



Note: Number pages sequentially (001, 002, 003) for each participant.

Page [][] [][]

MTN 012/IPM 010 (187)

AE-1 (460)

Participant ID

[][][] - [][][][][] - []
Site Number Participant Number Chk

Adverse Experience Log

Date Reported to Site

[][] [][][][] [][]
dd MMM yy

1. Adverse Experience (AE)

Record diagnosis (in English) if available. Include anatomical location, if applicable.

2. Onset Date

[][] [][][][] [][]
dd MMM yy

3. Severity

- Grade 1 – Mild
- Grade 2 – Moderate
- Grade 3 – Severe
- Grade 4 – Potentially life-threatening
- Grade 5 – Death

4. Relationship to Study Product

- Related
 - Not related
- Record rationale or alternative etiology in Comments.

5. Study Product Administration

- No change
- Held
- Permanently discontinued
- N/A

6. Status/Outcome

- Continuing
- Resolved
- Death
- Severity/frequency increased
Report as a new AE.
- Continuing at end of study participation

6a. Status/Outcome Date

Leave blank if Status/Outcome is "Continuing."

[][] [][][][] [][]
dd MMM yy

7. Treatment Mark "None" or all that apply.

- None
- Medication(s)
Report on Concomitant Medications Log.
- New/Prolonged hospitalization
Comment below.
- Procedure/Surgery
Comment below.
- Other
Comment below.

8. Is this an SAE according to ICH guidelines? yes no

9. Has/will this AE be reported as an EAE? yes no

10. At which visit was this AE first reported? [][][] . [][]
Visit code required (regular or interim).

11. Was this a worsening of a pre-existing condition? yes no

Comments: _____

Adverse Experience Log (AE-1)

Purpose: To document any Adverse Experience (AE) reported by the participant or clinically observed as defined by the protocol.

General Information/Instructions: Do not record a condition as an AE if it existed at enrollment as a pre-existing condition, unless it increases in severity or frequency. If a cluster of symptoms reported on separate AE Log pages is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, mark the AE Log pages for the other symptoms with the words “Delete due to diagnosis on AE page #” (specify page number of diagnosis AE).

Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers. Do not renumber any AE Log pages after faxing, unless instructed by SCHARP.
- **Item 1:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE Log. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, “decreased hematocrit” or “increased ALT.”
- **Item 2:** 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; if the AE is discovered during the study visit exam, record the date of the study visit exam; if the AE is an abnormal lab result, record the date on which the specimen was collected.
- **Item 3:** To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* and the *Male Genital Toxicity Table*.
- **Item 4:** Mark the assessment of the relationship between the AE and the study agent. 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,” record an alternative etiology, diagnosis, or explanation in the “Comments” field. For more information, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.
- **Item 5:**
 - **No change:** Mark if the participant is expected to continue to use study product and the AE does NOT result in a study product hold or permanent discontinuation.
 - **Held:** Mark if the AE results in a study product hold. If multiple AEs are reported at the same visit, mark “Held” for the AE(s) that contributed to the product hold.
 - **Permanently discontinued:** Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, only mark “Permanently discontinued” for the AE that contributed to the permanent discontinuation.
 - **N/A (not applicable):** Mark if the AE occurred after the participant had completed all administration of the study product, or the study product is held or permanently discontinued for a different AE or other reason, or the AE is Grade 5-death.
- **Item 6:**
 - **Continuing:** AE is continuing at the time it is reported.
 - **Resolved:** Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved.
 - **Death:** 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.”
 - **Severity/frequency increased:** If an AE increases in severity or frequency after it has been reported on the AE Log, line through the “Continuing” box previously marked and mark “Severity/frequency increased.” Record the date of increase in the “Status/Outcome Date.” Report the increase in severity or frequency as a new AE. For this new AE, the “Onset Date” will be the date that the severity or frequency increased. Update EAE form if applicable. Note that decreases in severity should not be recorded as new AEs.
 - **Continuing at end of study participation:** Mark this box whenever an AE is continuing at the time of participant study termination.
- **Item 6a:** At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant no longer experienced the AE; or the date of the study visit or specimen collection at which the change in status/outcome is first noted.
- **Item 7:** Indicate if treatment was clinically indicated for the AE, regardless of whether the treatment was actually used. Also mark this item if the participant self-treated.
- **Items 8 and 9:** For questions about ICH guidelines and EAE reporting, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.