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## MTN 001 Data Communiqué #4

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March 27, 2009

This is official study documentation for MTN 001. Please circulate it among relevant staff for their review, print it, and place it in your MTN 001 SSP Manual in the Data Communiqués section. This document is considered part of the MTN 001 SSP manual.

### UPDATES

#### 1. Completion of Behavioral CRFs During Periods of Temporary Hold and Permanent Discontinuation of Study Product

Per Clarification Memo #01 (dated Feb. 3, 2009) to protocol version 2.0, a change in administration of the behavioral, adherence, and acceptability assessments occurs during periods of temporary hold or permanent discontinuation of study product. Guidance on the administration of each assessment CRF is listed below.

*Note: For visits in which completion of an assessment is scheduled per protocol, the assessment form pages must be faxed to SCHARP DataFax. If a given assessment is not administered as scheduled due to a study product hold/discontinuation (per the guidance below), faxing of the assessment form pages to SCHARP DataFax is still required. Complete the header (PTID, Visit Code, Visit Date) at the top of each blank form page. Write a note at the top of the first page that states, "Form not administered due to study product [hold/discontinuation]." Initial and date the note. Mark the "No data recorded on this page" box in the upper-right corner of each form page in which it is present. Fax all form pages to SCHARP; these will serve as placeholders in the SCHARP DataFax database and provide documentation in DataFax as to why the data is missing. For assessments that are not administered, staff initials and date at the bottom right-corner of each page are not required.*

##### a. Study Product Adherence and Behavior Assessment

The Study Product Adherence and Behavior CRF (SPA) should be administered at Mid-Study and End-of-Study Period Visits only if study product was dispensed at or after the previous regularly scheduled visit the participant completed. Then, the SPA should not be administered again until such time as the participant resumes study product use, in which case administration of the CRF should resume as scheduled (at all subsequent Mid-Study and End-of-Study Period Visits). For example, a participant is dispensed study product at the 3-Week Visit. She then develops an AE a week later that warrants a temporary hold of study product. The SPA should be administered, as scheduled, at the 6-Week Visit, since the participant was dispensed study product at her previous regularly scheduled visit (3-Week Visit). If the participant's product hold turns into a permanent discontinuation of one of the study products (oral or vaginal), then the SPA should not be administered during any subsequent study period in which the discontinued product would have been used. In this case, if the participant's study product hold resulted in permanent discontinuation of oral study product, and her second and third study periods are "vaginal" and "dual" respectively, then the SPA is administered during the "vaginal" period (assuming vaginal product use) but not administered during the dual product use period. If the participant's product hold turns into a permanent discontinuation of both study products (oral and vaginal), then the SPA is not administered again for the participant (i.e., it is not completed at her remaining Mid-Study and End-of-Study Period Visits). Conversely, if the participant is cleared to use study product and is dispensed study product at the 7-Week Visit, then the SPA is administered, as scheduled, at each of the remaining Mid-Study and End-of-Study Period Visits (assuming no further study product holds or discontinuations).

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During periods of study product hold and discontinuation, documentation of the last three doses of study product (i.e., completion of items 2-3 on the SPA) is not required. Mark the “Not done/Not collected” boxes.

**b. Product Sharing Assessment**

Administration of the Product Sharing Assessment CRF (PSA) is required at the 6-Week Visit for all participants, regardless of whether or not study product was held or permanently discontinued during the first study period, since study product was dispensed at the Enrollment Visit. Administration of the PSA is required at the 13-Week Visit if the participant was dispensed study product at any time during the second study period (7-Week Visit through the 13-Week Visit). Administration of the PSA is required at the 20-Week Study Visit if the participant was dispensed study product at any time during the third study period (14-Week Visit through the 20-Week Visit). If no study product was dispensed during a given study period, then the PSA should not be administered/completed at the End-of-Study Period Visit (6-Week, 13-Week, or 20-Week Visit) for that study period.

**c. Acceptability Assessment & Final Acceptability Assessment**

Administration of the Acceptability Assessment CRF (AA) is required at the 6-Week Visit if the participant used at least one dose of study product during the first study period (Enrollment Visit through the 6-Week Visit). Administration of the AA is required at the 13-Week Visit if the participant used at least one dose of study product during the second study period (7-Week Visit through the 13-Week Visit). Administration of the Final Acceptability Assessment CRF (FAA) is required at the 20-Week Study Visit if the participant used at least one dose of study product during the third study period (14-Week Visit through the 20-Week Visit). If no study product was used during a given study period, then the assessment of acceptability for that period (AA or FAA) should not be administered/completed.

## CLARIFICATIONS

### 1. Documenting Genital Adverse Events (AEs)

As a general guideline for all genital AEs, please record in item 1 of the AE log the appropriate term as it is printed in the DAIDS Female Genital Toxicity Table. This ensures consistency in reporting/MedDRA coding across sites.

## REMINDERS

### 1. Documenting AEs Assessed as “Not Related” to Study Product

If the “Not related” box is marked for item 4 on the AE Log, an alternate etiology for the AE must be recorded in the Comments section of the AE Log.

### 2. Documenting Genital Bleeding Events

To maintain consistency in AE reporting across all MTN trials, the MTN has developed and uses standard terminology for reporting genital bleeding events. Please refer to section 10.5 of the Study-specific Procedures Manual (SSP) for detailed information on assessing genital bleeding, and for specific terms to use when completing the AE Log form (item 1). If the bleeding is a result of a pelvic exam finding, then record the name and location of the finding (e.g., “vaginal laceration”) as the AE (item 1) on the AE Log form.

For genital bleeding events in which the bleeding is not observed on exam (participant-reported only), or the bleeding is observed on exam but the source cannot be identified, please complete the non-DataFax Genital Bleeding Assessment form. This form serves as a tool to help sites determine whether or not an event is expected, and thus should not be reported as an AE, or if an event is *unexpected*, and thus should be reported as an AE on the AE Log form. For unexpected events, the form also lists out the possible AE terms to record in item 1 of the AE Log form.