

**EXPLORING NEW FRONTIERS**

**CULTIVATING TALENTS**

**REALISING NEW IDEAS**

**FWF**

Der Wissenschaftsfonds.

## **Invitation to Tender**

Evaluation  
FWF Programme for Clinical Research (KLIF)

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22 December 2021

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## 1. Client and Awarding Office

Austrian Science Fund (FWF)  
Sensengasse 1, A-1090 Vienna, Austria  
Phone: +43-1-5056740-0 Fax: +43-1-5056739  
[www.fwf.ac.at](http://www.fwf.ac.at)

Contact person: Dr. Elisabeth Nindl, +43-1-5056740-8664, [elisabeth.nindl@fwf.ac.at](mailto:elisabeth.nindl@fwf.ac.at)

This invitation to tender has been prepared in accordance with (i) the [FWF Rules](#) on Quality and Transparency for Evaluations and (ii) the [Evaluation Standards](#) in Research and Technology Policy developed by the Austrian Platform for Research and Technology Policy Evaluation ([fteval](#)). These standards are to be observed by companies and organisations submitting tenders.

### The FWF

The Austrian Science Fund (FWF) is Austria's leading organisation for the funding of basic research. The purpose of the FWF is to support the ongoing development of Austrian science and basic research at a high international level. In this way, the FWF makes a significant contribution to cultural development, to the advancement of our knowledge-based society, and thus to the creation of value and wealth in Austria. Further information on the FWF's responsibilities, and the values to which it is committed, can be found on the FWF's website at <https://www.fwf.ac.at/en/>.

## 2. Objectives of the Contract

The purpose of the contract to be awarded is to evaluate the FWF's Programme for Clinical Research ("*Initiative zur Förderung Klinischer Forschung*", KLIF). Specifically,

- to critically review the FWF's KLIF funding programme, to identify its strengths and weaknesses, and to quantify and qualify its output, outcomes, and potential impact pathways;
- to analyse and present the role of KLIF funding in the Austrian clinical research landscape, with the goal of delivering recommendations for optimal support of high-quality clinical research in Austria, starting from basic research to translating the results to later stages; and
- to provide evidence-based recommendations to the FWF and its supervisory boards on whether and how the KLIF programme should be continued, improved, or restructured.

The final evaluation report is expected to be delivered by Mid 2023 (see schedule below). It will serve as the basis for the further design of the KLIF programme.

### **3. Background**

The FWF programme for investigator-initiated clinical research (KLIF) aims at mobilising the clinical research potential in Austria by financing clinical research that is not in the direct interest of pharmaceutical firms and businesses.

While the pharmaceutical industry mainly finances studies on drug approval, the public will continue to demand that clinical research and related studies also be conducted independently of industrial interests. Research of a broad scope is needed, such as studies on how to optimise therapies (including surgical techniques), proof-of-concept studies, studies to compare and advance diagnostic techniques and therapeutic interventions or to test new indications for already approved drugs, as well as clinical epidemiological and non-interventional studies on topics related to prevention, prognosis, care, and nursing.

Moreover, the pressure on clinical researchers has grown over the past years due to increasing demands from the health system and new regulations on working hours, reducing the researchers' time and resources for research, and because of increasing administrative and regulatory requirements related to clinical trials. As a consequence, many researchers lack the operational resources to manage such projects effectively and successfully.

The FWF aims to meet societal demands and respond to the needs of researchers by funding investigator-initiated clinical trials (IIT). IIT are understood as clinical studies that are initiated by researchers and seek to gain new scientific knowledge or insights for the improvement of clinical practice and the treatment of patients. These studies develop potential diagnostic, prognostic, and therapeutic innovations that are not bound to commercial interests and may even run contrary to them. IIT thus usually exhibit a much broader scope with more wide-ranging clinical potential compared to industry-led clinical trials.

Against this background, the FWF designed, in close cooperation with international experts, a first experimental call that was launched in 2010. In order to identify funding gaps in clinical research and to define the appropriate scope of projects, two more targeted calls were carried out in 2011/2012 and 2012/2013. In 2014, the FWF finally introduced KLIF as a designated programme for clinical research, applying specific standards for the application and review processes, which have been further elaborated since the first experimental call.

In the period from 2011 to 2020, the KLIF programme funded a total of 126 investigator-initiated clinical trials (out of 912 proposals) with a funding volume of over €32 million.<sup>1</sup> The average award has a volume of €400,000 and a duration of 36-48 months.

