Participant ID:__ __ __ - __ __ __ __

SOURCE DOCUMENT WORKSHEET
FORM 19: ADVERSE EVENT (AE)

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

Serious Adverse Events (SAEs) Definition includes any of the following:
- Results in death
- Is life threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly/birth defect
- Is an important medical event that requires medical, surgical, behavioral, social or other intervention to prevent one of the outcomes above.

1. Is this AE considered serious? AESER Blank: -1
   - ☐ Yes **1** **Complete an Endpoint_SAE Form. Do not enter any additional data on this form.**
   - ☐ No **2**

2. Date site became aware of AE: __ __/__ __/__ __ __ __ **AERPTDAT**

3. AE onset date: __ __/ __ __ / __ __ __ __ **AESTDAT**

   4. Is this date an estimate? **AELNKSTDATEST**
      - ☐ Yes **1** **Blank: -1**
      - ☐ No **2**

5. Is the AE onset date [noted in Q3] more than 35 days after the participant's index angiography procedure at which they received study IV fluids [noted on Form 11, Q2]? **MoreThan35** **Blank: -1**
   - ☐ Yes **1** **If yes, form is complete. AE collection only required if onset date is within 35 days of the participant's index angiography procedure, unless the AE meets the SAE definition.**
   - ☐ No **2**

6. Is this AE reasonably related to either the study IV fluid or the study drug capsule? **Related** **Blank: -1**
   - ☐ Yes **1**
   - ☐ No **2** **If no, form is complete. Only related AEs are being collected, unless the AE meets the SAE definition.**

7. AE being reported (*If more than one event has occurred, report each on a separate form, unless they represent a group of symptoms due to a single event, such as nausea, vomiting and diarrhea or wheezing and shortness of breath*.) **AETERM**

   - ☐ Bad taste in mouth **1**
   - ☐ Diarrhea **2**
   - ☐ Dizziness **3**
   - ☐ Edema **4**
   - ☐ Fever **5**
   - ☐ Flushing **6**
   - ☐ Nausea **7**
   - ☐ Pharyngitis **8**
   - ☐ Pruritus (itchiness) **9**
   - ☐ Rash **10**
   - ☐ Rhinorrhea **11**
   - ☐ Rhonchi (wheezing) **12**
   - ☐ Shortness of breath **13**
   - ☐ Tachycardia (rapid heartbeat) **14**
   - ☐ Throat tightness **15**
   - ☐ Urticaria (hives) **16**
   - ☐ Vomiting **17**
   - ☐ Other (specify in Q8) **18**

8. Provide a brief description of the AE being reported including pertinent medical history, laboratory results and concomitant medications: **AECOMMENT**

Participant ID:__ __ __ - __ __ __ __

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9. What is the severity of this AE? **AESEV** **Blank: -1**
   - ☐ Mild (awareness of the event, but easily tolerated) **1**
   - ☐ Moderate (enough discomfort to interfere with usual activity) **2**
   - ☐ Severe (incapacitating with inability to do usual work or activity) **3**

10. Is this AE reasonably **related to the study IV fluid**? **AEIVREL** **Blank: -1**
   - ☐ Yes, related (If yes, answer Q11) **1**
   - ☐ Possibly related (If possibly, answer Q11) **2**
   - ☐ Not related (If not, go to Q12) **3**

11. What action was taken with the study IV fluid following the AE? **AEACNIV** **Blank: -1**
   - ☐ No Action Taken **1**
   - ☐ Unknown **2**
   - ☐ Dose Reduced **3**
   - ☐ Temporarily Interrupted **4**
   - ☐ Permanently Discontinued **5**

12. Is this AE reasonably **related to the study drug capsules**? **AENACREL** **Blank: -1**
   - ☐ Yes, related (If yes, answer Q13) **1**
   - ☐ Possibly related (If possibly, answer Q13) **2**
   - ☐ Not related (If not, go to Q14) **3**

13. What action was taken with the study drug capsules following the AE? **AEACNNAC** **Blank: -1**
   - ☐ No Action Taken **1**
   - ☐ Unknown **2**
   - ☐ Dose Reduced **3**
   - ☐ Temporarily Interrupted **4**
   - ☐ Permanently Discontinued **5**

14. AE Outcome (Check one) **AEOUT** **Blank: -1**
   - ☐ Recovering/Resolving (Ongoing - the participant has a good prognosis and is in the process of recovering or the problem is being resolved) **1**
   - ☐ Recovered/ Resolved **(Answer Q15-16)** **2**
   - ☐ Recovered/Resolved with Sequelae (no change expected) **(Answer Q15-16)** **3**
   - ☐ 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) **4**
   - ☐ Unknown **5**

15. Date resolved: __ __/ __ __ / __ __ __ __ **AEENDAT**

16. Is this date an estimate? **AEENDATEST** **Blank: -1**
   - ☐ Yes **1**
   - ☐ No **2**

17. Date Form Completed: __**F19Complete**__

Site Investigator or Co-Investigator Signature: _____