Instructions:

The annual safety report (ASR) summarises the actual state of knowledge and describe the handling of identified and potential risks.

The Ethics Committee considers the Development Safety Update Report (DSUR) equivalent to the ASR. The DSUR format (art. 3 ICH E2F) can therefore be used instead of this template.

For clinical trials with medicinal products or other interventions the ASR must be submitted to the competent Ethics Committee as per Art. 34 ClinO, and must also include any changes that do not require prior approval (i.e. all changes that are not substantial according to art. 29 ClinO).

For clinical trials with medical devices (MD) the ASR must include the events in accordance with art. 33 ClinO-MD and be submitted to the competent Ethics Committee as per art. 35 ClinO-MD, and must also include any changes that do not require prior approval (i.e. all changes that are not substantial according to art. 25 ClinO-MD).

The ASR must be submitted, even if no safety events occurred and even if no patients have yet been enrolled.

The ASR is submitted to the competent Ethics Committee through BASEC. A guidance document is published in the FAQ section in BASEC.

The ASR is submitted once a year, throughout the duration of the clinical trial in Switzerland, and the final ASR submission must cover the Last Patient Last Visit (LPLV) in Switzerland. In case of international clinical trials, after the submission of the ASR covering LPLV in Switzerland, there is no need for further ASR submissions. The information on safety occurring after the LPLV in Switzerland will be captured in the clinical study report.

The “Development International Birth Date (DIBD) is used to determine the start of the annual period for the ASR. This date is the sponsor’s first authorisation to conduct a clinical trial in any country worldwide. The start of the annual period for the ASR is the month and date of the DIBD (art 2.2 ICH E2F).

Complete the form by replacing **ALL** text modules in square brackets. Use “x” for check boxes.

General information

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| Title of the clinical trial |

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| --- | --- | --- | --- | --- | --- |
| Annual Safety Report number  [no.] | Trial code/ protocol number | BASEC number | SNCTP number | Swissmedic number | EC name (Lead EC and/or concerned EC)  text |
| Clinical trial with …  Investigational Medicinal Product (IMP)  Transplant Product  Other | | Medical Device (MD)  In Vitro Diagnostic (IVD) Device  Transplantation, FOPH number | | Category  A, for MD:  A1,  A2  B  C, for MD:  C1,  C2,  C3 | |
| Trial design  Randomised | | Open  Blinded | | Others: [free text] | |
| Product name / Intervention / IMP / MD / IVD Device | | | | | |
| Contact details of the sponsor-investigator | | | | | |
| Name and address of institution | | | | | |

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

Details of the clinical trial

Please specify the numbers for Switzerland and overall in case of international trials.  
  
For category C clinical trials with MD that are also being conducted in EU or EEA, please include the status of the clinical trial in the single participating countries  
(ClinO-MD, Art35 2bis)

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

|  |  |  |  |
| --- | --- | --- | --- |
| Number of participants | | | |
| Target number:  CH:  Total: 0 | Enrolled:  CH:  Total: 0 | Completed:  CH:  Total: | Prematurely terminated:  CH:  Total: |

Participant’s safety

Please include events that occurred both in Switzerland and abroad

Please include differences between study and control group if applicable. In case the trial is blinded, please add a comment, whether participants were unblinded.  
  
Delete boxes that are not applicable.

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| **Summary of the safety profile** |
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Summary of the safety evaluation

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

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| Relevant safety measures taken to prevent health hazards. (e.g. by sponsor, manufacturer/ marketing authorization holder, DSMB, agency, ethics committee) or indicate NONE  [free text] |
| New findings related to the safety of the product (from literature, new SmPC, from other trials, Swissmedic, market surveillance, etc.) or indicate NONE  [free text] |
| Impact of new findings related to the trial conduct (changes to IB, Informed Consent form, contraindications, adverse events of special interest) or indicate NONE  [free text] |
| Risk-benefit ratio and conclusion  [free text] |

Line listing

Line listing of SAEs, SADRs and SUSARs, and Device deficiencies (DD) including international cases, **for the period covered by the ASR**.  
(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 **IMPs or transplantation:** SAEs, SADRs and SUSARs
* For **Other clinical trials**: SAEs where a relationship with the study intervention cannot be excluded.
* For **MDs/IVD**: SADEs and Device Deficiencies with SADE potential. Refer to ISO 14155 and ISO 20916 (where a Serious Adverse Event (SAE) reporting table is available). For multi-centre international studies submit tabular SAE reports according to MDCG 2020-10/2 template
* For **TrP/GT/GMO**: SAEs, SADRs, SUSARs and quality defects. In the case of international multicentre trials, the data on patients treated in Switzerland should be presented separately.

Signature and approval

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

Appendix

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