
**Form CT 11**

## 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/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 <u>One</u> 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, <u>or</u> 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. _____ 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 One Response)

___Definitely ____Probably ____Possibly ____Not Related

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 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.

**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.