

Section 13. Data Collection

The purpose of this document is to provide site staff with the information they need to successfully complete and submit MTN 002 case report forms. For questions about this section or about general data collection policies, procedures, or materials, please contact Missy Cianciola <missy@scharp.org>.

For this study, the SDMC (Statistical and Data Management Center) is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, USA, and is in the US Pacific Coast time zone. The SCHARP MTN 002 team members, along with their job role and email address, are listed below.

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13.1 DataFax Overview

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

CRF Transmission

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

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

Data Entry/Quality Control

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

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

If a change is made to a CRF but the updated page is not re-faxed to SCHARP DataFax, the change will **not** be entered and the study database will continue to contain incomplete or incorrect data. Additionally, if the change was prompted by a QC, the QC will continue to appear on subsequent QC reports until the modified CRF is

received at SCHARP. Therefore, it is very important that the site refax updated CRF pages to SCHARP DataFax **any time** a change is made to a CRF, regardless of whether or not the change was made in response to a QC report.

13.2 DataFax Form Completion

13.2.1 Guidelines

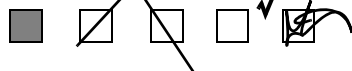
Based on the use of fax technology and Good Clinical Practices (GCPs), the following guidelines should be used for completing DataFax CRFs:

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

13.2.2 How to Mark Response Boxes

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

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

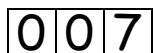
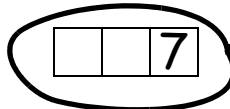
Correct:**Incorrect:**

13.2.3 How to Record Numbers

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

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

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

Correct:**Incorrect:**

→ This example would result in a QC note.

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

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

Correct:**Incorrect:**

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

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

Easily Identified:**Difficult to Identify:**

13.2.4 How to Record Dates

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

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

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

For example, June 6, 2008 is recorded as:

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

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

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

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

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

13.2.5 How to Record Time

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

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

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

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

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

13.2.6 Data Corrections and Additions

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

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

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

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:

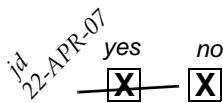
- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it unreadable with multiple cross-outs),
- place the correct or clarified answer near the box, and

- initial and date the correction as shown below:



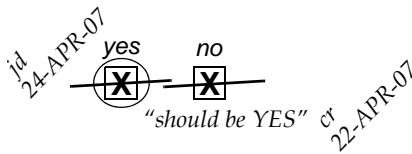
If an **X** is marked in the wrong response box, correct it by doing the following:

- 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:

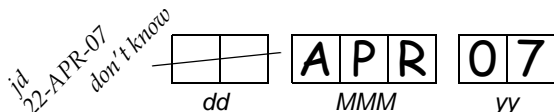


The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is faxed to SCHARP for the first time.

13.2.7 How to Handle Missing and Unknown Data

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

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



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

13.3 MTN 002 Study-Specific Data Collection Information

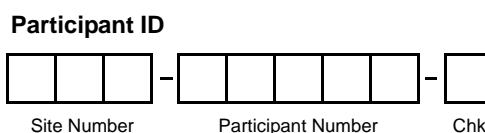
13.3.1 Participant ID numbers (PTIDs)

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

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

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

The PTIDs used for this study are nine digits and formatted as “XXX-YYYYY-Z.” The PTID consists of three parts: the site number (XXX), the participant number (YYYYY), and a numerical check digit (Z). The check digit (Z) is a number generated by SCHARP with the participant number, and helps ensure that the correct PTID is recorded. Below is an example of the PTID structure used in MTN 002.



13.3.2 Study Visit Timing

Screening and Enrollment

The screening and enrollment visit will occur approximately one to four weeks prior to the participant’s scheduled cesarean section (C/S), but no more than four weeks before the expected date of cesarean section.

For MTN 002, a participant is considered enrolled once it has been determined that she is eligible for the study as based on all available screening data. Participants will be considered enrollment into MTN 002 on the same day as the screening and enrollment visit.

If screening laboratory data is received after the screening and enrollment visit, and the laboratory data indicate the participant is not eligible, the site will contact the PSRT to request termination of the participant. If the termination is approved, the site will contact SCHARP for instructions on how to complete case report forms for the termination.

Follow-Up Visits

There are 3 required follow-up visits for this study: the Pharmacokinetic Measures/Gel Administration Day (Day 0) visit, the 24 Hour Evaluation, and the Two Week Phone Call. Per protocol, the 24 Hour Evaluating visit should be completed within between 22 and 26 hours following product administration, and the Two Week Phone Call visit should be completed within Day 10 and 18 following product administration. If these visits are not completed within these allowable time frames (visit windows), the visit is considered “missed.” A Missed Visit case report form is completed and faxed to SCHARP to document that the visit was missed.

Unscheduled (“Interim”) Visits

For this study, an unscheduled clinic visit is considered an “interim visit” when a participant presents at the site for additional clinical/laboratory assessments and/or procedures. An unscheduled/interim visit may occur at any time during study participation, and may be triggered by participant report of a new adverse event occurring between required study visits (i.e., onset of a new adverse experience (AE) between the 24 Hour Evaluation and Two Week Phone Call required visits).

Phone contact with a participant is also considered an unscheduled/interim visit if the phone contact results in reporting of a new AE.

Unscheduled/interim visits where DataFax CRF data are collected are assigned an interim visit code as described in section 13.3.3. The interim visit is documented using the Interim Visit case report form.

It is anticipated that there will be very few interim visits for this study. As such, detailed instructions for CRF completion for interim visits is not provided. For questions about assignment of visit codes and completion of case report forms for interim visits, please contact the SCHARP MTN 002 Project Manager.

