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| **Study (tick one):**  | [ ] MTN-042/DELIVER [ ] MTN-043/B-PROTECTED |
|  |
| **SITE AND PARTIPANT INFORMATION** |
| Site Name: |  | Query Date: | DD/MMM/YY |
| Staff Name: |  | Staff Email Address: |  |
| Participant ID: |  | Study Product Assigned | [ ]  DPV VR[ ]  Oral Truvada |
| Participant Type (Mother/Infant): | [ ]  Mother, complete🡪 | Gestational Age (weeks) or Pregnancy Outcome Date  | WW D/7 *or*DD/MMM/YY |
| [ ]  Infant, complete 🡪 | Infant Date of Birth | DD/MMM/YY |

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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? |
| [ ]  Request for consultation on AE management[ ]  Yes. Complete Section A and B, as appropriate [ ]  No. Skip to Narrative Summary |
| [ ]  Co-enrollment notification  |
| [ ]  Early termination based on IoR discretion (i.e. non-voluntary withdrawal) |
| [ ]  Notification of product not returned with protocol specified timeframes for holds/discontinuations  |
| [ ]  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/MMM/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/MMM/YY.[ ]  Permanently Discontinued, as of DD/MMM/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/MMM/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-042 or MTN-043 Protocol Safety Physicians mtn042safetymd@mtnstopshiv.org or mtn043safetymd@mtnstopshiv.org If an email response is not received from the PSRT within 3 business days, re-contact the Protocol Safety Physicians, copying the respective management team (mtn042mgmt@mtnstopshiv.org or mtn043mgmt@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. |