

Adverse event

Record ID (generated by database)

Serious adverse event

Type of report

- Initial
 Final

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

If yes, please specify

Was the event related to the intervention?

- Unrelated
 Possibly
 Probably
 Definitely

Serious adverse event onset date

Action taken as a result of the SAE

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

Treatment of the SAE

Outcome

- Unknown
 Unresolved
 Resolved
 Resolved with sequelae
 Death

Specify sequelae

Date resolution

Date death
