

MTN-020 Data Communiqué #8- May 10, 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. AE and GAE Log CRF Revisions (Revised forms dated 26-APR-13)

Protocol Team leadership has determined it is valuable to capture the rationale for both related and not related “relationship to study product” assessments when documenting adverse events (AEs). As such, item 4 of the AE and GAE Log will be revised so that there is no longer an arrow off of the “not related” box. When completing item 4 (relationship to study product) of the revised AE and GAE Log, a rationale should always be recorded (the “Record rationale” is a required field on the revised CRF). If the “Record rationale” field is left blank, this will result in a QC. Guidance on what type of information to record in the “Record rationale” field will be provided separately by the Protocol Safety Physicians.

For AEs already reported, SCHARP will follow-up with sites individually on needed form additions. The goal is to have sites add text to the “Record rationale” field for all previously-reported grade 2 and higher related AEs.

The updated versions of the revised AE and GAE Log CRFs are provided with this communiqué, and are also available via the CRF packets and “As Needed” pdf files on the MTN-020 Atlas web page.

2. HIV Confirmatory Results (HCR-1) CRF Revision (Revised form dated 26-APR-13)

An error has been identified on the HCR-1 CRF. The original form listed a “GP40” band in item 2. This should have read “P40”. The revised form, dated 26-APR-13, lists the correct P40 band. No action is needed on HCR-1 forms already submitted, as any information recorded in the row for the GP40 band will be reported as the P40 band.

The updated version of the revised HCR-1 CRF is provided with this communiqué, and is also available via the CRF packets and “As Needed” pdf files on the MTN-020 Atlas web page.

3. New Prevention Study Experiences (PSE-1) CRF

A New Prevention Study Experiences case report form has been created for use in ASPIRE. This new interviewer-administered form includes additional acceptability questions on the participant's perception of product efficacy and her product assignment, and assesses her understanding of the study randomization process. Completion of this form is required at all future Month 3 and Month 12 visits. This form should *not* be completed in retrospect for Month 3 and Month 12 visits that have already been completed or missed. In addition, it should not be completed for those Month 3 and Month 12 visits that occur after a participant has been confirmed as an HIV seroconverter based on protocol algorithm testing.

The site-ready English version of the PSE-1 is provided with this communiqué. SCHARP will e-mail sites to work on translation of this form and translated versions of this form will be added to the interviewer-administered visit-based packets on the MTN-020 Atlas web page when finalized.

CLARIFICATIONS

1. Ring Adherence (RA-1) CRF, item 5

When completing item 5 (reasons vaginal ring was out) which is a “mark all that apply” item, please keep in mind the following.

- For 5a, “ring caused discomfort”, mark this box (and not 5m) if the participant reports experiencing genital or other symptoms that caused her to remove the ring. If you wish to provide more details, these details can be added in the Comments field at the bottom of the page (these additional details are not required, however).
- For 5d, “had or was expecting menses”, mark this response if the participant removed the ring due to any type of genital bleeding or spotting (not just menses).
- Only mark 5m “other, specify” if the reason the participant removed the ring is not already listed. If you wish to provide additional details on an item that is marked among 5a-5l, use the Comments field at the bottom of the page.
- Only mark 5t “other, specify” if the reason the ring came out on its own is not already listed. If you wish to provide additional details on an item that is marked among 5n-5s, use the Comments field at the bottom of the page.

REMINDERS - None

iDATAFAX CORNER – No updates