



## MTN-005 Data Communiqué #3

February 9, 2012

This is official study documentation for MTN-005. Please circulate it among relevant staff for their review, print it, and place it in your MTN-005 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-005 SSP manual.

### 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