swiss clinical trial organisation

swissethics

Schweizerische Ethikkommissionen für die Forschung am Menschen
Commissions d'éthique suisses relative à la recherche sur l'être humain
Commissioni etiche svizzere per la ricerca sull'essere umano
Swiss Ethics Committees on research involving humans

ClinO clinical trials: Serious Adverse Event Report for investigational study drugs

Please complete the form by replacing all text modules in square brackets. Use "x" for check boxes.

In the absence of provisions to the contrary in the protocol, the investigator shall notify the responsible ethics committee of a fatal serious adverse event (SAE) occurring at a trial site in Switzerland within 7 days (ClinO Art. 40 Abs 2). In the case of a multicentre clinical trial, the coordinating investigator shall also report the SAE to the responsible ethics committee concerned within 7 days (ClinO Art. 40 Abs 3).

If, in the course of a clinical trial (ClinO, chapter 4 Other clinical trials) an SAEs occurs in a participant in Switzerland, and it cannot be excluded that the event is attributable to the intervention under investigation, the investigator must report the SAE to the responsible ethics committee within 15 days (ClinO Art. 63 Abs 1). If, in the case of a multicentre clinical trial, an SAE occurs at one of the trial sites, the coordinating investigator shall also report the event to the responsible ethics committee concerned, within 15 days (ClinO Art 63 Abs 4).

In the event that a sponsor takes responsibility for the research project, reporting procedures are adapted accordingly (ClinO Art. 2).

Serious Adverse Event (SAE) information

Participant ID [code]	Year of birth [year]	Sex [ ] F / [ ] M	SAE onset date [day/month/year]	SAE stop date [day/month/year or cont.]	Date of SAE awareness [day/month/year]
Report type [ ] initial [ ] follow up [ ] final					
Narrative: describe the SAE and the connection to project procedures (including relevant test/lab data) [free text]					Check SAE [ ] study participant died [ ] requires inpatient treatment not envisaged in the protocol or extends a current hospital stay [ ] results in permanent or significant incapacity or disability [ ] is life-threatening [ ] causes a congenital anomaly or birth defect

Evaluation of event

Severity (tick one)	Outcome (tick one)
[ ] mild [ ] moderate [ ] severe	[ ] recovered/resolved [ ] continuing [ ] recovered/resolved with sequelae [ ] unknown [ ] study participant died [ ] other [free text]
Was this an unexpected SAE? [ ] yes (if possible/probable relationship, SUSAR reporting rules apply) [ ] no	Did reaction abate after stopping the drug (or lowering the dose)? [ ] yes [ ] no [ ] n/a Did reaction reappear after reintroduction? [ ] yes [ ] no [ ] n/a

Suspected drug(s) information

Suspect drug(s) [free text]	
Route(s) of administration [free text]	Indication(s) for use [free text]
Daily doses(s) [free text]	Therapy dates and duration from: [day/month/year] to: [day/month/year or cont.]

SAE causality

Relationship of event to intervention:

[ ] Not related (clearly not related to the intervention)

[ ] Unlikely (any assessable reaction that does not fulfil the below conditions)

[ ] Possibly (temporal relationship, other cause possible)
(if unexpected SAE, SUSAR reporting rules apply)

[ ] Probably (temporal relationship, improve after dechallenge, no other cause evident)
(if unexpected SAE, SUSAR reporting rules apply)

[ ] Definitely (clearly related to intervention, temporal relationship, improve after dechallenge, recurrence after rechallenge, or other cause of drug cause)
(if unexpected SAE, SUSAR reporting rules apply)

Concomitant drug(s) and history

Concomitant drug(s) and dates of administration (exclude those used to treat event) [free text]
Other relevant history (e.g. diagnostics, allergies, etc.) [free text]

General and reporter information

Title of research project (short title) [short title]	BASEC research project number [year-xxxxx]	EC name (concerned EC) [EC name]	EC name (lead EC, if applicable) [EC name]
Sponsor name and address (if different from investigator) [name and address]	Contact details of the site of SAE occurrence [name and full address] [contact telephone, email address]		

Name and contact information of investigator [name] [contact telephone, email address]	Place, date and signature of investigator