

VERSION 2.1

SUBMISSION PERIOD FROM 24/1/2023 TO 21/12/2023 (12:00)

CALL GUIDELINE AUSTRIAN LIFE SCIENCES – 2023

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Changes from 2022

- Change to ongoing online submission (PDF upload of project description completed in Word to eCall no longer necessary, see [section 4](#))
- Maximum funding for Company Projects of Experimental Development (ED) and Company Projects of Industrial Research (IR) and Clinical Studies was raised to € 3 million (see [section 1](#))
- Focus of Flagship Projects on clinical research
- [Cost Guidelines, Version 2.2](#) (valid since 1/9/2022)
- Various linguistic clarifications to improve readability and understanding

1 KEY FACTS AT A GLANCE

The **Austrian Life Sciences Call** makes available a total of EUR 50 million in funding for the years 2022 and 2023. The following table presents the three relevant funding instruments covered by the Call.

Table 1: Overview of Austrian Life Sciences 2023 Call

Focal areas of the Call	Brief description and topics	max. funding (financing)	Funding rate	Running time (months)	Cooperation required?
<u>Company Projects of Industrial Research</u>	Funding of research and development projects in an early development stage that lead to exceptional findings, which provide the basis for subsequent innovative products, processes or services. <ul style="list-style-type: none"> • Digitalisation in healthcare • Medical devices • Medicines 	max. € 3,000,000	Grant up to maximum cash value of 50 % to 70 % depending on type of organisation	max. 18 months	No
<u>Company Projects of Experimental Development</u>	Research and development projects carried out by companies which result in commercially exploitable products , processes or services. <ul style="list-style-type: none"> • Digitalisation in healthcare • Medical devices • Medicines 	max. € 3,000,000	Grant up to maximum cash value of 25 % to 45 % depending on type of organisation	max. 18 months	No
Clinical Studies	Interventional phase I and II studies conducted in compliance with specific quality requirements (e.g. <u>ICH-GCP</u> , EU Directive 2001/20/EC) and clinical trials of medical devices in accordance with EU regulations.	max. € 3,000,000	Grant up to maximum cash value of 25 % to 45 % depending on type of organisation	max. 24 months	No
<u>Flagship Projects</u>	Flagship Project (comprehensive cooperative research and development project) in the field of clinical research designed to enable the linking and intelligent analysis of personal health and disease data in compliance with data protection law with the aim to produce novel solutions.	min. € 2 million to max. € 4 million	Grant up to maximum cash value of 35 % to 85 % depending on type of organisation and research category	max. 24 months	Yes

Table 2: Budget – Deadlines – R&D Company Projects

Further information	Company Projects
Brief description	Industrial Research (IR) and Experimental Development (ED) and Clinical Studies
Call topics	<ul style="list-style-type: none"> • Digitalisation in healthcare • Medical devices • Medicines • Clinical studies
Submission period 2023	24/1/2023 to 21/12/2023 (12:00) depending on budget availability
Language	German (English optional)
Online information	Austrian Life Sciences 2023
Submission portal	https://ecall.ffg.at

Table 3: Budget – Deadlines – Flagship Projects

Further information	Flagship Projects
Brief description	Comprehensive cooperative research and development projects in the categories of Industrial Research (IR) and/or Experimental Development (ED)
Call topic	Clinical research
Budget	Indicative budget: € 4 million
Submission period 2023	24/1/2023 to 30/6/2023 (12:00)
Mandatory preliminary meeting	The submission of a Flagship Project requires a mandatory preliminary meeting with the FFG no later than 31/5/2023 in order to clarify requirements and specifications. Meeting requests to be sent to marlene.zellner@ffg.at by 12/5/2023 at the latest.
Language	German (English optional)
Online information	Austrian Life Sciences 2023
Submission portal	https://ecall.ffg.at

Table 4: Contact persons

Name	Telephone	Email
Dr. Corinna Wilken	+43(0)5 7755 1314	corinna.wilken@ffg.at
Dr. Amrei Strehl	+43(0)5 7755 1325	amrei.strehl@ffg.at
Marlene Zellner	+43(0)5 7755 1518	marlene.zellner@ffg.at

The grant amount depends on the type of organisation and research category. The following table provides an overview of the funding rates (%).

