



MTN 004 Data Communiqué #3

July 28, 2009

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

None.

CLARIFICATIONS

1. Enrollment CRF and participants who do not provide consent for long-term specimen storage and future testing

For enrolled MTN 004 participants who **do not** consent to long-term specimen storage and future testing, please document this by adding a note in the “Comments” section of the Enrollment (ENR-1) CRF. For enrolled participants who do provide this consent, no additional documentation is needed on the CRF.

Once the study is completed and all specimens have been analyzed, SCHARP will provide each site with a listing of those participants who did not consent to long-term storage. Instructions will also be provided for destroying any remaining stored specimens from the listed participants.

2. Study Gel Adherence CRF (SGA-1) completion for participants who have a product hold and/or permanent product discontinuation

Items 2 and 2a of the SGA-1 form should be completed based on the actual number of days the participant reports using study product less than 2 times per day, even if the participant did not use product because she was on a product hold or had permanently discontinued study product. If the participant was on product hold or permanent discontinuation and this is the reason she did not use product twice/day, please indicate this in the “Comments” section by adding a note like “participant on [product hold or permanently discontinued] since dd/MMM/yy”.

REMINDERS

None.