

## MTN-017 Data Communiqué #1 - August 12, 2013

This is official study documentation for MTN-017. Please circulate it among relevant staff for their review, print it, and place it in your MTN-017 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-017 SSP manual.

### UPDATES

#### 1. Follow-up CASI Tracking (FCT-1) CRF, version 2, version date: 24-JUL-13

The Visit Code field was updated to remove the pre-printed “0” from the tenths digit box. This was done to allow sites to record an interim visit code as needed. CASI may be done at an interim visit (i.e., between regularly scheduled study visits) if:

- a. a participant terminates the study early and agrees to complete a CASI survey as part of the Early Termination Visit
- b. a participant completes CASI at an interim visit to make up for a missed CASI survey.

The CRF files on the Atlas page have been updated to include this new form version. The Atlas page is located at: <https://atlas.scharp.org/cpas/project/MTN/017/begin.view?>

#### 2. Safety Laboratory Results (SLR-1,2) CRF – Instructions version 2, version date: 24-JUL-13

On the back of both form pages, the instructions to “Severity Grade” were updated to separate instructions at screening/enrollment from instructions at follow-up visits.

- Severity Grade:
- If any values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the result. If value is below Grade 1, leave the severity grade box blank.
  - Always compare the severity grade range to the value that was recorded on the form (not the lab-reported value).
  - When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
    - Treat all missing digits in the lab value as zeros.
    - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
  - At Screening and Enrollment, record any Grade 1 or higher lab values on the Pre-existing Conditions form. Evaluate for eligibility.
  - During Follow-up, record any Grade 1 or higher lab values on the Adverse Experience (AE) Log as applicable.

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**CLARIFICATIONS** – None

**REMINDERS** – None