULTS**

2. HIV EIA .....  negative  positive

**If positive, complete HIV Test Results form.**

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## STI Laboratory Results (SLR-1)

*This form is used to document local laboratory results of blood and urine specimens collected at the Screening 1 Visit and when clinically indicated. Record specimen test results on this form as they become available. Fax this form to SCHARP DataFax once results for **all** collected specimens are recorded on this form.*

*If a test result(s) recorded on this form indicates that the participant has a laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as either a pre-existing condition on the Pre-existing Conditions form (for Screening/Enrollment test result(s) only), or an adverse experience on the Adverse Experience Log form (follow-up visit test result(s) only).*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 14.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the week on study plus 2.0. For example, the One-week Clinic Visit is assigned a visit code of “03.0,” the Two-week Clinic Visit is assigned a visit code of “04.0,” etc.
- **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. Complete date required.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form. Complete date required.
- **Results Reporting**
  - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
  - If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
- **AE Severity Grade:** This applies to follow-up visits only. If the visit is a Screening or Enrollment Visit, leave the AE Severity Grade box blank.
  - If any abnormal laboratory 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.
  - 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.
    - 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.
- **Not Reportable as an AE:** Mark if the lab value is gradable per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-Existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
- **AE Log Page #:** This applies to follow-up visits only. If the visit is a Screening or Enrollment Visit, leave the AE Log Page # box blank. If a follow-up visit lab value is reported as and/or associated with an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.
- **Items 1a–1c:** If clinically indicated, **both** a urine culture and sensitivity are required, per protocol. If there is no clinical indication for performing urine culture and sensitivity, mark the “not done” box for item 1a and proceed to item 2.
- **Item 2:** If the HIV EIA result is positive, conduct Western Blot testing and record the associated test results on the HIV Test Results form.

**Note:** *A participant must be confirmed HIV uninfected in order to be eligible for study participation.*

**SAMPLE**. Do NOT FAX  
TO DATAFAX

MTN 004 (136)



SLR-2 (132)

Visit Code

1

**Participant ID**

-      -   
Site Number Participant Number Chk

**STI Laboratory Results**

**3. STI SEROLOGY**

3a. Syphilis screening test.....

non-reactive reactive

**If non-reactive, go to item 4.**

3a1. Syphilis titer ..... 1:

3b. Syphilis confirmatory test

negative positive

**If positive, provide treatment. If positive at a Screening Visit, participant is ineligible. If positive during follow-up, complete Adverse Experience Log.**

**If negative, go to item 4.**

3b1. Syphilis titer ..... 1:

Not done/ Not collected  Alternat Collection Date dd MMM yy

Not done/ Not collected  Alternat Collection Date dd MMM yy

**4. OTHER STI TESTS**

4a. *N. Gonorrhea* .....

negative positive

4b. *C. Trachomatis* .....

**If either is positive, provide treatment. If positive at a Screening Visit, participant is ineligible. If positive during follow-up, complete Adverse Experience Log.**

Comments: \_\_\_\_\_

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## STI Laboratory Results (SLR-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of the form for a given participant and visit.
- **Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form. Complete date required.
- **Results Reporting**
  - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
  - If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
- **Item 3:** If the syphilis screening test is reactive, items 3a1 and 3b must be completed.
- **Item 3a1:** Remember to use leading zeros when recording a syphilis titer level. For example, a titer level of 1:20 would be recorded on the form as “1:0020.”
- **Items 3b–4b:** If a result is positive at any time during the study (screening through study exit), provide treatment according to CDC guidelines. If a result is positive at the Screening 1 Visit, the participant is ineligible for study participation. If a result is positive during study follow-up, report the relevant infection(s) as adverse experience(s) on the Adverse Experience Log form, hold study gel, complete a Study Gel Request Slip and mark “hold,” and complete items 1–3 of the Product Hold/Discontinuation form and fax to SCHARP.

**SAMPLE** *Do NOT FAX TO DATAFAX*



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

Page

MTN 004 (136)

CM-1 (423)

**Participant ID**

-      -   
 Site Number Participant Number Chk

**Concomitant Medications Log**

No medications taken at Screening/Enrollment. \_\_\_\_\_  
 Staff Initials/Date  
 ➔ Fax to SCHARP DataFax.

No medications taken throughout study. \_\_\_\_\_  
 Staff Initials/Date  
 ➔ End of form. Fax to SCHARP DataFax.

Medication (generic name)									
Indication								Staff Initials/Log Entry Date	
Date Started			Date Stopped					Taken for a reported AE?	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	Continuing at end of study
<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>				
Dose/Units	Route	PO	IM	IV	TOP	IHL	VAG	REC	other, specify:
	Mark only one.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Frequency	Mark only one.								
<input type="checkbox"/>	<i>prn</i>	<input type="checkbox"/>	<i>qd</i>	<input type="checkbox"/>	<i>tid</i>	<input type="checkbox"/>	<i>qhs</i>	<input type="checkbox"/>	<i>qhx: every</i> <input type="text"/> <i>hrs</i>
<input type="checkbox"/>	<i>once</i>	<input type="checkbox"/>	<i>bid</i>	<input type="checkbox"/>	<i>qid</i>	<input type="checkbox"/> other, specify: _____			

Medication (generic name)									
Indication								Staff Initials/Log Entry Date	
Date Started			Date Stopped					Taken for a reported AE?	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	Continuing at end of study
<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>				
Dose/Units	Route	PO	IM	IV	TOP	IHL	VAG	REC	other, specify:
	Mark only one.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Frequency	Mark only one.								
<input type="checkbox"/>	<i>prn</i>	<input type="checkbox"/>	<i>qd</i>	<input type="checkbox"/>	<i>tid</i>	<input type="checkbox"/>	<i>qhs</i>	<input type="checkbox"/>	<i>qhx: every</i> <input type="text"/> <i>hrs</i>
<input type="checkbox"/>	<i>once</i>	<input type="checkbox"/>	<i>bid</i>	<input type="checkbox"/>	<i>qid</i>	<input type="checkbox"/> other, specify: _____			

Medication (generic name)									
Indication								Staff Initials/Log Entry Date	
Date Started			Date Stopped					Taken for a reported AE?	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	Continuing at end of study
<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>				
Dose/Units	Route	PO	IM	IV	TOP	IHL	VAG	REC	other, specify:
	Mark only one.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Frequency	Mark only one.								
<input type="checkbox"/>	<i>prn</i>	<input type="checkbox"/>	<i>qd</i>	<input type="checkbox"/>	<i>tid</i>	<input type="checkbox"/>	<i>qhs</i>	<input type="checkbox"/>	<i>qhx: every</i> <input type="text"/> <i>hrs</i>
<input type="checkbox"/>	<i>once</i>	<input type="checkbox"/>	<i>bid</i>	<input type="checkbox"/>	<i>qid</i>	<input type="checkbox"/> other, specify: _____			

26-MAR-07

Language

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## Concomitant Medications Log (CM-1)

All medication(s) that are used by the participant during the study, other than study product, must be documented on this form. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.

- When to fax this form:
  - 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.
- **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 at the time of the Screening or Enrollment visit. Record “Staff Initials/Date.”
- **No medications taken throughout study:** Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study. Record “Staff Initials/Date.”
- **Medication:** Record the generic name for all medications. For combination medications, record the generic names of the first three main active ingredients.
- **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.”
- **Date Started:** If the participant is unable to recall the exact date, obtain participant’s best estimate. At a minimum, the year is required.
- **Date Stopped:** At the participant’s Termination 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 is required.
- **Dose/Units:** If the participant does not know the dose or units, draw a single line through the blank response boxes and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).
- **Route and Frequency:** Below is a list of common route and frequency abbreviations.

### Route Abbreviations:

<b>PO</b> oral	<b>IM</b> intramuscular	<b>IV</b> intravenous	<b>TOP</b> topical	<b>IHL</b> inhaled	<b>VAG</b> vaginal	<b>REC</b> rectal
----------------	-------------------------	-----------------------	--------------------	--------------------	--------------------	-------------------

### Frequency Abbreviations:

<b>prn</b> as needed	<b>qd</b> every day	<b>tid</b> three times daily	<b>qhs</b> at bedtime
<b>once</b> one time	<b>bid</b> twice daily	<b>qid</b> four times daily	<b>qXH</b> every x hours

- **Taken for a reported AE?:** If the medication was not taken for a reported AE, mark the “no” box and leave the AE Log page boxes blank

**SAMPLE: DO NOT FAX TO DATAFAX**

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

Site Number			Participant Number						Chk	

**Baseline Medical History**

**Visit Date**

dd		MMM		yy	

	If abnormal, date diagnosed		Description:	Ongoing?					
	normal	abnormal		yes	no				
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Lymphatic	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Liver	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Renal	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Neurologic	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Endocrine/Metabolic	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Hematologic	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Cancer	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Drug allergy	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Other allergy	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
<p><b>If yes at the time of enrollment, record on Pre-existing Conditions form.</b> ←</p>									
Alcohol use	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>
Drug use	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>					<input type="checkbox"/>	<input type="checkbox"/>



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## Baseline Medical History – 1 (nonDF)

*This form is used to document a participant's baseline medical history, prior to randomization. It is first completed at the Screening 1 Visit. It is then updated at any subsequent screening visits related to the same screening attempt, and updated again at the Enrollment Visit. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

**Note:** *If a participant is being re-screened, a new Baseline Medical History form must be completed as part of the subsequent screening attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

*It may be helpful to use a calendar as a probe to help participants recall dates.*

**Note:** *This form should contain information on the participant's medical history through the Enrollment Visit only. Do **not** update this form during follow-up unless the participant recalls additional information related to her medical history at baseline. Be sure to record all conditions that were ongoing at enrollment on the Pre-existing Conditions form.*

### Item-specific Instructions:

- **Normal/abnormal:** For each organ system/disease listed, mark the “abnormal” box if there is evidence (either by participant report or by medical records) that the participant has ever experienced any medical problem involving that organ system/disease **since becoming sexually active**. Mark the “normal” box for conditions not reported or documented in medical records.
- **If abnormal, date diagnosed:** For each organ system/disease marked “abnormal,” record the month and year the participant was diagnosed with the condition or began experiencing symptoms.
- **Description:** Provide a description of each reported diagnosis in the space provided.
- **Ongoing?:** For each organ system/disease marked “yes,” determine if the diagnosed condition is ongoing or resolved. Mark the “yes” box if the condition is ongoing (not resolved), and “no” if the condition is resolved. Review all ongoing conditions at the participant's Enrollment Visit. For conditions ongoing at Enrollment, record the condition on the participant's **Pre-existing Conditions** form.
- **Alcohol use:** Record information about the participant's current level of alcohol use.
- **Drug use:** Record information about the participant's current level of recreational drug use.

*If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don't know” or “refused” in the white space next to the response boxes, and initial and date.*

**SAMPLE: DO NOT FAX TO DATAFAX**

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

			-						-		
Site Number				Participant Number							Chk

**Baseline Medical History**

**Visit Date**

dd		MMM			yy

**Menstrual History**

Usual menstrual cycle: ..... *regular*  *irregular*

Usual length of menstrual cycle (days): .....   # of days

Usual number of bleeding days (record range): ..... *minimum*  # of days **TO** *maximum*  # of days

Age of menarche: .....   years

First day of last menstrual period: .....    *dd* *MMM* *yy* } *amenorrheic*  
 Last day of last menstrual period: .....    } **OR**

Usual type of menstrual flow (at the heaviest day of menses): ..... *light*  *moderate*  *heavy*

Usual menstrual symptoms (document type and severity, if any): \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Usual non-menstrual genital bleeding pattern (document frequency, duration, type of flow, and associated symptoms, if any):  
 \_\_\_\_\_  
 \_\_\_\_\_

Reproductive history: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

History of contraception/family planning use: \_\_\_\_\_  
 \_\_\_\_\_

Additional Notes: \_\_\_\_\_  
 \_\_\_\_\_

---

## Baseline Medical History – 2 (nonDF)

### Item-specific Instructions:

- **Usual length of menstrual cycle (days):** Record the average number of days between the start dates of two consecutive menstrual cycles. If the participant is amenorrheic, refer to her previous menstrual cycles that occurred prior to the amenorrhea.
- **Usual number of bleeding days:** Record as a range the average number of days (minimum and maximum) the participant reports bleeding during her menses. If the participant is amenorrheic, refer to her previous menstrual cycles that occurred prior to the amenorrhea.
- **Age of menarche:** Record the participant’s age of first menstrual period.
- **First day of last menstrual period:** Record the first day of the participant’s last menstrual period. Use a calendar to probe for the day, month, and year.
- **Last day of last menstrual period:** Record the last day of the participant’s last menstrual period. Use a calendar to probe for the day, month, and year.
- **amenorrheic:** Mark “amenorrheic” if the participant has been without menses for at least the past three cycle intervals or the past six months, whichever is shorter. If “amenorrheic” is marked, leave the “First day of last menstrual period” and “Last day of last menstrual period” boxes blank.
- **Usual menstrual symptoms:** Document the type and severity of any and all reported symptoms the participant commonly experiences in association with her menses. If the participant is amenorrheic, document any usual menstrual symptoms she experienced prior to becoming amenorrheic.
- **Usual non-menstrual genital bleeding pattern:** Document the frequency of bleeding, duration of bleeding, type of flow (e.g., light, moderate, or heavy), and associated symptoms (if any) of any and all reported non-menstrual bleeding commonly experienced by the participant. This includes intermenstrual bleeding (IMB) and/or any breakthrough genital bleeding/spotting associated with the participant’s contraceptive use.
- **Reproductive history:** Record the total number, date, and outcome (for example, full-term live birth, premature live birth, spontaneous abortion, etc.) of each of the participant’s pregnancies. This should include any gynecologic and obstetrical procedures/surgeries.
- **History of contraception/family planning use:** Record the method(s) of contraception/family planning the participant reports using in the past and currently. If the participant reports current use of hormonal contraception, be sure to record the hormonal contraception on the participant’s Concomitant Medications Log.
- **Additional Notes:** Record any necessary or additional information at the bottom of the form.

*If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused” in the white space next to the response boxes, and initial and date.*

**SAMPLE: DO NOT FAX TO DATAFAX**

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

Site Number			Participant Number						Chk	

**History of Genital Symptoms**

**Visit Date**

dd		MMM		yy	

Genital Symptoms	If yes, onset date/ date diagnosed		Description:	Ongoing?		
	yes	no		MMM	yy	yes
Genital sores	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Genital/vaginal itching	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Genital/vaginal burning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Genital/vaginal pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pain during sex	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficulty when urinating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Burning when urinating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abnormal or unusual genital/ vaginal discharge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unusual genital/ vaginal odor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abnormal or unusual menstrual cramping (dysmenorrhea)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other genital symptoms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vaginal bleeding or spotting between usual menstrual periods	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Blood-tinged discharge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>

**If yes to any evaluate for STIs/RTIs.** ←

Additional Notes: \_\_\_\_\_

26-MAR-07

Language

14-44  
Staff Initials / Date

---

## History of Genital Symptoms – 1 (nonDF)

*This form is used to document a participant's history of genital symptoms at the Screening 1 Visit. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

**Note:** *If a participant is being re-screened, a new History of Genital Symptoms form must be completed as part of the subsequent Screening Attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

*It may be helpful to use a calendar as a probe to help participants recall dates.*

**Note:** *Responses to all of the items on this form are based on participant recall at the time of the Screening 1 Visit. Once the participant has completed the Screening Visit, do not make any further updates or changes to the responses recorded on this form.*

### Item-specific Instructions:

- **Yes/no:** For each genital symptom listed, mark the “yes” box if the participant reports having experienced that symptom **since becoming sexually active**. Mark the “no” box for symptoms not reported.
- **If yes, onset date/date diagnosed:** For each symptom marked “yes,” record the month and year the participant began experiencing symptoms.
- **Description:** Provide a description of each reported symptom in the space provided.
- **Ongoing?:** For each symptom marked “yes,” determine if the symptom/condition is ongoing or resolved. Mark the “yes” box if the condition is ongoing (not resolved), and “no” if the condition is resolved. If the response is “yes,” evaluate for STIs/RTIs per the protocol and SSP. If the participant is diagnosed with an STI/RTI that is exclusionary per protocol, do **not** enroll the participant. Provide treatment as necessary (per CDC guidelines).

*If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don't know” or “refused” in the white space next to the response boxes, and initial and date.*

**SAMPLE** *Do NOT FAX TO DATAFAX*

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**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"/>
Site Number				Participant Number					Chk

**Physical Exam**

**Exam Date**

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

**VITAL SIGNS**

1. Were vital signs done?.....  *yes*  *no* → **If no, specify reason in Comments.**

Weight  kg    BP  /  mmHg

Height  cm    Pulse  per minute

Oral Temp  .  °C    Respirations  per minute

Vital Signs: \_\_\_\_\_ Staff Initials / Date

**FINDINGS**

*not evaluated*    *normal*    *abnormal*    **Item 2 is required. If not evaluated or abnormal, please specify.**

        2. Abdomen \_\_\_\_\_

*Items 3-14 are optional. If abnormal, please specify.*

        3. HEENT \_\_\_\_\_

        4. Neck \_\_\_\_\_

        5. Lymph Nodes \_\_\_\_\_

        6. Heart \_\_\_\_\_

        7. Lungs \_\_\_\_\_

        8. Extremities \_\_\_\_\_

        9. Neurological \_\_\_\_\_

        10. Skin \_\_\_\_\_

        11. Breast Exam \_\_\_\_\_

        12. Other, specify: \_\_\_\_\_

        13. Other, specify: \_\_\_\_\_

        14. Other, specify: \_\_\_\_\_

→ **If abnormal and ongoing for any at Enrollment, record on Pre-existing Conditions form. If abnormal during follow-up, update or complete Adverse Experience Log when applicable.**

Findings: \_\_\_\_\_ Staff Initials / Date

Comments: \_\_\_\_\_

26-MAR-07

Language

14-46

Staff Initials / Date

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## Physical Exam (nonDF)

*This form is used to document the participant's vital signs and physical exam findings. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

***Note:** If a participant is being re-screened, a new Physical Exam form must be completed as part of the subsequent screening attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

- **Vital Signs:** When recording weight, height, oral temp, blood pressure (BP), pulse, and respirations, remember to use leading zeros when needed. The staff member who completes these items should initial and date in the space provided.
- **Findings:** The staff member who completes these items should initial and date in the space provided.
- **Item 2:** An abdominal exam is required at the Screening 1, Enrollment, One-week, Two-week, and Three-week Clinic Visits. Record any abnormalities ongoing at enrollment on the participant's **Pre-existing Conditions** form. If abnormal during follow-up, update or complete **Adverse Experience Log** when applicable.
- **Items 3–11:** These items are optional. For each item marked abnormal, specify the reason the organ system was abnormal in the space provided. Record any abnormalities ongoing at enrollment on the participant's **Pre-existing Conditions** form. If abnormal during follow-up, update or complete **Adverse Experience Log** when applicable.
- **Items 12–14:** Use these items to list any additional organ systems that were evaluated. If no other organ systems other than the ones listed in items 1-11 were evaluated, mark items 12–14 as “not evaluated.” Record any abnormalities ongoing at Enrollment on the participant's **Pre-existing Conditions** form. If abnormal during follow-up, update or complete **Adverse Experience Log** when applicable.

**SAMPLE**. Do NOT FAX TO DATAFAX

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

Site Number			Participant Number						Chk	

**Screening 1 Visit Eligibility**

**Form Completion Date**

dd		MMM		yy	

**Complete items 1–3 before the interview.**

1. Was the participant willing and able to provide a written informed consent for screening? ..... yes  no  → **If no, participant is ineligible. End of form.**
2. Was the participant previously enrolled in this study? ..... yes  no  → **If yes, participant is ineligible. End of form.**
3. Is documentation of a normal Pap test result in the last 12 calendar months available? ..... yes  no  → **If no, perform Pap test as necessary.**

I am now going to ask you some more questions about yourself. Some of these questions are personal and sensitive, but remember that we do not have your name on these papers and all of your answers will be kept confidential.

4. Have you ever had an adverse or bad reaction to latex (such as latex condoms or gloves)? ..... yes  no
5. Has your male sex partner ever had an adverse or bad reaction to latex (such as latex condoms or gloves)? .....  no
6. Have you ever had an adverse or bad reaction to any component of the study product (VivaGel and/or applicator)? .....  no
7. Are you currently using oral and/or vaginal antibiotics or antifungal medications? .....  no
8. Are you breastfeeding? .....  no
9. Do you plan to use a diaphragm, vaginal ring, and/or spermicide for birth control at any time during your study participation? .....  no
10. In the past month (30 days), how many times have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina. ....   → **If < 4, participant is ineligible. Go to item 12 on page 2.**



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## Screening 1 Visit Eligibility – Page 1 (nonDF)

*This form is used to document the participant's eligibility for the study at screening. This is a mixed form—some of the items are interviewer-administered (items 4–25), while other items are not (items 1–3 and 26–27). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

***Note:** If a participant is being re-screened, a new Screening Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### **General Interviewer Tips:**

*See Section 14.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

*It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.*

***Note:** If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 25. Do not inform her that she is ineligible for the study until the form has been administered. Also, refrain from indicating to the participant the reason why she is ineligible, to prevent socially desirable reporting.*

### **Item-specific Instructions:**

- **Items 1–3:** These items are NOT interviewer-administered and should not be read aloud to the participant.
- **Item 2:** Review the Screening and Enrollment Log to verify that the participant has not previously enrolled in the study.
- **Item 3:** Per protocol, a participant must have either a normal Pap test result at screening or documentation of a normal Pap test result in the 12 calendar months prior to screening in order to be eligible to enroll in the study. If the participant does not provide documentation of a normal Pap test result in the 12 calendar months prior to screening, conduct a Pap Smear test for this participant as part of the Screening 1 Visit pelvic exam.

**SAMPLE** *DO NOT FAX TO DATAFAX*

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

Site Number			Participant Number						Chk	

**Screening 1 Visit Eligibility**

11. Do you anticipate having vaginal sex at the same approximate frequency during your study participation? .....  *yes*     *no* → **If no, participant is ineligible.**

12. Do you have a regular menstrual cycle that is 21 days or longer?  *yes*     *no*  
 → **If yes, go to item 13.**

12a. Is it because of the birth control you are using, such as Depo-Provera or Norplant? .....  *yes*     *no* → **If no, participant is ineligible.**

13. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion? .....  *yes*     *no* → **If no, go to item 14.**

13a. When did you last give birth, have a miscarriage or abortion?

dd                      MMM                      yy

↓  
**If date is within the last 54 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last pregnancy outcome.**

14. In the past 3 months (90 days), have you had any gynecological surgery? This would include such procedures as: dilation and curettage (D&C); surgery of the uterus, ovaries, or fallopian tubes, and biopsy or cryotherapy (freezing) of the cervix. ....  *yes*     *no* → **If no, go to item 15.**

14a. When did you last have gynecological surgery? .....

dd                      MMM                      yy

↓  
**If date is within the last 54 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last gynecological surgery.**

---

## Screening 1 Visit Eligibility – Page 2 (nonDF)

*This form is used to document the participant's eligibility for the study at screening. This is a mixed form—some of the items are interviewer-administered (items 4–25), while other items are not (items 1–3 and 26–27). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

**Note:** *If a participant is being re-screened, a new Screening Part 1 Visit Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### **General Interviewer Tips:**

*See Section 14.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

*It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.*

**SAMPLE**. Do NOT FAX TO DATAFAX

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

			-					-	
Site Number				Participant Number					Chk

**Screening 1 Visit Eligibility**

15. In the past 6 months, have you been diagnosed or treated for any sexually transmitted infection, other than genital herpes (HSV) or pelvic inflammatory disease? .....

yes

no

➔ **If no, go to item 16.**

15a. When were you last diagnosed with or treated for a sexually transmitted infection? .....

dd		MMM			yy		



**If date is within 6 months of enrollment, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 6 months of STI diagnosis or treatment.**

16. In the past year (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional? ...

yes

no

➔ **If no, go to item 17.**

16a. When did you last inject drugs that were not prescribed to you? .....

dd		MMM			yy		



**If date is within 12 calendar months of enrollment, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within one year of injection drug use.**

17. In the past month (30 days), have you participated in any study that uses spermicides, vaginal microbicides, or any other device or drug (including vaccine studies)? .....

yes

no

➔ **If no, go to item 18.**

17a. When did you last participate in one of these studies? .....

dd		MMM			yy		



**Schedule enrollment when participant is no longer within 30 days of other study participation.**

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## Screening 1 Visit Eligibility – Page 3 (nonDF)

*This form is used to document the participant's eligibility for the study. This is a mixed form—some of the items are interviewer-administered (items 4–25), while other items are not (items 1–3 and 26–27). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

**Note:** *If a participant is being re-screened, a new Screening Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### **General Interviewer Tips:**

*See Section 14.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

*It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.*

**SAMPLE**. Do NOT FAX TO DATAFAX

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

Site Number			Participant Number					Chk		

**Screening 1 Visit Eligibility**

18. Do you agree to not participate in any study that uses spermicides, vaginal microbicides, or any other device or drug (including vaccine studies) while participating in this study? .....  *yes*       *no*
19. From today, through one month after you finish using study products, do you agree to use one of the following types of birth control: Depo-Provera ("the shot"), hormonal contraceptives ("the pill"), Ortho-Evra ("the patch"), an intrauterine device (IUD - inserted at least 30 days prior to enrollment), female sterilization, or have vaginal sex with a male partner who has had a vasectomy?.....  *yes*       *no*
20. Do you agree to have your partner use study-provided condoms each time you have intercourse during your study participation? .....  *yes*       *no*
21. Do you agree to not receive oral or anal sex during your study participation? .....  *yes*       *no*
22. From 72 hours before your enrollment through the end of your study participation, do you agree to not use any intravaginal products (other than tampons) or devices, including sex toys? .....  *yes*       *no*
23. Are you willing to use the study product, which is VivaGel gel, or VivaGel placebo, or HEC gel twice a day for 14 days? .....  *yes*       *no*
24. Are you willing to attend all scheduled study visits? .....  *yes*       *no*
25. Are you willing to undergo all study evaluations, including a pelvic exam, colposcopy (when a clinician looks inside your vagina with a magnifying instrument), urine testing, and blood draws? .....  *yes*       *no*
- Complete item 26 when Screening 1 urine hCG result is available.**
26. Is the participant pregnant? .....  *yes*       *no*      **If no to any, participant is ineligible.**
27. Does the participant have any other condition that, in the opinion of the site investigator, would preclude provision or informed consent, make participation in the study unsafe, complicate interpretation of study objectives, or otherwise interfere with achieving study objectives? .....  *yes*       *no*      **If yes, participant is ineligible.**

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## Screening 1 Visit Eligibility – Page 4 (nonDF)

*This form is used to document the participant's eligibility for the study. This is a mixed form—some of the items are interviewer-administered (items 4–25), while other items are not (items 1–3 and 26–27). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

***Note:** If a participant is being re-screened, a new Screening Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### General Interviewer Tips:

*See Section 14.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

*It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.*

### Item-specific Instructions:

- **Item 19:** If the participant's chosen effective method of contraception is sexual activity with a vasectomized partner, site staff must obtain documentation of the vasectomy in order to enroll the participant.
- **Item 26:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Screening 1 Visit urine hCG result here.
- **Item 27:** This item is NOT interviewer-administered and should not be read aloud to the participant. This item should be completed by the site investigator or his/her designee once the Screening 1 Visit has been completed. If, for some reason other than those listed on any of the screening forms, the investigator or designee feels the participant is **not** a good candidate for the study, mark the "yes" box, record the reason in the participant's chart notes, and do not enroll the participant in the study.

**SAMPLE** *DO NOT FAX TO DATAFAX*

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**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"/>	
Site Number				Participant Number							Chk

**Clinical Eligibility**

**Visit Date**

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

1. At this visit, was the participant diagnosed by study staff with any of the following sexually transmitted infections (STIs) or reproductive tract infections (RTIs):

- |  | yes                      | no                       |
|--|--------------------------|--------------------------|
| 1a. chlamydia.....   | <input type="checkbox"/> | <input type="checkbox"/> |
| 1b. gonorrhea .....  | <input type="checkbox"/> | <input type="checkbox"/> |
| 1c. syphilis .....   | <input type="checkbox"/> | <input type="checkbox"/> |
| 1d. symptomatic BV .....   | <input type="checkbox"/> | <input type="checkbox"/> |
| 1e. symptomatic candidiasis (yeast).....   | <input type="checkbox"/> | <input type="checkbox"/> |
| 1f. trichomoniasis .....   | <input type="checkbox"/> | <input type="checkbox"/> |
| 1g. chancroid .....  | <input type="checkbox"/> | <input type="checkbox"/> |
| 1h. genital HSV-1 or HSV-2 (active lesions).....   | <input type="checkbox"/> | <input type="checkbox"/> |
| 1i. genital warts of the labia minora, vagina, or cervix, or any other symptomatic genital warts ..... | <input type="checkbox"/> | <input type="checkbox"/> |
| 1j. cervicitis .....   | <input type="checkbox"/> | <input type="checkbox"/> |
| 1k. vaginitis.....   | <input type="checkbox"/> | <input type="checkbox"/> |
| 1l. pelvic inflammatory disease (PID) .....  | <input type="checkbox"/> | <input type="checkbox"/> |
| 1m. genital sores or ulcers.....   | <input type="checkbox"/> | <input type="checkbox"/> |
| 1n. any other STI or RTI requiring treatment, specify:<br>_____  | <input type="checkbox"/> | <input type="checkbox"/> |

**If yes to any, participant is ineligible. End of form.**

2. At this visit, does the participant have an abnormal physical or pelvic exam finding that, in the opinion of the investigator, would exclude her from the study? .....

yes	<input type="checkbox"/>
no	<input type="checkbox"/>

**If yes, participant is ineligible at this time. End of form.**

3. Is the participant in general good health?.....

yes	<input type="checkbox"/>
no	<input type="checkbox"/>

**If no, participant is ineligible. End of form.**

4. Per clinical judgment of the colposcopist, does visualization of the vaginal and cervical anatomy lend itself to colposcopy? .....

yes	<input type="checkbox"/>
no	<input type="checkbox"/>

**If no, participant is ineligible.**

Comments: \_\_\_\_\_



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## Clinical Eligibility – Page 1 (nonDF)

*This form is completed at the Screening 1 and Enrollment Visits only, and is used to document the participant's clinical eligibility for the study. It is completed at the Screening 1 Visit, and again at the Enrollment Visit. For the Screening 1 Visit, this form is completed once the Screening 1 Visit pelvic exam and wet mount have been conducted, and is completed based on review of the following Screening 1 Visit forms: STI Laboratory Results, Screening and Enrollment Pelvic Exam, History of Genital Symptoms (non-DataFax), and the Baseline Medical History form (non-DataFax). For the Enrollment Visit, this form is completed once the Enrollment Visit pelvic exam and wet mount have been conducted, and is completed based on review of the following Enrollment Visit forms: STI Laboratory Results, Screening and Enrollment Pelvic Exam, Baseline Genital Symptoms, and the Baseline Medical History form (non-DataFax). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

***Note:** None of the STIs/RTIs listed on this form should be documented on the Pre-existing Conditions form, even if the participant tested positive for one or more of these STIs/RTIs during screening. Because a participant is not eligible for enrollment if she is currently diagnosed with any of these STIs/RTIs, and because the Pre-existing Conditions form only documents ongoing conditions at the time of enrollment, none of the STIs/RTIs recorded on this form should be documented on the Pre-existing Conditions form.*

*If a participant is being re-screened, a new Clinical Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

- **Item 1:** For each STI or RTI listed, record whether the participant is **currently** diagnosed with that STI/RTI.
- **Item 1h:** Record whether the participant **currently** has active HSV-1 or HSV-2 anogenital lesion(s).
- **Item 2:** Record whether the participant **currently** has an abnormal physical or pelvic exam finding that, in the opinion of the investigator, makes her ineligible for study participation. This includes anatomical abnormalities, non-iatrogenic colposcopic findings involving deep epithelial disruption, and women with HPV warts exterior to the labia minora that require treatment.
- **Item 3:** Record whether, in the judgment of the site clinician, the participant's current health status is good.

**SAMPLE** *DO NOT FAX TO DATAFAX*

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

Page 1 of 2

**Participant ID**

Site Number			Participant Number						Chk	

**Screening Summary**

**Form Completion Date**

dd		MMM			yy		

1. Is the participant eligible based on review of all screening data? .....  <sup>yes</sup>  <sup>no</sup>

→ **If yes, end of form.**
  
2. The participant is ineligible because she: *Mark all that apply.*
  - 2a. is not between the ages of 18 and 24 at screening and enrollment, inclusive
  - 2b. is not able and willing to provide written informed consent to be screened for and to take part in the study
  - 2c. is not in general good health, as determined by the site clinician
  - 2d. is HIV-infected
  - 2e. has an abnormal Pap test result
  - 2f. is not sexually active (has not had vaginal intercourse at least once a week in the 30 days prior to screening)
  - 2g. is unwilling to use an effective method of contraception (as defined in the protocol) during the study
  - 2h. has had an IUD inserted in the 29 days prior to enrollment
  - 2i. is unwilling to undergo all study-related assessments (clinical and laboratory)
  - 2j. is unwilling to adhere to follow-up visit schedule
  - 2k. is unwilling to use VivaGel, VivaGel placebo, or HEC gel as required by the protocol
  - 2l. does not agree to refrain from participation in another study that uses spermicides, vaginal microbicides, or any other device or drug, while enrolled in the study
  - 2m. is unwilling to have partner use study-provided condoms for each act of intercourse while on study
  - 2n. is unwilling abstain from oral-vaginal and penile-anal intercourse
  - 2o. does not have a predictable menstrual cycle
  - 2p. has vaginal and cervical anatomy that does not lend itself to colposcopy
  - 2q. has a history of adverse reaction to latex
  - 2r. has a male sex partner with a history of adverse reaction to latex
  - 2s. is using or plans to use a diaphragm, vaginal ring, and/or spermicide for contraception
  - 2t. used oral and/or vaginal antibiotics or antifungal medications at screening or within 30 days of enrollment

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## Screening Summary – Page 1 (nonDF)

*This form is used to document the participant's eligibility for the study based on the entire screening process. This form is completed once all Screening 1 and Screening 2 Visit evaluations and forms/documentation have been completed and reviewed. If a participant is found to be ineligible at the Screening 1, Screening 2, or Enrollment Visit (prior to randomization), use this form to document the reason(s) the participant was not eligible for study participation. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

**Note:** *If a participant is being re-screened, a new **Screening Summary** form must be completed as part of the subsequent screening attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

- **Item 2:** If the participant is NOT eligible for enrollment in the study, *mark all* of the listed reasons that apply:
  - **Item 2a:** Review **Demographics** form, item 1.
  - **Item 2b:** Review **Screening Consent** form, items 2 and 2a; *and* **Enrollment** form, items 1 and 1a.
  - **Item 2c:** Review **Clinical Eligibility** form, item 3, from the Screening 1 and Enrollment Visits.
  - **Item 2d:** Review **STI Laboratory Results** form, item 2 from the Screening 1 Visit, OR if an **HIV Test Results** form is completed at the Screening 1 Visit, review the **HIV Test Results** form, item 5.
  - **Item 2e:** Review **Pelvic Laboratory Results** form, item 2, from the Screening 1 Visit.
  - **Item 2f:** Review **Screening 1 Visit Eligibility** form, item 10.
  - **Item 2g:** Review **Screening 1 Visit Eligibility** form, item 19, and **Screening 2 Visit/Enrollment Eligibility** form, item 11.
  - **Item 2h:** Review **Screening 2 Visit/Enrollment Eligibility** form, item 10.
  - **Item 2i:** Review **Screening 1 Visit Eligibility** form, item 25; *and* **Screening 2 Visit/Enrollment Eligibility** form, item 12.
  - **Item 2j:** Review **Screening 1 Visit Eligibility** form, item 24.
  - **Item 2k:** Review **Screening 1 Visit Eligibility** form, item 23.
  - **Item 2l:** Review **Screening 1 Visit Eligibility** form, item 18.
  - **Item 2m:** Review **Screening 1 Visit Eligibility** form, item 20.
  - **Item 2n:** Review **Screening 1 Visit Eligibility** form, item 21.
  - **Item 2o:** Review **Screening 1 Visit Eligibility** form, items 12 and 12a; *and* **Screening 2 Visit/Enrollment Eligibility** form, items 13 and 13a.
  - **Item 2p:** Review **Clinical Eligibility** form, item 4, from the Screening 1 and Enrollment Visits.
  - **Item 2q:** Review **Screening 1 Visit Eligibility** form, item 4.
  - **Item 2r:** Review **Screening 1 Visit Eligibility** form, item 5.
  - **Item 2s:** Review **Screening 1 Visit Eligibility** form, item 9; *and* **Screening 2 Visit/Enrollment Eligibility** form, item 5.
  - **Item 2t:** Review **Screening 1 Visit Eligibility** form, item 7, *and* **Screening 2 Visit/Enrollment Eligibility** form, item 2.

**SAMPLE** *DO NOT FAX*  
*TO DATAFAX*

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

Site Number			Participant Number						Chk	

**Screening Summary**

- 2u. has a history of adverse reaction to study product (VivaGel and/or applicator)
- 2v. has a history of prior participation in the study
- 2w. has a Grade 3 or higher laboratory abnormality at screening, and confirmed by retest and/or redraw
- 2x. had a gynecological surgical procedure within 90 days of enrollment
- 2y. is pregnant
- 2z. is within 90 days of last pregnancy outcome at enrollment
- 2aa. has an abnormal physical or pelvic exam finding that is exclusionary, per investigator
- 2ab. is diagnosed with a current STI and/or other RTI requiring treatment according to CDC guidelines
- 2ac. was diagnosed with or treated for an STI (except genital HSV recurrence and PID) within 6 months of enrollment
- 2ad. has a history of non-therapeutic injection drug use in the 12 months prior to enrollment
- 2ae. has participated in another study that uses spermicides, vaginal microbicides, or any other device or drug in the 30 days prior to enrollment
- 2af. is unwilling to abstain from use of other intravaginal products and/or devices (not including tampons)
- 2ag. is breastfeeding
- 2ah. exceeded the 36-day screening window
- 2ai. has any other condition that, in the opinion of the Investigator or designee, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives

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## Screening Summary – Page 2 (nonDF)

### Item-specific Instructions:

- **Item 2u:** Review **Screening 1 Visit Eligibility** form, item 6.
- **Item 2v:** Review **Screening 1 Visit Eligibility** form, item 2; *and* Screening and Enrollment Log.
- **Item 2w:** Review **Safety Laboratory Results** form, items 1–5 from the Screening 1 Visit.
- **Item 2x:** Review **Screening 1 Visit Eligibility** form, items 14 and 14a; *and* **Screening 2 Visit/Enrollment Eligibility** form, item 4.
- **Item 2y:** Review **Screening 1 Visit Eligibility** form, item 26; *and* **Screening 2 Visit/Enrollment Eligibility** form, item 14.
- **Item 2z:** Review **Screening 1 Visit Eligibility** form, items 13 and 13a; *and* **Screening 2 Visit/Enrollment Eligibility** form, item 6.
- **Item 2aa:** Review Screening and Enrollment Pelvic Exam forms, items 1 and 2, from both the Screening 1 and Enrollment Visits; **and** the **Clinical Eligibility** forms, item 2, from both the Screening and Enrollment Visits.
- **Item 2ab:** Review **Clinical Eligibility** forms, item 1, from both the Screening and Enrollment Visits.
- **Item 2ac:** Review **Screening 1 Visit Eligibility** form, items 15 and 15a; *and* **Screening 2 Visit/Enrollment Eligibility** form, item 7.
- **Item 2ad:** Review **Screening 1 Visit Eligibility** form, items 16 and 16a; *and* **Screening 2 Visit/Enrollment Eligibility** form, item 9.
- **Item 2ae:** Review **Screening 1 Visit Eligibility** form, items 17 and 17a; *and* **Screening 2 Visit/Enrollment Eligibility** form, item 1.
- **Item 2af:** Review **Screening 1 Visit Eligibility** form, item 22.
- **Item 2ag:** Review **Screening 1 Visit Eligibility** form, item 8; *and* **Screening 2 Visit/Enrollment Eligibility** form, item 3.
- **Item 2ah:** Review **Screening Consent** form, item 2a; *and* date of enrollment as recorded on **Enrollment** form, item 2b.
- **Item 2ai:** Review **Screening 1 Visit Eligibility** form, item 27; **Screening 2 Visit/Enrollment Eligibility** form, item 15.

**SAMPLE**. Do NOT FAX TO DATAFAX

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

Site Number			Participant Number						Chk		

**Screening 2 Visit/  
Enrollment Eligibility**

**Visit Date**

dd		MMM		yy	

To confirm your eligibility for the study, I need to ask you a few more questions.

1. In the past month (30 days), have you participated in any study, or do you plan to participate in any study, that uses spermicides, vaginal microbicides, or any other device or drug (including vaccine studies)? yes  no
  2. In the past 30 days, have you used oral and/or vaginal antibiotics or antifungal medications? .....
  3. Are you breastfeeding? .....
  4. In the past 3 months (90 days), have you had any gynecological surgery? This would include such procedures as: dilation and curettage (D&C); surgery of the uterus, ovaries, or fallopian tubes, and biopsy or cryotherapy (freezing) of the cervix. ....
  5. Are you currently using, or do you plan to use a diaphragm, vaginal ring, and/or spermicide for birth control at any time during your study participation? .....
  6. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion? .....
  7. In the past 6 months, have you been diagnosed or treated for any sexually transmitted infection, other than genital herpes (HSV) or pelvic inflammatory disease? .....
  8. Are you currently using, or do you plan to use any intravaginal products (other than tampons) or devices, including sex toys? .....
  9. In the past year (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional? .....
  10. Have you had an intrauterine device (IUD) inserted in the past 29 days? .....
  11. From today through one month after you finish using study products, do you agree to use one of the following types of birth control: Depo-Provera ("the shot"), hormonal contraceptives ("the pill"), Ortho-Evra ("the patch"), an intrauterine device (IUD - inserted at least 30 days prior to enrollment), female sterilization, or have vaginal sex with a male partner who has had a vasectomy? ..... yes  no
- **If yes to any, participant is ineligible.**  
→ **If no, participant is ineligible.**

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## Screening 2 Visit/Enrollment Eligibility – Page 1 (nonDF)

*This form is used to document the participant's eligibility for the study at the Screening 2 Visit. It is an interviewer-administered form. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

***Note:** If the Enrollment Visit does not take place on the say day as the Screening 2 Visit, all items on this form must be re-assessed on the day of enrollment (prior to enrollment) to confirm participant eligibility. A pregnancy test must be repeated on the day of enrollment (prior to enrollment) and the results should be recorded in the participant chart notes only.*

***Note:** If a participant is being re-screened, a new Screening Eligibility form must be completed as part of the subsequent screening attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### General Interviewer Tips:

*See Section 14.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

*It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.*

### Item-specific Instructions:

- **Items 1–13a:** These items were also asked during the Screening 1 Visit. They must be asked again in order to confirm the participant's eligibility for the study per the inclusion/exclusion criteria stated in the protocol. If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 13a. Do not inform her that she is ineligible for the study until the form has been administered. Also, refrain from indicating to the participant the reason why she is ineligible, to prevent socially desirable reporting.
- **Item 11:** If the participant's chosen effective method of contraception is sexual activity with a vasectomized partner, site staff must obtain documentation of the vasectomy in order to enroll the participant.

**SAMPLE**. Do NOT FAX TO DATAFAX

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

			-						-		
Site Number				Participant Number							Chk

**Screening 2 Visit/  
Enrollment Eligibility**

**Visit Date**

dd		MMM			yy

12. Are you willing to undergo all study evaluations, including a pelvic exam, colposcopy (when a clinician looks inside your vagina with a magnifying instrument), urine testing, and blood draws? .....

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

**If no, participant is ineligible.**

13. Do you have a regular menstrual cycle that is 21 days or longer? .....

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

**If yes, go to statement above item 14.**

13a. Is it because of the birth control you are using, such as Depo-Provera or Norplant? .....

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

**If no, participant is ineligible.**

**Complete item 14 when Screening 2 urine HCG result is available.**

14. Is the participant pregnant? .....

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

**If yes, participant is ineligible.**

**Complete item 15 after reviewing all Screening forms.**

15. Does the participant have any other condition that, in the opinion of the site investigator, would preclude provision or informed consent, make participation in the study unsafe, complicate interpretation of study objectives, or otherwise interfere with achieving study objectives? .....

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

**If yes, participant is ineligible.**



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## Screening 2 Visit/Enrollment Eligibility – Page 2 (nonDF)

*This form is used to document the participant's eligibility for the study at enrollment. This is a mixed form—some of the items are interviewer-administered (items 1–13a), while other items are not (items 1 and 14–15). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

**Note:** *If the Enrollment Visit does not take place on the say day as the Screening 2 Visit, all items on this form must be re-assessed on the day of enrollment (prior to enrollment) to confirm participant eligibility. A pregnancy test must be repeated on the day of enrollment (prior to enrollment) and the results should be recorded in the participant chart notes only.*

**Note:** *If a participant is being re-screened, a new Screening Eligibility form must be completed as part of the subsequent screening attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### General Interviewer Tips:

*See Section 14.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

*It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.*

### Item-specific Instructions:

- **Item 14:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Screening 2 Visit urine hCG result here.
- **Item 15:** This item is NOT interviewer-administered and should not be read aloud to the participant. This item should be completed by the site investigator or his/her designee once the Screening 2 Visit has been completed. If, for some reason other than those listed on any of the screening forms, the investigator or designee feels the participant is **not** a good candidate for the study, mark the “yes” box, record the reason in the participant’s chart notes, and do not enroll the participant in the study.

**SAMPLE**. Do NOT FAX  
TO DATAFAX

MTN 004 (136)



HSR-1 (331)

Visit Code

.

**Participant ID**

-      -   
Site Number Participant Number Chk

**HSV-2 Culture**

**Initial Specimen Collection Date**

*dd MMM yy*

Not done/  
Not collected

1. HSV-2 culture.....

*negative*

*positive*

Comments: \_\_\_\_\_

\_\_\_\_\_

---

## HSV-2 Culture (HSR-1)

This form is used to document HSV-2 culture results of genital (GUD) swabs collected during follow-up. If a test result on this form indicates that a participant has a laboratory-confirmed infection or diagnosis, this diagnosis/infection must be recorded as an adverse experience on the **Adverse Experience (AE) Log**.

**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. Complete date required.

### Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.

<p><b>Participant ID</b></p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> </tr> <tr> <td style="text-align: center; font-size: small;">Site Number</td> <td colspan="2" style="text-align: center; font-size: small;">Protocol</td> <td colspan="4" style="text-align: center; font-size: small;">Participant Number</td> <td colspan="3" style="text-align: center; font-size: small;">Chk</td> </tr> </table>											Site Number	Protocol		Participant Number				Chk			<p><b>Visit Code (Vst)</b></p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> </tr> </table>					<p><b>Specimen Collection Date</b></p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> <td style="border: 1px solid black; width: 25px; height: 25px;"></td> </tr> <tr> <td colspan="2" style="text-align: center; font-size: small;"><i>dd</i></td> <td colspan="3" style="text-align: center; font-size: small;"><i>MMM</i></td> <td colspan="3" style="text-align: center; font-size: small;"><i>yy</i></td> </tr> </table>									<i>dd</i>		<i>MMM</i>			<i>yy</i>		
Site Number	Protocol		Participant Number				Chk																																			
<i>dd</i>		<i>MMM</i>			<i>yy</i>																																					

# of TUBES (or Specimens)	PRIMARY SPECIMEN TYPE	ADDITIVE	INSTRUCTIONS FOR LAB <i>Unless otherwise noted, enter sub add/derivative code as N/A</i>
<input type="checkbox"/>	Blood (BLD)	<b>EDT</b> (purple top)	At the Enrollment and 2-Week Visits, lab to divide plasma into as many 0.5 mL aliquots as available to store for plasma archive.  Store with derivative PL 1/2.
<input type="checkbox"/>	Blood (BLD)	<b>HEP</b> (green top)	At the Enrollment and 2-Week Visits, lab to divide plasma into (2) aliquots of approximately 2.5 mL each for SPL7013 level testing.  Store with derivative PL 1/2.
<input type="checkbox"/>	Vaginal Gram Stain Slide (VAG)	<b>NON</b> (no additive)	Re-label with LDMS label. Store duplicate slides (one for on-site storage, and one for shipping and testing at MTN Central Lab). Store with derivative SLD and sub add/derivative GMS.
<input type="checkbox"/>	Cervical Swab (CXS)	<b>PBS</b>	Re-label cryovial with LDMS label. Store with derivative CXS.
<input type="checkbox"/>	Vaginal Swab (VAG)	<b>PAC</b>	Re-label cryovial with LDMS label. Store with derivative SWB.

