SERIOUS ADVERSE EVENT Reporting Form

SENDER INFORMATION	
Sender Name:	
Phone:	**Fax:**
E-mail:	
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 Name:	
	Phone:	**Fax:**
	E-mail:	

KEY EAE REPORT INFORMATION	
Participant ID:	
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** ☐ **ALL** ☐ **OTHER** 9 **(**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**	

Participant ID: Site Report Date: DD/MON/YYYY

1. PARTICIPANT INFORMATION For each question below, please check the appropriate box.

Date of Birth: DD/MON/YYYY ***OR*** **Age at time of event:** ☐ Days * ☐ Months* ☐ Years

** Pediatric Studies Only*

Sex at Birth: ☐ Male ☐ Female ☐ Unknown

Height: ☐ cm ☐ in

If Female, Pregnant?: ☐ Yes ☐ No ☐ Unknown

(**If Yes**) **Duration**: week(s)

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

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): _____

Participant ID:

Site Report Date: _____
DD/MON/YYYY

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.

Participant ID: Site Report Date: DD/MON/YYYY

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)		**PROTOCOL #**	**PROTOCOL #**			
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.	*Tenofovir/ Lamivudine/ Efavirenz*					
Relationship to Primary AE*: Provide relationship of each component when using a combination study agent. Refer to example and form completion instructions for details.	*Not Related*					
	Abacavir = Related *Lamivudine = Related* *Zidovudine = Not Related*					

	Study Agent:		**Agent 1**		**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

Participant ID: Site Report Date: DD/MON/YYYY

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

Participant ID: Site Report Date: DD/MON/YYYY

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
1.							
2.							
3.							
4.							
5.							
6.							
7.							

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
1.			
2.			
3.			
4.			
5.			

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)
1.						
2.						
3.						
4.						

Participant ID: 604 8702 L

Site Report Date: 12/JUN/2020
DD/MON/YYYY

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
1.			
2.			
3.			
4.			

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)** ☐ **Laboratory Test(s)** ☐ **Discharge Summary**

☐ **Radiology Report(s)** ☐ **Diagnostic Test(s)** ☐ **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: