

MTN-017 Data Communiqué #5 - May 12, 2014

This is official study documentation for MTN-017. Please circulate it among relevant staff for their review, print it, and place it in your MTN-017 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-017 SSP manual and is posted on the MTN web site at <http://www.mtnstopshiv.org/node/4643>.

UPDATES

None

CLARIFICATIONS

1. Documenting Study Gel Leakage

The presence of study gel leakage by itself is not an AE and should not be reported on an AE Log CRF. However, any untoward effect the gel or gel leakage has on a participant – for example, “perianal irritation” or “anorectal discomfort” - should be reported as an AE on an AE Log CRF. Please refer to the list of verbatim terms in the MedDRA AE Preferred Terms document on the MTN web site (<http://www.mtnstopshiv.org/node/4524>) for a list of desirable terms to record for item 1 on the AE Log CRF.

The “Relationship to Study Product” question (item 4) on the AE Log CRF should be used to designate that the AE is “related” to study gel/study gel leakage. Marking the “related” box is sufficient for this purpose. Please do not add the words “gel leakage” anywhere on the AE Log CRF, as this will prevent the AE from mapping to the appropriate MedDRA code.

REMINDERS

1. Timeliness of AE Data Submission

As stated in each site’s Data Management SOP, it is expected that sites fax MTN-017 CRFs to SCHARP within 7 days of a completed study visit. Exceptions to these guidelines are allowed for CRFs that record local laboratory results (received after completion of a visit), and Screening Visit CRFs.

Adverse Experience Log (AE Log) forms documenting an Expedited Adverse Event (EAE) should be faxed to SCHARP within 3 business days.

To ensure that up-to-date and accurate data is available for ongoing study safety monitoring and reporting, we ask that sites prioritize submission of AE Log CRFs. Ideally, sites should fax AE Log CRFs to SCHARP within 3-4 working days of site awareness of the AE.