

## MTN-027 Data Communiqué #2 – September 15, 2015

This is official study documentation for MTN-027. Please circulate it among relevant staff for their review, print it, and place it in your MTN-027 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-027 SSP manual.

**UPDATES** – none

### CLARIFICATIONS

#### Documenting Abnormal and Normal Findings due to Observed Blood and a Healing Biopsy Site

Observation of any unexpected genital blood or bleeding is considered an abnormal finding. For example, a biopsy site that is considered to be healing abnormally or bleeding associated with the procedure exceeds that which is expected, per clinical judgment of the IoR or designee, would be considered an abnormal finding. “Abnormal findings” should be marked in Item 2 of the Pelvic Exam CRF and any associated findings should be marked in Item 2a. Unexpected genital bleeding should be documented as a reportable AE as well and an Adverse Experience Log (AE-1) CRF should be completed.

However, any genital blood or bleeding that is expected, per clinical judgment of the IoR or designee, is not considered an abnormal finding. In addition, any finding that is considered normal, per clinical judgment of the IoR or designee, is not reported as an abnormal finding. For example, a biopsy site that is consistent with normal healing, per clinical judgment of the IoR or designee, would not be reported as an abnormal finding. Thus, this is not a reportable adverse event. “No abnormal findings” can be marked on the Pelvic Exam (PE-1) CRF. If there is any expected non-menstrual bleeding associated with the biopsies during or after the pelvic exam procedure, the findings can be documented on the non-DataFax Pelvic Exam Diagrams as source documentation and chart notes as needed.

This guidance supersedes the current instructions on the back of the Pelvic Exam CRF. See Section 8.7.2 of the SSP for further clarification.

#### Documentation of cervical bleeding due to biopsy collection on Pharmacokinetics Specimens – Day 28 (PKS) CRF

Any cervical bleeding that occurs at the site of biopsy collection on the day of the Day 28 Visit should be recorded in item 1 on the Pharmacokinetics Specimens – Day 28 CRF. This includes bleeding considered to be expected/normal or unexpected/abnormal. If the participant experienced a bleeding episode prior to her study visit and subsequently experiences a second bleeding episode due to biopsy collection, complete Item 1 with the start and stop dates of the bleeding at the biopsy site. Record any prior bleeding episodes that the participant reports previous to the visit in the Comments section of the PKS CRF. As a reminder, if silver nitrate/monsels solution is used to stop bleeding during the collection of cervical biopsies, this also should be noted in the Comments section of the PKS CRF.

**REMINDERS** – none