



B.

Hospitalization

Increased Hospital Stay

Death

Congenital anomaly/birth defect

Persistent or significant disability/incapacity

Event requiring intervention (surgical or medical) to prevent SAE

Event which poses threat to life

Others

In case of death, state probable cause of death:

C. No permanent/significant functional/cosmetic impairment

Permanent/significant functional/cosmetic impairment

Not Applicable

9. Describe the medical management provided for adverse reaction (if any) to the research participants. (include the information on who paid, how much was paid and to whom)

10. Provide details of compensation provided/ to be provided to participants (include the information on who paid, how much was paid and to whom)

11. Outcome of SAE

Fatal

Continuing

Recovering

Recovered

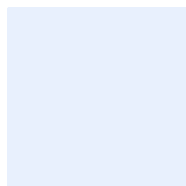
Unknown

others(*specify*)

12. Provide any other relevant information to that can facilitate assessment of the case such as medical history

13. Provide details about PI's final assessment of SAE relatedness to trial.

Signature of PI:



[Click here to enter a date.](#)