

10. Data Collection

The purpose of this document is to provide site staff with the information they need to successfully complete and submit MTN-011 case report forms. For questions about this section or about general data collection policies, procedures, or materials, please contact the SCHARP Project Manager for the study as listed below.

The SDMC (Statistical and Data Management Center) for this study is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, USA, and is in the US Pacific Time (PT) time zone. The SCHARP MTN-011 team members, along with their job role and e-mail address, are listed below.

MTN-011 Statistical and Data Management Center (SDMC) Staff

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10.1 DataFax Overview

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

CRF Transmission

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

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

Data Entry/Quality Control

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

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

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

10.2 DataFax Form Completion

10.2.1 General Guidelines

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

- Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool. Use only one color per form. That is, do not begin completing a form using a blue pen and then switch to a black pen during the same form completion session.
- Press firmly when recording data or writing comments.
- Print all data and comments legibly by hand. Entries that cannot be read will result in QC notes.
- Do not type data onto CRFs. Do not use cursive/script handwriting, as it can be difficult to read.
- Write numbers as large as possible while staying within the boundaries of the boxes.
- Record data on the front of CRFs only. DataFax cannot read the back of CRFs.
- Do not record data or make marks in the 0.5-inch/1.5-cm margins at the top, bottom, or sides of the CRF.
- If the lines provided for written responses are not long enough, continue in another blank area of the form (within the page margins).
- Mark only one answer except when given the instruction "Mark all that apply."
- A response is required for every item unless instructed otherwise by a skip pattern.
- **Never** obscure, mark over, or punch holes through the barcode at the top of each CRF. DataFax requires the barcode to identify the CRF.
- **Never** use correction fluid ("white-out") or correction tape on CRFs.
- Remove any paper clips, staples, or other attachments before faxing CRFs.

- The site staff person who initially completes the form **must** record his/her initials **and** the date in the space provided in the bottom right-hand corner of each CRF page.
- Fax forms as soon as possible after they have been completed and reviewed. Ideally, completed forms will be faxed to SCHARP within 1–2 days of completing the visit, though up to 5 days is allowed.

10.2.2 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.



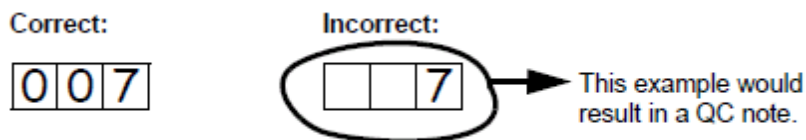
Mark only one response box for each item unless the “Mark all that apply” instruction is present.

10.2.3 How to Record Numbers

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

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

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



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

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



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

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

Easily Identified:

0 1 2 3 4 5 6 7 8 9

Difficult to Identify:

Ø 1 2 3 4 7

10.2.4 How to Record Dates

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

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

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

For example, June 6, 2012 is recorded as:

06 JUN 12
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:

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

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

O	C	T	1	1
<i>MMM</i>			<i>yy</i>	

10.2.5 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

12-hour clock (a.m.)	24-hour clock		12-hour clock (p.m.)	24-hour clock
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

10.2.6 Data Corrections and Additions

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

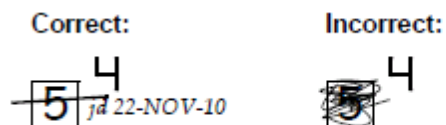
It is important to make these changes to the original CRF—**never** copy data onto a new form. After making the change, the CRF *must* be re-faxed to SCHARP DataFax.

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

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

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

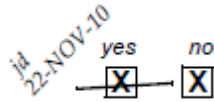
- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it un-readable with multiple cross-outs),
- place the correct or clarified answer near the box, and
- initial and date the correction as shown below:



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

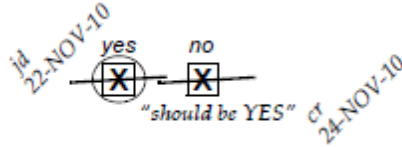
- draw a single horizontal line through the incorrectly marked box,
- mark the correct box, and

- 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:

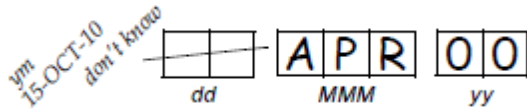


The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is faxed to SCHARP for the first time.

10.2.7 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.

10.2.8 Non-DataFax Forms

Non-DataFax forms are case report forms that are used for data documentation purposes, but are not faxed to SCHARP. These forms are created to ensure consistent and accurate data documentation across study sites for data that is not needed in the study database. Non-DataFax form is easily identifiable because there is no DataFax barcode along the top of the CRF. In place of the barcode, the following text appears: “NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.”

Non-DataFax forms are completed using the general guidelines presented above, and completed forms are stored similarly to DataFax forms in participant files/binders.

