

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)*

- | | |
|-----------------------------------|--|
| <input type="radio"/> Hospital | <input type="radio"/> Long-term care institution |
| <input type="radio"/> Home | <input type="radio"/> Unknown |
| <input type="radio"/> School/Work | <input type="radio"/> Other |

If OTHER,

1) Specify: _____

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

- | | |
|---|---|
| <input type="radio"/> Sudden, explained | <input type="radio"/> Following illness |
| <input type="radio"/> Sudden, unexplained | |

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? | <input type="radio"/> Yes <input type="radio"/> No | d. Interview of attending physician? | <input type="radio"/> Yes <input type="radio"/> No |
| b. Autopsy report? | <input type="radio"/> Yes <input type="radio"/> No | e. Interview of family member? | <input type="radio"/> Yes <input type="radio"/> No |
| c. Hospital report on fatal illness? | <input type="radio"/> Yes <input type="radio"/> No | f. Other? | <input type="radio"/> Yes <input type="radio"/> No |

If OTHER,

1) Specify: _____

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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:
