

Section 13. Data Collection

The purpose of this document is to provide site staff with the information they need to successfully complete and submit MTN-005 case report forms. For questions about this section or about general data collection policies, procedures, or materials, please contact the SCHARP Project Manager for the study as 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-005 team members, along with their job role and e-mail address, are listed below.

MTN-005 Statistical and Data Management Center (SDMC) Staff

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13.1 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 refaxed 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 refaxed 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.

13.2 DataFax Form Completion

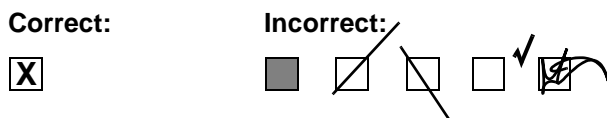
13.2.1 General Guidelines

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.

13.2.2 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.



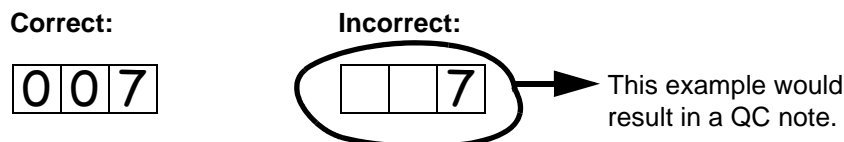
Mark only one response box for each item unless the “Mark all that apply” instruction is present.

13.2.3 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:



- 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:



- 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:



Difficult to Identify:



13.2.4 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
February	FEB	August	AUG
March	MAR	September	SEP
April	APR	October	OCT
May	MAY	November	NOV
June	JUN	December	DEC

For example, June 6, 2012 is recorded as:

0	6
---	---

J	U	N
---	---	---

1	2
---	---

dd *MMM* *yy*

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:

--	--	--

--	--

MMM *yy*

A diagnosis date of October, 2011 would be recorded as follows:

O	C	T
---	---	---

1	1
---	---

MMM *yy*

13.2.5 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
---	---

hr *min*

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

13.2.6 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. Initial and date all changes or additions.

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:

Correct:

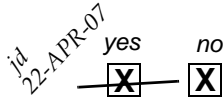
~~5~~ 4
jd 22-APR-07

Incorrect:

~~5~~ 4

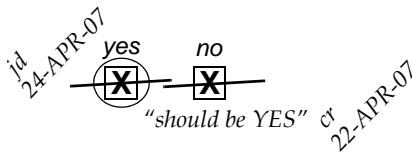
If an **X** is marked in the wrong response box, correct it by doing the following:

- 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:

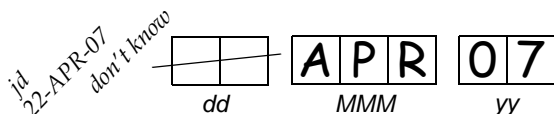


The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is faxed to SCHARP for the first time.

13.2.7 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.

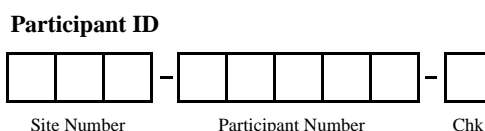
13.3 Study-Specific Data Collection Information

13.3.1 Participant ID numbers (PTIDs)

DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. Prior to study start, SCHARP provides each site with a list of PTIDs to be used for the study in the form of a study-specific MTN PTID Name-Linkage Log. The site assigns one PTID to each participant screened for the study. The PTIDs are assigned in sequential order as participants present for the screening visit. The site should ensure that each PTID is assigned only once. Once a participant has received a PTID, that same PTID is maintained throughout the entire study.

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

The PTIDs used for this study are nine digits and formatted as “XXX-YYYYY-Z.” The PTID consists of three parts: the DataFax 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-005.



13.3.2 Study Visit Timing

Screening and Enrollment

The initial screening visit is defined as the day the participant provided written informed consent to be screened for the study. The enrollment visit will be scheduled to take place within 45 days of the initial screening visit. The Enrollment Visit is considered Day 0.

Multiple Screening Attempts (Re-screens)

If a participant's first 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 provision of written informed consent. Once a PTID is assigned to a participant, that PTID is used for that participant for all re-screening attempts. If a participant re-screens and enrolls in the study, only case report forms from the successful screening and enrollment visit are faxed to SCHARP.

Follow-Up Visits

There are four required follow-up visits for MTN-005. For each of the four visits, the visit type, visit code, target visit day, and visit window are listed in the table. Target days and windows are listed in days, with the day of Enrollment Day 0.

Visit Type	Visit Code	Target Day	Window Opens	Window Closes
Week 4	3.0	28	21	35
Week 8	4.0	56	49	63
Week 12	5.0	84	77	91
Week 16/ Termination	6.0	112	105	119

Target Days and Visit Windows

Whenever possible, visits should be completed on the target day. If not possible to complete the visit on the target day, the visit should be completed within the visit window. Visits completed within the window will appear on the MTN-005 Retention Report as being completed “on-time”.

SCHARP will provide sites with a spreadsheet tool that may be used to generate individual participant follow-up visit calendars. The spreadsheet requires that the participant’s Enrollment date be entered. Once the enrollment date is entered, the target day and visit window for each of the 4 required follow-up visits will appear. The calendar can then be printed and added to the participant’s study notebook.

Split Visits

In those cases where a participant is not able to complete all required visit evaluations on the same day, the participant may come back and complete the remaining evaluations on another day, as long as the evaluations are completed within the visit window. For example, a participant comes in on her Week 4 target day and completes all required evaluations except for the pelvic exam. She comes back 5 days later and completes the pelvic exam and associated procedures.

See Section 13.3.3 for information on assigning visit codes to split visits.

Missed Visits

In those cases where a participant is not able to complete any part of a required visit within the visit window, the visit is considered “missed”. For example, an enrolled participant does not report to the clinic for her first follow-up visit until 36 days after enrollment. Per table 13-1, the Week 4 window closes on Day 35. In this case, since the visit window has “closed”, the Week 4 visit is missed, and is documented by completion of a Missed Visit case report form.

Interim Visits

A clinic visit is considered an Interim Visit if the visit occurs on a day that is not within a visit window. An Interim Visit also occurs when a participant completes all required visit procedures, but presents for additional evaluations before her next required visit. The following are examples of interim visits:

1. A participant completes all required evaluations for a scheduled study visit within the visit window. She then returns to the site clinic to request a replacement ring, and she is not within her next scheduled visit window.
2. A participant completes all required evaluations for a scheduled study visit within the visit window. She then returns to the clinic 10 days later (on a day that is not within any visit window) to request a pregnancy test.
3. A participant completes all required evaluations for the Week 4 visit within the window. At the Week 4 visit, deep epithelial disruption is noted during her pelvic exam. She then returns to the clinic 2 days later for a clinically-indicated follow-up pelvic exam.
4. A participant enrolls on 07-AUG-11. She returns to the site clinic three days later to request a replacement ring. Since 10-AUG-11 is not within any of the participant’s visit windows, it is an Interim Visit and is assigned an interim visit code (=2.1).

Phone contact with a participant is also considered an Interim Visit if the phone contact results in reporting of a new Adverse Experience (AE) or the participant withdraws consent for the study (termination). Phone contact is also considered an Interim Visit if, during the phone contact, the participant is instructed by site staff to hold, permanently discontinue, or resume product use. The following is an example of a phone contact that would be documented as an interim visit.

1. A participant completes her Week 8 visit on the target day. The next day, she calls the clinic to report a new symptom, which results in the reporting of a new adverse experience. The phone contact is assigned an interim visit code.

Assignment of visit codes to Interim Visits is covered later in the next section, section 13.3.3. For questions about phone contacts and assignment of visit codes to such contacts, please contact the SCHARP

Project Manager.

13.3.3 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 and will not appear on the CRF.

MTN-005 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 the visit codes assigned to each required study visit.

Visit Type	Visit Code
Screening	1.0
Enrollment	2.0
Week 4	3.0
Week 8	4.0
Week 12	5.0
Week 16/Termination	6.0

Visit Codes for Split Visits

See Section 13.3.2 for a definition of split visits. When split visits occur, the case report forms completed for the visit are all assigned the same visit (even though some forms and evaluations will have different visit dates). For example, a participant comes in on her Week 4 target day of 23-AUG-11 and completes all required evaluations except for the pelvic exam (she is on menses). She comes back on 28-AUG-11 and completes the pelvic exam and associated procedures. All case report forms completed on 23 and 28 August are assigned a visit code of 03.0 (since all evaluations are Week 4 evaluations).

Visit codes for interim visits

In addition to the scheduled, protocol-required visits listed in Table 13-1, interim visits may occur once the participant is enrolled (see Section 13.3.2 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 two days after her completed Week 12 Visit (Visit Code = 05.0). She is not yet in her Week 16 visit window. For this interim visit, record the following visit code:

Visit Code for this Interim Visit:

Visit Code .

Example #2: A participant returns one week after her 05.1 interim visit (described in Example #1), and is not yet in her Week 16 visit window. 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

Assign page numbers in sequential order, starting with 01 (or 001, for Adverse Experience Log CRFs). Assign numbers in sequential order (for example, the second Concomitant Medications Log page would be assigned page number 02, the third page would be assigned 03, and so on).

13.3.4 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.

13.3.5 Case Report Form Completion Schedule

The SCHARP-provided 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 13-2) lists the DataFax and non-DataFax forms that are required to be completed at each study visit.