13.3.3 Visit Codes and Page Numbers

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

MTN 002 has four scheduled study visits. When visit code boxes are provided, site staff are responsible for entering the visit code in the boxes provided in the upper right corner of each page.

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

Table 13-1: Visit Timing and Visit Codes

Visit Type	Visit Timing	Visit Code
Screening and Enrollment	Up to Day -28	01.0
Pharmacokinetic Measures/Gel Administration Day	Day 0	02.0
24 Hour Evaluation	Hour 22-26	03.0
Two-Week Phone Call	Day 10 to 18	04.0

Visit codes for interim visits

In addition to the scheduled, protocol-required visits listed in Table 13-1, interim visits may occur once the participant is enrolled (see Section 13.3.2 for a definition and examples of unscheduled/interim visits). Interim visit codes are assigned using the following guidelines:

- In the boxes to the left of the decimal point, record the two-digit visit code for the most recent scheduled visit (whether that visit was completed or missed).
- Use the guide below to complete the box to the right of the decimal point:

- ##.1 = the first interim visit after the most recent scheduled visit,
- ##.2 = the second interim visit after the most recent scheduled visit,
- ##.3 = the third interim visit after the most recent scheduled visit, and so on.

Example: A participant returns to the site clinic two days after she has completed her 24 Hour Evaluation visit (Visit Code = 03.0). The visit window of her Two Week Phone Call visit has not yet opened. For this interim visit, record the following visit code:

Visit Code for this Interim Visit:

Visit Code .

Page numbers

Other CRFs, such as log forms (e.g., Adverse Experience Log, Concomitant Medications 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). Assign numbers in sequential order (for example, the second Concomitant Medications Log page would be assigned page number 02, the third page would be assigned 03, and so on).

13.3.4 Staff Initials/Date

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

13.3.5 Form Completion Schedule

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

Some SCHARP-provided forms are required to be completed at each visit, while other forms are required only at one visit or only when specifically indicated. The following table (Table 13-2) lists the DataFax and non-DataFax forms that are required to be completed at each study visit.

Table 13-2: MTN 002 Form Completion Schedule

SCREENING AND ENROLLMENT (Up to Day -28)		VISIT CODE: 01.0
Acronym	Form Name	
ENR-1	Enrollment	
DEM-1	Demographics	
PE-1	Pelvic Exam	
Non-DataFax	Pelvic Exam Diagrams	
PRE-1	Pre-existing Conditions	
CM-1	Concomitant Medications Log	
Non-DataFax	Study Eligibility	
Non-DataFax	Targeted Physical Exam	
PHARMACOKINETIC MEASURES: GEL ADMINISTRATION DAY (Day 0)		VISIT CODE: 02.0
Acronym	Form Name	
SV-1	MTN 002 Study Visit	
PK-1	Pharmacokinetics	
PE-1	Pelvic Exam	
Non-DataFax	Pelvic Exam Diagrams	
Non-DataFax	Targeted Physical Exam	
CDI-1	C-section Delivery Information	
FC-1	Flow Cytometry	
Non-DataFax	MTN 002 Maternal PK LDMS Specimen Tracking Sheet	
Non-DataFax	MTN 002 C-section LDMS Specimen Tracking Sheet	
24 HOUR EVALUATION (Hour 22 – 26)		VISIT CODE: 03.0
Acronym	Form Name	
SV-1	MTN 002 Study Visit	
TWO WEEK PHONE CALL (Day 10 to 18)		VISIT CODE: 04.0
Acronym	Form Name	
SV-1	MTN 002 Study Visit	
PER-1	Participant Evaluability and Replacement	
ESI-1	End of Study Inventory	
TM-1	Termination	
IF NEEDED		WILL VARY
Acronym	Form Name	
AE-1	Adverse Experience Log	
MV-1	Missed Visit	
IV-1	Interim Visit	

13.3.6 Site Review of DataFax Forms

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

- Other than the participant ID number (PTID), there is no information on the form that could identify the participant (e.g., name, phone number, national identification number, or any other personal identifiers).
- A response has been recorded for each item, unless the item was skipped as instructed by a skip pattern or the item was marked as missing or unknown as described in 13.2.7.
- All text responses are clearly recorded.
- There are no marks on or above the DataFax barcode at the top of each DataFax page.
- There are no:
 - missing dates,
 - missing visit codes,
 - incorrect PTIDs,
 - incorrect visit codes,
 - missing data for items beginning a series of skip patterns, and/or
 - inconsistent or discrepant data.

While CRFs are being reviewed, it is important that they are stored and tracked systematically. It is also necessary to have a system to identify whether a CRF has been faxed to SCHARP DataFax. Such a system may include using a stamp to date the back of the CRF, or utilizing the SCHARP CRF Tracking System (see SSP Section 13.3.7 for more information).

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

13.3.7 Faxing DataFax Forms

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

It is important that the sites fax completed DataFax CRFs to SCHARP within the time period specified in the site's MTN 002 Data Management SOP, and that they respond promptly to requests for clarifications and corrections included in QC reports. Early detection of recurrent problems provides an opportunity to reduce errors and improve data quality.

For sites wishing to confirm the receipt of faxed forms at SCHARP, the CRF Tracking System (CTS) is available. This system generates two types of e-mails listings: 1) the number of form pages received at SCHARP; and 2) which specific forms were received at SCHARP for a given PTID and visit. Please contact the MTN 002 Project Manager if you would like to use the CRF Tracking System or for more information about the CRF Tracking System.

13.3.8 Non-DataFax Forms

MTN 002 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 13.3.1 through 13.3.4 should be applied when completing non-DataFax CRFs.

