

Zusammenfassung des Studienprotokolls (Synopsis)

- Die Zusammenfassung stellt ein Kerndokument für die Ethikkommission dar und soll für eine interdisziplinär zusammengesetzte Forschungsethikkommission zwar wissenschaftlich abgefasst, aber verständlich sein.
- Multizentrische klinische Versuche: In der Sprache der prüfenden (Leit) EK oder in Englisch.
Monozentrische klinische Versuche: In der Sprache der prüfenden EK.
- Die Zusammenfassung darf dem Studienprotokoll und andern Dokumenten nicht widersprechen.
- Die einzelnen Punkte treffen nicht auf jeden Studientyp zu. Die Vorlage ist deshalb gesuchspezifisch und sinngemäss zu verwenden.
- Der Teil in Tabellenform entspricht der ‚Summary‘ des Templates im Studienprotokoll. Er kann so in das Studienprotokoll (s. Template) übernommen werden.

Sponsor / Sponsor-Investigator	<i>Name of Sponsor / Sponsor-Investigator</i>
Study Title:	<i>Full title of protocol</i>
Short Title / Study ID:	<i>Short title of protocol or Study ID, if applicable</i>
Protocol Version and Date:	<i>The version number and the date of the valid study protocol.</i>
Trial registration:	<i>Provide the name of the study registry and the registration number and date (if not registered then indicate the anticipated registry)</i>
Study category and Rationale	<i>Provide the determined study category with explanation for this category</i>
Clinical Phase:	<i>For clinical trials with drugs: Clinical study phase or phase of clinical development (e.g. Phase 1, 2, 3 or 4; or according to ICH E8 para 3.1.3 Human Pharmacology, Therapeutic Exploratory, Therapeutic Confirmatory or Therapeutic Use); in case of Medical Device study rename and use e.g. "Phase of development"</i>
Background and Rationale:	<i>Provide a short background and the rationale for the study, this includes the health condition studied</i>
Objective(s):	<i>Brief statement of primary study objectives and the main secondary study objectives.</i>
Outcome(s):	<i>Brief statement of primary study outcome and the main secondary study outcome measures.</i>
Study design:	<i>Design attributes such as open label; randomised, placebo or active control; cross-over design, etc.</i>
Inclusion / Exclusion criteria:	<i>Brief description of the anticipated study population, the key inclusion and exclusion criteria and if applicable, the reasons for inclusion of vulnerable participants</i>
Measurements and procedures:	<i>Describe the study intervention (methodology, procedures, sampling if applicable)</i>
Study Product / Intervention:	<i>Describe the study specific intervention (product (drug / device name (generic), dose, route, regimen) used in the study). Duration of product administration (also run-in if applicable)</i>
Control Intervention (if applicable):	<i>Describe if applicable the comparator(s) (e.g. active control, reference therapy, placebo)</i>
Number of Participants with Rationale:	<i>Number of participants projected for the entire study (e.g. not for simply one site, rather for entire study, all sites combined). Give the total and the numbers for each treatment group.</i>
Study Duration:	<i>Estimated duration for the main investigational plan (e.g. from start of screening of first participant to last participant processed and finishing the study)</i>
Study Schedule:	<i>Month Year of First-Participant-In (planned) Month Year of Last-Participant-Out (planned)</i>
Investigator(s):	<i>Name(s) of Investigator(s) Full contact details</i>
Study Centre(s):	<i>Single-centre or multi-centre. If multi-centre note number of projected centres to be involved. Or countries if multi-national study</i>

Statistical Considerations:	<i>A very brief description of the main elements of the statistical methodology to be used in the study. Explanation to sample size</i>
GCP Statement:	This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP or ISO EN 14155 (as far as applicable) as well as all national legal and regulatory requirements.

Explanation for the Inclusion of vulnerable Subjects (if applicable):

Recruitment Procedure (if applicable : Advice/Flyer have to be submitted ; if applicable, please indicate the Localisation / Medium (which Newspaper))

Study Procedure/Flowchart with Timelines: Study specific Examinations have to be clearly identified

Risks/ Inconveniences, which are Study specific:

Coverage of Damages: Insurance (yes/no)? Sum?

Storage of Data-and Samples for Future Research Aims: yes/no?,

If yes, please indicate in which documents (for ex. study protocol, informed consent) and on which pages you have described this topic).

Ethical Considerations:

1. Please describe the potential gain of new knowledge obtained with this study, and its meaning for patients/society.
2. Please give an assessment of the benefit/risk relationship for the patient.
3. Please explain, why the methodology is also ethically appropriate to gain new generalizable knowledge (for ex. double-blind, placebo, sham, vulnerable subjects, emergency cases, partial information only etc.)

The most relevant References: