

MTN-017 Data Communiqué #2 - November 5, 2013

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. Adverse Experience Log (AE-1) CRF, version 2, version date: 29-OCT-13

Item 4-“Relationship to Study Product” was updated to remove the “Rationale” line. On version 2 of the form, if an AE is marked “not related”, record the reason for the “not related” assessment in the Comments section at the bottom of the form.

4. Relationship to Study Product	<i>related</i>	<i>not related</i>	→ <i>Record reason in Comments</i>
	<input type="checkbox"/>	<input type="checkbox"/>	

Sites may begin using version 2 of the form immediately. All sites are expected to use version 2 of the form exclusively beginning Monday, Nov. 11, 2013. Please discard all version 1 copies of the form at your site to ensure version 2 is used exclusively as of Nov. 11, 2013.

The CRF files on the Atlas page have been updated to include this new form version. Sites may print the new form version for data collection by accessing the Atlas page on-line at <https://atlas.scharp.org/cpas/project/MTN/017/begin.view?>

2. 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 his/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.

CLARIFICATIONS

1. Concomitant Medications Log (CM-1) CRF

If possible, record the trade name of a medication on the CM-1 log CRF. If a trade name is not available or not reportable per national guidelines, please record the generic name of the medication. A combination medication can be recorded as one entry using the generic name.

If a combination medication does not have a generic name, or the generic name is unknown, **each** active ingredient must be reported as a separate entry in order to be accurately coded at SCHARP.

Example: A combination medication with an unknown generic name and active ingredients Chloramphenicol and Dexamethason should be recorded as two separate entries on the CM-1; one entry for each active ingredient.

Minor spelling differences can affect the coding of these medications. Please ensure that the spelling of medications is both correct and consistently used throughout the study. For example, if a medication has multiple accepted spellings (such as Azithromycin Mylan and Azithromycine Mylan), be sure to use consistent spelling at each site throughout the study.

If a medication's trade or generic name is unknown, record "unknown" and a description of the drug class (e.g., "unknown white tablet", "unknown analgesic", "unknown antibiotic").

REMINDERS

1. Specimen Storage (SS-1) CRF – Date and Time of Last Dose

Sites must provide participants with a standard site document (e.g., appointment card) with a designated place for participants to record the date and time of the last dose of study product they took prior to each Mid-period and End-period Visit. If a participant complies and provides written documentation of the date and time of his/her last dose, mark item 6a "source documentation" and file the source document in the participant's study records. If the participant does not provide written documentation of his/her last dose of study product, record his/her best guess in item 6 and mark item 6a "best estimate".

6. Date and time of last dose:	dd	MMM	yy	24-hour clock hr	:	min	OR	<input type="checkbox"/>	<i>not required</i>	<i>If not required, end of form.</i>
6a. Is the date/time of last dose a best estimate, or did the participant provide source documentation?				<i>best estimate</i>		<i>source documentation</i>		<input type="checkbox"/>		<input type="checkbox"/>