Table 13-2: MTN-005 Schedule of Forms

Screening Visit - Visit Code 1.0	Form Acronym
Demographics	DEM-1 and DEM-2
Demographics - India or U.S.	DMI-1 or DMU-1
Pelvic Exam	PE-1 and PE-2
Vaginal Test Results	VTR-1
Local Laboratory Results	LLR-1
Concomitant Medications Log	CM-1
Specimen Storage	SS-1
(non-DataFax) Baseline Pregnancy/Contraceptive History	n/a
(non-DataFax) Menstrual History	n/a
(non-DataFax) Physical Exam	n/a
(non-DataFax) Pelvic Exam Diagrams	n/a
(non-DataFax) Screening Behavioral Eligibility	
(non-DataFax) LDMS Specimen Tracking Sheet	n/a
Enrollment Visit - Visit Code 2.0	
Pelvic Exam	PE-1 and PE-2
Vaginal Test Results	VTR-1
Pre-existing Conditions	PRE-1
Eligibility Criteria	ECI-1
Enrollment	ENR-1
Specimen Storage	SS-1
(non-DataFax) Physical Exam	n/a
(non-DataFax) Pelvic Exam Diagrams	n/a
(non-DataFax) LDMS Specimen Tracking Sheet	n/a
(non-DataFax) Enrollment Behavioral Eligibility	n/a
Week 4 - Visit Code 3.0	
Follow-up Visit	FV-1
Pelvic Exam Ring Assessment (IVR participants only)	PER-1
Ring Adherence (IVR participants only)	RA-1
Pelvic Exam	PE-1 and PE-2
Vaginal Test Results	VTR-1
Specimen Storage	SS-1

(non-DataFax) Follow-up Medical History Log	n/a
(non-DataFax) Physical Exam	n/a
(non-DataFax) Pelvic Exam Diagrams	n/a
(non-DataFax) LDMS Specimen Tracking Sheet	n/a
Week 8 - Visit Code 4.0	Form Acronym
Follow-up Visit	FV-1
Pelvic Exam Ring Assessment (IVR participants only)	PER-1
Ring Adherence (IVR participants only)	RA-1
Pelvic Exam	PE-1 and PE-2
Vaginal Test Results	VTR-1
Specimen Storage	SS-1
(non-DataFax) Physical Exam	n/a
(non-DataFax) Pelvic Exam Diagrams	n/a
(non-DataFax) LDMS Specimen Tracking Sheet	n/a
Week 12 - Visit Code 5.0	
Follow-up Visit	FV-1
Pelvic Exam Ring Assessment (IVR participants only)	PER-1
Ring Adherence (IVR participants only)	RA-1
Pelvic Exam	PE-1 and PE-2
Vaginal Test Results	VTR-1
Specimen Storage	SS-1
(non-DataFax) Physical Exam	n/a
(non-DataFax) Pelvic Exam Diagrams	n/a
(non-DataFax) LDMS Specimen Tracking Sheet	n/a
Week 16/Termination - Visit Code 6.0	
Follow-up Visit	FV-1
Pelvic Exam	PE-1 and PE-2
Vaginal Test Results	VTR-1
Specimen Storage	SS-1
Local Laboratory Results	LLR-1
Termination	TM-1
End of Study Inventory	ESI-1
(non-DataFax) Physical Exam	n/a

(non-DataFax) Pelvic Exam Diagrams	n/a
(non-DataFax) LDMS Specimen Tracking Sheet	n/a

13.3.6 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 Section 13.2.7.
- 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 13.3.7 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.

13.3.7 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-005 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-005 Project Manager if you would like to use the CRF Tracking System or for more information about the CRF Tracking System.

13.3.8 Non-DataFax Forms

MTN-005 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. When applicable, the guidelines described above for DataFax CRFs should also be applied when completing non-DataFax CRFs.

13.4 Form Supply and Storage

13.4.1 Form 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.).

13.4.2 Form Storage

Specifications for form storage will be detailed in the site's MTN-005 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, Follow-up Medical History, 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.

13.5 Completing 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.

13.6 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. Do 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.
- 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.
- For item 1, note that planned procedures or surgeries are not AEs. For example, a tonsillectomy is not an AE; rather, it is a treatment that will be collected in item 7 of the form. Any adverse experiences associated with the planned procedure or surgery are AEs.

Local Laboratory Results

- For items 1a (leukocyte esterase) and 1b (nitrites), if the laboratory result is “trace”, record the result as “negative”.

13.7 Case Report Forms

This section contains each MTN 005 case report form developed for the study (in alphabetical order by Form Title, DataFax forms first, followed by non-DataFax forms). Detailed form completion instructions for each form are provided on the back of each form page.

SAMPLE: DO NOT FAX TO DATAFAX



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

Page [][][]

MTN005 IVR Ring (148)

AE-1 (460)

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.

2. Onset Date

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

3. Severity

- Grade 1 – Mild
- Grade 2 – Moderate
- Grade 3 – Severe
- Grade 4 – Potentially life-threatening
- Grade 5 – Death

4. Relationship to Study Product

- Related
 - Not related
- Record rationale or alternative etiology in Comments.

5. Study Product Administration

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

6. Status/Outcome

- Continuing
- Resolved
- Death
- Severity/frequency increased
Report as a 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 an SAE according to ICH guidelines? yes no
- 9. Has/will this AE be reported as an EAE? yes no
- 10. At which visit was this AE first reported? [][] . [][]
Visit code required (regular or interim).
- 11. Was this AE a worsening of a pre-existing condition? yes no

Comments: _____

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:** Mark the assessment of the relationship between the AE and the study agent. Mark “Related” if there is a reasonable possibility that the AE may be related to the study agent. Mark “Not related” if there is not a reasonable possibility that the AE is related to the study agent. If “Not related,” record an alternative etiology, diagnosis, or explanation in the “Comments” field. For more information, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.
- **Item 5:** Provide the action taken by study staff with regard to study product.
 - **No change:** Mark if the participant is expected to continue to use study product and the AE does NOT result in a study product hold or permanent discontinuation.
 - **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 for participants randomized to the no IVR arm. 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. Update EAE form if applicable. 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, Version 2*.

SAMPLE *Do NOT FAX TO DATAFAX*



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

Page

MTN005 IVR Ring (148)

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.

1. Medication (generic name)										Staff Initials/Log Entry Date	
Indication										Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ➔ Record AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Date Started			Date Stopped			OR <input type="checkbox"/> Continuing at end of study					
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>			<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>								
Frequency <input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs Mark only one. <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____										<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
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"/> _____										<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

2. Medication (generic name)										Staff Initials/Log Entry Date	
Indication										Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ➔ Record AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Date Started			Date Stopped			OR <input type="checkbox"/> Continuing at end of study					
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>			<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>								
Frequency <input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs Mark only one. <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____										<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
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"/> _____										<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

3. Medication (generic name)										Staff Initials/Log Entry Date	
Indication										Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ➔ Record AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Date Started			Date Stopped			OR <input type="checkbox"/> Continuing at end of study					
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>			<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>								
Frequency <input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs Mark only one. <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____										<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
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"/> _____										<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

Concomitant Medications Log (CM-1)

Purpose: All medication(s) that are used by the participant during the study (including the protocol-defined screening period), 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.

General Information/Instructions: When to fax this form:

- once the participant has enrolled in the study;
- when pages have been updated or additional Log pages have been completed (only fax updated or new pages);
- when the participant has completed study participation; and/or
- when instructed by SCHARP.

Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.
- **No medications taken at Screening/Enrollment:** Mark this box if no medications were taken by the participant from Screening through the Enrollment visit. This box should only be marked on Page 01.
- **No medications taken throughout study:** Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study.
- **Medication:** For combination medications, record 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 are required.
- **Frequency:** Below is a list of common frequency abbreviations:

prn as needed	qd every day	tid three times daily	qhs at bedtime
once one time	bid twice daily	qid four times daily	

- Use “other, specify” for alternate dosing schedules.

- **Route:** Below is a list of common route abbreviations:

PO oral	IM intramuscular	IV intravenous	TOP topical	IHL inhaled	VAG vaginal	REC rectal
----------------	-------------------------	-----------------------	--------------------	--------------------	--------------------	-------------------

- **Dose/Units:** If the participant does not know the dose or units, draw a single line through the blank response box 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).

SAMPLE: Do NOT FAX TO DATAFAX



MTN005 IVR Ring (148)

DEM-1 (001)

Participant ID

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

Demographics

Visit Date

Visit Date form with boxes for dd, MMM, and yy

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

Question 1: What is your date of birth? with date boxes and 'If unknown, record age: years' option

NOT APPLICABLE FOR THIS PROTOCOL.

Question 2: What is your gender? with male/female options

Question 3: Are you currently married? with yes/no options and 'If yes, go to item 4a.' instruction

Question 4: Do you currently have a regular male sex partner? with yes/no options and 'If no, go to item 5 on page 2.' instruction

Question 4a: How old is he? with years and 'don't know' options

Question 4b: Are you currently living with him? with yes/no options

Question 4c: Does he have more than one sex partner? with yes/no/don't know options

Question 4d: Does he provide you with financial and/or material support? with yes/no options

Question 4e: What is his average monthly income? with income boxes and 'don't know'/'no income' options

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 the Study-specific Procedures Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.*

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of screening. If age is unknown, record the participant's best estimate of her age. Do not complete both answers.
- **Item 4:** Record whether or not the participant **currently** has a regular male sex partner.
- **Item 4a:** If the participant does not know her husband's or regular male sex partner's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 4d:** Record whether or not the participant's husband or regular male sex partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 4e:** Record the husband's or regular male sex partner's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

For example, if the income is 2,145 record:

0	0	0	2	1	4	5
---	---	---	---	---	---	---

If the husband's or regular male sex partner's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item.

SAMPLE. Do NOT FAX
TO DATAFAX



MTN005 IVR Ring (148)

DEM-2 (002)

Participant ID

Site Number			Participant Number						Chk	

Demographics

4f. What is his highest level of education?

U.S.

- no schooling
- primary school, not complete
- primary school, complete
- secondary, not complete
- secondary, complete
- attended college or university
- don't know

INDIA

- no schooling
- 1-3
- 4, complete
- 5-9
- 10, complete
- > 10
- don't know

5. Do you earn an income of your own? *yes* *no* → **If no, end of form.**

5a. What is your average monthly income? *don't know*
Record in local currency.

5b. How do you earn your income? *formal employment* *self-employed* *other, specify*

Mark all that apply......

Local Language: _____
English: _____

Demographics (DEM-2)

Item-specific Instructions:

- **Item 4f:** Record the primary partner's highest level of education in the box corresponding to the participant's site country (U.S. or India). If the participant does not know her primary partner's highest level of education, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box that corresponds to the appropriate site country.
- **Item 5a:** Record the participant's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

For example, if the income is 2,145 record:

0	0	0	2	1	4	5
---	---	---	---	---	---	---

If the participant's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 5b:** Record whether the participant's source(s) of income are from formal employment (for example: shop clerk, farmer, seamstress, teacher), self-employment (for example: shop owner, artist, restaurant owner), or other type of employment. If "other, specify below" box is marked, record the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

SAMPLE: Do NOT FAX
TO DATAFAX



MTN005 IVR Ring (148)

DMI-1 (020)

Page 1 of 1

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>
Site Number				Participant Number						Chk

Demographics-India

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

1. What is your highest level of education?

- no schooling
- 1-3
- 4, complete
- 5-9
- 10, complete
- > 10

2. Do you own your home? *yes* *no*

3. How many rooms are in your household? # of rooms

4. Do you have a private bathroom within your household?..... *yes* *no*

5. Do you have a private toilet within your household, use a toilet at home, a public toilet, and/or other? *yes* *no* *other* **If no, go to item 6.**

 →

5a. Is it an Indian or Western-style toilet? *Indian* *Western-style*

6. What is your ethnic group? *Read categories aloud. Mark all that apply.*

- Asian
- other, specify: *Local Language:* _____
English: _____

7. What is your religion?

- Hindu Buddhist
- Muslim other, specify: *Local Language:* _____
English: _____
- Christian

Demographics–India (DMI-1)

This is an interviewer-administered form that is used to collect additional demographic and socioeconomic information from participants in India.

