



MTN-005 Data Communiqué #2

November 15, 2011

This is official study documentation for MTN-005. Please circulate it among relevant staff for their review, print it, and place it in your MTN-005 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-005 SSP manual.

UPDATES

1. Revised LDMS Specimen Tracking Sheet – Version 4.0, 07-NOV-11

One item on the LDMS Specimen Tracking Sheet has been corrected – the primary additive code listed for the swab of used IVR for culture (2nd to last row) has been corrected to “NON”. This is now consistent with information in the Laboratory section of the SSP Manual.

Since this specimen is collected at the Week 12 visit only (and only for IVR participants), SCHARP will not be re-issuing any CRF form packets. Instead, we ask that the US sites please print the attached pdf of the revised sheet and use it to replace the LDMS Sheet currently in any unused Week 12 visit packets at your site. This includes notebooks for IVR participants who have not yet reached Week 12 as well as any unassigned notebooks with Week 12 visit packets in place.

This revised version will be included in the initial CRF supplies provided to the India site, so no action needed from that site. .

CLARIFICATIONS

\None

REMINDERS

None.

ATTACHMENTS

1. Revised (Version 4.0) of the MTN-005 LDMS Specimen Tracking Sheet.