



## MTN-013/IPM 026 Data Communiqué #1

September 15, 2011

This is official study documentation for MTN- 013/IPM 026. Please circulate it among relevant staff for their review, print it, and place it in your MTN-013/IPM 026 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-013/IPM 026 SSP manual.

### UPDATES

#### 1. Cervical Ectopy (CE-1) CRF

The Cervical Ectopy (CE-1) case report form has been added to the study since initial CRF supplies were provided to the site. This DataFax CRF, dated 12-SEP-11, captures cervical ectopy assessment at the Enrollment Visit. Please print out the CRF, either as provided by SCHARP via email attachment or via download from the MTN-013/IPM 026 Atlas web page: <https://atlas.scharp.org/cpas/project/MTN/013%20and%20IPM%20026/begin.view>  
Add this CRF to all unused Enrollment Visit packets and complete at each Enrollment Visit.

### CLARIFICATIONS

#### 1. Demographics CRF and documentation of female primary sex partners (items 4-4f)

If a participant reports having a female as a primary sex partner when asked Demographics form item 4, mark item 4 “no” and in the white space to the right of item 4a, add a note that items 4a-4f record responses based on a female primary sex partner. Initial and date the note. Complete items 4a-4f as usual if the participant is willing to provide this information regarding her primary female sex partner. If this occurs, please let SCHARP know so that we do not generate QCs based on the item 4 skip pattern not being **followed**.

#### 2. Eligibility Criteria, items 2a-2c

If the participant changes her decision with regard to agreeing to allow her study specimens to be stored long-term and tested in the future, update items 2a-2c as needed.

#### 3. Pelvic Exam Ring Assessment (PER-1) completion at Day 28 (end of product use visit)

When completing the PER-1 at the Day 28 visit, note that item 2 (when completed) will be “yes”, as you will remove the ring at this visit. Item 3 will be “not reinserted”, and for 3a, you can record “Day 28 – end of product use” as the reason the ring was not re-inserted.

#### 4. Pharmacokinetic Specimens (PK-1) and completion of menses stop date when menses is ongoing

Item 12 (last menstrual start and stop dates) is completed at the Enrollment, Day 28, and Day 52 visits. If the participant’s menses is ongoing, line through the stop date boxes and record “ongoing” in the white space and initial and date. Once the menses stop date is known, go back and add the stop date in the white space, initial, date, and refax.

### REMINDERS

#### 1. CRF files for printing available on Atlas

Please note that all study visit CRF packets and individual CRFs are available for download and printing via the MTN-013/IPM 026 Atlas web page (see link above). Please print additional CRFs as needed (2-sided, US-letter).