

INSTRUCTIONS: This form should be completed if a subject will not be completing any remaining study visits. It should be entered into the ADEPT system in the BASELINE event.

Section A: KEY IDENTIFYING INFORMATION

A1. Study Identification Number _____ - _____ - _____ - _____ - _____

A2. Last visit at which subject completed any study measures

ENTER THIS FORM INTO THE BASELINE EVENT

BASELINE 0

STUDY VISIT 1 (Month 6) 1

STUDY VISIT 2 (Month 12) 2

STUDY VISIT 3 (Month 24) 3

STUDY VISIT 4 (Month 36) 4

DOSE ADJUSTMENT 5

a. Date subject last seen for trial

____ / ____ / ____
M M D D Y Y Y Y

A3. Date of form completion

____ / ____ / ____
M M D D Y Y Y Y

A4. Name of person completing form

PRINT FULL NAME INITIALS

Section B: WITHDRAWAL FROM TRIAL

B1. Date of study withdrawal

____ / ____ / ____
M M D D Y Y Y Y

B2. Date last dose of study drug taken

____ / ____ / ____
M M D D Y Y Y Y

***If randomized subject withdrew before starting drug, enter special value '01/01/0101' and skip to B4.**
**** If consented, eligible for randomization subject (according to Form A105) withdrew before starting drug, enter special value '03/03/0303' and skip to B4.**

B3. Last dose of study drug taken

____ . ____ mg

B4. Primary indication for withdrawal from trial [circle first applicable reason]

- SUBJECT OR FAMILY WITHDREW FROM TRIAL 1 (B4b)
- SUBJECT HAD AN AORTIC DISSECTION 2 (B4c)
- SUBJECT REQUIRED AORTIC ROOT SURGERY 3 (B4d)
- SUBJECT DEATH..... 4 (B4e)
- PHYSICIAN WITHDREW SUBJECT FOR OTHER REASON 5 (B5)
- SUBJECT LOST TO FOLLOW-UP 6 (B5)
- OTHER 99

a. Specify OTHER _____

_____ (B5)

b. Primary reason family (subject) is withdrawing from trial

- TAKING TOO MUCH TIME 1 (B5)
- TRAVEL DISTANCE TO/FROM CENTER 2 (B5)
- BECAUSE INSURANCE IS NOT COVERING ECHOCARDIOGRAMS.... 3 (B5)
- INTOLERANCE TO STUDY DRUG 4 (B5)
- OTHER 99

i. Specify other reason _____ (B5)

c. Date of aortic dissection

____ / ____ / ____

M M D D Y Y Y Y

i. Did subject survive dissection? YES..... 1 NO..... 2 (B4e)

d. Date of aortic root surgery*

____ / ____ / ____

M M D D Y Y Y Y

**If subject did not require aortic root surgery for the dissection listed in B4c, enter special value '01/01/0101' and skip to B5.*

i. Did subject survive surgery? YES..... 1 (B5) NO..... 2

- | | | |
|---------------------------|-------------------|----|
| e. Primary cause of death | CARDIAC | 1 |
| | NON-CARDIAC | 2 |
| | UNKNOWN | -8 |

1. Cause of death (CTCAE Code) _____

2. Specify cause of death using short name from CTCAE Code List

3. Source of vital status
- | | |
|---------------------------|--------|
| RELATIVE OF SUBJECT | 1 (B5) |
| MD/HOSPITAL RECORDS..... | 2 (B5) |
| SSDI | 3 (B5) |
| OTHER..... | 99 |

- i. Specify source:

B5. Comments

Section Z: TIME TO COMPLETE FORM AND SIGNATURE

- Z1. How long did it take to complete this form? _____ minutes

Signature of PI: _____ Date: _____

END OF FORM