

Proposal Preparation Instructions

Clinical Trials Programme – Draft Proposals



Please write your proposal in English and use the Draft Proposal Template (DFG form 53.13).

www.dfg.de/formulare/53_13_elan

The proposal must not exceed 8 pages (DIN A4, 10 point Arial for the regular text and 9 point Arial for the synopsis, single line spacing). Make an entry under each heading/subheading. Original signatures of the principal/coordinating investigator and the responsible statistician on the compliance form are mandatory.

As a separate document submit a two-page CV for each applicant, co-applicant and statistician and include a listing of a maximum of ten publications considered to be the most important for each participant. For further information on the publication list, see:

www.dfg.de/formulare/1_91

Applications that fail to comply with these requirements will not be considered for review.

Submit the draft proposal and two-page CVs electronically via elan.

<https://elan.dfg.de>

1 Trial Synopsis

Applicant(s) / coordinating investigator(s)	<p>List the name(s) of the person(s) who will apply for funding and assume responsibility for conducting the clinical trial. The main applicant must be listed first.</p> <ul style="list-style-type: none"> ▪ First name, last name, academic title ▪ Employment status ▪ Institution and department (complete name) ▪ Postal address ▪ Telephone/e-mail address <p>Each applicant should submit a two-page CV including his/her ten most important publications.</p>
Statistician	<p>List the responsible statistician.</p> <ul style="list-style-type: none"> ▪ First name, last name, academic title ▪ Employment status ▪ Institution and department (complete name) ▪ Postal address ▪ Telephone/e-mail address <p>The statistician should submit a two-page CV including his/her ten most important publications.</p>
Co-applicant(s)	<p>List co-applicant(s), if applicable. Limit the number of co-applicant(s) by naming only those who will substantially contribute to the design, management and analysis of the trial but will not apply for funding. This usually does not include the main investigators of participating recruiting centres.</p>

	<ul style="list-style-type: none"> ▪ First name, last name, academic title ▪ Institution and department (complete name) ▪ Postal address ▪ Telephone / e-mail address <p>Each co-applicant should submit a two-page CV including his/her ten most important publications.</p>
Title of trial (English)	The title of the trial (not to exceed 300 characters) should be as precise as possible. If funding is granted, this title will be used in the DFG's annual report. An acronym is optional.
Title of trial (German)	The title of the trial (not to exceed 300 characters) should be as precise as possible. If funding is granted, this title will be used in the DFG's annual report. An acronym is optional.
Medical condition	The medical condition being studied (e.g. asthma, myocardial infarction, depression)
Hypothesis	Clearly specify the hypothesis of the trial that determines sample size calculation.
Participants / study population	<p>Specify the population to be studied.</p> <p>Key inclusion criteria:</p> <p>Key exclusion criteria:</p>
Trial type	<p>Please mark which trial type you are applying for under this programme.</p> <p>Interventional trial: <input type="checkbox"/></p> <p>Observational trial: <input type="checkbox"/></p> <p>If you have chosen an observational trial, please justify your decision briefly:</p> <p>-----</p> <p>Present key elements of your trial design here, e.g. randomized/non-randomized, type of masking (single, double, observer blind), type of controls (active/placebo), parallel group/cross-over, prognostic, diagnostic.</p> <p>Key elements:</p>
Treatments / procedures	<p>Detail your trial design by describing the treatments/procedures (intervention, dose and mode of application) that will be compared.</p> <p>Experimental intervention:</p> <p>Control intervention:</p> <p>Follow-up per patient:</p> <p>Duration of intervention per patient:</p>
Endpoint(s)	<p>Primary endpoint:</p> <p>Secondary endpoint(s):</p> <p>Assessment of safety:</p>
Trial duration	<p>First patient in to last patient out (months):</p> <p>Duration of the entire trial (months):</p> <p>Recruitment period (months):</p>

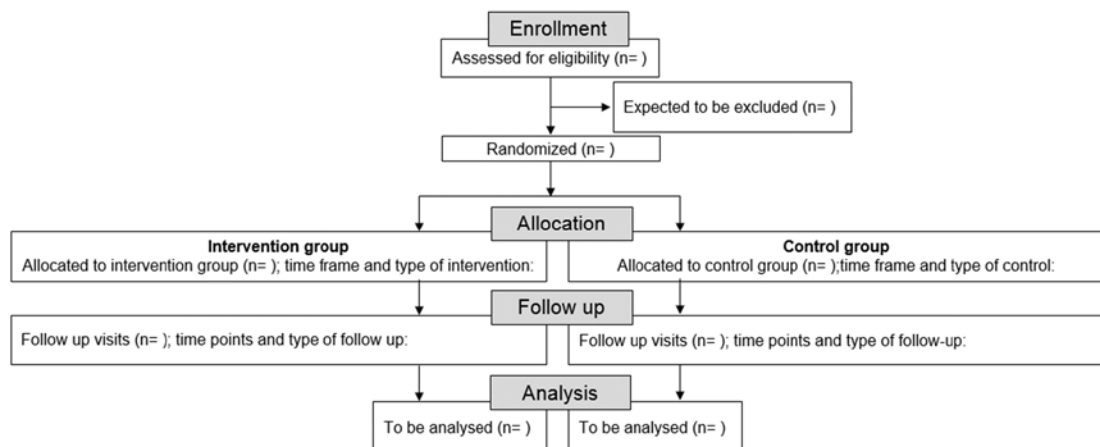
Statistical analysis	Statistical methods used to compare groups for primary and secondary outcomes: Methods for additional analyses, such as subgroup analyses and adjusted analyses:
Sample size	To be assessed for eligibility: (n =) To be assigned to the trial: (n =) To be analysed: (n =)
Participating sites	How many centres/sites will be involved and where are they located? No. of cities to be involved: No. of centres to be involved: Names of cities and centres:
Previous DFG project number	If applicable, provide the DFG project number of any previous proposal(s) for project funding concerning this trial.
Submission of proposal elsewhere	Please indicate whether the same or a similar version of the proposal is currently being submitted to another funding organisation.

2 Proposal History

- Briefly describe whether previous proposals (draft or full proposals) relating to this trial have been submitted to this programme.
- What important changes have been made with regard to previous versions or in response to reviewers' comments?
- Use this section also to comment on reviewers' suggestions and critiques. Separate rebuttal letters are not allowed.

3 Trial Design

- Provide a schematic diagram that describes the trial design, intervention(s)/observations and procedures. The diagram below represents an example of an interventional trial as recommended by CONSORT.



4 Medical Problem and Relevance

- Describe the medical problem in terms of prevalence, incidence, mortality and burden of the disease.
- What therapy options are available for treatment of the disease?
- What research question arises from the medical problem that will be addressed in the trial?
- What is the novel aspect of the proposed trial?
- What impact will the results have in terms of relieving the burden of disease and/or improving human health? That is, how will the individual patient and the patient population benefit from the trial?
- What impact will the results have on clinical practice?

5 Patient Involvement

- How have patients or their respective organisations been involved in planning the trial?
- What effect did patient involvement have on planning and designing the trial?

6 Evidence

6.1 Search Strategy

- Describe how you searched for the evidence. Indicate which databases were searched (such as DRKS, Clinicaltrials.gov, Cochrane, Medline). Include search terms, limits, date of search and time period covered.

6.2 Discussion of Evidence

- Cite and discuss the related literature and findings from e.g. relevant systematic review(s), (your own) pilot studies, feasibility studies, relevant previous/ongoing trials and case reports/series.
- Unpublished data should also be briefly summarised here.
- Use the existing evidence to put your trial into perspective and to substantiate your hypothesis.
- Justify why the pilot data is sufficient to plan a larger-scale confirmatory trial.

7 Justification of Design Aspects

7.1 Observational Trial, if Applicable

- If you are applying for an **observational trial** under this programme, justify your choice of an observational design and explain why an interventional design cannot be used to address your research question.

7.2 Control(s) / Comparator(s)

- Justify the choice of control(s)/comparator(s).

7.3 Participants / Study Population

- Justify the population to be studied, i.e. the selected inclusion and exclusion criteria, and include reflections on generalisability and representativeness.

7.4 Treatments / Procedures

- Justify and describe the chosen treatments/procedures (intervention, dose and mode of application) that will be compared in your trial.
- Justify the duration of treatments/procedures and follow-up per patient.

7.5 Outcome Measures

- Justify the endpoints chosen.
- Have the endpoints been validated in other clinical trials?
- Are standardized / core outcome sets included in the endpoints chosen? If not, please justify.
- Are there any guidelines proposing this endpoint/these endpoints?
- Discuss the clinical relevance of the outcome measures for the target population or the individual patient.
- Justify the mode of and rationale for data collection.

7.6 Methods Against Bias

- Name and discuss potential sources of bias.
- Justify your strategy to prevent bias by addressing randomization and blinding as well as potential trial-site effects and differences in expertise of persons executing treatments.

- If randomization and/or blinding is not feasible, explain why.
- For **observational trials**, describe how you aim to prevent bias in the selection and matching of patients. Consider confounders and their influence. List further sources of bias that apply to your trial (e.g. trial-site effects) and describe your strategy to address them.

7.7 Proposed Sample Size / Power Calculations

- What is the proposed sample size and what is the justification for the assumptions underlying the power calculations?
- Include a comprehensible, checkable description of how sample size was calculated.
- Detail outcome measures, event rates, means and medians, the software used for sample size calculation, etc., as appropriate.
- Take anticipated rates of non-compliance and losses to follow-up into account.

7.8 Feasibility of Recruitment / Access to Study Population

- What is the evidence that the intended recruitment rate or access to study population is achievable (e.g. pilot data)?
- Describe the data from which you have assessed the potential for recruiting/accessing the required number of suitable subjects.
- Comment on the occurrence of the disease, the access to patients and their willingness to take part in a trial, especially when randomized.

8 Statistical Analysis

- What is the proposed strategy of statistical analysis?
- What is the strategy for analysing the primary outcome? If applicable, how will multiple primary endpoints be analysed statistically?
- If interim analyses are planned, please specify.
- Will there be any subgroup analyses?
- How will missing data and/or subjects who have withdrawn from the trial be handled statistically?
- For **observational trials**, describe how the influence of confounding variables will be addressed in the statistical analysis.

9 Ethical Considerations

- Discuss briefly the acceptability of the risk incurred by the individual participant versus the potential benefit for the participant/population concerned.

10 Project-Related Publications by Applicant(s) and Co-Applicant(s)

- Please list up to ten of your most significant publications that relate directly to the proposed project and document your preliminary work regarding the planned trial. This list serves as an important basis for assessing your proposal.
- Please structure the list as follows:
 - a) articles which at the time of proposal submission have been published or officially accepted by publication outlets with scientific quality assurance, listed in standard format; book publications
 - b) other publications
- You may also list an unlimited number of patents, divided into the categories pending and issued. Please note the maximum number of works you may list under a) and b) combined. Please note the Guidelines for Publication Lists:

www.dfg.de/formulare/1_91

11 Budget Summary

- Please give a rough estimate of the costs expected for the entire duration of the trial and the funding period currently applied for.

Item	Amount for entire trial (€)	Amount for current funding period (€)
Clinical project management		
Project management		
Case payments		
Data management		
Biostatistics		
Quality assurance		
Travel		
Materials		
Trial drugs		
Fees and insurance		
Other		
Total (€)		

12 Commercial Interest

- Describe any potential commercial interest of a company in the results of the trial or explain why no such interest exists. Please note that proposals for trials whose outcomes are of direct commercial interest to a company are not eligible for funding.
- Is the trial drug or the therapeutic, diagnostic or prognostic procedure that is the object of this trial under patent protection?

Yes, until (date): No

If yes, please specify.

13 Co-Financing of the Trial by a Company or Other Third Party

Yes, until (date): No

If yes, please specify.

14 Cooperation with Other Researchers

- This information will assist the DFG Head Office in avoiding potential conflicts of interest during the review process.

14.1 Researchers with Whom You Have Agreed to Cooperate on This Project

14.2 Researchers with Whom You Have Collaborated Scientifically within the Past 3 Years

15 Bibliography

- In this bibliography, list only the works you cite in your presentation of the state of the art, the research objectives, and the work programme.
- This bibliography is not the list of your own project-relevant publications (see above).
- For further information, see the Guidelines for Publication Lists.

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Do not exceed a maximum of 8 pages including headings 1 to 15.