

MTN-011 Data Communiqué #1

2 October 2012

**This is official study documentation for MTN-011. Please circulate it among relevant staff for their review, print it, and place it in your MTN-011 SSP Manual in the Data Communiqués section.
This document is considered part of the MTN-011 SSP manual.**

REMINDERS

None.

CLARIFICATIONS

1. Pharmacokinetics form (PK-1), items 1 and 2

Height and weight (items 1 and 2, respectively) must be recorded on this form the first time it is completed (expected to be the Screening Visit). For all subsequent uses of this form, the “not done” box can be marked for these two items.

2. Pharmacokinetics form (PK-1), item 8

Due to a change in the specimen collection procedures for the rectal sponges, the “wet with PBS” weight (circled below) will no longer be collected. Leave this item blank on the form, but be sure to record the “dry” and “after” weights.

<input type="checkbox"/>	8. Rectal sponge	[] [] : [] []	24-hour clock
	<i>dry</i>	<i>wet with PBS</i>	<i>after</i>
	[] [] [] . [] [] weight (grams)	[] [] [] . [] [] weight (grams)	[] [] [] . [] [] weight (grams)

Leave these boxes blank ↑

3. Pharmacokinetics form (PK-1)

If vaginal spotting, either by participant report or clinical observation, occurs on the day of PK/PD specimen collection record the occurrence on the Comments line at the bottom of the form.

4. Screening Menstrual History form (non-DataFax), items 5 and 6

If the participant is unable to recall the complete date, obtain participant's best estimate. At a minimum, the month and year are required. Only record dates of menstrual period bleeding. Do not record dates of episodes of expected breakthrough bleeding experienced while a participant is on Depo, Mirena, or other continuous contraceptive method where a woman does not experience a monthly menstrual period.

UPDATES

1. Enrollment form, page 2 (ENR-2)

This form has been updated to accommodate recording coitus data for Group 1 participants. Items 12 and 12a must be completed for all Group 1 Female Participants, and must be left blank for all other participants (i.e. Group 2 Female Participants and all Male Participants).

You will need to dispose of all previous versions of page 2 of the Enrollment form (dated 01-AUG-12) in the Enrollment visit packets for Groups 1 and 2. Please note that there are two copies of the Enrollment form in each packet (one for the female participant and one for the male participant). Both copies of page 2 must be removed and replaced with the updated version (dated 25-SEP-12). Page 1 (ENR-1) is fine as is and does not need to be replaced.

The new version of page 2 has been emailed to the appropriate site staff with instructions for printing. In addition, all copies of the ENR-2 form have been updated in the corresponding files on Atlas.