

Participant ID:		Date of Registration:	
Local ID:		Letters:	
Status:			
Site:			

Mortality Event

* These fields are required in order to SAVE the form	
* These fields are required in order to COMPLETE the form	
Date of Visit: *	<input type="text"/> <input type="text" value="▼"/> <input type="text"/> Date
Interviewer User ID: *	<input type="text"/>

Complete this form if a participant dies during the study, regardless of whether the death was related to the study medication.

Additional form(s) that need to be completed:

- Adverse Event Report Form

Documentation that needs to be obtained:

- Death Certificate (when available)

- Autopsy report (when available)

A. REPORT INFORMATION

1. Date of Death: *

2. Type of Report: * Initial Follow Up

B. GENERAL EVENT CLASSIFICATION

1. Where did the death occur?

- Hospital Long-term care institution
 Home Unknown
 School/Work Other

If OTHER, specify:

2. The death was:

- Sudden, explained Following illness
 Sudden, unexplained Unknown

3. At the time of onset of the terminal event, the participant was

- Asleep Engaged in moderate physical activity
 Awake, but sedentary Engaged in heavy physical activity
 Engaged in light physical activity Unknown

4. Was the participant receiving study medications at the time of the death event? Yes No

5. Was the participant receiving study infusion at the time of death event? Yes No

6. Will an autopsy report be available? Yes No

7. Has a death certificate been obtained Yes No

If NO,

a. Has one been requested? * Yes No

8. Record the sources of information that were used to complete this form:

a. Death Certificate? Yes No

b. Autopsy Report? Yes No

c. Hospital report on fatal illness? Yes No

d. Interview of attending physician? Yes No

e. Interview of family member? Yes No

f. Other? Yes No

If OTHER, specify:

C. SPECIFIC EVENT INFORMATION

1. Describe the immediate cause of death

2. Describe the underlying cause of death

3. Describe any contributory causes of death

4. Specify which of the immediate, underlying and/or contributory causes of death were present at randomization