



## MTN 015 Data Communiqué #13

October 31<sup>st</sup>, 2018

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-020/ASPIRE and MTN-025/HOPE Participants

The purpose of this communication is to provide data collection/management guidance related to study exit/termination visits performed for MTN-020 and MTN-025 participants.

#### 1. Which participants should be exited, and when?

All MTN-015 participants will exit the study between November 1<sup>st</sup>, 2018 and June 30<sup>th</sup>, 2019. Cohort-specific guidance on when to schedule exit visits is provided below.

##### ASPIRE/MTN-015 Cohort:

SCHARP will provide each site with a listing of all PTIDs in follow-up whose parent protocol is MTN 020/ASPIRE. This listing will have the target dates and visit windows for the participant's next scheduled study visit. The site should make every effort to complete the MTN-015 Study Exit/Termination visit at the participants next scheduled MTN-015 visit, and within the November 1, 2018 – June 30, 2019 timeframe (inclusive). The site should complete the study exit visit within the visit window for their next scheduled MTN-015 visit and should schedule this visit based on the participant's needs/preferences.

##### HOPE/MTN-015 Cohort:

SCHARP will provide each site with a listing of all PTIDs in follow-up whose parent protocol is MTN 025/HOPE. This listing will have the target dates and visit windows for the participant's remaining MTN-015 study visits scheduled through 30 June 2019 as well as the participant's ART start date, if applicable. The site should make every effort to complete the Study Exit/Termination visit at the participant's last study visit that is scheduled to occur before 30 June 2019, and within a timeframe that permits at least one year of follow-up on ART, if applicable (see operational guidance on exit of ASPIRE/HOPE participants from MTN-015 for more information).

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

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**Study Exit Visit Required CRFs:**

Laboratory Results—Revised – Version 2

Specimen Storage

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

Pelvic Exam Diagrams (non-DataFax)

Physical Exam (non-DataFax)

MTN-015 LDMS Specimen Tracking Sheet (non-DataFax)

Sexually Transmitted Disease Results

Social Harms Assessment

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

Follow up Behavioral Questionnaire – Version 2.0 (if applicable)

ACASI Tracking (if applicable)

End of Study Inventory

Termination

*\*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.

Antiretroviral Treatment Regimen Log

Non-ART Concomitant Medications Log

HIV/AIDS-associated Events 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-020 and MTN-025 participants who exit the study anytime from November 1 2018 – June 30, 2019.

**5. Pregnancy Outcome Reporting for MTN-025/HOPE Participants**

If an MTN-025/HOPE 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 as part of MTN-015 follow-up (however, this should be captured as part of MTN-025/HOPE follow-up). For any ongoing pregnancies at MTN-015 exit, 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.

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**6. For either cohort, if participants are not present at the clinic prior to 30 June 2019, participants should be terminated in absentia. The following forms should be completed for terminations in absentia:**

- Termination
- End of Study Inventory
- Complete a Missed Visit CRF for each missed visit with a target date on or prior to the termination date, if applicable.
- Review and close-out all entries on log forms (listed below). Refax DataFax log forms with new or updated entries:
  - Antiretroviral Treatment Regimen Log
  - Non-ART Concomitant Medications Log
  - HIV/AIDS-associated Events Log