Proposal Preparation Instructions

Clinical Trials Programme – Proposals

Deutsche Forschungsgemeinschaft
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Please write your proposal in English and use the Proposal Template, headings 1 to 20 (DFG form 53.14).

www.dfg.de/formulare/53_14

Please submit the following documents as separate PDF files:
The **proposal** (DFG form 53.14); it must not exceed 25 pages in total (up to 19 pages for sections 1 through 15 and up to 6 pages for sections 16 to 20). The template formatting must be retained. In particular, the font should not be smaller than Arial 11 point, with line spacing of no less than 1.2. For the synopsis, tables and the section Project- and subject-related list of publications, the font should not be smaller than Arial 9 point. Make an entry under each heading.

- An academic **CV** with a list of the most important scientific results for each applicant, co-applicant and statistician. Please insert all CVs in one document. The template provided (DFG form 53.200) must be used for this purpose.

  www.dfg.de/formulare/53_200_elan
- For further information on the publication list, see:

  www.dfg.de/formulare/1_91
- **Declarations of commitment by participating recruiting centres**. Please use the template provided at the end of this document for the declarations and insert all declarations in one document.

Applications that fail to comply with these requirements will not be considered for review.
The project information must contain a summary of the proposal in German and in English.

Proposals must be submitted electronically via elan.

elan.dfg.de/en

The maximum funding period is 3 years. A **renewal proposal** enables trials that have been designed to run for more than three years to apply for further funding.

1 Trial Synopsis

Applicant(s) / coordinating investigator(s)	List the name of the person who will apply for funding and assume responsibility for conducting the clinical trial. Two applicants may only be listed in exceptional cases, for example, if the duty to cooperate (DFG form 55.01) applies. ▪ **First name, last name, academic title** ▪ **Employment status** ▪ **Institution and department (complete name)** ▪ **Postal address** ▪ **Telephone/e-mail address** Each applicant should submit an academic CV with a list of the most important scientific results
Statistician	List the responsible statistician. ▪ **First name, last name, academic title** ▪ **Employment status** ▪ **Institution and department (complete name)** ▪ **Postal address** ▪ **Telephone/e-mail address** The statistician should submit an academic CV with a list of the most important scientific results
Co-applicant(s)	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. ▪ **First name, last name, academic title** ▪ **Institution and department (complete name)** ▪ **Postal address** ▪ **Telephone/e-mail address** Each co-applicant should submit an academic CV with a list of the most important scientific results
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	Specify the population to be studied. **Key inclusion criteria:** **Key exclusion criteria:**
Trial type	Please mark which clinical trial type you are applying for under this programme. **Feasibility study (interventional design only)**: ☐

	Interventional trial: ☐ **Observational trial**: ☐ If you have chosen an **observational trial**, please **justify** your decision briefly: **----------** 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. **Key elements:**
Is the approval of a competent federal authority necessary	No ☐ Yes ☐ Give reasons for your answer and briefly explain which federal authority's approval is to be obtained.
Treatments / procedures	Detail your trial design by describing the treatments/procedures (intervention, dose and mode of application) that will be compared. **Experimental intervention:** **Control intervention:** **Follow-up per patient:** **Duration of intervention per patient:**
Endpoint(s)	**Primary endpoint:** **Secondary endpoint(s):** **Assessment of safety:**
Trial duration	**First patient in to last patient out (months):** **Duration of the entire trial (months):** **Recruitment period (months):**
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, i.e. recruited: (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.

