**Notification of the end of a clinical trial (ClinO), a clinical trial of medical device (ClinO-MD) or of a research project (HRO) to the Ethics Committee**

**Definition of study end:**

The end of a study involving persons in Switzerland is marked by the last participant’s final follow-up visit, in the absence of provisions to the contrary in the protocol (ClinO Art. 38, ClinO-MD Art. 36 and *per analogy* research projects under HRO chapter 2).

The end of a study not involving persons in the absence of informed consent in accordance with Art. 34 HRA is defined as the date of ‘the completion of the collection process’. The period of data collection should be defined in the research project protocol.

**Notification of regular end of the clinical trial or research project (ClinO, HRO):**

The end of a study (clinical trial or research project) has to be submitted to the (Lead-) Ethics Committee that approved the clinical trial or the research project within **90 days** of its conclusion (ClinO Art. 38; HRO Art. 22, 36, 40, 43 and 46).

The ‘end of study notification’ is submitted electronically through BASEC on screen 6 (Lead EC: General and main site’s documents) and category 39. Miscellaneous / Varia.

**Notification of regular end of the clinical trial of medical device (ClinO-MD):**

The end of a clinical trial of medical devices has to be submitted to the (Lead-) Ethics Committee that approved the clinical trial within **15 days** of its conclusion (ClinO-MD Art. 36).

The ‘end of study notification’ is submitted electronically through BASEC on screen 6 (Lead EC: General and main site’s documents) and category 36. Notification of completion, discontinuation or interruption of the clinical trial.

**Discontinuation (early termination) of the clinical trial (ClinO):**

The (Lead-) Ethics Committee must be notified within **15 days** of a discontinuation of the clinical trial (ClinO Art 38, Abs. 2). In a multicenter clinical trial, the Lead Ethics Committee will inform the concerned ECs.

**Discontinuation (early termination) of the clinical trial of medical device (ClinO-MD):**

The (Lead-) Ethics Committee must be notified within **15 days** of a discontinuation of the clinical trial of medical device (ClinO-MD Art 36, Abs. 3). In a multicenter clinical trial, the Lead Ethics Committee will inform the concerned ECs.

If the discontinuation is for safety reasons, the notification to the (Lead-) Ethics Committee must be made within **24 hours** (ClinO-MD Art. 36, Abs. 4)

**Discontinuation (early termination) of the research project (HRO):**

The (Lead-) Ethics Committee must be notified within **90 days** of the discontinuation of the **research project** (HRO Art 22, 36, 40). In a multicenter clinical trial, the Lead Ethics Committee will inform the concerned ECs.

**Final clinical study report (for clinical trials only - ClinO, ClinO-MD):**

A final clinical study report should be submitted to the (Lead-) Ethics Committee within **a year** after completion or discontinuation of the **clinical trial**, unless a longer period is specified in the protocol (ClinO Art. 38, Abs 3; ClinO-MD Art. 37 Abs 1, 2).

In multinational clinical trials, the clinical study report should be submitted within a year after the global completion or discontinuation of the multinational clinical trial.

Note: In case of discontinuation (early termination) of a clinical trial of medical device, the clinical study report will be submitted to the (Lead-) Ethics Committee within 3 months (ClinO-MD Art. 37, Abs 1).

For a ClinO clinical trial the clinical study report is submitted via BASEC on screen 6 (Lead EC: general and main site’s documents) and category 41. Final report.

For a ClinO-MD clinical trial the report is submitted on screen 6 and category 37. Final report.

|  |  |
| --- | --- |
| This notification concerns the end of a Clinical Trial (Clinical Trials Ordinance, ClinO) or the end of a Clinical Trial of medical device (ClinO-MD) | Yes  No  **If Yes, complete sections 1 - 8** |
| This notification concerns the end of a Research Project involving persons (Human Research Ordinance, HRO Chapter 2) | Yes  No  **If Yes, complete sections 1 - 6, 8** |
| This notification concerns the end of further use of health-related personal data and/or biological material for research, research involving deceased persons or research involving Embryos and Fetuses from induced abortion and from spontaneous abortions including stillbirths (Human Research Ordinance, HRO, Chapters 3, 4, 5) | Yes  No  **If Yes, complete sections 1 - 3, 8** |