13.4 Form Supply and Storage

13.4.1 Form and Specimen Label Supply

Prior to site activation, SCHARP will provide the site with 18 MTN 002 study participant notebooks. Each notebook contains a tabbed section for each of the 4 study visits. Each section contains all required CRFs for that visit. In addition, a tab for Adverse Experience Log forms is provided a, along with a tab for Concomitant Medication Log forms. SCHARP will also provide the site with bulk supplies of “if needed” CRFs, such as Interim Visit and Missed Visit CRFs.

In the case where a study notebook is assigned to a participant who does not enroll in the study (for example, the Screening and Enrollment visit is started, but the participant is found to be ineligible for the study), please contact the SCHARP MTN 002 Project Manager so that SCHARP can provide you with additional Screening and Enrollment Visit CRFs. Also, please contact the SCHARP MTN 002 Project Manager if any additional CRF supplies are needed for the study.

SCHARP is supplying the site with pre-printed specimen labels to be used on all primary specimen collection containers. One sheet for each PTID is provided, the sheet containing all of the labels needed for the duration of the participant’s study participation (including PK specimens). Please refer to the Laboratory section of the manual for more information on laboratory specimen collection and labeling.

13.5 Case Report Forms and Form-specific Completion Instructions

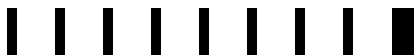
This section contains each MTN 002 case report forms developed for the study. On the back of each case report form are form-specific completion instructions. These instructions include the purpose of each form as well as how each form should be completed. Some items on forms are straightforward and do not require specific instructions. Therefore, you will not see all the items listed in the form-specific completion instructions, but rather, only those items needing detailed explanation.

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

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

- For the **Pre-existing Conditions** and **Concomitant Medication Log** forms, note that you should fax each page to SCHARP any time a new entry is added or modified, even if the page is not complete. You should **not** wait to complete all entries on a page before faxing to SCHARP.
- For the **Adverse Experience Log** form, do **not** wait until the AE resolves before faxing the form page to SCHARP. In most cases, when you first report the AE on an AE Log form, the AE will have a “continuing” status (form item 6). Once the AE resolves (the AE resolves, the AE is grade 5 - death, or the AE increases in severity/frequency), update item 6 and 6a of the **original** AE Log form page. Initial and date all additions, and refax the form page to SCHARP.
- Always make changes, corrections, and updates to the originally-completed **Adverse Experience Log** form page. Once an AE Log form page has been started and faxed to SCHARP, the data from that page should **never** be transcribed onto another AE Log form page. All updates and corrections should be made to the originally-completed form page (regardless of how messy or crowded the form page becomes).
- Note that for item 3 of the **Adverse Experience Log** form, the Female Genital Grading Table for Use in Microbicide Studies (Female Genital Tox Table) will be used to assign severity grades to AEs (in addition to the DAIDS Tox Table referred to in the form completion instructions. The Female Genital Tox Table is Appendix V of the protocol (the “protocol Specific Toxicity Table).
- There may be a situation where an AE reported on an **Adverse Experience Log** form needs to be deleted (in the case where the AE is later found to actually be a pre-existing condition, for example). If you have a situation where you need to mark for delete an AE Log form, please contact the MTN 002 Project Manager for instructions.
- On the **Adverse Experience Log** form, note that the Visit Code recorded in item 10 is the visit code assigned to the visit date in the “Date Reported to Site” field.

SAMPLE. Do NOT FAX
TO DATAFAX



MTN 002 (147)

DEM-1 (001)

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	

Demographics

Visit Date

<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 participant's date of birth?..... → If unknown, record age:
dd MMM yy years

male female

2. What is the participant's gender?

3. Does the participant consider herself to be Latina or of Hispanic origin?
yes no

4. What does the participant report as her race? *Mark all that apply.*

- 4a. American Indian or Alaskan Native
- 4b. Asian
- 4c. Black or African American
- 4d. Native Hawaiian or other Pacific Islander
- 4e. White
- 4f. other, specify: _____
(Note: Latina is not a race.)

Demographics (DEM-1)

Purpose: To document participant demographic information.

General Information/Instructions: This form is completed only once for each study participant, at the Screening/Enrollment visit.

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record participant's estimate of their age. Do not complete both answers.
- **Item 2:** This item does not require a response. This item (gender) has been hard-coded as "female" for all study participants.
- **Item 4:** Record the participant's race based on self-definition. In the case of mixed race, mark all that apply and/or "other" and indicate the mixed race background.

SAMPLE *Do NOT FAX*
TO DATAFAX



MTN 002 (147)

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

Visit Date

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

1. Date study informed consent signed or marked:

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

2. Is the participant eligible, based on assessment of all study inclusion and exclusion criteria?

yes

no

**If no, participant is not eligible.
End of form. Do not fax to
SCHARP DataFax.**

2a. Date of enrollment:

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

Comments: _____

Enrollment (ENR-1)

Purpose: This form is used to document participant enrollment into the study.

General Information/Instructions: This form is completed only once for each participant, at the Screening/Enrollment visit.

Item-specific Instructions:

- **Item 2a:** The date the participant was determined to be eligible for the study.

Pelvic Exam (PE-1)

Purpose: To document pelvic exams conducted during the study.

General Information/Instructions: This form is completed each time a pelvic exam is performed.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.

SAMPLE. DO NOT FAX
TO DATAFAX

MTN 002 (147)



CDI-1 (080)

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	

C-section/Delivery Information

Form Completion Date

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

1. Infant gestational age: *weeks*
dd *MMM* *yy* *hr* *min*
2. Skin incision: :
3. Infant delivery: :
4. Infant birth weight: *grams*
5. APGAR score at 1 minute:
6. APGAR score at 5 minutes:
7. APGAR score at 10 minutes: *not done*
8. Infant gender: *male* *female*

Comments: _____

C-section/Delivery Information (CDI-1)

Purpose: To document C-section/delivery details and information on infant status.

General Information/Instructions: This form is completed once for each study participant, when the delivery and infant information is available.

Item-specific Instructions:

- **Item 1:** Record infant gestational age in completed weeks.
- **Items 2 and 3:** When recording time, use a 24-hour clock (e.g., 8:12 p.m. is recorded as 20:12).

SAMPLE *Do NOT FAX*
TO DATAFAX

MTN 002 (147)



SV-1 (075)

Visit Code

.

Participant ID

- -

Site Number

Participant Number

Chk

MTN 002 Study Visit

Visit Date

dd

MMM

yy

1. Were any **new** adverse experiences reported at this visit? *yes* *no* → **If no, end of form.**

1a. How many **new** AE Log pages were completed for this visit? # of pages

Comments: _____

MTN 002 Study Visit (SV-1)

Purpose: To document the completion of the required Pharmacokinetic Measures/Gel Administration Day, 24-hour, and Two-week Phone Call visits and whether any new adverse experiences were reported.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Item 1:** 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 **1a** 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 11 of these two AE Log pages should be the same as the Visit Code recorded on this form.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code

. 0

1

MTN 002 (147)

PK-1 (061)

Participant ID

- -

Site Number Participant Number Chk

Pharmacokinetics

Visit Date

dd MMM yy

1. Participant height: cm
2. Participant weight: kg

MATERNAL BLOOD COLLECTION AND GEL ADMINISTRATION

Not done/
Not collected

- | | | <i>dd</i> | <i>MMM</i> | <i>yy</i> | <i>hr</i> | <i>min</i> |
|--------------------------|--|----------------------|----------------------|----------------------|----------------------|----------------------|
| <input type="checkbox"/> | 3. Pre-gel blood draw: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> | 4. Gel administration: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> | 5. 1-hour post-gel blood draw: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> | 6. 2-hour post-gel blood draw: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> | 7. 4-hour post-gel blood draw: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> | 8. 6-hour post-gel blood draw: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> | 9. 8-hour post-gel blood draw: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> | 10. 12-hour post-gel blood draw: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> | 11. 24-hour post-gel blood draw: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

STORED SPECIMEN COLLECTION

Not done/
Not collected

- | | | <i>dd</i> | <i>MMM</i> | <i>yy</i> | <i>hr</i> | <i>min</i> |
|--------------------------|-------------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| <input type="checkbox"/> | 12. Amniotic fluid: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> | 13. Cord blood: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> | 14. Placental tissue: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> | 15. Endometrial tissue: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Comments: _____

10-DEC-07

01

Language

Staff Initials / Date

Pharmacokinetics (PK-1)

Purpose: To document pharmacokinetics and stored specimen collection as well as study gel administration information.

General Information/Instructions: This form is completed once for each study participant, at the Pharmacokinetic Measures/Gel Administration visit (Day 0).

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Items 1 and 2:** Use leading zeros when needed.
- **Items 3–15:** When recording time, use a 24-hour clock (e.g., 8:12 p.m. is recorded as 20:12). If any of the specimens/procedures listed in items 3–15 were not collected or performed (or collected and not stored for items 12–15), mark the “Not done/Not collected” box and record the reason in the comments section at the bottom of the form.
- **Item 11:** Note that the 24-hour post-gel blood draw, which is technically part of the 24-hour Evaluation visit, appears on this form, which is completed at the Pharmacokinetic Measures/Gel Administration visit (Day 0). The 24-hour post-gel blood draw has been included here in order to have complete PK data on one form.

SAMPLE *DO NOT FAX*
TO DATAFAX

MTN 002 (147)



FC-1 (064)

Visit Code .

Participant ID

- -
Site Number Participant Number Chk

Flow Cytometry

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

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

1. FLOW CYTOMETRY

Not done/ Not collected

1a. Lymphocytes %
%

Absolute Count
cells/mm³

Not done/ Not collected

1b. CD4 (CD3/CD4) AND *MFI*

1c. CD38 (CD3/CD4/CD38) . AND AND

1d. CD95 (CD3/CD4/CD95) . AND AND

Comments: _____

Flow Cytometry (FC-1)

Purpose: To document flow cytometry laboratory results.

General Information/Instructions: This form is completed once for each study participant, at the Pharmacokinetic Measures/Gel Administration Visit (Day 0).

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.

SAMPLE *DO NOT FAX*
TO DATAFAX



MTN 002 (147)

PER-1 (145)

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 Evaluability and Replacement

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. Is this participant evaluable? That is, did she receive study gel and have a Cesarean delivery within 8 hours of gel administration? yes no

└─▶ **If yes, end of form.**

2. Why is this participant not evaluable?

- she did not receive study gel
- she received study gel but her time of Cesarean delivery was greater than 8 hours following the time of gel administration
- other, specify: _____

3. Will this participant be replaced? yes no

Comments: _____

Participant Evaluability and Replacement (PER-1)

Purpose: To document whether the participant was evaluable based on study criteria and, if not, whether she was replaced.

General Information/Instructions: This form is completed once for each enrolled study participant, and is completed once it is determined if the participant is evaluable.

