

---

## MTN-008 Data Communiqué #2

---

5 May 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. Home Breast Milk Specimens

We have created an LDMS Specimen Tracking sheet specifically to be used for logging the home breast milk specimens. Because these specimens are collected at home, during non-protocol specified visits, they should **not** be recorded on the MTN-008 Maternal PK – LDMS Specimen Tracking Sheet. The MTN-008 Home Breast Milk – LDMS Specimen Tracking Sheet will be used to record information for the 2 specimens collected by the participant at home. This Tracking Sheet will likely be completed at the Day 6 Visit. The new forms are being shipped to each site.

#### 2. Pelvic Exam form (PE-1)

The skip rule for item 1 is incorrect. This should read “If no abnormal findings, **go to item 2.**” Items 2, 3, and 4 must always be completed. If the specimen collection is not required for a specific visit, mark the “not required” box.

### CLARIFICATIONS

#### 1. Pelvic Laboratory Results form (PLR-1)

At the Screening Visit none of the evaluations are required unless clinically indicated. Therefore, it is likely that at the Screening Visit none of the listed laboratory evaluations will be done. The form, however, must still be completed. When none of the specimens for the three listed evaluations (i.e. vaginal wet prep studies, HSV culture, and pap smear) are collected, please record the visit date as the Initial Specimen Collection date on this form. Also, be sure to mark the “not done/not collected” boxes accordingly, following skip rules as needed.

Please note that item 1b is required at the Enrollment Visit and Day 6 Visit for women in the Pregnancy and Lactation Cohorts.

### REMINDERS

#### 1. Pre-existing Conditions form (PRE-1)

Only conditions which are ongoing at the time of enrollment/randomization should be recorded on the Pre-existing Conditions form. Please refer to section 10.1.1 of the MTN-008 SSP for more details.

## **2. Maternal Pharmacokinetics form (PKM-1)**

When this form is required, items 1-9 must be completed for all maternal participants. Item 10 must be completed for all maternal participants in the Pregnancy Cohort, and left blank for Lactation Cohort participants. Items 11-15 must be completed for all maternal participants in the Lactation Cohort, and left blank for Pregnancy Cohort participants.