Site Number: Participant ID:
Date of Visit: Participant Letters:
Person Completing Form:

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:	Documentation that needs to be obtained:
- Adverse Event Report Form	- 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	○	Long-term care institution
○	Home	○	Unknown
○	School/Work	○	Other

If OTHER,
1) Specify: _____

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

○	Sudden, explained	○	Following illness
○	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?	○ 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:

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: