

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
