



MTN-008 Data Communiqué #3

26 May 2011

This is official study documentation for MTN-008. Please circulate it among relevant staff for their review, print it, and place it in your MTN-008 SSP Manual in the Data Communiqués section.

This document is considered part of the MTN-008 SSP manual.

UPDATES

None.

CLARIFICATIONS

1. Adverse Experience Log form (AE-1)

Abnormal lab values reported as AEs: In general, report laboratory toxicities on the AE Log CRF as an abnormal lab value (e.g., decreased hemoglobin, increased ALT) *unless* the participant is to be treated for a specific diagnosis. For example, report a low hemoglobin value as "decreased hemoglobin" if the participant does not need to be treated for the condition, but report as "anemia" if the participant does require treatment. Treatments may include dietary (e.g. iron rich foods), vitamins, or mineral supplements (e.g., iron supplements or prenatal vitamins).

****Note:** Treatment is based on whether or not a clinician instructs a participant to take a given treatment, not on whether the participant actually takes the treatment.

REMINDERS

1. Standard forms used in multiple studies

Your sites are currently working on multiple MTN studies, and some CRFs look almost exactly the same across these studies (e.g. Pre-existing Conditions, Adverse Experience Log, and Concomitant Medications Log). However, the barcodes at the top of each CRF are what DataFax uses to guide each form into the corresponding study. For example, if an MTN-008 AE Log form is completed, regardless of the PTID, it will go to the MTN-008 database. If the PTID is from a study other than MTN-008 it will trigger several checks and be caught as an "illegal PTID."

How do you know which form goes with which study?

Answer: In the upper left corner on each CRF, just above the PTID boxes, the study number is printed (e.g. "MTN 008"). Please be sure to verify that the correct CRF is being completed for each participant.