Comments: \_\_\_\_\_

Initials: \_\_\_\_\_ LDMS Data Entry Date: 

--	--	--

 / 

--	--	--

 / \_\_\_\_\_  
Sending Staff    Receiving Staff    *dd*    *MMM*    *yy*    LDMS Staff

**LDMS Specimen Tracking Sheet (nonDataFax)**

*This form documents entry of specimens into the Laboratory Data Management System (LDMS). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

*A copy of this form accompanies LDMS specimens (in their original specimen collection containers) to each 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.*

**Item-specific Instructions:**

- **Visit Code:** Record the visit code of the visit at which the LDMS specimens were collected.
- **# of TUBES (or Specimens):** Record the total number of collected tubes or specimens of the listed primary specimen type that will be entered into LDMS. If no LDMS specimens of the primary specimen type were collected, record "0."
- **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 Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.

**SAMPLE**. Do NOT FAX  
TO DATAFAX



Visit Code

1

MTN 004 (136)

HTR-1 (351)

**Participant ID**

-       -   
Site Number Participant Number Chk

**HIV Test Results**

Sample 1

1. HIV Western Blot or IFA

Not done/ Not collected  Specimen Collection Date          
dd MMM yy

negative  positive  indeterminate

If negative, go to item 5, and contact MTN Central Lab.

If indeterminate, contact MTN Central Lab.

Sample 2

2. HIV Western Blot or IFA

Not done/ Not collected  Specimen Collection Date          
dd MMM yy

negative  positive  indeterminate

If positive, go to item 5.

If negative or indeterminate, contact MTN Central Lab.

Sample 3

3. HIV Western Blot or IFA

Not done/ Not collected  Specimen Collection Date          
dd MMM yy

negative  positive  indeterminate

Sample 4

4. HIV Western Blot or IFA

Not done/ Not collected  Specimen Collection Date          
dd MMM yy

negative  positive  indeterminate

**FINAL HIV STATUS**

5. Final status: ..... negative  positive  other, specify: \_\_\_\_\_

If positive at Screening, participant is ineligible.

Comments: \_\_\_\_\_

26-MAR-07

0  1   
Language

14-70  
Staff Initials / Date

---

## HIV Test Results (HTR-1)

*This form documents confirmatory HIV test results and final HIV status. This form is completed each time a participant has a positive HIV EIA test result.*

*Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax once results for **all** required specimens are available and recorded and item 5 has been completed.*

### Item-specific Instructions:

- **Visit Code:** The visit code recorded on this form should be the same visit code recorded on the STI Laboratory Results form documenting the positive HIV test result.
- **Specimen Collection Date:** Record the date the specimen was collected (NOT the date results were reported or recorded on the form). For Sample 1, the Specimen Collection Date should be the same date as the collection date of the HIV EIA positive specimen.
- **Not done/Not collected:** Mark this box in the event that a specimen is collected, but a result is not available due to specimen loss or damage. Explain in the Comments section at the bottom of the form why the result is not available.
- **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, mark the "other, specify" box and specify reason(s) on the line provided. If the participant's final HIV status is determined to be positive (according to the protocol testing algorithm) during study follow-up, report the HIV infection as an AE on the AE Log.
- **Comments:** Use this section to document any problems or reasons why expected results are not available; for example, if the sample was lost or damaged.

**SAMPLE** *Do NOT FAX TO DATAFAX*

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

-      -

Site Number      Participant Number      Chk

**Pelvic Exam Diagrams**

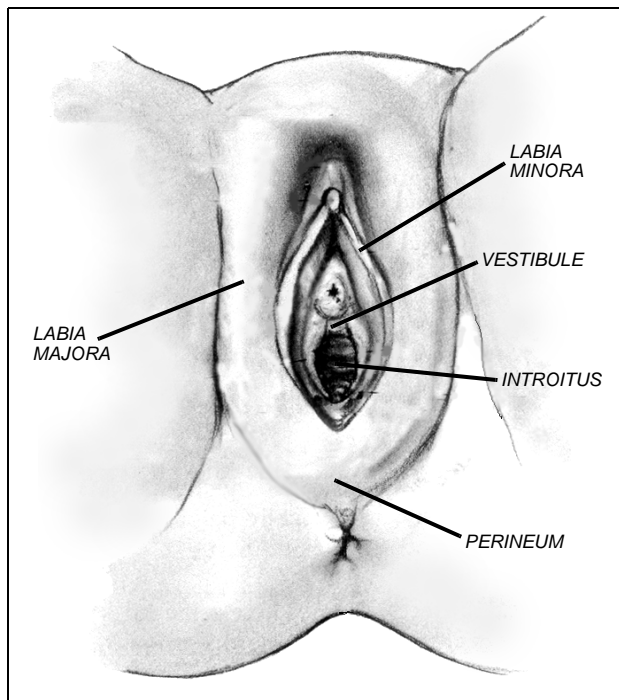
no normal variants or abnormal findings observed

**Exam Date**

/    /

dd      MMM      yy

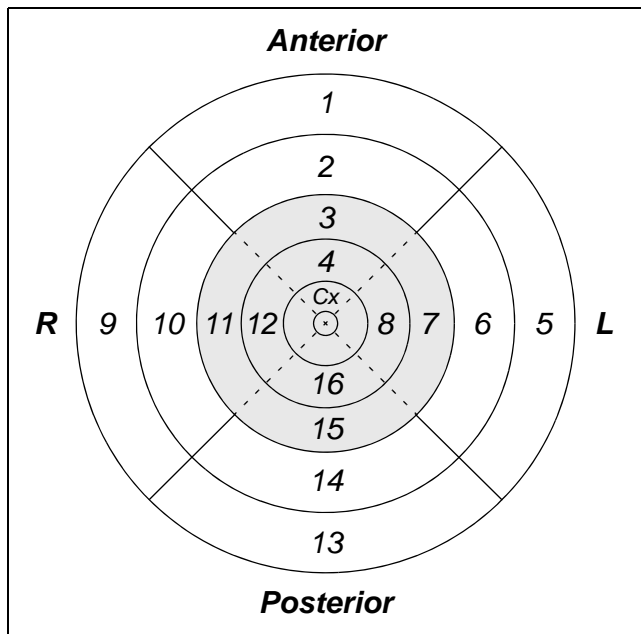
**External Genitalia**



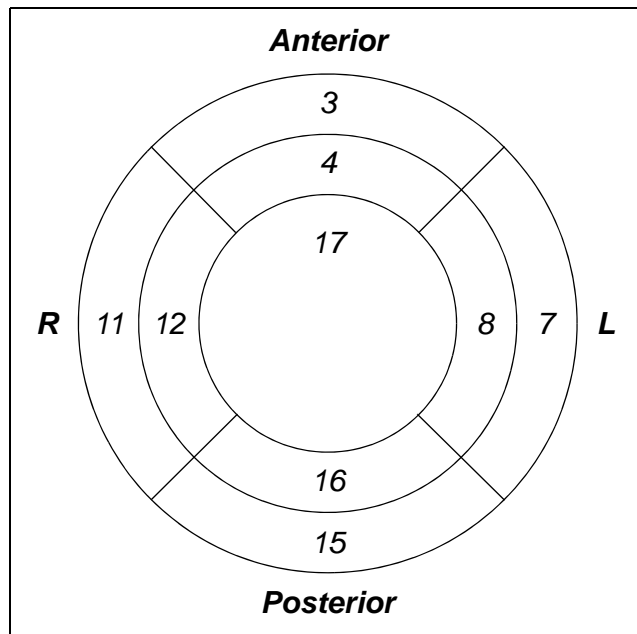
**Legend for Vagina/Cervix**

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

**Vagina**



**Cervix**





---

## **Pelvic Exam Diagrams (nonDF)**

*This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through study exit). This form is completed each time a pelvic or pelvic/colposcopy exam is performed. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

### **Item-specific Instructions:**

- 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 DataFax Pelvic Exam forms. The following findings are considered normal variants:
  - anatomic variants
  - mucus retention cysts
  - atrophic changes
  - Nabothian cysts
  - gland openings
  - Gartner's duct cysts
  - skin tags
  - ectopies
- If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box.
- Documenting findings on the cervix: If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).

**SAMPLE** *DO NOT FAX*  
*TO DATAFAX*

MTN 004 (136)

 Visit Code

**Participant ID**

-  -   
Site Number Participant Number Chk

**Family Planning Methods**

**Visit Date**

*dd MMM yy*

1. Which family planning method or methods is the participant currently using? Mark "none" or all that apply.

- 1a. none
- 1b. vaginal ring
- 1c. spermicide
- 1d. diaphragm
- 1e. sponge
- 1f. intrauterine device (IUD)
- 1g. natural methods such as the withdrawal or rhythm method
- 1h. male condoms
- 1i. female condoms
- 1j. family planning pills or birth control pills
- 1k. injectable contraceptives (such as Depo-Provera)
- 1l. Norplant inserts
- 1m. Ortho Evra/The Patch
- 1n. surgical sterilization (tubal ligation)
- 1o. sex with partner who had a vasectomy
- 1p. other, specify:

\_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

---

## Family Planning Methods (FPM-1)

*This form is completed by a site staff member to collect information about the family planning methods that the participant is currently using. It is completed at the Enrollment, One-week, Two-week, and Three-week Clinic Visits.*

### Item-specific Instruction:

- **Item 1:** Transcribe the family planning methods as documented on the non-DataFax **Baseline Medical History** form for the Enrollment Visit or as documented on the non-DataFax **Follow-up Medical History** form for follow-up visits.

SAMPLE. Do NOT FAX TO DATAFAX



MTN 004 (136)

BGS-1 (030)

Participant ID

Participant ID form with Site Number, Participant Number, and Chk fields.

Baseline Genital Symptoms

Visit Date

Visit Date form with dd, MMM, and yy fields.

1. Since your last study visit, have you experienced any of the following symptoms:

If yes: Are you currently experiencing this symptom?

- 1a. Genital sores?
1b. Genital/vaginal itching?
1c. Genital/vaginal burning?
1d. Genital/vaginal pain?
1e. Pain during sex?
1f. Difficulty when urinating?
1g. Burning when urinating?
1h. Abnormal or unusual genital/vaginal discharge?
1i. Unusual genital/vaginal odor?
1j. Abnormal or unusual menstrual cramping?
1k. Other genital symptoms?

1k1. If yes, specify below.

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

- 1l. Vaginal bleeding or spotting between your usual menstrual periods?
1m. Blood-tinged discharge?

Comments: \_\_\_\_\_

---

## Baseline Genital Symptoms (BGS-1)

*This form is interviewer-administered and is used to document genital symptoms reported by the participant at the Enrollment Visit.*

**Note:** *If a participant is being re-screened, a new Baseline Genital Symptoms form must be completed as part of the subsequent screening attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### Interview tips:

*See Section 14.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- It is important for you to review this form for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

**Note:** *Responses to all of the items on this form are based on participant recall at the time of the Enrollment Visit. When administering this form, do **not** refer back to the non-DataFax History of Genital Symptoms form. Any clarifications and/or updates to this form should be made during the Enrollment Visit only, unless requested otherwise by SCHARP. Once the participant has completed the Enrollment Visit, do **not** make any further updates or changes to the responses recorded on this form. Record symptoms that are ongoing at the time of enrollment on the Pre-existing Conditions form.*

### Item-specific Instructions:

**Note:** *There is no visit code field on this form since this form is only administered during enrollment.*

- **Item 1:** This item refers to any genitourinary symptoms the participant may have experienced since her last Screening Visit. This may include symptoms that were reported as ongoing at the last Screening Visit. Read each item 1a–1m aloud. For each item marked “yes,” complete the adjacent item, “If yes: Are you currently experiencing this symptom?” For items marked “no,” leave the adjacent item “If yes: Are you currently experiencing this symptom?” blank. For any item 1a–1k marked “yes,” evaluate the participant for STIs/RTIs per the protocol and SSP. If the participant is diagnosed with an STI/RTI that is exclusionary per protocol, do **not** enroll the participant. Provide treatment as necessary (per CDC guidelines).
  - **If yes: Are you currently experiencing this symptom?:** For any item 1a–1m marked “yes” (meaning the condition is ongoing), record the symptom on the Pre-existing Conditions form.
  - **Item 1j:** This item is intended to capture dysmenorrhea reported at baseline.
  - **Item 1k:** If “yes” is marked, record the participant’s verbatim response on the “Local Language” line. If the response is given in a language other than English, provide the English translation on the “English” line.

**If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused” in the white space next to the response boxes, and initial and date.**

**SAMPLE** Do NOT FAX  
TO DATAFAX



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

MTN 004 (136)

PRE-1 (012)

Participant ID

--  
Site Number Participant Number Chk

Pre-existing Conditions

Form Completion Date

dd MMM yy

No pre-existing conditions reported or observed. \_\_\_\_\_ → End of form. Fax to SCHARP DataFax.  
Staff Initials / Date

1. 

Description	Date of Diagnosis/Surgery <span style="float: right;">MMM yy</span> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Comments	Is condition ongoing? <span style="float: right;">yes no</span> <input type="checkbox"/> <input type="checkbox"/> <span style="float: right;">_____</span> Staff Initials / Date
2. 

Description	Date of Diagnosis/Surgery <span style="float: right;">MMM yy</span> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Comments	Is condition ongoing? <span style="float: right;">yes no</span> <input type="checkbox"/> <input type="checkbox"/> <span style="float: right;">_____</span> Staff Initials / Date
3. 

Description	Date of Diagnosis/Surgery <span style="float: right;">MMM yy</span> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Comments	Is condition ongoing? <span style="float: right;">yes no</span> <input type="checkbox"/> <input type="checkbox"/> <span style="float: right;">_____</span> Staff Initials / Date
4. 

Description	Date of Diagnosis/Surgery <span style="float: right;">MMM yy</span> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Comments	Is condition ongoing? <span style="float: right;">yes no</span> <input type="checkbox"/> <input type="checkbox"/> <span style="float: right;">_____</span> Staff Initials / Date
5. 

Description	Date of Diagnosis/Surgery <span style="float: right;">MMM yy</span> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Comments	Is condition ongoing? <span style="float: right;">yes no</span> <input type="checkbox"/> <input type="checkbox"/> <span style="float: right;">_____</span> Staff Initials / Date
6. 

Description	Date of Diagnosis/Surgery <span style="float: right;">MMM yy</span> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Comments	Is condition ongoing? <span style="float: right;">yes no</span> <input type="checkbox"/> <input type="checkbox"/> <span style="float: right;">_____</span> Staff Initials / Date

---

## Pre-existing Conditions (PRE-1)

This form is used to document the participant's pre-existing medical conditions. Only medical conditions experienced up to study product initiation should be recorded unless otherwise specified in the protocol or Study Specific Procedures (SSPs). Include current medical conditions and any ongoing conditions such as mental illness, alcoholism, drug abuse, and chronic conditions (controlled or not controlled by medication).

- **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.
- **Description:** 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."
- **Date of Diagnosis/Surgery:** If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required. If the date is within the same year as study enrollment, the month and year are both required. If the condition is diagnosed due to an abnormal lab result, record the date on which the specimen was collected. If a diagnosis is not available, record the date of onset of condition.
- **Comments:** This field is optional. Use it to record any additional relevant information about the condition.
- **Is condition ongoing?:** Mark "yes" if condition is ongoing at enrollment.
- **Pre-existing Conditions Revisions and Updates:**
  - If a participant recalls a pre-existing condition at a later date, update the form at that time. Refax updated page(s).

SAMPLE. Do NOT FAX TO DATAFAX



MTN 004 (136)

ENR-1 (071)

Participant ID

Participant ID form with Site Number, Participant Number, and Chk boxes.

Enrollment

Form Completion Date

Form Completion Date form with dd, MMM, and yy boxes.

1. Was the participant able and willing to provide written informed consent for enrollment? .....

Form for question 1 with yes/no checkboxes and instruction: 'If no, participant is ineligible. End of form.'

1a. When was the informed consent form for enrollment marked or signed? .....

Date form for question 1a with dd, MMM, and yy boxes.

2. Was a clinic randomization envelope assigned (or a replacement envelope, if a replacement participant)? .....

Form for question 2 with yes/no checkboxes and instruction: 'If no, specify reason in Comments. End of form.'

2a. Envelope number:.....

Form for question 2a with three boxes.

2b. Date assigned: .....

Date form for question 2b with dd, MMM, and yy boxes.

2c. Time assigned:.....

Time form for question 2c with hr and min boxes and '24-hour clock' label.

2d. First randomization code: .....

Form for question 2d with three boxes.

2e. Second randomization code: .....

Form for question 2e with three boxes, 'OR' text, and 'N/A' checkbox.

If not a replacement participant, go to item 3.

2f. Randomization code of previously enrolled participant: .....

Form for question 2f with three boxes.

3. Date study gel dispensed: .....

Date form for question 3 with dd, MMM, and yy boxes.

4. How many cartons of study gel were dispensed? .....

Form for question 4 with a box and '# of cartons dispensed' label.

5. Randomization code of first dispensed carton:.....

Form for question 5 with three boxes.

6. Randomization code of second dispensed carton:.....

Form for question 6 with three boxes.

Comments: \_\_\_\_\_



---

## Enrollment (ENR-1)

*This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for participants determined to be eligible for the study. This form is faxed to SCHARP DataFax only if the participant is enrolled (that is, she is assigned a clinic randomization envelope, or a replacement envelope, for replacement participants), and only after completion of the Enrollment Visit.*

### Item-specific Instructions:

*Note: There is no visit code field on this form since this form is only administered at the Enrollment visit.*

- **Item 1:** If this item is “no” (the participant is not able and willing to provide written informed consent for enrollment), end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.
- **Item 2:** If a clinic randomization envelope (or a replacement envelope, if a replacement participant) is not assigned, mark the “no” box and specify in the Comments section the reason an envelope was not assigned, then end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax if an clinic randomization envelope is not assigned.
- **Item 2a:** Record the 3-digit envelope number present on the envelope assigned to this participant.
- **Item 2b:** Record the date the envelope was assigned to the participant. This date should match the “date assigned” recorded for this envelope on the appropriate Envelope Tracking Record and on the study prescription inside the envelope.
- **Item 2c:** Record the time (using a 24-hour clock) when the envelope was assigned to the participant. This time should match the “time assigned” recorded for this envelope on the appropriate Envelope Tracking Record.
- **Item 2d:** Record the first 3-digit randomization code present on the prescription contained in the participant's randomization envelope.
- **Item 2e:** This item is for replacement participants only. Record the second 3-digit randomization code present on the participant's replacement prescription contained inside her replacement envelope. Record the second 3-digit randomization code present on the prescription contained in the participant's randomization envelope.
- **Item 2f:** This item applies only to replacement participants (i.e., participants who enroll in the study to replace previously enrolled, non-adherent participants). Record the first randomization code pre-printed on the prescription of the non-adherent participant who is being replaced.
- **Item 3:** Record the exact day, month, and year the study gel was first dispensed to this participant.
- **Item 4:** Record the number of study gel cartons dispensed to the participant. *NOTE: A standard number of two cartons should be dispensed at the Enrollment Visit. If more than two cartons are dispensed, record the reason why in the Comments section.*
- **Item 5:** From the site pharmacist (or designee), obtain and record the unique 3-digit randomization code present on the carton label of the first carton of study gel dispensed to the participant.
- **Item 6:** From the site pharmacist (or designee), obtain and record the 3-digit randomization code present on the carton label of the second carton of study gel dispensed to the participant.

**SAMPLE**. Do NOT FAX  
TO DATAFAX

MTN 004 (136)

PK-1 (061) Visit Code

□□□.□□

□  
1

**Participant ID**

□□□-□□□□□□-□  
Site Number Participant Number Chk

**Pharmacokinetics**

**Specimen Collection Date**

□□ □□□ □□  
dd MMM yy

1. Was a blood specimen collected for measuring SPL7013 levels for this participant? .....  *yes*

*no* → **If no, explain in Comments section. End of form.**

2. Participant height: ..... □□□ *cm*

3. Participant weight:..... □□□ *kg*

4. Blood draw time: ..... □□ : □□ *hr min 24-hour clock*

**Complete item 5 for follow-up visits only.**

5. Date and time of last study gel application before this visit:..... □□ □□□ □□ □□ : □□ □□ *dd MMM yy hr min 24-hour clock*

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

---

## Pharmacokinetics (PK-1)

*This form is used to document the required Pharmacokinetics (PK) specimen collections at the Enrollment and Two-week Clinic Visits.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 14.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the week on study plus 2.0. For example, the One-week Clinic Visit is assigned a visit code of “03.0,” the Two-week Clinic Visit is assigned a visit code of “04.0,” etc.
- **Item 1:** If a PK specimen was not collected, mark the “no” box and provide an explanation in the Comments section at the bottom of the form. If the specimen was collected but is not available for testing (i.e., due to specimen loss or damage), mark the “yes” box and provide an explanation in the Comments section at the bottom of the form.
- **Item 4:** Record the time (using a 24-hour clock) when the PK specimen was drawn.
- **Item 5:** Record the date and time of the participant’s last (most recent) application of study gel prior to the PK draw. If specimen is collected at the Enrollment Visit, leave this item blank.

**SAMPLE** *DO NOT FAX*  
*TO DATAFAX*

MTN 004 (136)



FV-1 (121)

Visit Code   .

**Participant ID**

-      -   
Site Number Participant Number Chk

**Follow-up Visit**

**Visit Date**

dd MMM yy

1. hCG for pregnancy:  *not done*  *negative*  *positive*  
1a. Specify reason(s):  *not done*  *negative*  *positive*  
\_\_\_\_\_ **If positive, complete Pregnancy Report and History form and Product Hold/Discontinuation form.**

2. Were any new adverse experiences reported at this visit? .....  *yes*  *no* **If no, go to item 3.**

2a. How many **new** AE Log pages were completed for this visit? .....   # of pages

3. At this visit, how many **unused** applicators did the participant return? .....   # of **unused** applicators returned

4. **NO LONGER APPLICABLE FOR THIS PROTOCOL.** applicators did the participant return? **NO LONGER APPLICABLE FOR THIS PROTOCOL.**   # of **unused** applicators returned

5. At this visit, how many cartons of study gel were dispensed to the participant? .....  # of cartons dispensed **If 0, end of form.**

5a. Randomization code of first dispensed carton: .....

5b. Randomization code of second dispensed carton: .....    OR  N/A

Comments: \_\_\_\_\_

---

## Follow-up Visit (FV-1)

*This form is used to document the required (regularly scheduled) One-week, Two-week, and Three-week Clinic follow-up visits. It is completed at each regularly scheduled follow-up visit, regardless of whether the visit is conducted within the protocol-specified window or made up outside the visit window.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 14.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the week on study plus 2.0. For example, the One-week Clinic Visit is assigned a visit code of “03.0,” the Two-week Clinic Visit is assigned a visit code of “04.0,” etc.
- **Item 1:** Record the hCG urine pregnancy test result. If a urine pregnancy test result is not available (specimen not collected and/or test not done), mark the “not done” box and complete item 1a. *Note: A Pregnancy Report and History form must be completed for each pregnancy.* Once a participant tests positive for hCG urine pregnancy and a Pregnancy Report and History form (PR-1) has been completed for this pregnancy, subsequent positive pregnancy test results should not be recorded on a new PR-1 unless they represent a new pregnancy.
- **Item 1a:** Specify the reason(s) why the required pregnancy test was not done.
- **Item 2:** Mark the “yes” box if a new (previously unreported) AE is reported or observed at this visit. If the box is marked “yes,” record in item 2a how many **new** AE Log pages were completed for this visit. For example, if two new AEs were reported, record “02.” Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
- **Item 3:** Record the number of **unused** study gel applicators the participant returned at this visit only.
- **Item 5:** Record the number of cartons of study gel given to the participant at this visit. This will be the same amount documented on the **Study Gel Request Slip** (and/or on the **Replacement Prescription**, if replacement carton(s) are also dispensed), unless documentation from the pharmacy staff states otherwise.
- **Item 5a:** From the site pharmacist (or designee), obtain and record the unique 3-digit randomization code present on the carton label of the first carton of study gel dispensed to the participant at this visit.
- **Item 5b:** From the site pharmacist (or designee), obtain and record the unique 3-digit randomization code present on the carton label of the second carton of study gel dispensed to the participant at this visit. If a second carton was not dispensed at this visit, mark the “N/A” box.

**SAMPLE**. Do NOT FAX  
TO DATAFAX

MTN 004 (136)



SGA-1 (173)

Visit Code

**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"/>	
Site Number				Participant Number						Chk	

**Study Gel Adherence**

**Visit 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"/>
dd		MMM			yy		

I know that you are counseled to insert the study gel in the morning and in the evening each day, but I also know that this is not always possible.

1. Since your last regularly scheduled study visit, how many applicators have you used? .....   # applicators

2. Since your last regularly scheduled study visit, was there ever a day in which you used the study gel less than two times? .....  *yes*     *no* → **If no, end of form.**

2a. How many days did you use the study gel less than two times? .....   # days

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

---

## Study Gel Adherence (SGA-1)

*This form is used to collect information on study gel adherence from study participants. This is an interviewer-administered form, and it is administered at the one-week and two-week clinic visits. Note: If the participant misses her two-week clinic visit, administer this form at her three-week clinic visit.*

### **Item-specific Instructions:**

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 2a:** Record the total number of days since the participant's last regularly scheduled visit that she reports using the study gel less than twice a day. The number of days reported should not exceed the number of days since the participant's last regularly scheduled visit.

*If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.*

SAMPLE Do NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

MTN 004 (136)

FGS-1 (136)

Participant ID

Site Number [ ][ ][ ] - Participant Number [ ][ ][ ][ ][ ] - Chk [ ]

Follow-up Genital Symptoms

Visit Date

dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]

1. Since your last study visit, have you experienced any of the following symptoms:

If yes: When did you first experience this symptom?

Continuing from previous visit

Table with 8 columns: Symptom description, yes, no, dd, MMM, yy, OR, and Continuing from previous visit. Rows include genital sores, itching, burning, pain, sex pain, urinating difficulty, burning, discharge, odor, and menstrual cramping.

1k1. If yes, specify below.

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

If yes to any, conduct pelvic exam if clinically indicated. Update or complete Adverse Experience Log when applicable.

Table with 8 columns: Symptom description, yes, no, dd, MMM, yy, OR, and Continuing from previous visit. Rows include vaginal bleeding and blood-tinged discharge.

If yes to any, complete Genital Bleeding Assessment form if indicated. Conduct pelvic exam if indicated.

Comments: \_\_\_\_\_



---

## Follow-up Genital Symptoms (FGS-1)

*This form is interviewer-administered, and is used to document genital symptoms reported by the participant during study follow-up. It is completed at each regularly scheduled follow-up visit (the One-week, Two-week, and Three-week Clinic Visits).*

### Interview tips:

*See Section 14.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- It is important for you to review this form for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

**Note:** Responses to all of the items on this form are based on participant recall at the time the form is being administered. When administering this form, **do not** refer back to previously completed Genital Symptoms forms (Baseline and Follow-up). Any clarifications and/or updates to this form should be made only during the visit in which this form is completed, unless requested otherwise by SCHARP. Once the participant has completed the visit, do not make any further updates or changes to the responses recorded on this form. If, at a subsequent study visit, the participant reports additional symptoms she experienced at baseline, or at a time point covered by a previous Follow-up Genital Symptoms form, do **not** update any of the previously completed forms. Instead, record the new information on the current Follow-up Genital Symptoms form and explain the discrepancy in both the Comments section and/or in the participant's chart notes. If the participant reports additional symptoms that were ongoing at enrollment, record these on the Pre-existing Conditions form.

**Once the interview is complete,** review the completed Genital Symptoms form (Baseline or Follow-up) from the previous visit and identify any symptoms that were a) reported as ongoing, and b) documented on an AE Log. If the same symptoms are reported as not present at the current visit (response on current visit's Follow-up Genital Symptoms form is "no"), query the participant for an outcome date and record this in item 6a of the associated AE Log.

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 14.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the week on study plus 2.0. For example, the One-week Clinic Visit is assigned a visit code of "03.0," the Two-week Clinic Visit is assigned a visit code of "04.0," etc.
- **Item 1:** Read each item 1a-1m aloud. For any item marked "yes," conduct a pelvic exam if clinically indicated (and not already required for the visit). For each item marked "yes," complete an Adverse Experience (AE) Log if this is the **first** time the symptom is reported since the participant enrolled in the study. If this is **not** the first time the condition has been reported since enrollment, an AE Log should already have been completed for this condition—review the previously completed AE Log and either update any relevant information, or complete a new AE Log as necessary (e.g., in cases where a previously reported AE has increased in severity or frequency). If the symptom was first reported on the participant's Baseline Genital Symptoms and Pre-existing Conditions forms and it has not increased in severity or frequency, **do not** complete an AE Log—do record on this form that the condition has not increased in severity or frequency since enrollment/baseline.
- **Item 1j:** This item is intended to capture dysmenorrhea reported during follow-up visits. If the participant reports dysmenorrhea and/or any other symptom(s) related to menstruation, probe for further information (i.e., type and severity of symptoms), then compare to participant's usual baseline menstrual symptoms (as documented on the non-DataFax Baseline Medical History form and Baseline Genital Symptoms form) to determine whether an AE should be reported.
- **Item 1k:** If "yes" is marked, record the participant's verbatim response on the "Local Language" line. If the response is given in a language other than English, provide the English translation on the "English" line.
- **If yes: When did you first experience this symptom?:** For each item marked "yes," record the day, month, and year the participant first began experiencing symptoms; if necessary, use a calendar to probe. If the participant provides a date that is prior to the date of the previous visit, mark "continuing from previous visit" and leave the day, month, and year boxes blank. If the participant states that a symptom began on the exact date of the previous visit, clarify whether or not the symptom was present at the time the visit occurred. If she states that the symptom was present during the previous visit, mark "Continuing from previous visit" and leave the day, month, and year boxes blank. If the participant states that the symptom occurred on the same day as the previous visit, but after she had completed the visit, record the day, month, and year of the previous visit and leave the "continuing from previous visit" box blank.
- **Continuing from previous visit:** Mark this box for symptoms reported as continuing since the time of the previous visit. If this box is marked, leave the "If yes: When did you first experience symptoms?" boxes blank. If a date is recorded, leave the corresponding "continuing from previous visit" box blank.

**Items 1l-1m:** If the participant reports vaginal bleeding or spotting between usual menstrual periods, or any blood-tinged genital/vaginal discharge, refer to Section 10 of the Study-Specific Procedures Manual and protocol Appendix II.

SAMPLE Do NOT FAX TO DATAFAX



Visit Code

Form boxes for Visit Code

Form box containing the number 1

MTN 004 (136)

FPE-1 (165)

Participant ID

Form boxes for Participant ID: Site Number, Participant Number, Chk

Follow-up Pelvic Exam

Exam Date

Form boxes for Exam Date: dd, MMM, yy

1. Naked eye, speculum, and bimanual exam assessments: not done, no abnormal findings, abnormal findings. Includes instructions for 'not done' and 'no abnormal findings'.

1a. Abnormal non-colposcopic findings: Mark all that apply.

- 1a1. enlarged/tender inguinal lymph nodes
1a2. abnormal vaginal discharge
1a3. abnormal cervical discharge
1a4. blood-tinged discharge
1a5. blood in vagina—no identified source
1a6. blood from cervical os
1a7. bleeding from site of epithelial disruption
1a8. erythema
1a9. ulceration
1a10. laceration
1a11. abrasion
1a12. peeling
1a13. petechia
1a14. ecchymosis
1a15. vesicles
1a16. edema
1a17. abnormal cysts
1a18. grossly white finding
1a19. mass
1a20. warts—on and/or interior to labia minora
1a21. warts—exterior to labia minora
1a22. adnexal tenderness
1a23. cervical motion tenderness
1a24. uterine tenderness
1a25. other abnormal findings, specify:

If finding is new, complete Adverse Experience Log as applicable.

2. Do any of these exam findings involve generalized erythema or severe edema...?
3. Do any of these exam findings involve deep epithelial disruption (ulceration)?
3a. Was the deep epithelial disruption (ulceration) observed in more than one distinct area?
4. Do any of these exam findings involve presumed cervicitis?
5. Do any of these exam findings involve superficial epithelial disruption (abrasion/peeling)?
6. Do any of these exam findings involve disrupted blood vessels?
6a. Were disrupted blood vessels observed in more than one distinct area?