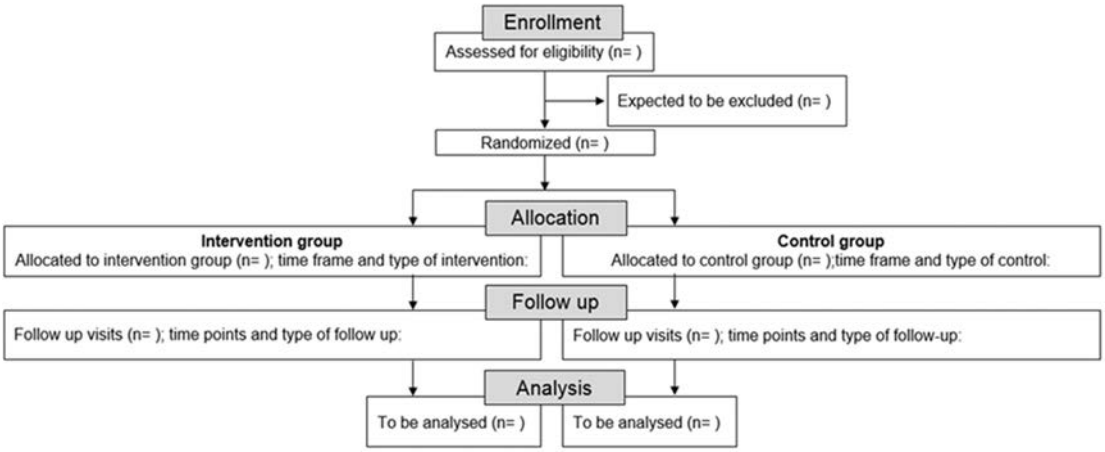
Submission of proposal elsewhere	Please indicate whether the same or a similar version of the proposal is currently being submitted to another funding organisation. Please note that when applying to this programme, parallel submission to other funding agencies is not allowed.

2 Proposal History / Project History

- Briefly describe whether previous proposals (draft or proposals) relating to this trial have been submitted to this programme and what important changes have been made with regard to previous versions or in response to reviewers' comments.
- For **revised proposals**, a separate five-page response letter (Arial 11 point) can be submitted to comment on reviewers' suggestions and critiques.
- For **renewal proposals**, describe the current stage of the trial with respect to the initially planned trial time flow.

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 Frequency and Scope of Trial Visits

- What is the proposed frequency and scope of patients' trial visits and, if applicable, the duration of post-trial follow-up? Give a schematic diagram or table.

- For **renewal proposals**, summarise all major changes concerning frequency and scope of patients´ trial visits implemented after start of funding.

5 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?

6 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?
- For **renewal proposals,** describe how patients or their respective organisations have been involved after start of funding.

7 Evidence

7.1 Search strategy and search results

- Describe how you searched for the evidence. Indicate which databases were searched (such as DRKS, Clinicaltrials.gov, Cochrane, and Medline). Include search terms, limits, date of search and time period covered.
- State the results of your database search by listing the number and type of hits per search term(s).

7.2 Discussion of evidence

- Cite and discuss the related literature and findings (e.g. proof-of-concept studies, pilot/feasibility studies, relevant previous/ongoing trials, systematic review(s), 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.
- For **renewal proposals**, has the evidence changes considerably since the start of the trial? If yes, what is the impact on the new evidence for the ongoing trial?

8 Justification of Design Aspects

8.1 Feasibility study, if applicable

- If you are applying for a **feasibility study** under this programme, please describe and justify to what extent the obtained results will provide important insights with regard to the planning and conduct of a subsequent larger-scale confirmatory interventional trial.

8.2 Observational trials, 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.

8.3 Control(s) / comparator(s)

- Justify the choice of control(s)/comparator(s).
- For **renewal proposals**, summarise and justify all major changes concerning the choice of comparators implemented after the start of funding.

8.4 Participants / study population

- Justify the population to be studied, i.e. the selected inclusion and exclusion criteria, and include reflections on generalisability and representativeness.
- For **renewal proposals**, summarise and justify all major changes concerning the study population implemented after the start of funding.

8.5 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.

- Justify how your **feasibility study** endpoints will inform a future larger-scale confirmatory interventional trial. Include thresholds and stop criteria.
- For **renewal proposals**, summarise and justify all major changes concerning treatments/procedures implemented after the start of funding.

8.6 Additional treatments

- Please describe the medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial, if applicable.

8.7 Outcome measures

- Justify the endpoints chosen.
- Have the endpoints been validated in other clinical trials?
- Are standardized/generally agreed 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.
- How will primary and secondary endpoints be derived from actual measurements?
- Justify the mode of and rationale for data collection.
- For **renewal proposals**, summarise and justify all major changes concerning outcome measures after the start of funding.

8.8 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 may apply to your trial (e.g. trial-site effects) and describe your strategy to address them.
- For **renewal proposals**, have there been any problems with the randomization procedure, cases of deliberate disregard of the randomization result, or cases of deliberate unblinding? If yes, please discuss their potential impact for the trial

results. Have any measures been implemented for prevention of further randomization or blinding issues?

8.9 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.
- For **renewal proposals**, has the sample size been recalculated after the start of funding? If yes, please describe reasons leading to recalculation and provide the new calculation.

8.9.1 Compliance / rate of loss to follow-up

- Provide details for assumptions on compliance issues. On what evidence are the compliance figures based?
- What is the assumed rate of loss to follow-up? On what evidence is the loss to follow-up rate based?
- How will losses to follow-up or non-compliance be handled in the statistical analysis?
- For **renewal proposals**, comment of the observed rates of non-compliance and drop out. Describe how this impacts the sample size and/or the planned analysis.

8.10 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/feasibility study)?
- 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.
- For **renewal proposals**, have there been any delays in recruitment so far? If yes, which measures were implemented to improve recruitment? Insert a recruitment graph to shows the current recruitment status. Use the graph to compare your current/actual recruitment rate to your originally planned recruitment rate.

8.10.1 Recruitment table

- Justify the numbers of eligible patients per trial site by filling in the table below.
- Please provide the signatures of the participating recruiting centres' main investigators on the declarations of commitment. The template for the declarations of commitment can be found at the end of this document.

Full name of Investigator	City and name of institution	No. of patients with relevant condition seen in the last 12 months fulfilling inclusion/exclusion criteria	Approx. no. of these patients who would agree to participate in the trial per year	Approx. no. of these patients who would be recruited during the entire trial
Sum of all patients expected to be recruited for the entire trial				

For **renewal proposals** use the table below:

Full name of Investigator	City and name of institution	No. of patients already included	Approx. no. of patients included per months in this site	Expected no. of patients to be recruited until end of trial
	Total:		Total:	

8.11 International trials, if applicable

- If the trial is part of an international trial, please state briefly which other countries are involved and how their funding is ensured. Full details of funding arrangements agreed or under consideration can be given in a separate document.
- Please detail the significance of the German component of the trial, both on its own and as part of the international trial.

9 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
- For **renewal proposals**, summarise and justify all major changes concerning the planned statistical analysis. Given the observed drop-out rates, are the planned methods for dealing with missing data still appropriate?

10 Ethical Considerations

- Discuss the acceptability of the risk incurred by the individual participant versus the potential benefit for the participant/population concerned.
- For **renewal proposals**, during conduct of the trial, have there been any events, which potentially change the initial safety and/or risk-benefit considerations?

11 Quality Assurance and Safety

11.1 Monitoring and data reviewing

- Describe and discuss the proposed measures for quality assurance (e.g. site monitoring and data reviewing, site selection/pre-trial visits).
- Describe and justify the monitoring strategy and provide the name of the institution that will perform the monitoring.
- Use the table below (11.2) to justify the amount of monitoring required for your trial.
- For **renewal proposals**, describe and justify if there are any reasons to change the monitoring strategy.

11.2 Intensity and Amount of Monitoring Required for Your Trial

Prediction for the intensity and amount of monitoring required for your trial	
No. of patients assigned to the trial	
No. of recruiting centres	
Average no. of patients per trial site	
Average no. of monitoring visits per trial site (site selection and close-out visits are excluded)	
No. of doctor's visits per patient during the course of the whole trial	
Expected number of AEs and SAEs	Please comment briefly:
Complexity of inclusion and exclusion criteria	Please comment briefly:

11.3 Involvement of independent experts

- Your trial must include an element of expert advice and supervision that is entirely independent of the applicant(s)/coordinating investigator(s) and the medical institution involved.
- Please comment on this envisaged expert advice and supervision by giving the name and affiliation of at least three people who are willing to serve as independent advisory board members (e.g. Data and Safety Monitoring Board, DSMB).

Independent experts		
#	**Name**	**Name of institution and city**
1		
2		
3		

11.3.1 Role of independent experts

- Use this heading to describe the role of the independent experts. For example, their role can comprise monitoring and supervising the trial's progress, reviewing relevant information from other sources, ensuring adherence to protocol, considering interim analyses, advising whether to continue, modify or stop a trial, and providing the DFG with information and advice.

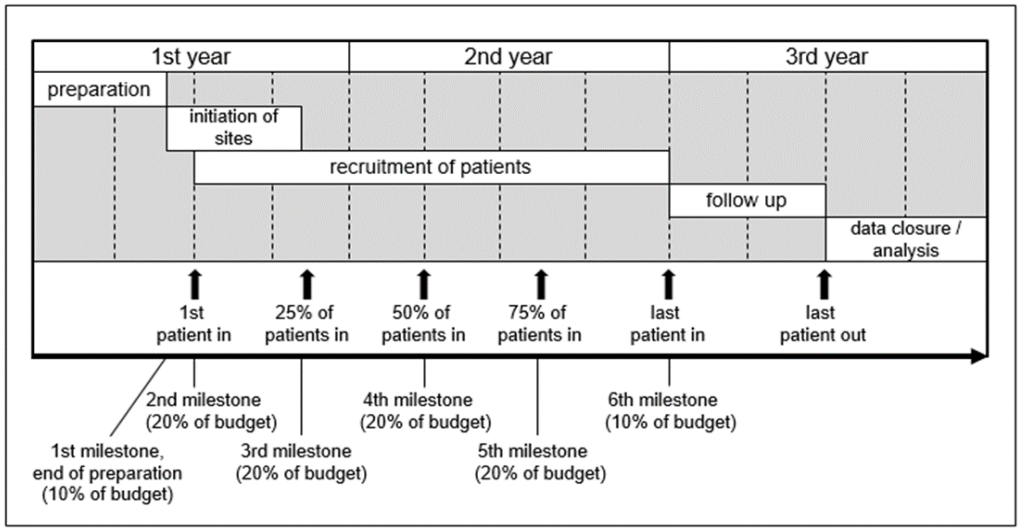
For **renewal proposals**, how many DSMB meetings have taken place, have there been any recommendations to change the trial or the trial conduct?

12 Trial Infrastructure

- Experience with conducting clinical trials is an important prerequisite for the success of a trial. Use this section to substantiate the main recruiting centres' experience in conducting clinical trials.
- Describe the available infrastructure of the main recruiting centres for conducting the clinical trial (e.g. trial-specific supporting facilities, Coordinating Centres for Clinical Trials (KKS), trial teams, opportunities for training trial staff) and thus substantiate why you have chosen to collaborate with them.

13 Trial Time Flow

- Funding by the DFG will critically depend on the trial progression according to milestones. Please provide a diagram reflecting the preparation, pre-trial visits to and initiation of centres, recruitment, follow-up and data cleaning/analysis. An example of such a diagram for a three-year trial is given below.
- As payments by the DFG will be made in instalments, please indicate the amount of funding required to reach each milestone.
- For **renewal proposals**, update the trial time flow if timelines and milestones have been changed as compared to the previous/initial proposal.



14 Strategies for Data Handling and the Dissemination of Results

- Describe what measures will be implemented to ensure data management, curation and long-term preservation for future re-use, also by third parties. Please take existing standards and data repositories into account where appropriate.

- Explain how the results of the trial will be disseminated, especially beyond regular journal publication.

- The DFG expects compliance with existing reporting guidelines (e.g. www.equator-network.org). Please indicate which of these guidelines will be followed.

15 Project- and Subject-Related List of Publications

This list of publications is used for general reference. This list should only contain the works you cited.

The font used for the publication list should not be less than Arial 9 point. For both new proposals and renewal proposals, you can refer to your own works and those of others; there is no limit to the total number of publications listed. Works which are not in the public domain are not considered publications and cannot be cited. An exception is made for papers that have already been accepted for publication, in which case the manuscript and the editor's confirmation of acceptance must be enclosed.

A maximum of ten of your own publications that are most relevant to the project can be highlighted in bold or some other way. Even if there are several applicants, the maximum of ten highlighted works may not be exceeded.

For further information, see the Guidelines for Preparing Publication Lists.
www.dfg.de/formulare/1_91

Sections 16-20 must not exceed 6 pages in total

16 List of Other Trial Participants

Name of trial sponsor		
Supporting facilities (central laboratories, pharmacies, etc.)		
Name	Name of institution and city	Responsibility/role
Other participating groups/bodies		
Name	Name of institution and city	Responsibility/role
Review of trial protocol		
Name	Name of institution and city	

17 Cooperation with Other Researchers

17.1 Researchers in Germany and abroad with whom you have agreed to cooperate on this project

List any researchers in Germany or abroad with whom you have agreed to cooperate on this project (other than collaboration with your host institution or host researcher as described in section 5). Any such agreements must be attached to the proposal.

17.2 Researchers with whom you have collaborated scientifically within the past three years

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

18 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.

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

☐ Yes ☐ No

If yes, please specify.

If co-financing (provision of funds, free services or consumables) is intended, the proposal should briefly describe the type and volume of the intended co-financing, including the name of the respective company or other third party.
Co-financing by industry or other third parties is possible if the applicant(s)/coordinating investigator(s) is/are independent, in particular with regard to the design, the conduct and the analysis of the trial as well as the publication of its results, and if the scientific independence of the investigators is ensured. A Material Transfer Agreement (MTA) must be drawn up in such cases and submitted to the DFG for approval before funding can be granted.
For scientific collaborations with commercial enterprises (DFG form 41.026) or not-for-profit private institutions (DFG form 41.026a), a cooperation agreement must be drawn up and submitted to the DFG for approval before funding can be granted.

20 Financial Details of the Trial

- List the approximate amount of funding (excluding overhead) needed for the entire duration of the trial as well as for the current funding period.

Amount for entire trial (€)	
Entire duration of the trial (months)	
Amount for the current funding period (€)	
Duration of the current funding period (months)	

20.1 Budget summary (for the current funding period)

- To request funding for the **current funding period**, fill in the relevant **white fields (only)** in the table below. Sum up the cost wherever useful. Do not include overhead. Staff funding requested from third parties, e.g. KKS, please do not list under 20.2.1 Funding for Staff, but under Other costs. You may delete headings that are not applicable and the examples in italic font.
- For listing staff, use the DFG Personnel Rates as categorised in DFG form 60.12.
  www.dfg.de/formulare/60_12

20.2.1. Funding for staff	DFG staff category[1] (e.g. postdoctoral researcher)	Amount	Percentage of full-time position	Duration (in months)	costs €
a. Clinical Project Management					
e.g. clinical project manager					
e.g. study nurse					
b. Project Management					
e.g. project manager					
c. Data Management					
e.g. data manager					
d. Biometry					
e.g. biometrician					
e. Monitoring/ Quality Assurance					
e.g. monitor					
f. Pharmacovigilance					
e.g. regulatory affair manager					
g. Other Staff					
…					
Total costs funding for staff					

20.2.2. Direct project costs	Specification	costs €
a. Equipment up to €10,000 and consumables		
Total costs for a.		
b. Travel expenses		
e.g. for scientific meetings		
e.g. travel expenses for monitoring		
Total costs for b.		
c. Visiting researchers		
Total costs for c.		
d. Other costs:		
e.g. third-party contract	*e.g. contract KKS*	
e.g. case payments		
e.g. fees		
e.g. trial medication		
…		
Total costs d.		
e. Project-related publication expenses		
Total costs e.		

20.2.3. Instrumentation	Specification	costs €
e.g. Equipment exceeding €10,000		
e.g. Major instrumentation exceeding €50,000		

20.2.4. Replacements	Specification		costs €

20.2.5 Temporary substitutes for clinicians	**Specification**	**Percentage of full-time position**	**Duration (in months)**	**costs €**
20.2.6. Mercator Fellows	**Specification**			**costs €**
20.2.7 Project-specific workshops	**Specification**			**costs €**
20.2.8. Public relations	**Specification**			**costs €**
Total amount for current funding period €				

20.2 Detailed budget plan (for the current funding period)

- Based on the budget summary above, provide a **detailed budget plan for the current funding period** to explain and justify the requested items and amounts.
- Under each heading, list each item and the costs per item, and provide a short explanation/justification.
- **In the detailed budget plan, you may delete headings that are not applicable.**

20.2.1 Funding for staff

- Subdivide the staff necessary for your trial into the following organisational segments: Clinical Project Management, Project Management, Data Management, Biometry, Monitoring/Quality Assurance, Pharmacovigilance.
- Under each organisational segment, list the staff categories (e.g. postdoctoral researcher or comparable) you wish to apply for and specify their tasks. Use DFG form 52.01 Basic Module for further information on possible staff categories.

  www.dfg.de/formulare/52_01
- The DFG generally grants funding for staff in the form of standard amounts. For specific rates and further details on the staff categories, please see the following overview.

  www.dfg.de/formulare/60_12

a. Clinical Project Management

b. Project Management

c. Data Management

d. Biometry

e. Monitoring/Quality Assurance

f. Pharmacovigilance

g. Other Staff

20.2.2 Funding for direct project costs

- If you wish to apply for direct project costs, please use DFG form 52.01 Basic Module for further information.
  www.dfg.de/formulare/52_01

a. Equipment up to €10,000, software and consumables

- Use this heading for equipment up to €10,000, software and consumables. Consumables may include costs for trial manuals, files and forms. List each item and the costs per item. Summarise items wherever useful.
- Third-party contracts and user fees for major instrumentation and core research facilities can be requested under “d. Other costs”.

b. Travel expenses

- Use this heading for travel expenses. Travel expenses can include costs for scientific meetings of investigators, independent experts and DSMB members as well as attendance by applicant(s) at scientific conferences. List each meeting, the number of persons involved and the travel expenses per person including travel and maintenance.
- Travel expenses for monitoring/quality assurance can also be claimed here by listing the amounts of monitoring visits per trial site, the number of trial sites and the average costs per visit. A justification for the amount of the monitoring necessary in your trial needs to be provided as well.

c. Visiting researchers (excluding Mercator Fellows)

- If necessary for your project, you can invite other researchers as guests. For this purpose, you may request an allowance to cover transportation and maintenance. Honoraria can only be funded in exceptional cases if it can be assumed that the guests are not participating to further their own careers or research.

d. Other costs

- Here you may request project-specific funds for purposes not included in any of the other categories, such as third-party contracts, documentation services, fees for the ethical approval and for legal authorities, insurance, case payments, trial medication and laboratory costs (e.g. blood sample analysis). List each item and the costs per item. Summarise items wherever useful.

- Costs for case payments must be broken down plausibly under this heading on about half a page, using the example of one patient. Please distinguish between staff and direct project costs. In addition to stating the case payment for one patient, also specify the total amount of case payments for all patients.
- Funding may also be requested for user fees for major instrumentation and core research facilities. The DFG can only cover such costs that are required specifically for the project. Basic funding for the individual instruments or core facilities must be financed through the institution's core support. Further information can be found in DFG form 55.04, available in German only.

  www.dfg.de/formulare/55_04

e. Project-related publication expenses

- The DFG may contribute up to €750 per year towards publishing the findings of a project. Publications may be in any form, with the exception of grey literature.

