Section 10. Data Collection

The purpose of this document is to provide site staff with the information they need to successfully complete and submit MTN-014 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-014 team members, along with their job role and e-mail address, are listed below.

MTN-014 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 and Troubleshooting

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:

Correct:

| 0 | 0 | 7 |

Incorrect:

| | | 7 | → This example would result in a QC note.

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

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

  Correct: Incorrect:

  | 4 | | 4 |

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

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

  Easily Identified:

  | 0 | | 1 | | 2 | | 3 | | 4 | | 5 | | 6 | | 7 | | 8 | | 9 |

  Difficult to Identify:

  | Ø | | 1 | | 2 | | 3 | | 4 | | 7 |

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 in the table 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, 2013 is recorded as:

```
┌──┬──┐  ┌──┬──┬──┐  ┌──┬──┐
│O │6 │  │J │U │N │  │1 │3 │
└──┴──┘  └──┴──┴──┘  └──┴──┘
  dd        MMM         yy
```

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

```
┌──┬──┬──┐  ┌──┬──┐
│  │  │  │  │  │  │
└──┴──┴──┘  └──┴──┘
  MMM          yy
```

A diagnosis date of October, 2013 would be recorded as follows:

```
┌──┬──┬──┐  ┌──┬──┐
│O │C │T │  │1 │3 │
└──┴──┴──┘  └──┴──┘
  MMM          yy
```

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 │
└──┴──┘   └──┴──┘
  hr        min
```

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

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

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

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

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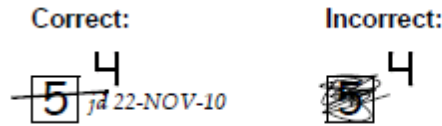
If an **X** is marked in the wrong response box, correct it by doing the following:

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

- mark the correct box, and

- initial and date the correction as shown below:
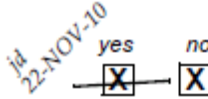
If the correct answer has previously been crossed out, do the following:

- circle the correct item,

- write an explanation in the white space near the item, and

- initial and date all corrections as shown below:
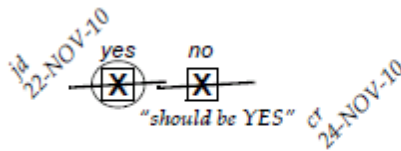
The standards above must ***always*** be followed whenever a CRF is changed, clarified, or amended, even if the change is made ***before*** the CRF is faxed to SCHARP for the first time.

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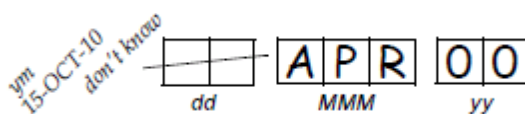
A skip pattern is the **only** valid reason to leave a response blank. Initials and date are required for any data item that is refused, missing, unknown, or not applicable, regardless of whether it is marked as such during the initial form completion, or as an update to the form.

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 just as 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, Clinical 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

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 her study participation.

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

The PTIDs used for this study are nine digits and formatted as "XXX-YYYYY-Z." The PTID consists of three parts: the DataFax site number (XXX), the participant number (YYYYY), and a numerical check digit (Z). The check digit (Z) is a number generated by SCHARP with the participant number, and helps ensure that the correct PTID is recorded. Below is an example of the PTID structure used in MTN-014.

Participant ID

Site Number   Participant Number   Chk
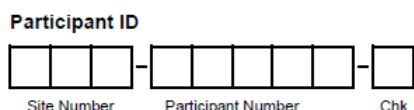
10.3.2   Study Visit Timing

Screening and Enrollment
The initial screening visit is defined as the day the participant provided written informed consent to be screened and enrolled for the study. The initial Screening Visit (that is, the date the informed consent form was signed for screening and enrollment) may take place up to 42 days prior to the Enrollment/Study Product Administration Visit/Initiate Period 1. The date the participant is enrolled/randomized is Study Day 0 for the participant.

Screening Attempts (Re-screens)

Refer to the protocol and the Participant Accrual section of this manual for guidance related to repeat screening attempts (re-screens) by a participant.

If a participant re-screens, all screening procedures and CRFs must be repeated with the exception of PTID assignment and Eligibility Criteria CRF completion (see paragraph below). 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).

If a participant re-screens and enrolls in the study, only case report forms from the successful screening and enrollment visits are faxed to SCHARP. Note that in this case, the Eligibility Criteria CRF completed during the failed screening attempt should be updated and re-faxed with CRFs from the participant's successful screening and enrollment visits (do not complete a new Eligibility Criteria CRF for the successful screening attempt).

Follow-Up Visits

For each required follow-up study visit, the visit type, visit code, target visit day, and visit window are listed in Table 10-1. Target days and windows are listed in days, with the day of enrollment/randomization as study day 0.

Target Days and Visit Windows

Whenever possible, visits should be completed on the target day or within the target window. SCHARP will provide sites with a spreadsheet tool that may be used to generate individual participant follow-up visit calendars based upon the participant's enrollment date and menstrual cycle. The spreadsheet requires that the participant's Enrollment date be entered. Once the enrollment date is entered, the target days and visit windows for follow-up Visits 3.0-18.0 will appear. The target dates and visit windows for Visits 19.0-32.0 are contingent on the actual visit date of the Study Product Administration Visit/Initiate Period 2 (Visit 18.0). The target date and visit window for the last Safety Phone Call/Study Termination Visit (Visit 33.0) is contingent on the actual visit date of the Period 2 End/Final Clinic visit (visit 32.0). The calendar can be printed, added to the participant's study notebook and updated as needed.

Split Visits

For MTN014, Enrollment Visits may not be split. Whenever possible, all required follow-up visit evaluations should be completed on the same day. In those cases where this is not possible, the participant may come back and complete the remaining evaluations on another day, as long as that day is within the allowable visit window. For example, a participant comes in on her Washout Visit target day (Day 35) and completes all of the required evaluations, but has to leave prior to completing a pregnancy test. She comes back 2 days later on Day 37 and completes the remaining required procedures. This is allowed, and is referred to as a "split" visit; as the participant completed all required visit evaluations on two separate days, both days being in the visit window.

Note that for split visits, only one Follow-up Visit Summary CRF is completed, and all CRFs completed for the visit are assigned the same visit code. The "Visit Date" on the Follow-up Visit Summary CRF is the date of the first part of the split visit. See Section 10.6.3 for more information on assigning visit codes to split visits.

Table 10-1: Visit Timing Requirements

Visit code	Visit type	target day	Visit Window
1.0	Screening Visit	</- 42 days to Enrollment	n/a
2.0	Enrollment/Study Product Admin Visit/Initiate Period 1	0	+42 days after 1.0
3.0	Study Product Administration Visit	1	no window
4.0	Study Product Administration Visit	2	no window
5.0	Study Product Administration Visit	3	no window
6.0	Study Product Administration Visit	4	no window
7.0	Study Product Administration Visit	5	no window
8.0	Study Product Administration Visit	6	no window
9.0	Study Product Administration Visit	7	no window
10.0	Study Product Administration Visit	8	no window
11.0	Study Product Administration Visit	9	no window
12.0	Study Product Administration Visit	10	no window
13.0	Study Product Administration Visit	11	no window
14.0	Study Product Administration Visit	12	no window
15.0	Study Product Administration Visit	13	no window
16.0	Period 1 End	14	+/-2 days
n/a	Safety Phone Call	21	Day 17-Day 27
17.0	Washout Visit	35	Day 28-Day 55
18.0	Study Product Admin Visit/Initiate Period 2	56 (3-7 days after menses)	56-119
19.0	Study Product Administration Visit	1 day after initiate period 2	no window
20.0	Study Product Administration Visit	2 days after initiate period 2	no window
21.0	Study Product Administration Visit	3 days after initiate period 2	no window
22.0	Study Product Administration Visit	4 days after initiate period 2	no window
23.0	Study Product Administration Visit	5 days after initiate period 2	no window
24.0	Study Product Administration Visit	6 days after initiate period 2	no window
25.0	Study Product Administration Visit	7 days after initiate period 2	no window
26.0	Study Product Administration Visit	8 days after initiate period 2	no window
27.0	Study Product Administration Visit	9 days after initiate period 2	no window
28.0	Study Product Administration Visit	10 days after initiate period 2	no window
29.0	Study Product Administration Visit	11 days after initiate period 2	no window
30.0	Study Product Administration Visit	12 days after initiate period 2	no window
31.0	Study Product Administration Visit	13 days after initiate period 2	no window
32.0	Period 2 End	14 day after Initiate period 2	+/-2 days
33.0	Safety Phone Call/Termination	7 days after Period 2 End Visit	77-140

Missed Visits

In those cases where a participant is not able to complete <u>any part</u> of a required follow-up visit within the allowable visit window, the visit is considered "missed". For example, an enrolled participant does not report to the clinic for her Period 1 End Visit until 18 days after enrollment. Per table 10-1, the Period 1 End visit has been missed. The missed visit is documented in the study database by completion of a Missed Visit CRF that is faxed to SCHARP.

Interim Visits

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

All interim contacts with the participant should be documented in a chart note. Additionally, if the interim contact results in at least one <u>newly-completed DataFax CRF</u>, the interim contact is assigned an interim visit code (visit code ending in something other than ".0"). All phone contacts, including the scheduled safety phone call on target day 21, that meet interim visit criteria per paragraph above are also assigned interim visit codes. Note that the last safety phone call is assigned a visit code of 33.0 as this phone call is also a participant's Termination Visit. See section 10.6.3 for information on how to assign visit codes to interim visits.

Note that for MTN-014, there is no Interim Visit CRF. Instead, a Follow-up Visit Summary CRF is completed for interim visits/contacts as needed. Item 4 of the Follow-up 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 participant completes her Washout visit as scheduled. The Initiate Period 2 visit window has not yet opened, and the participant reports to the clinic unexpectedly to report a new AE.

   Why is this an interim visit? The required visit procedures for the Washout visit have been completed already, and a new AE is reported. An interim visit code is assigned as new CRFs will be completed (Follow-up Visit Summary, AE Log, possibly others).

2. A participant completes her Period 1 End visit on the target day. The clinic calls the participant seven days later to conduct the Safety Phone Call and she reports a new symptom.

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

10.3.3   Visit Codes and Page Numbers

The MTN-014 non-log 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. When visit code

boxes are present, site staff is responsible for recording the appropriate visit code. The table below lists the visit codes assigned to each required follow-up visit.

Table 10-2: Visit Code Assignments for Required Follow-up Visits

Visit #	Visit	Visit Code
1	Screening Visit	01.0
2	Enrollment/Study Product Administration Visit/Initiate Period 1	02.0
3	Study Product Administration Visit	03.0
4	Study Product Administration Visit	04.0
5	Study Product Administration Visit	05.0
6	Study Product Administration Visit	06.0
7	Study Product Administration Visit	07.0
8	Study Product Administration Visit	08.0
9	Study Product Administration Visit	09.0
10	Study Product Administration Visit	10.0
11	Study Product Administration Visit	11.0
12	Study Product Administration Visit	12.0
13	Study Product Administration Visit	13.0
14	Study Product Administration Visit	14.0
15	Study Product Administration Visit	15.0
16	Period 1 End	16.0
17	Washout Visit	17.0
18	Study Product Administration Visit/Initiate Period 2	18.0
19	Study Product Administration Visit	19.0
20	Study Product Administration Visit	20.0
21	Study Product Administration Visit	21.0
22	Study Product Administration Visit	22.0
23	Study Product Administration Visit	23.0
24	Study Product Administration Visit	24.0
25	Study Product Administration Visit	25.0
26	Study Product Administration Visit	26.0
27	Study Product Administration Visit	27.0
28	Study Product Administration Visit	28.0
29	Study Product Administration Visit	29.0
30	Study Product Administration Visit	30.0
31	Study Product Administration Visit	31.0
32	Period 2 End/Final Clinic Visit	32.0
33	Safety Phone Call/Termination Visit	33.0

Visit Codes for Split Visits

See Section 10.6.2 for a definition of split visits. When split visits occur, the CRFs completed for the visit are all assigned the same visit code (ending in ".0"), even though the dates will differ between some of the CRFs.

Visit Codes for Interim Visits

For interim visits, 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 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 participant completes her Washout Visit (visit code = 17.0) on the target day. She returns to the site one day later to report a new symptom. This interim Visit is assigned an interim visit code of 17.1:

Visit code for this Interim Visit

Visit Code | 1 | 7 | . | 1 |

Page numbers

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

Page | | |

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

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

Sites are responsible for creating their own supplies of MTN-014 case report forms. Sites may either print CRFs (this is the preferred method) from pdf files provided by SCHARP (available on the MTN-014 Atlas web page), or via photocopy of hard-copy originals. CRF pdf files will include visit packets pdfs (containing all of the CRFs required to be completed for the visit) as well as a pdf file containing all of the CRFs created for the study.

Site are encourage to test and make sure the CRFs they have produced can be read into DataFax by using a test fax pdf provided by SCHARP. A test fax should be done each time new printing, photocopying, or faxing equipment is installed or modified, and also when paper used for CRFs changes.

10.4.6   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 table (Table 10-3) lists the DataFax and non-DataFax forms that are required to be completed at each study visit.

Table 10.3: Schedule of Forms – CRFs Required to be Completed at Each Visit

Visit 1 (Screening Visit): Visit Code 01.0	
DataFax forms	**Non-DataFax forms**
Anorectal Exam Concomitant Medications Log Demographics Eligibility Criteria Pelvic Exam Pre-existing Conditions Safety Laboratory Results Screening Visit Physical Exam Specimen Storage Biopsy Specimens	Pelvic Exam Diagrams Screening Menstrual History Screening LDMS Specimen Tracking Sheet
Visit 2 (Enrollment Visit): Visit Code 02.0	
DataFax forms	**Non-DataFax forms**
Abbreviated Physical Exam Anorectal Exam Enrollment Pelvic Exam Pharmacokinetics Product Dispensation and Returns STI Test Results Specimen Storage Vaginal and Rectal Practices Enrollment DOD Experience Assessment	Pelvic Exam Diagrams Enrollment LDMS Specimen Tracking Sheet
Visits 3-15 (Study Product Administration Visits): Visit Codes 03.0 – 15.0	
DataFax Forms	**Non-DataFax forms**

Follow-up Visit Summary Vaginal and Rectal Practices At Visit 15 only: Product Dispensation and Returns	

Visit 16 (Period 1 End): Visit Code 16.0	
DataFax forms	**Non-DataFax forms**
Abbreviated Physical Exam Anorectal Exam Directly Observed Dosing Follow-up Visit Summary Pelvic Exam Pharmacokinetics Specimen Storage STI Test Results Vaginal and Rectal Practices DOD Experience Assessment Biopsy Specimens	Pelvic Exam Diagrams LDMS Specimen Tracking Sheet
Visit 17 (Washout Visit): Visit Code 17.0	
DataFax forms	**Non-DataFax forms**
Follow-up Visit Summary Specimen Storage	n/a
Visit 18 (Study Product Administration Visit/Initiate Period 2: Visit Code 18.0	
DataFax forms	**Non-DataFax forms**
Abbreviated Physical Exam Anorectal Exam Follow-up Visit Summary HIV Results Pelvic Exam Pharmacokinetics Product Dispensation and Returns Specimen Storage STI Test Results Vaginal and Rectal Practices	Pelvic Exam Diagrams LDMS Specimen Tracking Sheet
Visits 19-31 (Study Product Administration Visits): Visit Codes 19.0 - 31.0	
DataFax forms	**Non-DataFax forms**
Follow-up Visit Summary Vaginal and Rectal Practices <u>At Visit 31 only:</u> Product Dispensation and Returns	
Visit 32 (Period 2 End): Visit Code 32.0	
DataFax forms	**Non-DataFax forms**
Abbreviated Physical Exam Anorectal Exam Directly Observed Dosing Follow-up Visit Summary HIV Results Pelvic Exam Pharmacokinetics Specimen Storage	Pelvic Exam Diagrams LDMS Specimen Tracking Sheet

STI Test Results Vaginal and Rectal Practices DOD Experience Assessment Biopsy Specimens	
Visit 33 (Safety Phone Call/Termination Visit): Visit Code 33.0	
DataFax forms	**Non-DataFax forms**
Follow-up Visit Summary Termination	n/a

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.

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.

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.

Pharmacokinetics (PK-1)

- If the participant is unable to recall the complete date of last menstrual period, obtain participant's best estimate. At a minimum, the month and year are required. Only record dates of menstrual period bleeding. Do not record dates of episodes of expected breakthrough bleeding experienced while a participant is on Depo, Mirena, or other continuous contraceptive method where a woman does not experience a monthly menstrual period. If the participant is currently on her menses, mark 'ongoing'. In these cases, this item does not need to be updated with a Stop Date at a later visit.

Concomitant Medications Log (CM-1)

- When recording injections (e.g., Hepatitis B vaccine, Depo-Provera), record each injection as its own separate entry. The "Date Started" and "Date Stopped" dates should be the same date. Mark the "once" box for "Frequency" and the appropriate box for "Route" (e.g., "IM", or "Other" for subcutaneous injections).

Product Dispensation and Returns (PDR-1)

- Complete this form for doses that are provided to participants for non-observed home use only. Doses that are provided to participants during off-site home visits and are observed by clinic staff do not need to be documented on this CRF. This form is required at both Period Initiate Visit and at the last Study Product Administration Visit for each Period. If a participant forgets to return her unused applicators for home use at Visit 15.0 or 31.0, study staff should instruct the participant to return these applicators at her next visit and the PDR-1 should be completed at her Period End Visit
- Items 1-4 should each have a response. If either rectal or vaginal product were not provided or returned, mark the 'not provided or 'not returned' box and go to the next item.

10.5   Case Report Forms

The MTN-014 CRFs will be posted both on the MTN-014 SSP webpage for reference and on the ATLAS webpage for downloading and printing.