



MTN-008 Data Communiqué #4

4 October 2011

This is official study documentation for MTN-008. Please circulate it among relevant staff for their review, print it, and place it in your MTN-008 SSP Manual in the Data Communiqués section.

This document is considered part of the MTN-008 SSP manual.

UPDATES

1. Enrollment form (ENR-1), item1

For all infants enrolled in the Lactation Cohort, you must record the **date of enrollment** rather than the date the informed consent form for (screening and) enrollment was signed. For all mothers enrolled in the Lactation Cohort, you must record the **date that the authorized clinician completes the study product prescription on Day 0**, which will likely be the same day she signs the informed consent for enrollment.

Per the MTN-008 SSP Section 4.5, “Infants in the Lactation Cohort will be considered enrolled in MTN-008 at the same time their mothers are enrolled. Mothers in the Lactation Cohort will be considered enrolled in MTN-008 once the authorized clinician completes the study product prescription on Day 0.”

The forms instructions have also been updated to reflect this clarification for these participants. Please reprint Enrollment forms (attached file this email) for all future Lactation Cohort participants (mothers and infants) so the instructions are correct. DO NOT transcribe any previously completed data onto a new form.

CLARIFICATIONS

None.

REMINDERS

None.