

Section 14. Data Collection

This section provides information needed to successfully complete and submit MTN-003 case report forms (CRFs). It is important for sites to collect and record data carefully on CRFs; by doing so, the Statistical and Data Management Center (SDMC) can be confident that the data they are analyzing are accurate and complete. For questions about this section or about general data collection policies, procedures, or materials, please contact Karen Patterson (karen@scharp.org) and Laura McKinstry (lamckins@scharp.org).

For this study, the SDMC is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, WA, USA, and is in the US Pacific Time (PT) time zone. The SCHARP MTN-003 team members, along with their job roles and e-mail addresses, are listed below.

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14.1 DataFax Overview

DataFax is the data management system used by SCHARP to receive and manage data collected at study sites. The site faxes an electronic image of each case report form (CRF) to SCHARP DataFax, and the original hard copy 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 sites 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 a 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.
- Each CRF is then reviewed by at least two members of SCHARP's Data Operations Group. Problems such as missing or potentially incorrect data are identified and marked with Quality Control notes (QCs).
- QCs are compiled into QC reports that are sent via e-mail to the study site on a regular basis. Sites are asked to correct or clarify any problems identified on the QC reports and refax the corrected CRFs to SCHARP DataFAX.
- When the re-faxed pages are received, SCHARP staff review the corrected pages and resolve the QCs.

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

14.2 DataFAX Form Completion

14.2.1 General Guidelines

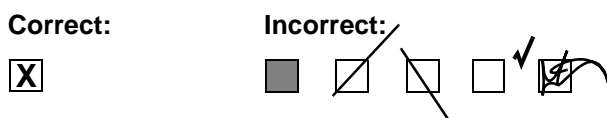
Based on the use of fax technology and Good Clinical Practices (GCPs), follow the guidelines below when completing DataFAX CRFs:

- Read carefully and follow all form instructions, which are printed on the back of each form
- 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 margins at the top, bottom, or sides of the CRF.
- Record written text responses on the lines provided. If additional space is needed, continue writing the response 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 the 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.
- Review completed CRFs, per local site SOP(s), for completeness and accuracy prior to faxing to SCHARP DataFax
- Fax CRFs as soon as possible after they have been completed and reviewed. Ideally, completed forms will be faxed to SCHARP within 1–2 days of completing the visit, though up to 5 days is allowed.

14.2.2 How to Mark Response Boxes

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



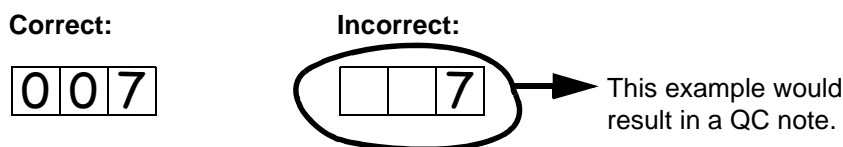
Mark only one response box for each item unless the “Mark all that apply” instruction is present.

14.2.3 How to Record Numbers

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

- Right justify **all** numbers and fill in any blank boxes with leading 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:

0 1 2 3 4 5 6 7 8 9

Difficult to Identify:

Ø 1 2 3 4 7

14.2.4 How to Record Dates

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

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

Month	Abbreviation	Month	Abbreviation
January	JAN	July	JUL
February	FEB	August	AUG
March	MAR	September	SEP
April	APR	October	OCT
May	MAY	November	NOV
June	JUN	December	DEC

For example, September 8, 2009 is recorded as:

08 SEP 09
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, 2010 would be recorded as follows:

OCT 10
MMM yy

14.2.5 How to Record Time

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

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

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

The following chart shows equivalencies between the 12- and 24-hour clocks. Please note that 12:00am is often referred to as “midnight” and 12:00pm is often referred to as “noon”.

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

14.2.6 Data Corrections and Additions

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

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

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

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

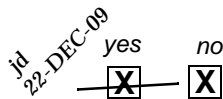
Whenever an entry on a DataFax CRF is changed, do the following:

- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it unreadable with multiple cross-outs),
- place the correct or clarified answer near the box, and initial and date the correction as shown below:



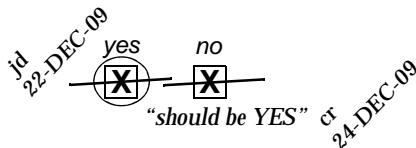
If an **X** is marked in the wrong response box, correct it by doing the following:

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



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

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

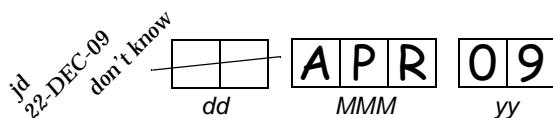


The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is faxed to SCHARP for the first time.

14.2.7 How to Handle Missing and Unknown Data

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

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



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

14.3 MTN-003 Study-Specific Data Collection Information

14.3.1 Participant ID numbers (PTIDs)

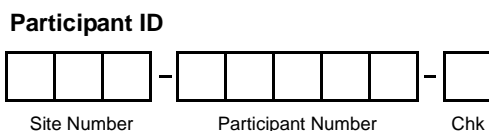
DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. SCHARP provides each site with a list of PTIDs, prior to study start-up, in the form of a PTID-Name Link Log. The site should assign one PTID to each participant screened for the study. Ideally, the PTIDs are assigned in sequential order as participants present for the Screening Part 1 Visit. The site should ensure that each PTID is assigned only once. Once a participant has received a PTID, she will maintain that same PTID throughout the entire study.

Note for sites participating in MTN-003B: The PTID that is given to a participant in MTN-003 will be the same PTID that is used for MTN-003B (see Section 18 for more information).

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

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

The PTIDs used for this study are nine digits long and are formatted as “XXX-YYYYY-Z.” The three parts of the PTID are: the site number (XXX), the participant number (YYYYY), and a numerical check digit (Z). The check digit (Z) is a number generated by SCHARP with the participant number, and helps ensure that the correct PTID is recorded. Below is an example of the PTID structure used in MTN-003.



14.3.2 Study Visit Timing

Screening and Enrollment

There are two Screening visits required prior to Enrollment into MTN-003. Screening Part 1 may take place up to 56 days prior to Enrollment. Multiple visits may be conducted to complete all required screening procedures if necessary. If more than one visit is needed to complete all required procedures, procedures not completed at the Screening Part 1 visit may be performed on the same day as Screening Part 2. Multiple visits may also be conducted to complete all required procedures for Screening Part 2, if necessary. The initial screening visit is defined as the day the participant provides written informed

consent to be screened for the study. The Enrollment Visit must take place no later than 56 days after the initial screening visit.

For MTN-003, a participant is considered enrolled once the participant has been assigned a MTN-003 Clinic Randomization Envelope. Assignment of MTN-003 randomization envelopes will be documented using the MTN-003 Clinic Randomization Envelope Tracking Record provided to each site by SCHARP.

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, the same PTID is used for that participant for all re-screens and enrollment into the study. If a participant re-screens, only case report forms from the successful screening and enrollment visits are faxed to SCHARP.

Follow-Up Visits

Participants in MTN-003 will have monthly, quarterly, semiannual, and annual follow-up visits while they are in the study. Follow-up visits are targeted to take place every 28 days based on the date of enrollment. The number of follow-up visits will vary by participant. Each participant is expected to have a minimum of 12 months and a maximum of 33 months of study product use. In addition, each participant will have approximately 8 weeks off study product followed by one final follow-up visit, the Study Exit/Termination Visit.

For a maximum of 33 months of study product use, the visit type, visit code, target visit day, and visit windows are listed in Table 14-1 below.

Product Use End Visit and Study Exit/Termination Visit

The last two scheduled visits for each participant are referred to as the Product Use End Visit (PUEV) and the Study Exit/Termination Visit. The PUEV will serve as the participant's last routine monthly follow-up visit. The study month when the PUEV is completed will vary for each participant, based on when a participant *terminates* from the study (and not necessarily when a participant permanently discontinues her use of study product).

- For participants who remain in study follow-up through their expected study product use end date, the Product Use End Visit (PUEV) is conducted when the participant is *expected* to permanently discontinue study product use. For example, a participant is expected to remain on study product for the maximum time allowed per protocol (33 months). If the participant remains in study follow-up through Month 33, she completes her PUEV at Month 33. This is true regardless of whether or not the participant permanently discontinued study product use prior to Month 33.
- For participants who terminate from the study prior to their expected product use end date, the PUEV is conducted when the participant terminates from the study. For example, a participant is expected to remain on study product for the minimum amount of time allowed per protocol (12 months). The participant presents to the site clinic for her Month 3 Visit and informs study staff that she no longer wants to participate in the study. If the participant is willing, study staff conduct the PUEV at this time (Month 3). This is true regardless of whether or not the participant permanently discontinued study product use prior to Month 3.

SCHARP will monitor study endpoints closely throughout the study. When the study begins to near the desired number of HIV endpoints, the Protocol Team will inform site staff when the study will be completed (study end date), and therefore, when the PUEV should be conducted for the remaining participants in study follow-up.

For each participant, the Study Exit/Termination visit will take place approximately 8 weeks after the target date of her PUEV.

Table 14-1: List of MTN-003 Visits, Visit Codes, Target Visit Dates, and Visit Windows

All visit windows are listed in days.

Visit	Visit Code	Visit Window Opens	Target Day	Visit Window Closes
Screening Part 1	1.0	Up to day -56	Not applicable	Not applicable
Screening Part 2	2.0	Not applicable	Not applicable	Day -1
Enrollment	3.0	Not applicable	0	56 days after screening consent date
Month 1	4.0	14	28	41
Month 2	5.0	42	56	69
Month 3	6.0	70	84	97
Month 4	7.0	98	112	125
Month 5	8.0	126	140	153
Month 6	9.0	154	168	181
Month 7	10.0	182	196	209
Month 8	11.0	210	224	237
Month 9	12.0	238	252	265
Month 10	13.0	266	280	293
Month 11	14.0	294	308	321
Month 12	15.0	322	336	349
Month 13	16.0	350	364	377
Month 14	17.0	378	392	405
Month 15	18.0	406	420	433
Month 16	19.0	434	448	461
Month 17	20.0	462	476	489
Month 18	21.0	490	504	517
Month 19	22.0	518	532	545
Month 20	23.0	546	560	573
Month 21	24.0	574	588	601
Month 22	25.0	602	616	629
Month 23	26.0	630	644	657
Month 24	27.0	658	672	685
Month 25	28.0	686	700	713
Month 26	29.0	714	728	741
Month 27	30.0	742	756	769
Month 28	31.0	770	784	797

Visit	Visit Code	Visit Window Opens	Target Day	Visit Window Closes
Month 29	32.0	798	812	825
Month 30	33.0	826	840	853
Month 31	34.0	854	868	881
Month 32	35.0	882	896	909
Month 33	36.0	910	924	937
Product Use End Visit (PUEV)	will vary	PUEV target day-14 days	will vary	PUEV target day +13 days
Termination*	89.0	Termination target day -14 days	PUEV target day +56 days	Study end date

* If a participant terminates early from the study, use the visit code, target day, and visit windows of the follow-up month (as listed above) in which the Study Exit/Termination Visit occurs.

Target Days and Visit Windows

Ideally, visits will be completed on the target day for the visit. Follow-up visits in MTN-003 are targeted to occur every 28 days following the participants enrollment date into the study (Enrollment = Day 0). Target dates are set based on the enrollment date and do not change if subsequent actual visits take place before or after the target date. Since the visit windows in MTN-003 are contiguous, visits may only be completed within the visit window. Completed visits will appear on the MTN-003 Retention Report as being completed “on-time”.

It is not always possible to complete a study visit on the target day. Therefore, follow-up visits may be completed within an approximate 4-week window around the target date (-14 days and +13 days from the target date). For example, if a participant enrolls into MTN-003 on 15 October 2009, her month 1 target day is 12 November 2009. However, she can complete her Month 1 visit any time between 29 October 2009 and 25 November 2009. For participants who do not complete scheduled visits within the visit window, the visit will be considered “missed” and relevant CRFs will be completed to document the missed visit.

SCHARP will provide sites with an Excel spreadsheet tool that may be used to generate individual participant follow-up visit calendars. Once the enrollment date is entered into the spreadsheet, the target day and visit windows for the participant’s follow-up visits will appear and can then be printed and added to the participant’s study notebook. The calendar tool provides target dates for each of the monthly follow-up visits, up to the maximum 33 months of study product use. The calendar tool also calculates the target date and visit windows for the Study Exit/Termination Visit, based on entry of the expected PUEV date.

There is no specific “Day Target Window Closes” for the Study Exit/Termination Visit. Study staff should make every effort to complete a participant’s Study Exit/Termination Visit 8 weeks (56 days) after her PUEV. However, if this is not possible, a woman can still return to the site clinic to complete her Study Exit/Termination Visit even though more than 8 weeks have passed since her PUEV. Sites should continue to make reasonable efforts to contact participants and complete the Study Exit/Termination Visit up until the study end date, as determined by SCHARP.

Split Visits

Split visits are allowed for all visits except the Enrollment Visit. All Enrollment Visit procedures must be conducted on the same day, with the exception of informed consent for enrollment and specimen storage, which may take place at a prior date.

In cases where a participant is not able to complete all required screening or follow-up visit evaluations on the same day, the participant may return and complete the remaining evaluations on another day - as long as the evaluations are completed within the visit window. For example, if a participant comes in on her Month 6 target day and completes all required evaluations except for the pelvic exam (she is on menses), she can return up to 13 days later (once she is off menses) to complete the pelvic exam and have the pelvic exam be considered part of the same Month 6 Visit. In another example, a participant enrolled in MTN-003B completes all required VOICE evaluations for the Month 12 Visit on the target day, but is unable to complete the MTN-003B Month 12 visit procedures that day. The participant can return to the site clinic up to 13 days later to complete the MTN-003B visit procedures as part of the same Month 12 Visit. See Section 14.3.3 for information on assigning visit codes to split visits.

Missed Visits

In 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, if a participant who enrolls in MTN-003 on 15 October 2009 shows up for her Month 1 Visit on 26 November 2009, her Month 1 Visit is considered missed, as she is now in the visit window for her Month 2 Visit. In this case, the participant's Month 1 Visit is considered missed, and is documented by completion of a Missed Visit case report form.

Interim Visits

A clinic visit is considered an Interim Visit when a participant presents at the site for reasons *other* than to complete required study visit procedures. Interim visits may be performed at any time during the study for reasons that may be administrative (a participant has study-related questions for the staff), product-related (a participant needs additional study product), lab-related (a participant needs a safety lab test repeated for confirmation), or clinical in nature (a participant needs management and/or follow-up of an AE), etc.

NOTE: *not all interim visits are assigned interim visit codes. An interim visit should be assigned an interim visit code only if 1) data collected at the visit warrants completion of a new DataFax form, such as an AE Log or Product Hold/Discontinuation (PH) Log form, or 2) product use was previously held and is now being resumed, resulting in an update to the PH Log form (items 4-4a). An Interim Visit form must be completed for each and every visit that is assigned an interim visit code. See section 14.3.3. below for instructions on how to assign interim visit codes.*

Below are examples of interim visits in MTN-003.

1. A participant completes all required evaluations for her Month 1 Visit. She then returns to the site clinic, within the Month 1 visit window, requesting additional study product to replace the study product she lost. An Interim Visit and Product Returns and Dispensations CRF are completed and assigned interim visit code 04.1.
2. A participant completes all required evaluations for her Month 2 Visit within the visit window. She then returns to the clinic within the same Month 2 visit window to request a pregnancy test. An Interim Visit CRF is completed, the pregnancy test result is recorded on the form, and interim visit code 05.1 is assigned.

3. A participant completes her Month 3 Visit on the target day. Her lab test results indicate that she has an abnormal serum creatinine level. Seven days later, she returns to the clinic for an interim visit to repeat the creatinine test. An Interim Visit and Safety Laboratory Results CRF are completed and assigned interim visit code 06.1.
4. A participant enrolls on 02-NOV-09. She returns to the site clinic three days later (05-NOV-09) requesting additional study product to replace lost study product. Since it is so early in her Month 1 visit window, and the participant has proved to be reliable, the site does not want to conduct the Month 1 Visit on 05-NOV-09. Instead, the site conducts an interim visit to re-supply the participant with study product. An Interim Visit and Product Returns and Dispensations CRF are completed and assigned interim visit code 02.1. The site then schedules the participant to return to the clinic on her Month 1 target day to complete her Month 1 Visit.

Phone contact with a participant is also considered an Interim Visit, and is assigned an interim visit code, if 1) the phone contact results in reporting of a new Adverse Event (AE), or 2) during the phone contact, the participant is instructed by site staff to hold, discontinue, or resume product use (after a product hold has been initiated). Below are examples of phone contacts that qualify as interim visits and are assigned interim visit codes.

1. A participant completes her Month 2 Visit on the target day. The next day (still within the Month 2 window), she calls the clinic to report a new symptom, which results in the reporting of a new adverse experience. The phone contact is considered an interim visit. The Interim Visit and AE Log CRF are completed and are assigned interim visit code 05.1.
2. A participant completes her Month 3 Visit within the visit window. The site clinic receives her lab report two days later, and it shows a lab value that warrants a study product hold. The site clinician calls the participant and instructs her to hold study product. Thus, the phone contact is considered an interim visit. The Interim Visit And Product Hold/Discontinuation Log CRF are completed and are assigned interim visit code 06.1.

For questions about interim visits, please contact the SCHARP MTN 003 Project Managers.

14.3.3 Visit Codes and Page Numbers

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

Site staff are responsible for entering the visit code in the boxes provided in the upper right corner of each page. For multiple-paged CRFs, site staff need to make sure that all the pages of the CRF are marked with the same visit code for a given participant and visit.

The following table lists the visit codes assigned to each study visit.

Table 14-2: Visit Code Assignments for Study Visits

Visit Type	Visit Code
Screening Part 1	01.0
Screening Part 2	02.0

Table 14-2: Visit Code Assignments for Study Visits

Visit Type	Visit Code
Enrollment	03.0
Month 1	04.0
Month 2	05.0
Month 3 (Quarterly Visit)	06.0
Month 4	07.0
Month 5	08.0
Month 6 (Semiannual Visit)	09.0
Month 7	10.0
Month 8	11.0
Month 9 (Quarterly Visit)	12.0
Month 10	13.0
Month 11	14.0
Month 12 (Annual Visit)	15.0
Month 13	16.0
Month 14	17.0
Month 15 (Quarterly Visit)	18.0
Month 16	19.0
Month 17	20.0
Month 18 (Semiannual Visit)	21.0
Month 19	22.0
Month 20	23.0
Month 21 (Quarterly Visit)	24.0
Month 22	25.0
Month 23	26.0
Month 24 (Annual Visit)	27.0
Month 25	28.0
Month 26	29.0
Month 27 (Quarterly Visit)	30.0
Month 28	31.0

Table 14-2: Visit Code Assignments for Study Visits

Visit Type	Visit Code
Month 29	32.0
Month 30 (Semiannual Visit)	33.0
Month 31	34.0
Month 32	35.0
Month 33	36.0
Product Use End Visit	Varies
Termination Visit	89.0

Visit Code Assignments for the Product Use End Visit and Study Exit/Termination Visit

The Product Use End Visit (PUEV) is assigned the visit code of the study month in which it is completed. For example, if a participant completes her PUEV at Month 33, then the PUEV is assigned the Month 33 visit code (36.0). If a participant terminates early from the study and completes her PUEV at Month 7, then her PUEV is assigned the Month 7 visit code (10.0).

For DataFax purposes, the Study Exit/Termination Visit is always assigned visit code 89.0.

Visit Codes for Split Visits

When split visits occur, the case report forms completed for the visit are all assigned the same visit code (even though some forms and evaluations will have different visit dates). For example, a participant goes to the site clinic for her Month 3 Visit on the target date, 23-SEP-09, and completes all required evaluations except for the blood draw (she had a family emergency and needed to leave the visit early). She returns to the site clinic on 25-SEP-09 (still within the Month 3 visit window) to complete the blood draw. All case report forms completed on 23 and 25 September are assigned visit code 06.0, since they were all completed to document Month 3 visit procedures.

Visit codes for Interim Visits

In addition to the scheduled, protocol-required visits listed in Table 14-1, interim visits may occur once a participant is enrolled in the study. Interim visit codes are assigned using the guidelines listed below.

- In the boxes to the left of the decimal point, record the two-digit visit code for the most recent scheduled visit (regardless of 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: A participant returns to the site clinic two days after her Enrollment Visit requesting additional study product to replace the study product that she lost. Since it is early in her Month 1 visit window, study staff decide to wait until closer to the Month 1 target day to complete the Month 1 Visit. At this time, she is only given additional study product. The visit is considered an interim visit and is assigned the interim visit code below.

Visit Code for this Interim Visit:

Visit Code .

Page numbers

Other CRFs, such as log forms (e.g., Adverse Experience Log, Product Hold/Discontinuation Log, Pre-existing Conditions), include boxes in the upper right corner for recording page numbers, as shown below.

Page

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

14.3.4 Staff Initials/Date

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

14.3.5 Case Report Form Completion Schedule

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

Some SCHARP-provided forms are required to be completed at each visit, while other forms are required only at one visit or only when specifically indicated. Table 14-3 lists the DataFax and non-DataFax forms that are **required** to be completed at each MTN-003 study visit.

Table 14-3: MTN-003 Case Report Form Completion Schedule

SCREENING PART 1 (DAY -56)		VISIT CODE: 01.0
Form Acronym	Form Name	
<i>REQUIRED</i>		
DEM	Demographics	
SC	Screening Consent	
SEH	Screening and Enrollment HIV Test Results	
SLR	STI Laboratory Results	
SL	Safety Laboratory Results	
Non-DataFax	Screening Part 1 Eligibility	

SCREENING PART 2 (BETWEEN DAY -56 and DAY 0)		VISIT CODE: 02.0
Form Acronym	Form Name	
<i>REQUIRED</i>		
SPE	Screening and Enrollment Pelvic Exam	
VTR	Vaginal Test Results	
SS	Specimen Storage/PK	
CM	Concomitant Medications Log	
CL	Contraceptives Log	
Non-DataFax	LDMS Specimen Tracking Sheet	
Non-DataFax	Participant-reported Baseline Medical and Menstrual History	
Non-DataFax	Physical Exam	
Non-DataFax	Pelvic Exam Diagrams	
Non-DataFax	Screening Part 2 Medical Eligibility	
Non-DataFax	Screening Part 2/Enrollment Behavioral Eligibility	
<i>AS NEEDED</i>		
SL	Safety Laboratory Results	
SLR	STI Laboratory Results	
PTR	Pap Test Results	

Enrollment (Day 0)		VISIT CODE: 03.0
Form Acronym	Form Name	
<i>REQUIRED</i>		
PRE	Pre-existing Conditions	
SEH	Screening and Enrollment HIV Test Results	
FPB	Baseline Family Planning	
BBA	Baseline Behavior Assessment	
ENR	Enrollment	
SS	Specimen Storage/PK	
Non-DataFax	Screening Part 2/Enrollment Behavioral Eligibility	
Non-DataFax	Enrollment Medical Eligibility	
Non-DataFax	LDMS Specimen Tracking Sheet	
<i>AS NEEDED</i>		
SPE	Screening and Enrollment Pelvic Exam	
VTR	Vaginal Test Results	
SL	Safety Laboratory Results	
Non-DataFax	Pelvic Exam Diagrams	

Monthly Visits - Months 1, 2, 4, 5, etc.		VISIT CODES: 04.0, 05.0, 07.0, 08.0, etc.
Form Acronym	Form Name	
<i>REQUIRED</i>		
PRD	Product Returns and Dispensations	
FV	Follow-up Visit	

FHT	Follow-up HIV Rapid Test Results
SL	Safety Laboratory Results (required only at first monthly visit)
FPF	Follow-up Family Planning
MBA	Monthly Product Adherence and Behavior Assessment
MS	Monthly Symptoms
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam (required only at first monthly visit)
<i>AS NEEDED</i>	
SLR	STI Laboratory Results
VTR	Vaginal Test Results
PTR	Pap Test Results
FPE	Follow-up Pelvic Exam
SCR	Seroconverter Laboratory Test Results
SS	Specimen Storage/PK
HTR	HIV Western Blot Test Results
PH	Product Hold/Discontinuation Log
AE	Adverse Experience Log
PR	Pregnancy Report and History
PO	Pregnancy Outcome
MV	Missed Visit
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Pelvic Exam Diagrams
Non-DataFax	Genital Bleeding Assessment

Quarterly Visits - Months, 3, 9, 15, 21, 27		VISIT CODES: 06.0, 12.0, 18.0, 24.0, 27.0
Form Acronym	Form Name	
<i>REQUIRED</i>		
PRD	Product Returns and Dispensations	
FV	Follow-up Visit	
FHT	Follow-up HIV Rapid Test Results	
SL	Safety Laboratory Results	
FPF	Follow-up Family Planning	
SS	Specimen Storage/PK	
OPA	Oral Product Adherence and Behavior Assessment (for participants in oral arm only)	
VPA	Vaginal Product Adherence and Behavior Assessment (for participants in vaginal arm only)	
MS	Monthly Symptoms	
Non-DataFax	LDMS Specimen Tracking Sheet	
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History	
Non-DataFax	Physical Exam	
<i>AS NEEDED</i>		
SLR	STI Laboratory Results	
VTR	Vaginal Test Results	
PTR	Pap Test Results	
FPE	Follow-up Pelvic Exam	
SCR	Seroconverter Laboratory Test Results	
HTR	HIV Western Blot Test Results	
PH	Product Hold/Discontinuation Log	
AE	Adverse Experience Log	
PR	Pregnancy Report and History	
PO	Pregnancy Outcome	
MV	Missed Visit	

Non-DataFax	Pelvic Exam Diagrams
Non-DataFax	Genital Bleeding Assessment

Semiannual Visits - Months 6, 18, 30		VISIT CODES: 09.0, 21.0, 33.0
Form Acronym	Form Name	
<i>REQUIRED</i>		
PRD	Product Returns and Dispensations	
FV	Follow-up Visit	
FHT	Follow-up HIV Rapid Test Results	
VTR	Vaginal Test Results	
FPE	Follow-up Pelvic Exam	
SL	Safety Laboratory Results	
FPF	Follow-up Family Planning	
SS	Specimen Storage/PK	
OPA	Oral Product Adherence and Behavior Assessment (for participants in oral arm only)	
VPA	Vaginal Product Adherence and Behavior Assessment (for participants in vaginal arm only)	
MS	Monthly Symptoms	
Non-DataFax	LDMS Specimen Tracking Sheet	
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History	
Non-DataFax	Physical Exam	
Non-DataFax	Pelvic Exam Diagrams	
<i>AS NEEDED</i>		
SLR	STI Laboratory Results	
PTR	Pap Test Results	
SCR	Seroconverter Laboratory Test Results	
HTR	HIV Western Blot Test Results	
PH	Product Hold/Discontinuation Log	
AE	Adverse Experience Log	
PR	Pregnancy Report and History	
PO	Pregnancy Outcome	
MV	Missed Visit	
Non-DataFax	Genital Bleeding Assessment	

Annual Visits - Months 12, 24		VISIT CODES: 15.0, 27.0
Form Acronym	Form Name	
<i>REQUIRED</i>		
PRD	Product Returns and Dispensations	
FV	Follow-up Visit	
SLR	STI Laboratory Results	
FHT	Follow-up HIV Rapid Test Results	
VTR	Vaginal Test Results	
FPE	Follow-up Pelvic Exam	
SL	Safety Laboratory Results	
FPF	Follow-up Family Planning	
SS	Specimen Storage/PK	
OPA	Oral Product Adherence and Behavior Assessment (for participants in oral arm only)	
VPA	Vaginal Product Adherence and Behavior Assessment (for participants in vaginal arm only)	
MPS	Menstrual Practices and Study Disclosure Assessment	
MS	Monthly Symptoms	
Non-DataFax	LDMS Specimen Tracking Sheet	

Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam
Non-DataFax	Pelvic Exam Diagrams
<i>AS NEEDED</i>	
PTR	Pap Test Results
SCR	Seroconverter Laboratory Test Results
HTR	HIV Western Blot Test Results
PH	Product Hold/Discontinuation Log
AE	Adverse Experience Log
PR	Pregnancy Report and History
PO	Pregnancy Outcome
MV	Missed Visit
Non-DataFax	Genital Bleeding Assessment

Product Use End Visit (PUEV)	
Form Acronym	Form Name
<i>REQUIRED</i>	
PRD	Product Returns and Dispensations
FV	Follow-up Visit
SLR	STI Laboratory Results
FHT	Follow-up HIV Rapid Test Results
VTR	Vaginal Test Results
PTR	Pap Test Results (for sites with capacity and/or where local standard of care)
FPE	Follow-up Pelvic Exam
SL	Safety Laboratory Results
FPF	Follow-up Family Planning
SS	Specimen Storage/PK
OPA	Oral Product Adherence and Behavior Assessment (for participants in oral arm only)
VPA	Vaginal Product Adherence and Behavior Assessment (for participants in vaginal arm only)
MPS	Menstrual Practices and Study Disclosure Assessment
PPA	Perceived Product Assessment
PEV	Product Use End Visit
MS	Monthly Symptoms
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam
Non-DataFax	Pelvic Exam Diagrams
<i>AS NEEDED</i>	
SCR	Seroconverter Laboratory Test Results
HTR	HIV Western Blot Test Results
AE	Adverse Experience Log
PR	Pregnancy Report and History
PO	Pregnancy Outcome
Non-DataFax	Genital Bleeding Assessment
	Note: If the PUEV is <i>not</i> completed, only the PPA and PEV forms are completed. Do not complete a Missed Visit form or any other CRFs for this visit.

Termination/Study Exit	
Form Acronym	Form Name
<i>REQUIRED</i>	
FHT	Follow-up HIV Rapid Test Results
FPF	Follow-up Family Planning
SS	Specimen Storage/PK
SEV	Study Exit Visit
MPS	Menstrual Practices and Study Disclosure Assessment
SBA	Study Exit Behavior Assessment
MS	Monthly Symptoms
ESI	End of Study Inventory
TM	Termination
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam
<i>AS NEEDED</i>	
PRD	Product Returns and Dispensations (to capture late product returns)
SLR	STI Laboratory Results
VTR	Vaginal Test Results
PTR	Pap Test Results
FPE	Follow-up Pelvic Exam
SCR	Seroconverter Laboratory Test Results
SL	Safety Laboratory Results
HTR	HIV Western Blot Test Results
AE	Adverse Experience Log
PR	Pregnancy Report and History
PO	Pregnancy Outcome
Non-DataFax	Pelvic Exam Diagrams
Non-DataFax	Genital Bleeding Assessment
	<p>Note: If the Study Exit/Termination Visit is <i>not</i> completed, only the SEV, TM, and ESI forms are completed. Do not complete a Missed Visit form or any other CRFs for this visit.</p>

Interim Visit	
Form Acronym	Form Name
<i>REQUIRED</i>	
IV	Interim Visit
<i>AS NEEDED</i>	
PRD	Product Returns and Dispensations
SLR	STI Laboratory Results
FHT	Follow-up HIV Rapid Test Results
VTR	Vaginal Test Results
PTR	Pap Test Results (for sites with capacity and/or where local standard of care)
FPE	Follow-up Pelvic Exam
SCR	Seroconverter Laboratory Test Results
SL	Safety Laboratory Results
FPF	Follow-up Family Planning

SS	Specimen Storage/PK
MS	Monthly Symptoms
HTR	HIV Western Blot Test Results
PH	Product Hold/Discontinuation Log
AE	Adverse Experience Log
PR	Pregnancy Report and History
PO	Pregnancy Outcome
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam
Non-DataFax	Pelvic Exam Diagrams
Non-DataFax	Genital Bleeding Assessment

14.3.6 Site Review of DataFax Forms

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

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

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

Important: If a date stamp is used to document when a form is faxed to SCHARP DataFax, 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 re-faxes.

14.3.7 Faxing DataFax Forms

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

It is important that the sites fax completed DataFax CRFs to SCHARP within the time period specified in the site's MTN 003 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-mail listings: 1) a listing of the number of form pages received at SCHARP; and 2) a listing of the specific forms that were received at SCHARP for a given PTID and visit. Please contact the MTN-003 Project Managers if you would like to use the CRF Tracking System or for more information about the CRF Tracking System.

14.3.8 Non-DataFax Forms

MTN-003 sites will receive non-DataFax forms from SCHARP. These forms will be easily identifiable because there will not be a DataFax barcode along the top of the CRF. In place of the barcode, the following text will appear: "NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX."

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

14.4 Form Supply and Storage

14.4.1 Form and Specimen Label Supply

The case report forms requiring completion at each visit will be supplied to sites in form visit packets. One packet contains all of the required CRFs for a given visit. For example, the Enrollment Visit packet contains all of the CRFs listed as "required" for the Enrollment Visit in the Case Report Form Completion Schedule (Table 14-3). In addition to form visit packets, bulk supplies of "as needed" CRFs (for example, the Pregnancy Report and History form, Pregnancy Outcome form, and Genital Bleeding Assessment form, etc.) will be provided to each site.

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

14.4.2 Form Storage

Specifications for form storage will be detailed in the site's MTN-003 Data Management SOP. It is recommended that study staff store each participant's CRFs in a hard-cover notebook designated as the participant's study notebook. SCHARP will provide a template for site's optional use in creating notebook cover labels and spine labels. At sites' request, SCHARP can also provide a template that sites can use to create tab dividers for the notebooks.

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

14.5 Completing Interviewer-administered Forms

In order to standardize interviewer-administered data collection from site to site and to maximize data quality, it is critical that site staff 1) complete interviewer-administered forms in a consistent manner from participant to participant 2) do not influence a participant's answer, and 3) help a participant feel comfortable enough to share personal information and opinions. By doing so, site staff ensure that the data they collect is honest, accurate, and unbiased.

In MTN-003 there are ten total interviewer-administered forms. Two of these are non-DataFax forms: the Screening Part 1 Eligibility form and the Screening Part 2/Enrollment Behavioral Eligibility form. The rest are DataFax forms: the Baseline Behavior Assessment, Oral Product Adherence and Behavior Assessment, Vaginal Product Adherence and Behavior Assessment, Menstrual Practices and Study Disclosure Assessment, Study Exit Behavior Assessment, Perceived Product Assessment, Monthly Product Adherence and Behavior Assessment, and Monthly Symptoms form. The DataFax interviewer-administered forms come with a Question by Question (Q x Q) guide, provided at the end of Section 14 of this SSP Manual, which provides specific guidelines on how to administer those forms. In addition to the guidance in the Q x Q, below are general interviewing tips and techniques that site staff can use to 1) obtain a participant's medical history, 2) encourage a participant to answer a question she might have trouble answering, and 3) probe a participant for additional information as needed.

Welcoming the Participant

- When a new participant arrives at the clinic, always make the participant feel comfortable.
- Introduce yourself, and try to create a rapport (connection) with her to help her feel comfortable during the interview.
- Let the participant know that you will be talking to her about personal and sensitive topics as part of the visit. Some DataFax forms include introduction statements before certain items to help prepare the participant for sensitive questions. Read each of these introductions aloud as they appear on the forms.

Asking Sensitive Questions

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

Pacing the Interview

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

Reading Items Aloud

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

For items with multiple sub-items, read all sub-items to the participant and record the appropriate response for each, based on participant report. Do not read response categories aloud unless the CRF specifically instructs to do so for the given item.

Vary your tone of voice so that you don't sound automated. Emphasize the important words in a given item, so that the participant understands the meaning of the question she is asked. When given the option, choose “clinical” versus “street” or “vernacular” language based on participant preferences/cues.

Probing

Participants may not remember or know the answer to every question they are asked. The technique for helping a participant remember an answer, clarify a response, decide between two similar but different answers, or report something more precisely is called “probing.”

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

The following are some probing strategies to use when a participant initially answers “don't know” to an item, or cannot refine her response enough to allow for adequate documentation.

- **Repeat Probe:** The repeat probe is used by repeating the item or response categories (if the response categories are part of the question). Although the participant might hear you the first time you ask a question, she may need to hear the question more than once to provide an answer. Instead of rephrasing a question if you notice the participant is confused, always first repeat the item as it is written. Sometimes hearing the question a second time is all that is needed.
- **Echo Probe:** The echo probe involves repeating the participant's exact response. Sometimes hearing the answer with a different voice will help her respond more precisely. Always repeat the participant's response in a neutral, non-judgmental way.
- **Silent Probe:** The silent probe is used by pausing briefly after a participant gives what seems to be an uncertain answer. Although silence can feel awkward, sometimes it is helpful when a participant is trying to determine the most accurate answer to a question. Use a silent probe when the participant sounds unsure of her answer and may need some extra time to think more carefully about the question.
- **Non-verbal Probe:** The non-verbal probe is used by giving hand or facial gestures that may help the participant to come up with an answer. Remember that all such gestures must be neutral and non-judgmental.
- **Specification Probe:** The specification probe is used by asking the participant to give a more precise answer. Although a participant may give an answer that she considers accurate, it may not be specific enough for purposes of form completion. For example, an item asks for the exact number of times the participant did something and she answers with a range (“5 to 10”). In this case, the probe, “Can you be more specific?” is often enough to help the participant give the most accurate response.
- **Historical Probe:** The historical probe is used by asking whether the event in question occurred anytime around major holidays or personal events such as a birthday or other life event. Some items

require the participant to recall dates, and initially she may be unable to recall a specific date. Referencing a calendar can also help the participant remember dates.

Watching for Non-verbal Cues

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

Checking Your Work

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

14.6 Form Completion Instructions

Detailed form completion instructions for each form are provided on the back of each form page. These instructions include the purpose of each form as well as how each form should be completed. Item-specific instructions are provided only for those items requiring additional clarification for purposes of form completion.

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

- Each time a new entry is added or an existing entry is modified, fax the form page to SCHARP DataFax - even if the page is not complete. Do **not** wait to complete all entries on a page before faxing it to SCHARP DataFax.

Safety Laboratory Results (SL) form

- Depending on a site's normal reference ranges, it is possible that a participant can have a value that falls within the normal range, but is still gradable per the DAIDS Toxicity Table. Always refer to the DAIDS Toxicity Table when determining whether or not a lab value is gradable and should be reported as an AE.
- If a lab value is gradable per the DAIDS Toxicity Table, regardless of whether the specimen was collected at screening, enrollment, or during follow-up, record the severity grade in the “**Severity Grade**” box. Record the “**AE Log Page #**” if the gradable lab value is reportable as a stand-alone AE (e.g., “proteinuria”), or is part of a clinical AE (e.g., “urinary tract infection”). If a gradable lab value does not meet the criteria for AE reporting (i.e., the specimen was collected at screening or enrollment, or the severity grade represents an ongoing pre-existing condition), mark the “**Not Reportable as an AE**” box. If a severity grade is recorded in the “Severity Grade” box, either an “AE Log Page #” must be recorded, or the “Not reportable as an AE” box must be marked. The same “AE Log Page #” may be recorded for the same item on SL forms completed at different visits, for example, if a lab value AE persists at the same severity across study visits.

Adverse Experience Log (AE Log)

- Fax AE Log pages to SCHARP as soon as they are completed. Do **not** wait until a given AE resolves before faxing the form page to SCHARP. In most cases, when you first report the AE the AE Log form will have a “continuing” status (item 6). Once the AE has an outcome (the AE resolves, the AE is grade 5 - death, or the AE increases in severity/frequency), update items 6 and 6a of the **original** AE Log form page. Initial and date all additions, and any other changes made to the form page, and refax the page to SCHARP.
- Always make changes, corrections, and updates to the **originally-completed** Adverse Experience Log form page. Once an AE Log form page has been started and faxed to SCHARP, the data from that page should **never** be transcribed onto another AE Log form page. All updates and corrections should be made to the originally-completed form page (regardless of how messy or crowded the form page appears).
- For item 1, note that planned procedures or surgeries are **not** AEs. The underlying condition that warranted the procedure or surgery constitutes the AE. In addition, any adverse consequence of the planned procedure or surgery is considered an AE and should be recorded on an AE Log form if reportable per protocol.
- For the “**Date Reported to Site**” field, record the date site clinic staff first become aware of the AE.
- For **item 3**, the Female Genital Grading Table for Use in Microbicide Studies (FGGT) is used to assign severity grades to AEs (in addition to the DAIDS “Tox. Table”).
- For **item 4**, note that if “not related” is marked, you need to record the reason the AE is determined to be “not related” in the Comments section of the form. For example, for an AE of headache that is judged “not related”, the Comments entry may be something like “#4 - not related in time to this AE onset”.
- For **item 7**, note that if the AE results in a new or prolonged hospitalization, the AE meets the criteria for a “serious” AE, and item 8 of the AE Log form should be marked “yes”.
- There may be situations where an AE Log form needs to be deleted (for example, in the case where a condition is thought to be an AE and is later determined to have been pre-existing). To mark an AE for deletion, draw a diagonal line across the entire AE Log form page, write “delete due to _____” (include the reason the AE is being deleted), and initial and date. Refax the form to SCHARP. Do **not** reassign the page number assigned to the deleted AE to another AE, and do not renumber the other AE Log pages completed for the participant, if any. Do not renumber AE Log pages after faxing unless specifically instructed to do so by SCHARP.
- For **item 10**, record the Visit Code that is assigned to the date recorded in the “Date Reported to Site” field. AEs of gradable lab results are the one exception, as it is expected that site clinic staff may receive some lab results after the date of specimen collection (see the bullet below).
- For AEs of gradable lab results (e.g., “Increased ALT”), the date the lab report is received at the site clinic should be recorded as the “Date Reported to Site” on the AE Log. The date of specimen collection should be recorded as **item 2** “Onset Date”. The **item 6a** “Status/Outcome Date” should be the collection date of the next follow-up specimen that yields one of the following: 1) a non-gradable result, 2) a return to baseline severity, or 3) a result of increased severity (thus requiring completion of a new AE Log). For **item 10**, record the visit code that is assigned to the specimen collection date; this should be the same visit code that is assigned to the AE “Onset Date”.

14.7 Case Report Forms

This section contains each MTN-003 case report form developed for the study. The forms are in plate order. Detailed form completion instructions for each form are provided on the back of each form page.

Refer to the Visit Checklist of a given visit for a suggested order in which the forms should be completed at that visit.

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SAMPLE: DO NOT FAX TO DATAFAX



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

Page [][][]

MTN003 VOICE (160)

AE-1 (420)

Participant ID

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

Adverse Experience Log

Date Reported to Site

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

1. Adverse Experience (AE)

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

2. Onset Date

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

3. Severity

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

4. Relationship to Study Product

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

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

5. Study Product Administration

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

Change in Administration NOT APPLICABLE FOR THIS PROTOCOL. Comment below.

6. Status/Outcome

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

6a. Status/Outcome Date

Leave blank if Status/Outcome is "Continuing."

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

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

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

8. Is this an SAE according to ICH guidelines?

yes no

11. Was this AE a worsening of a pre-existing condition?

yes no

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

10. This AE was first reported at visit:..... Visit code required (regular or interim)

[][] [][]

Comments: _____

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 *DAIDS Female Genital Grading Table for Use in Microbicide Studies* (as appropriate).
- **Item 4:** When judging causal association (relationship) between an AE and the study agent consult the terms used in DAIDS-sponsored studies as documented in the *Manual for Expedited Reporting of Adverse Events to DAIDS*.
 - **NOTE: IN CASES OF DEATH**, when relationship of study product is under investigation, write “Pending” in the adjacent white space until relationship has been determined. Update accordingly.
- **Item 5:**
 - **No change:** Mark if the AE does NOT result in a study product hold, permanent discontinuation, or change in administration.
 - **Held:** Mark if the AE results in a study product hold. If multiple AEs are reported at the same visit, mark “Held” for the AE(s) that contributed to the product hold.
 - **Permanently discontinued:** Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, mark “Permanently discontinued” for the AE(s) that contributed to the permanent discontinuation.
 - **N/A (not applicable):** Mark if the AE occurred after the participant had completed all administration of the study product, or the study product is held or permanently discontinued for a different AE or other reason, or the AE is Grade 5-death.
- **Item 6:**
 - **Continuing:** AE is continuing at the time it is reported.
 - **Resolved:** Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved.
 - **Death:** Mark only if the severity of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to “continuing at end of study participation.”
 - **Severity/frequency increased:** If an AE increases in severity or frequency after it has been reported on the AE Log, line through the “Continuing” box previously marked and mark “Severity/frequency increased.” Record the date of increase in the “Status/Outcome Date.” Report the increase in severity or frequency as a new AE. For this new AE, the “Onset Date” will be the date that the severity or frequency increased. Note that decreases in severity should not be recorded as new AEs.
 - **Continuing at end of study participation:** Mark this box whenever an AE is continuing at the time of participant study termination.
- **Item 6a:** At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant no longer experienced the AE; or the date of the study visit or specimen collection at which the change in status/outcome is first noted.
- **Item 7:** Indicate if treatment was clinically indicated for the AE, regardless of whether the treatment was actually used. Also mark this item if the participant self-treated.
- **Items 8 and 9:** For questions about ICH guidelines and EAE reporting, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS*.

SAMPLE: DO NOT FAX TO DATAFAX



MTN003 VOICE (160)

BBA-1 (060)

Participant ID

- -
 Site Number Participant Number Chk

Baseline Behavior Assessment

Visit Date

dd *MMM* *yy*

Thank you for coming today for the study. As part of this research study, you will be asked questions about yourself, your sexual behaviors and reproductive health. We are all concerned about HIV/AIDS and how it is affecting women in our community. Your participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so please be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential, and none of your answers will affect your ability to participate in this research study.

1. Have you talked with any of the following people about your participation in this research study? You can answer "yes" to more than one item.

- | | <i>yes</i> | <i>no</i> | <i>N/A</i> |
|--|--------------------------|--------------------------|--------------------------|
| 1a. Your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1b. Other sex partners? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1c. Your mother or father? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1d. Your sister or brother? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1e. Other family member? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1f. A friend or neighbor? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1g. A nurse or clinician or doctor outside of the study? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1h. An elder or community leader? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1i. Anyone else? If yes, specify: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Local
Language: _____

English: _____

Baseline Behavior Assessment (BBA-1)

Purpose: This form is used to collect baseline information about the participant's sexual behaviors and vaginal hygiene practices. This is a mixed form; items 1–6e are interviewer-administered, and items 7–9a are not. This form is administered only once to each enrolled participant as part of her Enrollment visit.

Item-specific Instructions:

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

- **Item 1:** Read each item 1a–1i aloud and mark the participant's answer. If “yes” is marked for item 1i, record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX



MTN003 VOICE (160)

BBA-2 (061)

Participant ID

Site Number			Participant Number						Chk	

Baseline Behavior Assessment

The next few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

2. In the **past 4 weeks** have you had vaginal sex? *yes* *no* → **If no, go to item 4.**

The next question is about vaginal sex in the **past 7 days**.

3. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? → **If 00, go to item 4.**

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

3a. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? **Use visual aid.** → **If 00, go to statement above item 5.**

4. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? **Use visual aid.** *yes* *no* → **If no, go to statement above item 5.**

4a. What type of condom was used during the **last act** of vaginal sex that you had? **Use visual aid.** *male condom* *female condom*

The next questions are about your menstrual period and items women sometimes insert inside their vagina for personal hygiene or other reasons.

5. In the **past 3 months**, have you had a menstrual period? *yes* *no* → **If no, end of interview. Go to statement above item 7 on page 3.**

Baseline Behavior Assessment (BBA-2)

Item-specific Instructions:

- **Item 3:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record “00” for this item.
- **Item 3a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record “00” for this item.

Baseline Behavior Assessment (BBA-3)

Item-specific Instructions:

- **Item 6:** Read each item 6a–6e aloud and mark the participant's answer. If “yes” is marked for item 6e be sure to record the participant's verbatim response. Also provide the English translation in the space provided.
- **Items 7, 8, 9, and 9a:** These items are not interviewer-administered. These items must be completed by transcribing data from the participant's Screening Part 1 Eligibility form (non-DataFax). For items 7 and 8, use leading zeros when needed so that all the boxes are filled.

SAMPLE: DO NOT FAX TO DATAFAX



MTN003 VOICE (160)

FPB-1 (055)

Participant ID

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

Site Number Participant Number Chk

Baseline Family Planning

Visit Date

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

dd MMM yy

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

1a. none —▶ **If none, participant is ineligible, end of form.**

- 1b. vaginal ring
- 1c. spermicide
- 1d. diaphragm
- 1e. sponge

▶ **Participant is ineligible.**

- 1f. intrauterine device (IUD)
- 1g. oral contraceptives/birth control pills
- 1h. injectable contraceptives (such as Depo-Provera)
- 1i. (Ortho Evra) The Patch
- 1j. implants

▶ **Record on Contraceptives Log.**

- 1k. female condoms
- 1l. natural methods such as the withdrawal or rhythm method
- 1m. male condoms

▶ **Must be combined with another effective method of contraception, per protocol, for participant to be eligible.**

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

1o. sex with partner who had a vasectomy

1p. other, specify: _____

▶ **Record on Contraceptives Log, if applicable. If participant does not report use of at least one effective method of contraception, per protocol, or reports use of an exclusionary method, per protocol, participant is ineligible.**

Comments: _____

Baseline Family Planning (FPB-1)

Purpose: This form is used to document the methods of contraception/family planning used by the participant at the time of her Enrollment Visit.

Note: There is no visit code field on this form, since this form is only completed at the Enrollment Visit.

Item-specific Instructions:

- **Item 1:** Complete this item based on source documentation recorded in the participant's Baseline Medical and Menstrual History.

SAMPLE: DO NOT FAX TO DATAFAX



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

Page

MTN003 VOICE (160)

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 <input type="checkbox"/> qxh: every <input type="text"/> <input type="text"/> hrs Mark only one. <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____											
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="checkbox"/> _____						

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 <input type="checkbox"/> qxh: every <input type="text"/> <input type="text"/> hrs Mark only one. <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____											
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="checkbox"/> _____						

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 <input type="checkbox"/> qxh: every <input type="text"/> <input type="text"/> hrs Mark only one. <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____											
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="checkbox"/> _____						

17-MAR-09

Language

Concomitant Medications Log (CM-1)

Purpose: All medication(s) that are used by the participant during the study, other than study product and contraceptives, 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	qxx every x hours

- **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).

Contraceptives Log (CL-1)

Purpose: All contraceptives used by the participant during the study must be documented on this form. This includes, but is not limited to oral contraceptives, injectable contraceptives, intrauterine devices, implants (e.g., Norplant), Ortho Evra, spermicide, diaphragm, and emergency contraception. Do not record male or female condom use.

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 Contraceptives Log pages after faxing, unless instructed by SCHARP.
- **No contraceptives 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 contraceptives taken throughout study:** Mark this box at the Termination visit if no contraceptive devices or medications were taken by the participant throughout the entire study.
- **Contraceptive:** If the contraceptive is an intrauterine device, record the brand name. For injectable contraceptives (e.g., Depo-Provera), record each injection as a separate entry.
- **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	qhx every x hours

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

PO oral	IM intramuscular	IU intrauterine	TOP topical	VAG vaginal
----------------	-------------------------	------------------------	--------------------	--------------------

- **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.

Demographics (DEM-1)

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

General Information/Instructions: This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment visit.

Note: There is no visit code field on this form, since this form is only completed at the Screening Part 1 Visit. 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. **NOTE:** *participant must be between the ages of 18 and 40 years (inclusive) at the time of screening to be eligible for study participation.*
- **Item 4:** Record whether or not the participant **currently** has a primary sex partner.
- **Item 5:** Read aloud "husband" or "primary sex partner," depending on the participant's response to item 3 and item 4 (if not currently married). If the participant does not know her husband's or primary partner's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 8:** Record whether or not the participant's husband or primary partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 9:** Record the husband's or primary 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	0	0	2	1	4	5
---	---	---	---	---	---	---	---	---

If the husband's or primary partner's average monthly income is greater than 999,999,999 write "999999999" in the boxes provided, and record the actual value in the white space near the item.

Demographics (DEM-2)

Item-specific Instructions:

- **Item 10:** If the participant does not know her husband or 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.
- **Item 11:** The intent of this item is to capture the circumcision status of the participant's husband/primary sex partner at the time this form is administered (Screening Part 1). If the participant's husband/primary sex partner (as reported in items 3–4) is circumcised after the Screening Part 1 Visit, do not update the response to item 11.
- **Item 12a:** 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	0	0	2	1	4	5
---	---	---	---	---	---	---	---	---

If the participant’s average monthly income is greater than 999,999,999 write “999999999” in the boxes provided, and record the actual value in the white space near the item.

- **Item 12b:** 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



MTN003 VOICE (160)

DEM-3 (003)

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

14. How many children have you given birth to who were alive at birth? # of children
15. Do you, or does someone in your family, own the house you are currently living in? *yes* *no*
16. How many rooms are in the house you are currently living in? # of rooms
17. What is your ethnic group or tribe? *ethnic/tribe code*
If other, specify:
- Local Language:* _____ *English:* _____

Interviewer: Complete item 18 after the interview.

18. Where was the participant referred/recruited from?..... recruitment code

Demographics (DEM-3)

Item-specific Instructions:

- **Item 14:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 15:** Record whether or not the participant (or someone in her extended family) owns the house she lives in.
- **Item 16:** Do not count bathrooms as rooms.
- **Item 17:** This item asks about ethnic group or tribe. Record the 2-digit country-specific code below that is associated with the participant’s ethnic group or tribe. If the participant responds with “other,” record, “99” and 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.

MALAWI	SOUTH AFRICA	UGANDA	ZAMBIA	ZIMBABWE
01 - Chichewa	07 - Zulu	11 - Black	12 - Bemba	16 - Shona
02 - Lombwe	08 - Xhosa	06 - White	13 - Chewa	17 - Ndebele
03 - Yao	09 - Indian	99 - Other	14 - Tonga	05 - Other African tribe
04 - Tumbuka	10 - Colored		15 - Lozi	06 - White
05 - Other African tribe	05 - Other African tribe		05 - Other African tribe	99 - Other
06 - White	06 - White		06 - White	
99 - Other	99 - Other		99 - Other	

- **Item 18:** This is not an interviewer-administered item. Record the 2-digit site-specific code associated with the location (or person) from where this participant was referred or recruited.

SAMPLE: DO NOT FAX TO DATAFAX



MTN003 VOICE (160)

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"/>
dd		MMM			yy		

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

visit code

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

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

of interim visits

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

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

3a. Adverse Experience Log (AE-1) *page #*

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

OR *no pages submitted*

(Include deleted AE Log pages.)

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

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

3c. Pre-existing Conditions (PRE-1) *page #*

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

3d. Product Hold/Discontinuation Log (PH-1) *page #*

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

OR *no pages submitted*

(Include deleted PH Log pages.)

3e. Contraceptives Log (CL-1) *page #*

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

Comments: _____

End of Study Inventory (ESI-1)

Purpose: This form is used to confirm that SCHARP has received all study data for a given participant.

General Information/Instructions: Complete this form once for each enrolled participant after the participant has terminated from the study (as documented by a Termination form).

Item-specific instructions:

- **Form Completion Date:** A complete date is required.
- **Item 1:** Record the highest visit code (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit code of the missed visit.
- **Item 2:** Record the total number of Interim Visit DataFax forms submitted for this participant. If no Interim Visit forms were submitted for the participant, record "000" in the boxes.
- **Item 3a:** Record the highest page number of the Adverse Experience Log submitted for this participant, even if that page was marked for deletion.
- **Item 3d:** 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



MTN003 VOICE (160)

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

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible. End of form.

 - 1a. When was the informed consent form for enrollment 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. Was the participant able and willing to provide written informed consent for specimen storage and future research?.....

yes	no	not yet consented	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	→ If no or not yet consented, go to item 3.

 - 2a. When was the informed consent form for specimen storage and future research 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 clinic randomization envelope assigned?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, specify reason in Comments. End of form.

 - 3a. Clinic randomization envelope number:

<input type="text"/>	<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 group was the participant randomized?

oral	vaginal
<input type="checkbox"/>	<input type="checkbox"/>

4. Did the participant complete the ACASI Baseline Behavioral Questionnaire?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If "no, vaccination not indicated" or "no, participant refused," end of form.

5. Did the participant receive a Hepatitis B vaccination (initial or follow-up) at this visit?

yes	no, vaccination not indicated	no, participant refused	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	→ If "no, vaccination not indicated" or "no, participant refused," end of form.

If yes, record the vaccination on the Concomitant Medications Log.

 - 5a. Which dose did she receive at this visit?

0 (initial dose)	1-2 months	4-6 months
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: _____

17-MAR-09

Language

Staff Initials / Date

Enrollment (ENR-1)

Purpose: This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for participants determined to be eligible for the study.

General Information/Instructions: This form is faxed to SCHARP DataFax only if the participant is enrolled (that is, she is assigned a clinic randomization envelope), and only after completion of the Enrollment Visit.

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

Item-specific Instructions:

- **Item 1:** If response to this item is “no” (the participant is not willing and able to provide written informed consent for enrollment), end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.
- **Items 1a and 2a:** If the participant marks the informed consent using her thumbprint, record the date the thumbprint was made.
- **Item 2:** Mark “yes” only if the participant gave consent to have her lab specimens stored for future research testing. Mark the “not yet consented” box if the participant is not asked for informed consent for specimen storage at enrollment (rather, it is deferred to a later visit). When the participant is asked to provide informed consent for specimen storage, update the response to item 2 and initial, date, and refax the form to SCHARP.
- **Item 3:** If a clinic randomization envelope was not assigned, mark the “no” box and specify on the Comments line the reason an envelope was not assigned, then end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax if a clinic randomization envelope was not assigned.
- **Item 3a:** Record the 4-digit clinic randomization envelope number present on the clinic randomization envelope assigned to this participant.
- **Item 3b:** Record the date the clinic randomization envelope was assigned to the participant. This date should match the “date assigned” recorded for this envelope on the MTN 003 Clinic Randomization Envelope Tracking Record.
- **Item 3c:** Record the time (using a 24-hour clock) the clinic randomization envelope was assigned to the participant. This time should match the “time assigned” recorded for this envelope on the MTN 003 Clinic Randomization Envelope Tracking Record.
- **Item 3d:** Record the participant's randomization assignment present on the prescription contained in the participant's clinic randomization envelope.
- **Item 4:** Completion of the ACASI Baseline Behavioral Questionnaire is required for all participants at the Enrollment Visit. If the required questionnaire was not done, specify the reason on the Comments line.
- **Item 5:** If a Hepatitis B vaccination was indicated per protocol but not offered, line through the response boxes and initial and date. Record the reason on the Comments line. If the participant has already completed the series, or is between shots at this visit, mark the “no, vaccination not indicated” box.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

□□.□□

1

MTN003 VOICE (160)

FPF-1 (155)

Participant ID

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

Follow-up Family Planning

Visit Date

□□ □□□ □□
dd MMM yy

1. Has the participant's method of contraception/family planning changed since her last visit? **yes** **no** → **If no, go to item 3.**

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

- 2a. none
- 2b. vaginal ring
- 2c. spermicide
- 2d. diaphragm
- 2e. sponge
- 2f. intrauterine device (IUD)
- 2g. oral contraceptives/birth control pills
- 2h. injectable contraceptives (such as Depo-Provera)
- 2i. (Ortho Evra) The Patch
- 2j. implants
- 2k. female condoms
- 2l. natural methods such as the withdrawal or rhythm method
- 2m. male condoms
- 2n. sterilization (tubal ligation/hysterectomy/laparoscopy /other surgical procedure that causes sterilization)
- 2o. sex with partner who had a vasectomy
- 2p. other, specify: _____

→ **During counseling session, counsel participant regarding use of allowable methods of contraception, per protocol.**

→ **Update Contraceptives Log.**

→ **If not used in combination with another effective method of contraception, per protocol, provide appropriate counseling during counseling session.**

→ **Update Contraceptives Log, if applicable. If participant does not report use of at least one effective method of contraception, per protocol, or reports use of an exclusionary method, per protocol, provide appropriate counseling during counseling session.**

3. First day of last menstrual period:

4. Last day of last menstrual period:

no menses since last visit
OR → **End of form.**

Follow-up Family Planning (FPF-1)

Purpose: This form is used to document the methods of contraception/family planning used by the participant during study follow-up. It is completed at each monthly follow-up visit through study exit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Items 1–4:** Complete these items based on source documentation recorded in the participant's Follow-up Medical and Menstrual History.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

MTN003 VOICE (160)

FHT-1 (134)

Participant ID

- -
Site Number Participant Number Chk

Follow-up HIV Rapid Test Results

Specimen Collection Date

dd MMM yy

Not done/
Not collected

1. HIV TEST RESULTS

Not done

1a. Rapid test 1

	<i>kit</i>	<i>negative</i>	<i>positive</i>
	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>

1b. Rapid test 2

If positive for either, complete an HIV Western Blot Test Results form and Product Hold/Discontinuation Log.

Comments: _____

Follow-up HIV Rapid Test Results (FHT-1)

Purpose: This form is used to document local laboratory HIV Rapid test results of blood collected during the follow-up visits.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. Record a complete date.
- **Not done/Not collected:** Mark *either* the “Not done/Not collected” box or enter a test result. If the “Not done/Not collected” box is marked, record reason on the Comments lines.
- **Not done:** Mark *either* the “Not done” box *or* enter a test result.

Item-specific Instructions:

- **Item 1:** Record the assigned two-digit rapid test kit code. As of March, 2008, the rapid test kit codes are as follows. **Note:** *More test kit codes may be added to the list below as the study proceeds.*

Rapid Test	Kit Code
Abbott Determine	01
OraSure OraQuick	02
Uni-Gold Recombigen	03

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code

Form boxes for Visit Code

Form box for page number 1

MTN003 VOICE (160)

FPE-1 (145)

Participant ID

Participant ID form boxes: Site Number, Participant Number, Chk

Follow-up Pelvic Exam

Exam Date

Exam Date form boxes: dd, MMM, yy

- 1. Pelvic exam assessments: abnormal findings, no abnormal findings, not done. Includes instructions: 'If not done, specify reason in Comments. End of form.' and 'If no abnormal findings, go to item 5.'

1a. Abnormal findings: Mark all that apply.

- Checkboxes for various findings: Enlarged/tender inguinal lymph nodes, Abnormal vaginal discharge, Abnormal cervical discharge, Blood-tinged discharge, Blood in vagina, Blood from cervical os, Bleeding from site of epithelial disruption, Erythema, Ulceration, Laceration, Abrasion, Peeling, Petechia, Ecchymosis, Vesicles, Cervical friability, Edema, Abnormal cysts, Mass, Warts, Adnexal tenderness, Cervical motion tenderness, Uterine tenderness, Other abnormal findings, specify: _____

Complete or update Adverse Experience Log when applicable.

- 2. Do any of these exam findings involve deep epithelial disruption? yes/no. Includes instruction: 'If no, go to item 3.'

- 2a. Was the deep epithelial disruption observed in more than one distinct area? yes/no

- 3. Do any of these exam findings involve unexpected genital bleeding? yes/no. Includes instruction: 'If no, go to item 4.'

- 3a. Was the genital bleeding observed with no identifiable source? Includes instruction: 'If yes, complete Genital Bleeding Assessment form if indicated.'

- 4. Do any of these exam findings warrant a product hold? Includes instruction: 'If yes, complete Product Hold/Discontinuation Log.'

- 5. Cervical Ectopy: Percentage of cervical surface area. 0%, 1-25%, 26-50%, 51-75%, > 75%, N/A

Comments: _____

Follow-up Pelvic Exam (FPE-1)

Purpose: This form, along with the non-DataFax Pelvic Exam Diagrams, is used to document the pelvic exams conducted during study follow-up. A pelvic exam is required at each semi-annual and annual visit, the Product Use End Visit, and when clinically indicated.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 1:** 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.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding on the line provided.
- **Item 3a:** If unexpected genital bleeding was observed with no identifiable source, complete a Genital Bleeding Assessment (non-DataFax) form if applicable (unless one has already been completed for this visit). Refer to the Clinical section of the Study-Specific Procedures (SSP) Manual for further information on how to manage and document genital bleeding.
- **Item 5:** Mark the “N/A” box if the participant does not have an intact cervix.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



FV-1 (121)

Visit Code

1

Participant ID

- -
Site Number Participant Number Chk

Follow-up Visit

Visit Date

dd MMM yy

1. hCG for pregnancy: *negative* *positive* *not done*
 1a. Record the reason why the pregnancy test was not done:

If negative or positive, go to item 2.
If newly positive, complete Pregnancy Report and History form and Product Hold/Discontinuation Log.
2. Were any **new** adverse experiences reported at this visit? *yes* *no* → **If no, go to item 3.**
- 2a. How many **new** AE Log pages were completed for this visit? # of **new** AE Log pages
3. Was a **new** study product hold or discontinuation initiated at this visit? *yes* *no* → **If no, go to item 4.**
- 3a. How many **new** Product Hold/Discontinuation Log pages were completed for this visit? # of **new** Product Hold/Discontinuation Log pages
4. Did the participant complete the ACASI Follow-up Questionnaire at this visit? *yes* *no* *not required* → **If no or not required, go to item 5.**
- 4a. Date ACASI Follow-up Questionnaire was completed:
dd MMM yy
5. Did the participant receive a Hepatitis B vaccination (initial or follow-up) at this visit? *yes* *no, vaccination not indicated* *no, participant refused* → **If "no, vaccination not indicated" or "no, participant refused," end of form.**
- If yes, record the vaccination on the Concomitant Medications Log.**
- 5a. Which dose did she receive at this visit? *0 (initial dose)* *1-2 months* *4-6 months*

Comments: _____

Follow-up Visit (FV-1)

Purpose: This form is used to document the required (regularly scheduled) follow-up visits. It is completed at each regularly scheduled follow-up visit, regardless of whether the visit is conducted within the protocol-specified window or made up outside the visit window.

General Information/Instructions:

- **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.

Item-specific Instructions:

- **Item 1:** Pregnancy testing is required at every regularly scheduled study follow-up visit through the Termination Visit. Record the hCG urine pregnancy test result. If a urine pregnancy test result is not available (specimen not collected and/or test not done), mark the “not done” box and complete item 1a. *Note: A Pregnancy Report and History form must be completed for each new pregnancy.* Once a participant tests positive for hCG urine pregnancy and a Pregnancy Report and History form (PR-1) has been completed for this pregnancy, subsequent positive pregnancy test results should not be recorded on a new PR-1 unless they represent a new pregnancy.
- **Item 2:** Mark the “yes” box if a new (previously unreported) AE is reported or observed at this visit. If the box is marked “yes,” record in item 2a how many **new** Adverse Experience Log pages were completed for this visit. For example, if two new AEs were reported, record “02.” Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
- **Item 3:** Mark the “yes” box if a product hold or discontinuation is initiated at this visit. If the box is marked “yes,” record, in item 3a, how many **new** Product Hold/Discontinuation Log pages were completed for this visit. 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 4:** Completion of the ACASI Follow-up Questionnaire is required at the quarterly, annual, Product Use End, and Termination Visits. If the questionnaire is required but not done, mark the “no” box and specify the reason on the Comments lines.
- **Item 5:** If a Hepatitis B vaccination was indicated per protocol but not offered, line through the response boxes and initial and date. Record the reason on the Comments lines. If the participant has already completed the series, or is between shots at this visit, mark the “no, vaccination not indicated” box.

HIV Western Blot Test Results (HTR-1)

Purpose: This form documents confirmatory HIV test results and final HIV status during study follow-up. This form is completed each time a participant has a positive HIV Rapid 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 Follow-up HIV Rapid Test Results form documenting the positive HIV Rapid test result. If this visit is the Study Exit Visit, record visit code 89.0.
- **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 Rapid test specimen that tested positive.
- **Not Done/Not Collected:** For every test, mark *either* the “Not Done/Not collected” box *or* enter a test result. If the “Not done/Not collected” box is marked, record reason on the Comments lines.
- **Not done:** Mark *either* the “Not done” box *or* enter a test result.

Item-specific Instructions:

- **Item 1a:** Record the participant’s HIV RNA PCR result exactly as it appears on the lab report source documentation, regardless of whether the result is more or less than the limit of detection for the assay. For example, if a participant is tested with an assay that has 400 viral copies/mL as the lower limit of detection, and the lab reports her result as “238 viral copies/mL,” mark the “=” box and record “00000238” viral copies/mL for item 1a.
- **Item 1c:** Mark the “positive” box if the participant’s HIV RNA PCR result is greater than the lower limit of detection as recorded in item 1b.
- **Item 4:** Once a participant’s HIV status has been determined, record the final HIV status. If the final HIV status is not clearly negative or clearly positive, mark the “other, specify” box and specify reason(s) on the line provided. If the participant’s final HIV status is determined to be positive (according to the protocol testing algorithm), update the Product Hold/Discontinuation Log.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

MTN003 VOICE (160)

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, if applicable.**
- 1b. phone call from participant to report new symptoms —▶ **Complete Adverse Experience Log, if applicable.**
- 1c. follow-up of symptoms and/or AE(s) —▶ **Update Adverse Experience Log, if applicable.**
- 1d. participant needs study product —▶ **Complete Product Returns and Dispensations form.**
- 1e. participant is returning unused study product —▶ **Complete Product Returns and Dispensations form.**
- 1f. other, specify: _____

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

- 2a. none
- 2b. Follow-up Pelvic Exam
- 2c. Vaginal Test Results
- 2d. Safety Laboratory Results
- 2e. Product Returns and Dispensations
- 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?
- 2h. other, specify: _____

3. hCG for pregnancy: negative positive not done

If newly positive, complete Pregnancy Report and History form and Product Hold/Discontinuation Log.

4. Did the participant receive a Hepatitis B vaccination (initial or follow-up) at this visit? yes no, vaccination not indicated no, participant refused

If yes, record the vaccination on the Concomitant Medications Log.

If "no, vaccination not indicated" or "no, participant refused," end of form.

4a. Which dose did she receive at this visit? 0 (initial dose) 1-2 months 4-6 months

Comments: _____

17-MAR-09

Language Staff Initials / Date

Interim Visit (IV-1)

Purpose: Complete this form when an interim visit occurs during study follow-up.

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

- **Visit Code:** The following guidelines should be used for assigning the interim visit code:
 - Record the two-digit whole number visit code for the most recent scheduled regular visit. For example, if the most recent scheduled regular visit was Month 1 (Visit Code = 04.0), record “04” to the left of the decimal point in the visit code field.
 - Record the number that corresponds to the Interim Visit in the third box (the box to the right of the decimal point):
XX.1 = First Interim Visit after the most recent scheduled regular visit.
XX.2 = Second Interim Visit after the most recent scheduled regular visit.

Item-specific instructions:

- **Item 2:** Note that marking a box other than “none” 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:** *A Pregnancy Report and History form must be completed for each new pregnancy.* Once a participant tests positive for hCG urine pregnancy and a Pregnancy Report and History form (PR-1) has been completed for this pregnancy, subsequent positive pregnancy test results should not be recorded on a new PR-1 unless they represent a new pregnancy.
- **Item 4:** If a Hepatitis B vaccination was indicated per protocol but not offered, line through the response boxes and initial and date. Record the reason on the Comments line. If the participant has already completed the series, or is between shots at this visit, mark the “no, vaccination not indicated” box.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



MPS-1 (240)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Menstrual Practices and Study Disclosure Assessment

Visit Date

dd MMM yy

The first questions ask about your menstrual period and items women sometimes insert inside their vagina for personal hygiene or other reasons.

1. In the **past 3 months**, have you had a menstrual period? *yes* *no* **▶ If no, go to statement above item 3.**
2. In the **past 3 months**, what have you used during your menstrual period? You can answer "yes" to more than one item.

- 2a. Paper or cloth or cotton wool—put inside the vagina? *yes* *no*
- 2b. Paper or cloth or cotton wool—placed in underwear? *yes* *no*
- 2c. Tampon? *yes* *no*
- 2d. Sanitary pad? *yes* *no*
- 2e. Anything else? If yes, specify: *yes* *no*
Local Language: _____
English: _____

The next questions are about people you may have talked to about this study.

3. In the **past year**, have you talked with any of the following people about your participation in this study? You can answer "yes" to more than one item.
- 3a. Your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner. *yes* *no* *N/A*
- 3b. Other sex partners? *yes* *no* *N/A*
- 3c. Your mother or father? *yes* *no* *N/A*
- 3d. Your sister or brother? *yes* *no* *N/A*
- 3e. Other family member? *yes* *no* *N/A*

Menstrual Practices and Study Disclosure Assessment (MPS-1)

Purpose: This form is used to collect information about the participant’s menstrual practices and disclosure of study participation. This is an interviewer-administered form, and it is administered at each annual visit, the Product Use End Visit, and the Study Exit Visit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 2:** Read each item 2a–2e aloud and mark the participant’s answer. If “yes” is marked for item 2e, record the participant’s verbatim response. Also provide the English translation in the space provided.
- **Item 3:** Read each item 3a–3e aloud and mark the participant’s answer.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

□□□.□□

1

MTN003 VOICE (160)

MPS-2 (241)

Participant ID

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

Menstrual Practices and Study Disclosure Assessment

- | | yes | no | N/A |
|--|--------------------------|--------------------------|--------------------------|
| 3f. A friend or neighbor? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3g. A nurse or clinician or doctor outside of the study? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3h. An elder or community leader? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3i. Anyone else? If yes, specify: | <input type="checkbox"/> | <input type="checkbox"/> | |
| <i>Local</i> | | | |
| <i>Language:</i> _____ | | | |
| <i>English:</i> _____ | | | |

4. In the **past year**, have you talked with any of the following people about the tablets or gel you are using for this study? You can answer "yes" to more than one item.

- | | yes | no | N/A |
|--|--------------------------|--------------------------|--------------------------|
| 4a. Your primary sex partner? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4b. Other sex partners? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4c. Your mother or father? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4d. Your sister or brother? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4e. Other family member? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4f. A friend or neighbor? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4g. A nurse or clinician or doctor outside of the study? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4h. An elder or community leader? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4i. Anyone else? If yes, specify: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <i>Local</i> | | | |
| <i>Language:</i> _____ | | | |
| <i>English:</i> _____ | | | |

Menstrual Practices and Study Disclosure Assessment (MPS-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 3f–3i:** Read each item aloud and mark the participant’s answer. If “yes” is marked for item 3i, record the participant’s verbatim response. Also provide the English translation in the space provided.
- **Item 4:** Read each item 4a–4i aloud and mark the participant’s answer. If “yes” is marked for item 4i, record the participant’s verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

MTN003 VOICE (160)

MPS-3 (242)

Participant ID

- -

Site Number Participant Number Chk

Menstrual Practices and Study Disclosure Assessment

5. In the **past year**, has your primary sex partner come to the study clinic for any reason?

yes no N/A

5a. Did he attend a study meeting?

If no or N/A, end of form.

5b. Did he accompany you to a study visit?

5c. Did he receive counseling or other clinical services?

5d. Did he come to the study clinic for any other reason?

If yes, specify: ←

Local Language: _____

English: _____

Menstrual Practices and Study Disclosure Assessment (MPS-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 5:** Read each item 5a–5d aloud and mark the participant’s answer. If “yes” is marked for item 5d, record the participant’s verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code

.

MTN003 VOICE (160)

MV-1 (463)

Participant ID

- -

Site Number Participant Number Chk

Missed Visit

Form Completion Date

dd MMM yy

1. Target Visit Date:

dd MMM yy

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 Adverse Experience Log, if applicable.**
- 2f. participant withdrew from the study → **Complete Termination form.**
- 2g. participant deceased → **Complete Termination form. Complete Adverse Experience Log and EAE Reporting form.**
- 2h. other, specify:

2i. participant relocated

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 and 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

MTN003 VOICE (160)



MBA-1 (275)

Visit Code

1

Participant ID

- -
Site Number Participant Number Chk

Monthly Product Adherence and Behavior Assessment

Visit Date

dd MMM yy

Thank you for coming today for the study. Your continued participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential and none of your answers will affect your ability to participate in this research study.

The first two questions are about vaginal sex.

1. In the **past 4 weeks**, have you had vaginal sex? yes no

If no, go to statement below item 2.

2. Now I would like to ask you about your most recent vaginal sex act, that is the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? **Use visual aid.** yes no

If participant permanently discontinued study product 7 or more days ago, or has been on product hold for the past 7 days, end of form.

If participant is in the vaginal group, go to statement above item 4.

Now I will ask about taking tablets in the **past 7 days** (not including today).

3. In the **past 7 days** (not including today),...

3a. on how many days did you take **no** tablets? # of days

3b. on how many days did you take the **lighter** tablet and not the darker tablet? # of days

3c. on how many days did you take the **darker** tablet and not the lighter tablet? # of days

3d. on how many days did you take **both** tablets? # of days

Now I will ask about inserting gel in the **past 7 days** (not including today).

End of form.

4. In the **past 7 days** (not including today),...

4a. on how many days did you **not** insert gel? # of days

4b. on how many days did you insert gel? # of days

17-MAR-09

0 1
Language

Staff Initials / Date

Monthly Product Adherence and Behavior Assessment (MBA-1)

Purpose: This form is used to collect information about the participant's product use while she is taking part in the study. This is an interviewer-administered form, and it is administered at each monthly visit.

General Information/Instructions:

- **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.

Item-specific Instructions:

- **Items 3–4:** If site permanently discontinued the participant's study product use 4 or more weeks ago, or has held the participant's study drug use for the past 4 weeks, leave items 3–4b blank.
- **Items 3a–3d:** If the participant reports "none" or "never" record "0." The sum of the responses to 3a–3d should equal "7."
- **Items 4a–4b:** If the participant reports "none" or "never" record "0." The sum of the responses to 4a–4b should equal "7."

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (146)



MS-1 (310)

Visit Code

Participant ID

- -
 Site Number Participant Number Chk

Monthly Symptoms

Visit Date

dd MMM yy

Since your last visit, have you experienced any of the following:

	yes	no	don't know	a. If yes, for how many days? number of days	b. Ongoing?	
	yes	no	don't know	number of days	yes	no
1. Fever?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Fatigue?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Sore throat?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Rash?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Headache?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Shortness of breath?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Abdominal pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Nausea?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Vomiting?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Diarrhea?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Excessive intestinal gas?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Increased or decreased urinary output?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Muscle weakness or pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Swelling of the feet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Joint pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Bone pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Bone fracture?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Numbness or tingling in your hands or feet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>

Complete or update an Adverse Experience Log, if applicable.

17-MAR-09

Language

Staff Initials / Date

Monthly Symptoms (MS-1)

Purpose: This is an interviewer-administered form. Each question should be asked as it is written. All information on this form is based on participant self-report.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- The information reported on this form should cover the period from the last time the participant was questioned about these symptoms to the current visit.
- For every “yes” answer, indicate the number of days the symptoms have persisted and whether or not the symptoms are ongoing. Evaluate the participant for each reported symptom.
- If “yes” to any question, update or complete AE Log if applicable.

Item-specific Instructions:

- **For how many days:** If the participant does not recall the exact number of days of the symptoms, she should be asked to provide an approximation.
- **Ongoing:** Ongoing is defined as present during the current visit.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



OPA-1 (210)

Visit Code

Participant ID

- -
 Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

Visit Date

dd MMM yy

Thank you for coming today for the study. Your continued participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential and none of your answers will affect your ability to participate in this research study.

The first few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

1. In the **past 3 months**, have you had vaginal sex? *yes* *no* **▶ If no, go to statement below item 3a.**

The next question is about vaginal sex in the **past 7 days**.

2. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? **▶ If 00, go to item 3.**

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

- 2a. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? **Use visual aid.** **▶ If 00, go to statement below item 3a.**

3. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? **Use visual aid.** *yes* *no* **▶ If no, go to statement below item 3a.**

- 3a. What type of condom was used during the **last act** of vaginal sex that you had? **Use visual aid.** *male condom* *female condom*

If participant permanently discontinued study product 4 or more weeks ago, or has been on a product hold for the past 4 weeks, go to statement above item 18 on page 6.

Oral Product Adherence and Behavior Assessment (OPA-1)

Purpose: This form is used to collect information about the participant's oral product use and possible problems (emotional, physical, social, or other difficulties) experienced while she is taking part in the study. This is an interviewer-administered form, and it is administered at each quarterly visit and at the Product Use End Visit.

General Information/Instructions:

- **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.

Item-specific Instructions:

- **Item 2:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record "00" for this item.
- **Item 2a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record "00" for this item.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



OPA-2 (211)

Visit Code

Participant ID

- -

Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

No data recorded on this page.

I will now ask some questions about taking study tablets. We need to understand how women in the study are taking their tablets. We know that some women take their tablets every day, while others miss some days or stop taking the tablets for some time. Do not worry about telling me if there were times when you were not able to take your tablets every day. I would like to know what is really happening for you.

4. In the **past 4 weeks**, at what time of day did you typically take your tablets (the lighter tablet and the darker tablet)? **Read response categories aloud. Use visual aid.**

morning

afternoon

evening

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

5. In the **past 4 weeks**, how often did you take your tablets at about the same time each day? **Read response categories aloud. Showcard #1**

always *sometimes* *never*

6. Different women have different ways of remembering to take their tablets. In the **past 4 weeks**, what has helped you remember to take your tablets? **Do not read response categories aloud. Mark all that apply.**

6a. nothing —————> **If nothing, go to item 7 on page 3.**

6b. calendar

6c. alarm/bell/cell phone ringer/pager

6d. pill box

6e. husband/primary sex partner

6f. family member or friend

6g. association with a daily activity

6h. association with having sex

6i. association with taking Oral Contraceptives

6j. association with taking other pills or medications

6k. other, specify: *Local* Language: _____ *English:* _____

17-MAR-09

Language

Staff Initials / Date

Oral Product Adherence and Behavior Assessment (OPA-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Items 4–17:** If the site permanently discontinued the participant’s study product use 4 or more weeks ago, or has held the participant’s study product use for the past 4 weeks, leave items 4–17 blank. Mark the “No data recorded on this page” box in the upper-right corner of pages 2–5, then proceed to the statement above item 18 on page 6.
- **Item 4:** Read each response category aloud and mark the participant’s answer. If the participant takes the lighter tablet at a different time of day than the darker tablet, mark the “other, specify” box and provide an explanation on the line provided. Also provide the English translation in the space provided. During the counseling session, counsel the participant on the importance of taking both the lighter and darker tablets together at the same time each day.
- **Item 5:** Read each response category aloud and mark the participant’s answer.
- **Item 6:** Do not read responses 6a–6k aloud. If the participant reports a response other than those listed, mark item 6k and be record the participant’s verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



OPA-3 (212)

Visit Code

Participant ID

- -
 Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

No data recorded on this page.

7. Different circumstances may prevent women from taking their tablets every day. Thinking about your experience in the **past 4 weeks**, please tell me **all** of the reasons that kept you from taking your tablets. **Do not read response categories aloud. Mark all that apply.**

- 7a. not applicable—participant always took both tablets every day → **Go to item 8 on page 4.**
- 7b. participant didn't have the tablets with her
- 7c. participant felt sick/was concerned about getting sick from the tablets
- 7d. participant ran out of or lost the tablets
- 7e. participant got tired of taking the tablets every day
- 7f. participant gave/sold/traded the tablets to someone else
- 7g. participant had a change in her daily routine
- 7h. participant forgot or was too busy
- 7i. participant was on menses
- 7j. participant did not have sex/was not intending to have sex
- 7k. participant had difficulty swallowing the tablets
- 7l. participant didn't like the tablets/taste of the tablets
- 7m. someone else took/stole some of participant's tablets
- 7n. participant's primary sex partner did not approve of her taking the tablets
- 7o. family member or friend did not approve of her taking the tablets
- 7p. other, specify: *Local Language:* _____ *English:* _____

17-MAR-09

Language

Staff Initials / Date

Oral Product Adherence and Behavior Assessment (OPA-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 7:** Do not read responses 7a–7p aloud. If the participant reports a response other than those listed, mark item 7p and record the participant’s verbatim response. Also provide the English translation in the space provided.
- **Item 7p:** If the participant missed taking some tablets due to a product hold/discontinuation, mark the “other, specify” box and record the reason in the space provided. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)

Visit Code

OPA-4 (213)

Participant ID

- -

Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

No data recorded on this page.

8. In the **past 4 weeks**, how often did you take both tablets (the lighter tablet and the darker tablet)? Was it...
Read response categories aloud. Showcard #2

- every day
- usually (most days)
- sometimes (some days)
- rarely (not many days)
- never —————▶ **If never, go to item 10.**

9. In the **past 4 weeks**, what is the longest **number of days** in a row that you did **not** take **both** tablets? # of days

10. Different circumstances may lead women to take **more** than one of each tablet per day. Thinking about your experience taking tablets in the **past 4 weeks**, please tell me **all** of the reasons that led you to take **more than one of either tablet** on any single day. **Do not read response categories aloud. Mark all that apply.**

- 10a. not applicable—never took more than 1 of each tablet per day —————▶ **If not applicable, go to item 13 on page 5.**
- 10b. participant forgot she had taken her tablets already
- 10c. participant did not understand the instructions for taking her tablets
- 10d. participant wanted to have the correct number of tablets in her bottles at her next study visit
- 10e. participant had sex without a condom/had risky sex
- 10f. participant had a new partner
- 10g. participant wanted to make up for not taking tablets on earlier days
- 10h. participant thought it would protect her more
- 10i. participant's husband/primary sex partner asked her to take more tablets
- 10j. participant vomited after taking the tablet
- 10k. other, specify: *Local Language:* _____ *English:* _____

17-MAR-09

Language

Staff Initials / Date

Oral Product Adherence and Behavior Assessment (OPA-4)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 8:** Read each response category aloud and mark the participant's answer.
- **Item 9:** Use leading zeros when needed so that all the boxes are filled. If the participant reports that she took both tablets every day, record "00" for this item.
- **Item 10:** Do not read responses 10a–10k aloud. If the participant reports a response other than those listed, mark item 10k and record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



OPA-5 (214)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

No data recorded on this page.

11. In the **past 4 weeks**, on how many days did you take the **lighter** tablet **more** than once per day? # of days

12. In the **past 4 weeks**, on how many days did you take the **darker** tablet **more** than once per day? # of days

13. Please rate your ability, over the **past 4 weeks**, to take tablets exactly as you were instructed. **Read response categories aloud. Showcard #3**

- very poor
- poor
- fair
- good
- very good
- excellent

Now I will ask about taking tablets in the **past 7 days** (not including today).

14. In the **past 7 days** (not including today),...

14a. on how many days did you take **no** tablets? # of days

14b. on how many days did you take the **lighter** tablet and not the darker tablet? # of days

14c. on how many days did you take the **darker** tablet and not the lighter tablet? # of days

14d. on how many days did you take **both** tablets? # of days

15. In the **past 7 days** (not including today),...

15a. on how many days did you take the **lighter** tablet **more** than once per day? # of days

15b. on how many days did you take the **darker** tablet **more** than once per day? # of days

17-MAR-09

Language

Staff Initials / Date

Oral Product Adherence and Behavior Assessment (OPA-5)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Items 11 and 12:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she did not take either tablet more than once per day, record “00.”
- **Item 13:** Read each response category aloud and mark the participant’s answer.
- **Items 14a–14d:** If the participant reports “none” or “zero,” record “0.” The sum of the responses to 14a–14d should equal “7.”
- **Items 15a–15b:** If the participant reports “none” or “zero,” record “0.”

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)

Visit Code

1

OPA-6 (215)

Participant ID

- -

Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

The next questions are about the **last time** you took the tablets.

16. The **last time** you took the **darker** tablet, was it in the morning, afternoon, or evening?

- morning
- afternoon
- evening

17. The **last time** you took the **lighter** tablet, was it in the morning, afternoon, or evening?

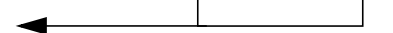
- morning
- afternoon
- evening

For the last set of questions, I will ask you about problems you may have had or are having while in this study. By problem, I mean any emotional, physical, social, or other difficulties.

18. In the **past 3 months**, have you had any problems with the following people as a result of being in this study:

	<i>yes</i>	<i>no</i>	<i>N/A</i>
18a. your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18b. people at home/family?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18c. your friends/personal relationships?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18d. people at work?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18e. people at school?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18f. a nurse or clinician or doctor outside of the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18g. your landlord or property owner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18h. anyone else? If yes, specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Local</i> Language: _____			
<i>English:</i> _____			

If no or N/A to all, end of form.



17-MAR-09

Language

Staff Initials / Date

Oral Product Adherence and Behavior Assessment (OPA-6)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 18:** Read each item 18a–18h aloud and mark the participant’s answer. If “yes” is marked for item 18h, record the participant’s verbatim response. Also provide the English translation in the space provided. If items 18a through 18h are all “no” or “N/A,” end the form. You must mark the “no data recorded on this page” box in the upper right corner of page 7. Also record the Visit Code, PTID, and staff initials and date on page 7 of this form. Leave all other items on page 7 blank. Fax all 7 pages of this form to SCHARP DataFax once the form has been completed.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



OPA-7 (216)

Visit Code

Participant ID

- -
 Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

No data recorded on this page.

19. Has this problem/have any of these problems resulted in:

19a. emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem. *yes* *no*

19b. physical harm to you? For example, has anyone physically hurt you as a result of this problem? *yes* *no*

19c. economic/financial harm to you? For example, has this problem resulted in the loss of your home, property, or ability to earn income? *yes* *no*

19d. physical or other harm to your children? *yes* *no*

20. Please describe the problem, including outcome, if any. **Do not record the participant's verbatim response.**

Local Language: _____

English: _____

End of interview.

Interviewer: Complete items 21–21a after the interview.

21. Did any of the problem(s) require reporting as an Adverse Event (AE)? *yes* *no* **➔ If no, end of form.**

21a. Record AE Log page number(s):

AE Log page # AE Log page # AE Log page #

17-MAR-09

Language

 Staff Initials / Date

Oral Product Adherence and Behavior Assessment (OPA-7)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 20:** Do not record the participant's verbatim response. Instead, listen to the participant's response and probe as necessary. Describe, in the local language, the problem, including all relevant details, and the outcome, if any. Also provide the English translation in the space provided.
- **Items 21 and 21a:** These items are not interviewer-administered. Complete these items after the interview.

SAMPLE: DO NOT FAX
TO DATAFAX



Visit Code

MTN003 VOICE (160)

PTR-1 (144)

Participant ID

- -
Site Number Participant Number Chk

PAP Test Result

Specimen Collection Date

dd MMM yy

Not done/
Not collected

1. PAP SMEAR

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

➔ **Consult protocol and SSP Manual for guidance on study eligibility (if Screening Part 2 Visit) and clinical management.**

Comments: _____

17-MAR-09

Language

Staff Initials / Date

PAP Test Result (PTR-1)

Purpose: This form is used to document results of Pap specimens collected during the Screening Part 2 and Product Use End Visit pelvic exams, and during follow-up when clinically indicated (at sites where Pap smears are the standard of care for women, and where cytopathology and referral services for dysplasia are available).

General Information/Instructions: Record test results on this form as they become available. If a test result recorded on this form indicates that the participant has a condition requiring further evaluation, record the result as a pre-existing condition on the Pre-existing Conditions form (if ongoing at enrollment), or an adverse experience on the Adverse Experience Log (for follow-up visit test result(s) only). Do not use this Pap smear to diagnose STIs, such as trichomoniasis.

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Specimen Collection Date:** Record the date that the specimen was *collected* (NOT the date results were reported or recorded on the form) for this visit. If the required specimen was not collected, record the date specimen collection should have occurred. A complete date is required.
- **Not Done/Not Collected:** Mark *either* the “Not Done/Not Collected” box *or* enter a test result. If the “Not Done/Not Collected” box is marked, please explain in Comments line.

Item-specific Instructions:

- **Item 1:** Record the Pap Smear result. Mark only one box.
 - **negative for intraepithelial lesion or cancer (malignancy):** Includes all normal findings and any findings of infection (trichomonas, candida, etc.), reactive changes/inflammation, glandular changes due to hysterectomy, or atrophic changes.
 - **ASCUS:** Mark this box when abnormal/atypical squamous cells of undetermined significance are reported.
 - **ASC-H:** Mark this box when abnormal/atypical squamous cells that cannot exclude high-grade squamous intraepithelial lesion (HSIL) are reported.
 - **SIL-low grade (LSIL):** Mark this box when low-grade squamous interepithelial lesions are reported. This category includes presence of human papillomavirus (HPV) infection, mild dysplasia, and cervical interepithelial neoplasia (CIN 1).
 - **SIL-high grade (HSIL):** Mark this box when high-grade squamous interepithelial lesions are reported. This category includes the presence of moderate to severe dysplasia, carcinoma in situ (CIS), CIN 2, and CIN 3, or changes suspicious for invasive cancer.
 - **AGC:** Mark this box when atypical/abnormal glandular cells are reported. This category includes endocervical (from cervical canal) atypical cells; endometrial atypical cells; glandular atypical cells.
 - **AGC-favor neoplastic:** Mark this box when atypical/abnormal glandular cells that favor cell growth (neoplastic changes) are reported. This category includes endocervical cells and glandular cells.
 - **cancer:** Mark this box when cancer or adenocarcinoma is reported. This includes endocervical, endometrial, extrauterine, and other (not specified) cancers/adenocarcinomas.

SAMPLE. Do NOT FAX
TO DATAFAX



MTN003 VOICE (160)

PRC-1 (466)

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	

Participant Receipt

Form Completion Date

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

Note: Do not assign a new Participant ID. Record the Participant ID assigned by the original study site.

1. Name of receiving study site: _____

2. Name of transferring study site: _____

3. Date informed consent signed at receiving study site:

dd MMM yy

4. Did participant provide informed consent for specimen storage at receiving study site? **If no, end of form.**

yes no

4a. Date informed consent for specimen storage signed:

dd MMM yy

Comments: _____

17-MAR-09

Language

Staff Initials / Date

Participant Receipt (PRC-1)

Purpose: Complete this form when a transferred participant has provided informed consent at the receiving study clinic/site.

General Information/Instructions: The Participant Receipt form is completed by the receiving site (the site at which the participant will be continuing his or her study visits).

For more information on Participant Transfer and Receipt, refer to the protocol and/or Study-Specific Procedures (SSPs) Manual.

Item-specific instructions:

- **Participant ID: Do not** assign a new Participant ID. Record the Participant ID assigned by the original study site.
- **Item 3:** A complete date is required.
- **Item 4a:** A complete date is required.

SAMPLE *DO NOT FAX*
TO DATAFAX



MTN003 VOICE (160)

PT-1 (465)

Participant ID

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

Participant Transfer

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. Name of transferring study site: _____

2. Name of receiving study site: _____

3. Visit Code of last completed contact with participant: .

4. Date participant records were sent to receiving study site:
dd MMM yy

Comments: _____

17-MAR-09

Language

Staff Initials / Date

Participant Transfer (PT-1)

Purpose: Complete this form when a participant is transferring to another study clinic/site.

General Information/Instructions: The Participant Transfer form is completed by the transferring site (the site that the participant is leaving).

For more information on Participant Transfer and Receipt, refer to the protocol and/or Study-Specific Procedures (SSPs) Manual.

Item-specific instructions:

- **Item 4:** A complete date is required.

SAMPLE: DO NOT FAX TO DATAFAX



MTN003 VOICE (160)

PPA-1 (270)

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	

Perceived Product Assessment

Visit Date

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

Items 1–2 are completed by the site clinician prior to the interview. If participant is in the vaginal group, go to item 2.

1. As you know, none of the study staff know which participants are taking tenofovir tablets, which participants are taking Truvada tablets, and which are taking placebo tablets. We would like you to say which study tablets you think the participant has been taking: tenofovir, Truvada, or placebo?

tenofovir	Truvada	placebo
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If participant completed a Product Use End Visit, go to item 3. If participant did not complete a Product Use End Visit, end of form.

2. As you know, none of the study staff know which participants are inserting tenofovir gel and which are inserting placebo gel. We would like you to say which gel you think the participant has been inserting: tenofovir or placebo?

tenofovir	placebo
<input type="checkbox"/>	<input type="checkbox"/>

If participant completed a Product Use End Visit, go to item 4. If participant did not complete a Product Use End Visit, end of form.

3. As you know, none of the women taking tablets in this study know if they were given tenofovir tablets, Truvada tablets, or placebo tablets. Now that you have finished taking the tablets, I would like you to say which study tablets you think you were taking: tenofovir, Truvada, or placebo?

tenofovir	Truvada	placebo
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

End of form.

4. As you know, none of the women inserting gel in this study know if they were given tenofovir gel or placebo gel. Now that you have finished inserting the gel, I would like you to say which gel you think you were inserting: tenofovir or placebo?

tenofovir	placebo
<input type="checkbox"/>	<input type="checkbox"/>

Perceived Product Assessment (PPA-1)

Purpose: This form is used to collect information about the site clinician’s perception and the participant’s perception of which product the participant was given. This a mixed form. Some items are completed by the site clinician (items 1–2) and some items are interviewer-administered (items 3–4). It is administered only once to each enrolled participant as part of her Product Use End Visit. If the participant did not complete a Product Use End Visit (for example, she is lost to follow up), complete this form when the site has determined that she has permanently discontinued study product use.

General Information/Instructions:

- **Visit Date:** If the participant completes a Product Use End Visit (PUEV), record the date when the PUEV is conducted. If the participant terminates from the study and does not complete a PUEV, record the date when this form is completed.

Item-specific Instructions:

- **Item 3:** This item should be answered by all participants taking tablets during the study. The participant should make her best guess, as there is no option for “don’t know.”
- **Item 4:** This item should be answered by all participants using gel during the study. The participant should make her best guess, as there is no option for “don’t know.”

SAMPLE *DO NOT FAX*
TO DATAFAX



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

Page

MTN 003 VOICE (160)

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

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

MTN003 VOICE (160)



PO-1 (442)

Visit Code

Outcome Number

Participant ID

- -
Site Number Participant Number Chk

Pregnancy Outcome

Outcome unobtainable
➔ 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) C-section vaginal
- 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: _____

4a1. Method:

If full term live birth, go to item 6 on page 2. If C-section was due to or resulted in maternal complications, report complications on AE Log and EAE Reporting form, if applicable.

Refer to the protocol for AE and EAE reporting requirements. Complete AE Log and 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 and History form that is completed for a participant.

Item-specific Instructions:

- **Visit Code:** Record the visit code of the participant's corresponding Pregnancy Report and History 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 4a1:** The C-section itself is not an Adverse Experience. If the C-section is performed due to or resulting from maternal complication(s), report each complication as an AE on an AE Log, if the onset date is prior to termination. If a maternal complication AE meets the requirements for EAE reporting, complete an EAE Reporting form.
- **Items 4c, 4d, and 4e:** Refer to the protocol and Study-Specific Procedures (SSP) Manual for EAE and AE reporting requirements for pregnancy losses.
- **Item 4f:** If the outcome is therapeutic/elective abortion, the abortion itself is not an Adverse Experience. If the abortion is performed due to a maternal pregnancy complication, the pregnancy complication should be reported on an Adverse Experience (AE) Log, if prior to termination, with "procedure/surgery" marked under "Treatment."
- **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

MTN003 VOICE (160)



PO-2 (443)

Visit Code [][] . []

Outcome Number []

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 item 7.

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: _____

7. Infant gender: male female unknown

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

9. Infant gestational age by examination: [][] [] weeks days 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] 17-MAR-09

[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:** 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



Visit Code [][] . []

1

MTN003 VOICE (160)

PR-1 (440)

Participant ID

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

Pregnancy Report and History

PREGNANCY REPORT

1. First day of last menstrual period: dd MMM yy
2. Estimated date of delivery: dd MMM yy
3. What information was used to estimate the date of delivery?
3a. last menstrual period
3b. initial ultrasound < 20 weeks
3c. initial ultrasound >= 20 weeks
3d. physical examination
3e. conception date by assisted reproduction
3f. other, specify:

PREGNANCY HISTORY

4. Has the participant ever been pregnant before? yes no
4a. Is this the participant's first pregnancy since enrollment in this study? yes no
4b. Number of full term live births (>= 37 weeks):
4c. Number of premature live births (< 37 weeks):
4d. Number of spontaneous fetal deaths and/or still births (>= 20 weeks):
4e. Number of spontaneous abortions (< 20 weeks):
4f. Number of therapeutic/elective abortions:
4g. Number of ectopic pregnancies:
5. Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies? yes no
5a. If yes, specify:

Comments: _____

[] [] [] [x] 17-MAR-09

0 1

Language

Staff Initials / Date

Pregnancy Report and History (PR-1)

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

General Information/Instructions: A Pregnancy Report and History form is required for each new pregnancy that the participant experiences during the study.

- **Visit Code:** 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.
- **Item 3d:** Physical examination includes fundal height, uterine size by pelvic exam, and/or fetal heart rate.
- **Item 5:** Include information on pregnancy complications and fetal/infant congenital anomalies experienced prior to enrolling in the study as well as any conditions experienced/reported during the study.

SAMPLE: DO NOT FAX TO DATAFAX



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

Page

MTN003 VOICE (160)

PH-1 (410)

Participant ID

- -

Site Number Participant Number Chk

Product Hold/Discontinuation Log

1. Date and visit code when study product hold was initiated:

 .

dd *MMM* *yy* **Visit Code**

2. Why is study product being held?

- pregnancy
- breastfeeding
- HIV positive result
- creatinine clearance < 50 mL/min
- Hepatitis B infection
- other adverse experience
- other, specify: _____

AE Log page #

3. Date of last study product use:

dd *MMM* *yy*

4. Was the participant instructed to resume study product 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 product use if not being held for another reason.

4a. Date and visit code when participant was instructed to resume or permanently discontinue study product use:

 .

dd *MMM* *yy* **Visit Code**

Comments: _____

Product Hold/Discontinuation Log (PH-1)

Purpose: This form is used to document temporary holds and early permanent discontinuations of study product use.

General Information/Instructions: This form is completed each time a participant is instructed to temporarily stop (hold) or permanently discontinue study product use prior to her expected Product Use End 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 1–3 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. Do not renumber any Product Hold/Discontinuation Log pages after faxing, unless instructed by SCHARP.
- **Item 2:** Mark the box to the left of the reason why the participant is being instructed to hold or permanently discontinue study product use. If product is being held or discontinued due to an adverse experience, record the page number of the AE Log documenting the product hold or permanent discontinuation. If the product hold/discontinuation is due to a reason other than the ones listed, mark “other, specify” box and record the reason for the hold/discontinuation on the line provided.
- **Item 3:** Record the date the participant last used study product. Use a best estimate if the actual date cannot be determined.
- **Item 4:** Complete this item once study staff have determined that the participant can resume study product use or have determined that she is permanently discontinued from study product use. Mark this item “yes” if study staff instructed the participant that she can resume use of study product. If the participant was permanently discontinued from study product use, mark the “no (permanently discontinued)” box. If the reason for the product hold, as recorded in item 2, has resolved but there is a concurrent reason (e.g., pregnancy) for continuing the product hold, mark “no (hold continuing for another reason).”
- **Item 4a:** Record the date and visit code on which the participant was told by a study staff member that she could resume or that she should permanently discontinue study product use. 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 study product use based on resolution of the reason marked in item 2 of the form.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



PRD-1 (080)

Visit Code

1

Participant ID

- -
Site Number Participant Number Chk

Product Returns and Dispensations

Visit Date

dd MMM yy

RETURNED

1. Did the participant return any **unused** study product at this visit?

yes no **If no, go to item 2.**

1a. Number of **unused applicators** of study gel returned:

unused applicators OR ^{N/A}

1b. Number of **TDF or placebo tablets** returned:

tablets OR ^{N/A}

1c. Number of **FTC/TDF or placebo tablets** returned:

tablets OR ^{N/A}

1d. Date study product was returned:

dd MMM yy

DISPENSED

2. Was any study product dispensed to the participant at this visit?

yes no **If no, go to item 3.**

2a. Number of **applicators** of study gel dispensed:

applicators OR ^{N/A}

2b. Number of **TDF or placebo tablets** dispensed:

tablets OR ^{N/A}

2c. Number of **FTC/TDF or placebo tablets** dispensed:

tablets OR ^{N/A}

2d. Date study product was dispensed:

dd MMM yy

RE-ISSUED

3. Was any study product re-issued to the participant at this visit?

yes no **If no, end of form.**

3a. Number of **applicators** of study gel re-issued:

applicators OR ^{N/A}

3b. Number of **TDF or placebo tablets** re-issued:

tablets OR ^{N/A}

3c. Number of **FTC/TDF or placebo tablets** re-issued:

tablets OR ^{N/A}

3d. Date study product was re-issued:

dd MMM yy

Product Returns and Dispensations (PRD-1)

Purpose: This form is used to document when study product is returned, dispensed, and/or re-issued during the study.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 1a:** Record the number of **unused** study gel applicators the participant returned at this visit only, as determined by site pharmacy staff. Mark the “N/A” box if the participant was randomized to the oral group.
- **Item 1b:** Record the number of **TDF or placebo study tablets** the participant returned at this visit only, as determined by site pharmacy staff. Mark the “N/A” box if the participant was randomized to the vaginal group.
- **Item 1c:** Record the number of **FTC/TDF or placebo study tablets** the participant returned at this visit only, as determined by site pharmacy staff. Mark the “N/A” box if the participant was randomized to the vaginal group.
- **Item 2a:** Record the number of newly dispensed **applicators** of study gel given to the participant at this visit. This will be the same amount documented on the **Participant-specific Pharmacy Dispensing Record**. Mark the “N/A” box if the participant was randomized to the oral group.
- **Item 2b:** Record the number of newly dispensed **TDF or placebo study tablets** given to the participant at this visit. This will be the same amount documented on the **Participant-specific Pharmacy Dispensing Record**. Mark the “N/A” box if the participant was randomized to the vaginal group.
- **Item 2c:** Record the number of newly dispensed **FTC/TDF or placebo study tablets** given to the participant at this visit. This will be the same amount documented on the **Participant-specific Pharmacy Dispensing Record**. Mark the “N/A” box if the participant was randomized to the vaginal group.
- **Item 3a:** Record the number of **applicators** of study gel returned by and given back to the participant at this visit. Mark the “N/A” box if the participant was randomized to the oral group.
- **Item 3b:** Record the number of **TDF or placebo study tablets** returned by and given back to the participant at this visit. Mark the “N/A” box if the participant was randomized to the vaginal group.
- **Item 3c:** Record the number of **FTC/TDF or placebo study tablets** returned by and given back to the participant at this visit. Mark the “N/A” box if the participant was randomized to the vaginal group.

Product Use End Visit (PEV-1)

Purpose: This form is used to document the required Product Use End Visit. It is administered only once to each enrolled participant as part of her Product Use End Visit. If the participant did not complete a Product Use End Visit (for example, she is lost to follow up), complete this form when it is determined that she has permanently discontinued study product use.

General Information/Instructions:

- **Visit Date:** If the participant completes a Product Use End Visit (PUEV), record the date when the PUEV is conducted. If the participant does not complete a PUEV, record the date when this form is completed.

Item-specific Instructions:

- **Item 1a:** Record the visit code assigned to the follow-up month when the Product Use End Visit is completed. For example, if the PUEV is completed at Month 33, record the Month 33 visit code (36.0). Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Item 1b:** This item is completed only for those participants who do not complete a PUEV. It is used to capture the date when **site staff** permanently discontinue a participant from study product use (either because of a safety reason, as documented on a Product Hold/Discontinuation Log, or because the participant has completed her expected study product use period). If site staff permanently discontinue study product use early due to a safety reason, record the date in item 4a of the Product Hold/Discontinuation Log documenting the permanent discontinuation. For all other participants, record the target date of the month in follow-up (Month 33, for example) when the participant was expected to complete the PUEV.

Safety Laboratory Results (SL-1)

Purpose: This form is used to document local safety laboratory results of specimens collected during screening, enrollment, and 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** collected specimens are recorded on the form.

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

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. 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* (NOT the date results were reported or recorded on the form) for this visit. Record a complete date.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen is collected after the Initial Specimen Collection Date for this same visit. Record a complete date.
- **Not Done/Not Collected:** For the hemogram and differential, mark *either* the “Not done/Not collected” box *or* enter a test result. If the “Not Done/Not Collected” box is marked, record reason on the Comments line.
- **Not reported:** If a hemogram or differential was done but a given result was not reported, mark the “Not reported” box.

Results Reporting:

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

Severity Grade:

- If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results.
- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).
- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
 - Treat all missing digits in the lab value as zeros.
 - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
- There may be situations in which a lab value falls within a site’s lab normal ranges and also within a gradable range per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table*.

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

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

Item-specific Instructions:

- Item 2a: Neutrophils must be recorded as both a percentage and absolute count.

Version 1.0, 17-MAR-09

/networks/hivnet/forms/MTN_003/forms/m003_safety_lab.fm

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [][] . []

1

MTN003 VOICE (160)

SL-2 (152)

Participant ID

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

Safety Laboratory Results

3. BLOOD CHEMISTRIES

Not done/ Not collected	Alternate Collection Date				U/L	Severity Grade If applicable	AE Log Page #	Not reportable as an AE
	dd	MMM	yy					
<input type="checkbox"/>	[][]	[][][]	[][]	3a. AST (SGOT)	[][][][]	<input type="checkbox"/>	[][][]	OR <input type="checkbox"/>
<input type="checkbox"/>	[][]	[][][]	[][]	3b. ALT (SGPT)	[][][][]	<input type="checkbox"/>	[][][]	OR <input type="checkbox"/>

<input type="checkbox"/>	[][]	[][][]	[][]	3c. Creatinine	[][] . []	<input type="checkbox"/>	[][][]	OR <input type="checkbox"/>
				3c1. Calculated creatinine clearance	[][][]			

Not done/ Not collected	Alternate Collection Date				mg/dL	Severity Grade If applicable	AE Log Page #	Not reportable as an AE
	dd	MMM	yy					
<input type="checkbox"/>	[][]	[][][]	[][]	3d. Weight	[][][]	kg		
<input type="checkbox"/>	[][]	[][][]	[][]	3e. Phosphorus (Phosphate)	[][] . []	<input type="checkbox"/>	[][][]	OR <input type="checkbox"/>

Not done/ Not collected	Alternate Collection Date			4. URINE TESTS				Severity Grade If applicable	AE Log Page #	Not reportable as an AE		
	dd	MMM	yy	negative	trace	1+	2+	3+	4+			
<input type="checkbox"/>	[][]	[][][]	[][]	4a. Protein	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	[][][]	OR <input type="checkbox"/>
<input type="checkbox"/>	[][]	[][][]	[][]	4b. Glucose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	[][][]	OR <input type="checkbox"/>

<input type="checkbox"/>	4c. Leukocyte esterase (LE)		<input type="checkbox"/>	negative	<input type="checkbox"/>	positive				
<input type="checkbox"/>	4d. Nitrites		<input type="checkbox"/>		<input type="checkbox"/>					

Comments: _____

[][][] [x] 17-MAR-09

01

Language

Staff Initials / Date

Safety Laboratory Results (SL-2)

Item-specific Instructions:

- **Item 3c1:** When calculating the participant's creatinine clearance, use the age and weight of the participant at the time the blood specimen is drawn. If the participant was not weighed at the visit when the blood specimen was drawn, but was weighed at a previous visit (within the allowable window for creatinine clearance per the SSP Manual), record the weight from the previous visit. Also, record in the "Alternative Collection Date" boxes the date of the previous visit when the participant was weighed. If the participant has a creatinine value but cannot have her creatinine clearance calculated (due to missing weight data), line through the response boxes and initial and date.
- **Item 4:** If a dipstick urinalysis was done but a given result was not reported, mark the "Not done" box.
- **Item 4b:** Grade the severity of the urine glucose value according to the "Proteinuria, random collection" row of the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*.
- **Items 4c–4d:** If the result is negative or trace, mark the "negative" box. If the result is 1+ or greater, mark the "positive" box.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



SEH-1 (034)

Visit Code

1

Participant ID

- -
Site Number Participant Number Chk

Screening and Enrollment HIV Test Results

Specimen Collection Date

dd MMM yy

1. HIV TEST RESULTS

	<i>kit</i>	<i>negative</i>	<i>positive</i>
1a. Rapid test 1	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
1b. Rapid test 2	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>

If positive for both, participant is ineligible. End of form. If discordant, notify Network Lab and perform Western blot.

Not done

	<i>negative</i>	<i>positive</i>	<i>indeterminate</i>
1c. HIV Western Blot	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If positive, participant is ineligible.

If indeterminate, participant is ineligible at this time. Repeat testing in approximately one month. Notify Network Lab.

Comments: _____

Screening and Enrollment HIV Test Results (SEH-1)

Purpose: This form is used to document local laboratory HIV test results of blood collected during the Screening and Enrollment Visits.

General Information/Instructions: 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.

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

Note: If a participant is being re-screened, a new Screening and Enrollment HIV Test Results form must be completed as part of the subsequent screening attempt. See the Study-Specific Procedures (SSP) Manual for more instructions regarding form completion and transmission procedures.

- **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.
- **Specimen Collection Date:** Record the date the specimen was *collected* (NOT the date results were reported or recorded on the form) for this visit. Record a complete date.

Item-specific Instructions:

- **Items 1a and 1b:** Record the assigned two-digit rapid test kit code. As of March, 2008, the rapid test kit codes are as follows. **Note:** *More test kit codes may be added to the list below as the study proceeds.*

Rapid Test	Kit Code
Abbott Determine	01
OraSure OraQuick	02
Uni-Gold Recombigen	03

- **Item 1c:** Mark *either* the “Not done” box *or* enter the test result.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

1

MTN003 VOICE (160)

SPE-1 (041)

Participant ID

--
Site Number Participant Number Chk

Screening and Enrollment Pelvic Exam

Exam Date

dd MMM yy

1. Pelvic exam assessments:

abnormal findings no abnormal findings

If no abnormal findings, go to item 3.

1a. Abnormal 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: _____ |
| | <input type="checkbox"/> Cervical friability | |

Record abnormal findings observed on Pre-existing Conditions form, if applicable.

2. Are any of these exam findings a severity Grade 2 or higher?.....

yes no

If yes, participant is ineligible at this time.

3. Cervical Ectopy: Percentage of cervical surface area.

0% 1-25% 26-50% 51-75% > 75% N/A

4. Weight:

kg **OR** not done

5. First day of last menstrual period:

dd MMM yy

6. Last day of last menstrual period:

dd MMM yy

Comments: _____

17-MAR-09

01
Language

Staff Initials / Date

Screening and Enrollment Pelvic Exam (SPE-1)

Purpose: This form, along with the non-DataFax Pelvic Exam Diagrams, is used to document the pelvic exam conducted during the Screening Part 2 Visit and the Enrollment Visit, if applicable. This form should be completed once for each participant to document the Screening Part 2 pelvic exam. If a pelvic exam is conducted as part of the Enrollment Visit, complete a new form to document the enrollment pelvic exam.

General Information/Instructions: This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment Visit.

Note: For each enrolled participant, only one Screening and Enrollment Pelvic Exam form for the Screening Part 2 Visit (assigned visit code 02.0) should be faxed to SCHARP DataFax. There may be cases where multiple screening pelvic exams are conducted as part of the SAME screening attempt (e.g., in cases where an otherwise eligible participant has a symptomatic STI at the initial screening pelvic exam that requires a second screening pelvic exam (prior to enrollment) within the 56-day window for screening). In such cases, use this form to document the initial screening pelvic exam only, and document the second screening exam in the chart notes only. A new Screening and Enrollment Pelvic Exam form should be completed for the Screening Part 2 Visit **only** if the participant re-screens for the study. If a participant does screen more than once for the study (i.e., has multiple screening attempts), and eventually enrolls in the study, only the Screening and Enrollment Pelvic Exam form from the successful screening attempt that led to enrollment should be faxed to SCHARP.

Item-specific Instructions:

- **Item 1:** If a pelvic exam is conducted at the Enrollment Visit, complete a new Screening and Enrollment Pelvic Exam form (assigned visit code 03.0) to document the enrollment exam.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding on the line provided.
- **Item 3:** Mark the “N/A” box if the participant does not have an intact cervix.
- **Item 4:** Participant weight is required at the Screening Part 2 Visit. Transcribe the participant’s weight from the non-DataFax Physical Exam form or other applicable source documentation. Remember to use leading zeros when needed and round to the nearest whole number. If participant weight was required but not done, mark the “not done” box and specify the reason on the Comments line.
- **Items 5–6:** Complete these items based on source documentation recorded in the participant’s Baseline Medical and Menstrual History.

SAMPLE: DO NOT FAX TO DATAFAX



MTN003 VOICE (160)

SC-1 (005)

Participant ID

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

Site Number Participant Number Chk

Screening Consent

Visit Date

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

dd *MMM* *yy*

1. Is the participant between the ages of 18 and 40 years old, as verified per site SOPs? yes no
If no, participant is ineligible. End of form.

2. Is the participant within the site local age range for study eligibility, per site SOPs? yes no
If no, participant is ineligible. End of form.

3. Was the participant willing and able to provide written informed consent for screening? yes no
If no, participant is ineligible. End of form.

- 3a. When was the informed consent form for screening marked or signed?

--	--

--	--	--

--	--

dd *MMM* *yy*

Comments: _____

Screening Consent (SC-1)

Purpose: This form is used to document that a participant provided written informed consent for screening for this study. This form must be completed for each participant who is assigned an MTN 003 Participant ID.

