

Adverse Event, Study Exit and Death

Center Code: _____

Patient ID: _____

Subject Initials Name/Surname: ____/____

Study Exit

Date of reporting: __/__/____

- Reasons for study exit:
- Death (complete the "Death section")
 - Lost to Follow up (minimum of 3 attempts to contact the subject)
 - Withdrawal for subject request, specify the reason: _____
 - Other, specify: _____

Notes/Additional information on study exit: _____

Adverse Event

Date of reporting: __/__/____

Describe the Adverse Event: _____

Management of the Event: _____

Death

Date of Death: __/__/____

Indicate the primary cause of death: _____

- Was death cardiac-related?
- NO
 - YES, sudden
 - YES, non sudden
 - YES, unknown
 - Unknown

Notes/additional information on Death: _____