Item-specific Instructions:

- **Item 1:** Mark “yes” if the participant met both criteria listed in item 1. If the participant met only one or neither of the criteria in item 1, mark the “no” box.
- **Item 2:** Mark the reason the participant is not evaluable. If the “other, specify” box is marked, specify the reason the participant is not evaluable in the space provided.
- **Item 3:** If item 3 is “no,” record the reason the non-evaluable participant will not be replaced in the comments field at the bottom of the form.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN 002 (147)

Participant ID

Site Number			Participant Number						Chk	

Study Eligibility

Form Completion Date

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

- | | | |
|--|--------------------------|--------------------------|
| | <i>yes</i> | <i>no</i> |
| 1. Is the participant age 18–45 years at screening and enrollment, inclusive, and verified per site standard operating procedure (SOP)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Is the participant willing and able to provide written informed consent for screening and enrollment? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Is the participant in general good health as determined by the site Investigator of Record (IoR) or designee at the Screening and Enrollment Visit? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Is the participant HIV-uninfected (per HIV Testing Algorithm, Appendix II)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Is the participant HBsAg negative at the Screening and Enrollment Visit, or documented negative during this pregnancy? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Is the participant pregnant with the following characteristics: | <i>yes</i> | <i>no</i> |
| 6a. viable? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6b. singleton? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6c. without ultrasound evidence of significant fetal congenital anomaly (in the opinion of the IoR or designee)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6d. term (37 0/7 to 41 6/7 weeks, inclusive, with gestational dating criteria per SOP) at the time of planned cesarean section? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6e. planned cesarean section? | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Does the participant have a normal pap (or completed evaluation of abnormal Pap) in the 12 calendar months prior to screening per SOP? | <i>yes</i> | <i>no</i> |
| | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Is the participant willing to: | <i>yes</i> | <i>no</i> |
| 8a. abstain from vaginal sex, anal sex, and receptive oral sex for at least 2 weeks after gel placement? | <input type="checkbox"/> | <input type="checkbox"/> |
| 8b. abstain from intravaginal practices (including douching) during study participation? | <input type="checkbox"/> | <input type="checkbox"/> |
| 8c. not participate in other drug or device study during study participation? | <input type="checkbox"/> | <input type="checkbox"/> |
| 8d. participate as required by protocol, including study product administration, assessments and follow-up schedule? | <input type="checkbox"/> | <input type="checkbox"/> |

If no to any, participant is ineligible.

Study Eligibility – Page 1 of 2 (nonDF)

Purpose: This form is used to document participant eligibility for the MTN 002 study.

General Information/Instructions: This form is completed only once for each participant, at the Screening/ Enrollment visit. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN 002 (147)

Participant ID

Site Number			Participant Number						Chk	

Study Eligibility

- | | yes | no |
|---|--------------------------|--------------------------|
| 9. Does the participant have a maternal or fetal condition that necessitates urgent cesarean section (e.g., active labor, non-reassuring fetal heart tracing)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Does the participant have documented rupture of the amniotic membranes, as defined in the SOP? | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Does the participant have known maternal disease with predictable negative affect on placental function (e.g., hypertension, diabetes mellitus, collagen vascular disease, clinically significant maternal anemia)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Does the participant have known placental/fetal abnormalities that could affect placental transfer (e.g., placental abruption, placenta previa, placenta accreta, intrauterine growth restriction, two vessel cord, etc.)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Is the participant's serum creatinine at Screening and Enrollment Visit greater than 1.0 mg/dL? | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Is the participant's AST and/or ALT at screening greater than 1.5 ULN (upper limit of normal)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Does the participant have current or recent (within 48 hours) use of vaginal medications at the Screening and Enrollment visit (per participant report)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. Does the participant currently have an untreated sexually transmitted infection or (as applicable) exposure to partner's infection, including chlamydia, gonorrhea, trichomoniasis, non-gonococcal urethritis? | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. Does the participant have symptomatic vaginitis, including bacterial vaginosis and vulvovaginal candidiasis? | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. Is the participant known to have participated in any other investigational drug or device trial within 30 days prior to enrollment visit? | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. At screening or enrollment, does the participant have any social or medical condition that, in the investigator's opinion, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives? | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. Does the participant have previously demonstrated hypersensitivity to any components of tenofovir 1% gel? | <input type="checkbox"/> | <input type="checkbox"/> |

If yes to any, participant is ineligible. ←

Study Eligibility – Page 2 of 2 (nonDF)

Item-specific Instructions:

- **Items 13 and 14:** Complete these items once the laboratory results are available. If these items are completed after the “Form Completion Date” recorded on page 1, be sure to initial and date these entries.
- **Item 16:** Per protocol, women diagnosed with an STI during screening or in the process of enrollment are eligible for enrollment once they have completed treatment(s) and are asymptomatic for the STI(s). If the participant is diagnosed with an STI during screening or enrollment, this item should originally be marked “yes.” Once treatment is completed and the participant is asymptomatic, this item should be updated to “no.”

SAMPLE *Do NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN 002 (147)

Participant ID

Site Number			Participant Number				Chk	

Targeted Physical Exam

Exam Date

dd		MMM			yy	

VITAL SIGNS

1. Were vital signs done? *yes* *no*
 → **If no, specify:** _____

Oral Temp . °C

BP / mmHg

Pulse per minute

Vital Signs: Staff Initials / Date

FINDINGS

not evaluated *normal* *abnormal*

Items 2 and 3 are required. If not evaluated or abnormal, please specify.

 2. General appearance _____

 3. Abdomen _____

Items 4–15 are optional. If abnormal, please specify.

 4. HEENT _____

 5. Neck _____

 6. Lymph Nodes _____

 7. Heart _____

 8. Lungs _____

 9. Extremities _____

 10. Neurological _____

 11. Skin _____

 12. Breast Exam _____

 13. Other, specify: _____

 14. Other, specify: _____

 15. Other, specify: _____

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

Findings: Staff Initials / Date

10-DEC-07

01
Language

Targeted Physical Exam (non-DataFax)

Purpose: To document the participant's vital signs and targeted physical exam findings.