20.2.3 Instrumentation

- If you wish to request funding for instrumentation, please use the DFG form 52.01 Basic Module for further information.

  www.dfg.de/formulare/52_01

  a) Equipment exceeding €10,000

  b) Major instrumentation exceeding €50,000

20.2.4 Replacements

- If your project requires that you be released from teaching or administrative duties, you can use this module to request funding for a replacement to take over these responsibilities.

  www.dfg.de/formulare/52_03

20.2.5 Temporary substitutes for clinicians

- If this project requires that clinicians conduct research, you can use this module to request funding for temporary substitutes to take over their patient-care responsibilities.

  www.dfg.de/formulare/52_04

20.2.6 Mercator Fellows

- This module enables you to pursue an intensive and long-term exchange with researchers in Germany and abroad. Fellows will partially be on site but will remain in contact with you even after their stay.

  www.dfg.de/formulare/52_05

20.2.7 Project-specific workshops

- If you would like to conduct workshops as part of your project, you may request funding to help you do so.

  www.dfg.de/formulare/52_06

20.2.8 Public relations

- To enable you to present your work to the general lay public, you can request funding for public relations.

  www.dfg.de/formulare/52_07

20.3 Additional funding

- Mention any funding proposals for this project and/or major instrumentation previously submitted to a third party.
- If this does not apply, please declare: “A request for funding of this project has not been submitted elsewhere. If I submit such a request, I will inform the DFG immediately.”

20.4 Contribution by the institution regarding staff and consumables (Core Support)

- Please indicate the names, academic titles and employment grades of participating scientists and the number of technical employees who will be working on the project but will not be funded through the DFG grant.

- Please state the annual amount for consumables and available supporting infrastructure (Grundausstattung) provided by the medical institution(s). Use estimates where applicable.

21 Considerations on aspects of ecological sustainability in the planning and implementation of the project

In research as well, there is an urgent need for a further shift towards sustainable practices. Use this space to reflect on how sustainability considerations are taken into account in the research processes proposed. Here, you are expected to provide a brief statement that refers specifically to the work programme to be undertaken in this project. Research quality is the pivotal factor for the funding decision, however, so this is the priority in terms of planning the research; for this reason, resource-saving and emission-reducing measures should not result in restrictions in the desired knowledge gain. If increased funding is required due to more sustainable research approaches, this can be taken into account when applying for funds. For further information, see the cross-disciplinary catalogue of guiding questions at:

www.dfg.de/reflection_sustainability.

Do not exceed the maximum of 25 pages including headings 1 to 20.

Declarations of commitment by participating centres

Please use the template provided here to declare the commitment of each participating centre (including the centre of the applicant(s)/coordinating investigator(s)). The template must be signed personally by the investigator at the respective site (as named in the table of heading 8.10.1 of the proposal).

Name of investigator	
Institution	

Information on the clinical trial (must be in accordance with the proposal)

Trial title	
Inclusion criteria	
Exclusion criteria	
Recruitment period (months)	

Strategy for the determination of recruitment figures

How many patients with the condition specified above have you seen in your institution during the last 12 months?	
How many of these patients would fulfil the inclusion criteria of the above-mentioned trial?	
Approximately how many of these patients would agree to participate in the above-named clinical trial per year?	
Approximately how many patients will be recruited during the entire trial?	
Trials currently recruiting at this institution (please provide the total number and registration no. of trials)	
No. of patients this institution has recruited to the above-mentioned trials during the last 12 months	

Which source did you use to estimate potential participants in the above-named clinical trial?

☐ Individual estimate

☐ Hospital data management system

☐ Patient registry

☐ Other

If other, please specify.

Are there any other ongoing clinical trials/projects competing for the same patients?

☐ Yes ☐ No

If yes: How will this affect recruitment for the above-named clinical trial?

Note: Reported recruitment will be checked if funding is provided (site selection visits). If inconsistencies exist between the estimated and verified numbers, the applicant(s)/coordinating investigator(s) will be asked to address this issue accordingly.

Commitment to participate

I hereby agree to participate in the above-named clinical trial and to support the trial by recruiting patients.

_____

Date / Signature

Conflicts of interest (Any conflicts of interest must be disclosed here.)

I hereby declare that I have no conflict of interest with regard to the above-mentioned clinical trial and the investigational drugs that will be used.

_____

Date / Signature