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

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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  [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)