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COMPETITIVE PROCEDURE
VERSION 1.0
CALL OPEN FROM 10/03/2020 TO 11/05/2020



CALL GUIDELINE FOR KLIPHA-COVID19

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The following three amendments were made to the Call Guideline between 10/3/2020 and 21/3/2020:

1. clinical trials are also included;
2. an additional second deadline of 11 May 2020 was introduced;
3. the budget was increased from € 1 million to € 21 million.

1 PREFACE

In response to the current coronavirus Sars-CoV-2 outbreak, the Federal Ministry for Digital and Economic Affairs (BMDW) has made available short-term funding of EUR 1 million and commissioned the Austrian Research Promotion Agency (FFG) to carry out an Emergency Call.

Due to the **rapid spread and escalating situation** in Europe, the [Federal Ministry for Digital and Economic Affairs](#) (BMDW) and the [Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology](#) (BMK) provide **an additional 20 million euros** in funding to enable the conduct of clinical trials.

It is important that the planned projects or trials can be conducted and implemented within a short period of time: the duration of the projects or clinical trials should be less than 12 months.

Funding is provided for individual R&D projects carried out by Austrian companies which focus on the following topics related to the coronavirus:

- **Virus biology and transmission;**
- **Infection prevention and control;**
- **Research and development of medicines and other treatments and development of new diagnostic methods;**
- **Planning and conduct of clinical trials.**

The Call Guideline describes the specifics of the Emergency Call. The general regulations can be found in the "Guideline for Company Projects of Experimental Development".

2 CALL OBJECTIVES

The Emergency Call aims to enable a quick response to the threats caused by the coronavirus Sars-CoV-2 and thus contribute to safeguarding public health care in crisis situations, keeping existing pharmaceutical manufacturers in Austria and bringing the production of active ingredients back to Europe over the medium to long term.

The planned measures should be designed for **rapid** implementation (development period \leq 12 months).

The following additional criteria apply to clinical trials:

- The development of the active ingredient to be tested should build on preliminary results and experience obtained with other coronaviruses (e.g. SARS, MERS), because although SARS-CoV-2 is a novel virus, vaccine developers have already gained experience with other types of coronavirus.
- Existing market products which have already demonstrated to be effective against coronaviruses in general or against symptoms similar to those caused by the SARS-CoV-2 virus (e.g. respiratory diseases) can be investigated in phase II clinical trials.
- The project duration for clinical trials may not exceed a maximum of 12 months.
- Compliance with quality standards (e.g. positive vote by the Ethics Commission, GCP).
- Eligible costs: The project costs are dependent on the trial phase, indication and drug status. All costs related to the trial are eligible in principle, including
 - CRO (Contract Research Organisation)
 - Centres including subjects and trial team
 - Trial material (CMO)
 - Corporate management (personnel costs, cost of materials, travel costs)
 - Third-party costs are not limited.

3 KEY FACTS AT A GLANCE

Table 1: Overview

Key facts	Description
Short description	Funding is provided for individual R&D projects of Austrian companies which focus on the following topics related to the coronavirus: <ul style="list-style-type: none"> – Virus biology and transmission; – Infection prevention and control; – Research and development of medicines and other treatments and development of new diagnostic methods; – Planning and conduct of clinical trials.
Thematic focus	Focus: Sars-CoV-2
Funding amount	max. € 3 million
Funding rate	Grant; max. cash value depending on company size; cooperation with scientific partners (e.g. university institutes, universities of applied sciences etc.) is possible and may result in a higher funding rate (bonus).
Duration (months)	12 months
Cooperation required	No
Total budget	€ 21 million
Submission deadlines	8 April 2020 (short-term) and 11 May 2020 (additional)
Language	German (English is possible)
Contact persons	Dr. Corinna Wilken, T: +43 (0)5 7755 - 1317 corinna.wilken@ffg.at Karin Ruzak, T: +43 (0)5 77 55 - 1507 karin.ruzak@ffg.at
Information online	Emergency Call

The grant amount depends on the company size and is usually as follows:

- Large enterprises: 25 %
- Medium-sized enterprises: 35 %
- Small enterprises: 45 %
- Startups: 45 %

4 CALL DOCUMENTS

Projects may only be submitted electronically via [eCall](#), the FFG’s electronic customer centre. In a first step, the Project Description template (funding application, PDF) must be attached using the eCall upload function. The cost plan must be completed online in eCall. All templates required are made available via eCall.

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

Table 2: Call documents

Document	Description
Documents	<ul style="list-style-type: none"> – Guideline for the Emergency Call (this document) and – Guideline for Company Projects of Experimental Development – Project Description template (see eCall “File Attachments”)
General cost regulations	Cost Guideline , latest version (cost recognition in FFG projects)
Separate provisions for costs of clinical trials	<p>All costs related to the trial are eligible in principle, including</p> <ul style="list-style-type: none"> – CRO (Contract Research Organisation) – Centres including subjects and trial team – Trial materials (CMO) – Corporate management (personnel costs, cost of materials, travel costs) <p>Third-party costs are not limited.</p>
Information online	Emergency Call

5 LEGAL BASIS

Funding is based on the following legal regulations ([Legal basis for FFG funding](#)):

- Guidelines for the Austrian Research Promotion Agency for the Promotion of Applied Research, Development and Innovation (SMEs, Industry) – **FFG-RL-KMU** and **FFG-RL-Industrie**.

The company size shall be established in accordance with the corresponding SME definition specified in EU competition law (from 1 January 2005: SME definition according to Commission Recommendation 2003/361/EC dated 6 May 2003, OJ L 124 dated 20 May 2003, p. 36–41).

All EU provisions shall be applicable as amended.