PHARMACY, MEDICINES & POISONS BOARD

SERIOUS ADVERSE EVENT FORM

PMPB Office Use Only

PMPB Office Phone: 265-1755166/165
PMPB Office Fax: 265-1755204

Record Number  Protocol Ref Number

Received Date Stamp  Report Received by:_______________Mail____________Fax

Type of Report:___ Initial___ Update

Site Report Date:__ DD__ MM__ YY__  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/Incacity  -- Grade 3 or 4 event  -- Other____________

Serious adverse events - Report Form
2. REPORTABLE SAE (Use Key Word, Diagnosis, Cause of Death, Lab Parameter)

TOXICITY GRADE (1-5)  

3. SAE ONSET DATE: __ DD-MM-YY __ STUDY WEEK: __ Yes __ No

4. VISIT NUMBER: __ __ __ IDENTIFIED POST-STUDY: __ Yes __ No

5. INVESTIGATIONAL PRODUCT

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

1. __ DD-MM-YY __ 3. __ DD-MM-YY __ 5. __ DD-MM-YY __ 7. __ DD-MM-YY __


B. NON-VACCINE PRODUCTS

Start Date: __ DD-MM-YY __ Date Last Administered or Tx End Date: __ 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.

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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. _____________________  
   2. _____________________  
   3. _____________________  
   4. _____________________  
   5. _____________________  
   6. _____________________

9. **RELEVANT LABORATORY TESTS**

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

<table>
<thead>
<tr>
<th>Lab Test</th>
<th>Abnormal Result</th>
<th>Site Normal Range</th>
<th>Collection Date (DD/MM/YY)</th>
<th>Lab Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous or subsequent to this event</td>
<td>Collection Date (DD/MM/YY)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   Relationship of SAE to Investigational Product: (Check One Response)

   ___ Definitely  ___ Probably  ___ Possibly  ___ Not Related

   Physician Signature: ____________________________________________  Date: ___ ___ \___ ___ \___ ___

   Signature indicates review and approval of data provided

   Physician Name Printed: _________________________________________

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

Shaded Box: Do Not Write in this Box. This is for PMPB Office use only.

Site Report Date: Enter the date the SAE Form was completed by the site.

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 Site Awareness Date been previously reported on an SAE form.

Clinical Site: Print the name of the clinical trial title reference

Telephone Number: Provide the most appropriate telephone number should the PMPB Office need to contact the site to obtain additional information

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.

Serious adverse events - Report Form
**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 Subinvestigator Physician listed on the clinical trial protocol approved by PMPB, 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.