Serious Adverse Event (SAE) Report Form for ClinO Chapter 4. Other clinical trials

Instructions:

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).

The SAE is reported to the responsible ethics committee through the submission portal BASEC. The procedure is given here.

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

Serious Adverse Event (SAE) information

Participant ID [code]	Year of birth [year]	Sex ☐ F / ☐ M ☐ other, please specify:	SAE onset date [day/month/year]	SAE stop date [day/month/year or cont.] ☐ ongoing	Date of SAE awareness [day/month/year]

Report type

☐ Initial (Date: [day/month/year]) / ☐ Follow up (if follow up, follow up number: [ ] Date: [day/month/year]
If it is a follow-up report, only additional information or information that has changed since previous

SAE Main Term/Diagnosis: [free text] Description: Describe the SAE and provide details of assessments used for the diagnosis of SAE and/or any other information of relevance (including relevant tests/lab data, further signs and symptoms, development of the event, action taken to treat SAE, etc.) [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

SAE causality

Relationship of event to intervention:

☐ Not related (clearly not related to the intervention).
If "not related" the SAE does not fulfil the requirements for reporting to the ethics committee.

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

☐ Possibly (temporal relationship, other cause possible)

☐ Probably (temporal relationship, improve after dechallenge, no other cause evident)

☐ Definitely (clearly related to intervention, temporal relationship, improve after dechallenge, recurrence after rechallenge, or other evident cause)

Evaluation of event

Severity (tick one)	Outcome (tick one)
☐ mild	☐ recovered/resolved ☐ recovered/resolved with sequelae
☐ moderate	Specify sequelae: [free text]
☐ severe	☐ continuing ☐ unknown
	☐ study participant died ☐ other [free text]

In case of death:

Cause of death: [free text] Date of death: [day/month/year]

Autopsy performed: ☐ Yes ☐ No

Autopsy report available: ☐ Yes ☐ No

Do not send the autopsy report to the ethics committee, unless the ethics committee has specifically requested it

General and reporter information

Clinical Trial Title [short title]	
EC name (concerned EC) [EC name]	EC name (lead EC, if applicable) [EC name]
BASEC Reference Number	[BASEC ID number]
Sponsor name and address (if different from investigator)	[address]
Investigator name and Site of SAE occurrence	[name and full address] [contact telephone, email address]

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