



MTN-005 Data Communiqué #1

June 8, 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. Due to shifting workloads, James Dai is now the Protocol Statistician assigned to MTN-005. Liza Noonan will no longer work on this study.

2. Updates to Screening Visit CRF form packets

The Screening Visit packets originally provided to the two US sites did not include the Specimen Storage and MTN-005 LDMS Specimen Tracking Sheets (required for documentation of gram stain slides collected at this visit). The Screening Visit packet cover sheets were revised to include these two forms (revised version number 2.0 dated 06-Jun-11), and these revised cover sheets were shipped to sites the week of June 6. Included in this shipment were Specimen Storage CRFs and LDMS Specimen Tracking Sheets. Once available on-site, sites are requested to go through all unused Screening Visit form packets and replace the cover sheet and add the Specimen Storage and LDMS Specimen Tracking Sheets to the packet.

Note that Screening Visit gram stain slides should only be entered into LDMS and stored for participants who enroll in the study. If a screened participant does not enroll, the Screening Visit gram stain slides should be destroyed and not logged into LDMS.

CLARIFICATIONS

1. Local Laboratory Results (LLR-1), item 1a (urine leukocyte esterase)

If a trace urine leukocyte esterase result is received, record this as “negative” on the LLR-1 case report form.

REMINDERS

None.