

Site Number: _____ Screening ID: _____ - ____ First 3 Letters of First Name: _____

Complete this form if a participant dies during the study, regardless of whether the death was related to the study medication. This form should be sent to the Coordinating Center within 24 hours of notification of the death. Once a death certificate has been obtained, a copy MUST be sent to the Coordinating Center.

Additional form(s) that need to be completed:

- Adverse Event Report Form (MMF07)

Documentation that needs to be obtained:

- Death Certificate (*when available*)
- Autopsy report (*when available*)

A. REPORT INFORMATION

1. Date of report:

____ / ____ / _____
MM DD YYYY

2. Date of death:

____ / ____ / _____
MM DD YYYY

3. Type of report:

₁ Initial ₂ Follow-up

B. GENERAL EVENT CLASSIFICATION

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

- ₁ Hospital
- ₂ Home
- ₃ School/Work

- ₄ Long-term care institution
- ₅ Unknown
- ₉ Other

IF OTHER,

a. Specify: _____

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

- ₁ Sudden, explained
- ₂ Sudden, unexplained

- ₃ Following illness

3. At the time of onset of the terminal event, the participant was (*check one*):

- ₁ Asleep
- ₂ Awake, but sedentary
- ₃ Engaged in light physical activity

- ₄ Engaged in moderate physical activity
- ₅ Engaged in heavy physical activity
- ₉ Unknown

4. Was the participant on study medication at the time of the death event?

Y N

5. Has an autopsy been performed at this point?

Y N

IF YES,

a. Is the autopsy report available?

Y N

6. Has a death certificate been obtained?

Y N

IF NO,

a. Has one been requested?

Y N

7. Indicate the sources of information that were used to complete this form:

- a. Death certificate? Y N
- b. Autopsy report? Y N
- c. Hospital report on fatal illness? Y N

- d. Interview of attending physician? Y N
- e. Interview of family member? Y N
- f. Other? Y N

IF OTHER,

1. Specify: _____

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

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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:

Initials (first, middle, last) of person completing this form: _____
F M L

Date form completed: _____ / _____ / _____
MM DD YYYY

Signature of Principal Investigator: _____
Signature Date

On all questions write “?” if the desired information is currently unavailable, but is being checked and will be known in future updates. Write “” if the desired information is permanently unavailable (i.e. will not be known in any future updates).*