**Instructions:** Email completed form to MTN Safety Physicians: mtn011safetymd@mtnstopshiv.org

IMPORTANT: Complete all required fields so the PSRT has all information needed to respond to your query.

**Site:**       **Query Date (dd-MMM-yy):**

**Completed by:**       **Email address:**

**PTID:**       **Participant Age** (in years):

**Gender:**       **Last Visit**:

**Study Group (1 or 2):**

**Reason for query:** [ ]  Product use consultation:

[ ]  Should use of study product be temporarily discontinued?

[ ]  Should use of study product be permanently discontinued?

[ ]  Should use of study product be resumed?

 [ ]  Request for consultation on AE management

 [ ]  Request to withdraw participant from the study

 [ ]  Other, specify:

**Is this query a request for the PSRT to consult on an adverse event (AE)?**

[ ]  Yes → continue completing this page

[ ]  No → skip to Comments on page 2

**Primary AE of concern:**

**AE onset date (dd-MMM-yy):**       **AE severity grade at onset:**

**Relatedness to study product: Current study product administration:**

[ ]  Related [ ]  No change

[ ]  Not related [ ]  On hold

 [ ]  Permanently discontinued

 [ ]  Not applicable

**Has this AE been reported on a SCHARP AE Log form?**

[ ]  Yes

[ ]  No

**Has this AE been reported as an EAE? Has this AE been assessed more than once?**

[ ]  Yes [ ]  Yes

[ ]  No [ ]  No → skip to Comments on page 2

**Date of most recent assessment (dd-MMM-yy):**

**Status of AE at most recent assessment:**

[ ]  Continuing, stabilized (severity grade unchanged)

[ ]  Continuing, improving → severity grade decreased to

[ ]  Continuing, worsening → severity grade increased to

[ ]  Resolved

**Comments:** Provide additional details relevant to this query. If product use has been held, include date of last reported product use prior to the hold (per participant report).

**End of Form for Site Staff.** Email completed form to the MTN-011 Protocol Safety Physicians, mtn011safetymd@mtnstopshiv.org. If an email response is not received from the PSRT within 3 business days, re-contact the Protocol Safety Physicians, copying the study management team (mtn011mgmt@mtnstopshiv.org), for assistance as soon as possible.

|  |
| --- |
| For PSRT use only — provide response to query here**PSRT Responding Member:**       **PSRT Response Date (dd-MMM-yy):**      **Query Outcome:**[ ]  Approved[ ]  Not approved[ ]  Not applicablePSRT Comments:  |