

## Résumé du protocole d'étude (synopsis)

- Le résumé constitue un document essentiel pour la commission d'éthique, composée de représentants de plusieurs disciplines. Il doit être rédigé dans un langage scientifique mais compréhensible.
- Essais cliniques multicentriques: Il doit être rédigé dans la langue de la commission d'éthique (directrice) chargée de l'évaluation ou en Anglais. Essais cliniques monocentriques: Il doit être rédigé dans la langue de la commission d'éthique chargée de l'évaluation.
- Le résumé ne doit pas contredire le protocole d'étude, ou d'autres documents.
- Chaque point ne s'applique pas à chaque type d'étude. Le modèle doit donc être utilisé de manière adéquate, selon la demande.
- La partie sous forme de tableau correspond au résumé du modèle dans le protocole d'étude. Elle peut être reprise telle quelle dans le protocole (cf. modèle) et doit être complétée par les informations ci-dessous

<b>Sponsor/Sponsor-Investigator</b>	Name of Sponsor/ Sponsor-Investigator
<b>Study Title:</b>	Full title of protocol
<b>Short Title/Study ID:</b>	Short title of protocol and Study ID, if applicable
<b>Protocol Version and Date:</b>	The version number and the date of the valid study protocol.
<b>Trial Registration:</b>	For clinical trials only (KlinV): Provide the name of the study registry and the registration number and date (if not registered, then indicate the anticipated registry)
<b>Study Category with Rationale</b>	Provide the determined study category with explanation for this category
<b>Clinical Phase, see Basisformular:</b>	For clinical trials with drugs only (KlinV): Clinical study phase (e.g. Phase 1, 2, 3 or 4); in case of MD rename and use e.g. "Phase of development"
<b>Background and Rationale:</b>	Provide a comprehensive background and the rationale for the study, this includes the health condition studied
<b>Objective(s):</b>	Brief statement of primary study objectives and the main secondary study objectives.
<b>Outcome (if applicable, see Basisformular): Primary Outcome Secondary Outcome</b>	Brief statement of primary study outcomes and the main secondary study outcome measures.
<b>Study Design, see Basisformular:</b>	Design attributes such as single blind, double blind or open label; Randomised, placebo or active control; cross-over design, etc.
<b>Inclusion/Exclusion Criteria, see Basisformular:</b>	Brief description of the anticipated study population, the key inclusion and exclusion criteria and if applicable, the reasons for inclusion of vulnerable participants
<b>Measurements and Procedures:</b>	Describe the study intervention (methodology, procedures, sampling if applicable)
<b>Study Product/Intervention according to KlinV, if applicable:</b>	Describe the study specific intervention (for example surgery technologies, product (drug/device name (generic), dose, route, regimen used in the study). Duration of product administration (also run-in if applicable)
<b>Comparator(s) (if applicable):</b>	Describe if applicable the comparator(s) (e.g. active control, reference therapy, placebo)
<b>Number of Participants with Rationale (if no Power Analysis conducted):</b>	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, and the explanation for this sample size, if there is no power analysis possible .
<b>Study Duration:</b>	Estimated duration for the main investigational plan (e.g. from start of screening to last participant processed and finishing the study)
<b>Study Schedule:</b>	Month Year of First-Participant-In (planned) Month Year of Last-Participant-Out (planned)
<b>Investigator(s):</b>	Name(s) of Investigator(s) Full contact details
<b>Study Centre(s):</b>	Single-centre or multi-centre. If multi-centre note number of projected centres to be involved. Or countries if multi-national study

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<b>Statistical Analysis incl. Power Analysis</b>	A very brief description of the main elements of the statistical methodology to be used in the study. Explanation to sample size
<b>GCP Statement:</b>	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.

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

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

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

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**Risks/ Inconveniences, which are Study specific:**

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

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**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).

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**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.)

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**The most relevant References:**