**Division of AIDS Safety Office** **EXPEDITED ADVERSE EVENT (EAE) Reporting Form**

| *Please type or print in English* |
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| **Why are you not using DAERS?** |
| **Reason for submitting report beyond the 3 reporting days** (if applicable)**:** |

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|  |  | **SENDER INFORMATION** |  |
| **To:**  **Fax:** | DAIDS SAFETY OFFICE  1-800-275-7619 (USA) or | **Sender Name:** |  |
|  | + 1-301-897-1710 (International) | **Phone:** | **Fax:** |
| **Phone:** | 1-800-537-9979 (USA) or  + 1-301-897-1709 (International) | **E-mail:** |  |
| **E-mail:** | [RSCSafetyOffice@Tech-Res.com](mailto:RSCSafetyOffice@Tech-Res.com) | **Date Sent:**  DD/MON/YYYY | **No. of Pages:**  (including this cover sheet) |

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|  | **REPORTER AND SITE INFORMATION** |  |
| **Site Name:** | **Site ID:** |  |
| **Site Awareness Date:**  DD/MON/YYYY | **Site Report Date:**  DD/MON/YYYY |  |
| **Reporter Same as Sender? YES NO**  If **YES**, do not repeat contact information provided above. | **Reporter Name:** |  |
|  | **Phone:** | **Fax:** |
|  | **E-mail:** |  |

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| **KEY EAE REPORT** | **INFORMATION** |
| **Participant ID:** | **Protocol No(s)/Version No(s):** |
| **New Report:**  (Send all pages of the completed form.)  **Update Report:** (Provide date of original report.) | **Date of Initial Report:**  DD/MON/YYYY |
| **Pages:  1  2  3  4  5  6  7  8**  **(**For Update Reports, submit only updated pages. Check all that apply.) | **ALL  OTHER** |

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| **- - - - SAFETY OFFICE USE ONLY - - - -** |

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| **Received Date Stamp:** |  |  |
| **AE NUMBER:** | |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  | | **PROTOCOL NUMBER(S):** |
| **Report Received By:** | **Fax  E-mail  Express Mail** |  |

|  | Participant ID: | Site Report Date:     DD/MON/YYYY |
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| **1.** | **PARTICIPANT INFORMATION** | For each question below, | please check the appropriate box. |
|  | **Date of Birth:**    DD/MON/YYY | ***OR* Age at time of event:** | Days \*  Months \*  Years \*  *\* Pediatric Studies Only* |
|  | **Sex at Birth:** Male  Female | Unknown | **Height:**  cm  in |
|  | **If Female,** Yes  No  **Pregnant?:**    (**If Yes**) **Duration**: week(s) | Unknown | **Weight:**  kg  lb |
|  | **Ethnicity:**  Hispanic or Latino  Non-Hispanic or Latino    Unknown  Not Reported  Other | **Race:** | American Indian or Alaska Native  Black or African American  White  Native Hawaiian or Other Pacific Islander  Asian  Not Reported  Unknown  Other |

|  | Participant ID: | Site Report Date:     DD/MON/YYYY |
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| **2.** | **PRIMARY ADVERSE EVENT** |

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| **Primary AE** List only one Primary AE | **Severity Grade of Primary AE**\* | **Onset Date** DD/MON/YYYY | **Status Code\*\*** | **Status Date** DD/MON/YYYY |
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| ***\*Severity Grade of Primary AE:***   1. – Mild 2. – Moderate 3. – Severe 4. – Life Threatening 5. – Death | ***\*\*Status Code at Most Recent Observation:***   1. – Recovered/Resolved 2. – Recovering/Resolving 3. – Not Recovered/Not Resolved 4. **–** Recovered/Recovered with Sequelae 5. – Death 6. – Unknown |

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| **Country of AE Origin:** |

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| **Is this a Serious Adverse Event (SAE) as defined by ICH\* E2A?**  ***(\*International Conference on Harmonization)*** | **YES**  **NO** |

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| **If Yes, check all that apply:**  Results in death  Is life-threatening  Requires inpatient hospitalization or prolongation of existing hospitalization  Results in persistent or significant disability/incapacity  Is a congenital anomaly/birth defect  Is an important medical event that may not be immediately life-threatening or result in death or hospitalization but may   jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above |
| **If No, check applicable box:**  None of the above – This is not an SAE, but is a protocol-specific reporting requirement  None of the above – This is not an SAE, but is of sufficient concern to report to DAIDS.  Comment(s): |

|  | Participant ID: | Site Report Date:     DD/MON/YYYY |
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| **3.** | **NARRATIVE CASE SUMMARY** | Include clinical course, therapeutic measures, outcome, relevant past medical history, any other contributing factors, alternative etiologies, and other relevant information. Use additional page(s) as needed. |

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|  | Participant ID: | Site Report Date:     DD/MON/YYYY |
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| **4a.** | **FOR STUDY AGENTS OTHER THAN VACCINES OR THERAPEUTIC VACCINES**  For therapeutics administered on a cyclic schedule, also complete the Supplemental DAIDS EAE Report Form and check here  if attached. |

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|  | **Protocol Number:**  (include information on  co-enrolled protocols here) |  |  |  |  |  |  |
|  | **Study Agent:** | ***Example*** | **Agent 1** | **Agent 2** | **Agent 3** | **Agent 4** | **Agent 5** |
|  | **Generic/INN Name: OR the Study Agent Name/Abbreviation as listed in the Protocol**  If combination agent, list as separate components separated by a slash. | *Abacavir Sulfate/ Lamivudine/ Zidovudine* |  |  |  |  |  |
|  | **Relationship to Primary AE\*:** | *Related* |  |  |  |  |  |
|  | Provide relationship of each component when using a combination study agent. Refer to example and form completion instructions for  details. | *Abacavir = Related*  *Lamivudine = Related*  *Zidovudine =  Not Related* |  |  |  |  |  |

***\* Related*** *— There is a reasonable possibility that the AE may be related to the study agent(s).*

***Not Related*** *— There is not a reasonable possibility that the AE may be related to the study agent(s).*

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|  | **Study Agent:** |  | **Agent 1** | **Agent 2** | **Agent 3** | **Agent 4** | **Agent 5** |
| **A** | **Dose/Unit/  Schedule:** |  |  |  |  |  |  |
| **B** | **Route:** |  |  |  |  |  |  |
| **C** | **Date of First Dose:**  DD/MON/YYYY |  |  |  |  |  |  |
| **D** | **Date of Last Dose:**  DD/MON/YYYY |  |  |  |  |  |  |
| **E** | **Action Taken with Study Agent\*\*:** |  |  |  |  |  |  |
| **F** | **Date of Action Taken With Study Agent:**  DD/MON/YYYY |  |  |  |  |  |  |
| **G** | **Distributed by DAIDS:** |  | Yes  No | Yes  No | Yes  No | Yes  No | Yes  No |
|  | **If No, specify manufacturer.**  **If unknown, specify**  **distributor.** |  |  |  |  |  |  |
| **H** | **Lot No:** |  |  |  |  |  |  |

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| \*\* | **C** | Continued without change | **O** | Course completed or Subject Off Study Agent at AE Onset | **D** | Permanently Discontinued | **R** | Dose or Schedule Reduced | **T** | Temporarily Held | **U** | Unknown |

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|  | Participant ID: | Site Report Date:     DD/MON/YYYY |
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| **4b.** | **FOR VACCINES ONLY (INCLUDING THERAPEUTIC VACCINES)**  For therapeutics administered on a cyclic schedule, also complete the Supplemental DAIDS EAE Report Form and check here  if attached. |

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| **Protocol Number:**  (include information on  co-enrolled protocols here) |  |  |  |  |  |
| **Study Arm:** |  |  |  |  |  |
| **Study Agent:** | **Agent 1** | **Agent 2** | **Agent 3** | **Agent 4** | **Agent 5** |
| **Generic/INN Name:  OR the Study Agent Name/Abbreviation as  listed in the Protocol** |  |  |  |  |  |
| **Relationship to Primary AE\*:** |  |  |  |  |  |

***\* Related*** *— There is a reasonable possibility that the AE may be related to the study agent(s).*

***Not Related*** *— There is not a reasonable possibility that the AE may be related to the study agent(s).*

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| **Dose/Unit:** |  |  |  |  |  |
| **Route:** |  |  |  |  |  |
| **Device Lot Number:**  (if known/if applicable) |  |  |  |  |  |

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| **List all dates (DD/MON/YYYY) of vaccine administration/agent(s) administered/site of administration** | **N/A** |

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| **A.**  DD/MON/YYYY  **Agent (s) Administered:**    **Site of Administration**  (if known/if applicable)**:   Left Arm  Right Arm**  **Left Leg  Right Leg**  **Other** | **B.**  DD/MON/YYYY  **Agent(s) Administered:**    **Site of Administration**  (if known/if applicable)**:   Left Arm  Right Arm**  **Left Leg  Right Leg**  **Other** | **C.**  DD/MON/YYYY  **Agent(s) Administered:**    **Site of Administration**  (if known/if applicable)**:   Left Arm  Right Arm**  **Left Leg  Right Leg**  **Other** | **D.**  DD/MON/YYYY  **Agent(s) Administered:**    **Site of Administration**  (if known/if applicable)**:   Left Arm  Right Arm**  **Left Leg  Right Leg**  **Other** | **E.**  DD/MON/YYYY  **Agent(s) Administered:**    **Site of Administration**  (if known/if applicable)**:   Left Arm  Right Arm**  **Left Leg  Right Leg**  **Other** |

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| **Action Taken with Study Agent\*\* (enter code for the vaccine treatment regimen from codes listed below)**: | **Date of Action Taken With Study Agent:**    DD/MON/YYYY |

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| \*\* | **C** | Continued without change | **O** | Course completed or Subject Off Study Agent at AE Onset | **D** | Permanently Discontinued | **R** | Dose or Schedule Reduced | **T** | Temporarily Held | **U** | Unknown |

|  | Participant ID: | Site Report Date:     DD/MON/YYYY |
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| **5.** | **CONCOMITANT MEDICATIONS**  If there were any concomitant medications that may have contributed to the primary adverse event, the details should be entered below. Any additional concomitant medications being taken at the onset of the primary adverse event should be faxed, emailed, or attached to this report. | **NONE** |

|  |  |  |  |  |  |  |  |
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| **Medication** | **Contributory to AE** | **Approximate Duration of Use** | **Date of Last Dose** | **Indication** | **Route of Administration** | **Schedule of Administration** | **Comments** |
| 1. |  |  |  |  |  |  |  |
| 2. |  |  |  |  |  |  |  |
| 3. |  |  |  |  |  |  |  |
| 4. |  |  |  |  |  |  |  |
| 5. |  |  |  |  |  |  |  |
| 6. |  |  |  |  |  |  |  |
| 7. |  |  |  |  |  |  |  |

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| **6.** | **OTHER CLINICALLY SIGNIFICANT EVENTS ASSOCIATED WITH PRIMARY AE** | **NONE** |

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| **Other Clinically Significant Events Associated with Primary AE** | **Severity Grade** | **Onset Date**  DD/MON/YYYY | **Comments** |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |

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| **7.** | **RELEVANT LABORATORY TESTS**  If there were any laboratory tests relevant to the primary adverse event, the details of the laboratory tests should be entered below. Any additional laboratory tests should be faxed, emailed, or attached to this report. | **NONE** |

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| **Test** | **Collection Date**  DD/MON/YYYY | **Result** | **Units** | **Lab Normal Range** | **Infectious Agent (for microbiological tests only)** | **Body Site (for microbiological tests only)** |
| 1. |  |  |  |  |  |  |
| 2. |  |  |  |  |  |  |
| 3. |  |  |  |  |  |  |
| 4. |  |  |  |  |  |  |
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|  | Participant ID: | Site Report Date:     DD/MON/YYYY |
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| **8.** | **RELEVANT DIAGNOSTIC TESTS (NON-LAB)**  If there were any diagnostic tests relevant to the primary adverse event, the details of the diagnostic tests should be entered below. Any additional diagnostic tests should be faxed, emailed, or attached to this report. | **NONE** |

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| **Test** | **Body Area** | **Test Date**  DD/MON/YYYY | **Results/Comments** |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |

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| **9.** | **ADDITIONAL INFORMATION**  Check the box for each type of document attached. Check all that apply. | **NONE** |

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| **Autopsy Report**  **Pathology Report(s)**  **Radiology Report(s)** | **Concomitant Medication(s)**  **Laboratory Test(s)**  **Diagnostic Test(s)** | **Progress Note(s)**  **Discharge Summary**  **Other, specify:** |

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| **CERTIFICATION INFORMATION** |
| **I CERTIFY THAT THE DATA PROVIDED ON THIS FORM ARE ACCURATE AND COMPLETE.**  **Site Investigator/Study Physician Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:**  DD/MON/YYYY  **Site Investigator/Study Physician Name Printed:** |

|  | Participant ID: | Site Report Date:     DD/MON/YYYY |
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| **SUPPLEMENTAL DAIDS EXPEDITED ADVERSE EVENT (EAE) FORM** |
| **Use for therapeutic study agents administered on a cyclic schedule.**  **For multiple study agents on a cyclic schedule, create one page for each study agent.** |

**Study Agent Name:**

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| --- | --- | --- | --- |
| **1.** | **If event occurred during a dosing cycle:  N/A**   1. Highest dose in this cycle: 2. Date this cycle started:   DD/MON/YYYY 3. Date previous cycle started:   DD/MON/YYYY 4. Number of previous cycles: | **2.** | **If event occurred did not occur during a  N/A dosing cycle:**   1. Highest dose in this cycle: 2. Date this cycle started:   DD/MON/YYYY 3. Number of previous cycles: |