Annotated form 5704244961

VA WEST HAVEN CSP530
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)
FORM 16 - SERIOUS ADVERSE EVENT

Date

SAENo

Hospital | PatID | PatInits | Date of Serious Adverse Event Onset (mm/dd/yy) | SAE No. this date

NOTES:
1. Only complete this form for SAEs occurring within 30 days of randomization.
2. Complete this form if a death occurred or if the event was both serious and thought to be related to the study therapy.
3. PLEASE NOTIFY THE WEST HAVEN CSPCC BY TELEPHONE AND BY FAXING THEM A COPY OF THIS FORM WITHIN 72 HOURS OF BECOMING AWARE OF THIS SAE.
4. You must also notify your IRB of SAEs in accordance with local IRB policy.

1. Type of SAE report (check one) SAEType ☐ Initial ☐ Follow-up ☐ Final
2. SAE Criteria (check all that apply)
   a. ☐ Death [Fill out Form 13 (Study Exit) and complete remainder of this form] Death
   b. ☐ Life-threatening LifeThreat
   c. ☐ Disability/Incapacity Disability
   d. ☐ Prolonged existing hospitalization Hospitalization
   e. ☐ Other event felt to be serious by the investigator (Specify) OtherCriteria

SAECriteriaDesc1

SAECriteriaDesc2

3. Was the Serious Adverse Event (check one) ☐ Expected* ☐ Unexpected* SAEExpected
   *See Ops Manual for definitions.

4. Serious Adverse Event (use diagnosis, keyword, or lab parameter) SAEDiagnosisDesc

5. Description (describe event, using symptoms, signs, and time course)

SAEDesc1

SAEDesc2

SAEDesc3

SAEDesc4

6. Serious Adverse Event Code* SAECode

*USE SERIOUS EVENT CODE LIST PROVIDED IN OPERATIONS MANUAL.
If the description of the event does not match any of the SAE codes, fill in 999.

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7. Action taken with respect to Renal Replacement Therapy (check one) RRTAction

☐ Patient was not on RRT at time of the event
☐ Not interrupted
☐ Treatment discontinued
☐ Study therapy permanently discontinued*
☐ Temporarily interrupted
☐ Other, specify:

RRTActionDesc

*NOTE: IF STUDY THERAPY PERMANENTLY DISCONTINUED, COMPLETE FORM 10.

8. Relationship of the Serious Adverse Event to the Study Intervention*

a. If event was death (check one): SAEDeathRelate
☐ Definitely related ☐ Possibly/Probably related ☐ Not related

b. For all non-death events (check one): SAENonDeathRelate
☐ Definitely related ☐ Possibly/Probably related

*See Ops Manual for definitions of relatedness

9. Final Outcome (Check one item only to indicate the worst outcome) FinalOutcome

a. ☐ SAE still present at time of report*

b. ☐ Chronic condition or sequelae resulted from SAE

c. ☐ Death [Complete Form 13 (Study Exit Form)]

d. ☐ SAE resolved-No sequelae

i. Date SAE resolved/no longer SAE ---------- FinalDate (mm/dd/yy)

*NOTE: If this is the initial report and the SAE is still present at the time of this report, be sure to send a follow-up or final Form 16 for the event with information current through when the SAE is resolved, death, hospital discharge, or 30 days post-randomization, whichever comes first.

FormDate
Signature of person completing form — Date of Form Completion (mm/dd/yy)

PISignDate
PI Signature — Date PI Signed (mm/dd/yy)

StaffInits Staff Initials