



MTN 015 Data Communiqué #1

October 29, 2009

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.

UPDATES

1. Overview of New Case Report Forms

a. ART Initiation Information (ART-1), dated 22-SEP-09

This new CRF captures information related to a participant's initiation of ART, including the reason why the participant initiated ART as well as the last known viral load and CD4+ count prior to initiating ART. This form is completed once for each participant enrolled in the ART follow-up track, and is completed at the visit where the participant enrolls into the ART track (the ART Enrollment Visit). This form will be included in all ART Enrollment Visit form packets as of 01-NOV-09.

b. Laboratory Results – Revised (LRR-1), dated 22-SEP-09

This new CRF is based on the Laboratory Results (LR-1) form, and will serve to replace the LR-1 form in MTN 015 as of 01-NOV-09. The new LRR-1 form has 3 new items. Item 2a1 has been added, which captures the lower limit of detection of the kit used to obtain the HIV RNA PCR result recorded in item 2a. Also, currently at the Zimbabwe sites, for some specimens, they perform two HIV RNA PCR tests on the same specimen. Due to this, we have added items 2b and 2b1, which collect the 2nd HIV RNA PCR result obtained for the specimen, as well as the kit's lower limit of detection used to obtain the 2nd HIV RNA PCR result.

2. Overview of Updated Case Report Forms

a. Enrollment (ENR-1), updated 22-SEP-09

The ART Initiation Information form has been added to the list of forms contained in the skip instruction off of the "ART" response box of item 5.

b. Non-ART Study Visit (NSV-1), updated 22-SEP-09

The ART Initiation Information form has been added to the list of forms contained in the skip instruction off of the "yes" response box of item 1.

c. Interim Visit (IV-1), updated 22-SEP-09

The ART Initiation Information form has been added to the list of forms contained in the skip instruction off of item 1a. Also, item 2b has been updated to read "Laboratory Results – Revised".

d. Sexually Transmitted Diseases Results (STR-1), updated 22-SEP-09

Items 4 and 5 have been added to capture rapid test results for trichomoniasis (item 4) and BV (item 5). While the form contains items to record both wet mount results and rapid test results, it is expected that only one type of test will be performed at each visit, and in most cases, this will be the rapid tests. When testing for BV or Trichomoniasis is performed, the rapid tests should be used, with the result recorded in items 4 and 5 (items 1a, 1c, 1d, and 1e

should be marked “not done”). A QC will result if there is a result marked for items 1a, 1c, 1d and item 5. Likewise, a QC will result if there is a result marked for both item 1e and item 4.

3. Overview of Archived Case Report Form – Laboratory Results (LR-1)

November 30, 2009 is the last possible day for any MTN 015 site to complete a new Laboratory Results (LR-1) form. For all visits on or after December 1, 2009, sites should use the Laboratory Results – Revised (LRR-1) form to report CD4+, HIV RNA PCR viral load, and/or pregnancy test results.

Any unused (blank) Laboratory Results forms present at the sites as of November 30, 2009 should be destroyed.

4. New code on Antiretroviral Medication Stop Code List

A new code of “88 – dose change” has been added as a stop code on the Antiretroviral Medications Stop Code List (revised Version 1.1, dated 30-OCT-09). This stop code should be used as the stop code on the TXR-1 form in cases where a participant has stopped taking an ART medication at a certain dose, but will continue to take the ART medication at a different dose (which will result in a new entry on the TXR-1).

CLARIFICATIONS

1. Procedures for Transcribing Data from Laboratory Results (LR-1) forms onto Laboratory Results – Revised (LRR-1) forms – Action needed by Friday, December 11, 2009.

Because the LRR-1 form is replacing the LR-1 form, we need to have sites transcribe all of the data collected so far on LR-1 forms onto LRR-1 forms. Please do this by following steps a through h below. Please try to complete these steps for all previously-completed LR-1 forms **by Friday, December 11, 2009.**

- a. Obtain blank copies of the LRR-1 form, along with a MTN 015 participant notebook (for a participant already enrolled in the study)
- b. Starting with the Screening/Enrollment Visit, find all LR-1 forms completed for the participant. Note that there should be a completed LR-1 form for each required (non-interim) visit the participant completed.
- c. For each completed LR-1 form, transcribe the PTID, Visit Code, Initial Collection Date, and data for items 1 and 3 onto a new LRR-1 form. These items should be exactly the same on both forms.
- d. For LRR-1 item 2a, record the HIV RNA PCR result exactly as it appears on the lab result source document from the local lab. In most cases, this will match what is recorded in LR-1 item 2a. It may differ, however, if for example, the result on the LR-1 is “< 400”, and the lab source document has a result of “= 356”. In this case, please record “= 356” in LRR-1 item 2a (per the LRR-1 form instructions).
- e. For LRR-1 item 2a1, record the HIV RNA PCR kit lower limit of detection (in copies/mL). Note that this item is not on the LR-1 form, so you will be recording this data for the first time on the LRR-1.
- f. **For all sites other than Zimbabwe:** Mark the “not done” box to the left of item 2b and go to step g. **Zimbabwe sites only:** If a second (ultrasensitive) assay was run on the same specimen documented in 2a, record the results of the ultrasensitive test in item 2b. In LRR-1 item 2b1, record the HIV RNA PCR kit lower limit of detection (in copies/mL). Note that these items are not on the LR-1 form, so you will be recording these data for the first time on the LRR-1.
- g. Complete the “Staff Initials/Date” field at the bottom of the form. Use the current date.

