

12. Data Collection

The purpose of this document is to provide site staff with the information they need to successfully complete and submit MTN-015 case report forms. For questions about this section or about general data collection policies, procedures, or materials, please contact the SCHARP Clinical Data 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-015 team members, along with their job role and e-mail address, are listed below.

MTN-015 Statistical and Data Management Center (SDMC) Staff

| Job Role | Name | Email Address |
|--------------------------------|-----------------|---------------------|
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12.1 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 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 Management 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.

12.2 DataFax Form Completion

12.2.1 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.

12.2.2 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.

12.2.3 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.

Correct:

0 0 7

Incorrect:

7

This example would result in a QC note.

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:

Correct:

4

Incorrect:

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

12.2.4 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:

dd *MMM* *yy*

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

MMM *yy*

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

MMM *yy*

12.2.5 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:

:
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 |

12.2.6 Data Corrections and Additions

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

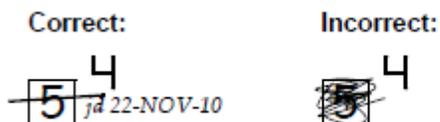
It is important to make these changes to the original CRF—**never** copy data onto a new form. After making the change, the CRF *must* be re-faxed to SCHARP DataFax.

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

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

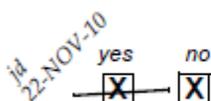
Whenever an entry on a DataFax CRF is changed, do the following:

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



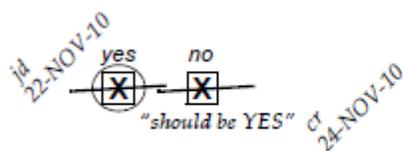
If an X is marked in the wrong response box, correct it by doing the following:

- 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:

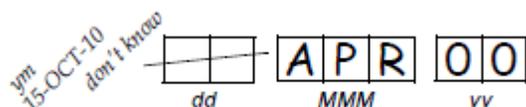


The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is faxed to SCHARP for the first time.

12.2.7 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.

12.2.8 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."

12.2.9 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.

12.2.10 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, Grade 1 Adverse Experience Log, Product Hold/Discontinuation Log, Protocol Deviations Log, and Social Impact 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.

12.2.11 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

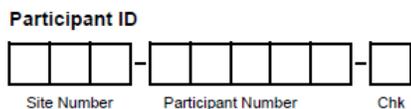
12.3 Study-Specific Data Collection Information

12.3.1 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.

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-020.



12.3.2 Study Visit Timing

Screening and Enrollment

The screening and enrollment visit will occur as soon as possible following the identification of HIV seroconversion. Enrollment into MTN-015 is defined as assignment of a MTN-015 PTID. Once the participant has provided written informed consent and it has been determined she is eligible for the study, she is assigned a MTN-015 PTID and considered enrolled into the study.

Participants will enroll into MTN-015 several weeks or months after their date of HIV seroconversion. Once enrolled, a 015 Follow-up Visit Calendar (non-ART or ART, as applicable) should be generated. Complete a Missed Visit form for those follow-up visits whose visit window has closed by the time the participant is enrolling into MTN-015 (that is, complete a Missed Visit form for all visits where the “window closes” date is before the participant’s 015 Enrollment Date). On the Missed Visit form, mark item 2 as “visit not required per protocol”. You will also need to complete a Missed Visit form for the follow-up visit whose visit window contains the participant’s MTN-015 Enrollment Date (item 2 of the Missed Visit form marked as described above).

For more information on completion of Missed Visit forms at the time of enrollment into MTN-015 and at the time of a participant’s switch to the ART track, please see the “**Missed Visit**” information later in this sub-section.

Follow-Up Visits

Required follow-up visits for MTN-015 are completed based on one of two schedules: the non-ART follow-up visit schedule or the ART follow-up visit schedule. The non-ART

schedule is used for participants with no prior or current use of HIV antiretroviral therapy (ART). The ART schedule is used for participants with a history of ART use.

Completion of the Enrollment CRF automatically assigns the participant to the non-ART follow-up visit schedule. To switch a participant to the ART follow-up visit schedule, complete the ART Enrollment CRF. Completion of the ART Enrollment CRF indicates the participant will be followed (from that point until the end of the study) on the ART follow-up visit schedule. The ART Enrollment CRF is completed as soon as it is determined the participant has used ART. This includes the 015 Screening/Enrollment visit.

Once a participant has switched to the ART schedule, she continues on the ART schedule for the remainder of her study participation, even if she is not currently on ART and/or ART use is discontinued at some time in the future.

Table 12-1 in Section 12.3.3 contains a detailed listing of the non-ART follow-up visit schedule and the ART follow-up visit schedule. Each schedule lists the required visits for that schedule, along with the visit code assigned to each visit, the target visit day, and the visit window for each visit. Note that for the non-ART visit schedule, Day 0 is defined as the date of HIV seroconversion. For the ART visit schedule, Day 0 is defined as the date of ART initiation.

Each site will be provided with a spreadsheet tool that may be used to generate MTN-015 follow-up visit schedules (non-ART or ART) for each participant. The spreadsheet requires that for non-ART schedules, the date of HIV seroconversion be entered. For the ART schedule, the date of ART initiation is required to be entered. Once this information is entered, the participant's follow-up visit schedule is created, listing the target dates and visit window dates for each visit.

Some examples of the different types of visit schedules are provided below.

1. **Participant enrolls as a Non-ART participant:** At the participant's Screening/Enrollment visit, she reports that she has never used ART. The participant is followed using the non-ART follow-up visit schedule, where Day 0 is the date of HIV seroconversion.
2. **Participant has or is using ART at the time of Enrollment:** At the participant's Screening/Enrollment visit, she reports she was on ART six months ago for a total of three weeks. The participant is followed using the ART follow-up visit schedule, where Day 0 is the date she initiated ART use.
3. **Participant is enrolled and initially followed on the Non-ART schedule, then during follow-up, switches to the ART visit schedule:** At the participant's Screening/Enrollment visit, she reports that she has never used ART. The participant is followed using the non-ART follow-up visit schedule, where Day 0 is the date of HIV seroconversion. At her non-ART Month 6 visit, the participant reports she began using ART 5 weeks (35 days) ago. The participant is now an ART participant and an ART follow-up visit schedule needs to be created (which she will follow for the rest of her study participation). ***At this visit, a Non-ART Study Visit form is completed, visit code of 04.0, and item 1 is completed to indicate the participant has initiated ART use since her last study visit. No other items on this form are completed. An ART Enrollment form is completed for the participant. Since the participant is now an ART participant, and ART follow-up visit calendar will be generated, and the rest of the visit will be completed as an ART visit.*** Because the participant initiated ART use 35 days ago, she is at study day 35 according to the ART follow-up schedule. Day 35 is within the ART Month 1 window (visit code of 31.0). ***An ART Study Visit form is completed (visit code 31.0). All other CRFs completed at this visit are assigned a visit code of 31.0.***

Visit Windows

Required follow-up visits must be completed within the visit window. Ideally, visits will be completed on the target day for the visit, or as close as possible to the target day. Table 12-1 in Section 12.3.3 contains a detailed listing of the visit windows for each non-ART follow-up visit as well as each ART follow-up visit. Note that for all visits except the non-ART Month 1 visit, the visit windows are continuous from visit to visit. This means that no matter what day it is, the participant is always within a follow-up visit window.

Split Visits

In those cases where a participant is not able to complete all required visit evaluations on the same day, the participant may come back and complete the remaining evaluations on another day, as long as the evaluations are completed within the visit window. For example, a participant comes in on her non-ART Month 18 target day and completes all required evaluations except for the pelvic exam (she is on menses). She comes back 5 days later (once she is off menses) and completes the pelvic exam and associated procedures. The Month 18 visit is considered a “split” visit since the required procedures for the visit were conducted over two days within the visit window.

See Section 12.3.3 for information on assigning visit codes to split visits.

Missed Visits

In those cases where a participant is not able to complete any part of a required visit within the visit window, the visit is considered “missed”. Missed visits are documented by completion of a Missed Visit case report form.