**1. General study information**

|  |  |
| --- | --- |
| BASEC or PB\_BASEC ID number |  |
| Title of the study |  |
| Lead Ethics Committee (Swiss EC only)  - For multicentric study with a Lead EC, or for monocentric research project.  - If the study has neither a BASEC nor a PB\_BASEC ID number, indicate here the Lead EC reference number. |  |
| Participating Ethics Committee (Swiss EC only)  - For multicentric study only.  - If the study has neither a BASEC nor a PB\_BASEC ID number, indicate here the participating ECs reference numbers. |  |
| Sponsor |  |
| Applicant  - If different from the sponsor. |  |

|  |  |
| --- | --- |
| **Was the study carried out in other countries than Switzerland?** | Yes  No  (Swiss study only) |

**2. Early termination**

|  |  |
| --- | --- |
| **Has the study been terminated prematurely?** | No  go to section 3. Study duration  Yes  globally  If yes, give the date of the early termination: [day/month/year]  Yes  in Switzerland only  If yes, give the date of the early termination in Switzerland: [day/month/year] |
| **If yes:**  **describe the reasons for the early termination**  - e.g. safety reason, difficulties recruiting participants, costs exceeded available budget, etc...  - If available, submit to the (Lead-) Ethics Committee any supporting document (e.g. DSMB report for early termination of the study).  **What are the consequences of the early termination for the evaluation of the results of the study?**  **If applicable, give the number of participants in Switzerland still receiving treatment or having further visits for safety reasons at the time of early termination. Describe the steps taken to address them.**  If applicable give the overall risk benefit assessment of the investigational medicinal product (IMP), resp. of the medical device under investigation (MD). |  |

**3. Study duration**

|  |  |
| --- | --- |
| Date: Study start in Switzerland   * Study involving persons: Date first patient/ first visit in Switzerland. * Study not involving people: data/sample collection started. | [day/month/year] |
| **Date: End of study in Switzerland**   * Study involving persons: Date last patient / last visit in Switzerland. * Study not involving persons: data/sample collection completed. | [day/month/year] |
| **Study completed globally?** | Yes  No  N/A  (Swiss study only) |

**4. Details on participating center(s)**

|  |  |
| --- | --- |
| **Number of participating center(s) in Switzerland** | |
| Open center(s):  [no.] | Active center(s): (center(s) that enrolled at least 1 participant)  [no.] |

**5. Details on recruitment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Number of participants in Switzerland** | | | |
| Target number:  [no.] | Enrolled:  [no.] | Prematurely terminated (drop-outs):  [no.] | Completed:  [no.] |
| **If possible, explain any gap between target number and enrolled number of participants** | |  | |

**6. Participants’ safety**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Number of safety cases of participants included in Switzerland** | | | | | |
| Fatal cases:  [no. or n/a] | SAE:  Serious Adverse Events  [no. or n/a] | SADR:  Serious Adverse Drug Reactions  (only for IMPs)  [no. or n/a] | SUSARs:  Suspected Unexpected Serious Adverse Reactions,  (only for IMPs)  [no. or n/a] | SADE:  Serious Adverse Device Effect  (only for MDs)  [no. or n/a] | DD[[1]](#footnote-1):  Device Deficiencies  (only for MDs)  [no. or n/a] |
| **Have all safety cases been reported to the (Lead-) Ethics Committee within the regulatory timelines?** | | Yes  No  N/A | | | |
| **If no, explain the reason**  - submit any outstanding safety reports, as applicable. | |  | | | |

**7. Final clinical study report (clinical trials only)[[2]](#footnote-2)**

|  |  |
| --- | --- |
| **Is a summary of the final clinical study report on the clinical trial available and enclosed with this form?** | Yes  No  If No, submit to the (Lead-) Ethics Committee within a year after completion or discontinuation of the clinical trial[[3]](#footnote-3). |

**8. Signature of the applicant**

I hereby confirm that / confirm on behalf of the sponsor that (cross out what is not applicable):

* The above information given on this declaration is correct; and
* for ClinO trials only, that the clinical study report will be submitted to the (Lead-) Ethics Committee within a year after completion or discontinuation of the clinical trial, unless a longer period is specified in the protocol.
* For ClinO-MD trials only, that the clinical study report will be submitted to the (Lead-) Ethics Committee within a year after the regular completion of the clinical trial, or within 3 months after discontinuation (early termination) of the clinical trial.

The clinical study report must be accompanied by a summary in plain language.

**Date and place:**

**Print name:**

**Signature:**

1. The definition includes deficiencies related to the investigational MD or the comparator MD. [↑](#footnote-ref-1)
2. The clinical study report must be accompanied by a summary in plain language. [↑](#footnote-ref-2)
3. For ClinO-MD trials only, the clinical study report must be submitted to the (Lead-) Ethics Committee within 3 months after discontinuation (early termination) of the clinical trial. [↑](#footnote-ref-3)