

Guidelines

Clinical Trials Programme



I Programme Information

1 Objective

The Clinical Trials Programme enables individuals who have completed their academic training to conduct, at any time, patient-oriented clinical research within a temporary project.

The programme provides funding for **interventional clinical studies**, including **feasibility studies**¹ and **interventional trials**.² The aim is to prove the efficacy of a therapeutic, diagnostic or prognostic method. For all studies, high scientific quality and originality as well as clinical relevance are required.

The programme also funds **observational trials**, provided that the study investigates a highly relevant research question that cannot demonstrably be answered using an interventional design.

Funding is not available for studies involving direct commercial interest or a patent-protected investigational agent or method.³

1.1 Explanatory notes on the types of studies

1.1.1 Feasibility studies

The aim of a feasibility study is to provide initial evidence of the efficacy of a method as well as to examine the feasibility of a subsequent interventional trial. The method can be therapeutic, diagnostic or prognostic in nature. In terms of feasibility, possible reasons for applying for funding include the validation of the intervention (e.g. dose finding), the operationalisation of the endpoints, the assessment of the effect size and the sample size, the assessment of the practicability of the randomisation procedure, and the investigation of the planned study design. The proposal must clearly show how the feasibility study will serve as the lead-up to a subsequent interventional trial. Feasibility studies must be prospective and include a control group, a randomised allocation of

¹ In terms of drug trial phases, these are phase II trials.

² In terms of drug trial phases, these are phase III trials.

³ Exceptions may be possible in certain individual cases. Upon request, the DFG Head Office can determine in advance whether such an exception can be made.

patients, and sample size calculations. Monocentric studies are possible. The grant amount may generally not exceed €350,000 per study.

A prerequisite for the funding of a feasibility study is preparatory work with human subjects, conducted by applicants or third parties, on the mechanism of action of the method to be investigated.

Studies seeking to establish a new method or investigate a mechanism of action are not eligible under this programme. Funding for such studies is available under the Research Grants Programme.

Information on the Research Grants Programme can be found at:

www.dfg.de/research_grants

1.1.2 Interventional trials

The aim of an interventional trial is to provide significant proof of the efficacy of a method. Interventional trials include therapeutic trials, such as pharmaceutical trials, prognostic trials and diagnostic trials, in which patients are randomly assigned to different intervention groups. Trials must be prospective and confirmatory.⁴ Due to the large sample size, several centres/sites must be involved in recruitment. Monocentric studies are eligible only in justified exceptional cases.

A prerequisite for the funding of an interventional trial is initial evidence of the efficacy of the method being investigated (from feasibility studies and/or pilot studies conducted by applicants or third parties) as well as cogent preparatory work on the effect size and the sample size, the practicability of the randomisation procedure and the investigation of the planned study design. The preparatory work must justify the undertaking of a confirmatory and correspondingly large-scale interventional trial.

1.1.3 Observational trials

The aim of an observational trial is to compare therapeutic, diagnostic or prognostic methods in a non-interventional design. Trials are subject to a pre-defined observation

⁴ These are trials with the aim of providing a significant proof of efficacy with an appropriate number of cases.

plan⁵, but treatment of the patients may be carried out according to medical or psychotherapeutic practice. Since the significance and the controllability of observational trials, in contrast to interventional trials, can be very limited, they can only be funded if the proposal convincingly shows why an interventional, randomised approach is not possible. Legitimate reasons include, in particular, ethical considerations. Trials must be prospective and confirmatory⁶ and include a control group. Due to the large sample size, several centres/sites must be involved in recruitment. Monocentric studies are eligible only in justified exceptional cases.

A prerequisite for the funding of an observational trial is initial evidence of the efficacy of the method being investigated (by applicants or third parties) as well as cogent preparatory work on the choice of study design, justifying the need for a large-scale observational trial.

Exploratory and/or retrospective observational studies, epidemiological studies with the aim of examining the incidence and/or prevalence of diseases, reviews, meta-analyses, and studies focused purely on health economics are not eligible under the Clinical Trials Programme. Funding for such studies is available under the Research Grants Programme.

Information on the Research Grants Programme can be found at:

www.dfg.de/research_grants

⁵ Cf. Guidelines and Recommendations to Assure Good Epidemiologic Practice by the German Society for Epidemiology (DGEpi). <http://dgepi.de/berichte-und-publikationen/leitlinien-und-empfehlungen>

⁶ These are trials with the aim of providing a significant proof of efficacy with an appropriate number of cases.

2 Proposals

2.1 Eligibility

Researchers in Germany, or those working at a German research institution abroad, who have completed their academic training (a doctorate as a rule) are eligible to apply.

In general you are not eligible to submit a proposal if you work at an institution that is not non-profit or one that does not allow immediate publication of research findings in a generally accessible form.

Researchers who are employed at one of the institutes or member organisations of the Max Planck Society, Fraunhofer Society, Helmholtz Association or Leibniz Association, researchers working at a publicly funded institute associated with one of these organisations, and researchers working at international research facilities located in Germany should note the rules on the duty to cooperate.

www.dfg.de/formulare/55_01

2.2 Format and deadline

Feasibility studies involve a *one-stage application process*. Full proposals must be submitted directly; they may be submitted at any time. Renewal proposals are not possible.

Interventional trials involve a *two-stage application process*. In the initial stage, draft proposals can be submitted at any time. Full proposals may be submitted only after explicit invitation by the DFG. The invitation will be based on a previously approved draft proposal.

If an interventional trial is proposed on the basis of a feasibility study funded under this programme, the submission of a draft proposal is not required. In this case, a full proposal can be submitted directly.

Observational trials also involve a *two-stage application process*. In the initial stage, draft proposals can be submitted at any time. Full proposals may be submitted only after

explicit invitation by the DFG. The invitation will be based on a previously approved draft proposal.

For **interventional trials** and **observational trials**, renewal proposals are possible. If a renewal proposal is submitted, the submission of a draft proposal is not necessary. Full proposals may be submitted directly. Renewal proposals should be submitted to the DFG no later than six months before the date on which the original grant is likely to be used up.

2.2.1 Draft proposals

Draft proposals can be submitted at any time via the **DFG's elan portal**.

<https://elan.dfg.de/en>

Draft proposals must be created using the appropriate template (DFG form 53.13).

www.dfg.de/formulare/53_13_elan

Explanations on the individual parts of the template can be found in the **Proposal Preparation Instructions: Clinical Trials – Draft Proposals** (DFG form 17.03).

www.dfg.de/formulare/17_03

Applicants as well as co-applicants, including the statistician, must also submit a **two-page scientific curriculum vitae** including a list of their most important publications (up to ten). Listed publications need not be related to the proposed project. The purpose of the curriculum vitae and the publication list is to substantiate your scientific expertise, especially with regard to clinical trials.

Guidelines for publication lists:

www.dfg.de/formulare/1_91

Draft proposals that do not conform to these guidelines will not be forwarded for review. In addition, proposals that exceed the specified number of pages and those in which signatures have been omitted will also be excluded from further processing.

2.2.2 Full proposals

Full proposals must be submitted electronically via the DFG's elan portal.

<https://elan.dfg.de/en>

Full proposals must be created using the appropriate **template** (DFG form 53.14).

www.dfg.de/formulare/53_14

Explanations on the individual parts of the template can be found in the **Proposal Preparation Instructions: Clinical Trials – Full Proposals** (DFG form 17.02).

www.dfg.de/formulare/17_02

Please submit the following documents as separate PDF files: (I) the **full proposal**, (ii) the **scientific curricula vitae** of the applicants and co-investigators, and (III) the **declarations of commitment** by the participating centres.

The **two-page scientific curricula vitae** must include the most important publications (up to ten). Listed publications need not be related to the proposed project. The purpose of the curriculum vitae and the publication list is to substantiate your scientific expertise, especially with regard to clinical trials.

Guidelines for publication lists:

www.dfg.de/formulare/1_91

For **declarations of commitment** by the participating centres, please use the template at the end of the full proposal.

www.dfg.de/formulare/17_02

Full proposals that do not conform to these guidelines will not be forwarded for review. In addition, proposals that exceed the specified number of pages and those in which signatures have been omitted will also be excluded from further processing.

3 Duration

The funding duration for **feasibility studies** is a maximum of 36 months; renewal proposals are not possible.

The funding duration of **interventional trials** and **observational trials** is initially 36 months. For longer studies, a renewal proposal may be submitted subsequently.

II Proposal Modules

Under the Clinical Trials Programme, you may submit one or more of the following modules. For more details, please see the respective guidelines for each module.