10.2.9 Faxing DataFax Forms

Each CRF with a bar code at the top is a DataFax form, and is faxed to SCHARP DataFax once completed and reviewed as described in the site's MTN Data Management SOP. Sites are encouraged to develop a system that identifies each time a form page is faxed so that re-faxing of unchanged forms can be avoided. A date stamp used on the back of the form page may be used for this purpose as long as the date stamp does not obscure data recorded on the front of the form page.

For sites wishing to confirm the receipt by SCHARP of faxed forms, 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 for each batch of forms faxed; and 2) which specific individual form pages were received at SCHARP for a given PTID and visit. Please contact the SCHARP DataFax Support Group (support@scharp.org) if you would like to use the CRF Tracking System or for more information about this fax confirmation system.

10.2.10 Form Storage

Specifications for form storage are described in the site's MTN Data Management SOP. It is recommended that for each participant, study CRFs be stored in a hard-cover notebook, with a tabbed section for CRFs completed at each study visit.

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

SCHARP can provide a template for use in creating notebook cover labels and spine labels. SCHARP can also provide a template that can be used to create tab divider labels.

10.2.11 MTN Data Management SOP

As a condition for study activation, each study site must have an SOP for MTN Data Management. This SOP should be reviewed and followed in combination with the information contained in the study protocol, this SSP Manual, and the site's Clinical Quality Management Plan (CQMP).

The MTN Data Management SOP contains information on and outlines site staff responsibilities for several data topics, including:

- Participant ID (PTID) assignment
- Participant study file organization
- Participant confidentiality
- Site data quality control (QC) processes
- Timing of DataFax form data transmission
- SCHARP data QC processes
- Electronically-captured study data
- Data storage

10.3 Study-Specific Data Collection Information

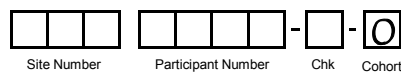
10.3.1 Participant ID numbers (PTIDs)

DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. Prior to study start, SCHARP provides each site with a list of PTIDs to be used for the study in the form of a study-specific MTN PTID Name-Linkage Log. The site assigns one PTID to each participant screened for the study. The PTIDs are assigned in sequential order as participants present for the screening visit. The site should ensure that each PTID is assigned only once. Once a participant has received a PTID, that same PTID is maintained for that participant for the duration of his/her study participation within that study group. If after completing follow-up for one study group, the participant screens and enrolls in another study group, new PTIDs must be assigned to the female and male participants.

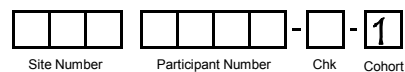
PTID boxes are located near the upper left corner of each CRF page.

The PTIDs used for this study are nine digits and formatted as “WWW-XXXX-Y-Z.” The PTID consists of four parts: the DataFax site number (WWW), the participant number (XXXX), a numerical check digit (Y), and the cohort identifier (Z). The check digit (Y) is a number generated by SCHARP with the participant number, and helps ensure that the correct PTID is recorded. The cohort identifier is used in MTN-011 to identify each participant as the female (0) or the male (1) participant. Below are examples of the PTID structure used in MTN-011.

Female Participant ID



Male Participant ID



10.3.2 Study Visit Timing

Screening and Enrollment

The initial screening visit is defined as the first day one of the participants in the couple provided written informed consent to be screened for the study. The enrollment visit will be scheduled to take place within 30 days of the initial screening visit. The date the couple is enrolled is Study Day 0 for the couple.

Screening Attempts (Re-screens)

If a couple's first screening attempt is unsuccessful, the couple may re-screen a maximum of one time for the study if they choose. If they do re-screen, all screening procedures and forms must be repeated with the exception of PTID assignments. Once a PTID is assigned to a participant that PTID is used for the re-screen procedures and forms completed for that participant (do not assign a new PTID unless the participant is screening for a different study group).

If a couple re-screens and enrolls in the study, only case report forms from the successful screening and enrollment visits are faxed to SCHARP.

Follow-Up Visits

For each follow-up visit, visit type, visit code, target visit day, and visit window are listed in Tables 10-1 and 10-2. Target days and windows are listed in days, with the day of enrollment being Study Day 0.

Target Days and Visit Windows

Whenever possible, visits should be completed on the target day. If not possible to complete the visit on the target day, the visit should be completed within the visit window.

SCHARP will provide sites with a spreadsheet tool that may be used to generate individual couple follow-up visit calendars. The spreadsheet requires that the couple's enrollment date be entered. Once the enrollment date is entered, the target day and visit window for each required follow-up visit will appear. The calendar can then be printed and added to the couple's study notebook. Please note that for several follow-up visits the female participant's last day of menstrual bleeding will also need to be taken into account.

