

MTN-020 Data Communiqué #16 – March 31, 2015

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 – none

CLARIFICATIONS – Product Use End Visits (PUEVs)

1. Split PUEVs

All PUEV procedures should be completed on the same day, if possible. However, if a PUEV is split across multiple days, HIV testing and plasma storage must be completed at the first part of the visit. The Study Exit Visit for non-seroconverters should occur approximately 4 weeks after the PUEV (i.e., 4 weeks after the PUEV date when the participant completed ring use, or for participants who discontinued ring use prior to the PUEV, four weeks after the date HIV testing was done as part of the PUEV).

2. STI Testing

If a participant completes her PUEV and then returns to complete STI testing, consider these visits as part of a split PUEV. Document the STI test results on the STI-1 CRF that was completed on the first day of her PUEV. Update this form using the alternate collection date boxes provided for each applicable item on the form, record the test results, and refax. If STI testing is completed at the SEV, document the results by completing a new STI Test Results CRF with the SEV visit code. If a pelvic exam is done at the SEV (e.g., to assess for STIs or to make up the PUEV pelvic exam requirement), complete a new PE-1 CRF and assign it the SEV visit code.

3. Ongoing AEs at Termination

If an AE is reported at the termination visit, item 6 should be marked 'continuing at the end of study participation' and the outcome date should be date of termination from the study. If the AE requires ongoing treatment, the corresponding concomitant medication stop date should be marked as 'ongoing at the end of the study' if the AE treatment continues past the termination visit.

4. Determining the Termination Date

The termination date recorded on the TM-1 CRF should reflect the date the site first considers a participant no longer part of the study. If a test result is still pending after the final clinic visit, it is up to the site's discretion as to when a participant is considered no

longer part of the study. For example, if the pap results of a participant who has seroconverted are still pending after a PUEV, we leave it up to the site to determine if the participant's termination date is the date of her PUEV or the date that her pap results were received. Note that the date on the PUEV Lab Results CRF should be the date that the first specimen(s) was collected, not the date the results were reported or recorded on the form. In other words, the date of the PUEV and the date on the PLR should be the same.

5. Data Collection After Termination

Data collected after the termination date (i.e., new data reflecting the participant's medical history or status after the termination date for purposes of ongoing AE or clinical management) should not be recorded on study CRFs and should not be submitted to SCHARP, with the exception of pregnancy outcome data and vaginal ring collection and storage. However, updates to existing study data, reflecting the participant's medical history/status during her study participation, can be made post study termination (up through database lock), as the data becomes available. For example, if additional information is available, based upon lab test results, which better characterizes an AE or provides a specific diagnosis, the AE term on the AE Log CRF can be updated and refaxed to SCHARP.

6. Visit Summary CRF (VS-1) - Item 4a

Item 4a on the VS-1 CRF should be marked "PUEV" for participants who are exiting the study at the PUEV and will not complete a Study Exit Visit (e.g., participants who have seroconverted prior to their PUEV). The "scheduled termination" box in item 4a should be marked only if the visit is the scheduled study exit visit and is being conducted after completion of a PUEV.

For more information related to operational considerations for the PUEV, please see priority emails from 5 March and 19 March 2015.

REMINDERS – none

iDATAFAX CORNER – No updates