1 Basic Module

Use the basic module to request funding for direct project costs, project-specific staff, and instrumentation necessary to carry out the project.

www.dfg.de/formulare/52_01

2 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

3 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

In combination with at least one of the modules above, you may also submit one or more of the following modules:

4 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

5 Project-Specific Workshops

If you would like to conduct workshops as part of your project, you may request funding to help you do so. Please note that this module cannot be submitted separately but only in conjunction with the proposed research project.

www.dfg.de/formulare/52_06

6 Public Relations

To enable you to present your work to the general lay public, you can request funding for public relations. Please note that this module cannot be submitted separately but only in conjunction with the proposed research project.

www.dfg.de/formulare/52_07

III Special Provisions

1 Requirements following grant approval

Following an approval, the following documents must be submitted to the DFG:

- vote of the local ethics committee, with involvement of the ethics committees responsible for the other participating sites
- commitment to adhere to good clinical practice (Verpflichtung zur Einhaltung der Guten Klinischen Praxis):
http://www.dfg.de/foerderung/programme/einzelfoerderung/klinische_studien/formulare_merkblaetter/
- registration of the trial in a public registry (e.g. drks-neu.uniklinik-freiburg.de/drks_web/ or ClinicalTrials.gov) and publication of the trial protocol/study plan or observation plan in the registry or a medical journal
- proof of the establishment of an independent data and safety monitoring board

2 Interim reports

Interventional trials and **observational trials** additionally require interim reports to be submitted every six months. Interim reports must be prepared using a **template** (DFG form 17.041).

www.dfg.de/formulare/17_041

Explanations on the individual parts of the template can be found in the **Preparation Instructions: Clinical Trials – Interim Report** (DFG form 17.04).

www.dfg.de/formulare/17_04

3 Final reports

Final reports must be prepared according to the **Guidelines for Final Reports** (appendix to DFG form 2.00).

www.dfg.de/formulare/2_00

The DFG accepts final reports only if the findings of the trial were published within two years after the end of the project.⁷

IV Obligations

In submitting a grant proposal for a clinical trial to the DFG, you agree to

1. adhere to the **rules of good scientific practice**.⁸

The general principles of good scientific practice include, among others: maintaining professional standards, documenting results, rigorously questioning all findings, and attributing honestly any contributions by partners, competitors and predecessors.

Scientific misconduct is defined as the intentional and grossly negligent statement of falsehoods in a scientific context, the violation of intellectual property rights or impeding another person's research work. The circumstances of each case will be considered on an individual basis. In cases where scientific misconduct has been established, the DFG may impose one or more of the following sanctions, depending on the nature and severity of the scientific misconduct:

- issuing a written reprimand to those involved;

⁷ Publications should usually be in a medical journal. However, other types of publications of the findings are also accepted, e.g. in publicly accessible databases (such as trial registries).

⁸ The rules of good scientific practice are presented in detail in the white paper entitled *Safeguarding Good Scientific Practice* and in the *Funding Guidelines – General Terms and Condition of DFG Grants* (DFG form 2.00).

- exclusion from the right to apply for DFG funds for a period of one to eight years, depending on the severity of the scientific misconduct;
- revoking funding decisions (complete or partial cancellation of the grant, recalling granted funds, demanding repayment of funds spent);
- demanding that those concerned either retract the discredited publications or correct the falsified data (in particular by publishing an erratum), or appropriately indicate the DFG's retraction of funding in the discredited publications;
- exclusion from acting as a reviewer or from membership in DFG committees for a period of one to eight years, depending on the severity of the scientific misconduct;
- denying voting rights and eligibility in elections for DFG statutory bodies and committees for a period of one to eight years, depending on the severity of the scientific misconduct.

By accepting funding, the recipient agrees to

2. use the grant exclusively and in a targeted manner to realise the funded project. The use and accounting of funds must conform to the relevant regulations of the DFG.
3. submit progress reports on the research according to the dates specified in the award letter and to present financial accounts to the DFG detailing the use of funds.

The DFG expects that the findings of the projects it funds be made available to the public.

V Publication of Data on Grant Holders and Research Projects

The data necessary for processing your proposal will be stored and processed electronically by the DFG.

By submitting a proposal you agree that, if the proposal is approved, your work address and contact details (name, institution and location, phone, fax, e-mail and website) as well as information about the content of the project (e.g. topic, summary, keywords, subject area, DFG programme, funding period, international connections) will be published in the GEPRIS information system

gepris.dfg.de/en

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and may be published in other, non-commercial publications and databases created in cooperation with the DFG.

You may withdraw your consent to full/partial publication at any time, without affecting the lawfulness of any processing carried out prior to your withdrawal. If you would like to withdraw your consent, please notify the responsible DFG programme contact, preferably in electronic form.