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

The annual safety report[[1]](#footnote-2) 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 |

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

|  |  |
| --- | --- |
| Date of report | Reporting period |

Details of the clinical trial

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

|  |  |  |  |
| --- | --- | --- | --- |
| Participating centre(s) | | | |
| Total: | Planned: | Open: | Closed: |

|  |  |  |  |
| --- | --- | --- | --- |
| Number of participants | | | |
| Target number: | Enrolled: | Completed: | Prematurely terminated: |

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.* |
|  |

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] |

Line listing

Signature and approval

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

Appendix

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

1. Refer to ClinO Art. 43 [↑](#footnote-ref-2)