



MTN 002 Data Communiqué #2

October 9, 2008

This is official study documentation for MTN 002. Please circulate it among relevant staff for their review, print it, and place it in your MTN 002 SSP Manual in the Data Communiqués section. This document is considered part of the MTN 002 SSP manual.

UPDATES

1. Revised Flow Cytometry case report form (FC-1)

A revised Flow Cytometry (FC-1) case report form has been issued. The date of this form (lower left-hand corner of the form) is 07-OCT-08. This revised one-page CRF should be printed and added to each MTN 002 Study Participant Notebook in the “Pharmacokinetic Measures: Gel Administration (Visit 2.0)” tab. Any previous versions of this CRF present in the notebooks should be removed and destroyed.

Note that for the first participant enrolled into MTN 002 (who did not complete the Gel Administration visit, Visit 2.0), the revised Flow Cytometry CRF does not need to be completed or faxed to SCHARP. For all other study participants, this CRF is completed as part of the Visit 2.0 evaluations.

CLARIFICATIONS

None.

REMINDERS

None