**Instructions:** Email completed form to MTN Safety Physicians: [mtn011safetymd@mtnstopshiv.org](mailto: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](mailto: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](mailto: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 applicable  PSRT Comments: |