



NHSRC 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 SAE REPORT INFORMATION

Participant ID:	Protocol No(s)/Version No(s):
New Report: <input checked="" type="checkbox"/> (Send all pages of the completed form.)	Date of Initial Report: DD/MON/YYYY
Update Report: <input type="checkbox"/> (Provide date of original report.)	
Pages: <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input checked="" type="checkbox"/> ALL <input type="checkbox"/> OTHER 9	
(For Update Reports, submit only updated pages. Check all that apply.)	

Promoting Scientific and Ethical Conduct of Health Research in Malawi
Executive Committee: *Dr M. Joshua (Chairperson), Dr S. Mndolo (Vice-Chairperson)*
 Registered with the USA Office for Human Research Protections (OHRP) as an International IRB
IRB Number IRB00003905 FWA00005976
 Email: *research@mail.gov.mw*

----- 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: <input type="checkbox"/> Days * <input type="checkbox"/> Months* <input checked="" type="checkbox"/> Years <i>* Pediatric Studies Only</i>
Sex at Birth: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female <input type="checkbox"/> Unknown	Height: <input checked="" type="checkbox"/> cm <input type="checkbox"/> in
If Female, Pregnant?: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown (If Yes) Duration: week(s)	Weight: <input checked="" type="checkbox"/> kg <input type="checkbox"/> lb
Ethnicity: <input type="checkbox"/> Hispanic or Latino <input checked="" type="checkbox"/> Non-Hispanic or Latino <input type="checkbox"/> Unknown <input type="checkbox"/> Not Reported <input type="checkbox"/> Other _____	Race: <input type="checkbox"/> American Indian or Alaska Native <input checked="" type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input type="checkbox"/> Not Reported <input type="checkbox"/> Unknown <input type="checkbox"/> 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): _____

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

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 <input type="checkbox"/> if attached.						
Protocol Number: (include information on co-enrolled protocols here)		PROTOCOL #				
Study Agent:	<i>Example</i>	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.	<i>Tenofovir/ Lamivudine/ Efavirenz</i>					
Relationship to Primary AE*: Provide relationship of each component when using a combination study agent. Refer to example and form completion instructions for details.	<i>Not Related</i>					
	<i>Abacavir = Related</i>					
	<i>Lamivudine = Related</i>					
	<i>Zidovudine = Not Related</i>					
* 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 <input type="checkbox"/> No <input checked="" type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
	If No, specify manufacturer. If unknown, specify distributor.					
H	Lot No:					

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IRB Number IRB00003905 FWA00005976

Email: research@mail.gov.mw

**	C <u>Continued</u> without change	O Course completed or Subject <u>Off</u> Study Agent at AE Onset	D Permanently <u>Discontinued</u>	R Dose or Schedule <u>Reduced</u>	T <u>Temporarily</u> Held	U Unknown
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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*:					
<p><i>* Related — There is a reasonable possibility that the AE may be related to the study agent(s).</i> <i>Not Related — There is not a reasonable possibility that the AE may be related to the study agent(s).</i></p>					
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					<input type="checkbox"/> 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): <input type="checkbox"/> Left Arm <input type="checkbox"/> Right Arm <input type="checkbox"/> Left Leg <input type="checkbox"/> Right Leg <input type="checkbox"/> Other _____	Site of Administration (if known/if applicable): <input type="checkbox"/> Left Arm <input type="checkbox"/> Right Arm <input type="checkbox"/> Left Leg <input type="checkbox"/> Right Leg <input type="checkbox"/> Other _____	Site of Administration (if known/if applicable): <input type="checkbox"/> Left Arm <input type="checkbox"/> Right Arm <input type="checkbox"/> Left Leg <input type="checkbox"/> Right Leg <input type="checkbox"/> Other _____	Site of Administration (if known/if applicable): <input type="checkbox"/> Left Arm <input type="checkbox"/> Right Arm <input type="checkbox"/> Left Leg <input type="checkbox"/> Right Leg <input type="checkbox"/> Other _____	Site of Administration (if known/if applicable): <input type="checkbox"/> Left Arm <input type="checkbox"/> Right Arm <input type="checkbox"/> Left Leg <input type="checkbox"/> Right Leg <input type="checkbox"/> 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 <u>Continued</u> without change	O Course completed or Subject <u>Off Study</u> Agent at AE Onset	D Permanently <u>Discontinued</u>	R Dose or Schedule <u>Reduced</u>	T <u>Temporarily</u> Held	U Unknown

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5. CONCOMITANT MEDICATIONS							NONE <input checked="" type="checkbox"/>
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.							
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 <input checked="" type="checkbox"/>
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							NONE <input type="checkbox"/>
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: _____

Site Report Date: _____
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8. RELEVANT DIAGNOSTIC TESTS (NON-LAB)			NONE <input checked="" type="checkbox"/>
Test	Body Area	Test Date DD/MON/YYYY	Results/Comments
1.			
2.			
3.			
4.			

9. ADDITIONAL INFORMATION			NONE <input checked="" type="checkbox"/>
Check the box for each type of document attached. Check all that apply.			
<input type="checkbox"/> Autopsy Report	<input type="checkbox"/> Concomitant Medication(s)	<input type="checkbox"/> Progress Note(s)	
<input type="checkbox"/> Pathology Report(s)	<input type="checkbox"/> Laboratory Test(s)	<input type="checkbox"/> Discharge Summary	
<input type="checkbox"/> Radiology Report(s)	<input type="checkbox"/> Diagnostic Test(s)	<input type="checkbox"/> 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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