General Information/Instructions: This form is completed each time a targeted physical exam is performed. Because this is a non-DataFax form, do NOT fax to SCHARP DataFax.

Item-specific Instructions:

- **Vital Signs:** Use leading zeros when needed. The staff member who completes these items should initial and date in the space provided.
- **Findings:** The staff member who completes these items should initial and date in the space provided.
- **Items 13–15:** Use these items to list any additional organ systems that were evaluated. If no other organ systems other than the ones listed in items 2–12 were evaluated, mark items 13–15 as “not evaluated.”

SAMPLE *Do NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN 002 (147)

Participant ID

- -

Site Number Participant Number Chk

Pelvic Exam Diagrams

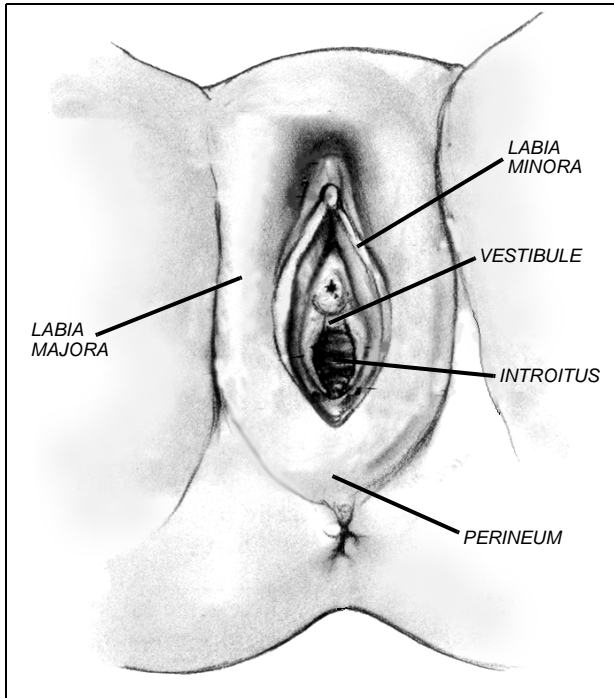
no normal variants or abnormal findings observed

Exam Date

/ /

dd MMM yy

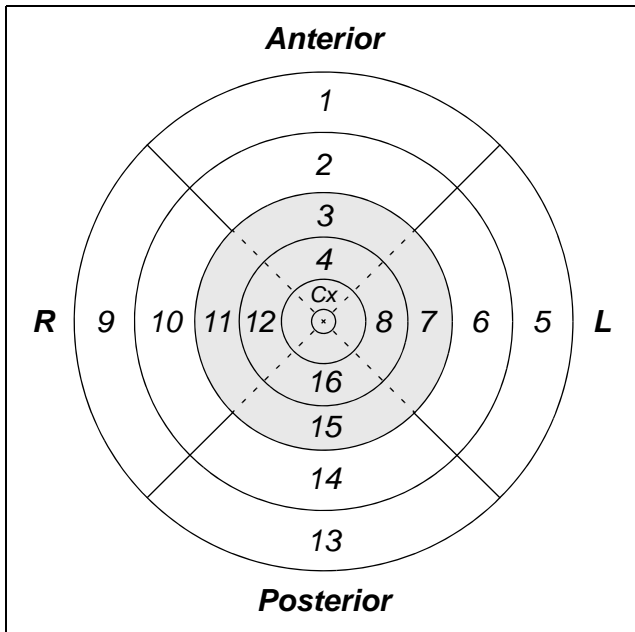
External Genitalia



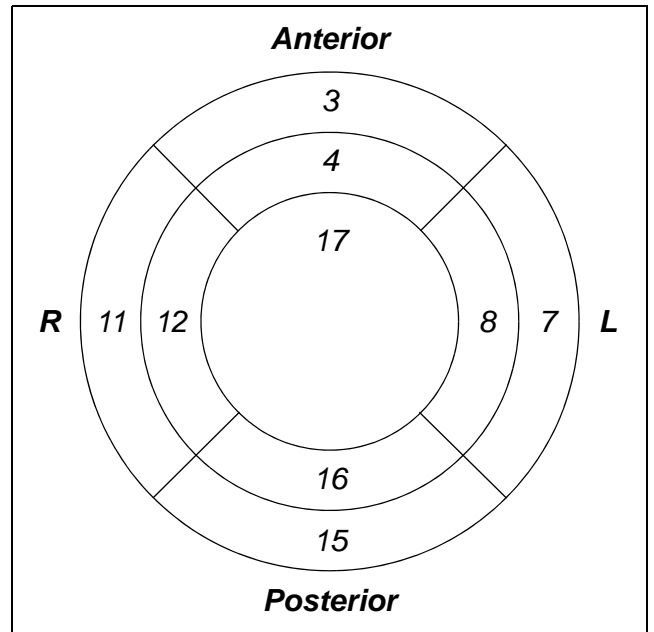
Legend for Vagina/Cervix

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

Vagina



Cervix



10-DEC-07

Language

Staff Initials / Date

Pelvic Exam Diagrams (non-DataFax)

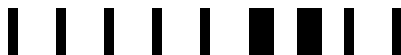
Purpose: To document all variants of normal and all abnormal findings observed during study pelvic exams.

General Information/Instructions: This form is completed each time a pelvic exam is performed. Because this is a non-DataFax form, do NOT fax to SCHARP DataFax.

Item-specific Instructions:

- All variants of normal (normal findings) and all abnormal findings must be documented on this form. 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



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

MTN 002 (147)

PRE-1 (012)

Participant ID

- -

Site Number Participant Number Chk

Pre-existing Conditions

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

- | | | | |
|-----------------------|-----------------------------------|--|---|
| 1. Description | <i>MMM</i> | <i>yy</i> | |
| | Date of Diagnosis/ Surgery | <input type="text"/> <input type="text"/> <input type="text"/> | <input type="text"/> <input type="text"/> |
| Comments | Is condition ongoing? | yes <input type="checkbox"/> no <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"/> <input type="text"/> |
| Comments | Is condition ongoing? | yes <input type="checkbox"/> no <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"/> <input type="text"/> |
| Comments | Is condition ongoing? | yes <input type="checkbox"/> no <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"/> <input type="text"/> |
| Comments | Is condition ongoing? | yes <input type="checkbox"/> no <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"/> <input type="text"/> |
| Comments | Is condition ongoing? | yes <input type="checkbox"/> no <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"/> <input type="text"/> |
| Comments | Is condition ongoing? | yes <input type="checkbox"/> no <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.
- **Is condition ongoing?:** Mark "yes" if condition is ongoing at enrollment.
- **Pre-existing Conditions Revisions and Updates:**
 - If a participant recalls a pre-existing condition at a later date, update the form at that time. Refax updated page(s).

SAMPLE. DO NOT FAX TO DATAFAX



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

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

MTN 002 (147)

AE-1 (420)

Participant ID

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

Adverse Experience Log

Date Reported to Site

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

1. Adverse Experience (AE)

2. Onset Date

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

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

3. Severity

4. Relationship to Study Product

5. Study Product Administration

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

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

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

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

6. Status/Outcome

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

- 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

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

- 8. Is this AE serious according to ICH guidelines? yes no
- 9. Has/will this AE be reported as an EAE? yes no
- 10. Was this AE a worsening of a pre-existing condition? yes no

- 11. This AE was first reported at visit: [][] [][] . [] Visit code required (regular or interim).
- 12. Is this AE reported for the mother or the infant? mother infant

Comments: _____

Adverse Experience Log (AE-1)

Any Adverse Experience (AE) reported by the participant or clinically observed after initiation of study product, regardless of whether or not it is related to study product, must be documented any time during study participation.

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.

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.

Adverse Experience (AE): 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.”

Onset Date: 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.

Severity: To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences*.

Relationship to Study Product:

- **Definitely related:** The adverse event and administration of study agent are related in time, and a direct association can be demonstrated.
- **Probably related:** The adverse event and administration of study agent are reasonably related in time, and the adverse event is more likely explained by study agent than other causes.
- **Possibly related:** The adverse event and administration of study agent are reasonably related in time, and the adverse event can be explained equally well by causes other than study agent.
- **Probably not related:** A potential relationship between study agent and the adverse event could exist (i.e., the possibility cannot be excluded), but the adverse event is most likely explained by causes other than the study agent.
- **Not related:** The adverse event is clearly explained by another cause not related to the study agent.
- **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.

Study Product Administration: N/A (not applicable) should be marked if the AE occurred after the participant had completed all administration of the study agent, or the study product is held or discontinued for a different AE or other reason, or the AE is Grade 5 - death.

Status/Outcome:

- **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 this box 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.

Status/Outcome Date: 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.

AE Revisions and Updates:

- 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).

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*



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

Page

MTN 002 (147)

CM-1 (423)

Participant ID

- -
 Site Number Participant Number Chk

Concomitant Medications Log

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

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

Medication (generic name)		Time Administered <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 24-hr clock hour:minutes		OR <input type="checkbox"/> N/A	
Indication					Staff Initials/Log Entry Date
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		OR <input type="checkbox"/> Continuing at end of study	
Dose/Units		Route PO IM IV TOP IHL VAG REC other, specify: <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"/>			
Frequency Mark only one.		<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			
		<input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____			
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"/>

Medication (generic name)		Time Administered <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 24-hr clock hour:minutes		OR <input type="checkbox"/> N/A	
Indication					Staff Initials/Log Entry Date
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		OR <input type="checkbox"/> Continuing at end of study	
Dose/Units		Route PO IM IV TOP IHL VAG REC other, specify: <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"/>			
Frequency Mark only one.		<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			
		<input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____			
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"/>

Medication (generic name)		Time Administered <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 24-hr clock hour:minutes		OR <input type="checkbox"/> N/A	
Indication					Staff Initials/Log Entry Date
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		OR <input type="checkbox"/> Continuing at end of study	
Dose/Units		Route PO IM IV TOP IHL VAG REC other, specify: <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"/>			
Frequency Mark only one.		<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			
		<input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____			
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"/>

10-DEC-07

Language

Concomitant Medications Log (CM-1)

Purpose: To document all medication(s) that are used by the participant during the study other than study product. 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. For MTN 002, this form also captures blood products/transfusions.

General Information/Instructions: This form is faxed: 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 at the time of the Screening or Enrollment visit. Record “Staff Initials/Date.”
- **No medications taken throughout study:** Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study. Record “Staff Initials/Date.”
- **Medication:** Record the generic name for all medications. For combination medications, record the generic names of the first three main active ingredients.
- **Time Administered:** Time administered is required for all medications taken/administered up until 24 hours following the administration of the study gel. Record time administered using a 24-hour clock (e.g., 8:12 p.m. is recorded as 20:12). Midnight is recorded as 00:00. For medications taken/administered more than 24 hours following administration of the study gel, mark the “N/A” box.
- **Indication:** For health supplements, such as multivitamins, record “general health.” For preventive medications, record “prevention of [insert condition]” (e.g., for flu shot, record “prevention of influenza”). For recreational drugs, record “recreation.”
- **Date Started:** If the participant is unable to recall the exact date, obtain participant’s best estimate. At a minimum, the year is required.
- **Date Stopped:** At the participant’s Termination visit, the “Date Stopped” must be recorded for each medication OR the “Continuing at end of study” box must be marked. At a minimum, the month and year is required.
- **Dose/Units:** If the participant does not know the dose or units, draw a single line through the blank response boxes and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).

