

Call for Proposals

Financing of regulatory consulting to promote translation of medical projects into the clinic

until 1st of October, 2025

A key challenge on the path from the laboratory to the clinic is the complex regulatory requirements that must be met for clinical trials to be approved. Numerous promising developments fail because project planning and preclinical study design are not aligned with regulatory requirements. Professional and early consultation with the relevant regulatory authorities – particularly in the form of an orientation (kick-off) meeting and/or a scientific advice meeting with the Paul Ehrlich Institute (PEI) or the Federal Institute for Drugs and Medical Devices (BfArM) – can be decisive in determining whether a project can be transferred to a first clinical trial (*first-in-human*) in a timely and successful manner. Without professional support in preparing and conducting scientific advice meetings with these authorities, crucial regulatory requirements are often not identified in time, which can lead to delays or even the failure of promising projects.

Aim of the call

In order to provide targeted funding for regulatory consulting services for translational projects in the field of drug development or medical technology, ForTra is making up to €100,000 available for each project selected by an external panel of experts. The aim is to prepare the project leaders optimally for an orientation meeting and/or a scientific advice meeting with the PEI or the BfArM and to accompany them to these 'pre-IND' meetings.

Funding conditions

Who can apply?

Clinician and medical scientists who work at a non-profit research institute (e.g. university, university hospital, Max Planck Institute, etc.) are eligible to apply. The projects should be at an advanced stage of development (preferably with initial preclinical data) and aim to bring a new drug or medical device into clinical trials.

What is funded?

Only the costs of the research institute for professional regulatory advice, including the preparation, implementation and follow-up of orientation (kick-off) meetings and scientific advice meetings with the regulatory authorities will be funded. The consulting firms should provide comprehensive support to the project leaders and accompany them to the meetings. In this way, the necessary preclinical data and other requirements for the planned clinical trial should be clarified at an early stage and in a professional manner, and project development should be optimised accordingly. Concrete order offers from the consulting firms do not need to be enclosed with the application, but a realistic cost estimate is required.

What is not eligible for funding?

Funding covers only costs incurred in connection with orientation meetings (kick-off meetings') and scientific advice from the relevant regulatory authorities. No funding will be provided for other project costs (e.g. for research, personnel, materials or clinical trials). These may, under certain circumstances, be applied for separately following the consultation with the regulatory authority as part of the normal ForTra funding procedure.

Selection process

The projects to be funded will be selected by an independent panel of experts. The decision on funding relates exclusively to the consulting services advertised here and does not constitute an assessment or preliminary decision on the overall eligibility of the project for funding.

Application

Applications must be submitted electronically to ForTra at:

antrag@fortra-forschungstransfer.de

They may be no longer than 8 pages and should include the following points:

- Project description and current state of development
- Objectives and relevance of the planned orientation and / or scientific advice meeting
- Selection and justification of the consulting firm
- Cost estimate for the planned consulting services
- Schedule and milestones
- Separate compilation of the applicants' CVs and publication lists, together with a list of patents and patent applications relevant to the project

ForTra gmbH for Research Transfer of the Else Kröner-Fresenius-Stiftung (ForTra)

ForTra is a non-profit subsidiary of the Else Kröner-Fresenius-Stiftung under German tax law and aims to accelerate the transfer of excellent medical research results into clinical application. ForTra particularly supports the transfer of innovative approaches from preclinical research into early clinical development in order to maximise patient benefit and close the translational gap.

Contact ForTra

Prof. Dr. Martin Zörnig

Managing Director ForTra

Rathausplatz 3-7 | 61348 Bad Homburg v. d. Höhe

m.zoernig@fortra-forschungstransfer.de, Tel.: 06172-8975-12