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–India form must be completed as part of the subsequent screening attempt. See the Study-specific Procedures Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.*

Item-specific Instructions:

- **Item 4:** A bathroom can be a space with a bath, sink, and/or toilet.
- **Item 6:** 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, record the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.
- **Item 7:** If the participant answers a religion other than the four religions listed, mark the "other, specify" box, record the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

SAMPLE. Do NOT FAX
TO DATAFAX



MTN005 IVR Ring (148)

DMU-1 (018)

Participant ID

--	--	--	--	--	--	--	--	--	--	--	--

Site Number Participant Number Chk

Demographics–United States

Visit Date

--	--	--	--	--	--

dd *MMM* *yy*

1. What is your highest level of education?

- | | |
|---|---|
| <input type="checkbox"/> no schooling | <input type="checkbox"/> secondary, not complete |
| <input type="checkbox"/> primary school, not complete | <input type="checkbox"/> secondary, complete |
| <input type="checkbox"/> primary school, complete | <input type="checkbox"/> attended college or university |

2. How many people, including children, live in your household?

2a. How many are children?

3. What is your household's average monthly income? This includes income from all sources, even income from people who may not live in the household.

<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i>don't know</i> <input type="checkbox"/>	<i>no income</i> <input type="checkbox"/>
---	--	---

4. Do you consider yourself to be Latina or of Hispanic origin?

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

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

- American Indian or Alaskan Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- other, specify: _____

Demographics–United States (DMU-1)

This is an interviewer-administered form that is used to collect additional demographic and socioeconomic information from U.S. participants.

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-United States form must be completed as part of the subsequent screening attempt. See the Study-specific Procedures Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.*

Item-specific Instructions:

- **Item 3:** Record the **average** monthly income for the household (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

For example, if the income is 2,145 record:

0	0	0	2	1	4	5
---	---	---	---	---	---	---

If the household's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 4:** Per NIH policy, Latina or Hispanic is considered an ethnic category and not a race. It includes a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
- **Item 5:** 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. If the participant states that she is "Latina", record this in item 4 only. Per NIH policy, "Latina" is an ethnic group and should not be recorded as a race category in item 5. For example, a participant originally from the Dominican Republic could have a response of "yes" to item 4, and "Black or African American" to item 5.

SAMPLE *Do NOT FAX TO DATAFAX*



MTN005 IVR Ring (148)

ECI-1 (023)

Participant ID

			-						-		
Site Number				Participant Number							Chk

Eligibility Criteria

Form Completion Date

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

1. Does this participant meet all eligibility criteria? *yes* *no*

***If no, participant is not eligible.
Do not fax to SCHARP DataFax.
Do not enroll participant.***

1a. Obtain signature: _____

Signature of Principal Investigator (or designee)

Date

1b. Obtain signature: _____

Signature of second staff member verifying eligibility

Date

2. Does the participant agree to long-term storage of specimens for future testing? *yes* *no*

Comments: _____

Eligibility Criteria (ECI-1)

General Information/Instructions: Submit this form to SCHARP DataFax only if participant is enrolled.

Item-specific Instructions:

- **Items 1a and 1b:** Local site SOPs must specify staff members designated to affirm eligibility.

SAMPLE *DO NOT FAX*
TO DATAFAX



MTN005 IVR Ring (148)

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"/>
----------------------	---	----------------------

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 #*

3d. Social Harm Log (SH-1) *page #* **OR** *no pages submitted*

3e. Product Hold/Discontinuation Log (PH-1) *page #* **OR** *no pages submitted*

Comments: _____

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 3a:** Record the highest page number of the Adverse Experience Log submitted for this participant, even if that page was marked for deletion.
- **Item 3e:** Record the highest page number of the Product Hold/Discontinuation Log submitted for this participant, even if that page was marked for deletion.

SAMPLE *Do NOT FAX TO DATAFAX*



MTN005 IVR Ring (148)

ENR-1 (070)

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	

Enrollment

1. Date the informed consent form for screening was marked or signed:

<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		

2. Date the informed consent form for enrollment was marked or signed:

<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		

3. Was a randomization envelope assigned?

yes no

 → **If no, specify reason in Comments. End of form.**

3a. Randomization envelope number:

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

3b. Date assigned:

<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		

3c. Time assigned:

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	24-hour clock
hr			min		

3d. To which study arm was the participant randomized?

IVR no IVR

 → **If no IVR, go to item 5.**

4. Date study IVR was first inserted:

<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		

5. Did the participant complete the Baseline ACASI questionnaire?

yes no

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 randomization envelope), and only after completion of the Enrollment Visit.

Item-specific Instructions:

- **Item 3:** If the “no” box is marked, do NOT fax this or any other forms completed for this participant to SCHARP DataFax.
- **Item 3b:** This date should match the “date assigned” recorded for this envelope on the MTN 005 Randomization Envelope Tracking Record and the date on the study prescription or randomization document inside the envelope.
- **Item 3c:** This time should match the “time assigned” recorded for this envelope on the MTN 005 Randomization Envelope Tracking Record.
- **Item 4:** A complete date is required.

SAMPLE. Do NOT FAX TO DATAFAX



Visit Code 0

1

MTN005 IVR Ring (148)

FV-1 (121)

Participant ID

- -
Site Number Participant Number Chk

Follow-up Visit

Visit Date

dd MMM yy

1. hCG for pregnancy: *not done* *negative* *positive* → **If newly positive, complete Pregnancy Report form and Product Hold/Discontinuation Log (IVR cohort only).**

2. How many **new** AE Log pages were completed for this visit? *# of pages* → **If participant is in the no IVR cohort, go to item 6.**

3. How many **used** study IVRs were collected at this visit? *# of used IVRs*

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

5. Was a new study IVR inserted at this visit? *yes* *no* → **If no, go to item 6.**

5a. Date new study IVR was inserted:
dd MMM yy

6. Which ACASI questionnaires were completed at this visit?

none → **If none, end of form.**

No IVR Follow-up → Date completed:
dd MMM yy

IVR Follow-up → Date completed:

IVR Week 12 (Final Acceptability Assessment) → Date completed:

Week 16/Termination → Date completed:

Comments: _____

Follow-up Visit (FV-1)

Item-specific Instructions:

- **Item 2:** Record in item 2 how many **new** AE Log pages were completed for this visit. For example, if two new AEs were reported, record “002.” 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 **used** study IVRs returned by the participant or removed by the study clinician at this visit only.
- **Item 4:** Record how many **new** Product Hold/Discontinuation Log pages were completed for this visit. For example, if two new product holds/discontinuations were reported, record “02.” Note that the Visit Code recorded in item 1 of the Product Hold/Discontinuation Log pages should be the same as the Visit Code recorded on this form.
- **Item 5a:** A complete date is required.
- **Item 6:** For each ACASI questionnaire completed, record the date the questionnaire was completed.

SAMPLE *DO NOT FAX*
TO DATAFAX



Visit Code .

1

MTN005 IVR Ring (148)

HTR-1 (351)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number						Chk	

HIV Test Results

Sample 1

1. HIV Western Blot or IFA

Not done/
Not collected

Specimen Collection Date

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

negative

positive

indeterminate

If negative or indeterminate, contact MTN Network Lab.

Sample 2

2. HIV EIA

Not done/
Not collected

Specimen Collection Date

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

negative

positive

indeterminate

If negative, contact MTN Network Lab.

3. HIV Western Blot or IFA

Not done/
Not collected

Specimen Collection Date

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

negative

positive

indeterminate

If negative or indeterminate, contact MTN Network Lab.

FINAL HIV STATUS

negative

positive

other, specify: _____

4. Final HIV status:

Comments: _____

HIV Test Results (HTR-1)

Purpose: 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 during study follow-up.

General Information/Instructions: 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 4 has been completed.

- **Visit Code:** The visit code recorded on this form should be the same visit code recorded on the Local Laboratory Results form documenting the positive HIV EIA 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 the “Not done/Not collected” box in the event that a specimen is collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments lines at the bottom of the form.

Item-specific Instructions:

- **Item 4:** Once a participant’s HIV status has been determined, record the final HIV status. If, per the appropriate algorithm, the final HIV status is not clear, mark the “other, specify” box and provide a reason(s) on the line provided.
- **Comments:** Document any problems or reasons why expected results are not available (for example, if the sample was lost or damaged), on the lines provided.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code .

1

MTN005 IVR Ring (148)

IV-1 (350)

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 symptoms and/or AE(s)
- 1d. for help with reinsertion or insertion of a new study IVR
- 1e. participant is returning a study IVR
- 1f. other, specify: _____

2. Besides this form, what other DataFAX forms were completed at this visit?
Mark "none" or all that apply.

- 2a. none
- 2b. Pelvic Exam
- 2c. Vaginal Test Results
- 2d. Specimen Storage
- 2e. Local Laboratory Results
- 2f. Adverse Experience Log (new)
 - 2f1. How many **new** AE Log pages were completed for this visit? *# of pages*
- 2g. Product Hold/Discontinuation Log (new)
 - 2g1. How many **new** PH Log pages were completed for this visit? *# of pages*
- 2h. other, specify: _____

3. Did the participant complete the Week 16 ACASI questionnaire? *not required* *completed* *not completed*

4. hCG for pregnancy: *not done* *negative* *positive* → **If newly positive, complete Pregnancy Report form and Product Hold/Discontinuation Log (IVR cohort only).**

No IVR Cohort: End of form.

5. At this visit, how many **used** study IVRs were collected? *# of used IVRs*

6. At this visit, was a new study IVR inserted? *yes* *no* → **If no, end of form.**

6a. Date new study IVR was inserted:
dd MMM yyyy

Interim Visit (IV-1)

Purpose: Complete this form when an interim visit occurs during study follow-up. See the Study-specific Procedures Manual for a definition and examples of interim visits that require an Interim Visit form to be completed.

General Information/Instructions: Any other forms completed for this visit must have the same Visit Code as this Interim Visit form.

Item-specific instructions:

- **Visit Code:** The following guidelines should be used for assigning the interim visit code:
 - Record the one-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 = 3.0), record “3” 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):
 - X.1 = First Interim Visit after the most recent scheduled regular visit.
 - X.2 = Second Interim Visit after the most recent scheduled regular visit.
- **Item 2:** Note that marking a box indicates that a DataFax form with the same visit code as this form will be faxed to SCHARP DataFax.
 - **Item 2a:** Mark the “none” box if the Interim Visit form is the **only** DataFax form completed for this visit.
 - **Item 2f:** 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 how many **new** AE Log pages were completed for this visit in item 2f1. 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 2g:** Mark this box if a new (previously unreported) product hold or discontinuation is reported at this visit. If the box to the left of “Product Hold/Discontinuation Log (new)” is marked, record how many **new** PH Log pages were completed for this visit in item 2g1. For example, if two new product holds were reported, record “02.” Note that the Visit Code recorded in item 1 of these two PH Log pages should be the same as the Visit Code recorded on this form.
- **Item 3:** Marking “completed” or “not completed” for an individual ACASI questionnaire indicates that it was required/expected at this visit. Marking “not required” indicates that no ACASI data should be expected from that questionnaire at this visit.
- **Item 5:** Record the number of used study IVRs returned by the participant or removed by the study clinician at this visit only.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code

1

MTN005 IVR Ring (148)

LLR-1 (131)

Participant ID

- -
Site Number Participant Number Chk

Local Laboratory Results

Initial Specimen Collection Date

dd MMM yy

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

1. URINE TESTS

Not done *negative* *positive*

1a.	Leukocyte esterase (LE)	<input type="checkbox"/>	<input type="checkbox"/>
1b.	Nitrites	<input type="checkbox"/>	<input type="checkbox"/>
1c.	Culture	<input type="checkbox"/>	<input type="checkbox"/>

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

2. STI TESTS

non-reactive *reactive*

2a. Syphilis RPR screening test

→ **If non-reactive, go to item 3.**

2a1. Syphilis titer 1:

negative *positive* *indeterminate*

2b. Syphilis confirmatory test

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

negative *positive*

3. *N. gonorrhea*

4. *C. trachomatis*

5. HIV EIA

indeterminate

If positive or indeterminate during follow-up, complete HIV Test Results form and Product/Hold Discontinuation Log (IVR cohort only).

Comments: _____

Local Laboratory Results (LLR-1)

*This form is used to document local laboratory results of blood and urine specimens. 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.*

Item-specific Instructions:

- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen is collected after the Initial Collection Date for this same visit. A complete date is required.
- **Results Reporting**
 - If a specimen was collected but results are not available because the specimen was lost or damaged, mark the “Not done” box, and write an explanation on the Comments lines.
- **Item 2a1:** 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.”

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code 0

1

MTN005 IVR Ring (148)

MV-1 (463)

Page 1 of 1

Participant ID

- -
Site Number Participant Number Chk

Missed Visit

Form Completion Date

dd MMM yy

1. Target Visit Date:

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

- 2a. unable to contact participant
- 2b. unable to schedule appointment(s) within allowable window
- 2c. participant refused visit
- 2d. participant incarcerated
- 2e. participant admitted to a health care facility —————> **Complete an Adverse Experience Log if applicable.**
- 2f. participant withdrew from the study —————> **Complete a Termination form.**
- 2g. participant deceased —————> **Complete a Termination form. Complete an Adverse Experience Log if applicable.**
- 2h. other, specify:

Comments: _____

Missed Visit (MV-1)

Purpose: Complete this form whenever an enrolled participant misses a required visit according to the visit window outlined in the protocol or Study-specific Procedures (SSP).

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



Visit Code .

1

MTN005 IVR Ring (148)

PE-1 (166)

Participant ID

- -

Site Number Participant Number Chk

Pelvic Exam

Exam Date

dd MMM yy

1. Naked eye, speculum, and bimanual exam assessments:..... *not done* *abnormal findings* *no abnormal findings*
- If not done, specify reason in Comments. End of form.* *If no abnormal findings, go to item 7 on page 2.*

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

- | | | |
|--|-------------------------------------|--|
| <input type="checkbox"/> Enlarged/tender inguinal lymph nodes | <input type="checkbox"/> Erythema | <input type="checkbox"/> Edema |
| <input type="checkbox"/> Abnormal vaginal discharge | <input type="checkbox"/> Ulceration | <input type="checkbox"/> Abnormal cysts |
| <input type="checkbox"/> Abnormal cervical discharge | <input type="checkbox"/> Laceration | <input type="checkbox"/> Mass |
| <input type="checkbox"/> Blood-tinged discharge | <input type="checkbox"/> Abrasion | <input type="checkbox"/> Warts |
| <input type="checkbox"/> Blood in vagina—no identified source | <input type="checkbox"/> Peeling | <input type="checkbox"/> Adnexal tenderness |
| <input type="checkbox"/> Blood from cervical os | <input type="checkbox"/> Petechia | <input type="checkbox"/> Cervical motion tenderness |
| <input type="checkbox"/> Bleeding from site of epithelial disruption | <input type="checkbox"/> Ecchymosis | <input type="checkbox"/> Uterine tenderness |
| | <input type="checkbox"/> Vesicles | <input type="checkbox"/> Other abnormal findings, specify: |

Complete or update Pre-existing Conditions, Follow-up Medical History, and/or Adverse Experience Log as applicable.

2. Do any of these exam findings involve generalized erythema or severe edema with an affected area of **more** than 50% of the vulvar surface or combined vaginal and cervical surface?..... *yes* *no*
3. Do any of these exam findings suggest cervicitis?..... *yes* *no*
4. Do any of these exam findings involve deep epithelial disruption?..... *yes* *no*
- If yes to any and participant is in the IVR cohort, remove study IVR and complete Product Hold/Discontinuation Log.* *If no, go to item 5 on page 2.*
- 4a. Was the deep epithelial disruption observed in more than one distinct area?..... *yes* *no*

Pelvic Exam (PE-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 study.

Item-specific Instructions:

- **Item 1:** 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 on the Comments lines at the bottom of page 2.
- **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 on the line provided.

SAMPLE *Do NOT FAX*
TO DATAFAX



Visit Code

MTN005 IVR Ring (148)

PE-2 (167)

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	

Pelvic Exam

5. Do any of these exam findings involve unexpected genital bleeding? ^{yes} ^{no} → **If no, go to item 6.**

5a. Was the genital bleeding observed with no identifiable source?
If yes, complete Genital Bleeding Assessment form if indicated. ←

6. Do any of these exam findings warrant a product hold? ^{yes} ^{no} ^{not applicable}
If yes, complete Product Hold/Discontinuation Log. ←

7. Colposcopic exam assessment: ^{not done} ^{abnormal findings} ^{no abnormal findings} → **If not done or no abnormal findings, end of form.**

7a. Abnormal **colposcopic** findings: *Mark all that apply.*

- | | | |
|---|-------------------------------------|---|
| <input type="checkbox"/> Abnormal vaginal discharge | <input type="checkbox"/> Erythema | <input type="checkbox"/> Vesicles |
| <input type="checkbox"/> Abnormal cervical discharge | <input type="checkbox"/> Ulceration | <input type="checkbox"/> Edema |
| <input type="checkbox"/> Blood-tinged discharge | <input type="checkbox"/> Laceration | <input type="checkbox"/> Abnormal cysts |
| <input type="checkbox"/> Blood in vagina—
no identified source | <input type="checkbox"/> Abrasion | <input type="checkbox"/> Mass |
| <input type="checkbox"/> Blood from cervical os | <input type="checkbox"/> Peeling | <input type="checkbox"/> Warts |
| <input type="checkbox"/> Bleeding from site of
epithelial disruption | <input type="checkbox"/> Petechia | <input type="checkbox"/> Other abnormal findings, specify:
_____ |
| | <input type="checkbox"/> Ecchymosis | |

Comments: _____

Pelvic Exam (PE-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 5a:** If unexpected genital bleeding was observed with no identifiable source, complete a Genital Bleeding Assessment form if applicable (unless one has already been completed for this visit).
- **Item 6:** Mark the “not applicable” box for screening and enrollment pelvic exams. Also mark during follow-up for participants in the No IVR cohort.
- **Item 7:** Colposcopy is required at the Enrollment, 12-week, 16-week/Early Termination Visits, and when clinically indicated. Document any abnormal findings observed during colposcopic examination **only**. 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 2.
- **Item 7a:** 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 on the line provided. *Note: Abnormal findings observed via colposcopy only (i.e., not seen on visual inspection) are not reportable as AEs per protocol.*

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code .

1

MTN005 IVR Ring (148)

PER-1 (168)

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	

Pelvic Exam Ring Assessment

Exam 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. Was the study IVR present in the vagina at the start of the exam? ^{yes} ^{no} → **If no, go to item 3.**
2. Was the IVR removed during the exam? ^{yes} ^{no} → **If no, end of form.**
3. Was the study IVR rinsed prior to insertion? ^{yes} ^{no} ^{not reinserted}
 - 3a. Specify reason ring not inserted: _____

If yes or no, end of form.

Pelvic Exam Ring Assessment (PER-1)

Purpose: The purpose of this form is to document presence/absence of the IVR during pelvic exams.

General Information/Instructions: This form is completed for participants randomized to the IVR cohort only. This form is completed each time an IVR participant has a pelvic exam performed.

SAMPLE *Do NOT FAX TO DATAFAX*



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

MTN005 IVR Ring (148)

PRE-1 (012)

Participant ID

- -
 Site Number Participant Number Chk

Pre-existing Conditions

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

1.	Description	Date of Diagnosis/Surgery		MMM	yy	Severity Grade <input type="checkbox"/> <input type="checkbox"/> not gradable Is condition ongoing? <input type="checkbox"/> yes <input type="checkbox"/> no Staff Initials / Date
	Comments	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
2.	Description	Date of Diagnosis/Surgery		MMM	yy	Severity Grade <input type="checkbox"/> <input type="checkbox"/> not gradable Is condition ongoing? <input type="checkbox"/> yes <input type="checkbox"/> no Staff Initials / Date
	Comments	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
3.	Description	Date of Diagnosis/Surgery		MMM	yy	Severity Grade <input type="checkbox"/> <input type="checkbox"/> not gradable Is condition ongoing? <input type="checkbox"/> yes <input type="checkbox"/> no Staff Initials / Date
	Comments	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
4.	Description	Date of Diagnosis/Surgery		MMM	yy	Severity Grade <input type="checkbox"/> <input type="checkbox"/> not gradable Is condition ongoing? <input type="checkbox"/> yes <input type="checkbox"/> no Staff Initials / Date
	Comments	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
5.	Description	Date of Diagnosis/Surgery		MMM	yy	Severity Grade <input type="checkbox"/> <input type="checkbox"/> not gradable Is condition ongoing? <input type="checkbox"/> yes <input type="checkbox"/> no Staff Initials / Date
	Comments	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
6.	Description	Date of Diagnosis/Surgery		MMM	yy	Severity Grade <input type="checkbox"/> <input type="checkbox"/> not gradable Is condition ongoing? <input type="checkbox"/> yes <input type="checkbox"/> no Staff Initials / Date
	Comments	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	

Pre-existing Conditions (PRE-1)

Purpose: This form is used to document the participant's pre-existing medical conditions.

General Information/Instructions: 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).

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.
- **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.
- **Severity Grade:** For each condition, grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* and the *DAIDS Female Genital Grading Table for Use in Microbicide Studies* (as appropriate). If a condition is not gradable, mark the "not gradable" box.
- **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) to SCHARP DataFax.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code .

MTN005 IVR Ring (148)

PR-1 (440)

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

Pregnancy Report

PREGNANCY REPORT

- Date of onset of last menstrual period:
- Estimated date of delivery:

Comments: _____

Pregnancy Report (PR-1)

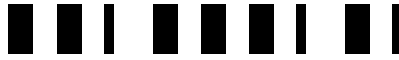
Purpose: Complete this form when reporting a pregnancy of a study participant post enrollment through termination.

General Information/Instructions: Record the visit code of the visit at which study staff became aware that the participant is/was pregnant.

Item-specific instructions:

- **Item 1:** A complete date is required. Record best estimate if date not known.
- **Item 2:** A complete date is required.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code .

Outcome Number

MTN005 IVR Ring (148)

PO-1 (442)

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	

Pregnancy Outcome

<input type="checkbox"/>	Outcome unobtainable
<input type="checkbox"/>	End of form.

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

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

2. Outcome Date:

dd MMM yy

3. Place of delivery/outcome:

- home
- hospital
- clinic
- unknown
- other, specify: _____

4. Specify Outcome: *Mark only one.*

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

C-section vaginal

4a1. Method:

If full term live birth, go to item 6 on page 2.

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

5. Provide a brief narrative of the circumstances: _____

Pregnancy Outcome (PO-1)

Purpose: This form is used to report pregnancy outcome information for a pregnancy reported post-enrollment. Complete this form when information about a pregnancy outcome becomes available to study staff or when it is determined that pregnancy outcome is unobtainable.

General Information/Instructions: A Pregnancy Outcome form is required for each Pregnancy Report form that is completed for a participant.

Item-specific Instructions:

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

SAMPLE Do NOT FAX TO DATAFAX



Visit Code [] [] . [] []

Outcome Number [] []

MTN005 IVR Ring (148)

PO-2 (443)

Participant ID

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

Pregnancy Outcome

[] No data recorded on this page.

6. Were any fetal/infant congenital anomalies identified? [] yes [] no [] unknown

If no or unknown, go to statement below item 6b.

6a. Congenital anomalies identified. Mark all that apply. Complete AE Log and EAE Reporting form.

- 6a1. Central nervous system, cranio-facial
6a2. Central nervous system, spinal
6a3. Cardiovascular
6a4. Renal
6a5. Gastrointestinal
6a6. Pulmonary
6a7. Musculoskeletal/extremities
6a8. Physical defect
6a9. Skin
6a10. Genitourinary
6a11. Chromosomal
6a12. Craniofacial (structural)
6a13. Hematologic
6a14. Infectious
6a15. Endocrine/metabolic
6a16. Other

6b. Describe the congenital anomaly/defect: _____

Complete items 7-10 for live births only. Otherwise, end of form.

7. Infant gender: [] male [] female [] unknown

8. Infant birth weight: [] [] . [] kg OR [] unavailable

9. Infant gestational age by examination: [] [] [] OR [] unavailable If unavailable, go to item 10.

9a. Method used to determine gestational age: [] Ballard [] Dubowitz [] other, specify: _____

10. Classification of the newborn by birth weight and gestational age (obstetric or by examination):

- [] Large for gestational age (> 90%)
[] Appropriate for gestational age
[] Small for gestational age (< 10%)
[] Intrauterine growth retardation (< 3%)
[] Classification not available

[] [] [] [x] 15-FEB-11

[0] [1] Language

Staff Initials / Date

Pregnancy Outcome (PO-2)

Item-specific Instructions:

- **Visit Code:** Record the visit code that is present on page 1 of this form.
- **No data recorded on this page:** This box must only be marked if all items on the page are left blank.
- **Outcome Number:** Record the outcome number that is present on page 1 of this form.
- **Item 6a:** If a woman on study has a baby with a congenital anomaly, report the event on an Adverse Experience (AE) Log, if prior to termination. On the AE Log, record “Congenital Anomaly in Offspring” on Item 1, record the Outcome Date as the Onset Date, and record the specific anomaly on the Comments line. Also submit an Expedited Adverse Event (EAE) Reporting form.
- **Item 8:** Record the infant’s birth weight as documented in medical records. If no medical record documentation of infant birth weight is available, complete this item based on participant report. Mark the “unavailable” box if no medical record documentation is available and the participant does not know the infant’s birth weight.
- **Item 9:** Record the infant’s gestational age at birth. If the infant’s gestational age is determined using the Ballard method, please record “0” in the “days” box. Mark the “unavailable” box if no medical record documentation of the infant’s gestational age is available.

SAMPLE. DO NOT FAX
TO DATAFAX



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

Page

MTN005 IVR Ring (148)

PH-1 (410)

Participant ID

- -
Site Number Participant Number Chk

Product Hold/Discontinuation Log

1. Date and visit code when study IVR hold was initiated:
dd MMM yy Visit Code .

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

pregnancy
 HIV positive result
 adverse experience → *AE Log page #*
 other, specify: _____

3. Date of last study IVR use:
dd MMM yy

4. Was the participant instructed to resume IVR use? *yes* *no (permanently discontinued)* *no (hold continuing for another reason)*

In item 4a, record the date and visit code on which the participant would have been instructed to resume IVR use if not being held for another reason.

4a. Date and visit code when participant was instructed to resume or permanently discontinue IVR use:
dd MMM yy Visit Code .

Comments: _____

Product Hold/Discontinuation Log (PH-1)

This form is used to document temporary holds and permanent discontinuations of study IVR use. This form is completed each time a participant is instructed to temporarily stop (hold) or permanently discontinue study IVR use prior to the 12-week Visit. If, at the same study visit, a product hold/discontinuation is initiated for more than one reason, complete a Product Hold/Discontinuation Log page for each reason. The same visit code should be used on each Log page.

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 page once item 4 has been completed.

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers.
- **Item 3:** Record the date the participant last used a study IVR (the last date the study IVR was present in the vagina). Use a best estimate if the actual date cannot be determined.
- **Item 4:** If the reason for the product hold, as recorded in item 2, has resolved but there is another reason (e.g., pregnancy) for continuing the product hold, mark “no (hold continuing 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 IVR use or the date it was determined study IVR use must be permanently discontinued. If “no (hold continuing for another reason)” is marked for item 4, in item 4a record the date and visit code that the participant would have been instructed to resume IVR use based on resolution of the reason marked in item 2 of the form.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code .

1

MTN005 IVR Ring (148)

RA-1 (170)

Participant ID

- -
Site Number Participant Number Chk

Ring Adherence

Visit Date

dd MMM yy

1. Dates covered by this review: *First date* *Last date*
dd MMM yy dd MMM yy

2. How many days of the diary were not completed (blank)? **# of days** → *If 00, go to item 3.*

2a. What was the main reason the participant did not complete the diary every day?
Diary Code
yes no

3. Has the ring been out at any time during this review period? → *If no, end of form.*

3a. How many times total has the ring been out? **# of times** → *If 6 or more, add Comment after completing items 4a-4e.*

4. For each instance the ring was out, complete the information below on when the ring was out, how long it was out, and why it was out.

	Date ring out			Duration ring was out			Is Duration an estimate?		Removal/Expulsion Code	If other, specify:
	dd	MMM	yy	days	hours	minutes	yes	no	<input type="text"/> <input type="text"/>	_____
4a.	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	_____
4b.	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	_____
4c.	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	_____
4d.	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	_____
4e.	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	_____

Comments: _____

Ring Adherence (RA-1)

Purpose: To collection information on ring adherence.

General Information/Instructions: This form is completed only for participants randomized to the IVR arm. Complete this form based on discussion with the participant. As part of the discussion, the participant's diary should be reviewed and used to help identify instances where the ring has been outside of the participant's vagina. The information recorded on this form does not need to match the information on the participant's diary, especially in cases where the diary is incomplete and/or inaccurate.

Item-specific Instructions:

- **Item 1:** Record the dates of the time period being reviewed. These dates may not match the first and last dates on the diary in cases where these dates are missing from the diary. The dates should cover the time period since the last time this form was completed for the participant up through the previous day.
- **Item 2:** If the diary is not available (participant did not bring it), count each day as not completed (blank). Record "5" for item 2a.
- **Item 2a, Diary Incompletion Code:** Select from the codes below and record the code that best describes why the participant did not complete all days of her diary.

Diary Incompletion Codes

1 participant forgot	5 participant did not bring diary
2 participant felt the diary was too difficult to complete	6 participant did not have privacy to complete the diary
3 participant felt the diary took too long to complete	7 participant's partner did not want her to complete
4 participant felt she could remember without completing the diary	8 other reason not listed

- **Items 4a–4e, Removal/Expulsion Code:** Select from the codes below and record the code that best describes why the ring was taken out or came out on it's own.

Removal/Expulsion Codes

Codes if the ring came out on its own
01 urinating
02 having a bowel movement
03 having sex or just finished having sex
04 physical activity or just finished physical activity
05 had or was expecting menses
06 other

Codes if the ring was taken out
10 ring caused discomfort
11 didn't feel it was correctly placed
12 had or was expecting menses
13 didn't want husband/male sex partner to know about ring
14 husband/male sex partner did not like ring and/or wanted her to remove ring
15 worried ring would be expelled during sex
16 didn't want to have vaginal sex with ring in vagina
17 site staff told her to remove ring
18 family member (other than husband/male sex partner) told her to remove ring
19 religious reasons
20 other

SAMPLE. DO NOT FAX
TO DATAFAX



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

Page

MTN005 IVR Ring (148)

SH-1 (151)

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	

Social Harm Log

1. Concisely describe the serious or unexpected social harm experienced by the participant:

2. Onset date:
dd MMM yy

3. Reported at visit:

4. Social harm code:

Social Harm Codes: See back for definitions.

- | | | |
|----------------------------------|----------------------------|--|
| 01 Personal Relationships | 05 Medical/Dental | 09 Military/Other Government Agency |
| 02 Travel/Immigration | 06 Health Insurance | 10 Other |
| 03 Employment | 07 Life Insurance | 11 Harassment, bullying, coercion |
| 04 Education | 08 Housing | |

Social Harm Log (SH-1)

Purpose: Complete this form to record the occurrence and resolution of a serious or unexpected participant social harm.

Item-specific instructions:

- **Item 4:** Use the following definitions to code the social harm:

Code	Definition
01 Personal Relationships	Had negative experiences with family, friends, significant others, or sex partners.
02 Travel/Immigration	Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization.
03 Employment	Been turned down for a new job, lost a job, or experienced other problems at work.
04 Education	Been turned down by an educational program, told to leave an educational program, or experienced other problems at school.
05 Medical/Dental	Been refused medical or dental treatment, or treated negatively by a health care provider.
06 Health Insurance	Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance.
07 Life Insurance	Lost life insurance, had a problem getting new life insurance, or experienced other problems related to life insurance.
08 Housing	Had trouble getting or keeping housing, or had other problems related to housing.
09 Military/Other Government Agency	Had a problem with the military or any other government agencies.
10 Other	Had other problems not covered in the codes above.
11 Harassment, bullying, coercion	Experienced persistent torment, repeated attacks, or intimidation.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code .

1

MTN005 IVR Ring (148)

SS-1 (164)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Site Number			Participant Number				Chk			

Specimen Storage

Initial Specimen Collection Date

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

Alternate Collection Date

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

		<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>
1.	Plasma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____

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

2.	Gram stain (vaginal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
----	----------------------	--------------------------	--------------------------	----------------------------	-------

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

3.	Vaginal swab for PCR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
----	----------------------------	--------------------------	--------------------------	----------------------------	-------

3a.	Was blood visible on the swab?	<input type="checkbox"/>	<i>yes</i>	<i>no</i>	<i>N/A</i>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Alternate Collection Date

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

		<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>
4.	Vaginal swab for culture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____

4a.	Was blood visible on the swab?	<input type="checkbox"/>	<i>yes</i>	<i>no</i>	<i>N/A</i>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Alternate Collection Date

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

		<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>
5.	Cervical swab for innate factors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____

5a.	Was blood visible on the swab?	<input type="checkbox"/>	<i>yes</i>	<i>no</i>	<i>N/A</i>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Alternate Collection Date

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

		<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>
6.	Swab of used IVR for culture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____

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

7.	Used IVR for FISH and SEM	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
----	---------------------------------	--------------------------	--------------------------	----------------------------	-------

Comments: _____

Specimen Storage (SS-1)

Purpose: This form is used to document collection and storage of specimens by the local site laboratory.

General Information/Instructions: Check the information on this form against the LDMS Specimen Tracking Sheet completed for this visit to make sure the information is the same.

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* for this visit. A complete date is required.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected on a different day than the Initial Collection Date. 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. A complete date is required.

Item-specific Instructions:

- **Items 1–7:** If the specimen is not required to be collected and stored at this visit, mark the “not required” box. If the specimen is required to be stored, but for some reason it is not stored at this visit, mark the “not stored” box and record the reason why on the line provided.
- **Items 3a, 4a, and 5a:** Mark the “N/A” box if a swab was not required or not stored at this visit.

SAMPLE. Do NOT FAX
TO DATAFAX



MTN005 IVR Ring (148)

TM-1 (490)

Participant ID

Site Number			Participant Number						Chk	

Termination

1. Termination Date: dd MMM yy

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 dd MMM yy

OR date unknown

2b2. cause of death _____ OR cause unknown

Complete or update Adverse Experience Log.

2c. participant refused further participation, specify: _____

2d. **NOT APPLICABLE FOR THIS PROTOCOL.**

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 ———▶ **End of form.**

2j. invalid ID due to duplicate screening/enrollment ———▶ **End of form.**

2k. other, specify: _____

2l. early study closure ———▶ **End of form.**

3. Was termination associated with an adverse experience? yes no don't know
 ———▶ **If no or don't know, end of form.**

3a. Record AE Log page:

Comments: _____

Termination (TM-1)

Purpose: This form should be completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.

General Information/Instructions: If a participant is terminated prior to completing study product administration, complete a Product Hold/Discontinuation Log.

Item-specific Instructions:

- **Item 1:** A complete date is required.
- **Item 2:** Mark only the primary reason for termination.
 - **Item 2a:** Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.
 - **Item 2b1:** At a minimum, the month and year are required.
 - **Item 2l:** Early study closure: Only mark 2l when instructed by SCHARP.
- **Item 3a:** Record the page number of the Adverse Experience Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate.

SAMPLE *Do NOT FAX TO DATAFAX*



Visit Code .

1

MTN005 IVR Ring (148)

VTR-1 (072)

Participant ID

- -
Site Number Participant Number Chk

Vaginal Test Results

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

Not done/ Not collected *dd* *MMM* *yy*

1. VAGINAL WET PREP STUDIES

Not done

1a. Homogeneous vaginal discharge	<input type="checkbox"/>	<i>negative</i>	<input type="checkbox"/>	<i>positive</i>
1b. pH..... <input type="text"/> <input type="text"/> →		<i>If > 4.5 mark as positive.</i>	→	<input type="checkbox"/>
1c. Whiff test	<input type="checkbox"/>		<input type="checkbox"/>	
1d. Clue cells > 20%.....	<input type="checkbox"/>		<input type="checkbox"/>	
1e. Buds and/or hyphae (yeast)	<input type="checkbox"/>		<input type="checkbox"/>	

Wet Prep: _____
Staff Initials/Date

Alternate Collection Date

Not done/ Not collected *dd* *MMM* *yy*

2. Trichomonas *negative* *positive*

Trichomonas: _____
Staff Initials/Date

Comments: _____

Vaginal Test Results (VTR-1)

Item-specific Instructions:

- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected after the Initial Collection Date for this same visit. A complete date is required.
- **Results Reporting**
 - If a specimen was collected but results are not available because the specimen was lost or damaged, mark the “Not done/Not collected” box and write an explanation on the Comments lines.
- **Item 1a:** Mark the “positive” box if homogeneous vaginal discharge was observed.
- **Item 1d:** Mark the “positive” box if more than 20% of cells were clue cells.
- **Item 1e:** Mark the “positive” box if yeast buds and/or hyphae were observed.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN005 IVR Ring (148)

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

**Baseline Pregnancy/
Contraceptive History**

Visit Date

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

Pregnancy History

Preg #	Outcome Date	Outcome (fullterm, preterm, ectopic, SAB, TAB, etc.)	Type of Delivery (vag, cesarean, D&C)	Alive now?	Congenital anomalies or problems with pregnancy (describe)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

Contraceptive History

Record current method on Concomitant Medications Log when applicable.

Current Method(s)	Approx. Dates of Use	Any problems?
Previously Used Method(s)	Approx. Dates of Use	Any problems?

Baseline Pregnancy/Contraceptive History (non-DataFax)

Item-specific Instructions:

- **Pregnancy History:** Record the outcome date, outcome (for example, full-term live birth, premature live birth, spontaneous abortion, etc.) and other relevant information regarding each of the participant's pregnancies.

SAMPLE *Do NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN005 IVR Ring (148)

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	

Enrollment Behavioral Eligibility

Form Completion Date

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

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

- | | | | |
|--|--------------------------|--------------------------|--|
| 1. In the past 7 days, have you inserted an intrauterine device (IUD)?..... | yes | no | |
| | <input type="checkbox"/> | <input type="checkbox"/> | |
| 2. In the past 14 days, have you used, or do you plan to use a diaphragm, spermicide, contraceptive vaginal ring, vaginal antibiotic or antifungal medication, sex toys, lubricants or condoms that contain silicone, or menstrual cups while participating in this study? | | | |
| | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3. In the past 14 days, have you been douching or practicing another type of cleansing inside the vagina, or do you plan to during your study participation? | | | |
| | <input type="checkbox"/> | <input type="checkbox"/> | |
| 4. Are you currently participating in or do you plan to participate in any study that involves any other device or drug while participating in this study? | | | |
| | <input type="checkbox"/> | <input type="checkbox"/> | |
| 5. Do you plan to become pregnant while participating in this study? | | | |
| | <input type="checkbox"/> | <input type="checkbox"/> | |
| | | | ➔ If yes to any, participant is ineligible. |
| 6. Do you plan to continue using your current birth control method for the duration of your study participation? | yes | no | |
| | <input type="checkbox"/> | <input type="checkbox"/> | |
| 7. In the last month (30 days), have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina. | | | |
| | <input type="checkbox"/> | <input type="checkbox"/> | |
| 8. Do you anticipate that you will have vaginal sex at least once a month during your study participation? | | | |
| | <input type="checkbox"/> | <input type="checkbox"/> | |
| | | | ➔ If no to any, participant is ineligible. |

Enrollment Behavioral Eligibility (non-DataFax)

This form is used to document the participant's behavioral eligibility for the study at enrollment. 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 Behavioral Eligibility form must be completed as part of the subsequent screening attempt. See the Study-Specific Procedures Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.*

General Information/Instructions: If the participant provides a response indicating she is ineligible, continue to administer this form until all items are completed. Refrain from indicating to the participant the reason why she is ineligible.

SAMPLE *Do NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN005 IVR Ring (148)

Participant ID

Site Number			Participant Number				Chk		

Follow-up Medical History Log

Page

Medical Condition	Onset Date (dd-MMM-yy)	Staff Initials/Log Entry Date	Is this condition reportable as an AE? yes <input type="checkbox"/> no <input type="checkbox"/>
	Outcome Date (dd-MMM-yy)	Severity Grade	AE Log Page #
Comments			Medication taken? yes <input type="checkbox"/> no <input type="checkbox"/> <i>Report on Concomitant Medications Log.</i>

Medical Condition	Onset Date (dd-MMM-yy)	Staff Initials/Log Entry Date	Is this condition reportable as an AE? yes <input type="checkbox"/> no <input type="checkbox"/>
	Outcome Date (dd-MMM-yy)	Severity Grade	AE Log Page #
Comments			Medication taken? yes <input type="checkbox"/> no <input type="checkbox"/> <i>Report on Concomitant Medications Log.</i>

Medical Condition	Onset Date (dd-MMM-yy)	Staff Initials/Log Entry Date	Is this condition reportable as an AE? yes <input type="checkbox"/> no <input type="checkbox"/>
	Outcome Date (dd-MMM-yy)	Severity Grade	AE Log Page #
Comments			Medication taken? yes <input type="checkbox"/> no <input type="checkbox"/> <i>Report on Concomitant Medications Log.</i>

Medical Condition	Onset Date (dd-MMM-yy)	Staff Initials/Log Entry Date	Is this condition reportable as an AE? yes <input type="checkbox"/> no <input type="checkbox"/>
	Outcome Date (dd-MMM-yy)	Severity Grade	AE Log Page #
Comments			Medication taken? yes <input type="checkbox"/> no <input type="checkbox"/> <i>Report on Concomitant Medications Log.</i>

Follow-up Medical History Log (non-DataFax)

This form is used to document and track **all** medical conditions observed in or reported by the study participant during follow-up. This includes all signs, symptoms, and laboratory-based medical conditions. This form is reviewed and updated at each study visit and participant contact (e.g., telephone contacts), including interim visits/contacts, unless stated otherwise by the protocol.

Item-specific Instructions

- **Page:** Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers.
- **Medical Condition:** Whenever possible, provide a diagnosis. Include anatomical location when applicable. Record only one diagnosis, sign, or symptom per entry.
- **Onset Date:** Record complete dates whenever possible. At a minimum, month and year are required. If the “day” portion is not known, record zeros for the day (example “00-JAN-11”).
- **Outcome Date:** Record a complete date whenever possible. At a minimum, month and year are required. Record the date on which the participant no longer experiences the medical condition or the date of the study visit or specimen collection at which the resolution/status outcome is first noted. If the outcome is not able to be obtained (for example, a participant is lost to follow-up), record “unknown”.
- **Severity:** Consult the appropriate *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* as specified by the protocol.
- **Is this condition reportable as an AE?:** Mark “yes” if the condition has been reported on an AE Log case report form. Refer to the protocol for a listing of which conditions are required to be reported on an AE Log form.

Review Documentation

For every follow-up visit, document that this log page was reviewed (and updated, as applicable) by recording a staff initials and date in one of the spaces below. Note that the page does not need to be reviewed once **all** conditions on the page have a recorded outcome date.

<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>
<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>
<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>
<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>	<hr/> <i>Staff Initials/Date</i>

SAMPLE *Do NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN005 IVR Ring (148)

Participant ID

Site Number			Participant Number						Chk		

Genital Bleeding Assessment

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:
Obtain from Follow-up Medical History Log.

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

2. Last day of participant's last menstrual period:
Obtain from Follow-up Medical History Log.

<i>dd</i>	<i>MMM</i>	<i>yy</i>	<i>If amenorrheic, go to item 4.</i>
<input type="text"/>	<input type="text"/>	<input type="text"/>	

3. Length in days of participant's last menstrual period
(based on dates recorded in items 1 and 2):

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

4. First day of genital bleeding episode:
Per participant report or clinical exam.

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

5. Last day of genital bleeding episode:

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

6. Total number of days of genital bleeding:

<input type="text"/>	<input type="text"/>	<i>days</i>	OR	<input type="checkbox"/>	<i>ongoing</i>
----------------------	----------------------	-------------	----	--------------------------	----------------

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?

<i>normal</i>	<i>lighter</i>	<i>heavier</i>	<i>unknown</i>	<i>N/A</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. According to the participant or the clinician, what color was the genital blood? *Mark "unknown," or all that apply.*

<i>bright red</i>	<i>brown</i>	<i>unknown</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. According to the participant, did she continue to use the study IVR during this genital bleeding episode?

<i>yes</i>	<i>no</i>	<i>N/A</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

→ *If yes or N/A, go to item 11 on page 2.*

Genital Bleeding Assessment (non-DataFax) - Page 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 the Study-specific Procedures Manual (SSP) to determine whether or not an episode of genital bleeding is unexpected.

Item-specific Instructions:

- **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.
- **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.
- **Item 9:** Mark “NA” if the participant’s study IVR use was held or permanently discontinued prior to this genital bleeding episode.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN005 IVR Ring (148)

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

Genital Bleeding Assessment

10. Number of days between last use of study IVR and first day of genital bleeding episode: days

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

	yes	no	
11a. vaginal sex?	<input type="checkbox"/>	<input type="checkbox"/>	
11b. painful vaginal sex?	<input type="checkbox"/>	<input type="checkbox"/>	
11c. painful or uncomfortable insertion or removal of the study IVR?	<input type="checkbox"/>	<input type="checkbox"/>	N/A <input type="checkbox"/>
11d. painful or uncomfortable insertion or removal of any other vaginal product/preparation?	<input type="checkbox"/>	<input type="checkbox"/>	
11e. a pelvic or colpo exam?	<input type="checkbox"/>	<input type="checkbox"/>	

If yes to any, record related details in Comments on page 3.

If yes, record date of last pelvic/colpo exam in Comments on page 3.

	yes	no
11f. condom use?	<input type="checkbox"/>	<input type="checkbox"/>

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

12b. When is/was her next injection due?	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	Go to item 14 on page 3.
--	---	---	---	---------------------------------

13. Is the participant currently using (non-injectable) hormonal contraceptives? *Review Concomitant Medications Log.* yes no **If no, go to item 14 on page 3.**

13a. Has the participant missed one or more days of contraceptives in the week before the genital bleeding started?	<input type="checkbox"/> yes <input type="checkbox"/> no	If no, go to item 14 on page 3.
---	--	--

13b. Did the participant miss two or more days of contraceptives?	<input type="checkbox"/> yes <input type="checkbox"/> no	If yes, go to item 14 on page 3.
---	--	---

Genital Bleeding Assessment (non-DataFax) - Page 2

Item-specific Instructions:

- **Item 11c:** Mark the “N/A” box if the participant is not in the IVR cohort.
- **Item 12:** If the participant reports currently using injectable contraceptives, make sure the injectable contraceptives are listed on the participant’s Concomitant Medications Log.
- **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.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN005 IVR Ring (148)

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

Genital Bleeding Assessment

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.

Comments: _____

Genital Bleeding Assessment (non-DataFax) - Page 3

Item-specific Instructions:

- **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 the Study-specific Procedures Manual (SSP) to determine whether or not the genital bleeding is unexpected.
- **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 Grading Table for Use in Microbicide Studies* (protocol Appendix IV).

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 the Study-specific Procedures Manual (SSP) for further information.

- **non-menstrual** - grade an AE of metrorrhagia (intermenstrual bleeding) using the “metrorrhagia” row of the *Female Genital Grading Table for Use in Microbicide Studies* (protocol Appendix IV). Grade an AE of postcoital bleeding using the “postcoital bleeding” row of the *Female Genital Grading Table for Use in Microbicide Studies*.

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 the Study-specific Procedures Manual (SSP) for further information.

Participant ID			Visit Code		Specimen Collection Date		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number - Participant Number - Chk					dd MMM yy		
# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB ADD/DER	INSTRUCTIONS FOR PROCESSING LAB		
<input type="checkbox"/>	Blood (BLD)	EDT <small>(purple top)</small>	PL1/2	N/A	At Enrollment (Visit Code 2.0): lab to make at least three (3) 1.5mL aliquots.		
<input type="checkbox"/>	Vaginal Smear for Gram Stain (VAG)	NON <small>(no additive)</small>	SLD	GRS	Re-label with LDMS label. Store duplicate slides (one for on-site storage and one for shipping and reading at the NL). India site: only 10% of slides will be sent to NL for QA.		
<input type="checkbox"/>	India Only: Vaginal Swab for PCR (VAG)	NON <small>(no additive)</small>	SWB	N/A	Store swab at ≤-70°C locally.		
<input type="checkbox"/>	US Only: Vaginal Swab for Culture (VAG)	PAC	SWB	N/A	Ship on ice packs to NL on the day of collection.		
<input type="checkbox"/>	US Only: Cervical Swab for innate factors (CXS)	PBS	SWB	N/A	Store swab at ≤-70°C locally.		
<input type="checkbox"/>	US Only: Swab of used IVR for Culture (IVR)	NON <small>(no additive)</small>	SWB	N/A	Ship on ice packs to NL on the day of collection.		
<input type="checkbox"/>	US Only: Used IVR for FISH and SEM (IVR)	NON <small>(no additive)</small>	IVR	PFM	Ship on ice packs to NL on the day of collection.		

Comments: _____

Initials: _____
Sending Staff Receiving Staff

LDMS Data Entry Date: /
dd MMM yy LDMS Staff

MTN-005

LDMS Specimen Tracking Sheet

For login of MTN-005 stored specimens into LDMS

MTN-005 LDMS Specimen Tracking Sheet (non-DataFax)

Purpose: This non-DataFax form is used to document collection and entry of MTN-005 specimens into the Laboratory Data Management System (LDMS).

