## MATRIX-001 Protocol Safety Review Team Query Form

**\*\*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):

**Reason for query:**  Consultation on AE assessment/management/reporting

Consultation on product use management

Consultation on participant eligibility and/or evaluability

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

**AE of concern:**

**Onset date:**

**Severity Grade:**

**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 an FHI360 Has this AE been assessed more than once?**

**AE Log form?**

Yes  Yes

No  No 🡪 skip to Comments on page 2

**Has this AE been reported as an SAE/EAE?**

Yes

No

**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. *Include date of last film insertion.*

**End of Form for Site Staff.** Email completed form to the MATRIX-001 Protocol Safety Physician, [(](mailto:mtn020safetymd@mtnstopshiv.org)[matrix001safetyphysician@lists.matrix4prevention.org](mailto:matrix001safetyphysician@lists.matrix4prevention.org)). If an email response is not received from the PSRT within 3 business days, re-contact the Protocol Safety Physicians, copying the following distribution list ([matrix001psrt@lists.matrix4prevention.org](mailto:matrix001psrt@lists.matrix4prevention.org); [matrix001mgmtteam@lists.matrix4prevention.org](mailto:matrix001mgmtteam@lists.matrix4prevention.org); matrix001protocolteam@lists.matrix4prevention.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):**

PSRT Comments: