



MTN 015 Data Communiqué #8

January 14, 2014

This is official study documentation for MTN 015. Please circulate it among relevant staff for their review, print it, and place it in your MTN 015 SSP Manual in the Data Communiqués section. This document is considered part of the MTN 015 SSP manual.

Completion of Study Exit/Termination Visits for MTN 003 Participants

The purpose of this communication is to provide data collection/management guidance related to study exit/termination visits performed for MTN 003 participants.

1. Which participants should be exited, and when?

SCHARP will provide each site with a listing of all PTIDs in follow-up whose parent protocol is MTN 003. This listing will have the target dates and windows for the participant's next 1-2 visits. The site should make every effort to complete the Study Exit/Termination visit within the January 2 – June 30, 2014 timeframe (inclusive). The site can complete the study exit visit anytime within this timeframe, and should schedule this visit based on the participant's needs/preferences.

2. Which CRFs are completed/updated at the Study Exit/Termination visit

Study Exit Visit Required CRFs:

Laboratory Results—Revised – Version 2

Specimen Storage

*Non-ART Study Visit, ART Study Visit, or Interim Visit CRF (as applicable)

Pelvic Exam Diagrams (non-DataFax)

Physical Exam (non-DataFax)

MTN-015 LDMS Specimen Tracking Sheet

Sexually Transmitted Disease Results

Social Harms Assessment

Antiretroviral Therapy Adherence (only if participant's exit visit is an ART Month 3 or later visit)

Termination

End of Study Inventory

**Note: if the participant reports initiation of ART at the exit visit, complete the Non-ART Study Visit CRF and the other CRFs listed above as well as:*

ART Enrollment

ART Initiation Information - Revised

Antiretroviral Treatment Regimen Log

Missed Visit (for any ART follow-up visits for which the window has already closed)

All participants - review and close-out all entries on log forms (listed below). Refax DataFax log forms with new or updated entries.

Concomitant Medications Log

Antiretroviral Treatment Regimen Log

Non-ART Concomitant Medications Log
HIV/AIDS-associated Events Log
Medical History Log

3. What Visit Code to Use

There is no special visit code assigned to the exit visit. Use the visit code assigned to the visit based on the participant's visit schedule. This can be a whole number or interim visit code. If the exit visit is an interim visit, assign the appropriate interim visit code and complete an Interim Visit CRF (and not a Non-ART or ART Study Visit CRF).

4. Termination CRF item 2

Mark response 2a ("scheduled exit visit/end of study") for MTN 003 participants who exit the study anytime from January 2 – June 30, 2014, inclusive.

5. Pregnancy Outcome Reporting for HPTN 035 Participants

If an MTN 003 participant is pregnant at the time of her termination from MTN-015, you do not need to follow her to obtain the pregnancy's outcome. You do need to complete a Pregnancy Outcome CRF at her study exit visit by recording the PTID and the Visit Code matching the Pregnancy Report CRF, and mark the "Outcome unavailable at end of study" box at the top right, record Staff Initials/Date on the line next to the box, and end the form. Fax this form to SCHARP with the participant's study exit DataFax CRFs.