When participants enroll into MTN-015 and are entering the study as non-ART participants, a non-ART follow-up visit schedule should be generated. The follow-up visit window in which the participant’s MTN-015 Enrollment date falls should be identified. For **this visit and all previous follow-up visits**, a Missed Visit form with item 2 = “visit not required per protocol” is completed. Because the visit windows for these follow-up visits have already closed at the time the participant is enrolling into MTN-015, and because we do not want a follow-up visit completed within the same visit window as the Enrollment Visit, these follow-up visits are not required per protocol but do need to be documented as “missed”. These missed visits will not count as “unretained” visits in the retention report.

Example: A participant enrolls into MTN-015 on 16-JUL-08 as a non-ART participant. The date of HIV seroconversion is 17-FEB-07 (= study day 0). Her enrollment date of 16-JUL-08 falls within the Month 18 non-ART follow-up visit window. For this participant, at her Screening/Enrollment visit, Missed Visit forms should be completed (with MV-1 item 2 = “visit not required per protocol”) for the Month 1, 2, 6, 12, and 18 non-ART follow-up visits. The participant’s first follow-up visit will be Month 24.

Similar instructions apply when a participant enrolls into MTN-015 as an ART participant. Once the participant’s ART follow-up visit schedule is generated, the follow-up visit window in which the participant’s ART Enrollment date falls should be identified. For **all previous ART follow-up visits** (all ART follow-up visits whose window has already closed), a Missed Visit form with item 2 = “visit not required per protocol” is completed. Because the visit windows for these follow-up visits have already closed at the time the participant is enrolling into the ART track, these follow-up visits are not required per protocol but do need to be documented as “missed”. These missed visits will not count as “unretained” visits in the retention report.

Example: A participant enrolls into 015 on 20-JUL-13 as an ART participant. Her date of ART initiation is 10-JUL-13 (= ART study day 0). Her ART Enrollment date of 20-JUL-13 falls within

the Week 2 ART follow-up visit window. For this participant, none of the ART follow-up visit windows has closed at the time she enrolls into the ART track, so no Missed Visit forms are required. The participant will be scheduled to complete her Week 2 ART visit on the target day of 24-JUL-13.

For participants who enroll into 015 as non-ART participants then switch to the ART track during follow-up, similar instructions apply. Once the participant's ART follow-up visit schedule is generated, the follow-up visit window in which the participant's ART Enrollment date falls should be identified. For **all previous ART follow-up visits** (all ART follow-up visits whose window has already closed), a Missed Visit form with item 2 = "visit not required per protocol" is completed. Because the visit windows for these follow-up visits have already closed at the time the participant is enrolling into the ART track, these follow-up visits are not required per protocol but do need to be documented as "missed". These missed visits will not count as "unretained" visits in the retention report.

Example: A participant enrolls into 015 on 11-JUN-13 as a non-ART participant, then switches to the ART track. She enrolls into the ART track on 09-AUG-13. The date of ART initiation is 10-JUL-13 (= ART study day 0). Her ART Enrollment date of 09-AUG-13 falls within the Month 1 ART follow-up visit window. For this participant, a Missed Visit form is completed for the ART Week 2 follow-up visit (with MV-1 item 2 = "visit not required per protocol") since this visit window has closed at the time she enrolls into the ART track. The participant will be scheduled to complete her Month 1 ART visit on 09-AUG-13.

Interim Visits

A clinic visit is considered an Interim Visit when a participant presents at the site for additional procedures *outside* of the protocol-required study visit procedures. A clinic visit is also considered an Interim Visit when the participant presents to the clinic early on in the visit window and the site decides to not complete the required visit (and instead wait until the participant is closer to her target visit day). The following are examples of interim visits for MTN-015:

1. A participant completes all required evaluations for a scheduled study visit within the visit window. She then returns to the site clinic within the same visit window to request STI testing.
2. A non-ART participant enrolls on 07-AUG-08. She returns to the site clinic three days later to request STI testing. Since she is not yet within the non-ART Month 1 window, this is an interim visit, and is assigned a visit code of 01.1.
3. A non-ART participant completes her non-ART Month 6 visit late in the window (study day 270). She comes back to the clinic 10 days later (study day 280) to request STI testing. Since the participant is very early in her non-ART Month 12 window, and because she just completed a study visit 10 days ago and the participant is judged reliable, the site decides not to complete the non-ART Month 12 visit (they will wait until closer to the non-ART Month 12 target day to complete the visit). This visit is completed as an Interim Visit, and is assigned an interim visit code of 04.1.

