✂ **Please remove the ‘General information and instructions’, the logo of swissethics, and the table ‘Change history’** ✂

Template for writing a Clinical Study Report of Clinical Trial conducted under Chapter 4. Other clinical trials, of the Clinical Trial Ordinance (ClinO).

**General information and instructions**

The template is intended for writing clinical study reports of clinical trials conducted under Chapter 4. Other clinical trials, of the Clinical Trial Ordinance (ClinO). The template meets the requirements set forth in Art. 38 ClinO.

swissethics explicitly recommends that researchers publish the results of their researches in scientific/medical journals. **If the results of the clinical trial have been published, the publication(s) shall be submitted to the Lead-ethics committee**. In this case, **it is not** necessary to submit the clinical trial report. Posters, abstracts or medical cases presented at a congress or conference do not replace the full clinical trial report.

**Do not use** this template for writing a clinical study report of a clinical trial with a medicinal product. Guidance how to write such a study report is given in ICH-E3 Guideline «Structure and Content of Clinical Study Reports».

The texts written in blue are instructions and serve purely as a guide for writing the report. Texts in blue should therefore not be seen as imperatives, and each chapter should therefore be written according to the particularity of the project. Similarly, Chapter 8. Appendices must be adapted accordingly.

**Delete** all instructions and explanations that are written in blue, including this page and the table ‘Change History’.

The template has been written to accommodate all types clinical trials under Chapter 4. ClinO, which variance is very broad. Hence, the template is quite long because exhaustive. Therefore, when writing the study report, **you must adapt the template to the specificities of the clinical trial.** Some of the subchapters, some appendices and some texts in blue (instructions) might not be applicable. If necessary, remove subchapters or rename them. Refresh the index if you change the structure of the chapters.

Some explanations in blue are redundant in the sense that they are repeated in different subchapters. However, one should not repeat in other chapters what has already been written in one chapter, but make sure that the report as a whole covers the different topics. Hence, the template allows for vast flexibility in report writing and editing.

The clinical study report can be written in English or in the language of the Lead-ethics committee that has approved the clinical trial.

Sumit the clinical study report through the submission portal BASEC at point 41. *Final report* on screen 6. *Lead EC: General and main site's documents.*

Refer questions regarding the use of this template to the Lead-ethics committee that has reviewed and approved the study, or to swissethics, info@swissethics.ch, phone: +41 31 306 93 95.

**Change history of the template:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Version Nr | Version date | Modified without version change | Description, comments | Control |
| 1.0 | 06.09.2023 |  | Initial version | PG |

✂ **Please remove the ‘General information and instructions’, the logo of swissethics, and the table ‘Change history’** ✂

**Clinical Study Report**

**Title page**

**Title of the study:** The title written here must match the title on the study protocol approved by the Lead-ethics committee.

**Study acronym:** Delete if not applicable

**BASEC No:** YYYY-xxxxx

**SNCTP No:** If the number is not known, search for it on the kofam webpage ([link](https://kofam.ch/de/studienportal/nach-klinischen-versuchen-suchen)). Contact swissethics if you can’t find the SNCTP ID of the study.

**NCT No.:** Delete if not applicable

**Study duration**

**Study Initiation date:** FPFV

**Study completion date:** LPLV

**Name(s) and affiliation(s) of the principal investigator(s), administrative structure**

**Principal (coordinating) Investigator and study site:** E.g., Dr. med. Otto Lowe, Universitätsklinik für Diabetologie, Endokrinologie, Ernährungsmedizin und Metabolismus, Inselspital, Bern

**Participating principal investigators at the local sites:** In the case of multi-centre studies, indicated here the full name of the principal investigator at each participating research sites. Give the full addresses of the local sites. Delete in case of a mono-centric study

Do not add sub-investigators, study coordinators, …

**Sponsor:** E.g., Universitätsklinik für Diabetologie, Endokrinologie, Ernährungsmedizin und Metabolismus, Inselspital, Bern.

**Sponsor’s representative in Switzerland:** Indicate only if the Sponsor is not located in Switzerland. Delete if not applicable

**Statistician(s):** Delete if not applicable

**Laboratory(s):** Delete if not applicable

**Others relevant contributors:** If pertinent, indicate full names, affiliations, roles

**Signature page**

The principal or coordinating investigator, the lead statistician, the sponsor and the sponsor's person responsible for medical/safety evaluation (if applicable), have approved the clinical study report [xx (dated DD.MM.YYYY), make sure this corresponds to the protocol ID and date in the footer], and confirm hereby that the study has been conducted according to the approved protocol and its amendments, current version of the World Medical Association Declaration of Helsinki, and Swiss law.

**Principal or coordinating investigator signature:**

Name: Name in print letters

\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Place and date Signature

**Lead statistician:** Delete if not applicable

Name: Name in print letters

\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Place and date Signature

**Sponsor:** Signature of the person representing the sponsor. If sponsor and principal investigator are the same person (“sponsor-investigator” initiated clinical trial), delete this additional signature line.

Name: Name in print letters

\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Place and date Signature

**Sponsor's person responsible for medical/safety evaluation:** If sponsor and principal investigator is the same person (“sponsor-investigator” initiated clinical trial), delete this additional signature line.

Name: Name in print letters

\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Place and date Signature

**Table of contents**

[List of abbreviations and definition of terms 7](#_Toc144212174)

[1 Executive summary 7](#_Toc144212175)

[2 Introduction 7](#_Toc144212176)

[2.1 Background and rationale for the study 7](#_Toc144212177)

[2.2 Research question and objectives 8](#_Toc144212178)

[3 Methods 8](#_Toc144212179)

[3.1 Study design and protocol, amendment(s) 8](#_Toc144212180)

[3.2 Eligibility criteria and participants selection 8](#_Toc144212181)

[3.3 Intervention(s) and comparator(s) 8](#_Toc144212182)

[3.4 Outcome measures and endpoints 8](#_Toc144212183)

[3.5 Sample size and power calculations, statistical analysis 9](#_Toc144212184)

[3.6 Validation, Compliance and Quality Control 9](#_Toc144212185)

[3.7 Ethical considerations 9](#_Toc144212186)

[4 Results 9](#_Toc144212187)

[4.1 Participant demographic and other baseline characteristics 9](#_Toc144212188)

[4.2 Protocol deviations 9](#_Toc144212189)

[4.3 Measurements of compliance 10](#_Toc144212190)

[4.4 Efficacy evaluation, primary and secondary outcomes and results 10](#_Toc144212191)

[4.5 Safety evaluation, summary, analysis and listing of serious adverse events and other adverse events of special interest 10](#_Toc144212192)

[4.6 Adjustments for covariates, handling of dropouts or missing data 11](#_Toc144212193)

[4.7 Interim analysis 11](#_Toc144212194)

[4.8 Subgroup analyses and any other additional analyses 11](#_Toc144212195)

[5 Discussion 11](#_Toc144212196)

[5.1 Interpretation of results and implications for clinical practice and research 11](#_Toc144212197)

[5.2 Strengths and limitations of the study 12](#_Toc144212198)

[5.3 Comparison with previous studies and meta-analyses 12](#_Toc144212199)

[5.4 Future research directions 12](#_Toc144212200)

[6 Conclusion 13](#_Toc144212201)

[7 References 13](#_Toc144212202)

[8 Appendices 13](#_Toc144212203)

[8.1 Lead Ethics committee and local Ethics committees 13](#_Toc144212204)

[8.2 Study protocol and amendments 13](#_Toc144212205)

[8.3 Statistical analysis plan 13](#_Toc144212206)

[8.4 Participant informed consent forms (ICF) 13](#_Toc144212207)

[8.5 Case report forms (CRF) and data collection instruments 14](#_Toc144212208)

[8.6 Protocol deviations 14](#_Toc144212209)

[8.7 Safety 14](#_Toc144212210)

[8.8 Data and safety monitoring board reports and recommendations (if available) 14](#_Toc144212211)

[8.9 Monitoring plan(s) 14](#_Toc144212212)

[8.10 Audit certificates (if applicable) 14](#_Toc144212213)

[8.11 Randomisation scheme (if applicable) 14](#_Toc144212214)

[8.12 Publications based on the clinical trial 14](#_Toc144212215)

List of abbreviations and definition of terms

AE Adverse Event
CRF Case Report Form
DSMB Data and Safety Monitoring Board
xxx xxx

1. Executive summary

Provide a concise high-level overview of the study objectives, methodology, key findings and important conclusions. The executive summary should be written in a clear, concise, and easily understandable manner, avoiding technical jargon and unnecessary detail. It should not be longer than 3 pages. The executive summary should include following elements:

Study Background: Provide a brief introduction to the research topic and its significance. Explain the purpose of the study, including any gaps in current knowledge or research objectives.

Study Design and Methodology: Summarize the study design, including the type of study (e.g., randomized controlled trial, double-blinded study, …), population characteristics, interventions or exposures, data collection methods, and any relevant statistical analyses.

Results: Highlight the key findings of the study, focusing on the most important outcomes and significant results. Mention any notable trends, effect sizes, or statistical significance observed. However, avoid excessive detail or raw data.

Safety and Adverse Events: Provide a summary of any safety concerns or adverse events observed during the study. This may include information on the frequency, severity, and potential implications of adverse events related to the study interventions or exposures.

Conclusion and Implications: Briefly discuss the overall conclusions drawn from the study findings. Highlight the implications of the results for clinical practice, patient care, or further research. If applicable, mention any limitations of the study that may affect the interpretation of the results.

Recommendations: Offer any recommendations based on the study's conclusions. These may include suggestions for changes in clinical practice, interventions, guidelines, or future research directions.

Key Takeaways: Summarize the most important points of the study in a concise and clear manner. This section should provide a quick overview of the study's significance and its main findings.

1. Introduction

Use the approved study protocol and its amendments to write this chapter.

* 1. Background and rationale for the study

Provide an overview of the topic and its significance in the field of study. Explain why this research was necessary and what knowledge gaps or problems it aims to address.

Identify the current state of knowledge and highlight any controversies, limitations, or gaps in existing research, literature and clinical practice, related to the study.

Explain how this study builds upon or fills gaps in the existing knowledge and clinical practice.

* 1. Research question and objectives

State the specific research question or questions that the study sought to answer.

Give the specific objectives or aims of the study. Explain why the chosen research question and objectives are important and relevant to the field.

Discuss how addressing these objectives contributes to existing knowledge, improve clinical practice, or provide insights into the subject matter.

1. Methods

Use the approved study protocol and its amendments to write this chapter.

* 1. Study design and protocol, amendment(s)

Describe the overall design of the study, such as whether it is a randomized controlled trial, double-blinded study, etc. Explain the rationale behind the chosen design and how it aligns with the research objectives.

If applicable, explain any modifications made to the original study protocol (amendments to the study protocol) during the study and the rationale for such changes.

* 1. Eligibility criteria and participants selection

Provide information about the characteristics of the study participants, including eligibility criteria, recruitment methods, and any relevant demographic information.

Describe how the process of obtaining informed consent from participants was conducted and any steps taken to ensure participant confidentiality and privacy during the consent process.

Describe how recruitment of the participants was conducted to ensure gender and age balance was achieved, or give a justification why this was not be possible.

If applicable, explain any modifications (amendments to the study protocol) made to the eligibility criteria and participants selection during the study and the rationale for such changes.

* 1. Intervention(s) and comparator(s)

Outline the interventions and procedures implemented in the study.

If applicable, explain any modifications (amendments to the study protocol) made to the intervention during the study and the rationale for such changes.

* 1. Outcome measures and endpoints

Specify the primary and secondary outcomes measured in the study.

Define any variables or endpoints of interest and provide a rationale for their selection. Include details on how these outcomes were assessed and measured, including any scales, questionnaires, or instruments utilized.

* 1. Sample size and power calculations, statistical analysis

Describe the statistical methods and analytical techniques employed to analyse the collected data. Discuss any specific software or algorithms used for data processing and statistical analysis.

