
MTN-023/IPM 030 Data Communiqué #1

24 June 2014

This is official study documentation for MTN-023/IPM 030. Please circulate it among relevant staff for their review, print it, and place it in your MTN-023/IPM 030 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-023/IPM 030 SSP manual.

REMINDERS

None.

CLARIFICATIONS

1. HIV and AE Reporting

HIV infection is not included in the DAIDS Toxicity Table, and is not considered an AE for data collection or reporting purposes. Thus, if a participant seroconverts during her study participation, HIV infection should not be reported as an AE or written anywhere on an AE Log CRF.

However, primary HIV infection is often symptomatic. If a participant seroconverts and develops one or more signs or symptoms of acute HIV-infection, it is appropriate to report each sign and symptom (e.g., fatigue, pharyngitis) as a separate AE on its own AE Log CRF. If item 4 is marked “not related”, record “due to alternate etiology” as the rationale in the Comments section of the AE Log CRF. Do not write “HIV” or “HIV infection” anywhere on the AE Log CRF.

UPDATES

1. STI Test Results (STI-1), item 1c.

Clue cells should be reported and marked as “positive” if 20% or more of the cells observed are clue cells. The form and the instructions are currently incorrect in that they indicate that only if *more than 20%* of the observed cells are clue cells should it be reported as “positive.”

2. STI Test Results (STI-1), item 2.

The CRF reads “Trichomonas rapid test” for item 2, but the Bronx site is not using a rapid test for this study. Instead this site will be using a NAAT test. The results for the NAAT test should be recorded in item 2 as “not done/not collected,” “negative,” or “positive.”