---

## Follow-up Pelvic Exam (FPE-1)

*This form, along with the non-DataFax Pelvic Exam Diagrams, is used to document the pelvic (and, when applicable, colposcopy) exams conducted during study follow-up.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 14.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the week on study plus 2.0. For example, the One-week Clinic Visit is assigned a visit code of “03.0,” the Two-week Clinic Visit is assigned a visit code of “04.0,” etc.
- **Item 1:** A pelvic exam is required at the One-week, Two-week, and Three-week Clinic Visits, and when clinically indicated. Document only those abnormal findings observed during naked eye, speculum, and bimanual examination. If a pelvic exam was required but not done, mark the “not done” box and record the reason the required pelvic exam was not done in the Comments section at the bottom of page 3. If no abnormal findings are observed, mark the “no abnormal findings” box, leave item 1a blank and go to item 9. If one or more abnormal findings are observed, mark the “abnormal findings” box and continue to item 1a.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed via naked eye, speculum, and bimanual examination **only**. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.
- **Items 1a2, 1a8, and 1a16:** If abnormal vaginal discharge, erythema, or edema are observed, refer to protocol Appendix II.
- **Items 2–6:** If the response to any of these items is “yes,” refer to protocol Appendix II for further instructions on study gel use and clinical follow-up. These questions refer to the abnormal findings documented in item 1a. They do **not** include abnormal findings observed by colposcopy only.

**SAMPLE**. Do NOT FAX  
TO DATAFAX



Visit Code

1

MTN 004 (136)

FPE-2 (166)

**Participant ID**

-      -   
Site Number Participant Number Chk

**Follow-up Pelvic Exam**

7. Was unexpected genital bleeding observed (that is **not** associated with an abnormal exam finding)? .....

yes  no

*If yes, refer to protocol Appendix II. Complete Genital Bleeding Assessment form.*

8. Do any pelvic exam findings from this visit warrant a product hold?.....

yes  no

*If yes, complete Product Hold/Discontinuation form.*

9. Colposcopic exam assessment: *Required at Two-week Clinic Visit.*

not done  no abnormal findings  abnormal findings

9a. Abnormal **colposcopic** findings: *Mark all that apply.*

*If not done OR no abnormal findings, go to item 10 on page 3.*

- 9a1. abnormal vaginal discharge
- 9a2. abnormal cervical discharge
- 9a3. blood-tinged discharge
- 9a4. blood in vagina—no identified source
- 9a5. blood from cervical os
- 9a6. bleeding from site of epithelial disruption
- 9a7. erythema
- 9a8. ulceration
- 9a9. laceration
- 9a10. abrasion
- 9a11. peeling
- 9a12. petechia
- 9a13. ecchymosis
- 9a14. vesicles
- 9a15. edema
- 9a16. abnormal cysts
- 9a17. grossly white finding
- 9a18. mass
- 9a19. warts—on and/or interior to labia minora
- 9a20. warts—exterior to labia minora
- 9a21. other abnormal findings, specify:  
\_\_\_\_\_

---

## Follow-up Pelvic Exam (FPE-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Items 7–8:** If the response to either of these items is “yes,” refer to protocol Appendix II for further instructions on study gel use and clinical follow-up. These questions refer to the abnormal findings documented in item 1a. They do **not** include abnormal findings observed by colposcopy only.
- **Item 9:** Colposcopy is required at the Two-week Clinic Visit, and when clinically indicated. Document any abnormal findings observed during colposcopic examination **only**. If the exam did not include colposcopy, mark the “not done” box, leave item 9a blank and go to item 2. If colposcopy was required but not done, also record the reason the required colposcopy was not done in the Comments section at the bottom of page 3. If no abnormal findings are observed, mark the “no abnormal findings” box, leave item 9a blank and go to item 2. If one or more abnormal findings are observed, mark the “abnormal findings” box and continue to item 9a. Note: Abnormal findings observed by colposcopy only are not reportable as AEs.
- **Item 9a:** Mark the box to the left of **each** abnormal finding observed on colposcopy **only**. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.

**SAMPLE** *DO NOT FAX*  
*TO DATAFAX*



Visit Code

MTN 004 (136)

FPE-3 (167)

**Participant ID**

-  -   
Site Number Participant Number Chk

**Follow-up Pelvic Exam**

10. Cervical Ectopy: Percentage of cervical surface area.

0%      1-25%      26-50%      51-75%      > 75%  
                       

*naked eye*      *colposcopy*

10a. Cervical ectopy assessed by: .....      

**Alternate Collection Date**

*dd*      *MMM*      *yy*  
           

*not required*      *stored*      *not stored*      *Reason:*

11. Gram stain (vaginal)                   → \_\_\_\_\_

12. Cervical swabs.....                   → \_\_\_\_\_

13. GUD swab(s) .....                   → \_\_\_\_\_  
# of swabs

14. Vaginal swab.....                   → \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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## Follow-up Pelvic Exam (FPE-3)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Items 10 and 10a:** When colposcopy is performed, cervical ectopy must be assessed by colposcopy and not by naked eye. If colposcopy is not performed, item 10a should be marked “naked eye.”
- **Items 11–14:** Record the alternate collection date when the specimen(s) was *collected* for this visit if the date is not the same as the Exam Date (NOT the date results were reported or recorded on the form). Complete date required.
- **Item 11:** Collection of a vaginal Gram Stain smear (duplicate slides) is required as part of the One-week, Two-week, and Three-week Clinic Visit pelvic exams. If a vaginal Gram Stain smear was not collected at one of these visits, mark the “not stored” box and record the reason.
- **Item 12:** Collection of cervical swabs for cytokine and innate factor testing is required as part of the One-week, Two-week, and Three-week Clinic Visit pelvic exams. If cervical swabs were not collected at one of these visits, mark the “not stored” box and record the reason.
- **Item 13:** A multiplex PCR swab for genital ulcer disease (GUD) is collected at the One-week, Two-week, and Three-week Clinic Visits for each genital ulcer, cluster of ulcers, and/or other anogenital finding thought to be Herpetic. If one or more swabs are collected, mark the “stored” box and record the number of swabs collected. If no swab collection is warranted, mark the “not required” box. If a genital ulcer, cluster of ulcers, and/or other potentially Herpetic anogenital finding is observed, but no swab is collected, mark the “not stored” box and record the reason.
- **Item 14:** Collection of a vaginal swab for quantitative culture is required as part of the One-week, Two-week, and Three-week Clinic Visits. If a vaginal swab was not collected at one of these visits, mark the “not stored” box and record the reason.
- **Comments:** Record any necessary or additional information at the bottom of the form.

**SAMPLE** *Do NOT FAX TO DATAFAX*

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**Participant ID**

Site Number			Participant Number						Chk	

**Follow-up Medical History**

**Visit Date**

dd		MMM		yy	

Since the last study visit, has the participant experienced any new conditions or changes in previously reported conditions (improvement or worsening)? ...  *yes*  *no*

**→ If no, go to page 2.**

			<i>If abnormal, onset date:</i>			<i>OR continuing from previous</i>	<i>Description:</i>
	<i>normal</i>	<i>abnormal</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>visit</i>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Lymphatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Liver	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Renal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Neurologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Endocrine/Metabolic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Hematologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Cancer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Drug allergy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Other allergy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
<b>→ If abnormal, update or complete Adverse Experience Log when applicable.</b>							
Alcohol use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Drug use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____



---

## Follow-up Medical History – 1 (nonDF)

*This form is used to document a participant's follow-up medical history during the study (that is, her medical history since her last study visit). It is completed at each regularly scheduled follow-up visit (the One-week, Two-week, and Three-week Clinic visits). Because this form is a non-DataFax form, this form should not be faxed to SCHARP DataFax.*

*It may be helpful to use a calendar as a probe to help participants recall dates.*

*If you need additional space for notation, use the space provided at the bottom of page 2.*

**Note:** *Each Follow-up Medical History form should contain medical information reported by the participant at the time the form was completed. If, at a subsequent study visit, the participant reports additional medical information related to the time period covered on a previous Follow-up Medical History form, **do not** update the previous form. Instead, record the new information on the current Follow-up Medical History form and explain the discrepancy in the "Additional Notes" section (may be documented in the participant's chart notes as well). If the participant reports additional medical information related to her baseline medical history, do update the Baseline Medical History (non-DataFax) form, and the Pre-Existing Conditions form (for conditions present at enrollment).*

### Item-specific Instructions:

- **Normal/abnormal boxes:** The first time this form is completed for a participant (at her first follow-up visit), review the participant's **Pre-existing Conditions** form. For each ongoing condition, review the condition with the participant and record updated information about the condition on this form. For all visits after the first follow-up visit, review the **Follow-up Medical History** form completed at the previous visit and record updated information on all conditions that were ongoing at the last visit on the **Follow-up Medical History** form for the current visit.
- **If abnormal, onset date:** For each item marked "abnormal," record the day, month, and year the participant was diagnosed with the condition. When applicable, complete an **Adverse Experience Log** for the condition recording this date as the AE Onset Date (item 2 of the **Adverse Experience Log** form).
- **Continuing from previous visit:** Mark this box for items that are continuing from a previous visit (that is, the onset date of the condition is recorded on a previously-completed medical history form). If this box is marked, leave the "If abnormal, onset date" boxes blank. If an onset date is recorded, leave the "continuing from previous visit" box blank.
- **Description:** Provide a description of each observed/reported condition in the space provided. Provide a diagnosis along with reported symptoms whenever possible. If the condition is continuing from a previous visit, use the same text to describe the condition.
- **Alcohol use:** Record information about the participant's current level of alcohol use. If there have been no changes since the previous visit record "no changes."
- **Drug use:** Record information about the participant's current level of drug use. If there have been no changes since the previous visit record "no changes."
- **If abnormal to any, update or complete Adverse Experience Log when applicable:** For each item marked as "abnormal," complete an **Adverse Experience (AE) Log** form if this is the **first** time the condition has been reported since the participant enrolled in the study. If this is **not** the first time the condition has been reported since enrollment, an **AE Log** form should already have been completed for this condition—review the previously completed **AE Log** form and either update any relevant information, or complete a new AE Log form as necessary (e.g., in cases where a previously reported AE has increased in severity or frequency). If the condition was first reported on the participant's **Baseline Medical History** and **Pre-existing Conditions** forms and it has not increased in severity or frequency, **do not** complete an **AE Log** form—do record on this form that the condition has not increased in severity or frequency since enrollment/baseline.

*If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused" in the white space next to the boxes, and initial and date.*

**SAMPLE** *DO NOT FAX TO DATAFAX*

**Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

**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"/>	
Site Number				Participant Number							Chk

**Follow-up Medical History**

**Visit Date**

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<i>dd</i>		<i>MMM</i>			<i>yy</i>

**Menstrual Information**

	<i>dd</i>	<i>MMM</i>	<i>yy</i>	} → <i>amenorrheic</i> <b>OR</b> <input type="checkbox"/>
First day of last menstrual period:	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Last day of last menstrual period:	<input type="text"/>	<input type="text"/>	<input type="text"/>	

Reproductive history: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

History of contraception/family planning use: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Additional Notes: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

---

## Follow-up Medical History – 2 (nonDF)

### Item-specific Instructions:

- **Menstrual Information**
  - **First day of last menstrual period:** Record the first day of the participant's last menstrual period. Use a calendar to probe for the day, month, and year.
  - **Last day of last menstrual period:** Record the last day of the participant's last menstrual period. Use a calendar to probe for the day, month, and year.
  - **Amenorrheic:** Mark "amenorrheic" if the participant has been without menses for at least the past three menstrual cycles or the past six months, whichever is shorter. If "amenorrheic" is marked, leave the "First day of last menstrual period" and the "Last day of last menstrual period" boxes blank and provide a response to the question, "If amenorrheic, is it due to an unexpected or unknown cause?" Amenorrhea that occurs during study follow-up (in other words, is not present at baseline), should be reported as an adverse experience on an AE Log form if it is due to an unexpected or unknown cause.
- **Reproductive History:** Record any relevant information on the participant's pregnancy or reproductive history since her last follow-up visit.
- **Additional Notes:** Record any necessary or additional information at the bottom of the form.

SAMPLE: Do NOT FAX TO DATAFAX



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

Page [ ][ ] [ ][ ] [ ][ ]

MTN 004 (136)

AE-1 (420)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]  
Site Number Participant Number Chk

Adverse Experience Log

Date Reported to Site

[ ][ ] [ ][ ][ ][ ] [ ][ ]  
dd MMM yy

1. Adverse Experience (AE)

Record diagnosis if available. Include anatomical location, if applicable.

English (if above is in Local Language): \_\_\_\_\_

2. Onset Date

[ ][ ] [ ][ ][ ][ ] [ ][ ]  
dd MMM yy

3. Severity

- Grade 1 - Mild
- Grade 2 - Moderate
- Grade 3 - Severe
- Grade 4 - Life-threatening
- Grade 5 - Death

4. Relationship to Study Product

- Definitely related
- Probably related
- Possibly related
- Probably not related
- Not related

Record reason why AE is "not related" in Comments below.

5. Study Product Administration

- No change
- Held
- Permanently discontinued
- N/A

Change in Administration NOT APPLICABLE FOR THIS PROTOCOL

6. Status/Outcome

- Continuing
- Resolved
- Death
- Severity/frequency increased Report as new AE.
- Continuing at end of study participation

6a. Status/Outcome Date

Leave blank if Status/Outcome is "Continuing."

[ ][ ] [ ][ ][ ][ ] [ ][ ]  
dd MMM yy

7. Treatment Mark "None" or all that apply.

- None
- Medication(s) Report on Concomitant Medications Log.
- New/Prolonged hospitalization Comment below.
- Procedure/Surgery Comment below.
- Other Comment below.

8. Is this AE serious according to ICH guidelines? .....

yes no

9. Has/will this AE be reported as an EAE? .....

10. This AE was first reported at visit:

Visit code required (regular or interim).

[ ][ ] [ ][ ]

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

English (if Comments above are in Local Language): \_\_\_\_\_

---

## Adverse Experience Log (AE-1)

**Purpose:** To document any Adverse Experience (AE) reported by the participant or clinically observed as defined by the protocol.

**General Information/Instructions:** Do not record a condition as an AE if it existed at enrollment as a pre-existing condition, unless it increases in severity or frequency. If a cluster of symptoms reported on separate AE Log pages is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, mark the AE Log pages for the other symptoms with the words "Delete due to diagnosis on AE page #" (specify page number of diagnosis AE).

### Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers. Do not renumber any AE Log pages after faxing, unless instructed by SCHARP.
- **Item 1:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE Log. 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."
- **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; if the AE is discovered during the study visit exam, record the date of the study visit exam; if the AE is an abnormal lab result, record the date on which the specimen was collected.
- **Item 3:** To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* and the Addendum 1 (*Female Genital Grading Table for Use in Microbicide Studies*.)
- **Item 4:** When judging causal association (relationship) between an AE and the study agent consult the terms used in DAIDS-sponsored studies as documented in the *Manual for Expedited Reporting of Adverse Events to DAIDS*.
  - **NOTE: IN CASES OF DEATH**, when relationship of study product is under investigation, write "Pending" in the adjacent white space until relationship has been determined. Update accordingly.
- **Item 5:**
  - **No change:** Mark if the AE does NOT result in a study product hold, permanent discontinuation, or change in administration.
  - **Held:** Mark if the AE results in a study product hold. If multiple AEs are reported at the same visit, mark "Held" for the AE(s) that contributed to the product hold.
  - **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 the AE(s) that contributed to the permanent discontinuation.
  - **N/A (not applicable):** Mark if the AE occurred after the participant had completed all administration of the study product, or the study product is held or permanently discontinued for a different AE or other reason, or the AE is Grade 5-death.
- **Item 6:**
  - **Continuing:** AE is continuing at the time it is reported.
  - **Resolved:** Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved.
  - **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 reported on the AE Log, line through the "Continuing" box previously marked and mark "Severity/frequency increased." Record the date of increase in the "Status/Outcome Date." Report the increase in severity or frequency as a new AE. For this new AE, the "Onset Date" will be the date that the severity or frequency increased. Note that decreases in severity should not be 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 no longer experienced the AE; or the date of the study visit or specimen collection at which the change in status/outcome is first noted.
- **Item 7:** Indicate if treatment was clinically indicated for the AE, regardless of whether the treatment was actually used. Also mark this item if the participant self-treated.
- **Items 8 and 9:** For questions about ICH guidelines and EAE reporting, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS*.

**SAMPLE** *DO NOT FAX*  
*TO DATAFAX*

MTN 004 (136)



PH-1 (410)

Visit Code .

**Participant ID**

--  
Site Number Participant Number Chk

**Product Hold/Discontinuation**

1. Date product hold was initiated: .....     
*dd MMM yy*

2. Why is product being held?

pregnancy

STI/RTI requiring treatment

other adverse experience

*AE Log page #(s)*

other, specify: \_\_\_\_\_

3. Date of last study gel application: .....     
*dd MMM yy*

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

yes

*no  
(permanently  
discontinued)*

**End of form.**

*no  
(hold continuing  
for another reason)*

**In item 4a, record the date on which study gel use would have been resumed if not being held for another reason.**

4a. Date participant instructed to resume study gel use: .....

*dd MMM yy*

Visit Code .

Comments: \_\_\_\_\_

---

## Product Hold/Discontinuation (PH-1)

*This form is used to document temporary holds and permanent discontinuations of study gel. This form is completed each time a participant is instructed to temporarily stop (hold) or permanently discontinue study gel use prior to the Two-week Clinic Visit. If, at the same study visit, a product hold/discontinuation is initiated for more than one reason, complete a Product Hold/Discontinuation form for each reason. The same visit code should be used on each form.*

*In the case of temporary product holds, do not wait for information about product resumption to fax the form—fax this form to SCHARP DataFax as soon as items 1 through 3 have been completed. Refax the form once item 4 has been completed.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code at which the participant was instructed by a study staff member to hold or permanently discontinue study gel use. If the product is being held or permanently discontinued as a result of an adverse experience, the Visit Code recorded on this form should match the visit code recorded in item 10 of the AE Log documenting the product hold/permanent discontinuation.
- **Item 1:** Record the date on which the participant was instructed to hold or permanently discontinue study gel use.
- **Item 2:** Mark the box to the left of the one reason which **best** describes why the participant is being instructed to hold or permanently discontinue gel use. Mark only one. If product is being held or discontinued due to an adverse experience, record the page number(s) of the AE Log documenting the product hold or permanent discontinuation. If the product hold/discontinuation is due to a reason other than the ones listed, mark “other, specify” and record the reason for the hold/discontinuation on the line provided.
- **Item 3:** Record the date the participant last applied study gel. Use a best estimate if the actual date cannot be determined.
- **Item 4:** Complete this item once study staff have determined that the participant can resume study gel use or have determined that she is permanently discontinued from study gel use. Mark this item “yes” if study staff instructed the participant that she can resume use of study gel. If the participant was permanently discontinued from study gel use, mark the “no (permanently discontinued)” box and end the form - leave item 4a blank. If the reason for the product hold, as recorded in item 2, has resolved but there is a concurrent reason (e.g., pregnancy) for continuing the product hold, mark “no (hold continuing for another reason).” In item 4a, record the date the participant would have been instructed (by site staff) to resume study gel use if it were not held for another reason.
- **Item 4a:** Record the date and visit code on which the participant was told by a study staff member that she could resume study gel use.

SAMPLE Do NOT FAX TO DATAFAX

MTN 004 (136)



GBA-1 (281)

Visit Code [ ][ ] . [ ]

1

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]  
Site Number Participant Number Chk

Genital Bleeding Assessment

Visit Date

[ ][ ] [ ][ ][ ][ ] [ ][ ]  
dd MMM yy

This form should not be completed for pregnant participants. This form is completed whenever an episode of unexpected genital bleeding is self-reported by the participant and/or clinically observed with no identifiable source. Completion of this form is not required for episodes of expected genital bleeding.

1. First day of participant's last menstrual period:..... [ ][ ] [ ][ ][ ][ ] [ ][ ] OR  *amenorrheic*  
*Obtain from Follow-up Medical History form.*  
**If amenorrheic, go to item 4.**
2. Last day of participant's last menstrual period:..... [ ][ ] [ ][ ][ ][ ] [ ][ ]  
*Obtain from Follow-up Medical History form.*
3. Length in days of participant's last menstrual period (based on dates recorded in items 1 and 2):..... [ ][ ] days
4. First day of genital bleeding episode:..... [ ][ ] [ ][ ][ ][ ] [ ][ ]  
*Per participant report or clinical exam.*
5. Last day of genital bleeding episode:..... [ ][ ] [ ][ ][ ][ ] [ ][ ] OR  *ongoing*
6. Total number of days of genital bleeding:..... [ ][ ] days OR  *ongoing*
7. According to the participant, was the amount of genital blood a normal amount, lighter amount, or heavier amount when compared to the heaviest flow day of her regular menses? .....  
 normal    lighter    heavier    unknown    N/A
8. According to the participant or the clinician, what color was the genital blood? Mark "unknown," or all that apply.....  
 bright red    brown    unknown
9. According to the participant, did she continue to use study gel during this genital bleeding episode? .....  
 yes    no    N/A  
**If yes or N/A, go to item 11.**



---

## Genital Bleeding Assessment (GBA-1)

*This form is completed by the study clinician, and used to guide study clinicians' assessment of genital bleeding events that occur during follow-up. This form is completed each time an episode of unexpected genital bleeding is self-reported by a study participant and is either not observed during pelvic examination, or is clinically-observed with no identifiable source. Specifically, this form guides clinicians to collect and consider information on the many factors that may contribute to the unexpected genital bleeding event. Study clinicians should review the Baseline Medical History form and refer to SSP Section 10 to determine whether or not an episode of genital bleeding is unexpected.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 14.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the week on study plus 2.0. For example, the One-week Clinic Visit is assigned a visit code of "03.0," the Two-week Clinic Visit is assigned a visit code of "04.0," etc.
- **Item 1:** Mark "amenorrheic" if the participant has been without menses for at least the past three cycle intervals, or the past 6 months, whichever is shorter. If "amenorrheic" is marked, leave items 1–3 blank and go to item 4.
- **Item 5:** If the participant experienced intermittent bleeding as part of the same episode of genital bleeding, record the last date in which she experienced bleeding for that episode.
- **Item 6:** Record the total number of days in which the participant experienced bleeding during this genital bleeding episode. For example, if the participant experienced bleeding over 7 consecutive days and bled each of the 7 days, record "07." If the participant experienced genital bleeding over a 6-day period, but only bled on days 1, 2, 4, and 7, record "04."
- **Item 7:** Mark "unknown" in cases where the information is not known by the participant. Mark "N/A" if the genital bleeding was not reported by the participant, but was observed during the pelvic examination only.
- **Item 8:** Mark "unknown" in cases where the information is not known by the participant or the clinician.

SAMPLE: Do NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

MTN 004 (136)

GBA-2 (282)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]  
Site Number Participant Number Chk

Genital Bleeding Assessment

10. Number of days between last application of study gel and first day of genital bleeding episode: [ ][ ] days

11. According to the participant, did the genital bleeding occur within 2 days after...

- 11a. vaginal sex? [ ] yes [ ] no
- 11b. painful vaginal sex? [ ] yes [ ] no
- 11c. application of the study gel? [ ] yes [ ] no [ ] N/A
- 11d. painful or uncomfortable application of the study gel? [ ] yes [ ] no [ ] N/A
- 11e. painful or uncomfortable insertion or removal of any other vaginal product/preparation? [ ] yes [ ] no [ ] N/A
- 11f. a pelvic or colpo exam? [ ] yes [ ] no

If yes to any, record related details in Comments.

If yes, record date of last pelvic/colpo exam in Comments.

11g. condom use? [ ] yes [ ] no

12. Is the participant currently using injectable contraceptives? Review Concomitant Medications Log. [ ] yes [ ] no -> If no, go to item 13.

12a. When was her last injection? [ ][ ] dd [ ][ ][ ] MMM [ ][ ] yy

12b. When is/was her next injection due? [ ][ ] dd [ ][ ][ ] MMM [ ][ ] yy -> Go to item 14.

13. Is the participant currently using (non-injectable) hormonal contraceptives? Review Concomitant Medications Log. [ ] yes [ ] no -> If no, go to item 14.

13a. Has the participant missed one or more days of contraceptives in the week before the genital bleeding started? [ ] yes [ ] no -> If no, go to item 14.

---

## Genital Bleeding Assessment (GBA-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Item 12:** If the participant reports currently using injectable contraceptives, make sure the injectable contraceptives are listed on the participant's Concomitant Medications Log.

**SAMPLE** *DO NOT FAX*  
*TO DATAFAX*



Visit Code

MTN 004 (136)

GBA-3 (283)

**Participant ID**

-      -   
Site Number Participant Number Chk

**Genital Bleeding Assessment**

13b. Did the participant miss two or more days of contraceptives? .....  *yes*  *no*  
If yes, go to item 14.

13c. **For participants using oral contraceptives only:**  
Did the participant make up the missed dose of oral contraceptives? .....  *yes*  *no*

14. Based on all information available, is this bleeding unexpected? .....  *yes*  *no*  
If no, end of form. DO NOT complete AE Log.

14a. Is this unexpected bleeding menstrual or non-menstrual?

*menstrual*  
  
↓  
**Complete AE Log.**  
**Report as "menorrhagia" or "menometrorrhagia." Grade per "menorrhagia" row of the Female Genital Toxicity Table.**

*non-menstrual*  
  
↓  
**Complete AE Log.**  
**Report as "metrorrhagia" or "postcoital bleeding." Grade per "metrorrhagia" or "postcoital bleeding" row of the Female Genital Toxicity Table.**

14b. Record Adverse Experience Log page: .....    **AE Log Page #**

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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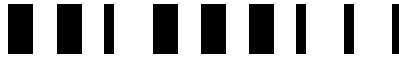
## Genital Bleeding Assessment (GBA-3)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Item 13:** Non-injectable hormonal contraceptives include oral contraceptives (“the pill”), Ortho-Evra (“the patch”), and vaginal rings. If the participant reports currently using non-injectable hormonal contraceptives, make sure these are listed on the participant’s Concomitant Medications Log.
- **Item 13c:** This item applies only to those participants using oral contraceptives. For participants who do not use oral contraceptives, leave item 13c blank and go to item 14.
- **Item 14:** Review the Baseline Medical History form and refer to SSP Section 10 to determine whether or not the genital bleeding is unexpected. If the response is “yes” and the genital bleeding is determined to be unexpected, refer to protocol Appendix II for guidance on study gel administration.
- **Item 14a:** If the unexpected genital bleeding is:
  - **menstrual** - grade the AE of menorrhagia [defined as prolonged (more than 7 days) or excessive (>80 mL) uterine bleeding] or menometrorrhagia (defined as prolonged uterine bleeding occurring at irregular intervals) using the “menorrhagia” row of the *Female Genital Toxicity Table* (protocol Appendix IX).  
*NOTE: unexpected menstrual bleeding is defined as menstrual bleeding that is heavier in volume or longer in duration than the participant’s usual menses (as documented on the Baseline Medical History form). Refer to SSP Section 10 for further information.*
  - **non-menstrual** - grade an AE of metrorrhagia (intermenstrual bleeding) using the “metrorrhagia” row of the *Female Genital Toxicity Table* (protocol Appendix IX). Grade an AE of postcoital bleeding using the “postcoital bleeding” row of the *Female Genital Toxicity Table*.  
*NOTE: unexpected non-menstrual genital bleeding—regardless of severity—that is associated with an observed pelvic exam finding should be reported as an AE, with the AE description = “bleeding source and location” (e.g., ulceration-vaginal). Unexpected non-menstrual bleeding—regardless of severity—that is associated with an underlying cause (e.g., fibroids, uterine laceration, trauma) should be reported as an AE, with the diagnosis as the AE description. Refer to SSP Section 10 for further information.*
- **Item 14b:** Record the AE Log page number of the AE reported for this unexpected genital bleeding episode. When determining the relationship to study product, carefully review the information recorded in items 11–13c of this form. Record information relevant to the product relatedness determination in the Comments section of the AE Log.
- **Comments:** Record any necessary or additional information at the bottom of the form.

**SAMPLE** *DO NOT FAX*  
*TO DATAFAX*

MTN 004 (136)



PR-1 (440)

Visit Code

**1**

**Participant ID**

-  -   
Site Number Participant Number Chk

**Pregnancy Report and History**

**PREGNANCY REPORT**

1. Date of last menstrual period: .....  <sup>dd</sup>  <sup>MMM</sup>  <sup>yy</sup>  
2. Estimated date of delivery: .....  <sup>dd</sup>  <sup>MMM</sup>  <sup>yy</sup>

**PREGNANCY HISTORY**

3. Has the participant ever been pregnant before? .....  <sup>yes</sup>  <sup>no</sup> → **If no, end of form.**  
3a. Is this the participant's first pregnancy since enrollment in this study? .....  <sup>yes</sup>  <sup>no</sup> → **If no, end of form.**  
3b. Number of full term live births (≥ 37 weeks): .....   
3c. Number of premature live births (< 37 weeks): .....   
3d. Number of spontaneous fetal deaths and/or still births (≥ 20 weeks): .....   
3e. Number of spontaneous abortions (< 20 weeks): .....   
3f. Number of therapeutic/elective abortions: .....   
3g. Number of ectopic pregnancies: .....

4. Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies before study enrollment? .....  <sup>yes</sup>  <sup>no</sup> → **If yes, document in participant's records.**

Comments: \_\_\_\_\_

---

## **Pregnancy Report and History (PR-1)**

This form is used to report the pregnancy of a study participant post enrollment through termination.

- **Visit Code:** Record the visit code of the visit at which the participant was determined to be pregnant.
- **Item 1:** Record the first day or best estimate of the participant's last menstrual period. Complete date required.

**Item 2:** Complete date required

**SAMPLE**. Do NOT FAX  
TO DATAFAX

MTN 004 (136)



PO-1 (441)

Visit Code

1

**Participant ID**

-      -   
Site Number Participant Number Chk

**Pregnancy Outcome**

Outcome unknown at end of study. \_\_\_\_\_  
Staff Initials/Date  
▶ **End of form. Fax to SCHARP DataFax.**

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

**2. OUTCOME #1**

dd MMM yy

2a. Outcome Date

2b. Specify Outcome: Mark only one.

- full term live birth (≥ 37 weeks)
  - premature live birth (< 37 weeks)
  - spontaneous fetal death and/or still birth (≥ 20 weeks)
  - spontaneous abortion (< 20 weeks)
  - ectopic pregnancy
  - therapeutic/elective abortion
- 2b1. Method:  C-section  vaginal
- Complete AE Log and EAE Reporting form.

2c. Were any fetal/infant congenital anomalies identified? .....  yes  no  not assessed

**If only one outcome, end of form.**

**3. OUTCOME #2**

dd MMM yy

3a. Outcome Date

3b. Specify Outcome: Mark only one.

- full term live birth (≥ 37 weeks)
  - premature live birth (< 37 weeks)
  - spontaneous fetal death and/or still birth (≥ 20 weeks)
  - spontaneous abortion (< 20 weeks)
  - ectopic pregnancy
  - therapeutic/elective abortion
- 3b1. Method:  C-section  vaginal
- Complete AE Log and EAE Reporting form.

3c. Were any fetal/infant congenital anomalies identified? .....  yes  no  not assessed

Comments: \_\_\_\_\_

26-MAR-07

0  1  
Language

14-112  
Staff Initials / Date



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## Pregnancy Outcome (PO-1)

This form is used to report the pregnancy outcome(s) of a pregnancy reported post enrollment through termination. A **Pregnancy Outcome** form is required for each **Pregnancy Report and History** form completed for a participant. This form is completed when information about a pregnancy outcome becomes available to study staff. If an outcome is unknown at study end, mark the “Outcome unknown at end of study” box at the top of the page and fax to DataFax. When the outcome is known, draw a line through this box, record the outcome, and refax. A pregnancy outcome can be an infant or a fetus. The conception of twins should result in reporting of two outcomes. If a pregnancy results in more than two outcomes, contact SCHARP for guidance on how to complete this form.

- **Visit Code:** Record the visit code of the participant’s corresponding **Pregnancy Report and History** form.
- **Specify Outcome:** If the outcome is therapeutic/elective abortion, note that while the abortion itself is not an Adverse Experience (AE), if the abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an **Adverse Experience Log**, with “procedure/surgery” marked under “Treatment.”

**Congenital anomalies:** This item should be updated if information becomes available during the mother’s (the study participant’s) study follow-up period regarding a congenital anomaly. If a woman on study has a baby with a congenital anomaly and the infant does not have his/her own participant ID, report the event as an AE and record in item 1 “Congenital Anomaly in Offspring.” Record the PTID of the woman on study (mother) on the form, just as you would for any other AE reported for the participant.

