18.06.2020

Guidelines for a special programme to accelerate research and development of urgently needed vaccines against SARS-CoV-2

(*English translation for information purposes only. The legal basis for applicants shall be exclusively the German text of the funding announcement.)*
from 18.06.2020 – Deadline for submission: 15 July 2020

1 Funding objective, funding purpose, legal basis

1.1 Funding objective and funding purpose

The COVID 19 pandemic is causing significant and long-lasting damage to global health and the world economy. An end to the pandemic will only be possible with the sufficient availability of safe and effective vaccines. Effective vaccination protection against SARS-CoV-2 is therefore a key to social and economic normalisation. As a strong research and development location, Germany feels a responsibility to promote promising approaches to vaccine development in the local research institutions and companies that have already carried out promising preliminary work. The Federal Ministry of Education and Research (BMBF) is already funding the development of vaccines against SARS-CoV-2 within the framework of the international initiative "Coalition for Epidemic Preparedness Innovations (CEPI)", which focuses on the global supply of vaccines. The present BMBF funding guideline complements these efforts by accelerating the development of vaccines in order to ensure the earliest possible and extensive provision of an effective and safe vaccine in Germany. The aim is to develop an effective vaccine and make it available for pharmaceutical production by the end of 2021. This is to be achieved by funding clinical trials, expanding study capacities and increasing production capacities for the vaccine candidates to be tested (funding purpose). This should also make it possible to include special target groups in Germany (e.g. health care personnel) in clinical trials on a larger scale. The funding is intended to support as many different technological approaches as possible in order to increase the probability of successful vaccine development up to approval.

The special programme is part of the Federal Government's Health Research Framework Programme and serves in particular action field 1: "Research funding - preventing and curing diseases".

1.2 Legal basis

The Federal Government will award grants in accordance with these funding regulations, sections 23 and 44 of the Federal Budget Code (BHO) and the administrative regulations adopted thereunder as well as BMBF's regulations governing applications for cost-based grants (AZK). There is no entitlement to the award of the funds. The funding authority will decide on the basis of its best judgement within the framework of the budget funds available.

These funding guidelines apply in conjunction with the Health Research Framework Programme.

The legal basis for state aid is § 1, § 2 and § 3 of the regulation on the temporary provision of aid within the territory of the Federal Republic of Germany in connection with the outbreak of COVID-19 ("Federal Regulation for Research, Development and Investment Aid"), approved by the European Commission on 28 April 2020 under the reference number SA.57100 and on the basis of points 3.6, 3.7 and 3.8 of the Temporary Framework of the European Commission for State aid to support the economy in view of the current outbreak of COVID-19[1]. The requirements specified therein apply. This funding guideline serves the administrative implementation of the legal basis for state aid; no further elaboration of the aid scheme will apply.

2 Object of funding

Funding is provided for individual projects of the research-driven pharmaceutical and biotechnology industry. Subjects of funding are

- Clinical vaccine development in phases I – III. The clinical development must be based on vaccine candidates against SARS-CoV-2, for which preclinical development has progressed to such an extent that the first clinical trials can be started before 15 November 2020.
- The early expansion of manufacturing and bottling capacities (also by subcontracting). The establishment or expansion of the grant recipient's own production and bottling facilities must take place in Germany. This includes in particular 1) preliminary work and procurement processes that are essential for the seamless transition to the respective subsequent trial phase and 2) preliminary work and procurement process-

[1] European Commission Communication C(2020) 1863 final of 19 March 2020 on the adoption of the Temporary Framework and its amendments C(2020) 2215 and C(2020) 3156 of 3 April 2020 and 8 May 2020 respectively

es that are required prior to approval in clinical development and that are necessary to expand and secure production capacities parallel to approval and thereafter (e.g. costs for bottling facilities).
- The extension of clinical trial capacities in Germany. This includes in particular the inclusion of additional volunteers in the clinical trials of phases II-III.

The above funding subjects must be addressed in their entirety in the projects.

3 Funding recipients

Eligible to apply are companies in the commercial sector. The existence of a permanent establishment or branch office (company) in Germany is required at the time of payment of the grant. It is expected that the R&D activities applied for will generally be carried out in Germany. Companies that were already in difficulties on 31 December 2019 pursuant to Article 2(18) of the General Block Exemption Regulation[2] are excluded from receiving funding.

In addition to other commercial companies, e.g. state and state-recognized universities, non-university research institutions and departmental research institutes can be involved by subcontracting.

Note for SMEs: Applicants from the commercial sector must check whether they meet the requirements for classification as a micro, small or medium-sized enterprise (SME) according to the EU Commission's definition of SMEs and declare their classification to the granting authority in the written application (cf. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, published under reference number C (2003) 1422 (2003/361/EC)): https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32003H0361&from=DE.

For the conditions if state aid is present/not present and to which extent aid can be granted free of state aid, see Commission Communication on the Union Framework for State Aid for Research, Development and Innovation of 27 June 2014 (OJ C 198, 27.6.2014, p. 1 et seq.); in particular section 2.

