



MTN-011 Data Communiqué #3

14 February 2013

This is official study documentation for MTN-011. Please circulate it among relevant staff for their review, print it, and place it in your MTN-011 SSP Manual in the Data Communiqués section.

This document is considered part of the MTN-011 SSP manual.

UPDATES

1. Pharmacokinetics form (PK-1), items 8-12

Rectal sponge and biopsy weights will no longer be recorded on the PK-1 CRF, but will now be documented on the LDMS Specimen Tracking Sheet and entered into the LDMS system. The MTN Network Lab will notify sites when the updated LDMS Specimen Tracking Sheet is available on the MTN website. PK-1 forms which were previously completed (prior to 19-FEB-13) do not need to be updated, but you will need to retroactively enter those weights into LDMS. Starting on 19-FEB-13 SCHARP will no longer accept the 01-AUG-12 (bottom left corner of CRF) version. The new version (dated 14-FEB-13) must be used for all visits starting on 19-FEB-13. The new PK-1 CRF has been emailed to each site, and has also been updated within each Visit Packet on the Atlas page as needed. Please print the new version and replace any of the blank old versions in the unused packets. The packets requiring replacements are:

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|--|--|
| - Group 1: Visit 1 (Screening Visit) | - Group 2: Visit 1 (Screening Visit) |
| - Group 1: Visit 2a/2b (Enrollment Visit) | - Group 2: Visit 2 (Enrollment Visit) |
| - Group 1: Visit 3a/3b | - Group 2: Visit 3a/3b |
| - Group 1: Visit 4a/4b | - Group 2: Visit 5 |
| - Group 1: Visit 5b | - Group 2: Visit 7a/7b |
| - Group 1: Visit 6b | - Group 2: Visit 9 (Termination Visit) |
| - Group 1: Visit 7a/7b (Termination Visit) | |

2. Pelvic Exam – Clinically-indicated form (PCI-1), item 2

The skip instruction for item 2 (off of the “no” box) has been corrected. It now reads “If no, go to item 3.” Previously completed forms do not need to be updated, but sites must use the updated version (dated 14-FEB-13) beginning on 19-FEB-13. The new PCI-1 CRF has been emailed to each site, and has also been updated within the affected Visit Packet (i.e. Group 1: Visit 1 Enrollment), as well as within the “Individual CRF” listing on the Atlas page. Please print the new version and replace any of the blank old versions in the unused packets.

CLARIFICATIONS

None.

REMINDERS**1. All CRFs**

When recording text responses (letters and/or numbers) please remember to write legibly. If the responses cannot be easily read QCs will be applied.