**SAMPLE** *DO NOT FAX*  
*TO DATAFAX*

MTN 004 (136)



MV-1 (463)

Visit Code

.  0

1

**Participant ID**

-      -

Site Number

Participant Number

Chk

**Missed Visit**

**Form Completion Date**

dd

MMM

yy

dd

MMM

yy

1. Target Visit Date:

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

- unable to contact participant
- unable to schedule appointment(s) within (allowable) window
- participant refused visit
- participant incarcerated
- participant institutionalized
- participant withdrew from the study —————> **Complete a Termination form.**
- participant deceased —————> **Complete a Termination form (Complete an Adverse Experience Log if applicable).**
- other, specify:

\_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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## 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).

**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 Code of the visit that was missed. Record the date that the form was completed. This will not necessarily be the 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.

**SAMPLE**. Do NOT FAX  
TO DATAFAX

MTN 004 (136)



AA-1 (272)

Visit Code   .

1

**Participant ID**

-      -   
Site Number Participant Number Chk

**Acceptability Assessment**

**Visit Date**

dd MMM yy

One goal of this research is to understand how acceptable study gel use is to women and their partners. I am now going to ask you some questions about your experiences using the study gel and how study gel use has affected your relationship(s) with sexual partners. Your honest answers will be very helpful to us.

1. If your study gel is found to protect people from getting HIV, how likely would you be to use it during vaginal intercourse?

**Showcard #1**      very likely      likely      unlikely      very unlikely  
                 

2. What do you like about your study gel? DO NOT read response categories aloud. Mark all that apply.

- 2a. no response
- 2b. nothing
- 2c. may protect against HIV
- 2d. may protect against STIs
- 2e. can use without partner's knowledge
- 2f. easy to use
- 2g. method is under her control
- 2h. made sex more pleasurable
- 2i. did not interrupt sex
- 2j. appearance/smell
- 2k. other, specify: ..... Local Language: \_\_\_\_\_

**If only one response box is marked, English: \_\_\_\_\_ go to item 3 on page 2.**

2l. Which of these do you like most? DO NOT read response categories aloud.

<input type="checkbox"/> no response	<input type="checkbox"/> method is under her control
<input type="checkbox"/> nothing	<input type="checkbox"/> made sex more pleasurable
<input type="checkbox"/> may protect against HIV	<input type="checkbox"/> did not interrupt sex
<input type="checkbox"/> may protect against STIs	<input type="checkbox"/> appearance/smell
<input type="checkbox"/> can use without partner's knowledge	<input type="checkbox"/> other, specify:
<input type="checkbox"/> easy to use	Local Language: _____
	English: _____

---

## Acceptability Assessment (AA-1)

*This form is used to collect study gel acceptability information from study participants. This is an interviewer-administered form, and it is administered only once to each enrolled participant at her Two-week Clinic Visit.*

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 2:** If the participant refuses or is unable to give a response to any item(s), mark the “no response” box.
- **Item 2:** Do not read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each reported characteristic the participant likes about the study gel. If the participant gives a response that does not correspond to one of the listed categories, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If “no response” or “nothing” is marked, no other response box should be marked. If only one response box is marked, leave item 21 blank and go to item 3.
- **Item 21:** Do not read any of the response categories aloud. Instead, read the question, and based on the participant’s responses to item 2, mark the box that corresponds to the one characteristic the participant likes most about the study gel. If she reports more than one, ask her to choose which of the characteristics she likes most. If the participant gives a response that does not correspond to one of the listed response categories, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response.

**SAMPLE**. DO NOT FAX  
TO DATAFAX

MTN 004 (136)

AA-2 (273) Visit Code

□□□.□□

□  
1

Participant ID

□□□-□□□□□□-□  
Site Number Participant Number Chk

Acceptability Assessment

3. What do you not like about your study gel? DO NOT read response categories aloud. Mark all that apply.

<input type="checkbox"/> 3a. no response	<input type="checkbox"/> 3g. remembering to use it
<input type="checkbox"/> 3b. nothing	<input type="checkbox"/> 3h. difficult to store and/or discard
<input type="checkbox"/> 3c. messy	<input type="checkbox"/> 3i. appearance/smell
<input type="checkbox"/> 3d. interrupted sex	<input type="checkbox"/> 3j. other, specify:
<input type="checkbox"/> 3e. made sex less pleasurable	<i>Local Language:</i>
<input type="checkbox"/> 3f. difficult to use, specify:	_____
<i>Local Language:</i>	<i>English:</i>
_____	_____
<i>English:</i>	
_____	

▶ If only one response box is marked, end of form.

3k. Which of these do you dislike most? DO NOT read response categories aloud.

- no response
- nothing
- messy
- interrupted sex
- made sex less pleasurable
- difficult to use
- remembering to use it
- difficult to store and/or discard
- appearance/smell
- other, specify:

*Local Language:* \_\_\_\_\_

*English:* \_\_\_\_\_

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## Acceptability Assessment (AA-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 3:** If the participant refuses or is unable to give a response to any item(s), mark the “no response” box.
- **Item 3:** Do not read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each characteristic the participant does not like about the study gel. If the participant gives a response that does not correspond to one of the listed categories, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response on the adjacent specify line(s). If the participant’s response is “difficult to use,” probe for more specific information as to why the study gel is difficult to use and record the participant’s verbatim (word-for-word) response on the adjacent specify line(s). If “no response” or “nothing” is marked, no other response box should be marked. If only one response box is marked, leave item 3k blank.
- **Item 3k:** Do not read any of the response categories aloud. Instead, read the question, and based on the participant’s responses to item 3, mark the box that corresponds to the one characteristic the participant dislikes most about the study gel. If she reports more than one, ask her to choose which of the characteristics she dislikes most. If the participant gives a response that does not correspond to one of the listed response categories, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response.

*If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.*

**SAMPLE**. Do NOT FAX  
TO DATAFAX

MTN 004 (136)



IV-1 (350)

Visit Code

1

**Participant ID**

-      -   
Site Number Participant Number Chk

**Interim Visit**

**Visit Date**

dd MMM yy

1. What is the reason for this interim visit? *Mark all that apply.*

- 1a. in-person visit to report new symptoms → **Complete Adverse Experience Log.**
- 1b. phone call from participant to report new symptoms → **Complete Adverse Experience Log.**
- 1c. follow-up of an AE → **Update Adverse Experience Log if indicated.**
- 1d. participant needs study gel
- 1e. participant is returning study gel
- 1f. other, specify: \_\_\_\_\_

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

2a. Specify reason(s): ←  \_\_\_\_\_

3. Besides this form, what other DataFax study forms (with the same visit code as this form) were completed for this visit? *Mark "none" or all that apply.*

- 3a. none
- 3b. Follow-up Pelvic Exam
- 3c. Pelvic Laboratory Results
- 3d. STI Laboratory Results
- 3e. Adverse Experience Log (new)
- 3f. Product Hold/Discontinuation
- 3g. Safety Laboratory Results
- 3h. Follow-up Genital Symptoms
- 3i. Genital Bleeding Assessment
- 3j. other, specify: \_\_\_\_\_

→ 3e1. How many **new** AE Log pages were completed for this visit? .....   # of pages

4. At this visit, how many **unused** applicators did the participant return?   # of **unused** applicators returned

5. ~~At this visit, how many **unused** applicators did the participant return?   # of **unused** applicators returned~~  
**NO LONGER APPLICABLE FOR THIS PROTOCOL.**

6. At this visit, how many cartons of study gel were dispensed to the participant? .....  # of cartons dispensed

6a. Randomization code of first dispensed carton: .....

6b. Randomization code of second dispensed carton: .....    OR  N/A

→ **If 0, end of form.**

Comments: \_\_\_\_\_



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## Interim Visit (IV-1)

The Interim Visit form is used to document interim visits that occur during study follow-up. Any other forms completed for this visit must have the same Visit Code as the corresponding Interim Visit form.

*This form is used to document interim visits during follow-up. See Section 14.3.2 of the Study-Specific Procedures Manual for a definition and examples of interim visits that require an Interim Visit form to be completed. Note that all DataFax forms completed for an Interim Visit must have the same interim Visit Code as the Interim Visit form.*

### Item-specific Instructions:

- **Visit Code:** The following guidelines should be used for assigning the interim visit code:
  - Record the two-digit whole number visit code for the most recent scheduled regular visit. For example, if the most recent scheduled regular visit was Week 4 (Visit Code = 03.0), record “03” to the left of the decimal point in the visit code field.
  - Record the number that corresponds to the Interim Visit in the third box (the box to the right of the decimal point):  
XX.1 = First Interim Visit after the most recent scheduled regular visit.  
XX.2 = Second Interim Visit after the most recent scheduled regular visit.
- **Item 1:** Mark the box to the left of each reason(s) this Interim Visit was conducted. Mark all that apply.
- **Item 2:** A urine pregnancy test is required at each interim visit. Record the hCG urine pregnancy test result. If a required urine pregnancy test result is not available (specimen not collected and/or test not done), mark the “not done” box and complete item 2a.  
*Note: A **Pregnancy Report and History** form must be completed for each pregnancy. Once a participant tests positive for hCG urine pregnancy and a **Pregnancy Report and History** form (PR-1) has been completed for this pregnancy, subsequent positive pregnancy test results should not be recorded on a new PR-1 (unless they represent a new pregnancy).*
- **Item 3:** For each DataFax form completed for this visit, mark the box to the left of the form name. Mark all boxes that apply. Note that marking a box indicates that a DataFax form with the same visit code as this form will be faxed to SCHARP DataFax.
  - **none:** Mark this box if the Interim Visit form is the **only** DataFax form completed for this visit.
  - **Adverse Experience Log (new):** Mark this box if a new (previously unreported) AE is reported or observed at this visit. If the box to the left of “Adverse Experience Log (new)” is marked, record in item 3a how many **new** AE Log pages were completed for this visit. For example, if two new AEs were reported, record “02.” Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
  - **other, specify:** Mark this box if a DataFax form(s) other than the ones listed was completed for this visit. Specify the form name(s) on the line provided.
- **Item 4:** Record the number of **unused** study gel applicators the participant returned at this visit only.
- **Item 6:** Record the number of cartons of study gel given to the participant at this visit. This will be the same amount documented on the **Study Gel Request Slip** (and/or on the **Replacement Prescription**, if replacement carton(s) are also dispensed), unless documentation from the pharmacy staff states otherwise.
- **Item 6a:** From the site pharmacist (or designee), obtain and record the unique 3-digit randomization code present on the carton label of the first carton of study gel dispensed to the participant at this visit.
- **Item 6b:** From the site pharmacist (or designee), obtain and record the unique 3-digit randomization code present on the carton label of the second carton of study gel dispensed to the participant at this visit. If a second carton was not dispensed at this visit, mark the “N/A” box.

**SAMPLE** *Do NOT FAX*  
*TO DATAFAX*

MTN 004 (136)



CT-1 (485)

**Participant ID**

			-						-		
Site Number				Participant Number							Chk

**CASI Tracking**

**Form Completion Date**

<i>dd</i>		<i>MMM</i>			<i>yy</i>

- |    |   |                          |                          |  |
|----|---|--------------------------|--------------------------|--|
|    |   | <i>completed</i>         | <i>not completed</i>     |  |
| 1. | Baseline Behavioral Questionnaire .....   | <input type="checkbox"/> | <input type="checkbox"/> |  |
|    |   | <i>not required</i>      | <i>completed</i>         | <i>visit code</i>  |
| 2. | Acceptability and Adherence Questionnaire | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   |
|    |   |                          |                          | <input type="text"/> <input type="text"/> . <input type="text"/> |
|    |   | <i>not required</i>      | <i>completed</i>         | <i>visit code</i>  |
| 3. | Study Burden Questionnaire .....          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   |
|    |   |                          |                          | <input type="text"/> <input type="text"/> . <input type="text"/> |

Comments: \_\_\_\_\_

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## CASI Tracking (CT-1)

**Purpose:** This form is used to document participant completion of the Computer-Assisted Self-Interview (CASI) web-based questionnaires during the study.

**General Information/Instructions:** This form is completed once for each enrolled participant at the scheduled exit/end of study visit, or when it is determined that the participant is no longer participating in the study.

### Item-specific instructions:

- **Item 1:** Mark the “completed” box if the participant completed all or only a portion of the Baseline Behavioral Questionnaire. Mark the “not completed” box if the participant did not complete any part of the questionnaire.
- **Item 2:** Mark the “not required” box if the participant terminated the study prior to her 2-Week Clinic Visit and did not complete the questionnaire. Mark the “completed” box if the participant completed all or only a portion of the Acceptability and Adherence Questionnaire. Record the Visit Code of the visit when the participant completed the questionnaire. Mark the “not completed” box if the participant completed her 2-Week Clinic Visit and/or her 3-Week Clinic Visit, but did not complete any part of the questionnaire.
- **Item 3:** Mark the “not required” box if the participant terminated the study prior to her 3-Week Clinic Visit and did not complete the questionnaire. Mark the “completed” box if the participant completed all or only a portion of the Study Burden Questionnaire. Record the Visit Code of the visit when the participant completed the questionnaire. Mark the “not completed” box if the participant completed her 3-Week Clinic Visit, but did not complete any part of the questionnaire.

**SAMPLE** *DO NOT FAX*  
*TO DATAFAX*



MTN 004 (136)

ESI-1 (489)

**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"/>	
Site Number				Participant Number						Chk	

**End of Study Inventory**

**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"/>
<i>dd</i>		<i>MMM</i>			<i>yy</i>		

1. What is the **highest** visit code (scheduled or interim) for this participant, recorded on a form submitted via DataFax?.....

*visit code*

<input type="text"/>	<input type="text"/>	.	<input type="text"/>
----------------------	----------------------	---	----------------------

2. How many interim visits were conducted for this participant during the study and recorded on a form submitted via DataFax?.....

*# of interim visits*

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

3. Indicate the **highest** page number submitted for this participant for each of the following forms:

3a. Adverse Experience Log (AE-1) *page #*  **OR** *no pages submitted*

3b. Concomitant Medications Log (CM-1) *page #*

3c. Pre-existing Conditions (PRE-1) *page #*  **OR** *no pages submitted*

Comments: \_\_\_\_\_

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## End of Study Inventory (ESI-1)

This form is used to confirm that SCHARP has received all study data for a given participant. Complete this form once for each enrolled participant after participant has terminated from the study (as documented by a Termination form).

- **Form Completion Date:** Complete date required.
- **Item 1:** Record the highest visit code (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 code of the missed visit.
- **Item 2:** Record the total number of Interim Visit DataFax forms submitted for this participant. If no Interim Visit forms were submitted for the participant, record "000" in the boxes.
- **Item 3a:** Record the highest page number of the Adverse Experience Log submitted for this participant, even if that page was marked for deletion.
- **Item 3b:** Record the highest page number of the Concomitant Medications Log submitted for this participant.
- **Item 3c:** Record the highest page number of the Pre-existing Conditions form submitted for this participant.

**SAMPLE** Do NOT FAX  
TO DATAFAX



MTN 004 (136)

TM-1 (490)

**Participant ID**

-      -   
 Site Number      Participant Number      Chk

**Termination**

1. Termination Date: <sup>dd</sup> <sup>MMM</sup> <sup>yy</sup> *Date the site determined that the participant was no longer in the study.*

2. Reason for termination. *Mark only one.*

2a. scheduled exit visit/end of study ———▶ **End of form.**

2b. death, *indicate date and cause if known*

2b1. date of death <sup>dd</sup> <sup>MMM</sup> <sup>yy</sup>    OR     date unknown  
 2b2. cause of death \_\_\_\_\_    OR     cause unknown

**Complete or update Adverse Experience Log.**

- 2c. participant refused further participation, specify: \_\_\_\_\_
- 2d. participant unable to adhere to visit schedule
- 2e. participant relocated, no follow-up planned
- 2f. investigator decision, specify: \_\_\_\_\_
- 2g. unable to contact participant
- 2h. **NOT APPLICABLE FOR THIS PROTOCOL.**
- 2i. inappropriate enrollment
- 2j. invalid ID due to duplicate screening/enrollment
- 2k. other, specify: \_\_\_\_\_
- 2l. early study closure
- 2m. participant unable to adhere to study requirements

3. Was termination associated with...

3a. Adverse Experience?     <sup>yes</sup>     <sup>no</sup>     <sup>don't know</sup>

Record Adverse Experience Log page:  <sup>page #</sup>

Comments: \_\_\_\_\_

26-MAR-07

Language

14-126  
Staff Initials / Date

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## Termination (TM-1)

The Termination form is 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. A complete date is required, unless termination is due to death.

- **Item 2:** Although more than one of the listed reasons may describe why a participant left the study early, 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.