Table 5: Funding rates according to type of organisation and research category

Type of organisation	Company Projects Industrial Research	Company Projects Experimental Development and Clinical Studies	Flagship Projects Industrial Research	Flagship Projects Experimental Development
Large enterprises	50 %	25 %	55 %	35 %
Medium-sized enterprises	60 %	35 %	70 %	50 %
Small enterprises	70 %	45 %	80 %	60 %
Startups	70 %	45 %	70 % to 80 %	50 % to 60 %
Research organisations	-	-	85 %	60 %
Other non-economic organisations	-	-	80 %	60 %

2 OBJECTIVES OF THE CALL

Life sciences and biotechnology are one of the fastest growing and most innovative research sectors. The COVID-19 pandemic clearly showed **the importance of health to a functioning economy and society**. With healthcare expenditure of over EUR 42.5 billion (11% of GDP) and more than 260,000 employees, Austria's healthcare system is already a significant factor in its national economy.

Austria plays an active role in the development of drug candidates, medical devices, diagnostic systems, and innovative technologies, products and services, and **enjoys international recognition as a flourishing research, business and production location in the Life Sciences sector** (look under [Federal Ministry Labour and Economy](#)).

The Austrian Life Sciences sector is broad based. It includes **startups, small, medium-sized and large enterprises**, and a whole series of **subsidiaries of international corporations**.

Through the targeted application of funding formats tailored to the Life Sciences sector, the **Austrian Life Sciences Call 2023** is designed to support **R&D activities** along the **entire development path** (bench to bedside) in order to meet the high capital requirements typical of the industry. It should also play a role in maintaining **Austria's attractiveness as a research location** for conducting clinical studies, so that it **remains internationally competitive**, and establishes more sustainable, robust, innovative, and high-quality health and care systems that put people at the centre.

Consequently, the Call 2023 has the following objectives:

2.1 Increasing Austria's attractiveness as a research location

High development costs, long development times and great technological development risks are particular challenges faced by companies in the Life Sciences sector. In order to meet these challenges and maintain Austria's attractiveness as a research and development location for companies, relevant funding opportunities are needed along the entire value chain. Research and development (R&D) of new, effective, high quality, safe, as well as available and affordable **medicines and medical devices which address unmet public health needs** are key to public healthcare provision. To prevent a brain drain and increase Austria's attractiveness as a research location, funding must be available to cover both early as well as later development phases.

2.2 Increasing Austria's competitiveness as a location for clinical studies

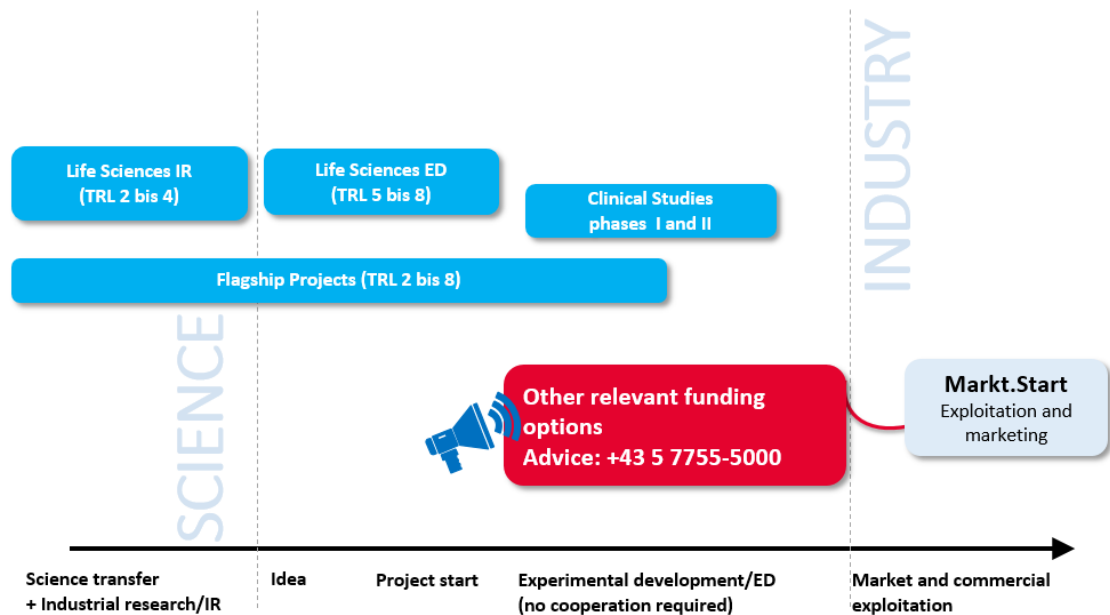
Clinical studies are a key component in translating new medical findings to healthcare practice. They contribute to an efficient and effective healthcare system focused on the needs of the patient and society as a whole and stimulate a competitive healthcare sector.

In view of the falling number of applications for drug studies, it is important to create an awareness among all stakeholders that global pharmaceutical companies select clinical study centres on the basis of international competition. As the priority always lies in patient benefits and safety, the regulatory requirements in the Life Sciences industry mean that, compared to other industries, drug development is not only a long-winded process, but also complex, risky, and above all, capital intensive. When selecting study centres and locations, some of the most important factors for companies in the Life Sciences industry include rapid implementation, reliability, patient numbers and quality, plus attractive financing options.

3 FOCUS OF THE CALL

The **Austrian Life Sciences Call 2023** offers funding along the entire Life Sciences value chain in order to secure **Austria's position as a research, business and production location** for medicines and medical devices over the long term. Innovative ideas for companies of all sizes across the **entire Life Sciences sector** should be addressed and turned into specific, successful R&D projects.

This Call Guideline outlines the **funding specifics along the entire value chain** in the Life Sciences sector.



The following projects are eligible for funding:

- **R&D Company Projects of Industrial Research (IR)** by Austrian companies
 - Digitalisation of **health aspects** (diagnostics, telemedicine, medical devices etc.)
 - Development of new, effective, high-quality, safe, available and affordable **medicines and medical devices**
- **R&D Company Projects of Experimental Development (ED)** by Austrian companies on the following topics:
 - **Digitalisation of health aspects** (diagnostics, telemedicine, medical devices etc.)
 - Development of new, effective, high-quality, safe, available and affordable **medicines and medical devices**
- **Interventional phase I and II clinical studies and clinical trials of medical devices** in accordance with EU regulations. Planning and implementation in compliance with specific quality requirements (e.g. [ICH-GCP](#), EU Directive 2001/20/EC).
- **Flagship Projects** in the field of clinical research

General regulations can be found in the guidelines of the corresponding funding instruments:

- Company Projects of Industrial Research
- Company Projects of Experimental Development (this guideline also applies to clinical studies)
- Flagship Projects

3.1 Company Project - Industrial Research

High development costs, long development times and great technological development risks are particular challenges faced by companies in the Life Sciences sector. In order to overcome these challenges and maintain Austria's attractiveness as a research and development location for companies, relevant funding opportunities must be provided along the **entire value chain**.

Company Projects of Industrial Research (IR) are projects with a **high technical risk** paired with significant prospects of economic success which are currently in a **very early stage of development** (up to and including TRL4). Funding for Company Projects of Industrial Research covers a maximum of 70% of project costs, allowing companies of all sizes involved in research and development in the field of **digitalisation in healthcare, medical devices and medicines** to set out on this growth path.

3.1.1 Funding instruments addressed by the Call

- Company Projects of Industrial Research

3.1.2 The following supplementary regulations apply:

- Funding is provided for R&D Company Projects IR in the field of health carried out by Austrian companies.
- Grant with max. cash value depending on funding instrument
- Companies may apply for max. 1 project per year and research category
- Project running time: max. 18 months
- The FFG Management makes the funding decision based on the recommendation of the evaluation committee.

3.2 Company Project - Experimental Development

High development costs, long development times and great technological development risks are particular challenges faced by companies in the Life Sciences sector. In order to overcome these challenges and maintain Austria's attractiveness as a research and development location for companies, relevant funding opportunities must be provided along the **entire value chain**.

Company Projects of Experimental Development (ED) are submitted and conducted by companies, and are focused on commercially exploitable products, processes or services. These projects follow the industrial research stage in the development pathway.

Funding for Company Projects of Experimental Development covers a maximum of 45% of project costs, allowing companies of all sizes involved in research and development in the field of digitalisation in healthcare, medical devices and medicines to continue on their growth path.

In terms of content, the projects should focus on researching and developing new and affordable **medicines, therapies and medical devices** to cover public health needs which are currently not being met. R&D projects may also address topics relating to the digital transformation process in the healthcare sector, including the potential use of AI applications in health and medical technology as well as in the fields of prevention, diagnosis and therapy in medicine, care and rehabilitation.

3.2.1 Funding instruments addressed by the Call

- Company Projects of Experimental Development

3.2.2 The following supplementary regulations apply:

- Funding is provided for R&D Company Projects (IR and ED) in the field of health carried out by Austrian companies.
- Grant with max. cash value depending on funding instrument
- Companies may apply for max. 1 project per year and research category
- Project running time: max. 18 months
- The FFG Management makes the funding decision based on the recommendation of the evaluation committee.

3.3 Company Project - Clinical Studies

The experience of the pandemic and the FFG's Emergency Call in 2020 clearly showed that there has been a lack of funding for clinical studies over the past years. Whereas the first year of the Austrian Life Sciences Programme limited clinical studies to the field of infectiology, in the second year there will be **no thematic restrictions**. The aim is to ensure that Austria remains attractive as a location for conducting clinical studies.

Funding will be available for **interventional phase I and II studies into novel therapies or processes** which are aimed at demonstrating either the safety or efficacy of a new process or a new therapy. They must be of a high scientific quality, offer an innovative approach, and be clinically relevant. Applicants must have completed trial-related preparatory work and the project must follow the rules of **Good Clinical Practice (ICH-GCP)**.

Funding is also available for **clinical trials of medical devices** in accordance with EU regulations. In this case, too, applicants must have carried out trial-related preparations, as well as work for the planned project, both of which must have been conducted in Austria.

These projects follow the experimental development stage in the development pathway.

3.3.1 Funding instruments addressed by the Call

- Company Projects of Experimental Development

3.3.2 The following supplementary regulations apply:

- Funding is provided for clinical studies of phase I and II conducted by Austrian companies.
- Grant with max. cash value depending on funding instrument
- Max. 1 project per year and company
- Project running time: max. 24 months
- The FFG Management makes the funding decision based on the recommendation of the evaluation committee.
- The active substances to be investigated should be based on research activities carried out in Austria.
- The Austrian company submitting the application is the sponsor of the study.
- At least one Austrian clinical centre must be involved (exception: clinical challenge studies).
- Compliance with quality requirements (e.g. positive vote of the ethics commission, **ICH-GCP**)

- **Eligible costs:** Project costs depend on the phase of the study, the indication and the status of the medicinal product. Eligible costs generally include all costs relevant to the study, such as
 - Contract Research Organisation (CRO)
 - Centres, including test subjects and study team
 - Trial material and Contract Manufacturing Organisation (CMO)
 - Company management (personnel costs, material costs, travel costs)
 - There is no limit on third-party costs.

3.4 Flagship Projects – Clinical Research

The Clinical Trials Regulation (EU) No. 536/2014, which came into force in early 2022, established a central submission and evaluation system for clinical trials in the European Union. Accordingly, Austria may quickly lose the advantage currently enjoyed as a result of its rapid approvals process for clinical trials. That makes it even more important for a small country to stand out in terms of quality, expertise and service. Opportunities to digitalise studies, and to network hospitals and registered healthcare professionals at federal level need to be explored to reach more patients and achieve internationally competitive scale.

Therefore, a Flagship Project should conduct research into the linking and intelligent analysis of personal health and disease data in compliance with data protection law. This should lead to novel solutions focused not only on direct users (doctors, hospitals, patients, research institutions), but also a series of potential commercial exploiters of these solutions, such as life sciences companies and technology providers in health IT, as well as health insurance funds. All relevant players should be involved in the research proposal.

3.4.1 Funding instruments addressed by the Call

- Flagship Project

3.4.2 The following supplementary regulations apply:

- Funding is provided for one or two Flagship Projects in the field of clinical research
- Grant with max. cash value depending on funding instrument
- Funding limit: € 4 million
- Project running time: max. 24 months
- The FFG Management makes the funding decision based on the recommendation of the evaluation committee.
- Submission deadline: **30/6/2023 (12:00)**
- The submission of a Flagship Project requires a **mandatory preliminary meeting** with the FFG no later than **31/5/2023** in order to clarify requirements and specifications.
- Meeting requests to be sent to marlene.zellner@ffg.at by **12/5/2023** at the latest.
- The selection and review process includes a mandatory hearing with the funding applicants. Each project will be assessed by external experts.

4 CALL DOCUMENTS

Projects must be submitted electronically via [eCall](#). The submission includes the following **online** elements which must be entered in the following [eCall](#) sections:

- **Content Description** presents the project content.
- **Work Plan** presents the work packages and project management elements such as a time management plan (GANTT chart), deliverables, milestones, results.
- **Consortium** describes the expertise of the individual consortium members.
- **Cost and Financing** describes all cost categories for each consortium member. The sums for each work package are automatically displayed in the online work plan.

Optional annexes relevant to the project, e.g. overviews, graphical representations, max. 5 pages (no template), may be attached to the electronic application.

The submission process, the procedure following the funding decision and the funding criteria are described in the guidelines for Company Projects of Industrial Research, Company Projects of Experimental Development, and Flagship Projects. The relevant documents are shown in the following overview.

Table 6: Call documents

Document	Description
Documents	<ul style="list-style-type: none"> – Call Guideline Austrian Life Sciences 2023 (this document) and – Guideline for Company Projects of Experimental Development (ED) or – Guideline for Company Projects of Industrial Research (IR) or – Guideline for Flagship Projects – R&D Company Projects IR and ED and clinical studies: online submission (see relevant guideline) – Flagship Project: online submission (see relevant guideline)
General cost regulations	Cost Guideline , latest version (cost recognition in FFG projects)
Supplementary regulations for costs of clinical studies	<p>Eligible costs generally include all costs relevant to the study, such as</p> <ul style="list-style-type: none"> – Contract Research Organisation (CRO) – Centres, including test subjects and study team – Trial material (CMO) – Company management (personnel costs, material costs, travel costs) <p>There is no limit on third-party costs.</p>
Online information	Austrian Life Sciences 2023

5 FUNDING DECISION AND LEGAL BASIS

The FFG Management makes the funding decision based on the recommendation of the evaluation committee. The [Austrian Life Sciences Call 2023](#) is based on

- the Guidelines of the Austrian Research Promotion Agency for the funding of research, technology, development and innovation with the aim to strengthen the competitiveness, innovativeness and internationalisation of enterprises ([FFG-KMU-Richtlinie](#)),
- the Guidelines of the Austrian Research Promotion Agency for the funding of research, technology, development and innovation with the aim to strengthen the competitiveness, innovativeness and internationalisation of large enterprises ([FFG-Industrie-Richtlinie](#)), and
- the Guidelines of the Austrian Research Promotion Agency for the funding of research, technology, development and innovation aimed at active, open-topic RTI funding ([FFG-Offensiv-Richtlinie](#)).

The three Guidelines mentioned above were approved by the [Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology](#), the [Federal Ministry for Digital and Economic Affairs](#) (as from August 2022: [Federal Ministry of Labour and Economy](#)), and the [Federal Ministry of Finance](#). The Guidelines enter into force on 01 January 2022 and shall be applied until such time as the last project funded under these Guidelines has been completed. Calls based on these Guidelines may be published until 31 December 2023. The Guidelines may be used as a basis for deciding on eligible projects until 30 June 2024.

Once this period has expired, the Guidelines may only be applied to projects with a funding agreement concluded on the basis of these Guidelines.

The funding guidelines shall apply as from 1 January 2022 with retroactive effect to ensure a seamless transition from the previous funding guidelines, which expired on 31 December 2021.

The company size shall be established in accordance with the corresponding SME definition specified in EU competition law. More detailed information can be found on our website under [SME Definition](#).

All EU provisions shall be applicable as amended.

6 FURTHER INFORMATION

This section contains information about further funding options and services which you may find useful in connection with funding applications or funded projects.

6.1 Support of public relations

The funding recipients are obliged to work together with the FFG and the responsible ministries to support PR work, if required. This includes in particular the provision of non-confidential project information and images for electronic dissemination portals and other media purposes. **The funding recipients must therefore send a publishable project abstract in German and English to the FFG prior to payment of the first instalment.**

6.2 FFG Project Database

The public access [FFG Project Database](#) provides the opportunity to publish brief information about funded projects and an overview of the project partners involved. This enables you to present your project and your project partners to the interested public. The database can also be used to search for cooperation partners.

Once funding is granted, the applicants are informed via the eCall system that they can publish specific brief information about their project in the FFG Project Database. The information will only be published if active consent is given in the eCall system.

More information on the Project Database can be found on the relevant page of the [FFG website](#).

6.3 Additional FFG funding opportunities

You are interested in other funding opportunities provided by the FFG?

The FFG Funding Service is the central contact point for your enquiries about FFG funding and advisory services. Please feel free to contact us, we are happy to help.

Contact: [FFG Funding Service](#), T: +43(0)5 7755-0, foerderservice@ffg.at