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

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the specimens were collected.
- **TUBES or SPECIMENS COLLECTED:** In the box provided, record the total number of tubes or specimens collected for that primary specimen type. If no LDMS specimens of the primary specimen type were collected, record "0."
- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials – Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
 - **LDMS Data Entry Date – LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN005 IVR Ring (148)

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

Menstrual History

Visit Date

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

Usual menstrual cycle: *regular* *irregular*

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

First day of last menstrual period: *dd* *MMM* *yy*

Last day of last menstrual period: *dd* *MMM* *yy*

amenorrheic for past 6 months **OR**

Reason for amenorrhea: _____

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

Usual menstrual symptoms (document type, severity, and usual duration, if any):

Menstrual History (non-DataFax)

Item-specific Instructions:

- **Usual number of bleeding days:** If the participant is amenorrheic, refer to her previous menstrual cycles that occurred prior to the amenorrhea.
- **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.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN005 IVR Ring (148)

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:* _____

Weight kg BP / mmHg

Height cm Pulse per minute

Oral Temp . °C Respirations per minute

Vital Signs: _____ Staff Initials / Date

FINDINGS

Items 2 and 3 are required at the Screening, Enrollment, and 16-Week Visits, and when clinically indicated. If abnormal, please specify.

<i>not</i>	<i>normal</i>	<i>abnormal</i>	
<i>evaluated</i>			

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. General appearance _____
--------------------------	--------------------------	--------------------------	-----------------------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Abdomen _____
--------------------------	--------------------------	--------------------------	------------------

Items 4–15 are evaluated only if clinically indicated. If abnormal, please specify.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. HEENT _____
--------------------------	--------------------------	--------------------------	----------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Neck _____
--------------------------	--------------------------	--------------------------	---------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Lymph Nodes _____
--------------------------	--------------------------	--------------------------	----------------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Heart _____
--------------------------	--------------------------	--------------------------	----------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Lungs _____
--------------------------	--------------------------	--------------------------	----------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Extremities _____
--------------------------	--------------------------	--------------------------	----------------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. Neurological _____
--------------------------	--------------------------	--------------------------	------------------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11. Skin _____
--------------------------	--------------------------	--------------------------	----------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12. Breast Exam _____
--------------------------	--------------------------	--------------------------	-----------------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13. Other, specify: _____
--------------------------	--------------------------	--------------------------	---------------------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14. Other, specify: _____
--------------------------	--------------------------	--------------------------	---------------------------

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15. Other, specify: _____
--------------------------	--------------------------	--------------------------	---------------------------

Findings: _____ Staff Initials / Date

Physical Exam (non-DataFax)

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.

Item-specific Instructions:

- **Vital Signs:** Remember to use leading zeros when needed. The staff member who completes these items should initial and date on the line provided.
- **Findings:** The staff member who completes these items should initial and date on the line provided.
- **Items 2 and 3:** These items are required as part of a complete physical exam per protocol. If required but not done, specify reason(s) on the line provided.
- **Items 4–15:** These items are optional.
- **Items 13–15:** Use these items to list any additional organ systems that were evaluated. If no other organ systems other than the ones listed in items 2–12 were evaluated, mark these items as “not evaluated.”

SAMPLE *Do NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN005 IVR Ring (148)

Participant ID

- -

Site Number Participant Number Chk

Pelvic Exam Diagrams

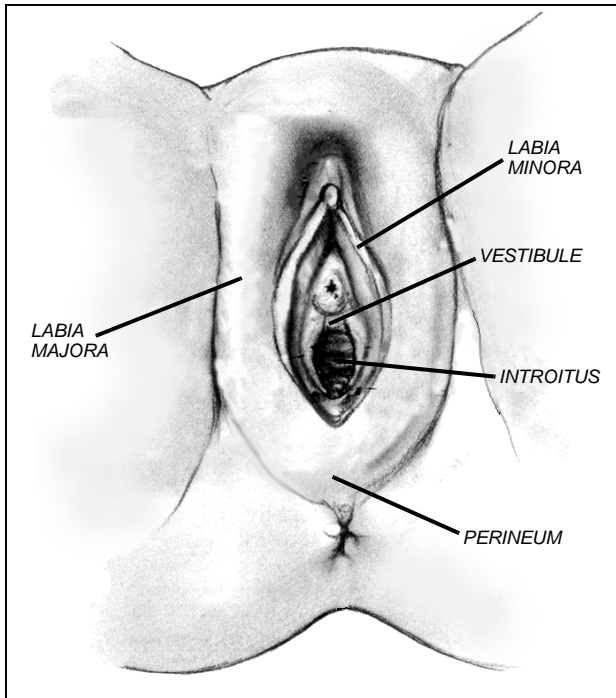
Exam Date

dd MMM yy

no normal variants or abnormal findings observed

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

External Genitalia

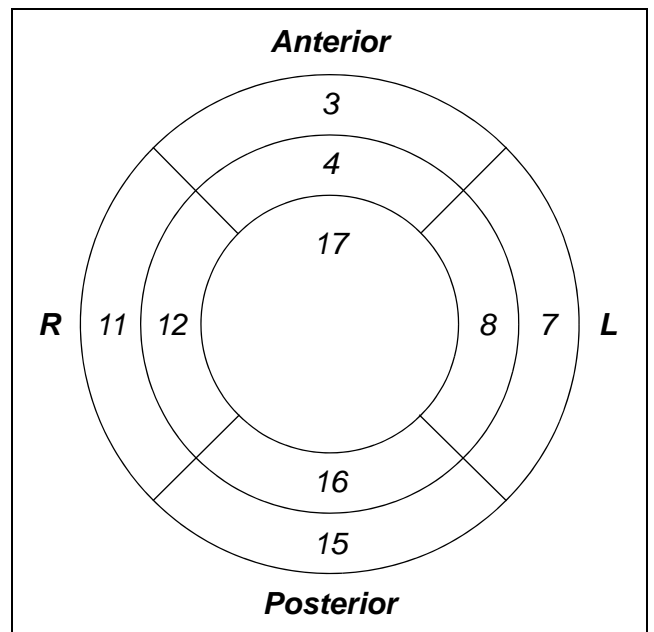
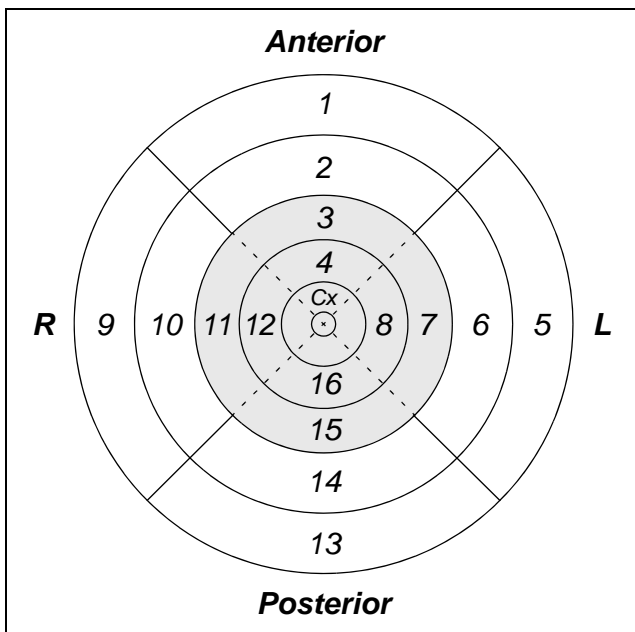


Vagina

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

Cervix



15-FEB-11

Language

Staff Initials / Date

Pelvic Exam Diagrams (non-DataFax)

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*

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MTN005 IVR Ring (148)

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

Screening Behavioral Eligibility

Form Completion Date

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

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.

1. Have you ever had an adverse or bad reaction to latex (such as latex condoms or gloves)?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>
 2. Have you ever had an adverse or bad reaction to silicone?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 3. Have you ever had an adverse or bad reaction to titanium dioxide?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 4. Do you have a current male sex partner who has had an adverse or bad reaction to latex, silicone, or titanium dioxide?

<input type="checkbox"/>	<input type="checkbox"/>	don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
 5. Do you plan to become pregnant while participating in this study?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 6. Starting 14 days before your Enrollment Visit and continuing throughout your study participation, do you plan to use spermicides, diaphragms, contraceptive vaginal rings, vaginal antibiotics or antifungal medications, sex toys, lubricants or condoms that contain silicone, or menstrual cups?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 7. Starting 14 days before your Enrollment Visit and continuing throughout your study participation, do you plan to douche or practice another type of cleansing inside the vagina?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
- ➔ **If yes to any, participant is ineligible.**
8. Do you agree to not use any intravaginal product (except tampons) including douches, creams, lubricants, etc. starting 14 days before your Enrollment Visit and continuing throughout your participation in this study?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>
 9. In the last month (30 days), have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.

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

 ➔ **If no to either, participant is ineligible.**
 10. In the last month (30 days), how many male sexual partners have you had?

# of male sex partners	
<input type="text"/>	<input type="text"/>

 ➔ **If 3 or more, participant is ineligible.**

Screening Behavioral Eligibility (non-DataFax) - Page 1

This form is used to document the participant's behavioral eligibility for the study at screening. 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 13.3.2 of the Study-specific Procedures Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.*

General Information/Instructions: If the participant provides a response indicating that she is ineligible for the study, continue to administer this form so that all items are completed. Refrain from indicating to the participant the reason why she is ineligible.

SAMPLE. Do NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN005 IVR Ring (148)

Participant ID

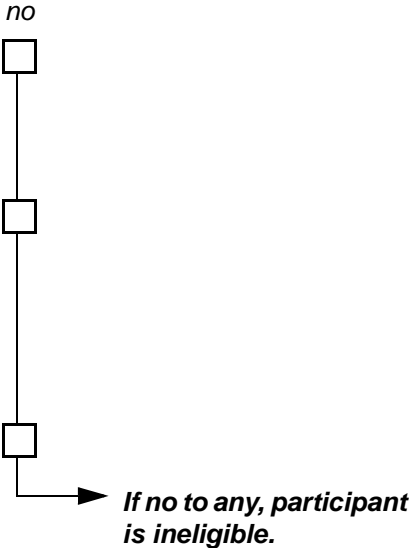
<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>
Site Number				Participant Number					Chk

Screening Behavioral Eligibility

Form Completion Date

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

11. Do you anticipate that you will have vaginal sex at least once a month during your study participation? *yes* *no*
12. Do you agree to not participate in any other study that involves a device or drug while participating in this study?..... *yes* *no*
13. For the duration of your study participation, are you willing to use one of the following types of birth control: hormonal contraceptives (except contraceptive vaginal rings), an intrauterine device (IUD)—inserted at least 7 days prior to enrollment, study provided male condoms, or sterilization of you or your male sex partner? *yes* *no*



Screening Eligibility (non-DataFax) - Page 2

No additional instructions.