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.

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

CLARIFICATIONS – None

REMINDERS – None