Include information on how missing data or outliers were handled, as well as any sensitivity analyses conducted.

If relevant, provide details on how the sample size was determined to ensure adequate statistical power. Explain the rationale behind the chosen effect size, level of significance, and power calculations.

Include information on how analyses to detect age and gender differences were done. Give a justification if such analyses were not possible or were not conducted.

If applicable, describe and explain any changes and modifications made from the original statistical analysis plan.

* 1. Validation, Compliance and Quality Control

If applicable, describe any efforts made to validate the study methods or ensure data quality. This may include inter-rater reliability assessments, data monitoring (e.g., from systematic review of site-visits monitoring reports), or quality control procedures.

Detail the methodology used to measure compliance in the study. This may include specific tools, instruments, or questionnaires utilized to assess compliance. Explain the rationale behind the chosen measurement approach and any modifications made to established methods.

* 1. Ethical considerations

Address ethical considerations related to the study.

Present the steps taken to ensure participant safety, privacy, and adherence to ethical guidelines throughout the study.

1. Results
	1. Participant demographic and other baseline characteristics

Present descriptive statistics to summarize the characteristics of the study population, such as age, gender distribution, and baseline demographics. This section may also include information about participants' medical history, co-morbidities, and any other relevant baseline characteristics.

* 1. Protocol deviations

Provide a clear and concise description of the protocol deviations that occurred during the study. Include information about the specific aspects of the protocol that were not adhered to and the reasons behind these deviations. This can range from deviations in recruitment procedures, sample sizes, interventions, measurements, or any other relevant aspect of the study. Line listing of deviations can be annexed to the clinical study report.

Present the frequency and distribution of protocol deviations within the study sample. This can be expressed as the number or percentage of participants or study sites that deviated from the protocol. Provide a breakdown of the deviations, if applicable, based on different variables such as demographic characteristics, treatment groups, or study sites. Tabulations of the deviations can be annexed to the clinical study report.

If possible, perform sensitivity analyses or statistical adjustments to account for the impact of the deviations on the study outcomes.

Describe any corrective actions or strategies implemented to mitigate the impact of the protocol deviations. This could include protocol amendments, additional data collection, statistical adjustments, or other measures taken to address the deviations and ensure the integrity of the study.

* 1. Measurements of compliance

Report any quantitative measurements related to compliance, such as the percentage of participants who adhered to the treatment/intervention regimen, frequency of missed treatments/interventions, or any other relevant numerical data. Include relevant statistical analyses if appropriate.

If applicable, discuss qualitative findings related to compliance. This could include insights obtained through participant-reported experiences. Summarize key themes or patterns that emerged from qualitative data.

If relevant, provide subgroup analysis of compliance based on factors like age, gender, or treatment/intervention groups.

Analyse any observed differences in compliance rates among different subgroups and discuss their implications in chapter 5. Address any limitations or challenges encountered during the compliance measurement process. This could include issues like self-reporting bias, missing data, or limitations of the measurement tools used.

Acknowledge any potential sources of error or bias that may have affected the compliance results.

* 1. Efficacy evaluation, primary and secondary outcomes and results

Report the main outcomes measured in the study and present the results in a clear and concise manner. This may include numerical data, such as means, medians, standard deviations, or proportions, depending on the nature of the variables. Use tables, charts, or graphs as appropriate to present the data effectively.

Report whether any differences were observed between genders. It should also be indicated if the analysis showed no gender effect.

Specify whether the reported results are statistically significant, using appropriate p-values or confidence intervals. Discuss the significance of the findings in relation to the study objectives and relevant literature (see chapter 5.1, 5.3).

* 1. Safety evaluation, summary, analysis and listing of serious adverse events and other adverse events of special interest

Provide information on any serious adverse events or safety concerns observed during the study.

Include details such as the frequency, severity, and relationship to the intervention or treatment being investigated. Line listing of safety events and tabulations of the safety adverse events per type, patient, study sites can be annexed to the clinical study report.

Provide a qualitative analysis of safety data. Report whether any differences were observed between genders. It should also be indicated if the analysis showed no gender effect.

Provide descriptions of any safety protective measures taken during the course of the study, if appliable.

* 1. Adjustments for covariates, handling of dropouts or missing data

Provide an overview of the number of participants who dropped out or had missing data and their characteristics. Describe the reasons for dropouts or missing data, if known. Explain the approach used to handle these missing data, such as complete case analysis, imputation methods (e.g., last observation carried forward, multiple imputation), or sensitivity analyses.

Present the results of the primary analysis with missing data handled according to the chosen approach. If sensitivity analyses were performed, report the results and discuss their implications for the robustness of the findings (see chapter 5.1).

Provide any relevant subgroup analyses or stratifications conducted based on covariates or missing data patterns. Discuss their implications for the robustness of the findings (see chapter 5.1).

* 1. Interim analysis

If interim analyses were performed during the course of the study, present these results separately in this chapter. Highlight any significant findings or notable trends observed.

If applicable, indicate if interim unplanned interim analyses were performed. Discuss rational and consequences of the unplanned interim analyses.

Discuss the results of the interim analysis in chapter 5 if these significantly differ from the results of the final analysis.

* 1. Subgroup analyses and any other additional analyses

If the study included subgroup analyses, present these results separately in this chapter. Highlight any significant findings or notable trends observed within these subgroups or secondary analyses.

Present any additional analyses performed beyond the primary and secondary study objectives (see chapter 4.4 and 4.6), such as exploratory or sensitivity analyses. These analyses may help provide further insights or support the robustness of the main findings (see chapter 5.1).

1. Discussion
	1. Interpretation of results and implications for clinical practice and research

Highlight the most significant findings and any unexpected or noteworthy outcomes and discuss the implications for clinical practice. Include in the discussion any difference observed between different populations groups (by gender, age, etc.).

Discuss the potential impact of the covariate adjustments and missing data handling on the study results and their interpretation (see chapter 4.4, 4.6, 4.8).

Discuss the potential impact of the protocol deviations on the study outcomes. Assess whether the deviations have introduced bias, affected the validity of the results, or compromised the interpretation of the findings (see chapter 4.2). Consider the potential effect on the generalizability of the results, the internal validity of the study, and the ability to draw definitive conclusions.

Offer an interpretation and discussion of the compliance results in light of the study objectives and the existing literature. Discuss any unexpected or notable findings and their potential implications for the study outcomes. Relate the compliance results to the overall findings of the study.

Discuss how the findings align with or challenge existing guidelines or clinical practices. This may include suggestions for changes in clinical protocols, guidelines, or practices. Discuss how the study results can be translated into clinical practice. Consider the potential impact on patient care, treatment strategies, diagnostic procedures, or interventions.

Offer practical recommendations for clinicians or researchers based on the study results, while addressing potential unintended consequences or risks that may arise from implementing the study results in clinical practice.

Consider ethical and social implications: Reflect on any ethical or social implications that arise from the study findings. Discuss potential implications for patient privacy, informed consent, equity, or social justice.

* 1. Strengths and limitations of the study

Discuss strengths and limitations of the study. This may include issues such as small sample sizes, potential biases, variations in study designs, or incomplete data.

Discuss how these limitations may impact the interpretation of the findings and may impact the generalizability or applicability of the findings to real-world clinical settings.

* 1. Comparison with previous studies and meta-analyses

This chapter serves to situate the current study within the broader context of previous research and to highlight the unique contributions or novel findings of the current study.

Analyse and compare the findings of the current study with those of previous studies, and acknowledge its strengths and weaknesses compared to previous research. Discuss potential reasons for any discrepancies: If the findings of the current study align with or confirm previous research, emphasize the consistency and strengthen the overall evidence base. Conversely, if the findings differ from previous studies, explore possible explanations for the disparity and consider the implications for clinical practice or future research. Support your claims and comparisons with appropriate citations from the literature.

If applicable, discuss meta-analyses or systematic reviews that have been conducted on the topic. Summarize the key findings of these analyses and evaluate how the current study contributes to or challenges the conclusions drawn from the meta-analyses. If there are discrepancies between the meta-analyses and the current study, provide a reasoned explanation for the differences.

* 1. Future research directions

Discuss the implications of the study's findings for future research. Identify areas that require further investigation or refinement based on the gaps identified in the existing literature. Suggest potential directions for future studies to build upon the current findings and address any remaining questions or controversies.

1. Conclusion

Summarize the key results of the study in a concise manner and write an overall conclusion.

1. References
2. Appendices
	1. Lead Ethics committee and local Ethics committees

List here the name of Lead ethics committee and, in case of a multi-centric study, the names of the concerned local ethics committee. E.g.:

* Lead ethics committee: Commission Cantonale d'Ethique de la Recherche sur l'être humain (CCER);
* Concerned local ethics committees: Comitato etico cantonale Ticino; Ethikkommission Nordwest- und Zentralschweiz EKNZ; Ethikkommission Ostschweiz EKOS.
	1. Study protocol and amendments

List here the protocol version numbers and version dates and the approval dates of the Lead-ethics committees. The list must match the one of the submitted protocol(s) and amendment(s) in the project form in BASEC (see screen 6. «Lead EC: General and main site's documents», point 4. «Study plan (protocol), signed and dated». Any discrepancies must be explained. List the documents in a table, if appropriate E.g.:

|  |  |  |  |
| --- | --- | --- | --- |
| Document | Version Nr | Version date | Approved by Lead-EC |
| Protocol *ABCD* | 1.0 | 23.07.2022 | 15.09.2022 |
| Amended protocol *ABCD* | 2.0 | 11.11.2022 | 10.12.2022 |
| Amended protocol *ABCD* | 3.0 | 12.03.2023 | 12.04.2023 |

Do not attach the study protocol(s) and amendments(s) to this report.

* 1. Statistical analysis plan

Identify the statistical analysis plan. E.g.:

* The statistical analysis plan is included in Chapter 5.1 of the Study protocol version 1.0, date 07.05.2022

Do not attach the statistical analysis plan to this report if it has already been submitted to the Lead-ethics committee.

* 1. Participant informed consent forms (ICF)

List here all the ICF used during the course of the study, with versions numbers and versions dates, as submitted and approved by the Lead-ethics committee. List the documents in a table E.g.:

|  |  |  |
| --- | --- | --- |
| Document | Version Nr | Version date |
| ICF for study participants | 1.0 | 23.07.2022 |
| ICF for relatives/parents/legal representatives | 1.0 | 23.07.2022 |
| revised ICF for study participants | 2.0 | 12.03.2023 |

Do not attach the ICF(s) to this report.

* 1. Case report forms (CRF) and data collection instruments

Identify the CRF. E.g.

* CRF, version 1.0, date 23.07.2022
* Revised CRF, version 1.0, date 12.03.2022

Do not attach the CRF to this report if it has already been submitted to the Lead-Ethics committee.

* 1. Protocol deviations

If appliable, line listing and tabulations of deviations (see chapter 4.2).

* 1. Safety

If applicable, line listing of safety events and tabulations of the safety adverse events per type, patient, study sites (see chapter 4.5).

* 1. Data and safety monitoring board reports and recommendations (if available)

If applicable, annex the reports and recommendations of the DSMB to the clinical study report.

* 1. Monitoring plan(s)

Identify the monitoring plan(s). E.g.

* Monitoring plan included in Chapter 9 of the Study protocol version 1.0, date 23.07.2022
* Revised monitoring plan included in Chapter 9 of the Study protocol version. 2.0, date 11.11.2022

Do not attach the monitoring plan(s) to this report if it has already been submitted to the Lead-ethics committee.

* 1. Audit certificates (if applicable)

Do not add here the full audit report, but the audit certificate(s) only (if applicable).

* 1. Randomisation scheme (if applicable)

If applicable, annex the randomisation scheme to the clinical study report.

* 1. Publications based on the clinical trial

If applicable, annex the publications to the clinical study report.