

Frequent Hemodialysis Network SERIOUS ADVERSE REACTION FORM - FORM #308

Instructions: This form is completed for serious adverse events (SAE). The definition of “serious” is that the event results in death, or is life threatening, or requires inpatient hospitalization or prolongation of existing hospitalization, or results in a persistent or significant/incapacity, or results in congenital anomaly/birth defect, or any medical event which requires treatment to prevent one of the medical outcomes listed above.

- For non-serious adverse events, complete Adverse Event Form 307 instead of this form.
- For hospitalizations, complete Forms 302 and 303 in addition to this form.
- In the event of a patient death, complete Forms 305 and 306 in addition to this form.

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1. Participant ID #

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2. Alpha Code

3. a. Date of onset: (dd/mon/yyyy) ___ / ___ / ___

b. Date Clinical Center learned of the SAE..... (dd/mon/yyyy) ___ / ___ / ___

4. SAE Categorization: (Code 0=No, 1=Yes)

a. Did the patient die?

b. Was the event life threatening?

c. Was there a hospitalization?

c.1. Date of hospitalization: (dd/mon/yyyy) ___ / ___ / ___

Be sure to complete and enter Forms 302 and 303.

d. Was there prolongation of existing hospitalization?

e. Did the event result in a persistent or significant incapacity?

f. Did the event result in a congenital anomaly/birth defect?

g. Was this a medical event which required treatment to prevent one of the medical outcomes listed above?

SAE Description: Record diagnoses and/or signs and/or symptoms below. The database will allow as many other conditions and MedDRA code numbers as needed for the SAE report.. Conditions and MedDRA codes you may see include, but are not limited to: hemorrhage (MedDRA code 10019595), device leakage (MedDRA 10012587), infection (MedDRA code 10021789), air embolism (MedDRA code 10001526).

Condition	MedDRA Code
5a.	
5b.	
5c.	

6. Has there been a prior history of similar event?
(0=No, 1=Yes, 9=Unknown)

10. Outcome of event
 0=Recovered without treatment
 1=Recovered with treatment
 2=Event continuing without treatment
 3=Event continuing and controlled with treatment
 4=Event continuing and not controlled with treatment
 5=Participant died (Be sure to complete Form 306.)
 6=Not yet available

11. Date of outcome..... (dd/mon/yyyy) __/__/____

12. Date clinical center became aware of the outcome (dd/mon/yyyy) __/__/____

13. Please write a brief summary of the outcome

200. Date this form completed (dd/mon/yyyy)..... __/__/____

201. Username of person completing/reviewing completeness of this form..... _____

For Clinical Center Use Only:

202. Username of person entering this form: _____

203. Date Entered: (dd/mon/yyyy) __/__/____