12.3.3 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 Termination form), the visit code will be automatically assigned in DataFax. 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, Table 12-1, lists visit type and DataFax visit codes assigned to each visit.

Table 12-1: Required Follow-up Visits: Visit Timing and Visit Codes**MTN 015 Visit Windows****I. Non-ART Ppts (Day 0 = date of HIV seroconversion)**

| Visit | Visit Code | Target Day | Window Opens Day | Window Closes Day |
|--------------|-------------------|-------------------|-------------------------|--------------------------|
| Month 1 | 2.0 | 30 | 15 | 60 |
| Month 3 | 3.0 | 90 | 61 | 136 |
| Month 6 | 4.0 | 182 | 137 | 273 |
| Month 12 | 5.0 | 365 | 274 | 456 |
| Month 18 | 6.0 | 548 | 457 | 639 |
| Month 24 | 7.0 | 730 | 640 | 821 |
| Month 30 | 8.0 | 913 | 822 | 1004 |
| Month 36 | 9.0 | 1095 | 1005 | 1186 |
| Month 42 | 10.0 | 1278 | 1187 | 1369 |
| Month 48 | 11.0 | 1460 | 1370 | 1551 |
| Month 54 | 12.0 | 1643 | 1552 | 1733 |
| Month 60 | 13.0 | 1825 | 1734 | 1916 |
| Month 66 | 14.0 | 2008 | 1917 | 2098 |
| Month 72 | 15.0 | 2190 | 2099 | 2281 |
| Month 78 | 16.0 | 2373 | 2282 | 2463 |
| Month 84 | 17.0 | 2555 | 2464 | 2646 |
| Month 90 | 18.0 | 2738 | 2647 | 2828 |
| Month 96 | 19.0 | 2920 | 2829 | 3011 |
| Month 102 | 20.0 | 3103 | 3012 | 3193 |
| Month 108 | 21.0 | 3285 | 3194 | 3376 |
| Month 114 | 22.0 | 3468 | 3377 | 3558 |
| Month 120 | 23.0 | 3650 | 3559 | 3741 |
| Month 126 | 24.0 | 3833 | 3742 | 3923 |
| Month 132 | 25.0 | 4015 | 3924 | 4106 |
| Month 138 | 26.0 | 4198 | 4107 | 4288 |
| Month 144 | 27.0 | 4380 | 4289 | 4471 |
| Month 150 | 28.0 | 4563 | 4472 | 4653 |

II. ART Ppts (Day 0 = date of ART initiation)

| Visit | Visit Code | Target Day | Window Opens Day | Window Closes Day |
|--------------|-------------------|-------------------|-------------------------|--------------------------|
| Week 2 | 30.0 | 14 | 0 | 22 |
| Month 1 | 31.0 | 30 | 23 | 60 |
| Month 3 | 32.0 | 90 | 61 | 136 |
| Month 6 | 33.0 | 182 | 137 | 273 |
| Month 12 | 34.0 | 365 | 274 | 456 |
| Month 18 | 35.0 | 548 | 457 | 639 |
| Month 24 | 36.0 | 730 | 640 | 821 |
| Month 30 | 37.0 | 913 | 822 | 1004 |
| Month 36 | 38.0 | 1095 | 1005 | 1186 |
| Month 42 | 39.0 | 1278 | 1187 | 1369 |
| Month 48 | 40.0 | 1460 | 1370 | 1551 |
| Month 54 | 41.0 | 1643 | 1552 | 1733 |
| Month 60 | 42.0 | 1825 | 1734 | 1916 |
| Month 66 | 43.0 | 2008 | 1917 | 2098 |
| Month 72 | 44.0 | 2190 | 2099 | 2281 |
| Month 78 | 45.0 | 2373 | 2282 | 2463 |
| Month 84 | 46.0 | 2555 | 2464 | 2646 |
| Month 90 | 47.0 | 2738 | 2647 | 2828 |
| Month 96 | 48.0 | 2920 | 2829 | 3011 |
| Month 102 | 49.0 | 3103 | 3012 | 3193 |
| Month 108 | 50.0 | 3285 | 3194 | 3376 |
| Month 114 | 51.0 | 3468 | 3377 | 3558 |
| Month 120 | 52.0 | 3650 | 3559 | 3741 |
| Month 126 | 53.0 | 3833 | 3742 | 3923 |
| Month 132 | 54.0 | 4015 | 3924 | 4106 |
| Month 138 | 55.0 | 4198 | 4107 | 4288 |
| Month 144 | 56.0 | 4380 | 4289 | 4471 |
| Month 150 | 57.0 | 4563 | 4472 | 4653 |

Visit Codes for Split Visits

See Section 12.3.2 for a definition of split visits. When split visits occur, the case report forms completed for the visit are all assigned the same visit (even though some forms and evaluations will have different visit dates). For example, a participant comes in on her non-ART Month 12 target day of 23-AUG-08 and completes all required evaluations except for the pelvic exam (she is on menses). She comes back on 28AUG-08 and completes the pelvic exam and associated procedures. All case report forms completed on 23 and 28 August are assigned a visit code of 05.0 (since all evaluations are completed as non-ART Month 12 evaluations).

Visit codes for Interim visits

In addition to the scheduled, protocol-required visits listed in Table 12.1, interim visits may occur once the participant is enrolled (as described in Section 13.3.2). 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 recently-required visit (whether that visit was completed or missed, and regardless of whether that visit window has closed or not).
- 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 non-ART Month 12 visit (Visit Code = 05.0). For this interim visit, use the 05.1 interim visit code.

Page numbers

Other CRFs, such as log forms (for example, the Concomitant Medications Log), may include boxes in the upper right corner for page numbers. In the example of the Concomitant Medications Log, the participant's first log page would be recorded as page "001", the second would be assigned page "002", and so on.

Recording Parent Protocol Visit Code

Item 3a on the Microbicide Trial Participation CRF asks that the visit code of a parent protocol visit be recorded if the participant completed an MTN-015 visit on the same day as a parent protocol visit. Visit codes (also known as visit numbers) in MTN-025/HOPE contain 2 digits to the right of the decimal point. For example, the visit number associated with the Month 1 Visit is 3.00.

When recording an MTN-025/HOPE visit code within item 3a of the Microbicide Trial Participation CRF, remove the first 0 after the decimal point in the MTN-025/HOPE visit code before recording it onto the MTN-016 CRF. For example, when recording MTN-025/HOPE visit code 3.02, remove the 0 after the decimal point and write "03.2" onto the MTN-016 CRF. If the parent protocol visit code is higher than 3.09 (e.g., 3.10), contact the SDMC Clinical Data Manager for additional guidance.

12.3.4 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.

12.3.5 Case Report Form Completion Schedule

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

Some SCHARP-provided forms are required to be completed at each visit, while other forms are required only at one visit or only when specifically indicated. The following table (Table 12-2) lists the DataFax and non-DataFax forms that are required to be completed at each study visit.

| ALL PARTICIPANTS - SCREENING/ENROLLMENT | | VISIT CODE: 01.0 |
|---|---|--|
| Form Acronym | Form Name | Notes |
| ENR-1 | Enrollment | |
| DEM-1, 2 | Demographics | |
| FP-1 | Family Planning | <i>Complete once site is operating under v2.0. To be completed at enrollment and when the participant's method changes</i> |
| ASA-1 | Acute Seroconversion Assessment | |
| SCS-1 | Seroconversion Symptoms | |
| LAB-1 | Laboratory Results—Revised—Version 2 | |
| STR-1 | Sexually Transmitted Diseases Results | <i>Current version dated 17Dec12</i> |
| SS-1 | Specimen Storage | |
| MTP-1 | Microbicide Trial Participation | |
| BBQ-1 to BBQ-8 | Baseline Behavioral Questionnaire | <i>Complete by MTN003 participants only</i> |
| BQ-1 | Abbreviated Baseline Behavioral Questionnaire | <i>Completed by all non-MTN003 participants once site is operating under v2.0</i> |
| ACT-1 | ACASI Tracking | <i>Completed by all non-MTN003 participants once site is operating under v2.0. Required at baseline, Mns 3, 12 and 24.</i> |
| HA-1 | HIV/AIDS-associated Events Log | <i>Complete/fax only if data present.</i> |
| NCM-1 | Non-ART Concomitant Medications Log | <i>Complete/fax only if data present</i> |
| MV-1 | Missed Visit | <i>Complete as needed per section 12.3.2</i> |
| n/a | Medical History Log (non-DataFax) | |
| n/a | Concomitant Medications Log (non-DataFax) | |
| n/a | Pelvic Exam Diagrams (non-DataFax) | |
| n/a | Physical Exam (non-DataFax) | |

| | | |
|--|--|--|
| n/a | MTN-015 LDMS Specimen Tracking Sheet | |
| <i>If enrolling into MTN-015 as an ART participant, the following additional forms are required</i> | | |
| AEN-1 | ART Enrollment - Revised Version 2 | |
| TXR-1 | Antiretroviral Treatment Regimen Log | |
| AIN-1 | ART Initiation Information--Revised | |
| ATA-1 to ATA-4 | Antiretroviral Therapy Adherence | <i>Current version dated 17Dec12</i> |
| NON-ART MONTH 1 (Day 15 to 60) | | VISIT CODE: 02.0 |
| Form Acronym | Form Name | Notes |
| LAB-1 | Laboratory Results --Revised - Version 2 | |
| SS-1 | Specimen Storage | |
| NSV-1 | Non-ART Study Visit | |
| n/a | Pelvic Exam Diagrams (non-DataFax) | |
| n/a | Physical Exam (non-DataFax) | |
| n/a | MTN-015 LDMS Specimen Tracking Sheet | |
| NON-ART MONTH 3 (Day 61 to 136) | | VISIT CODE: 03.0 |
| Form Acronym | Form Name | Notes |
| LAB-1 | Laboratory Results --Revised - Version 2 | |
| SS-1 | Specimen Storage | |
| NSV-1 | Non-ART Study Visit | |
| FBQ-1 to FBQ-10 | Follow-up Behavioral Questionnaire | <i>Complete by MTN003 participants only</i> |
| FQ-1 | Abbreviated Follow-up Behavioral Questionnaire | <i>Completed by all non-MTN003 participants once site is operating under v2.0</i> |
| ACT-1 | ACASI Tracking | <i>Completed by all non-MTN003 participants once site is operating under v2.0. Required at baseline, Mns 3, 12 and 24.</i> |
| SH-1 to SH-4 | Social Harms Questionnaire | |
| n/a | Pelvic Exam Diagrams (non-DataFax) | |
| n/a | Physical Exam (non-DataFax) | |
| n/a | MTN-015 LDMS Specimen Tracking Sheet | |
| NON-ART MONTHS 6, 18, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96, 102, 108, 114, 120, 126, 132, 138, 144, 150 | | VISIT CODE: 04.0, 06.0, 08.0 – 28.0 |
| Form Acronym | Form Name | Notes |
| LAB-1 | Laboratory Results --Revised - Version 2 | |
| SS-1 | Specimen Storage | |
| NSV-1 | Non-ART Study Visit | |
| SH-1 to SH-4 | Social Harms Questionnaire | |
| STR-1 | Sexually Transmitted Diseases Results | <i>Current version dated 17Dec12</i> |
| | | <i>Required at months 36, 48, 60, 72, 84, 96, 108, 120, 132, and 144 only</i> |
| n/a | Pelvic Exam Diagrams (non-DataFax) | |
| n/a | Physical Exam (non-DataFax) | |
| n/a | MTN-015 LDMS Specimen Tracking Sheet | |
| NON-ART MONTHS 12 and 24 | | VISIT CODE: 05.0, 07.0 |

| Form Acronym | Form Name | Notes |
|-----------------|--|--|
| LAB-1 | Laboratory Results --Revised - Version 2 | |
| SS-1 | Specimen Storage | |
| STR-1 | Sexually Transmitted Diseases Results | <i>Current version dated 17Dec12</i> |
| NSV-1 | Non-ART Study Visit | |
| FBQ-1 to FBQ-10 | Follow-up Behavioral Questionnaire | Complete by MTN003 participants only; Required at 3, 12 and 24 mns |
| FQ-1 | Abbreviated Follow-up Behavioral Questionnaire | Completed by all non-MTN003 participants once site is operating under v2.0; Required at 3, 12 and 24 mns |
| ACT-1 | ACASI Tracking | <i>Completed by all non-MTN003 participants once site is operating under v2.0. Required at baseline, Mns 3, 12 and 24.</i> |
| SH-1 to SH-4 | Social Harms Questionnaire | |
| n/a | Pelvic Exam Diagrams (non-DataFax) | |
| n/a | Physical Exam (non-DataFax) | |
| n/a | MTN-015 LDMS Specimen Tracking Sheet | |

| | | |
|--|--|--|
| ART ENROLLMENT (use at Non-ART Follow-up Visit or Interim Visit where participant switches to ART schedule) | | |
|--|--|--|

| Form Acronym | Form Name | Notes |
|---------------|--------------------------------------|--|
| | | VISIT CODE: Will vary |
| NSV-1 or IV-1 | Non-ART Study Visit or Interim Visit | <i>Complete only 1 – NSV or IV</i> |
| AEN-1 | ART Enrollment | |
| TXR-1 | Antiretroviral Treatment Regimen Log | |
| AIN-1 | ART Initiation Information - Revised | |
| MV-1 | Missed Visit | <i>Complete as needed per section 12.3.2</i> |

| | | |
|---------------------------------|--|-------------------------|
| ART WEEK 2 (Day 0 to 22) | | VISIT CODE: 30.0 |
|---------------------------------|--|-------------------------|

| Form Acronym | Form Name | Notes |
|--------------|--|-------|
| LAB-1 | Laboratory Results --Revised - Version 2 | |
| SS-1 | Specimen Storage | |
| ASV-1 | ART Study Visit | |
| SH-1 to SH-4 | Social Harms Questionnaire | |
| n/a | Pelvic Exam Diagrams (non-DataFax) | |
| n/a | Physical Exam (non-DataFax) | |
| n/a | MTN-015 LDMS Specimen Tracking Sheet | |

| | | |
|--------------------------------|--|-------------------------------|
| ART MONTH 1 and MONTH 3 | | VISIT CODE: 31.0, 32.0 |
|--------------------------------|--|-------------------------------|

| Form Acronym | Form Name | Notes |
|--------------|--|-------|
| LAB-1 | Laboratory Results --Revised - Version 2 | |
| SS-1 | Specimen Storage | |
| ASV-1 | ART Study Visit | |
| SH-1 to SH-4 | Social Harms Assessment | |

| | | |
|--|--|---|
| FBQ-1 to FBQ-10 | Follow-up Behavioral Questionnaire | Complete by MTN003 participants only; Required at 3, 12 and 24 mns |
| FQ-1 | Abbreviated Follow-up Behavioral Questionnaire | Completed by all non-MTN003 participants once site is operating under v2.0; Required at 3, 12 and 24 mns |
| ACT-1 | ACASI Tracking | <i>Completed by all non-MTN003 participants once site is operating under v2.0. Required at baseline, Mns 3, 12 and 24.</i> |
| ATA-1 to ATA-4 | Antiretroviral Therapy Adherence | <i>Current version dated 17Dec12 Month 3 only</i> |
| n/a | Pelvic Exam Diagrams (non-DataFax) | |
| n/a | Physical Exam (non-DataFax) | |
| n/a | MTN-015 LDMS Specimen Tracking Sheet | |
| ART MONTHS 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96, 102, 108, 114, 120, 126, 132, 138, 144, 150 | | VISIT CODE: 33.0, 35.0, 37.0 – 58.0 |
| Form Acronym | Form Name | Notes |
| LAB-1 | Laboratory Results --Revised – Version 2 | |
| SS-1 | Specimen Storage | |
| ASV-1 | ART Study Visit | |
| SH-1 to SH-4 | Social Harms Assessment | |
| FBQ-1 to FBQ-10 | Follow-up Behavioral Questionnaire | Complete by MTN003 participants only; Required at 3, 12 and 24 mns |
| FQ-1 | Abbreviated Follow-up Behavioral Questionnaire | Completed by all non-MTN003 participants once site is operating under v2.0; Required at 3, 12 and 24 mns |
| ACT-1 | ACASI Tracking | <i>Completed by all non-MTN003 participants once site is operating under v2.0. Required at baseline, Mns 3, 12 and 24.</i> |
| ATA-1 to ATA-4 | Antiretroviral Therapy Adherence | <i>Current version dated 17Dec12</i> |
| STR-1 | Sexually Transmitted Diseases Results | <i>Current version dated 17Dec12</i> <i>Required at months 12, 24, 36, 48, 60, 72, 84, 96, 108, 120, 132, and 144 only</i> |
| n/a | Pelvic Exam Diagrams (non-DataFax) | |
| n/a | Physical Exam (non-DataFax) | |
| n/a | MTN-015 LDMS Specimen Tracking Sheet | |