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<sup>1</sup> The evaluation will be able to include the results of the 2021 funding period. The data can be obtained from the FWF's statistics dashboard: [dashboard.fwf.ac.at/en/](https://dashboard.fwf.ac.at/en/)

## **Mission**

The aim of the KLIF programme is to fund investigator-initiated clinical trials (hereinafter referred to as “projects”) that involve patients or healthy volunteers and aim at gaining new scientific knowledge about clinical manifestations, improvements in clinical practice, new or modifiable therapeutic approaches, or improved treatment of patients. In the long term, the KLIF funding provided by the FWF should contribute to the overall enhancement of clinical research in Austria and promote the training of highly skilled personnel in this area.

## **Objectives of the KLIF programme**

1. Improve independent academic clinical research in Austria
2. Expand the numbers of highly qualified personnel in clinical research
3. Raise the standing of academic clinical research in general

A specific characteristic of the FWF’s approach is that the choice of research topics is entirely investigator driven. The FWF uses its financial and administrative support to increase the potential for ground-breaking fundamental research to occur rather than as means to promote specific research topics. This bottom-up principle is consequently also applied to the KLIF programme, with the funding decisions being made by the [FWF Board](#) on the basis of an international review process.

Funding is provided for projects that are precisely defined in terms of objectives and methodology, are limited in duration and funding, and whose results are not directly linked to commercial interests. A further prerequisite to funding is proof of approval or endorsement by the relevant ethics committee. The project duration is usually 36 to 48 months with the possibility of a twelve-month cost-neutral extension. Cooperation with national and/or international partners and transdisciplinary approaches are possible and desired.

The projects must involve patients or healthy volunteers and be aimed at gaining scientific knowledge and insights to improve clinical practice and optimise diagnostic and therapeutic procedures. Examples would be studies on special subpopulations of patients, steps towards personalised medicine, proof-of-concept studies, studies to compare and advance diagnostic techniques and therapeutic interventions or to test new indications for already approved drugs, as well as clinical epidemiological and non-interventional studies in the areas of prevention, prognosis, and care.

The FWF only funds project-specific costs for personnel and materials that are necessary for the implementation of the project and are not borne by the research institution. Requests to fund infrastructure and basic equipment for a research institution are not eligible. Costs for equipment will not be covered as these are understood to be components of basic equipment and are to be provided by the research institutions. Costs for animals and animal husbandry are also generally not funded under this initiative. A co-financing of the projects is allowed but requires a statement declaring the nature of the cooperation.

## 4. Data Availability

The evaluation team will be provided with all the information and data available to the FWF regarding the KLIF programme and the applicants. Information on the selection procedure (review and decision-making) will also be made available. For projects already completed (from 2011 until now), the evaluation team will have access to the final scientific reports (including project outputs) and ex-post evaluation outcomes (see preliminary information listed in the Appendix).

- All FWF projects (1997–2021) can be found in the FWF project finder: <https://pf.fwf.ac.at/en/research-in-practice/project-finder>
- Data on FWF programmes (2009–2020) can be found at and downloaded from the FWF Statistics Dashboard: [dashboard.fwf.ac.at/en/](https://dashboard.fwf.ac.at/en/)

### Other sources

Links to other sources (e.g., FWF annual reports) are listed at the end of this document ('Suggestions for Further Reading').

## 5. Methods

In 2016, the Austrian Institute of Advanced Studies (IHS) and the Austrian Science Council (*Wissenschaftsrat*) published extensive and detailed reports on clinical research in Austria (see section 13 for references to the reports), and gathered important information regarding the FWF's funding of investigator-initiated clinical trials. The successful bidder is expected to employ methods such that recent developments linked to key results of these reports can be reviewed. The focus should be on whether and how main critical points regarding general aspects of clinical research have developed in the past years and how the FWF in particular has contributed to this. These aspects are, for example,

- Projects/funding
  - outputs and outcomes of funded projects, and if applicable, impact
  - education and training of young researchers
- Proposals
  - quality of KLIF proposals
  - quality of FWF peer reviews
  - standing of clinical research in the FWF
- General environment
  - compatibility of clinical work and research
  - skills for clinicians to successfully participate in KLIF
  - availability of funding other than from the FWF
  - support structures for clinical research

The contractor is expected to deliver a statistical analysis of funded and declined projects/applications, as well as an analysis of project outputs and outcomes (and if possible, impacts). This should involve a bibliometric study of publications that shows the quality of publications, as well as an assessment of other outputs and outcomes.

Moreover, a set of suitable qualitative and quantitative methods should deliver information on the perception of KLIF proposals, the peer review, and the overall standing of clinical research, as well as on the general environment for clinical research in Austria as perceived by the medical universities, the researchers, and the FWF. Besides the requirement to use a suitable mix of methods, the contractor is encouraged to propose specific methods to evaluate the appropriateness of the KLIF programme and to account for the specificities of clinical research.

Another central element of the KLIF programme is the education and training of young researchers. The evaluation is expected to deliver insights into the training processes and the career pathways of young researchers who have participated in KLIF projects.

Given the special case of clinical research, it will be necessary to reflect on the general aspects of clinical research in Austria with a particular focus on the compatibility of clinical work and research. Also, the availability of research support structures, personnel, and databases, and the role of the ethics committees and the clinical trials coordination centres should be investigated.

Regarding the clinical research landscape in Austria, the analysis should focus on the FWF's role in this system, and address questions related to the continuous financing of large and long-duration projects. Furthermore, the roles of other funding agencies (regional, national, and international) and financing by firms along the project chain is of interest. Ideally, the evaluation will show best practice programmes to fund clinical research in other countries and which aspects can be meaningfully transferred to the Austrian context.

## **6. Evaluation Questions**

The FWF would like the tender bids to include considerations regarding the following broad questions and encourages prospective evaluators to suggest additional areas that might be important to consider. The FWF will work with the successful bidder to shape and prioritise these questions during a kick-off meeting.

### **A: Were the objectives of the KLIF programme fulfilled, in terms of**

- Increased quality and reputation of academic clinical research in Austria, including
  - quality of research outputs and outcomes (in a broad sense)
  - (international) competitiveness of clinical research in Austria
  - quality of research project proposals and projects for FWF programmes and other funding sources (e.g., EU)
- Improved environment for research personnel, including
  - increase in highly qualified personnel in clinical research

- better education and training of young researchers
  - increase of research time for clinical researchers
- Broader effects for clinical research achieved in Austria, including
  - Were clinical research profiles of medical universities and other research institutes improved?
  - Did clinical research also generate a stimulus for project chains in higher clinical research phases and the potential translation to the market/into clinical practice (also involving additional funding and/or potential co-financing)?

**B. Are programme implementation and management appropriate and efficient in terms of**

- Grant preparation (coaching, information events, consultation services)
- Processes and FWF resources (application, review, decision-making)
- Evaluation design (project evaluation criteria, selection criteria)
- FWF regulations (guidelines, KLIF statutes, contracts)
- Quality of reviews
- Assistance offered by the FWF to proposers throughout the lifecycle of a KLIF project (from planning to termination)
- Appropriateness of KLIF funding to support clinical research

**C. Meta-analysis:**

- In-depth analysis of how the KLIF programme fits into the FWF's funding portfolio as well as into the Austrian research funding landscape in general.
- Identification of an ideal support structure for clinical research in Austria, starting from basic research to the transfer of the results towards application. What role does KLIF play here, which other funding programmes are relevant, and how are they intertwined?
- Analysis of important external factors such as regulations (in Austria, and on the EU-level) that affect the successful implementation of funded projects and how KLIF should react to these.
- Adaptation of the KLIF programme in light of planned structural changes in clinical research in Austria (e.g., the Ludwig Boltzmann Society plans to offer competitive funding for research groups with a strong societal impact in the field of health sciences and as such funds clinical research groups to support (and train) early-stage clinician-scientists to become equipped for KLIF applications).<sup>2</sup>

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<sup>2</sup> See the current government programme p. 216, <https://www.bundeskanzleramt.gv.at/en/federal-chancellery/the-austrian-federal-government/government-documents.html>

## 7. Recommendations

As a summary of the evaluation questions and recommendations, evidence-based statements should finally address the following questions

- How could/should the appropriateness of the KLIF programme for Austrian clinical research be improved in terms of
  - funding and duration of the projects
  - education and training of young clinical researchers
  - transforming high-quality basic research into clinical research
  - strengthening clinical research in Austria in general
- What could/should the FWF improve/change regarding
  - the programme design (e.g., volume, duration, review process, etc. of both individual projects and of the entire programme)
  - the organisation and management of the programme
  - the funding structure
  - the standing of the KLIF programme in the FWF
  - the planned introduction of research funding by the Ludwig Boltzmann Society
  - continuing/terminating the programme (e.g., is the programme in its current form suitable for Austria?)

## 8. Deliverables, Meetings, and Presentations

All deliverables and reports must be provided in English, some of them additionally in German. The final reports will be published.

### Reports:<sup>3</sup>

- 1) A final evaluation report (in English)
- 2) An executive summary (in English and German) of no more than five pages in length
- 3) A one-page summary (in English and German)
- 4) A research publication in a peer-reviewed venue on a topic of choice (related to the evaluation) by the evaluators after the evaluation is finalised

### Meetings and Presentations:

- 1) Kick-off workshop
- 2) Mid-term report and presentation
- 3) Discussion of final report (draft version)
- 4) Presentation of the final report

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<sup>3</sup> All reports as well as the underlying materials resulting from the evaluations should be published using a [CC BY licence](#).

## 9. Schedule

Invitation to tender:	20 December 2021
Deadline for tenders:	18 February 2022, 4:00 PM CET
Invitation for hearings:	11 March 2022
Hearings:	End of March 2022
Decision:	Mid-April 2022
Kick-off workshop:	End of April 2022
Mid-term report and presentation:	November 2022
Final report (draft version):	April 2023
Public presentation of final report:	June 2023

## 10. Price and Payments

Prices must be fixed amounts, which are not subject to change and which include all charges including travel and subsistence expenses. The price must be presented as a lump sum; separately reimbursable expenses will not be accepted. The estimated travel and subsistence expenses considered necessary by the tenderer in order to carry out the study must be indicated separately (for information purposes only).

The price quoted in the tender must be in euros. Tenderers from countries outside the euro zone are also subject to this requirement. The price quoted may not be adjusted for exchange rate fluctuations at any time. It is up to the tenderer to select an exchange rate and to assume the potential risks or benefits arising from any variations.

The total price for the services offered (including travel and subsistence expenses) is expected to be no more than **€80,000** *excluding* VAT.

Payments: Three payments will be made under the contract. The first payment (corresponding to 20% of the contractually agreed price) will be effected after conclusion of the contract. The second (interim) payment (corresponding to 50% of the contractually agreed price) will be released after approval of the interim presentation and made within 30 days of the approval date. Should the interim presentation not be approved, the contractor shall have 20 days to respond to suggested changes and to submit a revised document. Once the FWF approves the final deliverables, the contractor may request the final balance due (30%).

## 11. Deadline for Tenders / Communication of Decisions

Tenders must be submitted as a PDF document by 4:00 PM CET 18 February 2022 at the latest to Dr. Elisabeth Nindl, [elisabeth.nindl@fwf.ac.at](mailto:elisabeth.nindl@fwf.ac.at)

The FWF expressly welcomes submissions from international consortia. Hearings will take place in Vienna with shortlisted tenderers. Decisions will be made by the FWF based on the suggestion of a panel. The members of this panel are Christof Gattringer (FWF), Ellen Zechner

(FWF), Iris Fortmann (FWF), Stephanie Resch (FWF), Elisabeth Nindl (FWF), Falk Reckling (FWF), and Silvia Knapp from the Medical University of Vienna.

Criteria are (i) competences of the evaluation team: knowledge of the Austrian science system, and experience and knowledge in research assessments; (ii) utility (to which extent will the evaluation outputs and recommendations help the FWF to meet its needs); (iii) feasibility and appropriateness of the approach with respect to the aims of the evaluation; and (iv) appropriateness of the costs.

**Important note:** The FWF requests bidders with recent activities in international research, research management, or research funding in Austria and/or bidders recently commissioned by Austrian national ministries or other stakeholders in supporting the shaping of Austria's Research, Technology, and Innovation policy to declare potential conflicts of interest.

### **Contact person**

*For details regarding the tender information about the KLIF programme:*

Dr. Elisabeth Nindl

T: +43 1 505 67 40 8864

[elisabeth.nindl@fwf.ac.at](mailto:elisabeth.nindl@fwf.ac.at)

## 12. Transparency of the Tender

The tender is published on the FWF website and distributed via the FWF newsletter and fteval. Furthermore, an invitation has been sent to the following institutions:

<ul style="list-style-type: none"> <li>• <b><a href="#">AIT – Austrian Institute for Technology</a></b> <a href="#">Michael Dinges</a> Tech Gate Vienna, Donau-City-Straße 1, A-1220 Vienna</li> <li>• <b><a href="#">Convelop Cooperative Knowledge Design GmbH</a></b> <a href="#">Karin Grasenick</a>, <a href="#">Markus Gruber</a> Bürgergasse 8-10/I, A-8010 Graz</li> <li>• <b><a href="#">Fraunhofer ISI</a></b> <a href="#">Susanne Bühner</a>, <a href="#">Niclas Meyer</a> Breslauer Straße 48, D-76139 Karlsruhe</li> <li>• <b><a href="#">DZHW – Deutsches Zentrum für Hochschul- und Wissenschaftsforschung</a></b> <a href="#">Sophie Biesenbender</a> Goseriede 9, D-30159 Hannover</li> <li>• <b><a href="#">IGES Institut GmbH</a></b> <a href="#">Dr. Friederike Haaß</a> Friedrichstraße 180, D-10117 Berlin</li> <li>• <b><a href="#">IHS – Institute for Advanced Studies</a></b> <a href="#">Thomas Czypionka</a> Josefstädter Straße 39, A-1080 Vienna</li> <li>• <b><a href="#">Joanneum Research</a></b> <a href="#">Wolfgang Polt</a> Haus der Forschung Sensengasse 1, A-1090 Vienna</li> <li>• <b><a href="#">KMU Forschung Austria</a></b> <a href="#">Mario Steyer</a> Gusshausstraße 8, A-1040 Vienna</li> <li>• <b><a href="#">National Centre for Research Methods (NCRM)</a></b> <a href="#">Gabriele Durrant</a> University of Southampton Southampton SO17 1BJ, United Kingdom</li> </ul>	<ul style="list-style-type: none"> <li>• <b><a href="#">NIFU -R-Quest</a></b> <a href="#">Liv Langfeldt</a> P. O. Box 2815 Tøyen, NOR - 0608 Oslo</li> <li>• <b><a href="#">RAND Europe</a></b> <a href="#">Steven Wooding</a> Westbrook Centre/Milton Rd, Cambridge CB4 1YG, UK</li> <li>• <b><a href="#">SPRU - Science and Technology Policy Research</a></b> <a href="#">Ben Martin</a> University of Sussex. Sussex House Jubilee Building Jub-363 Brighton, BN1 9RH, UK</li> <li>• <b><a href="#">Technopolis Group</a></b> <a href="#">Katharina Warta</a> Technopolis Group Limited 3 Pavilion Buildings, Brighton, BN1 1EE, UK</li> <li>• <b><a href="#">The University of Manchester</a></b> <a href="#">John Rigby</a> Harold Hankins Building-9.08 Manchester Business School Manchester, M13 9PL, UK</li> <li>• <b><a href="#">WIFO - Austrian Institute of Economic Research</a></b> <a href="#">Ulrike Famira-Mühlberger</a> Arsenal, Objekt 20, PF 91, A-1103 Vienna</li> <li>• <b><a href="#">ZSI – Centre for Social Innovation</a></b> <a href="#">Klaus Schuch</a> Linke Wienzeile 246, A-1150 Vienna</li> </ul>
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## 13. Suggestions for Further Reading<sup>4</sup>

### Austrian Research System

*Bundesgesetz zur Förderung der Forschung und Technologieentwicklung (Forschungs- und Technologieförderungsgesetz - [FTFG](#))*

*Austrian Research and Technology Report [2021](#)*

The Austrian Research and Technology Reports are status reports to the Austrian parliament on the nation's federally funded research, technology, and innovation. The report draws on

<sup>4</sup> The FWF does NOT expect the evaluators to consider all of these suggestions in their report.

current data to present an overview of specific trends in research, technology, and innovation (RTI) and show how Austria ranks internationally in selected categories.

### **Clinical Research in Austria**

Czypionka, T. et al. (2016): [Rahmenbedingungen der klinischen Forschung in Österreich](#). Studie im Auftrag des Österreichischen Wissenschaftsrates (ÖWR), Wien.

Österreichischer Wissenschaftsrat (2016): [Klinische Forschung in Österreich: Stellungnahme und Empfehlungen](#), Wien.

Österreichischer Wissenschaftsrat (2016 a): [Klinische Forschung in Österreich: Stellungnahme und Empfehlungen](#). Anhang 2, Wien.

### **FWF Annual Reports**

Including mission statement, overview of grants, numbers of applications and approvals, and funding requested/approved; [German](#) or [English](#) from 2010 onwards.

### **Principles of the FWF Decision-Making Procedure**

The document [General principles of the FWF decision-making procedure](#) provides a brief overview of the application process, from the submission of proposals to the peer review process and the final funding decision. The process described in the document forms the basis for all FWF programmes. In certain programmes, exceptions to the general decision-making principles are possible; these exceptions are described in separate documents.

### **Guidelines and Application Forms:**

<https://www.fwf.ac.at/en/research-funding/fwf-programmes/programme-clinical-research-klif>

### **Final Reports of KLIF Projects**

Will be provided by the FWF.

### **Evaluation Reports and Studies on the FWF**

<https://www.fwf.ac.at/en/about-the-fwf/publications>