

MTN-020 Data Communiqué #9- August 5, 2013

This is official study documentation for MTN- 020. Please circulate it among relevant staff for their review, print it, and place it in your MTN-020 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-020 SSP manual.

UPDATES

1. Ring Adherence (RA-1) CRF, version 1.0 (version date: 30-JUL-13)

The RA-1 CRF was updated as follows:

- a. The item 4 text “In the past month” was added to clarify the time frame in question.
- b. Item 5 response boxes were replaced with Reason Code boxes.
- c. The form instructions in the General Information/Instructions, item 1, and item 2 sections were updated to clarify the intent of data capture, based on common site e-mail queries received to date.
- d. Reason Codes were added to the item 5 form instructions, and bolded lead-in text was added to the reason text.
- e. Reason Codes for ring removals were grouped into categories (Hygienic or Physical Reasons, Social or Sexual Reasons, Study-related or Procedural Reasons).
- f. The text for Reason Codes 10 and 14 was amended to incorporate language from Data Communiqué # 8.
- g. Additional reasons were added (Reason Codes 13, 15, 16, 23, 27, 28, 32-34) based on a review of common “other” site responses to date.

A separate document, entitled “MTN-020 Ring Adherence CRF: Item 5 Reason Code List”, has been developed to aid site staff in completing item 5 during participant interviews. The document has been posted on the MTN-020 Atlas page in the “Visit Packets and All CRFs” section under “Other Documents”. Site staff are encouraged to print this document and have it available for reference when completing the RA-1 CRF.

The visit packets posted on Atlas have been updated to include this new version of the RA-1 CRF. Sites may begin transitioning to use of this new version immediately. The old version of the form may continue to be used until **Aug. 12, 2013**, at which time all **sites are expected to use the new version exclusively**.

2. Ring Worries (RW-1) CRF – Item 3

If a participant permanently discontinues study product prior to the scheduled PUEV, complete all items on the Ring Worries CRF, including item 3, at the permanent discontinuation visit instead of at the PUEV.

CLARIFICATIONS

1. Updates to AE Log (AE-1)/ Grade 1 AE Log (GAE-1) CRFs – Item 4 Rationale

If a previously completed GAE/AE Log CRF page is updated with new information (such as any medications taken for the AE, or a change to product relatedness), review the other items on the

page for consistency and update responses as appropriate. In particular, if the AE relationship to study product changes due to test results that confirm a diagnosis, update both item 1 and item 4.

Example: An AE is reported as “vaginal discharge” per participant report in Item 1, and deemed ‘related’ in Item 4 with the rationale that the discharge presented after the participant started using the ring. Subsequently, she tested positive for Trichomoniasis. The AE Log page was updated from ‘related’ to ‘not related’ in Item 4. The rationale was updated to document the presence of an STI. In this example, Item 1 should also be updated to reflect this new information and accurately report on the presence of an STI (i.e., line through “vaginal discharge” and record “vaginal trichomoniasis”). **Discordant text in Item 1 and Item 4 will result in a QC.**

2. Concomitant Medications Log (CM-1) CRF – Coding Queries

If possible, record the trade name of a medication on the CM-1 log CRF. If a trade name is not available or not reportable per national guidelines, please record the generic name of the medication. A combination medication can be recorded as one entry using the generic name.

If a combination medication does not have a generic name, or the generic name is unknown, **each** active ingredient must be reported as a separate entry in order to be accurately coded at SCHARP.

Example: A combination medication with an unknown generic name and active ingredients Chloramphenicol and Dexamethason should be recorded as two separate entries on the CM-1; one entry for each active ingredient.

Minor spelling differences can affect the coding of these medications. Please ensure that the spelling of medications is both correct and consistently used throughout the study. For example, if a medication has multiple accepted spellings (such as Azithromycin Mylan and Azithromycine Mylan), be sure to use consistent spelling at each site throughout the study.

3. Ring Collection/Insertion (RCI-1) CRF – Item 4a

Mark ‘participant declined study ring’ if the participant declined the study ring herself or if the participant declined the study ring due to the wishes of her family or friends.

4. Product Hold Log (PH-1) CRF – Item 4 ‘early termination’ response

If a participant terminates early from the study and the site has placed the participant on a clinical product hold that has not yet been resolved (i.e., Item 4 on the PH-1 CRF has not yet been completed), mark “no-early termination” as a response to Item 4 and enter the participant’s termination date in the corresponding date boxes.

REMINDERS – None

iDATAFAX CORNER – No updates