Quality Medicines for Malawi

PHARMACY AND MEDICINES REGULATORY AUTHORITY

SERIOUS ADVERSE EVENT FORM

PMRA Office Use Only

PMRA Office Phone: 265-1755166/165

PMRA Office Email: info@pmra.mw, registration@pmra.mw

Record Number:…….. Protocol Ref Number:……..

Received Date Stamp Report Received by:……..Mail: ……Email……

Type of Report: ___Initial ___Update

Site Report Date: _ __ __ _ (DD MM Y) Site Awareness Date: _ __ __ _ (DD MM YY)

Event Previously Reported: __ Yes __No

Clinical Site: _____ Telephone Number: (__) _____

Completed by: _____ Signature: _____

(Print name/title)

Trials Program (Circle) Protocol Number Volunteer ID Number

_ _ _ ___ _____ _

Age: __ __ Years/Months/Days (Circle) Sex: __ Male__ Female__

_____

COMPLETE ONE SAE FORM FOR EACH REPORTABLE EVENT

1. PRIMARY REASON SAE IS BEING REPORTED (Check One Category)

__Death	__Overdose or error in administration	___Grade 1 or 2 event
__Cancer	__HIV Infection	__Recurrent event
__Congenital anomaly/Birth defect	__Immune dysfunction	__Other
__Permanent disability/Incapacity	__Grade 3 or 4 event	__Other_____

2. REPORTABLE SAE (Use Key Word, Diagnosis, Cause of Death, Lab Parameter)

_____

TOXICITY GRADE (1-5)

_____

3. SAE ONSET DATE: __ ____ ____ __ **STUDY WEEK: __Yes __No**
DD MM YY

4. VISIT NUMBER: __ __ __ **IDENTIFIED POST-STUDY: __Yes __No**

5. INVESTIGATIONAL PRODUCT

A. VACCINE PRODUCTS (List ALL immunization date - DD MM YY

1. __ ____ __ __ __ 3. __ ____ __ __ __ 5. __ ____ __ __ __ 7. __ ____ __ __ __

2. __ ____ __ __ __ 4. __ ____ __ __ __ 6. __ ____ __ __ __ 8. __ ____ __ __

B. NON-VACCINE PRODUCTS

Start Date: __ ____ __ __ __ **Date Last Administered or Tx End Date:** __ ____ __ __ __
DD MM YY DD MM YY

Dose, route, schedule at SAE onset: _____

6. MANAGEMENT OF STUDY TREATMENT (Check One Response)

__Continued __Temporarily held __Off Investigational Product at SAE onset or
__Reduced dose or schedule __Permanent discontinued treatment course completed

_____

7. EVENT SUMMARY

Include clinical of event, associated signs and symptoms, alternative etiologies being considered, medical management, test results, and relevant past medical history below, or attach summary.

_____
_____
_____
_____
_____
_____

_____
_____
_____
_____
_____
_____

8. CONCOMITANT MEDICATIONS

List ALL non-study Concomitant Medications being taken one month prior to SAE onset below, or attach a copy of the medication profile.

1. _____ 3. _____ 5. _____

2. _____ 4. _____ 6. _____

9. RELEVANT LABORATORY TESTS

Complete the table below, or send copies of data forms or other lab slips with equivalent information.

Lab Test	Abnormal Result	Site Normal Range	Collection Date (DD/ MM / YY)	Lab Value Previous or subsequent to this event	Collection Date (DD/ MM / YY)

Relationship of SAE to Investigational Product: (Check <u>One</u> Response)

___Definitely ____Probably ____Possibly ____Not Related

10. PHYSICIAN DETAILS

Physician Signature: _____ Date: _ _ _ _\ _ _

Signature indicates review and approval of data provided

Physician Name Printed: _____

INSTRUCTIONS FOR COMPLETING THE SERIOUS ADVERSE EVENT (SAE) FORM HEADER INFORMATION

Shaded Box:	Do Not Write in this Box. This is for PMRA Office use only.
Site Report Date:	Enter the date the SAE Form was completed by the site.
Site Awareness Date:	Enter the date the site first became aware OR was first notified of the SAE.
Event Previously Reported:	Check the appropriate response that indicates whether or not this event has been previously reported on an SAE form
Clinical Site:	Print the name of the clinical trial title reference
Contact details:	Provide the most appropriate contact details should the PMRA Office need to contact the site to obtain additional information including email, tel no.
Completed by:	Print the name and title of the person filling out the SAE Form
Trials Program:	Circle the trials program that your clinical site is affiliated with
Protocol Number:	Enter the oral protocol number that this volunteer is currently enrolled in
Volunteer ID Number:	Enter the volunteer ID Number used in the trial to identify the trial volunteer
Age:	Enter the age of the volunteer and circle the appropriate units
Sex:	Check the appropriate sex of the volunteer.

ITEM 1
Check one (1) primary reason this SAE is being reported

ITEM 2
Reportable SAE: Enter a key word, laboratory parameter, diagnosis or cause of death on the line provided.
Toxicity Grade: Enter a toxicity grade (1-5) to indicate the severity of the event being reported.

ITEM 3
SAE Onset Date: Enter the date when the SAE first occurred at this toxicity grade level. (For SAEs which are lab abnormalities, use the specimen collection date).
Study Week: Enter the week of study (counting from enrollment) during which the event occurred.

ITEM 4
Visit Number: Enter the visit number when the SAE was first assessed.
If Unscheduled Visit: Record the two-digit Visit Code for the most recent scheduled visit.
Note: Use this code even when that scheduled visit was not completed. Use the guide below to complete the third box (after the decimal point). **Num Visit Type**
1. First Unscheduled Visit after the most recent scheduled visit.
2. Second Unscheduled Visit after the most recent scheduled visit.
Identified Post-Study: If this serious Adverse Event has been identified by the site in the Post-Study period, then Study Week and Visit **Number** do not need to be completed.

ITEM 5

A. **Vaccine Products**: Sequentially list the dates of all immunizations received by the volunteer. For protocols where a "dose" of vaccine product consists of sequential immunizations, include the schedule of administration in item #7 or in an attached summary.

B. **Non-Vaccine Products**:
Start Date: Enter the Initial Date that the volunteer began taking the Investigational Product.
Date Last Administered: Enter the Last Date that the volunteer received the Investigational Product. If the volunteer is being continued on the Investigational Product, this date field should be left blank.
Dose, route schedule at SAE onset: Enter the dose, route and schedule that was administered at the time of the SAE onset.

ITEM 6
Check the appropriate response that represents the management of the study treatment as a result of the SAE.

ITEM 7
Summarize the event in the space provided, or attach a narrative summary. Include all relevant information and details surrounding the event.

ITEM 8
List the concomitant medications taken one month prior to/at SAE onset which may have contributed to the event or attach a copy of the medication profile.

ITEM 9
If the SAE being reported is a lab Abnormality, complete the Table provided OR attach copies of Laboratory Reports. Remove personal identifiers from copies of medical record documents, and include only the volunteer ID number. If the SAE being reported is a Clinical Event, enter the laboratory information which is relevant to the diagnosis or clinical event.

ITEM 10
Signature of an Investigator or Sub-Investigator Physician listed on the clinical trial protocol approved by PMRA, who has reviewed and verified the data on the SAE Form for accuracy and completeness and has assessed the relationship of the SAE to study treatment.