



MTN-003 (VOICE) Operational Reminder Documentation of Adverse Events

- ❖ Document in source documents all AEs reported by or observed in MTN-003 participants, whether or not they are reportable*
- ❖ Source documentation for all AEs should minimally include the following:
 - AE term/diagnosis
 - Severity grade
 - Onset date
 - Outcome
 - Outcome date
 - Treatment (if any)
- ❖ Sites should use AE tracking tools to ensure that all AEs are source documented[‡] and properly followed, and that all reportable AEs are reported to the MTN SDMC within one working day of site awareness. Any additional information related to the AE should be documented in chart notes.
 - Sample MTN-003 Adverse Event Tracking Log (available at <http://www.mtnstopshiv.org/node/737>):

Adverse Event	Onset Date	Severity Grade	SAE?	EAE?	Product Hold or Perm Discon? If yes, specify	Report on AE Log Form? If yes, enter AE Log Page	Staff Initials and Date	Resolution Date	Staff Initials and Date

- ❖ Questions about AE documentation and reporting? Contact the MTN-003 Management Team (mtn003mgmt@mtnstopshiv.org)

* *NOTE:* Reportable AEs are defined in protocol section 8.2 and are AEs that are submitted to MTN SDMC via the Adverse Experience Log form

[‡] *NOTE:* If the AE Tracking Log is used as source documentation, ensure it is listed as such in the site's study-specific Source Documentation SOP.