

English translation of excerpts from the BMBF COVID-19 call (202):
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Funding announcement for research on COVID-19 in the wake of the Sars-CoV-2 outbreak

dated 3 March 2020 - deadline for submission: from now until 11 May 2020

Due to the current outbreak of the corona virus Sars-CoV-2, the German Federal Ministry of Education and Research is opening "Module 3 (Rapid Response) of the funding announcement "Guideline for the funding of a "National Research Network for Zoonotic Infectious Diseases"; Federal Gazette of 15.02.2016.

The relevant points of the funding announcement are specified as follows.

This call for proposals is only valid in conjunction with the above funding regulations.

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2 Object of funding

Funding will be provided for individual projects and, in justified exceptions, small research consortia (with up to 3 partners at different institutions), which are oriented towards the WHO's priority setting (<https://www.who.int/news-room/detail/12-02-2020-world-experts-and-funders-set-priorities-for-covid-19-research>) and intend to conduct research on the following points:

- the biology of the virus and its transmission;
- animal and environmental research on the origin of the virus, including control measures at the human-animal interface;
- epidemiological studies;
- clinical characterisation and clinical management of diseases caused by the virus;
- infection prevention and control, including the best ways to protect health care workers;
- research and development of drugs and other therapeutic methods and the development of new diagnostic approaches (research into vaccine development and near-market diagnostic development are not covered by the funding);
- accompanying research and ELSA research in connection with the outbreak.

Funding will also be provided for individual projects by German applicants who wish to participate in international research consortia within the framework of the global research response to COVID-19 coordinated by the WHO. An application according to the guidelines (http://www.dlr.de/pt/Portaldata/45/Resources/Dokumente/Leitfaden/Leitfaden_covid19_EN.pdf) must be submitted for the German individual project.

Funding for a period of up to 18 months is available in the following modules:

Module 1 - Combating COVID-19 through early clinical studies for the application of already known therapeutic approaches to Sars-CoV-2

Funding will be provided for early phase I, I/II and possibly II clinical studies on therapeutic approaches that have a reasonable chance of being transferrable to Sars-CoV-2.

Module 2 - Control of COVID-19 through new therapeutic and diagnostic approaches

Eligible for funding are:

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- clinical studies to expand the diagnostic possibilities for a better understanding of serology and thus of the course of infection, the effectiveness control of new therapeutic approaches and the effectiveness of infection and transmission control measures
- the development of therapeutic approaches in the late pre-clinical phase (proof-of-concept studies) up to the clinical testing of phase I

Module 3 - Research that contributes to the understanding of the virus and its spread

- Research on human pathogenic properties of the virus, infection chains and conditions of spread
- Approaches for testing the transferability of existing animal models to Sars-CoV-2
- Development of new clinically relevant animal models and human cell models (e.g. lung infection model)
- Epidemiological approaches
- Infection prevention (without vaccine development) and control, also for the protection of healthcare workers
- Research on ethical, legal and socio-economic aspects (ELSA) related to the current outbreak situation

Module 4 - Support of already ongoing research projects on corona viruses

Under Module 4, publicly funded German research projects on coronaviruses and related ELSA research that are already underway can apply for a grant for limited additional work of up to 50,000 euros.

3 Grant recipients

The underlying call for proposal applies

4 Prerequisites for funding

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Beneficiaries are obliged to,

- comply with uniform standards for quality assurance of biomaterial banks, patient registers, IT networking, animal studies (including ARRIVE Guidelines¹) and when carrying out clinical studies according to international standards (including the Helsinki Declaration, ICH Guideline on Good Clinical Practice, EU Directive 2001/20 / EC), CONSORT statement²;
- comply with internal scientific codes and recommendations for security-related research;
- participate in possible evaluative measures and provide information for evaluating the success of the funding measure.

For the purpose of better global coordination of the use of funding, the BMBF intends to share relevant application and project data with international sponsors who are WHO-coordinated in GloPID-R³. Applicants must already give their written consent when submitting the application, but can exclude details relevant to patent law from this by highlighting these in the application

¹ <https://www.nc3rs.org.uk/arrive-guidelines>

² <http://www.consort-statement.org/>

³ <https://www.glopid-r.org/>

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accordingly.

Funded projects must be application-oriented research and development. Purely or mainly basic research projects cannot be funded.

Further requirements apply to individual modules:

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Module 1 - Applicants must plausibly demonstrate how the therapeutic approach can be quickly and reliably introduced into clinical practice.

Purely academic consortia or individual projects must have the consent of any intellectual property rights holders.

Module 2 - For preclinical approaches, it must be plausibly demonstrated that the approaches can be transferred into a phase I clinical trial within 12-18 months from the start of the project.

5 Type, scope and amount of the grant

The funding period is up to 18 months.

Grants may be awarded as non-repayable subsidies in the form of project funding.

Applicants from outside industry are eligible for funding for project-related additional expenditure such as personnel, equipment and travel funds as well as, in justified exceptional cases and up to a maximum amount of 5,000.00 euros, project-related investments that are not part of the applicant's basic equipment. Funds for doctoral students are not eligible for funding.

Funds for Master students may be applied for only in projects on ELSA research.

In addition, expenditure/costs relating to the following items are also eligible:

- Expenditure on the preparation of the detailed study protocol;
- expenditure on registration of the study;
- expenditure on publication fees incurred for the open-access publication of the preliminary results during the lifetime of the project;
- Expenditure/costs incurred during the lifetime of the project which are necessary to obtain and validate patents and other industrial property rights are generally eligible for funding.
- Cooperation with thematically related R&D projects abroad is possible, although the international partner(s) must in principle have their own funding for their part(s) of the project. Additional funds, e.g. for scientific communication, for the organization of workshops and working meetings, are eligible for funding
- If cooperation with a foreign working group is necessary for the processing of an essential work package, personnel and material resources in the form of a subcontract are eligible for funding. The existing need and the scientific added value must be justified.

Project-related surveys of patients in participating institutions should generally be remunerated by means of flat-rate allowances for expenses; these should be linked to quality criteria with regard to data collection. Expenses for the preparation of an ethics opinion by the university's own ethics committee are included in the basic budget and cannot be funded.

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Under Modules 1 and 2, research projects/ research consortium projects can be applied for with up to 2 million euros per project or per research consortium. This also includes funds for pharmacological-toxicological testing and GMP production - if necessary for the implementation of the research project

Under Module 3, research projects with up to 0.5 million euros per project or per consortium can be applied for.

Under Module 4, German universities and non-university research institutions can apply for funding under a simplified, "summary" approval for limited additional work on already ongoing, publicly funded research projects on coronaviruses or related ELSA-research if the financial framework does not exceed the total expenditure of 50,000 euros.

In the case of research projects at universities, a lump-sum project allowance of 20% will be granted in addition to the eligible expenditure.

6 Other grant provisions

Regulations of the underlying call for proposals apply

7 Procedures

7.1 Involvement of a project management agency, application documents, other documents and use of the electronic application system

The BMBF has currently commissioned the following project management organisation to manage the funding measure:

DLR Project Management Agency

- Health research -

Heinrich-Konen-Strasse 1

53227 Bonn

Phone: 02 28/38 21-12 10, Fax: 02 28/38 21-12 57

E-mail: gesundheitsforschung@dlr.de

Internet: www.gesundheitsforschung-bmbf.de

Contact persons are:

Frau Dr. Laura de la Cruz

E-Mail: covid19@dlr.de

Telefon: +(0)49 30 670 557985

Frau PD Dr. Barbara Junker

E-Mail: covid19@dlr.de

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Telefon: +49 (0)228 3821 1274

Only for ELSA projects:

Frau Dr. Katja Hüttner

E-Mail: covid19@dlr.de

Telefon: + 49 (0)228 3821 2177

Any changes in this regard will be announced in an appropriate manner.

It is recommended to contact the project management agency for advice on applications. Forms for funding applications, guidelines, information sheets, instructions and ancillary provisions can be downloaded from the Internet at <https://foerderportal.bund.de/easyonline/> or requested directly from the above-mentioned project management organization.

7.2 One-step procedure

The application procedure has a single-stage structure. Formal applications for funding can be submitted to the DLR project management organisation on an ongoing basis from now until 11 May 2020 at the latest. The application will be reviewed, including a technical review by external experts, immediately upon receipt. In order to ensure rapid approval, it is recommended not to wait until the end of the submission period before submitting the application.

All formal applications for funding must be accompanied by a detailed project outline (see Guidelines). The project outline is the basis for the expert evaluation. With regard to the international evaluation procedure, it is recommended that the project outline be submitted in English.

Applications received will first be examined by the promoter in terms of their form and compliance with the objectives and conditions set out in points 2 and 4 of this call for proposals. The further technical examination will then be carried out by written procedure with the participation of external experts. The evaluation will be based on the following criteria:

- Fulfilment of the funding objectives and eligibility conditions (see sections 2 and 4);
- scientific and methodological quality of the research projects as well as a high degree of relevance and feasibility;
- realistic work, time and milestone planning;
- management and coordination of the consortium (if applicable);
- appropriateness of the financial planning.

Together with the formal applications for funding, additional information supplementing the project outline must also be submitted:

Required documents:
Electronic version of the final version of the AZA/AZAP/AZK

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German project description with exploitation plan according to the structure of AZA/AZAP 6 in the "Richtlinien für Zuwendungsanträge auf Ausgabenbasis" (Guidelines for applications for grants on an expenditure basis) or Richtlinien für Zuwendungsanträge auf Kostenbasis von Unternehmen der gewerblichen Wirtschaft (AZK) (Guidelines for applications for grants on a cost basis from commercial enterprises)
Statements on industrial property rights (patents) or applications for industrial property rights (patent applications): brief description of whether industrial property rights and applications for industrial property rights may prevent a later exploitation of results
Explanatory notes to the financing plan in easy AZA/AZAP or as a separate file in German
Official copy* from the responsible state ministry (only applies to universities)
Printed copy legally binding signed
Submission of personal data when requesting personnel already known by name
Resource-related work plan (see Guidelines)
For clinical studies: recruitment plan (see Guidelines)
For clinical studies: termination criteria for individual study centers: please formulate criteria for the exclusion or termination of already initiated study centers, unless this has been done in the informal application.
Tenders (equipment, contract awards)

The project ideas suitable for funding are selected based on the criteria and evaluation given above. Interested parties will be informed of the selection result in writing.

7.3 Regulations to be considered

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8 Entry into force

This call for funding comes into force on the day of its publication.