General Information/Instructions: This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment visit.

Note: There is no visit code field on this form, since this form is only completed at the Screening Part 1 Visit. If a participant is being re-screened, a new Screening Consent 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:** Per protocol, a participant must be between the ages of 18 and 40 (inclusive) *at the time of screening* as verified according to site standard operating procedures (SOPs). Participants who are under 18 years or over 40 years of age should not be screened for the study.
- **Item 3a:** If the participant marks the informed consent form using her thumbprint, record the date the thumbprint was made.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



SCR-1 (147)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Seroconverter Laboratory Test Results

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

Not done/
Not collected

dd MMM yy

1. T CELL SUBSETS

Unable to analyze

1a. Absolute CD4+ OR
cells/mm³

not available

1a1. CD4+ % OR . %

Alternate Collection Date

Not done/
Not collected

dd MMM yy

2. HIV RNA

viral copies/mL

2a. HIV RNA PCR
> = <

2b. HIV RNA PCR kit lower limit of detection:

50 400 OR
viral copies/mL

Comments: _____

17-MAR-09

Language

Staff Initials / Date

Seroconverter Laboratory Test Results (SCR-1)

Purpose: This form is used to document CD4+ and HIV RNA test results obtained during the study.

General Information/Instructions: Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax when results for all collected specimens are available and recorded.

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. 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* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected on a different day than the Initial Specimen 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.
- **Not done/Not collected:** For every test, mark *either* the “Not done/Not collected” box *or* enter a test result. If the “Not done/Not collected” box is marked, record reason on the Comments lines.

Item-specific Instructions:

- **Item 1a1:** If automatically calculated, record the CD4+ percentage that was reported for the specimen in item 1a. If the CD4+ percentage is not available (was not reported and would have to be manually calculated), mark the “not available” box.
- **Item 2:** Note that the “>” symbol is “greater than” and the “<” symbol is “less than.”
- **Item 2a:** Record the participant’s HIV RNA PCR result exactly as it appears on the lab report source documentation, regardless of whether the result is more or less than the limit of detection for the assay. For example, if a participant is tested with an assay that has 400 viral copies/mL as the lower limit of detection, and the lab reports her result as “238 viral copies/mL,” mark the “=” box and record “00000238” viral copies/mL for item 2a.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

1

MTN003 VOICE (160)

SS-1 (161)

Participant ID

--
Site Number Participant Number Chk

Specimen Storage/PK

dd MMM yy

SPECIMEN STORAGE

Alternate Collection Date
dd MMM yy

		<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	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"/> <input type="text"/>	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"/> <input type="text"/>	3. Vaginal swab for biomarker analyses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____

Alternate Collection Date
dd MMM yy

	3a. Was blood visible on the swab?		<i>yes</i>	<i>no</i>	<i>N/A</i>
		<input type="checkbox"/>	<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"/> <input type="text"/>	4. Endocervical swab for biomarker analyses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
	4a. Was blood visible on the swab?		<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
dd MMM yy

5. Height cm *not done*

At Screening Part 2 or Enrollment Visit, end of form.

PK INFORMATION

	dd	MMM	yy	24-hour clock		
				hr	min	N/A
6. Date and time of last study gel insertion:	<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"/>	OR <input type="checkbox"/>
7. Date and time of last dose of darker tablet:	<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"/>	OR <input type="checkbox"/>
8. Date and time of last dose of lighter tablet:	<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"/>	OR <input type="checkbox"/>

If N/A to all, end of form.

9. Is the time of the last dose/insertion a best estimate, or did the participant provide source documentation?

best estimate *source documentation*

Comments: _____

17-MAR-09

01

Language Staff Initials / Date

Specimen Storage/PK (SS-1)

Purpose: This form is used to document collection and storage of MTN 003 specimens that will be tested at a lab other than the local site laboratory.

General Information/Instructions: Check the information on this form against the MTN 003 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. If this visit is the Study Exit Visit, record visit code 89.0. 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 Specimen 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 1–4:** If the specimen is not required to be collected and stored at this visit, mark “not required.” If the specimen is required to be stored, but for some reason it is not stored at this visit, mark “not stored” and record the reason why on the line provided.
- **Item 3a:** Mark the “N/A” box if a vaginal swab was not collected at this visit.
- **Item 4a:** Mark the “N/A” box if an endocervical swab was not collected at this visit.
- **Item 5:** Participant height may be transcribed from the Physical Exam (non-DataFax) form, if completed for this visit. Participant height is required at the Screening Part 2, semi-annual, annual, and Product Use End Visits.
- **Items 6–8:** Documentation of the date and time of last dose is required at each quarterly visit and the Product Use End Visit.
 - **Item 6:** Mark the “N/A” box if the participant is in the oral group or if the participant is in the vaginal group and has not yet used study gel.
 - **Items 7 and 8:** Mark the “N/A” box if the participant is in the vaginal group or if the participant is in the oral group and has not yet taken the study tablets. The “darker tablet” refers to Truvada or placebo, and the “lighter tablet” refers to tenofovir or placebo.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

MTN003 VOICE (160)

SLR-1 (131)

Participant ID

- -
Site Number Participant Number Chk

STI Laboratory Results

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

Not done/ Not collected dd MMM yy

1. STI SEROLOGY

1a. Syphilis RPR screening test non-reactive reactive
If non-reactive, go to item 2. ←

1a1. Syphilis titer 1:

1b. Syphilis confirmatory test negative positive indeterminate (MHA-TP or TPHA)

If positive, provide treatment and document treatment on Concomitant Medications Log if applicable. If positive at Screening, participant must complete treatment and be asymptomatic to enroll. If positive during follow-up, complete Adverse Experience Log.

2. OTHER STI TESTS

Not done/ Not collected dd MMM yy

2a. *N. gonorrhoea* negative positive
2b. *C. trachomatis*

If positive, provide treatment and document treatment on Concomitant Medications Log if applicable. If positive at Screening, participant must complete treatment and be asymptomatic to enroll. If positive during follow-up, complete Adverse Experience Log.

Not done/ Not collected dd MMM yy

2c. Hepatitis B Surface Antigen non-reactive reactive
2d. Hepatitis B Surface Antibody

Offer participant HBV vaccination unless contraindicated. Refer to protocol Appendix IV.

If reactive at Screening, participant is ineligible. If reactive during follow-up, complete Product Hold/ Discontinuation Log and Adverse Experience Log.

Comments: _____

17-MAR-09

Language

Staff Initials / Date

STI Laboratory Results (SLR-1)

Purpose: This form is used to document local STI laboratory results of specimens collected during screening and 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** collected specimens are recorded on the form.

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

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. 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* (NOT the date results were reported or recorded on the form) for this visit. Record a complete date.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen is collected after the Initial Specimen Collection Date for this same visit. Record a complete date.
- **Not Done/Not Collected:** For every test, mark *either* the “Not done/Not collected” box *or* enter a test result. If the “Not done/Not collected” box is marked, record reason on the Comments line.

Item-specific Instructions:

- **Item 1a:** If the syphilis screening test is reactive, items 1a1 and 1b must be completed.
- **Item 1a1:** Use leading zeros when recording a syphilis titer level. For example, a titer level of 1:20 would be recorded on the form as “1:0020.”
- **Items 1b, 2a–2b:** If a result is positive at any time during the study (screening through study exit), provide treatment according to WHO guidelines. If a result is positive at screening, the participant must complete treatment(s) and be asymptomatic in order to be eligible for enrollment. If a result is positive during study follow-up, report the relevant infection(s) as adverse experience(s) on the Adverse Experience Log.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



SBA-1 (260)

Visit Code 89.0

1

Participant ID

Site Number - Participant Number - Chk

Visit Date

dd MMM yy

Study Exit Behavior Assessment

Thank you for coming today for the study. Your participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential.

The first few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

1. In the past 2 months, have you had vaginal sex? ... yes no [] [] If no, go to statement above item 4 on page 2.

The next question is about vaginal sex in the past 7 days.

2. In the past 7 days (not including today), how many acts of vaginal sex did you have? ... # of acts [] [] If 00, go to item 3.

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

2a. In the past 7 days (not including today), during how many acts of vaginal sex was a male or female condom used? Use visual aid. ... # of acts with condom [] [] If 00, go to statement above item 4 on page 2.

3. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the last act of vaginal sex that you had, was a male or female condom used? Use visual aid. ... yes no [] [] If no, go to statement above item 4 on page 2.

3a. What type of condom was used during the last act of vaginal sex that you had? Use visual aid. ... male condom female condom [] []

Study Exit Behavior Assessment (SBA-1)

Purpose: This form is used to collect information about the participant's sexual behavior and possible problems (emotional, physical, social, or other difficulties) experienced while she took part in the study. This is an interviewer-administered form, and it is administered only once to each enrolled participant as part of her Study Exit Visit.

Item-specific Instructions:

- **Item 2:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record "00" for this item.
- **Item 2a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record "00" for this item.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

8	9	0
---	---	---

1

MTN003 VOICE (160)

SBA-2 (261)

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		

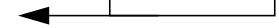
Study Exit Behavior Assessment

For the last set of questions, I will ask you about problems you may have had or are having while in this study. By problem, I mean any emotional, physical, social, or other difficulties.

4. In the **past 2 months**, have you had any problems with the following people as a result of being in this study:

	<i>yes</i>	<i>no</i>	<i>N/A</i>
4a. your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4b. people at home/family?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4c. your friends/personal relationships?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4d. people at work?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4e. people at school?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4f. a nurse or clinician or doctor outside of the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4g. your landlord or property owner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4h. anyone else? If yes, specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Local</i> Language: _____ <i>English:</i> _____			

If no or N/A to all, end of form.



Study Exit Behavior Assessment (SBA-2)

Item-specific Instructions:

- **Item 4:** Read each item 4a–4h aloud and mark the participant’s answer. If “yes” is marked for item 4h, record the participant’s verbatim response. Also provide the English translation in the space provided. If items 4a through 4h are all “no” or “N/A,” end the form. Mark the “No data recorded on this page” box in the upper right corner of page 3. Also record the Visit Code, PTID, and staff initials and date on page 3 of this form. Leave all other items on page 3 blank. Fax all 3 pages of this form to SCHARP DataFax once the form has been completed.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code 8 9 . 0

1

MTN003 VOICE (160)

SBA-3 (262)

Participant ID

Site Number - Participant Number - Chk

Study Exit Behavior Assessment

No data recorded on this page.

5. Has this problem/have any of these problems resulted in:

- 5a. emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem.
5b. physical harm to you? For example, has anyone physically hurt you as a result of this problem?
5c. economic/financial harm to you? For example, has this problem resulted in the loss of your home, property, or ability to earn income?
5d. physical or other harm to your children?

6. Please describe the problem, including outcome, if any. Do not record the participant's verbatim response.

Local Language:
English:

End of interview.

Interviewer: Complete items 7-7a after the interview.

7. Did any of the problem(s) require reporting as an Adverse Event (AE)?

7a. Record AE Log page number(s):

AE Log page # AE Log page # AE Log page #

Study Exit Behavior Assessment (SBA-3)

Item-specific Instructions:

- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 6:** Do not record the participant's verbatim response; describe the problem and outcome, if any, in the local language. Also provide the English translation in the space provided.
- **Items 7 and 7a:** These items are not interviewer-administered. Complete these items after the interview.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)

SEV-1 (221) Visit Code

8 9 0

1

Participant ID

Site Number Participant Number Chk

Study Exit Visit

Visit Date

dd MMM yy

1. Was the Study Exit Visit conducted? yes no

1a. Specify the reason the visit was not conducted: End of form.

2. hCG for pregnancy: negative positive not done
2a. Specify the reason the pregnancy test was not done: If negative or positive, go to item 3. If newly positive, complete Pregnancy Report and History form.

3. Were any new adverse experiences reported at this visit? yes no If no, go to item 4.

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

4. Did the participant complete the ACASI Follow-up Questionnaire at this visit? yes no If no, specify reason in Comments. Go to item 5.

4a. Date ACASI Follow-up Questionnaire was completed: dd MMM yy

5. Did the participant receive a Hepatitis B vaccination (initial or follow-up) at this visit? yes no, vaccination not indicated no, participant refused If yes, record the vaccination on the Concomitant Medications Log. If no, vaccination not indicated or no, participant refused, end of form.

5a. Which dose did she receive at this visit? 0 (initial dose) 1-2 months 4-6 months

Comments:

Study Exit Visit (SEV-1)

Purpose: This form is used to document the required Study Exit/Termination Visit. It is completed once for each study participant at either the scheduled Study Exit Visit or when it is determined that the participant is no longer participating in the study.

General Information/Instructions:

- **Visit Date:** If the participant completes a Study Exit Visit, record the date when the Study Exit Visit is conducted (regardless of whether the Study Exit Visit occurs prior to, on, or after the month when the participant is expected to terminate from the study). If the participant does not complete a Study Exit Visit, record the date when this form is completed.

Item-specific Instructions:

- **Item 1:** If the participant did not complete a Study Exit Visit (e.g., due to loss to follow-up), mark the “no” box and complete item 1a.
- **Item 2:** Pregnancy testing is required at the Study Exit/Termination Visit. Record the hCG urine pregnancy test result. If a urine pregnancy test result is not available (specimen not collected and/or test not done), mark the “not done” box and complete item 2a. *Note: A Pregnancy Report and History form must be completed for each new pregnancy.*
- **Item 3:** Mark the “yes” box if a new (previously unreported) AE is reported or observed at this visit. If the box is marked “yes,” record in **item 3a** how many **new** AE Log pages were completed for this visit. For example, if two new AEs were reported, record “02.” Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
- **Item 4:** Completion of the ACASI Follow-up Questionnaire is required at the Study Exit/Termination Visit. If the questionnaire was not done, mark the “no” box and record reason on the Comments lines.
- **Item 5:** If a Hepatitis B vaccination was indicated per protocol but not offered, line through the response box, initial and date. Record reason on the Comments lines. If the participant has already completed the series, or is between shots at this visit, mark the “no, vaccination not indicated” box.

SAMPLE *DO NOT FAX*
TO DATAFAX



MTN003 VOICE (160)

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 _____ cause unknown

Complete or update Adverse Experience Log. Complete EAE Reporting form.

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: _____

17-MAR-09

Language

Staff Initials / Date

Termination (TM-1)

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

Item-specific Instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



VPA-1 (230)

Visit Code

1

Participant ID

- -
Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

Visit Date

dd MMM yy

Thank you for coming today for the study. Your continued participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential and none of your answers will affect your ability to participate in this research study.

The first few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

1. In the **past 3 months**, have you had vaginal sex? *yes* *no* **▶ If no, go to statement below item 3a.**

The next question is about vaginal sex in the **past 7 days**.

2. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? **▶ If 00, go to item 3.**

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

- 2a. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? **Use visual aid.** **▶ If 00, go to statement below item 3a.**

3. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? **Use visual aid.** *yes* *no* **▶ If no, go to statement below item 3a.**

- 3a. What type of condom was used during the **last act** of vaginal sex that you had? **Use visual aid.** *male condom* *female condom*

If participant permanently discontinued study product 4 or more weeks ago, or has been on a product hold for the past 4 weeks, go to statement above item 15 on page 6.

Vaginal Product Adherence and Behavior Assessment (VPA-1)

Purpose: This form is used to collect information about the participant's vaginal product use and possible problems (emotional, physical, social, or other difficulties) experienced while she is taking part in the study. This is an interviewer-administered form, and it is administered at each quarterly visit and at the Product Use End Visit.

General Information/Instructions:

- **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.

Item-specific Instructions:

- **Item 2:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record "00" for this item.
- **Item 2a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record "00" for this item.

Vaginal Product Adherence and Behavior Assessment (VPA-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Items 4–14:** If the site permanently discontinued the participant’s study product use 4 or more weeks ago, or has held the participant’s study product use for the past 4 weeks, leave items 4–14 blank. Mark the “No data recorded on this page” box in the upper-right corner of pages 2–5, then proceed to the statement above item 15 on page 6.
- **Item 4:** Read each response category aloud and mark the participant’s answer.
- **Item 5:** Read each response category aloud and mark the participant’s answer.
- **Item 6:** Do not read responses 6a–6j aloud. If the participant reports a response other than those listed, mark item 6j and record the participant’s verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

MTN003 VOICE (160)

VPA-3 (232)

Participant ID

- -
 Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

No data recorded on this page.

7. Different circumstances may prevent women from inserting their gel every day. Thinking about your experience in the **past 4 weeks**, please tell me **all** of the reasons that kept you from inserting your gel. **Do not read response categories aloud. Mark all that apply.**

- 7a. not applicable—participant inserted gel every day → **Go to item 8 on page 4.**
- 7b. participant didn't have the gel with her
- 7c. participant felt sick/was concerned about getting sick from the gel
- 7d. participant ran out of or lost the gel
- 7e. participant got tired of inserting the gel every day
- 7f. participant gave/sold/traded the gel to someone else
- 7g. participant had a change in her daily routine
- 7h. participant forgot or was too busy
- 7i. participant was on menses
- 7j. participant did not have sex/was not intending to have sex
- 7k. participant had difficulty inserting the gel
- 7l. participant didn't like the smell or feel of the gel
- 7m. someone else took/stole some of participant's gel
- 7n. participant's primary sex partner did not approve of her inserting the gel
- 7o. family member or friend did not approve of her inserting the gel
- 7p. other, specify: *Local* Language: _____ *English:* _____

17-MAR-09

Language

Staff Initials / Date

Vaginal Product Adherence and Behavior Assessment (VPA-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 7:** Do not read responses 7a–7p aloud. If the participant reports a response other than those listed, mark item 7p and record the participant’s verbatim response. Also provide the English translation in the space provided.
- **Item 7p:** If the participant did not insert gel due to a product hold/discontinuation, mark the “other, specify” box and record the reason in the space provided. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



VPA-4 (233)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

No data recorded on this page.

8. In the **past 4 weeks**, how often did you insert the gel? Was it...
Read response categories aloud. Showcard #2

- every day
- usually (most days)
- sometimes (some days)
- rarely (not many days)
- never —————▶ **If never, go to item 10.**

of days

9. In the **past 4 weeks**, what is the longest **number of days** in a row that you did **not** insert the gel?

10. Different circumstances may lead women to insert the study gel **more** than once per day. Thinking about your experience inserting gel in the **past 4 weeks**, please tell me **all** of the reasons that led you to insert gel **more** than once on any single day. **Do not read response categories aloud. Mark all that apply.**

- 10a. not applicable—never inserted study gel more than once per day —————▶ **If not applicable, go to item 12 on page 5.**
- 10b. participant forgot she had inserted gel already
- 10c. participant did not understand the instructions for inserting gel
- 10d. participant wanted to have the correct number of applicators at her next study visit
- 10e. participant had sex without a condom/had risky sex
- 10f. participant had a new partner
- 10g. participant wanted to make up for not inserting gel on earlier days
- 10h. participant thought it would protect her more
- 10i. participant's husband/primary sex partner asked her to insert more gel
- 10j. participant thought that the gel leaked out
- 10k. other, specify: *Local Language:* _____ *English:* _____

17-MAR-09

Language

Staff Initials / Date

Vaginal Product Adherence and Behavior Assessment (VPA-4)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 8:** Read each response category aloud and mark the participant's answer.
- **Item 9:** Use leading zeros when needed so that all the boxes are filled. If the participant reports that she inserted gel every day, record "00" for this item.
- **Item 10:** Do not read responses 10a–10k aloud. If the participant reports a response other than those listed, mark item 10k and record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160)



VPA-5 (234)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

No data recorded on this page.

11. In the **past 4 weeks**, on how many days did you insert gel **more** than once per day? # of days

12. Please rate your ability, over the **past 4 weeks**, to insert gel exactly as you were instructed. **Read response categories aloud. Showcard #3**

- very poor
- poor
- fair
- good
- very good
- excellent

Now I will ask about inserting gel in the **past 7 days** (not including today).

13. In the **past 7 days** (not including today),...

- 13a. on how many days did you **not** insert gel? # of days
- 13b. on how many days did you insert gel **once** per day? # of days
- 13c. on how many days did you insert gel **more than once per day**? # of days

This next question is about the **last time** you inserted the gel.

14. The **last time** you inserted the gel, was it in the morning, afternoon, or evening?

- morning
- afternoon
- evening

Vaginal Product Adherence and Behavior Assessment (VPA-5)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 11:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she never inserted gel more than once per day, record “00” for this item.
- **Item 12:** Read each response category aloud and mark the participant’s answer.
- **Items 13a–13c:** If the participant reports “none” or “zero,” record “0.” The sum of the responses to 13a–13c should equal “7.”

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code

□ □ □ . □

1

MTN003 VOICE (160)

VPA-6 (235)

Participant ID

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

Vaginal Product Adherence and Behavior Assessment

For the last set of questions, I will ask you about problems you may have had or are having while in this study. By problem, I mean any emotional, physical, social, or other difficulties.

15. In the **past 3 months**, have you had any problems with the following people as a result of being in this study:

- 15a. your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.
- 15b. people at home/family?
- 15c. your friends/personal relationships?
- 15d. people at work?
- 15e. people at school?
- 15f. a nurse or clinician or doctor outside of the study?
- 15g. your landlord or property owner?
- 15h. anyone else? If yes, specify:

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

Local Language: _____ English: _____

If no or N/A to all, end of form.

16. Has this problem/have any of these problems resulted in:

- 16a. emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem.
- 16b. physical harm to you? For example, has anyone physically hurt you as a result of this problem?
- 16c. economic/financial harm to you? For example, has this problem resulted in the loss of your home, property, or ability to earn income?
- 16d. physical or other harm to your children?

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

Vaginal Product Adherence and Behavior Assessment (VPA-6)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 15:** Read each item 15a–15h aloud and mark the participant’s answer. If “yes” is marked for item 15h, record the participant’s verbatim response. Also provide the English translation in the space provided. If items 15a through 15h are all “no” or “N/A,” end the form. Mark the “No data recorded on this page” box in the upper right corner of page 7. Also record the Visit Code, PTID, and staff initials and date on page 7 of this form. Leave all other items on page 7 blank. Fax all 7 pages of this form to SCHARP DataFax once the form has been completed.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

MTN003 VOICE (160)

VPA-7 (236)

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	

Vaginal Product Adherence and Behavior Assessment

No data recorded on this page.

17. Please describe the problem, including outcome, if any. **Do not record the participant's verbatim response.**

Local Language: _____

English: _____

End of interview.

Interviewer: Complete items 18–18a after the interview.

18. Did any of the problem(s) require reporting as an Adverse Event (AE)? yes no **If no, end of form.**

18a. Record AE Log page number(s):

AE Log page #	AE Log page #	AE Log page #
<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"/>

Vaginal Product Adherence and Behavior Assessment (VPA-7)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 17:** Do not record the participant's verbatim response. Instead, listen to the participant's response and probe as necessary. Describe, in the local language, the problem, including all relevant details, and the outcome, if any,. Also provide the English translation in the space provided.
- **Items 18 and 18a:** These items are not interviewer-administered. Complete these items after the interview.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

MTN003 VOICE (160)

VTR-1 (143)

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

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

Alternate Collection Date

Not done/
Not collected dd MMM yy

2. Trichomonas Rapid Test *negative* *positive*

3. BV Rapid Test *negative* *positive*

At Screening:
If participant is diagnosed with trichomoniasis, symptomatic bacterial vaginosis, or symptomatic vulvo-vaginal candidiasis, she must complete treatment and be asymptomatic (within 56-day screening window) to enroll.

During Follow-up:
If participant is diagnosed with trichomoniasis, symptomatic bacterial vaginosis, or symptomatic vulvo-vaginal candidiasis, complete an Adverse Experience Log. Note: asymptomatic bacterial vaginosis and asymptomatic vulvo-vaginal candidiasis are not reportable as AEs.

Comments: _____

Vaginal Test Results (VTR-1)

Purpose: This form is used to document results of specimens collected during the Screening Part 2, Enrollment, (if applicable), and follow-up pelvic exams.

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

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. 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* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form. A complete date is required.
- **Not done/Not collected:** Mark this box in the event that a specimen is collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments lines. For item 1, mark the “Not done/Not collected” box only if no vaginal wet prep results are available.

Item-specific Instructions:

- **Item 1:** A vaginal wet prep is required only when clinically indicated. If a vaginal wet prep was performed but not all assays were completed, mark the “Not done” box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason on the Comments lines. If a positive result from a Screening Part 2 or Enrollment Visit sample confirms a diagnosis of symptomatic vaginal candidiasis, symptomatic bacterial vaginosis (BV), or trichomoniasis, the participant must complete treatment and be asymptomatic to enroll. If a positive result from a follow-up sample confirms a diagnosis of symptomatic vaginal candidiasis, symptomatic bacterial vaginosis (BV), or trichomoniasis, record as an adverse experience on the Adverse Experience Log.
- **Item 1a:** Mark the “positive” box if homogeneous vaginal discharge was observed.
- **Item 1d:** Mark the “positive” box if 20% or more of the cells were clue cells.
- **Item 1e:** Mark the “positive” box if trichomonads were observed.
- **Item 1f:** Mark the “positive” box if yeast buds and/or hyphae were observed.
- **Item 2:** A Trichomonas Rapid Test is required at the Screening Part 2 Visit, annual visits, the Product Use End Visit, and when clinically indicated during study follow-up.
- **Item 3:** A BV Rapid Test is required only when clinically indicated, or when necessary to confirm participant eligibility for study participation.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk	

Enrollment Medical Eligibility

Visit Date

dd		MMM		yy	

1. At any time during the Screening Part 1, Screening Part 2, and Enrollment Visits, was the participant diagnosed by study staff with any of the following conditions requiring treatment per protocol:

If yes: Has condition been treated and have any associated symptoms resolved as of the day of enrollment?

	yes	no	▶	yes	no
1a. urinary tract infection (UTI)	<input type="checkbox"/>	<input type="checkbox"/>	▶	<input type="checkbox"/>	<input type="checkbox"/>
1b. chlamydia.....	<input type="checkbox"/>	<input type="checkbox"/>	▶	<input type="checkbox"/>	<input type="checkbox"/>
1c. gonorrhea	<input type="checkbox"/>	<input type="checkbox"/>	▶	<input type="checkbox"/>	<input type="checkbox"/>
1d. syphilis	<input type="checkbox"/>	<input type="checkbox"/>	▶	<input type="checkbox"/>	<input type="checkbox"/>
1e. symptomatic BV.....	<input type="checkbox"/>	<input type="checkbox"/>	▶	<input type="checkbox"/>	<input type="checkbox"/>
1f. symptomatic vaginal candidiasis	<input type="checkbox"/>	<input type="checkbox"/>	▶	<input type="checkbox"/>	<input type="checkbox"/>
1g. trichomoniasis	<input type="checkbox"/>	<input type="checkbox"/>	▶	<input type="checkbox"/>	<input type="checkbox"/>
1h. active genital herpes lesions	<input type="checkbox"/>	<input type="checkbox"/>	▶	<input type="checkbox"/>	<input type="checkbox"/>
1i. genital warts requiring treatment per protocol	<input type="checkbox"/>	<input type="checkbox"/>	▶	<input type="checkbox"/>	<input type="checkbox"/>
1j. pelvic inflammatory disease (PID)	<input type="checkbox"/>	<input type="checkbox"/>	▶	<input type="checkbox"/>	<input type="checkbox"/>
1k. any other STI or RTI requiring treatment, specify:	<input type="checkbox"/>	<input type="checkbox"/>	▶	<input type="checkbox"/>	<input type="checkbox"/>

If no to any, participant is ineligible. Treat per protocol and SSP Manual. Participants found to meet all other eligibility criteria may be enrolled (or have another screening attempt) after treatment is completed and symptoms (if any) have resolved.

Enrollment Medical Eligibility (non-DataFax) - Page 1

This form is completed at the Enrollment Visit only, and is used to document the participant's medical eligibility for the study. This form is completed based on review of all clinical and lab test results documentation from the participant's Screening Part 1, Screening Part 2, and Enrollment Visits. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

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

If a participant is being re-screened, a new Enrollment Medical Eligibility form must be completed as part of the subsequent Screening Attempt. See the Study-specific Procedures (SSP) Manual for more instructions regarding re-screening form completion and transmission procedures.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number					Chk		

Enrollment Medical Eligibility

2. Please answer the following questions based on the participant's Baseline Medical and Menstrual History.

- | | | |
|---|--------------------------|--------------------------|
| | <i>yes</i> | <i>no</i> |
| 2a. Did the participant report any pathologic bone fracture not related to trauma (ever)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2b. Did the participant report receiving post-exposure prophylaxis (PEP) for HIV infection within 6 months prior to enrollment? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2c. Did the participant report any gynecologic or genital procedure (e.g., biopsy, tubal ligation, dilation and curettage, piercing) in the past 6 weeks (42 days)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2d. Did the participant report that she is currently using spermicide; interferon or interleukin therapy; medication(s) with significant nephrotoxic potential, including but not limited to amphotericin B, aminoglycosides, cidovir, foscarnet and systemic chemotherapy; medication(s) that may inhibit or compete for elimination via active renal tubular secretion (including but not limited to probenecid)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2e. Did the participant report, as determined by the IoR/designee, any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease, including active tuberculosis? | <input type="checkbox"/> | <input type="checkbox"/> |

3. Does the participant have a clinically apparent Grade 2 or higher pelvic exam finding (observed by study staff)?

Note: Cervical friability judged to be within the range of normal according to the clinical judgment of the IoR/designee is not exclusionary.

