

Sample MTN-003 Adverse Event Tracking Log

PTID _____

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Adverse Event	Onset Date	Severity Grade	SAE?	EAE?	Product Hold or Permanent Discontinuation?	Report on AE Log Form? <small>If yes, enter AE Log Page</small>	Staff Initials and Date	Resolution Date	Staff Initials and Date

The following AEs must be reported on AE Log forms:

- All genital, genitourinary, and reproductive system AEs
 - All fractures
 - All AEs of severity grade 3 or higher
 - All SAE and EAEs
- All AEs of severity grade 2 or higher in the following categories: dizziness, headache, nausea, vomiting, diarrhea, abdominal pain, rash
 - All AEs that result in permanent discontinuation of study product use
 - All laboratory test abnormalities not otherwise associated with a reported clinical AE