



## MTN-013/IPM 026 Data Communiqué #4

February 15, 2012

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. pH collection and Pelvic Exam CRF completion at Day 31 Visit

The Pelvic Exam CRF (PE-1) is now required at Day 31 for all participants, even those who are randomized to Day 35 or Day 42 for the PK assessments. The Pelvic Exam CRF is required at Day 31 for non-PK participants to collect vaginal pH data. As always, a pelvic exam is not required on Day 31 for participants randomization to Day 35 or 42 PK procedures, but an exam may be done if clinical indicated. If a pelvic exam is not clinical indicated, mark item 1 as “not done” at the Day 31 visit, complete Item 6 (vaginal pH), leave all other items blank, and fax to SCHARP with all other Day 31 DataFax CRFs.

For participants who are randomized to Day 31 for the PK procedures, conduct a pelvic exam as required, complete all items on the Pelvic Exam form at Day 31 and fax into SCHARP.

Note: For each participant who has already completed their Day 31 visit and who was not randomized to Day 31 for her PK procedures, please obtain a new Pelvic Exam CRF (exam date = date of Day 31 visit), mark item 1 as “not done”, and transcribe vaginal pH result from Day 31, if available, onto item 6, and fax into SCHARP.

The Day 31 CRF packet title sheet and CRF packet have been updated to include the Pelvic Exam CRF completion for all participants at the Day 31 visit. This packet may be accessed/printed by going to the MTN-013 Atlas web page (see “Visit Packets and Individual CRFs” header towards the bottom of the page – no sign-in required):

<https://atlas.scharp.org/cpas/project/MTN/013%20and%20IPM%20026/begin.view?>

### CLARIFICATIONS

#### 1. Item 1 of AE Log CRF (AE descriptive text)

When completing item #1 of the AE Log CRF, please do not add text that comments on the AE’s relationship to study product or timing with regard to product use, as this information is captured in Items #2 and #4. For Item #1, describe the medical condition, including the anatomical location when needed.

If the AE is deemed “Related”, do not add information in the “Comments” section of the AE Log describing the relatedness of the AE to study product. Including these details in the AE text or “Comments” field will affect the MedDRA coding and where the AE appears in safety reports. We want to avoid this whenever possible so that AEs are coded the same way across participants and across study sites.

For example, if vaginal edema near the site of ring placement is observed, record “vaginal edema” as the AE text, not “vaginal edema near site of ring placement”. Also, if a related AE has an onset 2 days after ring insertion, do not add this information in the AE text or “Comments” field – we will be able to obtain this from other data already recorded.

**2. Guidance for AE text to use when reporting abnormal vaginal discharge AEs**

When reporting abnormal vaginal discharge as an AE on the AE Log CRF, please include in the AE text whether the discharge was per participant report only, per clinician observation only, or both. For example, use “abnormal vaginal discharge – ppt report” as the AE text for cases where vaginal discharge is reported by the participant but not observed by clinician (and not associated with a diagnosis).

For reference, below are the rows from the Tox Table used to grade vaginal discharge events

PARAMETER	Grade 0 NORMAL	Grade 1 MILD	Grade 2 MODERATE
Vaginal discharge by participant report **	Participant's usual amount of discharge, regardless of color or quantity	Mild-moderate increase in amount above participant baseline - no sanitary protection required	Profuse increase in discharge requiring pad use or other hygienic intervention
Vaginal discharge as observed by clinician ** (red or brown discharge should be reported under bleeding, not discharge)	Slight amount of discharge, any color	Mild-moderate increase in amount	Significant increase in amount with pooling in vagina on examination

**REMINDERS**

None