

VA COOPERATIVE STUDY #578

Participant ID: _____ - _____

SOURCE DOCUMENT WORKSHEET
FORM 21: ENDPOINT_SAE FOLLOW-UP

Once completed, this data should be entered into eDC and this document should be filed in the Participant's Study Binder.

1. Date of Follow-up Report: ____/____/____ **AESFUDAT**

2. Do you have a dialysis discontinuation/stop date now which was not included on the initial report?
AESFURRTEND **Blank: -1**
 Yes (Answer Q3-Q4) **1**
 No **2**

3. Date dialysis discontinued/stopped: ____/____/____ **AESFURRTENDDat**

4. Was dialysis discontinued/stopped due to recovery of kidney function?
AESFURRTENDREASON **Blank: -1**
 Yes **1**
 No **2**

5. Do you have a hospital discharge date now which was not included on the initial report?
AESFUHOSDICHARGE **Blank: -1**
 Yes (Answer Q6-Q15) **1**
 No (Go to Q16) **2**

6. Discharge date: ____/____/____ **AESFUHOSDISCHARGEDAT**

7. Primary discharge diagnosis as documented in the medical record or discharge summary (Check one) **AESFUHOSPRIM** **Blank: -1**
 Acute coronary syndrome **1**
 ST elevation myocardial infarction (STEMI) **2**
 Non-ST elevation myocardial infarction (NSTEMI) **3**
 Unstable angina **4**
 Heart failure **5**
 Cerebrovascular accident (stroke) **6**
 Other primary discharge diagnosis **7**
(8. Specify: _____ **AESFUHOSPRIMoth** _____)

- Secondary discharge diagnosis as documented in the medical record or discharge summary (Check all the apply) **Yes: 1** **No: 2** **Blank: -1**
 9. Acute coronary syndrome **AESFUHOSSECCACS**
 10. ST elevation myocardial infarction (STEMI) **AESFUHOSSECSTEMI**
 11. Non-ST elevation myocardial infarction (NSTEMI) **AESFUHOSSECNSTEMI**

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- 12. Unstable angina **AESFUHOSSECUA**
- 13. Heart failure **AESFUHOSSECHF**
- 14. Cerebrovascular accident (stroke) **AESFUHOSSECCVA**
- 15. None of the above **AESFUHOSSECCNone**

16. Follow-up Outcome **AESFUOUT** **Blank: -1**

- Fatal (**Answer Q17-Q18**) **1**
- Ongoing (Recovering/Resolving - The subject has a good prognosis and is in the process of recovering or the problem is being resolved) (Submit follow-up information until resolved.) **2**
- Recovered/ Resolved (**Answer Q17-Q18**) **3**
- Recovered/Resolved with Sequelae (no change expected) (**Answer Q17-Q18**) **4**
- Not recovered/not resolved (The subject has not recovered yet and the prognosis is unsure or the problem has not been resolved and the resolution is unclear) **5**
- Unknown **6**

17. Date resolved: ____/____/____ **AESFUENDAT**

18. Check if this date is an estimate **AESFUENDATEST** **Yes: 1** **No: 2** **Blank: -1**

19. Note any additional new information to report on this event: **AESFUDESC**

20. Date Form Completed: **F21Complete**

Site Investigator or Co-Investigator Signature: _____