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  [free text] |

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| --- | --- | --- | --- | --- | --- | --- |
| 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)  Transplant Product  Other | | Medical Device (MD)  In Vitro Diagnostic (IVD) Device  Transplantation, FOPH number [no.] | | | 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  [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 (split numbers CH / worldwide).

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: [No.]  Total: [No.] | Planned:  CH: [No.]  Total: [No.] | Open:  CH: [No.]  Total: [No.] | Closed:  CH: [No.]  Total: [No.] |

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| Number of participants | | | |
| Target number:  CH: [No.]  Total: [No.] | Enrolled:  CH: [No.]  Total: [No.] | Completed:  CH: [No.]  Total: [No.] | Prematurely terminated:  CH: [No.]  Total: [No.] |

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** |
| **IMPs (or transplant products):** Delete if not applicable.  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. These events are called Serious Adverse Drug Reaction (SADR).  The most frequent related SAEs (i.e., SADR) 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. |
| **MD or IVD devices:** Delete if not applicable.  During the reporting period, a total of [xx] serious adverse events (SAEs) have been reported.  [xx]out of [xx] SAEs ([xx] %) were classified “related” to the MD or to an intervention (procedure) undertaken in the clinical trial. Such events are also defined Serious Adverse Device Effects (SADE).  In [xx] of [xx] SADEs ([xx] %) it cannot be excluded that the events are attributable to the medical device under investigation.  In [xx] of [xx] SADEs ([xx] %) it cannot be excluded that the events are attributable to an intervention undertaken in the clinical trial.  The most frequent SADEs documented were [xxx, yyy and zzz].  Occurrence of SAE in the trial arm versus control arm (if applicable).  With respect to the expectedness of the event, [xx] ([xx] %) of the SADEs were expected/anticipated and [xx] ([xx] %) were classified as unexpected/unanticipated.  [xx] device deficiencies were observed (Includes malfunctions, use errors, inadequacies in the information supplied by the manufacturer including labelling)  [xx]out of [xx] device deficiencies ([xx] %) could have led to serious adverse events if suitable action had not been taken, intervention had not been made, or circumstances had been less fortunate (device deficiencies with a SAE potential).  [xx] health hazards that required safety-related measures occurred.  Safety and protective measures taken by the investigator / sponsor (including those requested by the ethics committee and Swissmedic and authorities abroad) taken in Switzerland and abroad: [free text] |
| **Other clinical trials**: Delete if not applicable.  During the reporting period, [xx] of [xx] participants ([xx] %) reported a total of [xx] serious adverse events (SAEs) with possible relationship to the study intervention.  The most frequent documented SAEs with possible relationship to the intervention were [xxx, yyy and zzz]. |
| **TrP/GT/GMO**: Delete if not applicable  During the reporting period, a total of [xx] Serious Adverse Events (SAEs) occurred.  [xx]out of [xx] SAEs ([xx] %) were classified as Serious Adverse Drug Reaction (SADR) i.e., serious adverse events with possible relationship to the TrP/GT/GMO administered. The most frequent SADR documented were [xxx, yyy and zzz]*.*  In [xx] out of [xx] SADRs ([xx] %) it cannot be excluded that the events are attributable to the TrP/GT/GMO itself.  In [xx] out of [xx] SADRs ([xx] %) it cannot be excluded that the events are attributable to other factors like quality defects, contaminations, administration and preparation procedures of TrP/GT/GMO, etc.  [xx] Suspected Unexpected Serious Adverse Reactions (SUSARs) occurred during the reporting period.  Other new relevant safety aspects (including details regarding exposure): [free text] |

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| **IMP**  Delete table if not applicable. | Serious Adverse Events, SAEs, with fatal outcome | Other Serious Adverse Events (non-fatal SAEs) | Serious Adverse Drug Reactions, SADRs | Suspected Unexpected Serious Adverse Reactions, SUSARs |
| 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] |

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| **Other clinical trial**  Delete table if not applicable. | SAEs with fatal outcome where a causality to the intervention cannot be excluded | Other SAEs where a causality to the intervention cannot be excluded |
| Number of cases (during reporting period) | [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] |

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| **MD /IVD Device**  Delete table if not applicable. | Serious Adverse Device Effects SADE[[1]](#footnote-2) | Device Deficiencies that *could have* led to an SAE (serious deficiencies) | Safety and protective measures taken in Switzerland and abroad. |
| Number of cases (during reporting period) | [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] |

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| **TrP/GT/GMO**  Delete table if not applicable. | SAEs with fatal outcome | Other Serious Adverse Events (non-fatal SAEs) | Non-Serious Adverse Drug Reactions, NSADRs | Serious Adverse Drug Reactions, SADRs | Suspected Unexpected Serious Adverse Reactions, SUSARs |
| Number of cases (during reporting period) | [no. or n/a] | [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] | [no. or n/a] |

Summary of the safety evaluation

If relevant, please consider regulations as ISO, 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.

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| SAE /  SADR /  SUSAR / DD | Event / reaction No. | Participants ID | Age / Sex (F=female, M=male) | Country and site in which participant is/was enrolled (for multicentre, international trials) | AE term | Description of intervention (dosage, schedule, route, if applicable)/trial or control arm | 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).  For clinical with MDs indicate in addition the **severity** of the event (ClinO-MD art. 35 abs. 1) |
| [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

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

Appendix

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

1. SADE: Serious Adverse Device Effect. MD: Adverse event possibly, probably or causally related to the use of an investigational device or procedures (ISO 14155). IVD device: Adverse event related to the use of an IVD medical device under investigation (ISO 20916).

   Notes:

   - This includes any adverse event resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, operation, or any malfunction of the device under investigation (= device deficiencies, malfunctions).

   - Device Deficiency (art. 2(59) MDR; art. 2(62) IVDR): Inadequacy of a device related to its identity, quality, durability, reliability, safety or performance, of an investigational device, resp. of a device for performance study, including malfunction, user errors and inadequate information supplied by the manufacturer.

   - Malfunction (ISO 20916): Failure of an IVD medical device under investigation to perform in accordance with its intended use when used in accordance with the instructions for use

   - The definition includes deficiencies related to the investigational device or the comparator. [↑](#footnote-ref-2)