VA COOPERATIVE STUDY #578

Participant ID:__ __ __ - __ __ __ __

SOURCE DOCUMENT WORKSHEET FOR FORM 16: 5 DAYS POST PROCEDURE

To be completed by study personnel via medical record review along with an interview with hospitalized participants and via telephone interview with non-hospitalized participants. Once completed, this data should be entered into eDC and this form should be filed in the Participant's Study Binder.

1. Date the participant was discharged from hospital following their index admission which included their angiography and administration of study treatments: **ProcDischargeDate**

   __ __/__ __/__ __ __ __

2. Was the participant's 96 hour post procedure blood sample to be sent to the Central Lab for renal function assessment collected? **Blood96hr** **Blank: -1**

   ☐ Yes **1**

   ☐ Not yet, but collection is scheduled **2**

   ☐ No (Complete a Protocol Deviation form if needed) **3**

Beginning on the day of the participant's angiography, note the date and number of study drug capsules taken and whether the source of the information was the medical record or participant self report

3.1 Date study drug capsules taken **NacDat**	**3.2 Number of study drug capsules taken*** **NacNumber**	**3.3 Information source (participant self report or medical record?)** **NacSource**
Day One (Angiography) __ __/__ __/__ __ __ __		
Day Two __ __/__ __/__ __ __ __		
Day Three __ __/__ __/__ __ __ __		
Day Four __ __/__ __/__ __ __ __		
Day Five __ __/__ __/__ __ __ __		

* 100% compliance=8 capsules a day for 5 days for a total of 40 capsules

4. Was the 5 day post procedure participant interview completed? **Interview5Day** **Blank: -1**

   ☐ Yes **1**

   ☐ No **(Skip remaining questions and note the date the form was completed. If the reason was due to death or another SAE type, complete an Endpoint_SAE form. Complete a Protocol**

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Deviation Form if needed.) **2**

5. Date of participant interview: __ __/__ __/__ __ __ __ **Day5InterviewDat**

6. Were you able to take all of your study drug capsules as directed? **NACComp** **Blank: -1**
   - ☐ Yes **1**
   - ☐ No (If no, answer Q7) **2**

7. Why didn't you take all of your study drug capsules as directed? **NACNonCompReason** **Blank: -1**
   - ☐ Experienced an AE or SAE (Complete an AE or Endpoint/SAE Form) **1**
   - ☐ Forgot **2**
   - ☐ Study drug was lost **3**
   - ☐ No particular reason **4**
   - ☐ Other reason **5** (8. Specify: ___**NACNonCompReasonOth**____)

9. As you know, when you were enrolled in this study you were given either N-acetylcysteine (NAC) or placebo capsules. What type of capsule (NAC or placebo) do you think you were given? **NACGuess** **Blank: -1**
   - ☐ NAC **1**
   - ☐ Placebo **2**
   - ☐ I don't know **3**

10. You were also given either IV saline or IV sodium bicarbonate before, during and after your angiography procedure. What type of IV fluid (saline or sodium bicarbonate) do you think you were given?
    IVGuess **Blank: -1**
    - ☐ Saline **1**
    - ☐ Sodium bicarbonate **2**
    - ☐ I don't know **3**

11. Did you experience any change in or worsening of your medical condition that required you to seek medical care while taking the study drug capsules? **DaySAE** **Blank: -1**
    - ☐ Yes **(If yes, complete AE or Endpoint_SAE Form as needed)** **1**
    - ☐ No **2**

12. Since the angiography procedure you had at the start of this study, have you been admitted to a hospital?
    Day5Hosp **Blank: -1**

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☐ Yes **(If yes, complete Endpoint_SAE Form)** **1**

☐ No **2**

13. Since the angiography procedure you had at the start of this study, have you needed to receive dialysis?

Day5Dialysis **Blank: -1**

☐ Yes **(If yes, complete an Endpoint_SAE Form)** **1**

☐ No **2**

14. Date Form Completed: ___**F16Complete**_____

Signature of person completing the form: _____