



Adverse Experience Log (AE-1)	
<b>Purpose:</b>	To document all MTN-011 Adverse Experiences (AEs) required to be reported on Log per protocol for female and male participants.
<b>General Information/Instructions:</b>	Whenever possible, report a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate AE on separate AE/GAE Log pages as applicable. If a cluster of symptoms reported on separate AE/GAE Log page is later attributed to a single diagnosis, change the earliest reported symptom page to the diagnosis. In addition, mark the AE/GAE Log pages for the other symptoms with the words "Delete due to diagnosis on AE Log pages (insert page #s) and/or GAE Log pages (insert page #s)."
<b>Item-specific Instructions:</b>	
<b>Page:</b>	Number pages for this Log sequentially throughout the study for each PTID, starting with 001. Do not repeat page numbers on this log. If an AE Log page is marked for deletion, do not change the page number or re-assign that page number to another AE Log page.
<b>Date Reported to Site:</b>	Record the date the site became aware of the AE. For lab AEs, record the date the lab result was received.
<b>Item 1:</b>	Use medical terminology to describe the AE. Do not include text on the relationship to study product or timing of AE onset with regard to product use. For lab abnormalities, record the lab name with the direction (i.e., increased or decreased). For example, "increased ALT."
<b>Item 2:</b>	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE (onset of first symptom if diagnosis has multiple associated symptoms); date of the study visit/study exam (for physical or pelvic exam findings); specimen collection date (for lab abnormality AEs).
<b>Item 3:</b>	Record the severity grade using the current version of the <i>Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events</i> (including relevant appendices/addendums).
<b>Item 4:</b>	Mark "related" if there is a reasonable possibility that the AE may be related to the study agent. Mark "not related" if there is not a reasonable possibility that the AE is related to the study agent. If "not related" is marked, record an alternative etiology or explanation on the line provided.
<b>Item 5:</b>	<ul style="list-style-type: none"> <li>• <b>no change:</b> Mark if there is no change in the participant's planned use of study product as a result of the AE. That is, the participant is still in the product use period and the AE does not result in a clinician initiated product hold or permanent discontinuation of study product.</li> <li>• <b>held:</b> Mark if the AE results in a clinician initiated product hold. If multiple AEs are reported at the same visit, mark "held" for each AE contributing to the hold. A Product Hold/Discontinuation (PH) Log should be completed for each AE page with "held" marked. If an AE results in a hold, then a permanent discontinuation, update this item to "permanently discontinued" at the time of permanent discontinuation.</li> <li>• <b>permanently discontinued:</b> Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, mark "permanently discontinued" for each AE contributing to the permanent discontinuation. For each AE page with this box marked, there should be a PH Log page with item 4 marked "no-permanently discontinued."</li> <li>• <b>N/A (not applicable):</b> Mark if the AE's onset date (item 2) is on or after the participant's PUEV/early termination visit date. Also mark this box if the AE's onset date is on or after the date of permanent discontinuation.</li> </ul>
<b>Item 6:</b>	<ul style="list-style-type: none"> <li>• <b>continuing:</b> AE is continuing at the time it is first reported.</li> <li>• <b>resolved:</b> AE is no longer present or has returned to baseline severity/frequency. Note that if a participant started taking medication once enrolled to control an AE, the AE is not considered resolved while the medication is still indicated.</li> <li>• <b>death:</b> Mark only if the severity of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation."</li> <li>• <b>severity/frequency increased:</b> If an AE increases in severity or frequency after it has been first reported on this form, line through the "continuing" box and mark "severity/frequency increased." Record the date of increase as the "Status/Outcome Date." Report the increase in severity/frequency as a new AE on a new AE Log page. For this new AE, the "Onset Date" (item 2) will be the same as the "Status/Outcome Date" (item 6a) of the AE Log page used to first report the AE. Note that decreases in severity (AE improvements) are not recorded as new AEs.</li> <li>• <b>continuing at end of study participation:</b> Mark this box whenever an AE is continuing at the time of participant termination.</li> </ul>
<b>Item 6a:</b>	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports no longer experiencing the AE or associated symptoms; or the date of the study visit or specimen collection at which it is first noted the AE has resolved or returned to baseline status.
<b>Item 7:</b>	Mark "medication(s)" only if participant reports taking the medication. If medication indicated but not yet used, mark "other" and describe the medication indicated; mark "medication(s)" once the medication has been used.
<b>Items 8 and 9:</b>	For questions about ICH guidelines and EAE reporting, refer to the current <i>Manual for Expedited Reporting of Adverse Events to DAIDS</i> . If item 9 is "yes," be sure to make any subsequent updates made to this form on the applicable EAE form.
<b>Item 10:</b>	Record the Visit Code that corresponds to the "Date Reported to Site." For lab AEs, record the Visit Code that matches the "Onset Date." Note that the Visit Summary form with this visit code should have item 6 = "yes" or (for interim visits) the AE Log page marked in item 5b.