Route Abbreviations:

PO oral	IM intramuscular	IV intravenous	TOP topical	IHL inhaled	VAG vaginal	REC rectal
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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	qxh every x hours

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

SAMPLE. Do NOT FAX
TO DATAFAX

MTN 002 (147)



IV-1 (350)

Visit Code .

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
- 1b. phone call from participant to report new symptoms
- 1c. other, specify: _____

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

- 2a. none —▶ ***If none, end of form.***
- 2b. Adverse Experience Log (AE-1)
 - 2b1. How many new AE Log pages were completed for this visit? # of pages
- 2c. other, specify: _____

Comments: _____

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.

Item-specific instructions:

- **Item 2b1:** If any new AE Log pages were completed for AEs newly reported/diagnosed at this visit, record the number of AE Log pages completed at this visit. That is, record the number of AE Log pages with an interim visit code in item 11 that matches the Interim Visit code assigned to this interim visit.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code

. 0

1

MTN 002 (147)

MV-1 (463)

Participant ID

- -

Missed Visit

Form Completion Date

Site Number

Participant Number

Chk

dd

MMM

yy

dd

MMM

yy

1. Target Visit Date:

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

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

Comments: _____

Missed Visit (MV-1)

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

General Information/Instructions: If the QC Report indicates that a visit is overdue, confirm that the visit was missed before completing a Missed Visit form. Fax this form when it is determined that a visit has been missed and cannot be completed within the visit window. Record the Visit Code of the visit that was missed. Record the date that the form was completed. This will not necessarily be the date of the missed visit. A complete date is required.

Item-specific Instructions:

- **Item 1:** Record the target date of the visit. A complete date is required.
- **Item 2:** Record the reason the participant missed the visit.

SAMPLE. *DO NOT FAX*
TO DATAFAX



MTN 002 (147)

ESI-1 (489)

Participant ID

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

End of Study Inventory

Form Completion Date

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

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

visit code

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

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

of interim visits

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

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

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

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

OR *no pages submitted*

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

Comments: _____

End of Study Inventory (ESI-1)

Purpose: 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 participant has terminated from the study (as documented by a Termination form).

Item-specific Instructions:

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

Termination (TM-1)

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

Item-specific Instructions:

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

MTN 002 Maternal PK- LDMS Specimen Tracking Sheet

For login of MTN 002 stored specimens into LDMS

Participant ID

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

Site Number

Participant Number

Chk

Visit Code

--	--	--

PK SPECIMEN TIME POINT	PRIMARY SPECIMEN TYPE	DATE COLLECTED dd-MMM-yy	TIME COLLECTED hh:mm 24-hr clock	NUMBER OF TUBES COLLECTED	INSTRUCTIONS FOR PROCESSING LAB
Pre-Gel	Maternal Blood (BLD)			<input type="checkbox"/> Non (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER
1 Hour	Maternal Blood (BLD)			<input type="checkbox"/> Non (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER.
2 Hour	Maternal Blood (BLD)			<input type="checkbox"/> Non (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER
4 Hour	Maternal Blood (BLD)			<input type="checkbox"/> Non (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER
6 Hour	Maternal Blood (BLD)			<input type="checkbox"/> Non (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER
8 Hour	Maternal Blood (BLD)			<input type="checkbox"/> Non (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER
12 Hour	Maternal Blood (BLD)			<input type="checkbox"/> Non (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER
24 Hour	Maternal Blood (BLD)			<input type="checkbox"/> Non (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER Enter into LDMS with Visit Code 03.0

Comments: _____

Initials: _____

Sending Staff

Receiving Staff

LDMS Data Entry Date: _____

--	--

dd

--	--	--	--

MMM

--	--

yy

/

LDMS Staff

MTN 002 Maternal PK- LDMS Specimen Tracking Sheet

For login of MTN 002 stored specimens into LDMS

Maternal PK - LDMS Specimen Tracking Sheet (nonDataFax)

Purpose: This non-DataFax form is used to document collection and entry of MTN 002 maternal PK blood specimens into the Laboratory Data Management System (LDMS).

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

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the LDMS specimens were collected. Use a Visit Code of 02.0 for all specimens except the 24 Hour specimen. The 24 Hour specimen is collected at Visit Code 03.0.
- **NUMBER OF TUBES COLLECTED:** In the box to the left of each additive type, record the total number of tubes collected. If no LDMS specimens of the primary specimen type were collected, record "0."
- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials - Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
- **LDMS Data Entry Date - LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.

MTN 002 C-section- LDMS Specimen Tracking Sheet

For login of MTN 002 stored specimens into LDMS

C-section - LDMS Specimen Tracking Sheet (nonDataFax)

Purpose: This non-DataFax form is used to document collection and entry of MTN 002 c-section stored specimens into the Laboratory Data Management System (LDMS).

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

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the LDMS specimens were collected. Use a Visit Code of 02.0 for all specimens.
- **NUMBER OF TUBES/VIALS COLLECTED:** In the box to the left of each additive type, record the total number of tubes or vials collected. If no LDMS specimens of the primary specimen type were collected, record "0."
- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials - Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
- **LDMS Data Entry Date - LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.