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## MTN 004 Data Communiqué #2

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November 12, 2008

This is official study documentation for MTN 004. Please circulate it among relevant staff for their review, print it, and place it in your MTN 004 SSP Manual in the Data Communiqués section. This document is considered part of the MTN 004 SSP manual.

### UPDATES

#### 1. Enrollment case report form (ENR-1)

A revised Enrollment CRF was distributed to both sites via email on 28-Oct-08. This revised form, dated 28-Oct-08, had a revision made to item 2a (the number of boxes for envelope number has been updated to 3 boxes). The previous version of the form should be removed and not used for any participants enrolling on or after October 28, 2008.

#### 2. Recall and Re-issue of randomization envelopes

Due to an error identified in the Tampa randomization envelopes (a separate Memo to File has been provided to the site to document these events), all un-assigned MTN 004 Clinic and Replacement randomization envelopes provided to both sites in September, 2008 were recalled by SCHARP. These envelopes were reassembled at SCHARP, and re-issued to the sites during the first week of November, 2008. For the Tampa site, Clinic envelopes numbered 104-133 were re-issued, as were Replacement envelopes numbered 101-R and 102-127. For the San Juan site, Clinic envelopes numbered 134-166 and Replacement envelopes numbered 134-160 were re-issued. All of the re-issued envelopes are stamped with the date of "Nov 04 2008".

### CLARIFICATIONS

#### 1. Safety Laboratory Results (SL-1) form, item 2

For items 2a and 2b of the SL-1 CRF (neutrophils and lymphocytes), please record **both the percentage and absolute count results** for these items. For items 2c-2h, only a percentage **or** absolute count is needed. Please go back and record the absolute count for items 2a and 2b for all participants previously enrolled in the study (enrolled in 2007).

### REMINDERS

#### 1. Faxing of the CASI Tracking (CT-1) CRF

Note that the CASI Tracking CRF should be submitted to SCHARP once the participant has completed her participation in the study (along with the End of Study Inventory and Termination CRFs). Please do not fax this form to SCHARP until this time.