If yes to any, participant is ineligible.

4. Does the participant have a normal Pap result documented in the last 12 months?

<i>yes</i>	<i>no</i>	<i>N/A</i>	▶ If yes or N/A, go to item 5 on page 3.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

4a. Does participant have a Grade 2 or higher Pap result?

If yes, participant may be ineligible. Participants with abnormal Pap results who are found to meet all other eligibility criteria may be enrolled upon completion of the initial phase of evaluation if no current treatment is indicated. If grade 2 or higher Pap result, specify evaluation and treatment plan in the space provided, clearly noting whether treatment is currently indicated.

Enrollment Medical Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Item 4:** Mark the “yes” box if the participant has documentation in the last 12 months of a Pap result that is negative for intraepithelial lesion or cancer (malignancy). Mark the “no” box if the participant only has documentation in the last 12 months of a Pap result that is anything other than negative for intraepithelial lesion or cancer (malignancy). Mark the “N/A” box if a Pap result is not required per protocol to determine the participant’s eligibility.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

			-					-	
Site Number				Participant Number					Chk

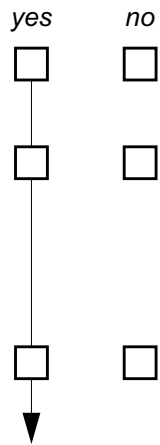
Enrollment Medical Eligibility

5. Is the participant pregnant? yes no

6. Is the participant HIV-infected per the screening algorithm in protocol Appendix II? yes no

Answer item 7 based on all available screening information.

7. Does the participant have any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives? yes no



If yes to any, participant is ineligible.

Enrollment Medical Eligibility (non-DataFax) - Page 3

No additional instructions.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

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

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 and Menstrual History.

dd	MMM	yy	amenorrheic
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2. Last day of participant's last menstrual period:
Obtain from Follow-up Medical and Menstrual History.

dd	MMM	yy
<input type="text"/>	<input type="text"/>	<input type="text"/>
<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"/>	days
----------------------	----------------------	------
4. First day of genital bleeding episode:
Per participant report or clinical exam.

dd	MMM	yy
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
5. Last day of genital bleeding episode:

dd	MMM	yy	ongoing
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
6. Total number of days of genital bleeding:

<input type="text"/>	<input type="text"/>	days	OR	<input type="text"/>	ongoing
----------------------	----------------------	------	----	----------------------	---------
7. According to the participant, was the amount of genital blood a normal amount, lighter amount, or heavier amount when compared to the heaviest flow day of her regular menses?

normal	lighter	heavier	unknown	N/A
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
8. According to the participant or the clinician, what color was the genital blood? Mark "unknown," or all that apply.

bright red	brown	unknown
<input type="text"/>	<input type="text"/>	<input type="text"/>
9. According to the participant, did she continue to use the study product during this genital bleeding episode?

yes	no	N/A
<input type="text"/>	<input type="text"/>	<input type="text"/>

OR
↓
If amenorrheic, go to item 4.

→ 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 participant's Baseline Medical and Menstrual History 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 the “amenorrheic” box 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 the “unknown” box cases where the information is not known by the participant. Mark the “N/A” box if the genital bleeding was not reported by the participant, but was observed during the pelvic examination only.
- **Item 8:** Mark the “unknown” box in cases where the information is not known by the participant or the clinician.
- **Item 9:** Mark the “NA” box if the participant's study product use was held or permanently discontinued prior to this genital bleeding episode.

Genital Bleeding Assessment (non-DataFax) - Page 2

Item-specific Instructions:

- **Item 11d:** Mark the “N/A” box if the participant is not in the vaginal group.
- **Item 12:** If the participant reports currently using injectable contraceptives, make sure the injectable contraceptives are listed on the participant’s Contraceptives Log.
- **Item 12b:** If the participant is currently overdue for an injection, record the date when she was supposed to have her next injection, per her injection schedule.
- **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 Contraceptives Log.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

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 participant's Baseline Medical and Menstrual History 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*.

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 in the participant's Baseline Medical and Menstrual History). 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*. 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 (SSP) Manual for further information.

MTN 003 Non-DataFax LDMS Specimen Tracking Sheet

For login of MTN 003 stored specimens into LDMS

Participant ID

- -

Site Number Participant Number Chk

Visit Code

.

Specimen Collection Date

dd MMM yy

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB ADDITIVE/ DERIVATIVE	NOTES FOR LAB
<input type="checkbox"/>	Blood (BLD) <i>Plasma</i> Collection Time: ____:____ hour : min	EDT (purple top)	PL 1/2	N/A	Store in aliquots of 1-2 ml. If held at room temperature, plasma must be frozen within 4 hours of collection. If refrigerated or on ice, plasma must be frozen within 24 hours of collection.
<input type="checkbox"/>	Endocervical Swab (CXS) Collection Time: ____:____ hour : min	PBS (Phosphate buffered saline)	CXS	N/A	Place swab in cry vial with PBS. Freeze within 8 hours of collection.
<input type="checkbox"/>	Vaginal Swab (VAG) Collection Time: ____:____ hour : min	PBS (Phosphate buffered saline)	SWB	N/A	Place swab in cry vial with PBS. Freeze within 8 hours of collection.
<input type="checkbox"/>	Vaginal Gram Stain Slide (VAG)	NON (no additive)	SLD	GRS	Re-label with LDMS label. Store duplicate slides (one for on-site storage, and one for shipping and testing at MTN Network Lab).

Comments: _____

Initials: _____
Sending Staff Receiving Staff

LDMS Data Entry Date: / / _____
dd MMM yy LDMS Staff

MTN 003 Non-DataFax LDMS Specimen Tracking Sheet

For login of MTN 003 stored specimens into LDMS

LDMS Specimen Tracking Sheet (nonDataFax)

Purpose: This non-DataFax form is used to document collection and entry of MTN 003 specimens into the Laboratory Data Management System (LDMS).

General Information/Instructions: A copy of this form accompanies LDMS specimens in their original specimen collection containers to each LDMS entry laboratory. Once the specimens have been entered into LDMS, this form is kept on file at the LDMS entry laboratory. If the site chooses, a copy of this completed form may be made once the specimens have been entered into LDMS and the copy kept in the participant's study notebook. This is not required, however. 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 LDMS specimens were collected.
- **# of TUBES or SPECIMENS:** Record the total number of collected tubes or specimens of the listed primary specimen type that will be entered into LDMS. If no LDMS specimens of the primary specimen type were collected, record "0."
- **Collection Time:** When collection time is present, record the time the specimen was collected using a 24-hour clock. For example, a specimen collected at 2:36pm would have "14:36" recorded as the collection time.
- **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.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk	

Participant-reported Baseline Medical and Menstrual History

Visit Date

dd		MMM		yy	

	Medical problem?		If yes, date diagnosed		Description:	Ongoing?		Severity Grade
	yes	no	MMM	yy		yes	no	
HE (head/eyes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
ENT (ears/nose/throat)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Lymphatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Liver	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____

If yes to any at the time of enrollment, record on Pre-existing Conditions form.

17-MAR-09

Language

Staff Initials / Date

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 1

This form is used to document a participant's baseline medical history, since becoming sexually active. It is first completed at the Screening Part 2 Visit. It is then updated at any subsequent visits related to the same screening attempt, and updated again at the Enrollment Visit. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

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

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

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

Item-specific Instructions:

- **Medical problem (yes/no):** For each organ system/disease listed, mark the “yes” box if there is evidence (either by participant report or by medical records) that the participant has ever experienced any medical problem involving that organ system/disease since becoming sexually active. Mark the “no” box for conditions not reported or documented in medical records.
- **If yes, date diagnosed:** For each organ system/disease marked “yes,” record the month and year the participant was diagnosed with the condition or began experiencing symptoms.
- **Ongoing?:** For each diagnosed or reported condition, determine if it is ongoing or resolved. Mark the “yes” box if the condition is ongoing (not resolved), and “no” if the condition is resolved. Review all ongoing conditions at the participant's Enrollment Visit. For conditions ongoing at Enrollment, record the condition on the participant's Pre-existing Conditions form.
- **Severity Grade:** Assign a severity grade to all diagnosed conditions that are ongoing. To grade the severity, consult 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, write “NG.”

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk		

Participant-reported Baseline Medical and Menstrual History

	Medical problem?		If yes, date diagnosed		Description:	Ongoing?		Severity Grade
	<i>yes</i>	<i>no</i>	<i>MMM</i>	<i>yy</i>		<i>yes</i>	<i>no</i>	
Renal <i>(including urinary symptoms)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Musculoskeletal <i>(including bone fractures)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Neurologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Endocrine/ Metabolic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____

If yes to any at the time of enrollment, record on Pre-existing Conditions form.

17-MAR-09

Language

Staff Initials / Date

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 2

Item-specific Instructions:

- **Medical problem (yes/no):** For each organ system/disease listed, mark the “yes” box if there is evidence (either by participant report or by medical records) that the participant has ever experienced any medical problem involving that organ system/disease since becoming sexually active. Mark the “no” box for conditions not reported or documented in medical records.
- **If yes, date diagnosed:** For each organ system/disease marked “yes,” record the month and year the participant was diagnosed with the condition or began experiencing symptoms.
- **Ongoing?:** For each diagnosed or reported condition, determine if it is ongoing or resolved. Mark the “yes” box if the condition is ongoing (not resolved), and “no” if the condition is resolved. Review all ongoing conditions at the participant’s Enrollment Visit. For conditions ongoing at Enrollment, record the condition on the participant’s Pre-existing Conditions form.
- **Severity Grade:** Assign a severity grade to all diagnosed conditions that are ongoing. To grade the severity, consult 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, write “NG.”

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk		

Participant-reported Baseline Medical and Menstrual History

	Medical problem?		If yes, date diagnosed		Description:	Ongoing?		Severity Grade
	<i>yes</i>	<i>no</i>	<i>MMM</i>	<i>yy</i>		<i>yes</i>	<i>no</i>	
Hematologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Cancer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Drug Allergy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Other Allergy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Mental Illness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____

If yes to any at the time of enrollment, record on Pre-existing Conditions form.

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 3

Item-specific Instructions:

- **Medical problem (yes/no):** For each organ system/disease listed, mark the “yes” box if there is evidence (either by participant report or by medical records) that the participant has ever experienced any medical problem involving that organ system/disease since becoming sexually active. Mark the “no” box for conditions not reported or documented in medical records.
- **If yes, date diagnosed:** For each organ system/disease marked “yes,” record the month and year the participant was diagnosed with the condition or began experiencing symptoms.
- **Ongoing?:** For each diagnosed or reported condition, determine if it is ongoing or resolved. Mark the “yes” box if the condition is ongoing (not resolved), and “no” if the condition is resolved. Review all ongoing conditions at the participant’s Enrollment Visit. For conditions ongoing at Enrollment, record the condition on the participant’s Pre-existing Conditions form.
- **Severity Grade:** Assign a severity grade to all diagnosed conditions that are ongoing. To grade the severity, consult 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, write “NG.”

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 4

Item-specific Instructions:

- **Medical problem (yes/no):** Mark the “yes” box for each STI/RTI (evidenced by participant report or by medical records) that the participant has ever experienced since becoming sexually active, if any. For each STI/RTI reported, mark the box that corresponds to the specific STI/RTI the participant experienced (e.g., “Gonorrhea”). Mark the “no” box for the remaining STI/RTI items.
- **If yes, date diagnosed:** For each item marked “yes,” record the month and year the participant was diagnosed with the condition or began experiencing symptoms.
- **Ongoing?:** For each diagnosed or reported condition, determine if it is ongoing or resolved. Mark the “yes” box if the condition is ongoing (not resolved), and “no” if the condition is resolved. Review all ongoing conditions at the participant’s Enrollment Visit. For conditions ongoing at Enrollment, record the condition on the participant’s Pre-existing Conditions form.
- **Severity Grade:** Assign a severity grade to all diagnosed conditions that are ongoing. To grade the severity, consult 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, write “NG.”

SAMPLE: DO NOT FAX TO DATAFAX

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MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk	

Participant-reported Baseline Medical and Menstrual History

Genital Symptoms			If yes, date diagnosed		Description:	Ongoing?		Severity Grade
	yes	no	MMM	yy		yes	no	
Genital sores?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Genital/vaginal itching?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Genital/vaginal burning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Genital/vaginal pain? (other than during sex)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Pain during sex?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Abnormal genital/ vaginal discharge?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Unusual genital/ vaginal odor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Lower abdominal pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Other genital symptoms? Specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____

If yes to any, evaluate for STIs/RTIs.

If yes to any, evaluate for eligibility. If yes to any at time of Enrollment, record on Pre-existing Conditions form.

Blood-tinged discharge?			If yes, date diagnosed		Description:	Ongoing?		Severity Grade
	yes	no	MMM	yy		yes	no	
Blood-tinged discharge?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____

If yes, evaluate for eligibility.

If yes at the time of Enrollment, record on Pre-existing Conditions form.

Other medical problem?			If yes, date diagnosed		Description:	Ongoing?		Severity Grade
	yes	no	MMM	yy		yes	no	
Other?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Other?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
Other?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____

If yes to any at the time of Enrollment, record on Pre-existing Conditions form.

02-SEP-09

Language

Staff Initials / Date

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 5

Item-specific Instructions:

- **Genital Symptoms:** These questions refer to any genital symptoms the participant may have experienced since becoming sexually active. For each item marked “yes,” complete the adjacent item, “If yes: Is she currently experiencing this symptom?” For items marked “no,” leave the adjacent item “If yes: Is she currently experiencing this symptom?” blank. For any item marked “yes,” evaluate the participant for STIs/RTIs per the protocol and SSP. If the participant is diagnosed with a STI/RTI that is exclusionary per protocol, do not enroll the participant. Provide treatment as necessary (per WHO guidelines).
- **If yes, date diagnosed:** For each item marked “yes,” record the month and year the participant was diagnosed with the condition or began experiencing symptoms.
- **Ongoing?:** For each reported symptom or condition, determine if it is ongoing or resolved. Review all ongoing symptoms/conditions at the participant’s Enrollment Visit. For symptoms/conditions ongoing at Enrollment, record the condition on the participant’s Pre-existing Conditions form.
- **Severity Grade:** Assign a severity grade to all diagnosed conditions that are ongoing. To grade the severity, consult 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, write “NG.”
- **Other medical problem (yes/no):** For each “other” symptom or condition that the participant has ever experienced since becoming sexually active (either by participant report or by medical records), mark the “yes” box. Mark the “no” box for the remaining “other?” items.
- **Other:** Record any symptom or condition reported by the participant that is not recorded elsewhere on this form.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

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

Participant-reported Baseline Medical and Menstrual History

Menstrual History

	<i>dd</i>	<i>MMM</i>	<i>yy</i>
First day of last menstrual period:	<input type="text"/>	<input type="text"/>	<input type="text"/>
Last day of last menstrual period:	<input type="text"/>	<input type="text"/>	<input type="text"/>

If participant's last menstrual period was more than one month ago, record relevant clinical history (include severity grade, if missed menses is unexpected).

	<i>regular</i>	<i>irregular</i>	
Usual menstrual cycle:	<input type="checkbox"/>	<input type="checkbox"/>	
Usual number of days between menses:	<input type="text"/>	# of days	
	<i>minimum</i>	<i>maximum</i>	
Usual number of bleeding days (record range):	<input type="text"/>	# of days TO <input type="text"/> # of days	
Age of menarche:	<input type="text"/>	years	
	<i>light</i>	<i>moderate</i>	<i>heavy</i>
Usual type of menstrual flow (at the heaviest day of menses):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Usual menstrual symptoms (document start date, type and severity, if any): _____

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

History of any other menstrual problems not recorded above (record severity grade, if ongoing): _____

17-MAR-09

Language Staff Initials / Date

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 6

Item-specific Instructions:

- **First/Last day of last menstrual period:** Record the dates relating to the participant's most recently completed menses regardless of how long ago it occurred. At minimum, month and year are required.
- **Usual number of days between menses:** If the participant is amenorrheic, refer to her previous menstrual cycles that occurred prior to the amenorrhea.
- **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.
- **Usual non-menstrual genital bleeding pattern:** Document the frequency of bleeding, duration of bleeding, type of flow (e.g., light, moderate, or heavy), and associated symptoms (if any) of any and all reported non-menstrual bleeding commonly experienced by the participant. This includes intermenstrual bleeding (IMB) and/or any breakthrough genital bleeding/spotting associated with the participant's contraceptive use.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

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	

Participant-reported Baseline Medical and Menstrual History

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

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

Note: To be eligible for study participation, participant must report at enrollment use of an effective method of contraception (hormonal methods, intrauterine contraceptive device, or sterilization of participant or her partner) for the next 24 months. Reported use of spermicide, vaginal ring, diaphragm, or other vaginal products is exclusionary per protocol.

17-MAR-09

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Language	

Staff Initials / Date

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 7

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.

MTN003 VOICE (160)

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

**Participant-reported Baseline
Medical and Menstrual History**

History of sexual assault (if any): _____

History of any other obstetric, gynecologic, or reproductive problems, and/or procedures not recorded elsewhere on this form (record severity grade, if ongoing):

**Participant-reported Baseline Medical and Menstrual History (non-DataFax) -
Page 8**

No additional instructions.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk			

Participant-reported Follow-up Medical and Menstrual History

Visit Date

dd		MMM		yy	

	Medical problem since last visit?		If yes, onset date			OR	continuing from previous visit	Description <i>(include severity grade and outcome date, if applicable)</i>
	yes	no	dd	MMM	yy			
HE (head/eyes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
ENT (ears/nose/throat)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Lymphatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Liver	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Renal (including urinary symptoms)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Musculoskeletal (including bone fractures)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		

Update or complete Adverse Experience Log when applicable.

17-MAR-09

Language

Staff Initials / Date

Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 1

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

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

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

Item-specific Instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk	

Participant-reported Follow-up Medical and Menstrual History

	Medical problem since last visit?		If yes, onset date			OR	continuing from previous visit	Description <i>(include severity grade and outcome date, if applicable)</i>
	<i>yes</i>	<i>no</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>			
Neurologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Endocrine/ Metabolic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Hematologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Cancer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Drug Allergy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Other Allergy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Mental Illness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		

Update or complete Adverse Experience Log when applicable.

Any changes in alcohol use since last study visit?

Any changes in recreational drug use since last study visit?

Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 2

Item-specific Instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk	

Participant-reported Follow-up Medical and Menstrual History

Since her last study visit, has the participant experienced any of the following symptoms:

Genital Symptoms			If yes, onset date			OR	continuing	Description (include severity grade and outcome date, if applicable)
	yes	no	dd	MMM	yy	from previous visit		
Genital sores?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Genital/vaginal itching?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Genital/vaginal burning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Genital/vaginal pain? (other than during sex)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Pain during sex?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Abnormal genital/ vaginal discharge?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Unusual genital/ vaginal odor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Menstrual symptoms worse than her usual menstrual symptoms?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Lower abdominal pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Other genital symptoms? Specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		

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

Vaginal bleeding or spotting between her usual menstrual periods?			If yes, onset date			OR	continuing	Description (include severity grade and outcome date, if applicable)
	yes	no	dd	MMM	yy	from previous		
Vaginal bleeding or spotting between her usual menstrual periods?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Blood-tinged discharge?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Post-coital bleeding?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		

If yes to any, complete Genital Bleeding Assessment form if indicated. Conduct pelvic exam if indicated. Update or complete Adverse Experience Log when applicable.

Other medical problem since last visit?			If yes, onset date			OR	continuing	Description (include severity grade and outcome date, if applicable)
	yes	no	dd	MMM	yy	from previous		
Other?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		
Other?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>		

Update or complete Adverse Experience Log when applicable.

17-MAR-09

Language

Staff Initials / Date

Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 3

Item-specific Instructions:

- **Genital Symptoms:** For any item marked “yes,” conduct a pelvic exam if clinically indicated (and not already required for the visit). Evaluate the participant for STIs/RTIs per the protocol and SSP. If the participant is diagnosed with a STI/RTI, provide treatment as necessary (as per WHO guidelines).
- **Menstrual symptoms worse than her usual menstrual symptoms:** This item is intended to capture dysmenorrhea reported during follow-up visits. If the participant reports dysmenorrhea and/or any other symptom(s) related to menstruation, probe for further information (i.e., type and severity of symptoms), then compare to the participant’s usual baseline menstrual symptoms to determine whether an AE should be reported.
- **Genital Bleeding:** If the participant reports vaginal bleeding or spotting between usual menstrual periods, blood-tinged genital/vaginal discharge, or any post-coital bleeding, refer to the Study-Specific Procedures (SSP) Manual.
- **If yes, onset date:** For each item marked “yes,” record the day, month, and year the participant was diagnosed with the condition or began experiencing symptoms. When applicable, complete an Adverse Experience Log form for the condition recording this date as the AE Onset Date (item 2 of the Adverse Experience Log form).
- **Continuing from previous visit:** Mark this box for items that are continuing from a previous visit (that is, the onset date of the symptom or condition is recorded on a previously-completed medical history form). If this box is marked, leave the “If yes, onset date” boxes blank. If an onset date is recorded, leave the “continuing from previous visit” box blank.
- **Update or complete Adverse Experience Log when applicable:** For each item, complete an Adverse Experience Log form (if applicable) if this is the **first time** the symptom or condition has been reported since the participant enrolled in the study. If this **not** the first time the symptom/condition has been reported since enrollment, an AE Log should already have been completed for this symptom/condition—review the previously completed AE Log and either update any relevant information, or complete a new AE Log as necessary (e.g., in cases where a previously reported AE has increased in severity or frequency). If the symptom/condition was first reported on the participant’s Baseline Medical History and Pre-existing Conditions forms and it has not increased in severity or frequency, **do not** complete an AE Log—do record on this form that the condition has not increased in severity or frequency since enrollment/baseline.
- **Other:** Record any symptom or condition reported by the participant that is not recorded elsewhere on this form.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

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

Participant-reported Follow-up Medical and Menstrual History

Did the participant have a bone fracture since her last study visit?

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

Is there suspicion of lactic acidosis?

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

If yes to either, refer to protocol and SSP Manual for guidance on clinical management and study product administration. Complete Adverse Experience Log and Product Hold/ Discontinuation Log if applicable.

Menstrual Information

First day of last menstrual period:

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

Last day of last menstrual period:

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

no menses since last visit
OR

If no menses since last visit, is it unexpected or unexplained?

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

If yes, document Severity Grade here: _____ and complete Adverse Experience Log, when applicable.

Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 4

Item-specific Instructions:

- **No menses since last visit:** If the participant has not had a menstrual period since her last study visit, mark this box and leave the date boxes (ddMMMyy) blank for First and Last day of last menstrual period.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk	

Participant-reported Follow-up Medical and Menstrual History

Any changes to contraception/family planning use not recorded elsewhere on this form?

yes no

If yes, specify below. Include start and stop dates. Update Contraceptives Log when applicable.

Any changes to obstetric/gynecologic/reproductive history since last study visit?

yes no

If yes, specify below.

Additional Notes: _____

**Participant-reported Follow-up Medical and Menstrual History (non-DataFax) -
Page 5**

No additional instructions.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

- -

Site Number Participant Number Chk

Pelvic Exam Diagrams

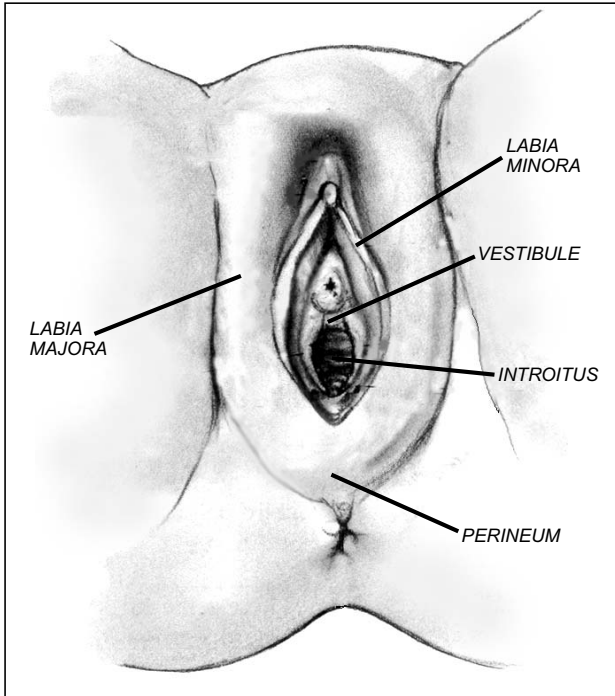
Exam Date

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"/>

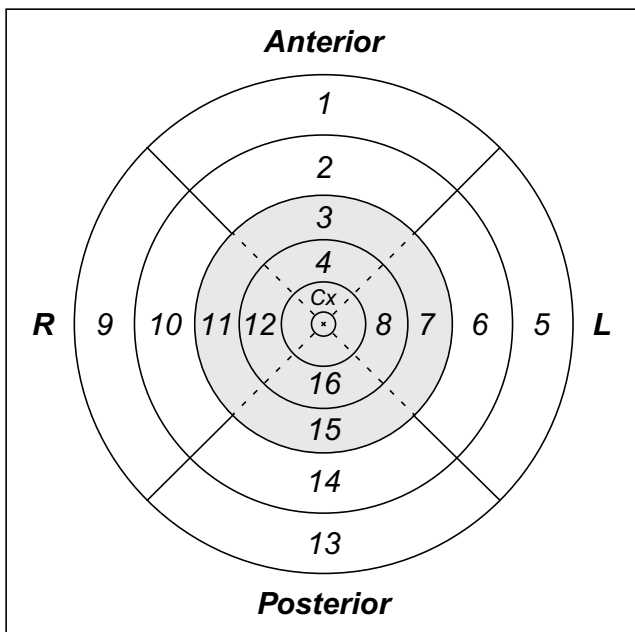
External Genitalia



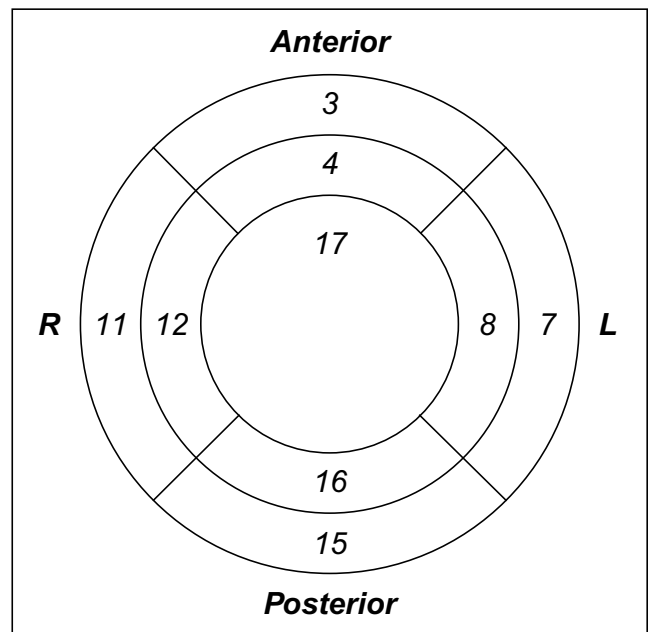
Legend for Vagina/Cervix

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

Vagina



Cervix



17-MAR-09

Language

Staff Initials / Date

Pelvic Exam Diagrams (non-DataFax) - Page 1

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 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

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk	

Physical Exam

Exam Date

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

If abnormal, please specify. Include severity grade, if applicable.

<i>not evaluated</i>	<i>normal</i>	<i>abnormal</i>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. General appearance _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Abdomen _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. HEENT _____ _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Lymph Nodes _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Neck _____
<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. Breast Exam _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. Extremities _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11. Skin _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12. Neurological _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13. Musculoskeletal (including bone fractures): _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14. Other, specify: _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15. Other, specify: _____

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

Findings: _____ Staff Initials / Date

Physical Exam (non-DataFax) - Page 1

This form is used to document the participant's vital signs and physical exam findings at Screening Part 2 and during study follow-up. 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 and round to the nearest whole number. 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 14–15:** Use these items to list any additional organ systems that were evaluated. If no other organ systems other than the ones listed in items 2–13 were evaluated, mark these items as “not evaluated.”

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

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 Part 1 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 some questions about you, your sexual behaviors and your health. There are no right or wrong answers, and every answer is important, so please be as honest and as accurate as you can. Some of the questions may seem personal, but please remember that all of your answers will be kept confidential.

- Have you ever had a bad reaction to latex (such as latex condoms or gloves)?..... *yes* *no* **If yes, participant is ineligible.**
- Have you ever used tenofovir gel, tenofovir tablets, or Truvada tablets? **Use visual aid.** **If no, go to item 4.**
- Have you ever had a bad reaction to tenofovir gel, tenofovir tablets, or Truvada tablets?**Use visual aid.** **If yes, participant is ineligible.**
- In the **past year** (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional? **If yes, participant is ineligible.**
- In the **past 3 months**, have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina. **If no, participant is ineligible. Go to item 9.**
- In the **past 7 days** (not including today), how many acts of vaginal sex did you have? # of vaginal sex acts **If 00, go to item 8.**
- In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? # of vaginal sex acts with condom
- Now I would like to ask you about your most recent vaginal sex act. That is, the very **last vaginal sex act** that you had, including today. During the last act of vaginal sex that you had, was a male or female condom used? **Use visual aid.** *yes* *no* **If no, go to item 9.**
- 8a. What type of condom was used during the **last act** of vaginal sex that you had? **Use visual aid.** *male condom* *female condom*
- In the **past 6 weeks** (42 days), have you been pregnant, given birth (including stillbirth), or had a pregnancy terminated?..... *yes* *no* **If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 43 days after last pregnancy outcome.**

Screening Part 1 Eligibility (non-DataFax) - Page 1

This form is used to document the participant's eligibility for the study at the Screening Part 1 Visit. This is a mixed form—some of the items are interviewer-administered (items 1–19), while other items are not (items 20–22). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

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

Item-specific Instructions:

- **Items 1–19:** If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 19. Do not inform her that she is ineligible for the study until the form has been administered. Also, refrain from indicating to the participant the reason why she is ineligible, to prevent socially desirable reporting.
- **Item 2:** Mark the “no” box if the participant does not recall having ever used tenofovir gel, tenofovir tablets, or Truvada tablets.
- **Item 3:** Mark the “no” box if the participant does not recall having had an adverse reaction to tenofovir gel, tenofovir tablets, or Truvada tablets

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

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

Screening Part 1 Eligibility

10. Are you breastfeeding now? *yes* *no*
 If yes, participant is ineligible.
11. Do you and your partner intend to have a child in the future? *yes* *no* *don't know*
 If no or don't know, go to item 13.
12. When do you and your partner intend to have your future child? # *months from now* OR *years from now*
13. If you were to join this research study, would you be willing to use a reliable method of contraception for the next 2 years (24 months)?
 The methods that are considered reliable include: oral contraceptive pills, contraceptive injections (for example, depo-provera), contraceptive implants (for example, norplant or jadelle), contraceptive patches, intrauterine contraceptive devices, and surgical sterilization of you or your partner(s)..... *yes* *no*
 If no, participant is ineligible.
14. Do you plan to move away from this area in the next 2 years (24 months)? *yes* *no* *don't know*
 If yes, participant is ineligible.
15. Do you plan to be away from this area for more than 8 weeks in a row in the next two years (24 months)? This includes seasonal travel, and travel for farming, trade, or other purposes. *yes* *no* *don't know*
 If yes, participant is ineligible.
16. In the past 30 days, have you taken part in any other research study of medicines, medical devices, or vaginal products? *yes* *no*
 If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 31 days after exit from other study.
17. If you were to join this study, would you agree to not take part in any other research study of medicines, medical devices, or vaginal products for the next 2 years (24 months)? *yes* *no*
 If no, participant is ineligible.

Screening Part 1 Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Item 12:** Record in months or years the amount of time expected to pass before the participant gives birth to a future child. For example, if the participant reports that she plans to give birth to a future child in a year and a half, record “18” in the “#” boxes and mark the “months from now” box. Record her best estimate.
- **Item 16:** Mark the “no” box if the participant does not recall having participated in another research study of medicines, medical devices, or vaginal products in the past 30 days.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk	

Screening Part 1 Eligibility

18. Do you currently have tuberculosis, also known as TB? yes no don't know

19. Are you currently taking any medication used to treat tuberculosis or TB? yes no don't know

If yes, refer participant to site medical officer. ←

If no or don't know, and participant's response to item 18 is "yes" or "don't know," refer participant to site medical officer. If site medical officer determines that participant has active TB, participant is ineligible.

End of interview. Site staff to complete items 20–22.

20. Per the site Investigator of Record or designee, does the participant currently have active tuberculosis (TB)? yes no

→ **If yes, participant is ineligible.**

21. Based on the urine hCG test result, is the participant pregnant? yes no

→ **If yes, participant is ineligible.**

22. Transcribe, in months, the response recorded for item 12 here: months from now

→ **If 33 months or less, participant is ineligible.**

Screening Part 1 Eligibility (non-DataFax) - Page 3

No additional instructions.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk	

Screening Part 2 Medical Eligibility

Form Completion Date

dd		MMM		yy	

1. At Screening Part 1 or Screening Part 2, was the participant diagnosed by study staff with any of the following conditions requiring treatment per protocol:

- | | yes | no |
|---|--------------------------|--------------------------|
| 1a. urinary tract infection (UTI) | <input type="checkbox"/> | <input type="checkbox"/> |
| 1b. chlamydia..... | <input type="checkbox"/> | <input type="checkbox"/> |
| 1c. gonorrhea | <input type="checkbox"/> | <input type="checkbox"/> |
| 1d. syphilis | <input type="checkbox"/> | <input type="checkbox"/> |
| 1e. symptomatic BV | <input type="checkbox"/> | <input type="checkbox"/> |
| 1f. symptomatic vaginal candidiasis | <input type="checkbox"/> | <input type="checkbox"/> |
| 1g. trichomoniasis | <input type="checkbox"/> | <input type="checkbox"/> |
| 1h. active herpes lesions | <input type="checkbox"/> | <input type="checkbox"/> |
| 1i. genital warts requiring treatment per protocol | <input type="checkbox"/> | <input type="checkbox"/> |
| 1j. pelvic inflammatory disease (PID) | <input type="checkbox"/> | <input type="checkbox"/> |
| 1k. any other STI or RTI requiring treatment, specify:
_____ | <input type="checkbox"/> | <input type="checkbox"/> |

If yes to any, treat per protocol and SSP Manual. Participant is ineligible until treatment is completed and symptoms (if any) have resolved. Participants found to meet all other eligibility criteria may be enrolled after treatment is completed and symptoms (if any) have resolved within the 56-day screening window.

2. Please answer the following questions based on the participant's Baseline Medical and Menstrual History.

- | | | |
|---|--------------------------|--------------------------|
| 2a. Did the participant report any pathologic bone fracture not related to trauma (ever)? | yes | no |
| | <input type="checkbox"/> | <input type="checkbox"/> |
| 2b. Did the participant report taking post-exposure prophylaxis (PEP) for HIV infection within the past 6 months? | yes | no |
| | <input type="checkbox"/> | <input type="checkbox"/> |

If yes, participant is ineligible.

If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 6 months after last use of PEP.

Screening Part 2 Medical Eligibility (non-DataFax) - Page 1

This form is completed at the Screening Part 2 Visit and is used to document the participant's medical eligibility for the study. It is completed based on review of all Screening Part 1 and Part 2 clinical and lab test results documentation.

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

If a participant is being re-screened, a new Screening Part 2 Medical Eligibility form must be completed as part of the subsequent Screening Attempt. See the Study-specific Procedures (SSP) Manual for more instructions regarding re-screening form completion and transmission procedures.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk	

Screening Part 2 Medical Eligibility

2c. Did the participant report any gynecologic or genital procedure (e.g., biopsy, tubal ligation, dilation and curettage, piercing) in the past six weeks (42 days)?

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

If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 43 days after procedure.

2d. Did the participant report that she is currently using spermicide; interferon or interleukin therapy; medication(s) with significant nephrotoxic potential, including but not limited to amphotericin B, aminoglycosides, cidofovir, foscarnet and systemic chemotherapy; medication(s) that may inhibit or compete for elimination via active renal tubular secretion (including but not limited to probenecid)?

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

If yes, participant is ineligible for as long as she uses the reported medication(s).

2e. Did the participant report, as determined by the IoR/designee, any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease, including active tuberculosis?.....

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

If yes, participant is ineligible.

3. Does the participant have a clinically apparent Grade 2 or higher pelvic exam finding (observed by study staff)?.....
Note: Cervical friability judged to be within the range of normal according to the clinical judgment of the IoR/designee is not exclusionary.

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

If yes, participant is currently ineligible. Provide treatment if clinically indicated. Participants with exclusionary pelvic exam findings who are found to meet all other eligibility criteria may be enrolled after the exclusionary pelvic exam findings have improved to a non-exclusionary severity grade or have resolved.

4. Does the participant have a normal Pap result documented in the last 12 months?
If yes and participant meets all other eligibility criteria, schedule Enrollment Visit to occur within 12 months of normal Pap result. Go to item 5 on page 3.

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

If N/A, go to item 5 on page 3.

4a. Does participant have a Grade 2 or higher Pap result?

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

If yes, participant may be ineligible. Participants with abnormal Pap results who are found to meet all other eligibility criteria may be enrolled upon completion of the initial phase of evaluation if no current treatment is indicated. If grade 2 or higher Pap result, specify evaluation and treatment plan in the space provided, clearly noting whether treatment is currently indicated.

Screening Part 2 Medical Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Item 4:** Mark the “yes” box if the participant has documentation in the last 12 months of a Pap result that is negative for intraepithelial lesion or cancer (malignancy). Mark the “no” box if the participant only has documentation in the last 12 months of a Pap result that is anything other than negative for intraepithelial lesion or cancer (malignancy). Mark the “N/A” box if a Pap result is not required per protocol to determine the participant’s eligibility.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN003 VOICE (160)

Participant ID

Site Number			Participant Number						Chk	

Screening Part 2 Medical Eligibility

5. Please answer the following questions based on the participant's laboratory results from the Screening Part 1 and Screening Part 2 Visits.

- | | yes | no |
|---|--------------------------|--------------------------|
| 5a. Is the participant pregnant? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5b. Is the participant HIV-infected per the screening algorithm in protocol Appendix II? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5c. Is the participant's AST or ALT greater than 1.5 times the site lab upper limit of normal (ULN)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5d. Is the participant's calculated creatinine clearance < 60 mL/min?..... | <input type="checkbox"/> | <input type="checkbox"/> |
| 5e. Is the participant's serum creatinine greater than the site lab ULN for women? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5f. Is the participant's hemoglobin less than 10.0g/dl? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5g. Is the participant's platelet count less than 100,000/mm ³ ? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5h. Is the participant's serum phosphate level below the site lab lower limit of normal (LLN)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5i. Did the participant test positive for Hepatitis B surface antigen (HBsAg)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5j. Is the participant's dipstick urinalysis for protein 2+ or greater from a single visit? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5k. Does the participant have at least two dipstick urinalysis protein results of 1+ or greater at separate visits? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5l. Is the participant's dipstick urinalysis result for glucose 2+ or greater from a single visit? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5m. Does the participant have at least two dipstick urinalysis glucose results of 1+ or greater at separate visits? | <input type="checkbox"/> | <input type="checkbox"/> |

If yes to any, participant is ineligible. For all exclusionary test results, except HIV infection, Hepatitis B infection, and dipstick urinalysis results, participant may be retested and enrolled (or have another screening attempt) if the retest result is not exclusionary per protocol.

6. Does the participant have any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives?.....

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

If yes, participant is ineligible.

31-AUG-09

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Language

Staff Initials / Date

Screening Part 2 Medical Eligibility (non-DataFax) - Page 3

No additional instructions.

SAMPLE: DO NOT FAX TO DATAFAX

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MTN003 VOICE (160)

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 Part 2/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	

I am now going to ask some questions about you, your sexual behaviors and your health. I know that you have been asked these questions before, but I need to ask them again to confirm your eligibility for the study. There are no right or wrong answers, and every answer is important, so we need you to be as honest and as accurate as you can. Some of the questions may seem personal, but please remember that all of your answers will be kept confidential.

1. In the **past six weeks** (42 days), have you been pregnant, given birth (including stillbirth) or had a pregnancy terminated?.....

yes no

If yes at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 43 days after last pregnancy outcome.

If yes at enrollment, participant is ineligible.

2. Are you breastfeeding now?

If yes, participant is ineligible.

3. What method(s) of contraception or family planning are you currently using? **Mark all that apply.**

- Oral contraceptive pills
- Contraceptive injections
- Contraceptive implants
- Contraceptive ring → *If "Contraceptive ring" is reported at enrollment, participant is ineligible.*
- Contraceptive patch
- Intrauterine contraceptive device
- Surgical sterilization of participant (as verified per site SOP)
- Surgical sterilization of partner(s) (as verified per site SOP)
- Other, specify: _____ → *If "Other" is reported at enrollment, evaluate for eligibility.*
- None → *If "None" is reported at enrollment, participant is ineligible.*

Screening Part 2/Enrollment Behavioral Eligibility (non-DataFax) - Page 1

This form is used to document the participant's eligibility for the study at the Screening Part 2 and Enrollment Visits. It is completed once at the Screening Part 2 Visit, and again at the Enrollment Visit. This is a mixed form—some of the items are interviewer-administered (items 1–6), while other items are not (item 7). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Note: *If a participant is being re-screened, a new Screening Part 2/Enrollment Behavioral Eligibility form must be completed as part of the subsequent screening attempt. See the Study-specific Procedures (SSP) Manual for more instructions regarding re-screening form completion and transmission procedures.*

Item-specific Instructions:

- **Items 1–6:** Many of these items were also asked during the Screening Part 1 Visit. They must be asked again in order to confirm the participant's eligibility for the study per the inclusion/exclusion criteria stated in the protocol. If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 6. Do not inform her that she is ineligible for the study until the form has been administered. Also, refrain from indicating to the participant the reason why she is ineligible, to prevent socially desirable reporting.

SAMPLE: DO NOT FAX TO DATAFAX

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Participant ID

Site Number			Participant Number						Chk	

Screening Part 2/Enrollment Behavioral Eligibility

4. If you were to join this study, would you be willing to use a reliable method for the next 2 years (24 months)? The methods that are considered reliable include: oral contraceptive pills, contraceptive injections (for example, depo provera), contraceptive implants (for example, norplant or jadelle), contraceptive patches, intrauterine contraceptive devices, and surgical sterilization of you or your partner(s).

yes no

 → *If no, participant is ineligible.*

5. In the past 30 days, have you taken part in any other research study of medicines, medical devices, or vaginal products?

→ *If yes at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 31 days after exit from other study.*

If yes at Enrollment, participant is ineligible.

6. If you were to join this study, would you agree to not take part in any other research study of medicines, medical devices, or vaginal products for the next 2 years (24 months)?

yes no

 → *If no, participant is ineligible.*

End of interview. Complete item 7 after the interview.

7. Was the participant willing and able to provide adequate locator information as defined in site SOPs?

yes no

 → *If no at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, and only needs more time to provide adequate locator information, schedule Enrollment Visit (or another screening attempt) to occur when adequate locator information is available.*

If no at Enrollment, participant is ineligible.

Screening Part 2/Enrollment Behavioral Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Items 1–6:** Many of these items were also asked during the Screening Part 1 Visit. They must be asked again in order to confirm the participant’s eligibility for the study per the inclusion/exclusion criteria stated in the protocol. If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 6. Do not inform her that she is ineligible for the study until the form has been administered. Also, refrain from indicating to the participant the reason why she is ineligible, to prevent socially desirable reporting.
- **Item 7:** This item is NOT interviewer-administered and should not be read aloud to the participant.

**MTN-003 (VOICE)
Behavioral CRF
Question by Question
(Q x Q) Guide**

Question by Question (Q x Q) Instructions for MTN 003 Adherence and Behavioral Assessment Case Report Forms

Introduction

This guide provides instruction for site staff in the use of the adherence and behavioral assessment CRFs (including the Baseline Behavior Assessment, Oral Product Adherence and Behavior Assessment, Vaginal Product Adherence and Behavior Assessment, Menstrual Practices and Study Disclosure Assessment, Study Exit Behavior Assessment, Perceived Product Assessment, and the Monthly Product Adherence and Behavior Assessment) and presents general guidelines for administering these forms. It supplements the training sessions conducted by FHI and SCHARP. The overall objective of this document is to help study interviewers be consistent when administering these CRFs. Consistency is crucial for the data to be meaningful. By administering the adherence and behavioral assessments the same way from site to site, you will avoid biasing the participants' responses.

The assessment CRFs consist of a list of questions that you will read aloud to the participant. If you deviate from asking the questions properly (for example, by making it into a conversation of sorts), the investigators of the study will not be able to interpret the data appropriately. It is important that you do not inject your personality and try hard to limit your influence (i.e., you have worked with the participant throughout the trial, she has received continuous counseling on protocol requirements, and now we're asking her to answer honestly about how she use the product, her sexual behaviors, etc.), because you might unintentionally influence a participant to answer the way you want her to, or the way the participant *thinks* you want her to answer. For this reason, it is crucial that the participant receives risk-reduction and product adherence counseling after the forms are administered, and from a different site staff member than the one who administers the forms to her.

Before the trial begins, it is suggested that each staff person who will administer these assessments conduct several role-play scenarios with other staff in-house. Conduct enough role-plays until you are comfortable with the assessments before administering them to the participants. By familiarizing yourself with the questions, wording and skip

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patterns, you will ultimately help the participants feel more comfortable as they answer the questions and will ensure that the assessments are administered smoothly and clearly.

General Information

Privacy: The behavioral and adherence assessments need to be conducted in private (and only in locations and situations approved by the site supervisors). Otherwise, the participant may not report behaviors that she does not want overheard. If a participant asks for others to be present, respond with, “Because this is a research study, we need to administer these forms in the same way for every participant. Bringing other people into the situation would make this different, even if the other people didn’t say anything.” This response can also address other deviations that a participant may request, such as being allowed to complete one particular assessment at several time points.

Administration: The behavioral and adherence assessments are administered by reading each item aloud to the participant at a relaxed pace. Inform the participant that is okay to tell you if the pace is too fast or too slow. Your intonation should go up slightly (a raised voice pitch) at the end of each question to indicate that it is a question. Be attentive and respectful during the interview. There are some brief explanations of items that go with certain questions. Avoid adding any extra verbiage between questions other than mild, occasional *general* encouragement such as, “You’re giving this good effort,” or “OK, let’s move on,” or “We’re making good progress.” These statements should be made at “section breaks” in the assessments, for example when you are moving from sexual behavior questions to study product adherence questions in the Vaginal Product Adherence and Behavior Assessment, and the Oral Product Adherence and Behavior Assessment.

A professional approach in the interview session involves being courteous while moving at a reasonable pace through the assessment. Although the questions involve sensitive topics, the participants are aware of the purpose of the study and its confidential nature. If you are comfortable with the administration and content of the forms, then the participants will be as well. However, do not be disturbed if some participants have negative emotional reactions to question content. This is understandable given the anxiety that sexual topics or adherence questions can evoke. It is important that you not get defensive or judgmental, but take negative reaction in stride with a brief empathic statement (e.g., “I know sometimes these questions can seem very personal.”). If the

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participant seems unusually uncomfortable, remind her that she does not have to respond to a particular question. You will usually find that participants are willing to respond if you have established some rapport and ensured their confidentiality.

Note: For guidance on the use of specific probes during the interview, please refer to the Data Collection section of the Study-specific Procedures Manual (SSP).

Feedback: Please do not agree with, disagree with, or correct statements made by participants. If they want to know particular pieces of information about the study products or HIV, for example, you can give them handouts or other information after you finish administering the assessments. If they ask questions about the study itself, you may decide to provide a brief and straightforward answer. If you are uncertain how to answer, you may need to direct participants to the Site/Study Coordinator, the Site Principal Investigator, and/or the site contact number on the informed consent form. It is preferable to politely defer general questions until the end of the interview, at which point you may need to consult a local referral sheet, which lists sources of information. It is important that, in general, you not offer feedback: no inferences or judgments.

Referral needed: The participant may bring up concerns that need to be addressed for ethical reasons. For example, the participant may talk about a particular social harm she has experienced as a result of being in this study, such as domestic violence. There are local referrals available to you for people in crisis. Although we will be providing important services in the course of the study, you cannot try to solve the participants' problems yourself in the interview situation via counseling or practical assistance such as money, goods, or transportation. This is inappropriate for your role as interviewer and could compromise the study. This does not mean that you cannot listen to comments the participant makes about her problems. State that it sounds like she has some important concerns, and that you would like to address them at the end of the interview. If she is emotionally upset, however, the interview may need to be postponed in light of that distress. You should always try to administer the behavioral and adherence assessments according to the visit checklists in the Study-specific Procedures Manual (SSP). If this is not possible, contact FHI and SCHARP, and they will advise you how to manage these instances. If you are in a situation that you are not sure how to handle, call your supervisor. If a participant talks about incorrect facts regarding HIV/STD transmission,

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use a brochure or other site resource to go over the facts with the participant **after** administering the assessments.

Question Order: Questions must be read in the order they appear on each assessment. Read each question verbatim, that is, word-for-word as written. If the participant wants the question repeated, read it again verbatim. If the participant does not understand, ask her to give it her best answer, based on her current interpretation. The exception is if a participant asks about a term that is defined in the QxQ. If the participant asks, “Do you mean _____?” respond “yes” or “no.” You should be clear on all definitions prior to administering these assessments. Looking items up in the QxQ takes time away from the interview and could affect your rapport with the participant.

Participants may, of course, refuse to answer specific questions. However, you should encourage them to respond by reminding them of the confidential nature of the interview and the importance of the information. In addition, you should remind the participant that there is no right or wrong answer. If, after reminding them of this, they still wish to refuse a question, that is okay; record the refusal and move on. If the participant offers an “I don’t know” answer, respond with, “Well, let me repeat the question...” If the participant is wavering back and forth between two responses reply, “Which do you think is the answer that best applies for you?”

Showcards: Some questions have accompanying showcards with the answer choices listed, which the participant can look at, refer to, and study. Provide the cards at the time the question is read. In addition, read the answer choices aloud to the participant while indicating with your finger which response you are reading. Read all possible answers on the showcard to the participant before recording an answer; if a participant interrupts while you are reading the showcard, wait until she is done and continue with the list. Although some categories are very close in meaning, the participant must select the one (and only one) that best applies. When you have finished reading all the response options, remove your fingers/hands so as not to inadvertently indicate a response. When the participant responds, remove the showcard.

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The Interview

1. Before you administer these assessment CRFs to a participant, record on the form her participant ID, the Visit Date, and, when required, the Visit Code.
2. Welcome the participant and make her feel as comfortable as possible.
3. Begin each interview with a general statement that lets the participant know what to expect in the next few minutes, such as: "I'm now going to administer a behavior questionnaire." Depending on the participant and the situation, the introductory statement on the assessment itself may be enough to accomplish this goal.
4. For some participants, sitting across the table/desk from them is appropriate and feels to be the best option. For others, it may help them feel more comfortable to sit beside you. Either method is fine. What's important is making the participant feel as comfortable as possible.
5. Don't read the CRF titles or question numbers aloud to the participants.
6. As you read the questions, vary your tone of voice, so that you don't sound automated. Emphasize the important words in an item (words or phrases that are **bolded**), so that the meaning of the question comes through.
7. Avoid re-phrasing items because this can change the meaning of the item, making it inconsistent with another participant's interview.
8. Do not read the 'N/A (not applicable)' responses to participants. These are for our coding only.
9. Do NOT read the response categories aloud on questions that give that specific instruction (for example, Q6 on the Oral Product Adherence and Behavior Assessment and Q6 on the Vaginal Product Adherence and Behavior Assessment).
10. If a question has an "other, specify" option, but you are not allowed to read response categories aloud, wait for the participant to answer the question. If she does not answer the question with a response that is listed, ask the participant to

- be specific or use one of the following: “give me an example”, or “such as...” or “tell me the specifics.”
11. If a participant gives a response that fits in the “other, specify” option, record the response in the local language and, *after* the interview, translate the response into English (if it wasn’t given in English during the interview) on the line provided in the CRF.
 12. If a participant interrupts you, let her know you need to finish the question.
 13. If a question has multiple yes/no responses, pause following each question to allow a response. For example, in the Menstrual Practices and Study Disclosure Assessment, Q2, a participant is offered the chance to answer yes or no to each item in Q2a-Q2e. Read each sub-question and pause while waiting for the participant to answer “yes” or “no” before moving on to the next sub-question.
 14. Sometimes participants get uncomfortable if you look up at them, especially with certain questions. Use your social judgment and monitor the participant’s responses (verbal and nonverbal) to gauge the most comfortable posture for a given participant.
 15. If the participant looks confused, unsure, uncomfortable, say, “Let me re-read the question,” and re-read it *verbatim*. Pause again and wait for a response.
 16. When asking for a participant’s best guess, be sure to ask, “What is your best guess?” rather than “Could you give me your best guess?”
 17. Remember that silence is a probe. Sometimes, when giving the participant time to think, the silence alone will prompt a response – or a question.
 18. Always proceed to the next sub-question or question unless an appropriate skip pattern is indicated by an arrow (→) and instructions on the form.
 19. Before you end the assessment session, be sure to take a moment to review all pages for any errors, skipped questions, or inconsistencies. Be sure to correct any errors, skipped items that should have been answered, or reconcile inconsistencies before the participant leaves.

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20. When the interview has finished, thank the participant for her time and effort in answering the questions.

GLOSSARY

Female condom: a polyurethane sheath with two rings at either end. One ring goes into the vagina and anchors the condom, the other stays outside the vagina. A man can then place his penis in the female condom as he enters the woman's vagina.

Gel: an almost clear jelly-like substance.

Male condom: a latex or polyurethane sheath, sometimes called a "rubber," that is put onto a man's erect penis, prior to his penis entering the vagina or anus, for birth control.

Primary sex partner: a man with whom a woman has sex on a regular basis, such as a boyfriend, husband, someone with whom she lives, or someone she is more serious about than other partners.

Items used during menstrual periods: forms or types of absorbent materials, such as paper, tissue, toilet paper, cloths, and rags used to absorb blood flow during menstruation.

Sanitary pad: a (commercial) product made of absorbent material that women can buy at the store. Women can place it in their underwear and use it to absorb the blood flow during their menstrual period. Women usually throw away the pad and replace it with a new one every 4-6 hours."

Tampon: cotton or other material some women insert in their vagina during their menstrual period to absorb the blood flow.

Vaginal sex: when a male partner puts his penis inside a woman's vagina.

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Question by Question (Q x Q) Instructions MTN 003**Baseline Behavior Assessment**

Read the introductory statement.

Proceed to **Q1**.

Q1. If further clarification is needed say, “I am going to read a list of people with whom you may have talked about your participation in this research study. You can answer ‘yes’ to more than one person on the list.”

Q1a: If further clarification is needed, say “By primary sex partner, I mean a boyfriend, a husband, someone with whom you live, or a male sex partner that you are more serious about than other sex partners.” If the participant states that she does not have a primary sex partner, mark the “N/A” box.

Q1b: If clarification is needed, say “someone else that you have sex with other than your primary sex partner.” If the participant states that she does not have other sex partners, mark the “N/A” box.

Q1e: If clarification is needed, say “someone besides the family members I already asked about, such as your aunt, uncle, cousin, niece, nephew, etc.”

Q1g: If clarification is needed say, “any medical professional who you have talked to who is not involved in this research study.”

Q1i: If “anyone else” prompts a “yes” response from the participant, ask her to specify who it was and write down her verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the

translation on the “English” line. If the participant reports talking with any of the people listed in 1a-h, do not record them in the response to Q1i. Instead, update the response(s) to Q1a-h, as applicable.

Read statement before **Q2**.

Proceed to **Q2**.

Q2. Emphasize “**past four weeks**”. If further clarification is needed say, “in the past 28 days.”

Read statement before **Q3**.

Proceed to **Q3**.

Q3. Emphasize “**past 7 days**”. If clarification is needed indicate that the past 7 days do NOT include today. The interviewer can also say “now we are asking about the past seven days” or “in the last week, from last X [insert day of week 8 days ago] to YESTERDAY.” If clarification is needed about “acts of vaginal sex”, say “by ‘acts of vaginal sex’, I mean ‘rounds of vaginal sex’.”

Read statement before **Q3a**.

Proceed to **Q3a**.

Q3a: Read the question and present the participant with the pictures of male and female condoms (**visual aid**). Emphasize “**past 7 days**”. If clarification is needed indicate that the past 7 days do NOT include today. The interviewer can also say “now we are asking about the past seven days” or “in the last week, from last X [insert day of week 8 days ago] to YESTERDAY.” If clarification is needed about “acts of vaginal sex”, say “by ‘acts of vaginal sex’, I mean ‘rounds of vaginal sex’.”

NOTE: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise

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or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

NOTE: The number entered here should be less than or equal to the number of times the respondent reported having vaginal sex in **Q3**. If the participant’s response to Q3a is greater than her response to Q3, attempt to resolve the inconsistency by asking the participant for clarification. Correct the responses to Q3 and Q3a as appropriate.

Q4. Read the question and present the participant with the pictures of male and female condoms (**visual aid**). Emphasize “**last act**”. If clarification is needed, indicate that the last act could have happened TODAY. If clarification is needed about “last act of vaginal sex”, say “by ‘last act of vaginal sex’, I mean ‘last round of vaginal sex’.”

NOTE: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

Q4a: Read the question and present the participant with the pictures of male and female condoms (**visual aid**). Emphasize “**last act**”. If clarification is needed, indicate that the last act could have happened TODAY. If clarification is needed about “last act of vaginal sex” say, “by ‘last act of vaginal sex’, I mean ‘last round of vaginal sex’.”

Read statement before **Q5**.

Proceed to **Q5**.

Q5. Emphasize “**past 3 months**”. If further clarification is needed, say “in the past 3 months, between (early/mid/late [insert month that was three months ago] and

now, early/mid/late [insert current month]).” For example, if the interview was being conducted in late January, the interviewer would say “in the past three months, between late October and now, late January.”

Q6. Emphasize “**past 3 months**”. If further clarification is needed, say “I am going to read a list of items that you may have used during your menstrual period in the past 3 months. You can answer ‘yes’ to more than one item on the list.”

Q6a: If clarification is needed about what “put inside the vagina” means say “inserted inside the vagina.” If clarification is needed about the type of items referred to in the question, say “Non-commercial items such as newspaper or other kinds of paper, tissue, toilet paper, rags, cloths or other kinds of absorbent materials.” Only mark the “yes” box if the participant reports that she inserted at least one of these items inside her vagina in the past 3 months.

