



## MTN-015 Data Communiqué #10

July 18, 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.**

### Terminating MTN-003 Participants Lost to Follow-up

The purpose of this communication is to provide guidance on how to terminate from MTN-015 any MTN-003 participants who did not complete an MTN-015 Study Exit/Termination Visit as of June 30, 2014. These participants are considered lost to follow-up. To terminate these participants from MTN-015, complete the following steps:

1. Complete the Termination CRF.
  - a. Record as the termination date the date when the site considered the participant's study participation to have ended; that is, when the participant was first considered no longer in the study. The termination date may be June 30, 2014 or later, per site discretion. Do not mark item 2a as the reason for termination if the participant did not complete a Study Exit/Termination Visit. Instead, mark one of the other item 2 reasons, as applicable; for example, 2g-“unable to contact participant”.
2. Complete the End of Study Inventory CRF
3. Complete a Missed Visit CRF for each missed visit with a target date on or prior to the termination date
4. Review and close out all entries on all log CRFs (listed below)
  - a. Antiretroviral Treatment Regimen Log
  - b. Non-ART Concomitant Medications Log
  - c. HIV/AIDS-associated Events Log

For those sites that still have VOICE participants in MTN-015 follow-up, SCHARP will provide site-specific PTID lists to guide efforts in terminating the remaining VOICE participants.