| | | |
|--|--|---|
| ALL PARTICIPANTS – STUDY EXIT/EARLY TERMINATION | | VISIT CODE: Will vary (use visit code assigned based on participant’s follow-up visit schedule – regular or interim visit code) |
| Form Acronym | Form Name | Notes |
| LAB-1 | Laboratory Results --Revised – Version 2 | |
| SS-1 | Specimen Storage | |

| | | |
|--|---|---|
| ASV-1 | ART Study Visit | Complete this form if on ART track |
| NSV-1 | Non-ART Study Visit | Complete this form if on Non-ART track |
| IV-1 | Interim Visit | Complete as applicable |
| n/a | Pelvic Exam Diagrams (non-DataFax) | |
| n/a | Physical Exam (non-DataFax) | |
| n/a | MTN-015 LDMS Specimen Tracking Sheet | |
| STR-1 | Sexually Transmitted Diseases Results | <i>Current version dated 17Dec12</i> <i>Required at months 12, 24, 36, 48, 60, 72, 84, 96, 108, 120, 132, and 144 only</i> |
| SH-1 to SH-4 | Social Harms Assessment | |
| ATA-1 to ATA-4 | Antiretroviral Therapy Adherence | <i>Current version dated 17Dec12</i> |
| TM-1 | Termination | |
| ESI-1 | End of Study Inventory | |
| If the participant reports initiations of ART at the exit visits complete the following CRFs in addition to those listed above. | | |
| AEN-1 | ART Enrollment | |
| AIN-1 | ART Initiation Information - Revised | |
| TXR-1 | Antiretroviral Treatment Regimen Log | |
| MV-1 | Missed Visit | |
| All Participants: review and close-out all entries on log forms (listed below) and refax DataFax log forms with new or updated entries | | |
| n/a | Concomitant Medications Log (non-DataFax) | |
| TXR-1 | Antiretroviral Treatment Regimen Log | |
| HA-1 | HIV/AIDS-associated Events Log | <i>Complete/fax only if data present.</i> |
| NCM-1 | Non-ART Concomitant Medications Log | <i>Complete/fax only if data present</i> |
| n/a | Medical History Log (non-DataFax) | |

12.3.6 Site Review of DataFax Forms

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

- Other than the participant ID number (PTID), there is no information on the form that could identify the participant (e.g., name, phone number, national identification number, or any other personal identifiers).
- A response has been recorded for each item, unless the item was skipped as instructed by a skip pattern or the item was marked as missing or unknown as described in Section 12.2.7.
- 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 12.3.7 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.

12.3.7 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-015 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.

CRF Tracking System

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-015 Clinical Data Manager if you would like to use the CRF Tracking System or for more information about the CRF Tracking System.

12.3.8 Non-DataFax Forms

MTN-015 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 12.2.1 through 12.2.7 should be applied when completing non-DataFax CRFs.

12.4 Form Supply

Sites are responsible for creating their own supplies of MTN-015 case report forms. Sites should print CRFs from pdf files provided by SCHARP, all files available on the MTN-015 Atlas web page. Forms are provided in visit packets and as individual (as needed) pdf files. Each CRF visit packet contains a cover page and all required non-translated CRFs required to be completed for the visit.

For translated form, local-language Screening and Enrollment and Follow-up packets are provided. The local-language versions of interviewer-administered forms will need to be inserted into the appropriate form visit packet. The cover pages of the form visit packets list which local-language form versions need to be added.

12.5 Case Report Forms and Form-specific Completion Instructions

This section contains each MTN-015 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 for a suggested order in which the forms should be completed at each visit.