
Termination (TM-1)

Purpose: This form should be completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.

Item-specific Instructions:

- **Item 1:** A complete date is required.
- **Item 2:** Mark only the primary reason for termination.
 - **Item 2a:** Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.
 - **Item 2b1:** At a minimum, the month and year are required.
 - **Item 2l:** Early study closure: Only mark 2l when instructed by SCHARP.
- **Item 3a:** Record the page number of the Adverse Experience Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the “specify” line.