Q6b: Only mark the “yes” box if the participant reports use outside the vagina (placed in the underwear). If clarification is needed about the type of items referred to in the question, say “Items such as newspaper or other kinds of paper, tissue, toilet paper, rags, cloths or other kinds of absorbent materials.”

Q6c: If more clarification is needed, say “A tampon is a commercial product usually made of cotton that women insert in their vagina during their menstrual period to absorb the blood flow.”

Q6d: If more clarification is needed, say “A sanitary pad is product made of absorbent material that women can buy at the store. Women can place it in their underwear and use it to absorb the blood flow during their menstrual period. Women usually throw away the pad and replace it with a new one every 4-6 hours.”

Q6e: If “anything else” prompts a “yes” response from the participant, ask her to specify what it was and write down her verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line. If the participant reports using any of the items listed in Q6a-d, do not record these in the response to Q6e. Instead, update the response(s) to Q6a-d, as applicable.

Read the statement after Q6.

End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

Remember to complete items 7-9a after the interview.

Question by Question (Q x Q) Instructions MTN 003**Oral Product Adherence and Behavior Assessment**

Before the interview, **check study records to see if the participant has permanently discontinued study product use or is currently on a temporary product hold.** If the participant permanently discontinued study product use 4 or more weeks ago, or has been on a product hold for the past 4 or more weeks, do not administer or complete questions 4-17 of this form.

Read the introductory statement.

Read the statement before **Q1.**

Proceed to **Q1.**

Q1. Emphasize **“past 3 months”**. If further clarification is needed, say “in the past 3 months, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]).” For example, if the interview was being conducted in late January, the interviewer would say “in the past three months, between late October and now, late January.”

Read statement before **Q2.**

Proceed to **Q2.**

Q2. Emphasize **“past 7 days”**. If clarification is needed indicate that the past 7 days do NOT include today. The interviewer can also say “now we are asking about the past seven days” or “in the last week, from last X [insert day of week 8 days ago] to YESTERDAY.” If clarification is needed about “acts of vaginal sex”, say “by ‘acts of vaginal sex’, I mean ‘rounds of vaginal sex’.”

Read statement before **Q2a.**

Proceed to **Q2a.**

Q2a: Read the question and present the participant with the pictures of male and female condoms (**visual aid**). Emphasize **“past 7 days”**. If clarification is

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needed indicate that the past 7 days do NOT include today. The interviewer can also say “now we are asking about the past seven days” or “in the last week, from last X [insert day of week 8 days ago] to YESTERDAY.” If clarification is needed about “acts of vaginal sex”, say “by ‘acts of vaginal sex’, I mean ‘rounds of vaginal sex’.”

NOTE: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

NOTE: The number entered here should be less than or equal to the number of times the respondent reported having vaginal sex in **Q2**. If the participant’s response to Q2a is greater than her response to Q2, attempt to resolve the inconsistency by asking the participant for clarification. Correct the responses to Q2 and Q2a as appropriate.

Q3. Read the question and present the participant with the picture of male and female condoms (**visual aid**). Emphasize “**last act**”. If clarification is needed, indicate that the last act could have happened TODAY. If clarification is needed about “last act of vaginal sex”, say “by ‘last act of vaginal sex’, I mean ‘last round of vaginal sex’.”

NOTE: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

Q3a: Read the question and present the participant with the picture of male and female condoms (**visual aid**). Emphasize “**last act**”. If clarification is needed, indicate that the last act could have happened TODAY. If clarification is needed

about “last act of vaginal sex”, say “by ‘last act of vaginal sex’, I mean ‘last round of vaginal sex’.”

Remember: If the participant permanently discontinued study product 4 or more weeks ago or has been on a study product hold for the past 4 or more weeks, skip questions 4-17 of this questionnaire and go to the statement above **Q18**.

Read statement before **Q4**.

Proceed to **Q4**.

Q4. State that the next few questions will ask about “the past four weeks”. Read the question and emphasize “**past 4 weeks**”. If further clarification is needed say “in the past 28 days.” Read each response category aloud. Present the participant with the picture of the different times of day (**visual aid**). If further clarification is needed, probe by saying “By the same time of day, I mean how often did you take your tablets in the morning each day? Or how often did you take your tablets in the afternoon each day? Or how often did you take your tablets in the evening each day? Or how often did you take your tablets at bedtime each day? Or how often did you take your tablets after breakfast each day?” etc. Use the “other” category for cases in which the participant reports taking the tablets at different times of day each day, or for cases in which the participant takes the lighter tablets at a different time of day than the darker tablets. If the participant’s response indicates “other”, ask her to specify when she took her pills and write down her verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line.

Q5. Read the question and emphasize “**past 4 weeks**”. Present the appropriate showcard and read each response category aloud, indicating each with your finger

- as you read the response. Leave the showcard out and wait for the participant's response.
- Q6.** Read the lead-in (the first sentence of the question) one time and **do not** read any of the response categories (6a-6k) aloud. Read the question. Emphasize “**past 4 weeks**”. Mark all applicable boxes that correspond to each reason reported by the participant. Remind the participant to state all possible reasons. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant's verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line. If the participant has trouble coming up with a response, probe by saying “Has there been anything or anyone in your daily life, or anything you have done, that has helped you to remember to take your tablets in the past 4 weeks?”
- Q7.** Read the lead-in (the first sentence of the question) one time and **do not** read any of the response categories (7a-7p) aloud. Read the question and emphasize “**past 4 weeks**”. Mark all applicable boxes that correspond to each reason reported by the participant. Remind the participant to state all possible reasons. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant's verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line. If the participant has trouble coming up with a response, probe by saying “Has there been any circumstance in your daily life, anything you have done, or anyone that has prevented you from taking your tablets in the past 4 weeks?”
- Q8.** Read the question and emphasize “**past 4 weeks**”. Present the appropriate showcard and read each response category aloud, indicating each with your finger

- as you read the response. Leave the showcard out and wait for the participant's response.
- Q9.** Emphasize “**past 4 weeks**”. Emphasize “**number of days in a row**” as well as “**not**” and “**both**”. If more clarification is needed say “during how many **consecutive days** did you none or only one tablet?”
- Q10.** Read the lead-in (the first sentence of the question) one time and **do not** read any of the response categories (10a-10k) aloud. Read the question and emphasize “**more than one of each tablet** per day”. Emphasize “**past 4 weeks**”. Emphasize “**all of the reasons**”. Emphasize “**more than one of either tablet**”. Mark all applicable boxes that correspond to each reason reported by the participant. Remind the participant to state all possible reasons. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant's verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview), and record the translation on the “English” line. If the participant has trouble coming up with a response, probe by saying “Has there been any circumstance in your daily life, anything you have done, or anyone that has led you to take more than one lighter tablet or more than one darker tablet on a single day in the past 4 weeks?”
- Q11.** Emphasize “**past 4 weeks**”. Emphasize “**lighter tablet**”. Emphasize “**more than once**”.
- Q12.** Emphasize “**past 4 weeks**”. Emphasize “**darker tablet**”. Emphasize “**more than once**”.

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Q13. Read the question and emphasize “**past 4 weeks**”. Present the appropriate showcard and read each response category aloud, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response. If the participant needs clarification, say “ Please choose the response category that best corresponds to how well you were able to take your tablets over the past 4 weeks exactly as you were told by the study staff.”

Read the statement before **Q14** and emphasize “**past 7 days**”. If clarification is needed indicate that the past 7 days do NOT include today. If clarification is needed, say “in the last week, from last X [insert today’s day of week] to YESTERDAY.”

Proceed to **Q14**.

Q14a: Emphasize “**no tablets**”. Re-emphasize “past 7 days” as needed.

Q14b: Emphasize “the **lighter** tablet and **not** the darker tablet”. Re-emphasize “past 7 days” as needed.

Q14c: Emphasize “the **darker** tablet and **not** the lighter tablet”. Re-emphasize “past 7 days” as needed.

Q14d: Emphasize “**both** tablets”. Re-emphasize “past 7 days” as needed.

Proceed to **Q15**.

Q15a: Emphasize “the **lighter** tablet”. Emphasize “**more than once** per day”. Re-emphasize “past 7 days” as needed.

Read the statement before **Q16** and emphasize “**last time**”. If the participant needs clarification say “The last time can be today or any prior day. I am asking about the most recent time you took the tablets.”

Proceed to **Q16**.

Q16. Emphasize “**last time**”. Emphasize “the **darker** tablet”.

Q17. Emphasize “**last time**”. Emphasize “the **lighter** tablet”.

Read statement before **Q18**.

Proceed to **Q18**.

Q18. Emphasize “**past 3 months**”. Read response list (18a to 18h) and check the appropriate box for each response. If further clarification is needed say “in the past 3 months, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). For example, if the interview was being conducted in late January, the interviewer would say “in the past three months, between late October and now, late January.” If further clarification is needed say “I am going to read a list of people with whom you may have had problems as a result of being in this study. You can answer ‘yes’ to more than one of them.”

Q18h: If “anyone else” prompts a “yes” response from the participant, ask her to specify who it was and write down her verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line. If the participant reports problems with people already listed in Q18a-g, do not record them in the response to Q18h. Instead, update the response(s) to Q18a-g, as applicable.

Remember: If a participant answers “no” to all of the people in Q18a-h, end the interview. Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

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Q19. Depending on whether the participant reported *one or more* problems in 18a-h, say “**has this** problem...” or say “**have any of these** problems...”

Q19a: Emphasize “**emotional harm**”.

Q19b: Emphasize “**physical harm**”.

Q19c: Emphasize “**economic/financial harm**”.

Q19d: Emphasize “**physical or other harm**”. Emphasize “**your children**”.

Q20. Ask the participant to provide additional information and details about the problem. Probe as needed. Summarize the participant’s response in the local language and record it on the “Local Language” line. **The response should be the site interviewer’s summary of the problem, rather than the participant’s verbatim (word-for-word) response.** After the interview translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line.

End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

If at least one of the participant’s responses to Q18a-h is “yes”, remember to complete items 21-21a after the interview.

Question by Question (Q x Q) Instructions MTN 003**Vaginal Product Adherence and Behavior Assessment**

Before the interview, **check study records to see if the participant has permanently discontinued study product use or is currently on a temporary product hold.** If the participant permanently discontinued study product use 4 or more weeks ago, or has been on a product hold for the past 4 or more weeks, do not administer or complete questions 4-14 of this form.

Read the introductory statement.

Read the statement before **Q1.**

Proceed to **Q1.**

Q1. Emphasize **“past 3 months”**. If further clarification is needed, say “in the past 3 months, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). For example, if the interview was being conducted in late January, the interviewer would say “in the past three months, between late October and now, late January.”

Read statement before **Q2.**

Proceed to **Q2.**

Q2. Emphasize **“past 7 days”**. If clarification is needed, indicate that the past 7 days do NOT include today. The interviewer can also say “now we are asking about the past seven days” or “in the last week, from last X [insert day of week 8 days ago] to YESTERDAY.” If clarification is needed about “acts of vaginal sex”, say “by ‘acts of vaginal sex’, I mean ‘rounds of vaginal sex’.”

Read statement before **Q2a.**

Proceed to **Q2a.**

Q2a: Read the question and present the participant with the picture of male and female condoms (**visual aid**). Emphasize **“past 7 days”**. If clarification is

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needed, indicate that the past 7 days do NOT include today. The interviewer can also say “now we are asking about the past seven days” or “in the last week, from last X [insert today’s day of week] to YESTERDAY.” If clarification is needed about “acts of vaginal sex”, say “by ‘acts of vaginal sex’, I mean ‘rounds of vaginal sex’.”

NOTE: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

NOTE: The number entered here should be less than or equal to the number of times the respondent reported having vaginal sex in **Q2**. If the participant’s response to Q2a is greater than her response to Q2, attempt to resolve the inconsistency by asking the participant for clarification. Correct the responses to Q2 and Q2a as appropriate.

Q3. Read the question and present the participant with the picture of male and female condoms (**visual aid**). Emphasize “**last act**”. If clarification is needed, indicate that the last act could have happened TODAY.

If clarification is needed about “last act of vaginal sex”, say “by ‘last act of vaginal sex’, I mean ‘last round of vaginal sex’.”

NOTE: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

Q3a: Read the question and present the participant with the picture of male and female condoms (**visual aid**). Emphasize “**last act**”. If clarification is needed, indicate that the last act could have happened TODAY.

If clarification is needed about “last act of vaginal sex”, say “by ‘last act of vaginal sex’, I mean ‘last round of vaginal sex’.”

.Remember: If the participant permanently discontinued study product 4 or more weeks ago or has been on a study product hold for the past 4 or more weeks, skip questions 4-14 of this questionnaire and go to the statement above **Q15**.

Read statement before **Q4**.

Proceed to **Q4**.

Q4. State that the next few questions will ask about “the past four weeks”. Read the question and emphasize “**past 4 weeks**”. If further clarification is needed say “in the past 28 days.” If further clarification is needed about what is meant by “insert”, say “By ‘insert’, I mean putting the gel inside your vagina.”

Read each response category aloud. Present the participant with the picture of the different times of day (**visual aid**). If further clarification is needed, probe by saying “By the same time of day, I mean how often did you take your tablets in the morning each day? Or how often did you take your tablets in the afternoon each day? Or how often did you take your tablets in the evening each day? Or how often did you take your tablets at bedtime each day? Or how often did you take your tablets after breakfast each day?” etc. Use the “other” category for cases in which the participant reports taking the tablets at different times of day each day, or for cases in which the participant takes the lighter tablets at a different time of day than the darker tablets. If the participant’s response indicates “other”, ask her to specify when she took her pills and write down her verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line.

Q5. Read the question. Emphasize “**past 4 weeks**.” Present the showcard and read each response category aloud, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.

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- Q6.** Read the lead-in (the first sentence of the question) one time and **do not** read any of the response categories (6a-6j) aloud. Read the question and emphasize “**past 4 weeks.**” Mark all applicable boxes that correspond to each reason reported by the participant. Remind the participant to state all possible reasons. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line. If the participant has trouble coming up with a response, probe by saying “Has there been anything or anyone in your daily life, or anything you have done that has helped you to remember to insert your gel in the past 4 weeks?”
- Q7.** Read the lead-in (the first sentence of the question) one time and **do not** read any of the response categories (7a-7p) aloud. Read the question and emphasize “**past 4 weeks.**” Mark all applicable boxes that correspond to each reason reported by the participant. Remind the participant to state all possible reasons. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line. If the participant has trouble coming up with a response, probe by saying “Has there been any circumstance in your daily life, anything you have done, or anyone that has prevented you from inserting your gel in the past 4 weeks?”
- Q8.** Read the question and emphasize “**past 4 weeks.**”. Present the appropriate showcard and read each response category aloud, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response.

- Q9.** Emphasize “**past 4 weeks**”. Emphasize “**number of days in a row**” as well as “**not** insert the gel”. If more clarification is needed say “During how many **consecutive days** did you not insert the gel?”
- Q10.** Read the lead-in (the first sentence of the question) one time and **do not** read any of the response categories (10a-10k) aloud. Read the question and emphasize “**more than once** per day”. Emphasize “**past 4 weeks**”. Emphasize “**all** of the reasons”. Emphasize “**more than once** on any single day”. Mark all applicable boxes that correspond to each reason reported by the participant. Remind the participant to state all possible reasons. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line. If the participant has trouble coming up with a response, probe by saying “Has there been any circumstance in your daily life, anything you have done, or anyone that has led you to insert the gel more than once per day?”
- Q11.** Emphasize “**past 4 weeks**”. Emphasize “**more than once**”.
- Q12.** Read the question and emphasize “**past 4 weeks**”. Present the appropriate showcard and read each response category aloud, indicating each with your finger as you read the response. Leave the showcard out and wait for the participant’s response. If the participant needs clarification say “Please choose the response category that best corresponds to how well you were able to insert your gel over the past 4 weeks exactly as you were told by the study staff.”

Read statement before **Q13.** Emphasize “**past 7 days**”. If clarification is needed indicate that the past 7 days do NOT include today. If clarification is needed, say “in the last week, from last X [insert today’s day of week] to YESTERDAY.”

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Proceed to **Q13**.

Q13a: Emphasize “**not** insert gel”. Re-emphasize “past 7 days” as needed.

Q13b: Emphasize “**once** per day”. Re-emphasize “past 7 days” as needed.

Q13c: Emphasize “**more than once** per day”. Re-emphasize “past 7 days” as needed.

Read statement before **Q14**. Emphasize “**last time**”. If participant needs clarification say “The last time can be today or any prior day. I am asking about the most recent time you inserted the gel.”

Proceed to **Q14**.

Q14. Emphasize “**last time**”.

Read statement before **Q15**.

Proceed to **Q15**.

Q15. Emphasize “**past 3 months**”. If further clarification is needed say “in the past 3 months, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). For example, if the interview was being conducted in late January, the interviewer would say “in the past three months, between late October and now, late January.” If further clarification is needed say “I am going to read a list of people with whom you may have had problems as a result of being in this study. You can answer ‘yes’ to more than one of them.”

Q15h: If “anyone else” prompts a “yes” response from the participant, ask her to specify who it was and write down her verbatim (word-for-word) response in the

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local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line. If the participant reports problems with people already listed in Q15a-g, do not record them in the response to Q15h. Instead, update the response(s) to Q15a-g, as applicable.

Remember: If a participant answers “no” to all of the people in Q15a-h, end the interview. Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

Q16. Depending on whether the participant reported *one or more* problems in 15a-h, say “**has this** problem...” or say “**have any of these** problems...”

Q16a: Emphasize “**emotional harm**”.

Q16b: Emphasize “**physical harm**”.

Q16c: Emphasize “**economic/financial harm**”.

Q16d: Emphasize “**physical or other harm**”. Emphasize “**your children**”.

Q17. Ask the participant to provide additional information and details about the problem. Probe as needed. Summarize the participant’s response in the local language and record it on the “Local Language” line. **The response should be the site interviewer’s summary of the problem, rather than the participant’s verbatim (word-for-word) response.** After the interview translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line.

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End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

If at least one of the participant's responses to Q15a-h is "yes", remember to complete Q18-18a after the interview.

Question by Question (Q x Q) Instructions MTN 003**Menstrual Practices and Study Disclosure Assessment**

Read the introductory statement.

Proceed to **Q1**.

Q1. Emphasize “**past 3 months**”. If further clarification is needed say “in the past 3 months, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]).” For example, if the interview was being conducted in late January, the interviewer would say “in the past three months, between late October and now, late January.”

Q2. Emphasize “**past 3 months**”. If further clarification is needed say “I am going to read a list of items that you may have used during your menstrual period. You can answer ‘yes’ to more than one item on the list.”

Q2a: If clarification is needed about what “put inside the vagina” means say “inserted inside the vagina.” If clarification is needed about the type of items referred to in the question, say “Non-commercial items such as newspaper or other kinds of paper, tissue, toilet paper, rags, cloths or other kinds of absorbent materials.” Only mark the “yes” box if the participant reports that she inserted at least one of these items inside her vagina in the past 3 months.

Q2b: Only mark the “yes” box if the participant reports use outside the vagina (placed in the underwear). If clarification is needed about the type of items referred to in the question, say “Items such as newspaper or other kinds of paper, tissue, toilet paper, rags, cloths or other kinds of absorbent materials.”

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Q2c: If more clarification is needed, say “A tampon is a commercial product usually made of cotton that women insert in their vagina during their menstrual period to absorb the blood flow.”

Q2d: If more clarification is needed, say “A sanitary pad is product made of absorbent material that women can buy at the store. Women can place it in their underwear and use it to absorb the blood flow during their menstrual period. Women usually throw away the pad and replace it with a new one every 4-6 hours.”

Q2e: If “anything else” prompts a “yes” response from the participant, ask her to specify what it was and write down her verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation in the space provided. If the participant reports using any of the items listed in Q2a-d, do not record these in the response to Q2e. Instead, update the response(s) to Q2a-d, as applicable.

Read the statement above **Q3**.

Proceed to **Q3**.

Q3. Emphasize “**past year**”. If further clarification is needed say “I am going to read a list of people with whom you may have talked about your participation in this research study. You can answer ‘yes’ to more than one person on the list.”

Q3a: If further clarification is needed, say “By main partner I mean a boyfriend, husband, someone with whom you live, or a male sex partner you are more serious about than other sex partners.” If the participant states that she does not have a primary sex partner, mark the “N/A” box.

- Q3b:** If clarification is needed, say “someone else that you have sex with other than your primary male sex partner.” If the participant states that she does not have other sex partners, mark the “N/A” box.
- Q3e:** If clarification is needed say, “someone besides the family members I already asked about, such as your aunt, uncle, cousin, niece, nephew, etc.”
- Q3g:** If clarification is needed, say “any medical professional who you have talked to who is not involved in this research study.”
- Q3i:** If “anyone else” prompts a “yes” response from the participant, ask her to specify who it was and write down her verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line. If the participant reports talking with any of the people listed in Q3a-h, do not record them in the response to Q3i. Instead, update the response(s) to Q3a-h, as applicable.
- Q4.** Read **Q4**. Emphasize “**past year**”. If further clarification is needed say, “I am going to read a list of people with whom you may have talked about the tablets or gel you are using for this study”. You can answer ‘yes’ to more than one of the people on the list.”
- Q4a:** If further clarification is needed, say “By primary sex partner I mean a boyfriend, a husband, someone with whom you live, or a male sex partner you are more serious about than other sex partners.” If the participant states that she does not have a primary sex partner, mark the “N/A” box.
- Q4b:** If clarification is needed, say “someone else that you have sex with other than your primary male sex partner.” If the participant states that she does not have other sex partners, mark the “N/A” box.

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Q4g: If clarification is needed, say “Any medical professional who you have talked to who is not involved in this research study.”

Q5. Emphasize “**past year.**” If further clarification is needed, say “By primary sex partner I mean a boyfriend, a husband, someone with whom you live, or a male sex partner you are more serious about than other sex partners.”

Q5d: If this question prompts a “yes” response from the participant, ask her to provide clarification and write down her verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line. If the participant reports a reason already listed in Q5a-c, do not record that the reason in the response Q5d. Instead, update the response(s) to Q5a-c, as applicable.

End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

Question by Question (Q x Q) Instructions MTN 003
Study Exit Behavior Assessment

Read the introductory statement.

Read the statement before **Q1**.

Proceed to **Q1**.

Q1. Emphasize “**past 2 months**”. If further clarification is needed say “in the past 2 months, between (early/mid/late [insert month that was two months ago] and now, early/mid/late [insert current month]). For example, if the interview was being conducted in late January, the interviewer would say “in the past two months, between late November and now, late January.”

Read statement before **Q2**.

Proceed to **Q2**.

Q2. Emphasize “**past 7 days**”. If clarification is needed indicate that the past 7 days do NOT include today. The interviewer can also say “now we are asking about the past seven days” or “in the last week, from last X [insert day of week 8 days ago] to YESTERDAY.” If clarification is needed about “acts of vaginal sex”, say “by ‘acts of vaginal sex’, I mean ‘rounds of vaginal sex’.”

Read statement before **Q2a**.

Proceed to **Q2a**.

Q2a: Read the question and present the participant with the pictures of male and female condoms (**visual aid**). Emphasize “**past 7 days**”. If clarification is needed indicate that the past 7 days do NOT include today. The interviewer can also say “now we are asking about the past seven days” or “in the last week, from last X [insert today’s day of week] to YESTERDAY.” If clarification is needed about

“acts of vaginal sex”, say “by ‘acts of vaginal sex’, I mean ‘rounds of vaginal sex’.”

NOTE: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

NOTE: The number entered here should be less than or equal to the number of times the respondent reported having vaginal sex in **Q2**. If the participant’s response to Q2a is greater than her response to Q2, attempt to resolve the inconsistency by asking the participant for clarification. Correct the responses to Q2 and Q2a as appropriate.

Q3. Read the question and present the participant with the pictures of male and female condoms (**visual aid**). Emphasize “**last act**”. If clarification is needed, indicate that the last act could have happened TODAY.

If clarification is needed about “last act of vaginal sex”, say “by ‘last act of vaginal sex’, I mean ‘last round of vaginal sex’.”

NOTE: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

Q3a: Read the question and present the participant with the pictures of male and female condoms (**visual aid**). Emphasize “**last act.**” If clarification is needed, indicate that the last act could have happened TODAY. If clarification is needed about “last act of vaginal sex”, say “by ‘last act of vaginal sex’, I mean ‘last round of vaginal sex’.”

Read statement before **Q4**.

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Proceed to **Q4**.

Q4. Emphasize “**past 2 months**”. If further clarification is needed say “in the past 2 months, between (early/mid/late [insert month that was two months ago] and now, early/mid/late [insert current month]). For example, if the interview was being conducted in late January, the interviewer would say “in the past two months, between late November and now, late January.” If further clarification is needed say “I am going to read a list of people with whom you may have had problems as a result of being in this study. You can answer ‘yes’ to more than one of the people on the list.”

Q4h: If “anyone else” prompts a “yes” response from the participant, ask her to specify who it was and write down her verbatim (word-for-word) response in the local language in which she responded. After the interview, translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line. If the participant reports problems with people already listed in Q4a-g, do not record them in the response to Q4h. Instead, update the response(s) to Q4a-g, as applicable.

Remember: If a participant answers “no” to all of the people in Q4a-h, end the interview. Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

Q5. Depending on whether the participant reported one or more problems in Q4a-4h, say “**has this** problem...” or say “**have any of these** problems...”.

Q5a: Emphasize “**emotional harm**”.

Q5b: Emphasize “**physical harm**”.

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Q5c: Emphasize “**economic/financial harm**”.

Q5d: Emphasize “**physical or other harm**”. Emphasize “**your children**”.

Q6. Ask the participant to provide additional information and details about the problem. Probe as needed. Summarize the participant’s response in the local language and record it on the “Local Language” line. **The response should be the site interviewer’s summary of the problem, rather than the participant’s verbatim (word-for-word) response.** After the interview translate the response into English (if it was not given in English during the interview) and record the translation on the “English” line.

End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

Question by Question (Q x Q) Instructions MTN 003
Perceived Product Assessment

Item-specific Instructions:

- Q1.** Complete this question (**only if the participant is in the oral** group) prior to the interview.
- Q2.** Complete this question (**only if the participant is in the vaginal** group) prior to the interview.
- Q3. Remember:** This question is asked only of those women in the oral group. If further clarification is needed, say “take your best guess at which study product you were given: tenofovir tablets, Truvada tablets, or placebo tablets?”
- Q4. Remember:** This question is asked only of those women in the vaginal group. If further clarification is needed, say “take your best guess at which study product you were given: tenofovir gel, or placebo gel?”

End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.

Question by Question (Q x Q) Instructions MTN 003**Monthly Product Adherence and Behavior Assessment**

Before the interview, **check study records to see if the participant permanently discontinued study product use or is currently on a temporary product hold.** If the participant permanently discontinued study product use 7 or more days ago, or has been on a product hold for the past 7 or more days, do not administer or complete questions 3-4b of this form.

Read the introductory statement.

Read the statement before **Q1.**

Proceed to **Q1.**

Q1. Emphasize “**past 4 weeks.**” If further clarification is needed say “in the past 28 days.” If clarification is needed say “By vaginal sex I mean when a man puts his penis inside your vagina.”

Q2. Read the question aloud and present the participant with the pictures of the male and female condoms (**visual aid**). Emphasize “**last act**”. If clarification is needed, indicate that the last act could have happened TODAY. If clarification is needed about “last act of vaginal sex”, say “by ‘last act of vaginal sex’, I mean ‘last round of vaginal sex’.”

NOTE: “Condom use” does not have a strict definition; rather, it is based on the participant’s understanding of what “condom use” means to her. If questions arise or if condoms were used incompletely, say “your answer to this question should be based on your own judgment of whether or not you used condoms during vaginal sex.”

Remember: If the participant permanently discontinued study product use 7 or more days ago or has been on a study product hold for the past 7 or more days, skip questions 3-4b and end the form.

Remember: Question 3 is only asked of participants in the oral group.

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Read statement before **Q3**. Emphasize “**past 7 days**”. If clarification is needed indicate that the past 7 days do NOT include today. If clarification is needed, say “in the last week, from last X [insert today’s day of week] to YESTERDAY.”

Proceed to **Q3**.

Q3a: Emphasize “**no** tablets”. Re-emphasize “past 7 days” as needed.

Q3b: Emphasize “the **lighter** tablet and **not** the darker tablet”. Re-emphasize “past 7 days” as needed.

Q3c: Emphasize “the **darker** tablet and **not** the lighter tablet”. Re-emphasize “past 7 days” as needed.

Q3d: Emphasize “**both** tablets”. Re-emphasize “past 7 days” as needed.

Remember: Question 4 is only asked of participants in the vaginal group.

Q13a: Emphasize “**not** insert gel”. Re-emphasize “past 7 days” as needed.

Q13b: Emphasize “**once** per day”. Re-emphasize “past 7 days” as needed.

Read the statement before **Q4**. Emphasize “**past 7 days**”. If clarification is needed indicate that the past 7 days do NOT include today. If clarification is needed, say “in the last week, from last X [insert today’s day of week] to YESTERDAY.”

Proceed to **Q4**.

Q4a: Emphasize “**not** insert gel”. Re-emphasize “past 7 days” as needed.

Q4b: Re-emphasize “past 7 days” as needed.

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End of form: Review the form for completeness. Clarify any missing or conflicting responses with the participant. Thank the participant for her time and effort in completing the interview.