DLR Projektträger

Bundesministerium für Bildung und Forschung

Leitfaden für die Erstellung von Projektskizzen zum „Förderaufruf zur Erforschung von COVID-19 im Zuge des Ausbruchs von Sars-CoV-2“

Version vom 03.03.2020

Dieser Leitfaden stellt die Anforderungen für die Erstellung von beurteilungsfähigen Projektskizzen im Rahmen der Module 1 bis 4 des o.g. Förderaufrufs (https://www.gesundheitsforschung-bmbf.de/de/10592.php) dar. Er ergänzt den am 03. März 2020 veröffentlichten o.g. Förderaufruf und soll offene Fragen im Vorfeld der Einreichung klären.

Projektskizzen, die den Vorgaben des Förderaufrufs und des folgenden Leitfadens nicht entsprechen, können ohne weitere Prüfung abgelehnt werden.

Es wird dringend empfohlen, zur Beratung mit dem DLR Projektträger Kontakt aufzunehmen. Ansprechpartnerinnen sind:

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Nur für ELSA-Projekte:

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Die Fördermaßnahme wird in enger Abstimmung mit den Sofortmaßnahmen anderer internationaler Forschungsförderorganisationen (u.a. Wellcome Trust, Canadian Institutes for Health Research, der EU-Kommission sowie der Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) und der Weltgesundheitsorganisation (WHO) durchgeführt. **Doppeleinreichungen bei verschiedenen internationalen Förderern von Sofortmaßnahmen zu Sars-CoV-19 sind nicht zulässig und führen zum Ausschluss aus dem Verfahren. Bei der Einreichung von mehreren Anträgen beim BMBF wie auch anderen Forschungsförderern ist eine Abgrenzung der beantragten Arbeiten darzulegen.**

Einreichungsverfahren

In allen Modulen ist eine einstufige, fachliche Begutachtung vorgesehen. Für Module 1-3 ist eine **englische Projektskizze** einzureichen, die von unabhängigen, externen Gutachtenden bewertet wird. Zusätzlich ist der **deutsche Formantrag inkl. der deutschen Vorhabenbeschreibung und weiterer Anlagen** einzureichen. Es besteht die Möglichkeit die englische Projektskizze max. bis zu einer Woche **vor** dem Formantrag einzureichen. Es ist angeraten, die vollständigen Unterlagen so früh wie möglich einzureichen, spätestens am 11. Mai 2020, da die Anträge in der Reihenfolge ihres Eingangs geprüft und bewilligt werden. Es gilt das Eingangsdatum des deutschen Formantrags inkl. deutscher Vorhabenbeschreibung!

Für Antragstellende unter Modul 4

Für Anträge, die unter Modul 4 eingereicht werden, ist nur die Einreichung des Formantrags und der deutschen Vorhabenbeschreibung entsprechend der Gliederung in den Richtlinien für Zuwendungsanträge auf Ausgabenbasis des BMBF notwendig. Zusätzlich sind eine deutsche Kurzbeschreibung des bereits geförderten Projektes zu Coronaviren bzw. eines Projektes mit eng verwandter und übertragbarer Fragestellung (mit Angabe des Förderers, der Förderlaufzeit und Fördersumme) sowie eine Abgrenzung zum hier neu zu beantragten Projekt einzureichen (max. 2 Seiten).

Vorgaben für die englischen Projektskizzen

Die Projektskizzen müssen den Vorgaben und der Formatierung der Mustervorlagen (Schriftart Arial, Schriftgrad 11, Zeilenabstand 1,0 Zeilen) entsprechen und **in englischer Sprache** verfasst werden. Die vorgegebenen Seitenzahlen dürfen nicht überschritten werden. Die Kopfzeile soll das Akronym des Projektes enthalten. Anträge, die diese formalen Vorgaben nicht erfüllen, können von der Bewertung ausgeschlossen und ohne weitere Begründung abgelehnt werden.