[2] Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty on the Functioning of the European Union, Official Journal of the European Union L 187, 26.6.2014, p. 1. Where reference is made in this scheme to the definition of 'firm in difficulty' in Article 2(18) of Regulation (EU) No 651/2014, this is also a reference to the definitions in Article 2(14) of Regulation (EU) No 702/2014 and Article 3(5) of Regulation 1388/2014 respectively.

4 Specific eligibility criteria

In the context of an application for state aid, the requirements under state aid regulations listed in the Annex (not included in the English translation) must be considered.

Preparatory requirements to be met

Applicants must:

- provide evidence of relevant preparatory work in the development of vaccines against SARS-CoV-2 and, if possible, have completed the pre-clinical testing of the vaccine candidates proposed for further development in accordance with the requirements of the responsible regulatory authority;
- provide, together with the application, documentation of scientific advice from the responsible regulatory authorities (e.g. Paul-Ehrlich-Institut, European Medicines Agency) including the respective documents submitted to these authorities. Part of the consultation with the responsible regulatory authority should in particular include the clinical development programme. The information provided in this regard should demonstrate in a sufficiently credible manner that the clinical trials will be started, if possible, before 15 November 2020;
- demonstrate in a verifiable and reliable manner that the structural, regulatory and financial conditions for the implementation of the project are in place (e.g. when applying for costs for reservations or the establishment of manufacturing facilities);
- demonstrate in a verifiable and reliable manner that they hold the required intellectual property rights for the development, production, commercialisation and marketing of the vaccine in Germany and that they are not subject to any restrictions in the development, production, commercialisation and marketing in Germany;
- demonstrate in a verifiable and reliable manner that the structural and financial conditions are in place for the proper termination of the clinical trials after the funding phase, if the duration of the clinical trials exceeds the maximum possible funding period.

Scientific standards

In addition to the legal provisions applicable to clinical trials, the applicants are obliged to comply with the applicable national, European and international standards for the planning, realization and reporting of clinical trials, which reflect the current state of scientific knowledge and the state of the art.

Accessibility and long-term preservation of research data and results

Access to scientific knowledge and data is an essential basis for research, development and innovation. The long-term preservation and availability of research data contributes to the transparency and quality of scientific work. Therefore, the following conditions apply:

- Research results that have been achieved within the scope of these funding regulations must be published, even if the study hypothesis has not been confirmed (null hypothesis).
- The publication of research/study results shall generally be in the format of open access publications.
- Original data used in the publications should be made available for subsequent use in accordance with the FAIR principles; (findable, accessible, interoperable and reusable, see also https://data.europa.eu/euodp/data/dataset/open-research-data-the-uptake-of-the-pilot-in-the-first-calls-of-horizon-2020/resource/7bde6e00-e516-4bac-9c72-16b1e542dc27) and in compliance with the rights of third parties, in particular data protection and copyright.

In the aforementioned conditions the interests of utilization must be appropriately taken into account.

Possibilities for exploitation and application

The planned exploitation as well as strategies for a sustainable implementation must already be addressed in the concept of the project applied for and described on a structural and procedural level. This also includes information on exploitation beyond the German and European area as well as information on pricing.

It is also expected that an appropriate share of the production of an approved vaccine will be made available for demand-oriented supply in Germany.

In case of discontinuation or significant delay of their vaccine development, applicants must be prepared to make available the production and trial capacities (built up with the funds and no longer required), including the use of already reserved capacities at third-party companies - if justifiable at reasonable expense - for the development or production of other vaccines. A respective declaration must be attached to the application.

5 Type and volume, amount of the grant

The funding of projects ends at the latest on 31 December 2021.

The grants will be awarded as non-repayable grants on the basis of a milestone planning.

Grants will be paid in instalments. By derogation from the usual rules in cost-based funding, it is intended to make an initial instalment at the beginning of the project and to make further instalments dependent on the achievement of milestones. The design of the project applied for must address the milestones on a structural and procedural level (milestone plan) and couple them to the respective instalments. A parallelisation of the development steps is not excluded. Milestones may include the successful completion of phase I, IIa, IIb in the clinical trials. A failure in achieving milestones may lead to the termination of the funding.

The basis for calculating the grants to commercial companies are the eligible project-related costs. These costs can be partly financed in accordance with the regulations governing grants (see Annex, English translation not included in this document). In accordance with BMBF policy, an appropriate own contribution to the resulting eligible costs is assumed.

The state aid requirements stipulated in the legal basis must be complied with when determining the relevant eligible costs and when calculating the respective funding intensity (see Annex, English translation - not included in this document).

General information on eligible costs can be found in the Guidelines for Grant Applications on Cost Basis (AZK) and the information sheet on Preliminary Calculation for Grants on Cost Basis (AZK 4). All documents can be found under https://foerderportal.bund.de/easy/easy_index.php?auswahl=easy_formulare&formularschrank=bmbf#t2. In addition, especially the following costs are eligible for funding:

- publication fees for open-access publication of the preliminary results in the funding period of the project;
- costs occurring in the funding period of the project for obtaining and validating patents and other industrial property rights are generally eligible.

6 Other grant provisions

The "Auxiliary Terms and Conditions for Grants on Cost Basis to Commercial Enterprises for Research and Development Projects" (NKBF 2017) of the Federal Ministry of Education and Research (BMBF)" will generally be part of the official notification of grants on cost basis.

Research, development and investment grants may be awarded until the legal basis for state aid expires, currently until 31 December 2020.

To enable success control in accordance with VV number 11a under section 44 of the Federal Budget Code (BHO), the grant recipients are obliged to provide the respective necessary data to BMBF or the institutions commissioned to carry out such reviews in a timely manner. The information will be used exclusively in the course of the accompanying research and, if applicable, the subsequent evaluation, it will be treated confidentially and published in an anonymized form without possibilities to identify individual persons or organizations. Appropriate consideration is also given to the interests of utilization.

7 Procedure

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

The BMBF has commissioned the following project management organization to manage this funding measure:

DLR Project Management Agency
- Health Research -
Heinrich-Konen-Strasse 1
53227 Bonn
Phone: 02 28 / 3821-1210
Fax: 02 28 / 3821-1257
gesundheitsforschung@dlr.de
Internet: www.gesundheitsforschung-bmbf.de

Contact persons:

Dr. Roland Bornheim,
Dr. Andreas Künne and
Dr. Andreas Theilmeier
Phone: 02 28 / 3821-2323
E-mail: vaccine-covid19@dlr.de

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

It is recommended to contact the project management agency for advice. Further information and explanations are available there.

Forms for funding applications, guidelines, leaflets, information and auxiliary conditions can be downloaded from the following website

https://foerderportal.bund.de/

or can be requested directly from the above-mentioned project management organization.

7.2 Single-stage application procedure

The application procedure is a single-stage procedure. Formal funding applications which are legally binding signed can be submitted to the DLR Project Management Agency right away until 15 July 2020. It is recommended to contact the responsible project management organisation in advance.

A complete funding application is only submitted if at least the requirements of Article 6(2) of the General Block Exemption Regulation[3] are met. The requirements specified in the Annex (English translation not included in this document) to these funding guidelines must be considered. The deadline for submission is not a cut-off deadline. However, applications for funding received after the deadline mentioned above may not be considered. In the case of late submission, it is strongly recommended that applicants contact the responsible project management organisation in advance.

[3] Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty on the Functioning of the European Union (OJ L 187, 26.6.2014, p. 1)

The examination procedure involving external experts will be initiated immediately after receipt of the application. In case of a positive result due to the comparative review procedure, approval may be granted even before the end of the submission period. Therefore, it is strongly recommended not to postpone the submission of an application until the end of the submission period.

Formal applications for funding must be accompanied by a description of the project in both German and English, as international experts may be consulted for the review purposes while maintaining confidentiality. All parts of the application must be submitted in both written and electronic form.

The electronic application system "easy-Online" shall be used to prepare formal applications for funding. The link for submitting formal applications will be provided by the responsible project management organization on request.

The applications received will first be formally examined by the project management organization and with regard to their compliance with the objectives and conditions specified under sections 2 to 4 of this call for proposals. Applications that do not comply with the objectives and conditions will be rejected without further examination.

The subsequent review will then be carried out under participation of external experts and in a written procedure.

Outlines for the German and English project description will be provided by the project management organisation.

The project description has to be submitted electronically via an internet portal. The address will be provided by the responsible project management organization upon request.

Submission of the documents by e-mail or fax is not possible.

The grant applications received will be evaluated and examined according to the following criteria:

- Fulfilment of the funding objectives and eligibility criteria (see sections 2 to 4);
- Quality and level of development of the preparatory work and feasibility in the clinical trial (e.g. based on the presentation of the status of preclinical development, the vac-

cine candidates to be developed, the scientific and methodological bases and the possibility of rapid admission to the clinical trial);
- Quality, level of development and feasibility of the approaches for upscaling of productions (in particular based on the representation of the establishment of new own production and filling capacities as well as the financial, technical and structural requirements for this);
- Presentation of realistic work, time and milestone planning;
- Reliability of commitments made (e.g. place of study, production capacities, pricing, property rights, provision of reserved capacities at third party companies);
- Presentation of the appropriateness of the financial planning, plausibility of the requested milestone-based payments.

The funding goal to support different vaccine technologies can be taken into account in the funding decision.

According to the criteria and evaluation given above, a decision will be made on funding after the application has been examined.

The applicants will be informed of the result in writing.

7.3 Relevant regulations

Sections 48 to 49a of the Administrative Procedures Act, Sections 23 and 44 of the BHO and the related provisions apply to the approval, payment and settlement of the grant as well as for the proof and examination of the use and the possibly necessary cancellation of the grant notice and the recovery of the granted grant general administrative regulations, unless deviations from the general administrative regulations have been permitted in this funding guideline. The Federal Audit Office is authorized to audit in accordance with § 91 BHO.

8 Period of validity

This guideline enters into force on the day of its publication in the Federal Gazette and is valid until 30 June 2022.

Berlin, 11 June 2020

Federal Ministry of Education and Research

Spelberg