

Site Number:  
Date of Visit:  
Person Completing Form:

Participant ID:  
Participant Letters:

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 report:

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
DAY MONTH YEAR

2. Date of death:

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
DAY MONTH YEAR

3. Type of report:

Initial  Follow-up

**B. GENERAL EVENT CLASSIFICATION**

1. Where did the death occur? (*check one*)

Hospital  
 Home  
 School/Work

Long-term care institution  
 Unknown  
 Other

If OTHER,

1) Specify: \_\_\_\_\_

2. The death was (*check one*):

Sudden, explained  
 Sudden, unexplained

Following illness

3. Was the participant receiving study medication at the time of the death event?

Yes  No  Unknown

4. Will an autopsy report be available?

Yes  No  Unknown

5. Has a death certificate been obtained?

Yes  No  Unknown

If NO,

a. Has one been requested?

Yes  No  Unknown

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

a. Death certificate?

Yes  No

d. Interview of attending physician?

Yes  No

b. Autopsy report?

Yes  No

e. Interview of family member?

Yes  No

c. Hospital report on fatal illness?

Yes  No

f. Other?

Yes  No

If OTHER,

1) Specify: \_\_\_\_\_

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**C. SPECIFIC EVENT INFORMATION**

1. Describe the immediate cause of death:

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2. Describe the underlying cause of death:

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3. Describe any contributory causes of death:

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

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DR