Participant ID:__ __ __ - __ __ __ __

SOURCE DOCUMENT WORKSHEET
FORM 20: ENDPOINT_SAE FORM

The study endpoints reported on this form include any of the following events occurring within 90 days of study enrollment:

- **Death**
- **Initiation of dialysis (any form of renal replacement therapy)**
- **Hospitalization**

All other Serious Adverse Events occurring within 90 days of study enrollment are also reported on this form.

1. Date Site Investigator became aware of the event: __ __/ __ __ / __ __ __ __ **AESDATSI**
2. Onset date: __ __/ __ __ / __ __ __ __ **AESSTDAT**
3. Event being reported: **AESDESCLIST**
   (Provide a diagnosis. Do not write hospitalization or death. You must note the relevant diagnosis responsible for the hospitalization or death. If more than one event occurred, report each on a separate form, unless part of a related syndrome.)

   _____

4. Did the event result in **death**? **AESDTH** **Blank: -1**
   - ☐ Yes (Answer Q5-Q6) **1**
   - ☐ No **2**

   5. Date of death: __ __/ __ __ / __ __ __ __ **AESDTHDAT**

   6. Check if this date is an estimate ☐ **AESDTHDATEST** **Yes: 1** **No: 2** **Blank: -1**

7. Did the event result in the **initiation of dialysis (any form of renal replacement therapy)**? **AESRRT** **Blank: -1**
   - ☐ Yes (Answer Q8-Q9) **1**
   - ☐ No **2**

   8. Date dialysis initiated: __ __/__ __/__ __ __ __ **AESRRTSTART**

   9. Is dialysis ongoing? **AESRRTONGOING** **Blank: -1**
      - ☐ Yes (Note discontinuation/stop date on follow-up form once known.) **1**
      - ☐ No (Answer Q10-Q11) **2**

      10. Date dialysis discontinued/stopped: __ __/__ __/__ __ __ __ **AESRRTENDDat**

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

Participant ID:__ __ __ - __ __ __ __

12. Did the event result in an **inpatient hospitalization** or prolongation of hospitalization?
AESHOSP **Blank: -1**
- ☐ Inpatient hospitalization 1
  (13. Date admitted: __ __/__ __/__ __ __ __) **AESHOSADMINDAT**
- ☐ Prolongation of existing hospitalization **2**
- ☐ No, participant not hospitalized (If no, go to Q25) **3**

14. Is the participant still in the hospital? **STILLHOSPITALIZED** **Blank: -1**
- ☐ Yes (Note discharge date and diagnoses on follow-up form once known.) **1**
- ☐ No **(If no, answer Q15-Q24)** **2**

. 15. Discharge date: __ __/__ __/__ __ __ __ **AESHOSDISCHARGEDAT**
Blank: -1

16. Primary discharge diagnosis as documented in the medical record or discharge summary **AESHOSPRIM** **Blank: -1**
(Check one)
- ☐ 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**
  (17. Specify: ____**AESHOSPRIMOth**___)

Secondary discharge diagnosis as documented in the medical record or discharge summary (Check all the apply) **Yes: 1** **No: 2** **Blank: -1**
- ☐ 18. Acute coronary syndrome **AESHOSSECACS**
- ☐ 19. ST elevation myocardial infarction (STEMI) **AESHOSSECSTEMI**
- ☐ 20. Non-ST elevation myocardial infarction (NSTEMI) **AESHOSSECNSTEMI**
- ☐ 21. Unstable angina **AESHOSSECUA**
- ☐ 22. Heart failure **AESHOSSECHF**
- ☐ 23. Cerebrovascular accident (stroke) **AESHOSSECCVA**
- ☐ 24. None of the above **AESHOSSECNone**

Did the event meet any of the following criteria: **Yes: 1** **No: 2** **Blank: -1**
- ☐ 25. Resulted in a life threatening experience **AESLIFE**
- ☐ 26. Resulted in a persistent or significant disability or incapacity **AESDISAB**
- ☐ 27. Resulted in a congenital anomaly/birth defect **AESCONG**
- ☐ 28. Required medical or surgical treatment to prevent death, hospitalization, or one of the above results (based on medical judgment) **AESMIE**

Participant ID:__ __ __ - __ __ __ __

29. Is this event reasonably **related to the study IV fluid**? **AESIVREL** **Blank: -1**
- □ Yes, related (If yes, answer Q30) **1**
- □ Possibly related (If possibly, answer Q30) **2**
- □ Not related (If not, go to Q31) **3**

30. What action was taken with the study IV fluid following the event? **AESACNIV** **Blank: -1**
- □ No Action Taken **1**
- □ Unknown **2**
- □ Dose Reduced **3**
- □ Temporarily Interrupted **4**
- □ Permanently Discontinued **5**

31. Is this event reasonably **related to the study drug capsules**? **AESNACREL** **Blank: -1**
- □ Yes, related (If yes, answer Q32) **1**
- □ Possibly related (If possibly, answer Q32) **2**
- □ Not related (If not, go to Q33) **3**

32. What action was taken with the study drug capsules following the event? **AESACNNAC** **Blank: -1**
- □ No Action Taken **1**
- □ Unknown **2**
- □ Dose Reduced **3**
- □ Temporarily Interrupted **4**
- □ Permanently Discontinued **5**

33. In your opinion, is this event **unexpected** in terms of nature, severity or frequency of occurrence as documented in the protocol, informed consent form, or drug information report (DIR) or unexpected in terms of the participant's underlying disease and treatment? **AESEXP** **Blank: -1**
- □ Yes *[Note: The final determination for expectedness will be made by the Sponsor.]* **1**
- □ No **2**

34. Describe **any other relevant information** related to the event such as treatment, participant medical history, lab results, pertinent concomitant medications, etc. **AESDESC**

_____

_____

35. Event Outcome (Check one) **AESOUT** **Blank: -1**
- □ Fatal **(Answer Q36-Q37)** **1**
- □ Ongoing (Recovering/Resolving - The participant 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 Q36-Q37)** **3**
- □ Recovered/Resolved with Sequelae (no change expected) **(Answer Q36-Q37)** **4**
- □ Not recovered/not resolved (The participant has not recovered yet and the prognosis is unsure or the problem has not been resolved and the resolution is unclear) **5**

Participant ID:__ __ __ - __ __ __ __
Visit Date: _____

□ Unknown **6**

36. Date resolved: __ __/ __ __ / __ __ __ __ **AESENDAT**

37. Check if this date is an estimate ☐ **AESENDATEST**
Yes: 1 No: 2 Blank: -1

38. Date Form Completed: ____**F20Complete**_____

Signature of Site Investigator or Co-Investigator: _____