

# Adverse event

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Record ID (generated by database)

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## Serious adverse event

Type of report

- Initial  
 Final

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Has there been any unexpected event that:

- Yes  
 No

Caused death Was life threatening May cause  
prolongation of hospitalization May result in  
significant disability/incapacity

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If yes, please specify

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Was the event related to the intervention?

- Unrelated  
 Possibly  
 Probably  
 Definitely

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Serious adverse event onset date

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Action taken as a result of the SAE

- No action taken  
 Study intervention temporarily discontinued  
 Study intervention permanently discontinued

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Treatment of the SAE

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Outcome

- Unknown  
 Unresolved  
 Resolved  
 Resolved with sequelae  
 Death

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Specify sequelae

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Date resolution

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Date death

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Response from PI

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