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| **SITE AND PARTIPANT INFORMATION** | | | |
| Site Name: |  | Query Date: | DD/MM/YY. |
| Staff Name: |  | Staff Email Address: |  |
| Participant ID: |  | Participant Age: |  |

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| **REASON FOR QUERY** |
| Request for consultation on clinical/laboratory evaluations related to eligibility determination |
| Request for consultation on clinical/laboratory evaluations related to study product management  Should study product be continued?  Should study product be temporarily held?  Should study product be permanently discontinued?  Should study product be resumed?  Select associated study product:  Vaginal Ring  Truvada Tablet |
| Request for consultation on AE management  Yes. Complete Section A and B, as appropriate  No. Skip to Narrative Summary |
| Other. Please Describe:  Click or tap here to enter text. |

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| **SECTION A: ADVERSE EVENT (AE) INFORMATION** | |
| Primary AE of Concern: |  |
| Onset Date: | DD/MM/YY. |
| Severity Grade at Onset: | Grade 1 Mild  Grade 2 Moderate  Grade 3 Severe  Grade 4 Potentially Life-Threatening  Grade 5 Death |
| Relatedness to Study Product: | Related  Not Related |
| Relatedness to Study Procedure (Record explanation in the Narrative Summary section): | Yes  No |
| Current Study Product Administration: | Not Applicable  Continuing  Temporarily Held, as of DD/MM/YY.  Permanently Discontinued, as of DD/MM/YY. |
| Has this AE been reported on a SCHARP AE Log form? | Yes  No |
| Has this AE been reported as an SAE/EAE? | Yes  No |
| Has this AE been evaluated more than once? | Yes. Complete Section B  No. Skip to Narrative Summary |

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| **SECTION B: ADVERSE EVENT (AE) RE-ASSESSMENT INFORMATION** | |
| Date of Most Recent Evaluation: | DD/MM/YY. |
| Status of AE at Most Recent Evaluation: | Continuing, stabilized (severity grade unchanged)  Continuing, improving → severity grade decreased to: Enter Grade.  Continuing, worsening → severity grade increased to: Enter Grade.  Resolved |

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| **NARRATIVE SUMMARY** |
| *Describe the sequence of the signs and/or symptoms, relevant past medical history, diagnosis, intervention and/or treatment, relevant lab tests and results and current status of participant:* |
| Click or tap here to enter text. |
| *Proposed course of action:* |
| Click or tap here to enter text. |

**END OF FORM FOR SITE STAFF.**

Email completed form to the MTN-034 Protocol Safety Physicians [mtn034safetymd@mtnstopshiv.org](mailto:mtn034safetymd@mtnstopshiv.org). If an email response is not received from the PSRT within 3 business days, re-contact the Protocol Safety Physicians, copying the MTN-034 management team ([mtn034mgmt@mtnstopshiv.org](mailto:mtn034mgmt@mtnstopshiv.org)) for assistance.

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| **PSRT USE ONLY** | |
| PSRT Responding Member Name: |  |
| PSRT Response Date: |  |
| PSRT Comments: | |
| Click or tap here to enter text. | |