## 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, (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; 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: