

MTN-017 Data Communiqué #4 - April 18, 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

1. New Rectal Practices CRF (RP)

SCHARP has issued a new Rectal Practices CRF, dated 15-APR-14, to document rectal insertion of any products (e.g., douches, enemas, lubricants) or other items in the week prior to enrollment, and each regularly scheduled follow-up visit. The purpose of this form is to identify any potential impact these rectal practices may have on the rectal tissue, and PK lab specimen collection or analysis. The Rectal Practices CRF is interviewer-administered; questions are asked directly of the participant, and the responses are recorded on the CRF, which serves as the source document. Completion of the form is required for each participant at the Enrollment Visit, and at each regularly scheduled follow-up visit.

All sites administering the English version of this form are expected to begin implementing this form by April 25, 2014 at the latest. The SCHARP Program Manager will work with individual sites as needed to develop local language versions of this form, and will work with site staff to set site-specific implementation dates for these local language versions.

The CRF packet files for the Enrollment and follow-up visits will be updated on the Atlas web site to include the Rectal Practices CRF (<https://atlas.scharp.org/cpas/project/MTN/017/begin.view?>).

2. Rectal Douches/Lubes No Longer Documented as Concomitant Medications

Going forward, the Rectal Practices CRF (RP) will satisfy protocol requirements for documentation of rectal douche and lubricant use. Once a site begins implementation of the RP, the guidance in Data Communiqué #3 will apply, and use of rectal douches and lubricants should no longer be recorded on the Concomitant Medications Log CRF.

3. Safety Laboratory Results CRF (SLR) – items 3a and 3b

For urine leukocyte esterase (LE) and nitrites, results of 1+ or greater are considered “positive”. Negative or trace results are considered “negative”. This guidance applies to all urine LE and nitrites results since study start.

CLARIFICATIONS

1. MedDRA AE Preferred Terms

The MTN-017 Study Implementation page of the MTN web site (<http://www.mtnstopshiv.org/node/4524>) has a link to the MedDRA AE Preferred Terms document. The purpose of the document is to show sites the recommended verbatim AE terms that they should use, as applicable, to describe each AE and record in item 1 of the AE Log CRF. Sites are asked to locate and use the applicable terms from the “Verbatim term” column of the document only. The second column, labeled “MedDRA Preferred Term (PT)”, is included in the document for site reference only, to show the MedDRA term that maps to each verbatim term.

REMINDERS

None