Split Visits

Screening Visit may be split as long as all screening procedures are completed within the allowable 30 day window before enrollment.

Enrollment Visits may not be split. Refer to the Accrual section of this manual for more information regarding Enrollment Visit procedures and timing.

Follow-up visits may not be split. In rare cases where a split visit may be necessary, the site should contact the MTN-011 Management Team for guidance.

Table 10-1: Visit Timing Requirements – Group 1

Group 1: Visit Codes, Visit Types, Target Days, and Windows

Visit Code	Visit Type	Gel/Coitus	Target Day From ENR	Target Day From Prev. Visit	Visit Window (based on previous visit)	Comments
01.0 <i>All ppts</i>	1 Screen	No gel No coitus	n/a	n/a	Up to -30	No more than 30 days prior to planned Enrollment day
02.0 <i>All ppts</i>	2a/2b Enroll	No gel Coitus at visit	0	0	n/a	To take place approx. 2-12 days after last day of menstrual bleeding 2b (sampling) for Females only, to occur approximately 2 hours after coitus
03.0 <i>All ppts</i>	3a/3b	Gel -1 hour Coitus (both at visit)	3-90	+3	+ (3-90)	3b (sampling) for Females only, to occur approximately 2 hours after coitus
04.0 <i>Fem. only</i>	4a/4b	Gel -1 hour (at visit) No coitus	14-146	+11	+ (11-56)	To occur at least 10 days, but not more than 56 days, after Visit 3a/3b, and not while participant is menstruating 4b (sampling) to occur at similar time point to 3b
05.0 <i>All ppts</i>	5a	Gel -24 hours (at home) No coitus	25-236	+11	+ (11-90)	Provision of 1 gel applicator; gel applied at home ~24 h prior to coitus (range of 20-28 hours) To occur at least 10 days, but not more than 90 days, after Visit 4a/4b and not while participant is menstruating or within 2 days of expected start of bleeding
06.0 <i>Fem. only</i>	5b	No gel Coitus within 2 hours of visit	26-237	+1	+ 1	To occur the day after Visit 5a, approximately 24 hours post-gel. Present for visit no more than 2 hours post-coitus; coitus to occur at hotel.
07.0 <i>Fem. only</i>	6a	Gel -24 hours (at visit) No coitus	37-293	+11	+ (11-56)	To occur at least 10 days, but not more than 56 days, after Visit 5b and not while participant is menstruating or within 2 days of expected start of bleeding
08.0 <i>Fem. only</i>	6b	No gel No coitus	38-294	+1	+ 1	To occur the day after Visit 6a, approximately 24 hours post-gel Sampling to occur at similar time point to 5b
09.0 <i>All ppts</i>	7a/7b (BAT) Term/ Exit	Gel -1 hour Coitus Gel +1 hour (all at visit)	49-384	+11	+ (11-90)	To occur at least 10 days, but not more than 90 days, after Visit 6b and not while participant is menstruating 7b (sampling) to occur approximately 2 hours post coitus

Screening to Enrollment Period: up to 30 days; Follow-up Period: approximately 7-55 weeks

Table 10-2: Visit Timing Requirements – Group 2

Group 2: Visit Codes, Visit Types, Target Days, and Windows

Visit Code	Visit Type	Gel/Coitus	Target Day From ENR	Target Day From Prev. Visit	Visit Window (based on previous visit)	Comments
01.0 <i>All pts</i>	1 Screen	No gel No coitus	n/a	n/a	Up to -30	No more than 30 days prior to planned Enrollment day
02.0 <i>All pts</i>	2 Enrollment	Gel (at visit and at home) No coitus	0	0	n/a	Females will insert 1 gel at visit, doses 2-6 at home To occur approx. 2-12 days after last day of menstrual bleeding and not on a Monday
23.0 <i>All pts</i>	3a/3b	Gel -1 hour Coitus (both at visit)	6-7	+6	+ (6-7)	7 th gel dose inserted at visit, to occur 6 days after Visit 2; approximately 1 hour before coitus 3b (sampling) for Females only, approximately 2 hours after coitus
24.0 <i>Fem. only</i>	4	Gel (at visit and home) No coitus	27-63	+21	+ (21-56)	Will insert 1 gel at visit, doses 2-6 at home To occur at least 20 days, but not more than 56 days, after Visit 3, not while participant is menstruating, and not on Monday
25.0 <i>Fem. only</i>	5	Gel (at visit) No coitus	33-70	+6	+ (6-7)	7 th gel dose inserted at visit, To occur 6 days after Visit 4; sampling to occur at a similar time point to 3b relative to 7 th dose of gel application
26.0 <i>Fem. only</i>	6	Gel (at visit and home) No coitus	54-160	+21	+ (21-90)	Will insert 1 gel at visit, doses 2-7 at home To occur at least 20 days, but not more than 90 days, after Visit 5, not while participant is menstruating, and not on Thursday or Friday
27.0 <i>All pts</i>	7a/7b	No gel Coitus at visit (72 hrs post-gel)	63-169	+9	+ 9	To occur 9 days after Visit 6 and approx. 72 hrs after 7 th gel dose 7b (Females only) to occur approximately 2 hours after coitus
28.0 <i>Fem. only</i>	8	Gel (at visit and home) No coitus	84-225	+21	+ (21-56)	Will insert 1 gel at visit, doses 2-7 at home To occur at least 20 days, but not more than 56 days, after Visit 7, not while participant is menstruating, and not on Thursday or Friday
29.0 <i>All pts</i>	9 Term/Exit	No gel No coitus	93-234	+9	+ 9	To occur 9 days after Visit 8 approx. 72 hours after 7 th gel dose Sampling to occur at a similar time point relative to last gel dosing as for Visit 7b

Screening to Enrollment Period: up to 30 days; Follow-up Period: approximately 14-34 weeks

Missed Visits

In those cases where a couple is not able to complete any part of a required follow-up visit within the visit window, the visit is considered “missed.” For example, an enrolled couple does not report to the clinic for their first follow-up visit for Group 1 (visits 3a and 3b) until 10 days after enrollment. Per table 10-1, visits 3a and 3b have been missed. Missed visits are documented differently for female and male participants.

- **For female participants:** once a required visit has been missed (that is, once the visit window has closed), complete a Missed Visit form and fax it to SCHARP DataFax.
- **For male participants:** once a required visit (Visits 3a/3b, 5a, 7a/7b for Group 1; Visits 3a/3b, 7a/7b, 9 for Group 2) has been missed (that is, once the visit window has closed), do NOT complete a Missed Visit form for the male participant.
 - For **Group 1 males**, complete the following forms to indicate the missed visit for the male participant:
 - Group 1 Visits 3a/3b, 5a, 7a/7b: Complete the Male Practices – Group 1 CRF, mark item 1 “no.”
 - For **Group 2 males**, you will complete the following forms to indicate the missed visit for the male participant:
 - Group 2 Visits 3a/3b, 7a/7b: Complete the Male Practices – Group 2 CRF, mark item 1 “no.”
 - Group 2 Visit 9: Complete the Study Exit CASI Tracking CRF, mark item 2 “no.”

Note: The Male Practices – Group 2 CRF is not completed at Visit 9 for Group 2.

Interim Visits

An interim visit occurs when there is a clinic visit with the participant, but required follow-up visit procedures are not done, either because the required follow-up visit has already been completed, or it is too early in the visit window to complete the required visit. An interim visit may also occur via a phone contact if the participant reports a new AE requiring reporting on an AE-1 CRF, or the participant is instructed by study staff to hold or permanently discontinue study product use.

All interim visits/contacts with the participant should be documented in a chart note. Additionally, if the interim contact results in at least one newly-completed DataFax CRE, the interim visit is assigned an interim visit code (visit code ending in something other than “.0”). All phone contacts that meet interim visit criteria per paragraph above are also assigned interim visit codes. See section 10.3.3 for information on how to assign visit codes to interim visits.

Note that for MTN-011, there is no Interim Visit CRF. Instead, a Visit Summary CRF is completed for interim visits/contacts as needed. The Visit Code of the Visit Summary CRF will document whether the visit is a required (regular) visit or an interim visit.

The following are some examples of interim visits:

1. A Group 2 couple completes all required evaluations for Visit 2 (Visit Code 02.0) on the target day. The female participant returns to the clinic 3 days later to request more study product for the home dosing (she has misplaced several applicators). The site pharmacy dispenses 2 additional study applicators.

Why interim visit? The couple has already completed all Enrollment Visit procedures, and it is too early (and not in the visit window) for Visit 3a/3b (Visit Code 23.0). This is an interim visit, conducted between Enrollment and Visit 3a/3b, and is assigned an interim

visit code as a new CRF will be completed (Visit Summary and Study Product Accountability).

2. A Group 1 female participant completes Visit 5b (Visit Code 06.0) as scheduled. Her Visit 6a (Visit Code 07.0) visit window opens on November 12. The participant reports to the clinic unexpectedly on November 13 to report new genital AE symptoms. She is currently menstruating.

Why interim visit? The participant is in the Visit 6a (Visit Code 07.0) visit window, but the visit cannot be conducted because she is menstruating. An interim visit code is assigned as new CRFs will be completed (Visit Summary, AE Log, possibly others).

