Division of AIDS Safety Office

### EXPEDITED ADVERSE EVENT (EAE) Reporting Form

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| *Please type or print in English* | | | | | | | | |
| **Why are you not using DAERS?** | | | | | | | | |
| **Reason for submitting report beyond the 3 reporting days** (if applicable)**:** | | | | | | | | |
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| **SENDER INFORMATION** | | | | | | | | |
| **To:** | DAIDS SAFETY OFFICE | | | **Sender Name:** | | | | |
| **Fax:** | 1-800-275-7619 (USA) or  + 1-301-897-1710 (International) | | | **Phone:** | | | **Fax:** | |
| **Phone:** | 1-800-537-9979 (USA) or  + 1-301-897-1709 (International) | | | **E-mail:** | | | | |
| **E-mail:** | RCCSafetyOffice@Tech-Res.com | | | **Date Sent:**        (DD/MON/YYYY) | | | **No. of Pages:**  (including this cover sheet) | |
|  | | | | | | | | |
| **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:** | | | | |
|  | | | | | | | | |
| **KEY EAE REPORT INFORMATION** | | | | | | | | |
| **Participant ID:** | | | | | **Protocol No(s)/Version No(s):** | | | |
| **New Report:** | | | (Send all pages of the completed form.) | | **Date of Initial Report:**        DD/MON/YYYY | | | |
| **Update Report:** | | | (Provide date of original report.) | |  | | | |
| **Pages:**  **1**  **2**  **3**  **4**  **5**  **6**  **7  8  ALL  OTHER**  **(**For Update Reports, submit only updated pages. Check all that apply.) | | | | | | | | |
|  | | | | | | | | |
| **- - - - SAFETY OFFICE USE ONLY - - - -** | | | | | | | | |
| **Received Date Stamp:** | | | | | | | | |
| **AE Number:** | | |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  | | | | | **Protocol Number(s):** | |  |
| **Report Received By:**  **Fax**  **E-mail**  **Express Mail** | | | | | | | | |

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| 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:** | |  | | ***OR*** | **Age at time of event:** | |  | Days \* | Months\* | Years |
| DD/MON/YYYY | | | | | | | | *\* Pediatric Studies Only* | | |
| **Sex at Birth:** | | Male | Female | | Unknown | | **Height:** |  | cm  in | |
| **If Female, Pregnant?:** | | Yes | No | | Unknown | | **Weight:** |  | kg  lb | |
| (**If Yes**) **Duration**:     week(s) | | | | | | |  |  |  | |
| **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 | | | | |

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| **2.** | **PRIMARY ADVERSE EVENT** | | | | | |
| **Primary AE** List only one Primary AE | | **Severity Grade of Primary AE\*** | **Onset Date** DD/MON/YYYY | **Status  Code\* \*** | | **Status Date** DD/MON/YYYY |
|  | |  |  |  | |  |
| ***\*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 | | | |
|  | | | | | | |
| **Country of AE Origin:** | | | | | | |
|  | | | | | | |
| **Is this a Serious Adverse Event (SAE) as defined by ICH\* E2A?**  ***(\*International Conference on Harmonization)*** | | | | | **YES**  **NO** | |
| **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): | | | | | | |
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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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| **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. | | | | | | | | |
| **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\*:**  Provide relationship of each component when using a combination study agent. Refer to example and form completion instructions for details. | | | *Related* | |  | |  |  |  |  |
|  | | | *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).* | | | | | | | | | | |
|  | **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:** | | |  | |  |  |  |  |  |
| |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **\*\*** | **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. | | | | | | | | | | | | | | | | | | | | |
| **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).* | | | | | | | | | | | | | | | | | | | | | | |
| **Dose/Unit:** | | | | | | |  | | |  | |  | | |  | | | |  | | | |
| **Route:** | | | | | | |  | | |  | |  | | |  | | | |  | | | |
| **Device Lot Number:** (if known/if applicable) | | | | | | |  | | | | | | | | | | | | | | | |
| **List all dates (DD/MON/YYYY) of vaccine administration/agent(s) administered/site of administration** | | | | | | | | | | | | | | | | | | | | **N/A** | |
| **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** | | | | |
| **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 | | | | | | | |
| **\*\* 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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| **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** |
| **Medication** | | **Contributory to AE** | **Approximate Duration of Use** | | **Date of Last Dose** | | | **Indication** | | | | **Route of Administration** | | | **Schedule of Administration** | | | **Comments** |
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| **6.** | **OTHER CLINICALLY SIGNIFICANT EVENTS ASSOCIATED WITH PRIMARY AE** | | | | | | | | | | | | | | | | **NONE** | |
| **Other Clinically Significant Events Associated with Primary AE** | | | | | | **Severity Grade** | | | **Onset Date** DD/MON/YYYY | | | | **Comments** | | | | | |
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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** | | |
| **Test** | | | | **Collection Date**  DD/MON/YYYY | | | **Result** | | | **Units** | **Lab Normal Range** | | | **Infectious Agent (for microbiological tests only)** | | **Body Site (for microbiological tests only)** | | |
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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** |
| **Test** | | **Body Area** | **Test Date**  DD/MON/YYYY | | | | **Results/Comments** | |
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| **9.** | **ADDITIONAL INFORMATION** Check the box for each type of document attached. Check all that apply. | | | | | | | **NONE** |
| **Autopsy Report** | | **Concomitant Medication(s)** | | **Progress Note(s)** | | | | |
| **Pathology Report(s)**  **Radiology Report(s)** | | **Laboratory Test(s)**  **Diagnostic Test(s)** | | **Discharge Summary**  **Other, specify:** | | | | |
|  | | | |  | | | | |
|  | | | | | | | | |
| **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:** | | | | |  | | | |

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| 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:**

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