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

Investigator initiated trials (IITs) under ClinO: Annual Safety Report

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

The annual safety report[1] shall summarise the actual state of knowledge and describe the handling of identified and potential risks. The sponsor-investigator must submit the annual safety report for clinical trials once a year to the ethics committee (EC); for Category B and C additionally to the Agency.

General information

Title of the clinical trial [free text]

Annual Safety Report number [no.]	Trial code/ protocol number [no.]	BASEC number [year-xxxxx]	SNCTP number [no.]	Swissmedic number [no. or n/a]	EC name (Lead EC and/or concerned EC) [EC name]
Clinical trial with … [ ] Investigational Medicinal Product (IMP) [ ] Medical Device [ ] Transplant Product [ ] Other				Category [ ] A [ ] B [ ] C	
Trial design [ ] Randomised [ ] Open [ ] Blinded [ ] Others: [free text]					
Product name / Intervention [free text]					
Contact details of the sponsor-investigator [name, email and phone number]					
Name and address of institution [name and address]					

Date of report [day/month/year]	Reporting period [day/month/year] to [day/month/year]

Details of the clinical trial

Please specify the numbers for Switzerland and overall in case of international trials.

Participating centre(s)			
Total: [no.]	Planned: [no.]	Open: [no.]	Closed: [no.]

Number of participants			
Target number: [no.]	Enrolled: [no.]	Completed: [no.]	Prematurely terminated: [no.]

[1] Refer to ClinO Art. 43

Participant's safety

Please include differences between study and control group if applicable. In case the trial is blinded, please add a comment, whether participants were unblinded.

Summary of the safety profile *Please delete boxes, which are not applicable.*
For IMPs (or transplant products): During the reporting period, [xx] of [xx] participants ([xx] %) reported a total of [xx] serious adverse events (SAEs). [xx] of [xx] SAEs ([xx] %) were classified "related" to the IMP. The most frequent related SAEs documented were [xxx, yyy and zzz]. [xx] Suspected Unexpected Serious Adverse Reactions (SUSARs) occurred during the reporting period, which have been notified to the Swiss competent authorities.
For medical devices: During the reporting period, a total of [xx] serious adverse events (SAEs) have been reported. In [xx] of [xx] SAEs ([xx] %) it cannot be excluded that the events are attributable to the medical device under investigation. In [xx] of [xx] SAEs ([xx] %) it cannot be excluded that the events are attributable to an intervention undertaken in the clinical trial. The most frequent SAEs documented were [xxx, yyy and zzz]. With respect to the expectedness of the event, [xx] ([xx] %) of the SAEs were expected and [xx] ([xx] %) were classified as unexpected. [xx] device deficiencies were observed. [xx] health hazards that required safety-related measures occurred.
For other clinical trials: During the reporting period, [xx] of [xx] participants ([xx] %) reported a total of [xx] serious adverse events (SAEs; with possible relationship to the intervention). The most frequent SAEs documented were [xxx, yyy and zzz].

	Fatal cases	Serious Adverse Events[2], SAEs	Serious Adverse Drug Reactions[3], SADRs (only for IMPs)	Suspected Unexpected Serious Adverse Reactions, SUSARs (only for IMPs)
Number of cases (during reporting period)	[no. or n/a]	[no. or n/a]	[no. or n/a]	[no. or n/a]
Number of cases (cumulative) since the start of the clinical trial	[no. or n/a]	[no. or n/a]	[no. or n/a]	[no. or n/a]

Summary of the safety evaluation

If relevant, please consider regulations as MedDev, CIOMS, etc.

Relevant safety measures (e.g. by sponsor, manufacturer/ marketing authorization holder, DSMB, agency, ethics committee) [free text]
New findings related to the safety of the product [free text]
Impact of new findings related to the trial conduct (changes to IB, Informed Consent form, contraindications, adverse events of special interest) [free text]
Risk-benefit ratio and conclusion [free text]

[2] Refer to ICH GCP E6(R1) 1.50
[3] Refer to ICH GCP E6(R1) 1.50

Line listing

Line listing of SAEs, SADRs and SUSARs, including international cases (code and version of used standard (e.g. MedDRA or CTCAE) should be indicated, details on SUSARs will be attached as appendices) *In case the line listing is generated automatically by your database, please replace the table below, considering all relevant information. For medical devices you may refer to MEDDEV 2.7/3.*										
SAE / SADR / SUSAR	Serious adverse event/ reaction No.	Participants ID	Age / Sex (F=female, M=male)	Country and site in which participant is/was enrolled (for multicentre, international trials)	Description of event/ reaction	Description of intervention (dosage, schedule, route, if applicable)	Date of onset	Date of treatment (start and stop)	Outcome (e.g. resolved, fatal, improved, sequel, unknown)	Comments, if relevant (e.g. causality assessment, relationship)
[type]	[no.]	[no.]	[age] / [sex]	[country, site]	[as recorded]	[text]	[dd/mm/yyyy]	[dd/mm/yyyy]	[text]	[text]
[type]	[no.]	[no.]	[age] / [sex]	[country, site]	[as recorded]	[text]	[dd/mm/yyyy]	[dd/mm/yyyy]	[text]	[text]
[type]	[no.]	[no.]	[age] / [sex]	[country, site]	[as recorded]	[text]	[dd/mm/yyyy]	[dd/mm/yyyy]	[text]	[text]
[type]	[no.]	[no.]	[age] / [sex]	[country, site]	[as recorded]	[text]	[dd/mm/yyyy]	[dd/mm/yyyy]	[text]	[text]

Signature and approval

Place / date	Name and signature of sponsor-investigator
[place and date]	

Appendix

SUSAR reports	If applicable, please list the reports including reference number
[no. or n/a]	[free text]