3. A Group 1 female participant completes all required evaluations for Visit 3b (Visit Code 03.0) on the target day, January 15. During the required pelvic exam a grade 3 AE is noted, and the IoR and PSRT agree that product use can continue. Per the protocol, the participant must be reevaluated at least weekly for up to 2 weeks. The participant returns to the clinic one week later, on January 22 for a pelvic exam to reevaluate the AE.

Why interim visit? This reevaluation visit is outside of the next follow-up visit window for Visit 4a/4b (Visit Code 04.0). An interim visit code is assigned, as a new Pelvic Exam and Visit Summary form will be completed. The Adverse Experience Log may need to be updated.

4. A Group 2 couple completes Visit 7a/7b (Visit Code 27.0) on the target day. The next day, the female participant calls the clinic to report a new genital symptom.

Why interim visit? During the phone contact, the participant reported a new symptom which will result in completion of new CRFs (the AE Log and the Visit Summary). Since new CRFs are completed, an interim visit code must be assigned.

10.3.3 Visit Codes and Page Numbers

Most 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. For CRFs completed only once per participant (the Enrollment CRF, for example), there is no place to record a visit code, as the visit code has been automatically assigned by SCHARP.

For MTN-011, note that the visit codes used for the Screening or Enrollment visits are the same for Group1 and Group 2 (i.e. 01.0 and 02.0). For follow-up visits, however, the visit codes are different for the 2 groups.

The table below lists the visit codes assigned to each required follow-up visit.

Table 10-3: Visit Code Assignments for Required Follow-up Visits

Group 1		Group 2	
Visit Type	Visit Code	Visit Type	Visit Code
1 (screening)	01.0	1 (screening)	01.0
2a/2b (enrollment)	02.0	2 (enrollment)	02.0
3a/3b	03.0	3a/3b	23.0
4a/4b	04.0	4	24.0
5a	05.0	5	25.0
5b	06.0	6	26.0
6a	07.0	7a/7b	27.0
6b	08.0	8	28.0
7a/7b (termination)	09.0	9 (termination)	29.0

Visit Codes for Interim Visits

Note that interim visit codes are not used for visits/contacts between the Screening Visit and Enrollment Visit, as CRFs completed for screening and enrollment have the visit code automatically-assigned.

For interim visits occurring after the Enrollment Visit, interim visit codes are assigned using the following guidelines:

- In the two boxes to the left of the decimal point, record the two-digit visit code for the most recently required follow-up visit, even if the visit was missed and/or if the participant is within the next visit's window.
- For the box to the right of the decimal point:
 - #.1 = the first interim visit after the most recently-required follow-up visit,
 - #.2 = the second interim visit after the most recently-required follow-up visit,
 - #.3 = the third interim visit after the most recently-required follow-up visit, and so on.

Example #1: A Group 2 couple completes the 7a/7b visit (Visit Code = 27.0) on the target day. The female participant returns to the site 2 days later to report a new genital symptom. This interim visit is assigned a Visit Code of 27.1:

Visit Code for this Interim Visit

Visit Code

2	7	.	1
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The examples below are from section 10.3.2, where interim visits are defined. These examples now have Visit Code information added to each example:

1. A Group 2 couple completes all required evaluations for Visit 2 (Visit Code 02.0) on the target day. The female participant returns to the clinic 3 days later to request more study product for the home dosing (she has misplaced several applicators). The site pharmacy dispenses 2 additional study applicators.

Why interim visit? The couple has already completed all Enrollment Visit procedures, and it is too early (and not in the visit window) for Visit 3a/3b (Visit Code 23.0). This is an interim visit, conducted between Enrollment and Visit 3a/3b, and is assigned an interim visit code as a new CRF will be completed (Visit Summary and Study Product Accountability).

Interim Visit Code = 02.1

2. A Group 1 female participant completes Visit 5b (Visit Code 06.0) as scheduled. Her Visit 6a (Visit Code 07.0) visit window opens on November 12. The participant reports to the clinic unexpectedly on November 13 to report new genital AE symptoms. She is currently menstruating.

Why interim visit? The participant is in the Visit 6a (Visit Code 07.0) visit window, but the visit cannot be conducted because she is menstruating. An interim visit code is assigned as new CRFs will be completed (Visit Summary, AE Log, possibly others).

Interim Visit Code = 06.1

3. A Group 1 female participant completes all required evaluations for Visit 3b (Visit Code 03.0) on the target day, January 15. During the required pelvic exam a grade 3 AE is noted, and the IoR and PSRT agree that product use can continue. Per the protocol, the participant must be reevaluated at least weekly for up to 2 weeks. The participant returns to the clinic one week later, on January 22 for a pelvic exam to reevaluate the AE.

Why interim visit? This reevaluation visit is outside of the next follow-up visit window for Visit 4a/4b (Visit Code 04.0). An interim visit code is assigned, as a new Pelvic Exam and Visit Summary form will be completed. The Adverse Experience Log may need to be updated.

Interim Visit Code = 03.1

4. A Group 2 couple completes Visit 7a/7b (Visit Code 27.0) on the target day. The next day, the female participant calls the clinic to report a new genital symptom.

Why interim visit? During the phone contact, the participant reported a new symptom which will result in completion of new CRFs (the AE Log and the Visit Summary). Since new CRFs are completed, an interim visit code must be assigned.

Interim Visit Code = 27.1

Page numbers

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

Page

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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.

10.3.4 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.

10.3.5 Form Supply

An initial supply of case report forms needed for the Screening and Enrollment Visits will be supplied by SCHARP as visit packets, where each packet contains the required CRFs for the visit. For example, the Group 1: Screening Visit packet will include all of the CRFs listed for this visit in the Schedule of Forms table (Table 10-4). When a form must be completed for both the female and male participant (e.g. the Enrollment CRF) there are two copies of the form in the appropriate packet. The follow-up visit form packets listed in Table 10-4, and any "as needed" CRFs (for example, Adverse Experience Log forms, Concomitant Medications Log forms, etc.) will be available for printing from the Atlas webpage (<https://atlas.scharp.org/cpas/project/MTN/011/begin.view?>).

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

10.3.6 Case Report Form Completion Schedule

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

Some SCHARP-provided forms are required to be completed at each visit, while other forms are required only at one visit or only when specifically indicated. The following tables (Table 10-4 and 10-5) list the DataFax and non-DataFax forms that are required to be completed at each study visit for Group 1 and 2, respectively.

Table 10-4: Schedule of Forms – CRFs Required to be Completed at Each Visit: Group 1

Visit 1 (Screening Visit): Visit Code 01.0	
DataFax forms	Non-DataFax forms
Demographics (<i>female and male</i>) Pelvic Exam Physical Exam Laboratory Results STI Test Results Pharmacokinetics Family Planning Pre-existing Conditions Concomitant Medications Log (<i>female and male</i>)	Pelvic Exam Diagrams Genital Exam – Male Physical Exam – Male Screening Menstrual History LDMS Specimen Tracking Sheet
Visit 2a/2b (Enrollment Visit): Visit Code 02.0	
DataFax forms	Non-DataFax forms
Enrollment (<i>female and male</i>) Pelvic Exam Pelvic Exam – Clinically-indicated Physical Exam STI Test Results Pharmacokinetics Family Planning Male Practices – Group 1	Pelvic Exam Diagrams Pelvic Exam Diagrams (for 2 nd exam) Genital Exam – Male Physical Exam – Male LDMS Specimen Tracking Sheet
Visit 3a/3b: Visit Code 03.0	
DataFax forms	Non-DataFax forms
Visit Summary Pelvic Exam Physical Exam STI Test Results Pharmacokinetics Study Product Accountability Male Practices – Group 1	Pelvic Exam Diagrams Physical Exam – Male LDMS Specimen Tracking Sheet
Visit 4a/4b: Visit Code 04.0	
DataFax forms	Non-DataFax forms
Visit Summary Pelvic Exam Physical Exam STI Test Results Pharmacokinetics Study Product Accountability	Pelvic Exam Diagrams LDMS Specimen Tracking Sheet
Visit 5a: Visit Code 05.0	
DataFax forms	Non-DataFax forms
Visit Summary Physical Exam STI Test Results Study Product Accountability Male Practices – Group 1	Physical Exam – Male

Visit 5b: Visit Code 06.0	
DataFax forms	Non-DataFax forms
Visit Summary Pelvic Exam STI Test Results Pharmacokinetics	Pelvic Exam Diagrams LDMS Specimen Tracking Sheet
Visit 6a: Visit Code 07.0	
DataFax forms	Non-DataFax forms
Visit Summary Physical Exam STI Test Results Study Product Accountability	none
Visit 6b: Visit Code 08.0	
DataFax forms	Non-DataFax forms
Visit Summary Pelvic Exam STI Test Results Pharmacokinetics	Pelvic Exam Diagrams LDMS Specimen Tracking Sheet
Visit 7a/7b (Termination Visit): Visit Code 09.0	
DataFax forms	Non-DataFax forms
Visit Summary Pelvic Exam Physical Exam Laboratory Results STI Test Results Pharmacokinetics Study Product Accountability Male Practices – Group 1 Study Exit CASI Tracking End of Study Inventory Termination (<i>female and male</i>)	Pelvic Exam Diagrams Genital Exam – Male Physical Exam – Male LDMS Specimen Tracking Sheet

Table 10-4: Schedule of Forms – CRFs Required to be Completed at Each Visit: Group 2

Visit 1 (Screening Visit): Visit Code 01.0	
DataFax forms	Non-DataFax forms
Demographics (<i>female and male</i>) Pelvic Exam Physical Exam Laboratory Results STI Test Results Pharmacokinetics Family Planning Pre-existing Conditions Concomitant Medications Log (<i>female and male</i>)	Pelvic Exam Diagrams Genital Exam – Male Physical Exam – Male Screening Menstrual History LDMS Specimen Tracking Sheet
Visit 2 (Enrollment Visit): Visit Code 02.0	
DataFax forms	Non-DataFax forms
Enrollment (<i>female and male</i>) Pelvic Exam Physical Exam STI Test Results Family Planning Study Product Accountability	Pelvic Exam Diagrams Genital Exam – Male Physical Exam – Male LDMS Specimen Tracking Sheet
Visit 3a/3b: Visit Code 23.0	
DataFax forms	Non-DataFax forms
Visit Summary Pelvic Exam Physical Exam STI Test Results Pharmacokinetics Study Product Accountability Group 2 – Participant-reported Dosing Male Practices – Group 2	Pelvic Exam Diagrams Physical Exam – Male LDMS Specimen Tracking Sheet
Visit 4: Visit Code 24.0	
DataFax forms	Non-DataFax forms
Visit Summary STI Test Results Study Product Accountability	none
Visit 5: Visit Code 25.0	
DataFax forms	Non-DataFax forms
Visit Summary Pelvic Exam STI Test Results Pharmacokinetics Study Product Accountability Group 2 – Participant-reported Dosing	Pelvic Exam Diagrams LDMS Specimen Tracking Sheet
Visit 6: Visit Code 26.0	
DataFax forms	Non-DataFax forms
Visit Summary STI Test Results Study Product Accountability	none

Visit 7a/7b: Visit Code 27.0	
DataFax forms	Non-DataFax forms
Visit Summary Pelvic Exam Physical Exam STI Test Results Pharmacokinetics Group 2 – Participant-reported Dosing Male Practices – Group 2	Pelvic Exam Diagrams Physical Exam – Male LDMS Specimen Tracking Sheet
Visit 8: Visit Code 28.0	
DataFax forms	Non-DataFax forms
Visit Summary STI Test Results Study Product Accountability	none
Visit 9 (Termination Visit): Visit Code 29.0	
DataFax forms	Non-DataFax forms
Visit Summary Pelvic Exam Physical Exam Laboratory Results STI Test Results Pharmacokinetics Group 2 – Participant-reported Dosing Study Exit CASI Tracking End of Study Inventory Termination (<i>female and male</i>)	Pelvic Exam Diagrams Genital Exam – Male Physical Exam – Male LDMS Specimen Tracking Sheet

10.3.7 Completing Interviewer-administered Forms

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

10.3.8 Site Review (Quality Control) of DataFax Forms

As described in the site's MTN Data Management SOP (and referenced in the site's Clinical Quality Management Plan, CQMP), each site must perform two Quality Control (QC) review steps prior to faxing DataFax forms to SCHARP. While DataFax CRFs are being reviewed, it is important that they are stored and tracked systematically.

Below are specific review guidelines that should be followed for these QC review steps.

10.3.9 MTN-011 QC Review Step #1

- Review visit checklist and pelvic exam checklist (if used) to ensure all required procedures were completed
- Review CRFs based on participant responses to ensure completeness.
 - For the Screening Visit, Enrollment Visit, and all follow-up visits review all required and completed CRFs as listed in Tables 10-4 and 10-5 above. In addition, be sure to review any CRFs completed "as needed."

10.3.10 MTN-011 QC Review Step #2

This QC review step should occur before forms are faxed to SCHARP. Ideally, this review will happen once all lab results are available, so that all forms for a particular visit can be reviewed for consistency across documents. The goal, as outlined in the site's MTN Data Management SOP, is to correct data inconsistencies/errors prior to faxing forms to SCHARP so that QC notes are prevented.

General QC #2 procedures for all visits:

- Review visit checklist to ensure all required procedures were completed
- Ensure no participant identifies other than the PTID are present on DataFax forms.
- Ensure the PTID is correct, and is the same on all forms/documents.
- Ensure the Visit Code assigned is correct, and is the same on all documents.
- Make sure a response has been recorded for each item, as required. Make sure skip patterns have been followed correctly.
- If a response box has a line for "other," "specify," or "describe," ensure text is recorded on the line.
- Make sure text responses are clearly recorded.

Additional QC #2 procedures for Screening Visit documents:

- Review Pelvic Exam, Physical Exam, and Screening Menstrual History and ensure medical conditions are recorded appropriately on the Pre-existing Conditions form for female participants. Refer to the Pre-existing Conditions form instructions for further guidance.
- Review the Family Planning form and if contraceptive marked requires documentation on Concomitant Medications Log (per instruction), make sure this has been done correctly.
- Ensure that the Laboratory Results form and the STI Test Results form have the correct Initial Specimen Collection Date. If any labs were repeated and more than one Laboratory Results form or STI Test Results form are completed for a participant make sure only 1 CRF is faxed (once participant enrolls).
- If a second (repeat) pelvic exam is performed during screening, make sure a new Pelvic Exam form is completed for the 2nd screening pelvic exam, and that only this form is faxed to SCHARP once the participant enrolls.
- Review all laboratory items on the CRFs and confirm that the information matches information documented on the visit checklist and LDMS Specimen Tracking Sheet (or local lab requisition sheet).

Additional QC #2 procedures for Enrollment Visit documents:

- If a 2nd pelvic exam is performed during the screening period for a participant, only fax the 2nd Pelvic Exam form to SCHARP (the Pelvic Exam form documenting the participant's eligibility for the study). Only fax 1 Pelvic Exam CRF for each participant within the screening window.
- If any screening visit lab assays were repeated, ensure results documenting the participant's eligibility are on the Laboratory Results form and/or the STI Test Results form faxed to SCHARP. Only fax 1 Laboratory Results form and 1 STI Test Results form for each participant within the screening window.

- Wait until the couple enrolls in the study before faxing any CRFs to SCHARP. Once enrolled and after Enrollment Visit CRFs have been reviewed, fax all Screening Visit and Enrollment Visit DataFax CRFs to SCHARP DataFax as appropriate.

Additional QC #2 procedures for follow-up visit documents:

- If a new AE Log for the female participant is completed at a visit, make sure the Visit Summary CRF completed for the visit has the correct number of female participant AE Logs recorded in item 4 (Visit Summary form with the same Visit Code as AE Log item 10).
- If a new AE Log for the male participant is completed at a visit, the Visit Summary form should not be completed for the male participant (i.e. the Visit Summary form is not completed/required for male participants).
- If a new Product Hold/Discontinuation Log is completed at a visit, make sure the Visit Summary CRF completed for the visit has the correct number of Product Hold/Discontinuation Logs recorded in item 5 (Visit Summary form with the same Visit Code as PH-1 item 1).
- On the Family Planning form: if contraceptive marked requires documentation on Concomitant Medications Log (per instruction), make sure this is done accurately.
- On the Concomitant Medications Log: if "yes" marked for "Taken for a reported AE?", make sure the AE Log page number recorded has "medication(s)" marked in item 7, and vice-versa.
Note: The Concomitant Medications Log and AE Log forms may be completed for both female and male participants.

10.4 Form-Specific Completion Instructions

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

Some forms in MTN-011 will be completed for the female participants only (e.g. Visit Summary, Pelvic Exam, and Laboratory Results). For these forms the cohort digit of the PTID on those forms is hard-coded with a "0." Other forms will be completed for the male participants only, and the cohort digit of the PTID on those forms is hard-coded with a "1." Additionally, some forms will be completed for both the female and the male participants (e.g. Demographics and Enrollment), and the cohort digit of the PTID on those forms is blank.

Forms to be completed for male participants ONLY:

- Male Practices – Group 1
- Male Practices – Group 1
- Genital Exam – Male (non-DataFax)
- Physical Exam – Male (non-DataFax)

Forms to be completed for BOTH female and male participants:

- Demographics
- Enrollment
- Concomitant Medications Log
- Adverse Experience Log (if needed)

- Termination
- Protocol Deviation Log (if needed)

Below are additional instructions for some of the CRFs used in this study. These instructions do not appear on the back of the form page due to lack of space.

Adverse Experience Log (AE-1)

- Do not wait until the AE resolves before faxing the form page to SCHARP.
- Always make changes, corrections, and updates to the originally-completed form page (do not complete a new form). 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.
- Note that AE Log page numbers do not need to be assigned in any special order with regard to AE onset date or date reported to site. For example, if it is discovered that for a participant, page 001 and 003 were assigned, but not 002, simply assign page # 002 to the next AE Log form you complete. It does not matter if the AE's onset date or date reported to site on page 002 is later than these dates reported on AE Log page 003 (a QC will not be generated).
- For item 1, note that planned procedures or surgeries are not AEs. For example, a tonsillectomy is not an AE; rather, it is a treatment that will be collected in item 7. Any adverse experiences associated with the planned procedure or surgery, are AEs.
- If an AE is marked as "related", please avoid putting additional detail regarding relatedness in the "Comments" section. Rather, provide as much relevant information as possible in item 1 (the text description of the AE). This will help avoid MedDRA coding queries during the study.

10.5 Case Report Forms

The current version of the MTN-011 case report forms (not for actual data collection purposes use) can be found on the MTN-011 SSP web page on the MTN website (www.mtnstopshiv.org).