

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

Please type or print in English

To: DAIDS SAFETY OFFICE

Sent by: _____

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: _____

Email: RCCSafetyOffice@Tech-Res.com

Date Sent:

D	D	/	M	O	N	/	Y	Y	Y	Y

No. of Pages: _____ (Including this cover sheet)

Patient/Volunteer ID Number: _____

REPORTER AND SITE INFORMATION

Site Name: _____ **Site Number:** _____

Site Awareness Date:

D	D	/	M	O	N	/	Y	Y	Y	Y

Site Report Date:

D	D	/	M	O	N	/	Y	Y	Y	Y

Reporter Same as Sender? YES NO

If YES, do not repeat contact information provided above.

Reporter Name: _____

Phone: _____ **Fax:** _____

Email: _____

New Report: (Send all pages of the completed form.)

Follow-up Report: (If Follow-up Report, provide Date of Original Report.) **Date of Original Report:**

D	D	/	M	O	N	/	Y	Y	Y	Y

Pages: 1 2 3 4 5 6 7 ALL (For Follow-up Reports, submit only updated pages. Check all that apply.)

SAFETY OFFICE USE ONLY

Received Date Stamp: _____

AE NUMBER:

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PROTOCOL NUMBER(S): _____

Report Received By: Fax E-mail Express Mail



Patient/Volunteer ID Number: _____

Site Report Date:
D D / M O N / Y Y Y Y

Is this a Serious Adverse Event (SAE) as defined in ICH* E6 ? (* International Conference on Harmonisation) **YES** **NO**

- Results in death
- Is a congenital anomaly/birth defect
- Results in persistent or significant disability/incapacity
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization

1. PROTOCOL INFORMATION

Protocol Number: _____ Network Affiliation (check one): <input type="checkbox"/> None <input type="checkbox"/> AACTG <input type="checkbox"/> AIEDRP <input type="checkbox"/> CIPRA <input type="checkbox"/> CPCRA <input type="checkbox"/> ESPRIT <input type="checkbox"/> HPTN <input type="checkbox"/> HVTN <input type="checkbox"/> IRP <input type="checkbox"/> PACTG <input type="checkbox"/> SMART <input type="checkbox"/> Other Network, specify _____ _____	Protocol Number: _____ <input type="checkbox"/> N/A Network Affiliation (check one): <input type="checkbox"/> None <input type="checkbox"/> AACTG <input type="checkbox"/> AIEDRP <input type="checkbox"/> CIPRA <input type="checkbox"/> CPCRA <input type="checkbox"/> ESPRIT <input type="checkbox"/> HPTN <input type="checkbox"/> HVTN <input type="checkbox"/> IRP <input type="checkbox"/> PACTG <input type="checkbox"/> SMART <input type="checkbox"/> Other Network, specify _____ _____	Protocol Number: _____ <input type="checkbox"/> N/A Network Affiliation (check one): <input type="checkbox"/> None <input type="checkbox"/> AACTG <input type="checkbox"/> AIEDRP <input type="checkbox"/> CIPRA <input type="checkbox"/> CPCRA <input type="checkbox"/> ESPRIT <input type="checkbox"/> HPTN <input type="checkbox"/> HVTN <input type="checkbox"/> IRP <input type="checkbox"/> PACTG <input type="checkbox"/> SMART <input type="checkbox"/> Other Network, specify _____ _____
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2. SUBJECT INFORMATION For each question below, please check the appropriate box.

Age: _____ Days* Months* Years **Race:** Native American or Alaska Native Asian Black or African American

Sex at Birth: Male Female Unknown Native Hawaiian or Other Pacific Islander Unknown White

Pregnant: Yes No Unknown Other, specify _____

(If Yes) Duration _____ week(s)

Height * : _____ cm in

Weight: _____ kg lb

* Pediatric Studies Only

Patient/Volunteer ID Number: _____

Site Report Date:
D D / M O N / Y Y Y Y

3. FOR ALL STUDY AGENTS For therapeutics administered on a cyclic schedule, also complete the Supplemental DAIDS EAE Report Form and check here if attached.

A	Protocol Number					
	Study Agent	Agent 1	Agent 2	Agent 3	Agent 4	Agent 5
B	Generic/INN Name or the Study Agent Name/ Abbreviation as listed in the Protocol. If Combination Agent, use Study Agent name/abbreviation or list individual components.					
C	Dose					
D	Route					

4. FOR STUDY AGENTS OTHER THAN VACCINES OR THERAPEUTIC VACCINES N/A

* 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

	Study Agent	Agent 1	Agent 2	Agent 3	Agent 4	Agent 5
A	Schedule of Administration					
B	Date of First Dose (DD/MON/YYYY)					
C	Date of Last Dose (DD/MON/YYYY)					
D	Action Taken with Study Agent *					
E	Date of Action Taken with Study Agent (DD/MON/YYYY)					
F	Distributed by DAIDS	Yes <input type="checkbox"/> No <input type="checkbox"/>				
	If No, specify manufacturer. If unknown, specify distributor.					

