MTN-028 Data Communiqué #1

2 September 2015

This is official study documentation for MTN-028. Please circulate it among relevant staff for their review, print it, and place it in your MTN-028 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-028 SSP manual.

REMINDERS

None.

CLARIFICATIONS

Documenting Abnormal and Normal Findings due to Observed Blood and the 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 if bleeding associated with the procedure exceeds that which is expected, per clinical judgment of the IoR or designee, this would be considered an abnormal finding. Also, this should be documented as a reportable AE. "Abnormal findings" can be marked on the Pelvic Exam CRF as well as its associated findings. An Adverse Experience Log CRF should also 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 (AE). "No abnormal findings" can be marked on the Pelvic Exam 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.

See Section 8.7.2 of the SSP for further clarification.

UPDATES

None.