



MTN-013/IPM 026 Data Communiqué #3

December 19, 2011

This is official study documentation for MTN- 013/IPM 026. Please circulate it among relevant staff for their review, print it, and place it in your MTN-013/IPM 026 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-013/IPM 026 SSP manual.

UPDATES

1. **Version 2.0: LDMS Specimen Tracking Sheet and LDMS Specimen Track Sheet for Enrollment and Day 28**

The LDMS Specimen Tracking Sheets have been updated to provide new guidelines for PK blood collection storage. The LDMS Specimen Tracking Sheet Version 2.0, dated 16-DEC-11, clarifies that the PK-Single time-point blood draw can be frozen within 8 hours of blood collection. The revised LDMS Specimen Tracking Sheet for Enrollment and Day 28 Version 2.0, dated 16-DEC-11 clarifies that the 0, 1, 3, 4 and 6 Hour PK Blood draws can be frozen within 8 hours of collection. Please print out these forms, either as provided by SCHARP via email attachment or via download from the MTN-013/IPM 026 Atlas web page:

<https://atlas.scharp.org/cpas/project/MTN/013%20and%20IPM%20026/begin.view>.

Add LDMS Specimen Tracking Sheet Version 2.0 to all unused:

- Enrollment Visit Packets
- Day 1, 2, 5 Visit Packets
- Day 7 Visit Packets
- Day 14 and 21 Visit Packets
- Day 28 Visit Packets
- Day 29 and 30 Visit Packets
- Day 21, 35, 42 Visit Packets
- Day 52 Visit Packets

Discard the previous LDMS Specimen Tracking Sheets, dated 01-AUG-11, and continue to complete at each Visit.

Add the Version 2.0 LDMS Specimen Tracking Sheet for Enrollment and Day 28 to the Enrollment and Day 28 Visit packets, discard the previous LDMS Specimen Tracking Sheet, dated 01-AUG-11, and continue to complete at both visits.

CLARIFICATIONS

1. **Adverse Experience Log (AE-1) CRF**

In the event that an AE Log page needs to be deleted after being faxed into DataFax, please fax the original AE Log page back to SCHARP with a diagonal line across the entire form with a note documenting the reason for this deletion, and initial and date this change.

REMINDERS

None