

# Serious Adverse Event (SAE) Report Form

**STUDY NAME**

**Protocol Number:**

**Site Name:**

**Pt ID:**

**Date Participant Reported/Date of Site Awareness:**

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1. SAE Event Term (Diagnosis, ex: Stroke, Myocardial Infarction).
2. SAE onset date: \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_

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1. SAE stop date: \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_

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1. Location of SAE:
2. Was this an unexpected adverse event?  Yes  No
3. Brief description of participant with no personal identifiers:

Sex:   F  M Age:

Diagnosis for study participation:

1. Brief description of the nature of the SAE (attach description if more space is needed):

1. Category of the SAE:

 Date of death \_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_

 (dd/mmm/yyyy)

 Life threatening

 Hospitalization – initial or prolonged

 Disability/incapacity

 Congenital anomaly/birth defect

 Required intervention to prevent permanent impairment

 Other:

1. Intervention type:

 Medication or nutritional supplement (specify):

 Device (specify):

 Surgery (specify):

 Behavioral/lifestyle (specify):

1. Relationship of event to intervention:

 Unrelated (clearly not related to the intervention)

 Possible (may be related to the intervention)

 Definite (clearly related to the intervention)

1. Was study intervention discontinued due to event?  Yes  No
2. What medications or other steps were taken to treat the SAE?

1. List any relevant tests, laboratory data, and history, including preexisting medical conditions.

1. Was this event a study related endpoint?
2. Type of report:

 Initial

 Followup

 Final

Signature of principal investigator: Date: