
MTN-024/IPM 031 Data Communiqué #1

20 March 2014

This is official study documentation for MTN-024/IPM 031. Please circulate it among relevant staff for their review, print it, and place it in your MTN-024/IPM 031 SSP Manual in the Data Communiqués section.

This document is considered part of the MTN-024/IPM 031 SSP manual.

REMINDERS

None.

CLARIFICATIONS

1. **Specimen Storage CRF, SS-1**

If “Not done/Not collected” is marked, but the specimen is required for that visit, record the item number and the reason the specimen was not collected in the Comments. No comment is needed if the specimen was not required. At this point there is no need to correct forms which were already completed. If we identify any that do need updating we will let you know.

2. **Pharmacokinetics, CRF, PK-1**

If “Not done/Not collected” is marked, but the specimen is required for that visit, record the item number and the reason the specimen was not collected in the Comments. No comment is needed if the specimen was not required. At this point there is no need to correct forms which were already completed. If we identify any that do need updating we will let you know.

3. **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

None.