



MTN 001 Data Communiqué #2

October 28, 2008

This is official study documentation for MTN 001. Please circulate it among relevant staff for their review, print it, and place it in your MTN 001 SSP Manual in the Data Communiqués section (Section 14). This document is considered part of the MTN 001 SSP manual.

UPDATES

1. SCHARP Staffing Changes

Karen Patterson has taken over as sole SCHARP Project Manager on MTN 001. Please contact Karen (karen@scharp.org or karenp@scharp.org) regarding any questions related to data collection or data management in MTN 001.

Sara Jasinski (Jasinski@scharp.org) has replaced Jennifer Schille as the Data Coordinator for MTN 001. Sara is responsible for creating and sending out the Data Quality Control (QC) reports.

2. New Flow Cytometry Form, Dated 10-SEP-08

On 29-SEP-08, SCHARP issued a new Flow Cytometry (FC) form (dated 10-SEP-08) to capture flow cytometry test results of PK specimens collected at each End-of-study period Visit. Those sites with capacity for flow cytometry testing (all sites except Umkomaas and Botha's Hill) are required to complete this form and fax it to SCHARP DataFax. The Cleveland and Pittsburgh sites were instructed to print the form on-site and complete it retrospectively for the participants enrolled at their sites who already completed End-of-study Period Visits. The UAB, Bronx, and Uganda sites will receive hard copies of this form from SCHARP as part of their initial CRF shipment.

3. Revised Study Product Adherence and Behavior Assessment Form, Dated 24-OCT-08

On 27-OCT-08, SCHARP issued a revised Study Product Adherence and Behavior Assessment, dated 24-OCT-08. The form was revised, per decision on the 07-OCT-08 Investigators' Call, to include additional questions on vaginal sex in the past 24 hours and questions on anal study gel use. The Cleveland and Pittsburgh sites were instructed to print the form on-site and replace all old versions (dated 21-MAR-08) of the forms with this new version. All unused old versions of the form must be destroyed, as DataFax will no longer accept new submissions of the old form version as of 28-OCT-08. The UAB, Bronx, Uganda, and Durban sites (Umkomaas and Botha's Hill) will receive hard copies of the revised form from SCHARP as part of their initial CRF shipment.

4. Revised LDMS Specimen Tracking Sheets

A revised version of the MTN 001 US Sites - LDMS Specimen Tracking Sheet version 2.0, dated 10-OCT-08 was issued. No changes were made to page 1, except for the version number and date in the footer. On page 2, the information in the “Instructions for Processing Lab” column was updated for the cervical cytology brush (CER) and vaginal tissue (VGL) specimens. These changes are simply corrections to reflect appropriate lab processing procedures. They do not represent any updates made in protocol version 2.0. No changes were made to the instructions on the back of page 2, except for the version number and date in the footer. The Cleveland and Pittsburgh sites were instructed to print the new version of the sheet on-site and replace all old versions (dated 15-APR-08) of the sheet with this new version. The UAB and Bronx sites will receive hard copies of the revised sheet from SCHARP as part of their initial CRF shipment.

The MTN 001 Africa – LDMS Specimen Tracking Sheet was revised (new version 1.0, dated 03-SEP-08). No changes were made to the front of the sheet, except for the date in the footer. The only content change was to correct the “Purpose” section in the instructions on the back of the sheet by removing the text “(US sites only)”. The Uganda and Durban sites (Umkomaas and Botha’s Hill) will receive hard copies of the revised sheet from SCHARP as part of their initial CRF shipment.

5. Revised Replacement Randomization Documents

Both the US and African site versions of the MTN 001 Replacement Randomization Document were revised. On both versions, the text “Date Envelope Opened” was replaced with “Date” to clarify that these documents do not come in randomization envelopes. Also, the “clinic” copy of the US site MTN 001 Replacement Randomization Document was corrected to state “Intensive PK” instead of “Non-Intensive PK”. The revised documents will be included in the original shipment of MTN 001 randomization materials that SCHARP will send to the Durban, UAB, and Bronx sites. SCHARP will mail the revised documents to the Cleveland, Pittsburgh, and Uganda sites with instructions to dispose of copies of the old version.

CLARIFICATIONS

1. Pelvic Laboratory Results form, item 3 - Pap Smear

For participants who provide adequate documentation of a normal Pap Smear result in the 12 months prior to screening (and thus do not require a Pap test at screening), do **not** record the result on the Pelvic Lab Results form. Instead, item 3 should be marked “Not done/Not collected”. The documentation should be placed in the participant’s chart, and should be documented in the chart notes only. Record on the Pelvic Laboratory Results form, item 3, only those Pap Smear results of Pap specimens collected as part of the study.

2. Documenting Lab Value AEs on the Adverse Experience Log

For AEs of gradable laboratory results (e.g., “Increased ALT”), the date the laboratory report is received should be recorded as the “Date Reported to Site” on the AE Log. The date of specimen collection should be recorded as the “Onset Date” on the AE Log.

3. Documenting Syphilis Results

Per SSP Manual Section 12, sites may choose to conduct TPHA testing only. For sites that do not conduct RPR and titer testing, complete these form items (items 2a-2a1 on the Screening and Enrollment STI Laboratory Results form, and items 2a-2a1 on the STI Laboratory Results form), by lining through the response boxes, and initialing and dating the items.

4. Documenting Auxiliary Temperature on the non-DataFax Physical Exam Form

If possible, measure the participant's temperature orally and record it on the form. If only the auxiliary temperature can be measured, record it on the form by lining through the word "oral", writing "auxiliary", and initialing and dating the correction.

5. Documenting Labial Stretching as a Vaginal Practice

If a participant reports labial stretching as a vaginal practice during the behavioral interviews, please record this practice in item 9g on the Enrollment Behavior Assessment or in item 18g on the Study Product Adherence and Behavior Assessment, dated 24-OCT-08. If a stretched labia is observed during the pelvic exam, and is known to be due to the practice of labial stretching, please record this condition on the non-DataFax Pelvic Exam Diagrams form. Do not record this condition on the Screening and Enrollment Pelvic Exam form or on the Follow-up Pelvic Exam form, as it is considered a variant of normal.

REMINDERS

1. Updating Source Documentation Standard Operating Procedure (SOP)

Each time a new or revised case report form (CRF) is issued, please review your site's MTN 001 Source Documentation SOP. Revise the SOP as necessary to account for the new or revised CRF and send the revised SOP to SCHARP (karen@scharp.org) and FHI (kgomez@fhi.org, sjohnson@fhi.org) for their study records.