

MTN-017 Data Communiqué #3 - February 21, 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. Concomitant Medications Log (CM-1) CRF – Coding Queries

Alcohol consumption and recreational drugs should not be reported as concomitant medications on the CM-1 CRF. Instead, excessive alcohol consumption and recreational drug use may be considered pre-existing conditions, per site clinician judgment, in which case they should be recorded on the Pre-Existing Conditions CRF (PRE-1).

Sexual lubricants and douches also are not considered concomitant medications, and should not be recorded on the CM-1 CRF. Examples of products used as sexual lubricants and douches include commercial products, oils, household cleaners, water, and elbow grease.

REMINDERS

None