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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](mailto:mtn042safetymd@mtnstopshiv.org) or [mtn043safetymd@mtnstopshiv.org](mailto: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](mailto:mtn042mgmt@mtnstopshiv.org) or [mtn043mgmt@mtnstopshiv.org](mailto: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. | |