Patient/Volunteer ID Number: _____

Site Report Date:

D	D	/	M	O	N

 /

Y	Y	/	Y

Y	Y	/	Y

Y	Y	/	Y

5. FOR VACCINES ONLY (INCLUDING THERAPEUTIC VACCINES)

List all dates (DD/MON/YYYY) of vaccine administration.

N/A

* **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

a.

_	_	/	_	_	_	/	_	_	_	_	_
D	D	/	M	O	N	/	Y	Y	Y	Y	Y

c.

_	_	/	_	_	_	/	_	_	_	_	_
D	D	/	M	O	N	/	Y	Y	Y	Y	Y

e.

_	_	/	_	_	_	/	_	_	_	_	_
D	D	/	M	O	N	/	Y	Y	Y	Y	Y

b.

_	_	/	_	_	_	/	_	_	_	_	_
D	D	/	M	O	N	/	Y	Y	Y	Y	Y

d.

_	_	/	_	_	_	/	_	_	_	_	_
D	D	/	M	O	N	/	Y	Y	Y	Y	Y

f.

_	_	/	_	_	_	/	_	_	_	_	_
D	D	/	M	O	N	/	Y	Y	Y	Y	Y

Action Taken with Study Agent * (enter code for the vaccine treatment regimen from codes listed above): _____

Patient/Volunteer ID Number: _____

Site Report Date:

D	D	/	M	O	N	/	Y	Y	Y

6. PRIMARY ADVERSE EVENT

PRIMARY AE List only one Primary AE.	Relationship to Study Agent(s) Listed in Section 3 *					Severity Grade of Primary AE	Onset Date (DD/MON/YYYY)	Status Code **	Status Date (DD/MON/YYYY)
	Agent 1	Agent 2	Agent 3	Agent 4	Agent 5				

<p>* Relationship Code</p> <ul style="list-style-type: none"> 1 – Definitely Related 2 – Probably Related 3 – Possibly Related 4 – Probably Not Related 5 – Not Related 6 – Pending (temporary assignment for death) 	<p>** Status Code at Most Recent Observation</p> <ul style="list-style-type: none"> 1 – Recovered / Resolved 2 – Recovering / Resolving 3 – Not Recovered / Not Resolved 4 – Recovered / Resolved with Sequelae 5 – Death 6 – Unknown
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7. OTHER CLINICALLY SIGNIFICANT EVENTS ASSOCIATED WITH PRIMARY AE None

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

Patient/Volunteer ID Number: _____

Site Report Date:

D	D	/	M	O	N	/	Y	Y	Y	Y

8. RELEVANT LABORATORY TESTS List normal or abnormal tests that help explain the Primary AE. List tests below OR attach copy of test results. None

Test	Collection Date (DD/MON/YYYY)	Result	Units	Lab Normal Range	Lab Value Previous to this AE	Previous Lab Collection Date (DD/MON/YYYY)
1.						
2.						
3.						
4.						

9. RELEVANT DIAGNOSTIC TESTS (NON-LAB) List tests below OR attach copy of test results. None

Test	Test Date (DD/MON/YYYY)	Results/Comments
1.		
2.		
3.		
4.		

10. CONCOMITANT MEDICATIONS List Concomitant Medications being taken at onset of primary AE OR attach copy of concomitant medication(s) list. None
DO NOT list medications used to treat the AE.

Concomitant Medication	Approximate Duration of Use
1.	
2.	
3.	
4.	
5.	
6.	
7.	

Patient/Volunteer ID Number: _____

Site Report Date:

D	D	/	M	O	N	/	Y	Y	Y	Y

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, use one page for each study agent.

Study Agent Name: _____

<p>1. If event occurred during a dosing cycle: <input type="checkbox"/> N/A</p> <p>a. Highest dose in this cycle: <input style="width: 150px; height: 20px;" type="text"/></p> <p>b. Dose at time of AE onset: <input style="width: 150px; height: 20px;" type="text"/></p> <p>c. Date this cycle started: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr><tr><td>D</td><td>D</td><td>/</td><td>M</td><td>O</td><td>N</td><td>/</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table></p> <p>d. Date previous cycle started: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr><tr><td>D</td><td>D</td><td>/</td><td>M</td><td>O</td><td>N</td><td>/</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table></p> <p>e. Number of previous cycles: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td><td> </td><td> </td></tr></table></p>									D	D	/	M	O	N	/	Y	Y	Y	Y									D	D	/	M	O	N	/	Y	Y	Y	Y				<p>2. If event did <u>not</u> occur during a dosing cycle: <input type="checkbox"/> N/A</p> <p>a. Highest dose in previous cycle: <input style="width: 150px; height: 20px;" type="text"/></p> <p>b. Last dose in previous cycle: <input style="width: 150px; height: 20px;" type="text"/></p> <p>c. Date previous cycle started: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr><tr><td>D</td><td>D</td><td>/</td><td>M</td><td>O</td><td>N</td><td>/</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table></p> <p>d. Number of previous cycles: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td><td> </td><td> </td></tr></table></p>									D	D	/	M	O	N	/	Y	Y	Y	Y			
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