Im Fall von Verbundprojekten stellt der Verbundkoordinator oder die Verbundkoordinatorin **EINEN** Antrag für den Verbund. Dieser enthält den Mantelantrag und die Teilprojekte nach den Vorgaben dieses Leitfadens und wird als ein Gesamtdokument im PDF-Format eingereicht. Weitere Anlagen, wie beispielsweise Lebenslauf oder „Letter-of-Intent“, sind nicht zugelassen.

Die Laufzeit der beantragten Projekte ist auf **maximal 18 Monate** begrenzt. Innerhalb der Laufzeit ist eine Aufnahme der geförderten Gruppen als Mitglieder des Forschungsnetzes Zoonosen vorgesehen. Hierfür ist unter den Geförderten eine Vertreterin oder ein Vertreter zu wählen.

Für Einzelvorhaben deutscher Antragstellender an internationalen Forschungskonsortien

Einzelvorhaben deutscher Antragstellender, die sich an internationalen Forschungskonsortien im Rahmen der weltweiten und von der WHO koordinierten Forschungsantwort zu COVID-19 beteiligen, müssen zusätzlich zu ihrer Projektskizze den Mantelantrag für den Verbund für das internationale Konsortium ausfüllen. Antragstellende müssen bei Antragstellung das Interesse der ausländischen Kooperationspartner schriftlich möglichst in Form einer formalen Absichtserklärung (Memorandum of Understanding) nachweisen. Eine rechtlich verbindliche Kooperationsvereinbarung ist innerhalb des ersten Fördermonats vorzulegen. Widrigenfalls wird die Förderung widerrufen.

Mustervorlagen für die Projektskizzen

Mustervorlagen und Erläuterungen zu den Projektskizzen sind in diesem Leitfaden eingefügt

- Mustervorlage für die übergreifende Darstellung eines Verbundvorhabens (ab S. 5);
- Mustervorlage für frühe klinische Studien in Modulen 1 und 2 (ab S. 7);
- Mustervorlage für präklinische Forschungsprojekte in Modulen 2 und 3 sowie ELSA-Projekte in Modul 3 (ab S. 17);
- Mustervorlage für eine epidemiologische Studie in Modul 3 (ab S. 22).

Einreichen von Projektskizzen

Die Projektskizzen sind i**m PDF-Format** elektronisch unter https://ptoutline.eu/app/covid19 einzureichen.

Einreichen der deutschen Formanträge für alle Module

Die deutschen Formanträge (AZA/AZAP/AZK) inkl. der deutschen Vorhabenbeschreibung gemäß der Gliederung in den "Richtlinien für Zuwendungsanträge auf Ausgabenbasis" bzw. „Richtlinien für Zuwendungsanträge auf Kostenbasis von Unternehmen der gewerblichen Wirtschaft (AZK)“sind unter https://foerderportal.bund.de/easyonline/reflink.jsf?m=KI1ZOONOSEN&b=KI1PLATTFORMCOVID einzureichen. Den Link bitte ggf. in den Browser kopieren.

Bei administrativen Fragen zum Formantrag sind Ihre Ansprechpartnerinnen:

Frau Kerstin Paffenholz
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Frau Aldona Solda
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Mustervorlagen und Erläuterungen zur Erstellung der Anlagen zum Formantrag:

- Mustervorlage Ressourcenbezogener Arbeitsplan
- Mustervorlage Verwertungsplan
- Checkliste zum Erstellen des Formantrages inkl. Aussage zu Schutzrechten und Notwendigkeit der Zuwendung
- Verpflichtung ICH-GCP *(für Klinische Studien)*
- DSMB Erklärung *(für Klinische Studien)*
- Rekrutierungsplan *(für Klinische Studien)*

Allgemeine Hinweise

Nachfolgende Hinweise sind bei der Planung und Einreichung aller Projektskizzen zu beachten.

Wissenschaftliche Standards
Die Antragstellenden sind verpflichtet, nationale und internationale Standards zur Qualitätssicherung der präklinischen bzw. klinischen Forschung einzuhalten. Hierzu sind auch die nachfolgenden Dokumente in der jeweils geltenden Fassung zu berücksichtigen:

- Deklaration von Helsinki,
- ICH-Leitlinie zur Guten Klinischen Praxis (ICH-GCP),
- EU-Richtlinie 2005/28/EG und EU-Verordnung Nr. 536/2014,
- CONSORT-, STARD- und PRISMA-Statements[1].
- ARRIVE Guidelines[2]
- PREPARE Guidelines
- GEP[3]
- Leitlinie zur Guten Zellkulturpraxis (Good Cell Culture Practice, GCCP)

Zudem sind für klinische Studien die „Grundsätze und Verantwortlichkeiten bei der Durchführung klinischer Studien“ des BMBF verpflichtend zu beachten:
https://www.dlr.de/pt/Portaldata/45/Resources/Dokumente/GF/Grundsaetze_Verantwortlichkeiten_Klinische_Studien.pdf

Es wird empfohlen, die Arbeitshilfen der TMF (Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V.) zu verwenden, z.B. zu Datenschutz oder Patienteneinwilligung.

[1] http://www.consort-statement.org/
[2] https://www.nc3rs.org.uk/arrive-guidelines
[3] https://www.dgepi.de/assets/Leitlinien-und-Empfehlungen/Recommendations-for-good-Epidemiologic-Practice.pdf

Registrierung und Zugänglichkeit des Studienprotokolls sowie der Forschungsergebnisse

Für klinische Forschung
Die Registrierung von klinischen Studien im nationalen oder in einem internationalen Studienregister ist vor Beginn der Studie nachzuweisen. Um Transparenz über die durchgeführte Forschung zu erreichen, ist bei Förderung das Studienprotokoll inklusive aller Dokumentationsformulare (CRF) in einer einschlägigen wissenschaftlichen Fachzeitschrift zu veröffentlichen.

Des Weiteren müssen die Ergebnisse der Forschungsvorhaben innerhalb von 1–2 Jahren nach Beendigung der Arbeiten veröffentlicht werden. Bei klinischen Studien sollen die Ergebnisse innerhalb eines Jahres nach Schließen der Datenbank in einem WHO-zertifizierten Primär-Register (z.B. im Deutschen Register Klinischer Studien, DRKS) eingestellt werden. Die Veröffentlichung der Ergebnisse der Forschungsvorhaben beinhaltet mindestens die Publikation der Ergebnisse auf einem wissenschaftlichen Kongress und die Publikation der Ergebnisse (auch negativer Ergebnisse) in einer einschlägigen wissenschaftlichen Fachzeitschrift. Die Veröffentlichung des Studienprotokolls sowie der aus dem Forschungsvorhaben resultierenden Ergebnisse soll in einer wissenschaftlichen Zeitschrift so erfolgen, dass der Öffentlichkeit der unentgeltliche elektronische Zugriff (Open Access) auf den Beitrag möglich ist. Für eine Open Access Veröffentlichung der Vorhabenergebnisse können nur solche Zeitschriften ausgewählt werden, deren Artikel unmittelbar mit Erscheinen über das Internet für Nutzer entgeltfrei zugänglich sind und die im jeweiligen Fach anerkannte, strenge Qualitätssicherungsverfahren anwenden. Publikationsgebühren für Open Access Publikationen sind zuwendungsfähig.

Unter dem Punkt „Quality assurance, data sharing“ in den Projektskizzen ist zu beschreiben, wie, in welchem Umfang, in welcher Verarbeitungsstufe und in welchem zeitlichen Rahmen die Forschungsdaten zugänglich gemacht werden, um eine sinnvolle Nachnutzung durch Dritte zu ermöglichen (unter Wahrung der Rechte Dritter insbesondere Datenschutz, Urheberrecht). Weitere Informationen unter:
http://www.dfg.de/download/pdf/foerderung/antragstellung/forschungsdaten/guidelines_research_data.pdf.

Cover template for a Consortium Application (Modules 1-3) within the „Funding announcement for research on COVID-19 in the wake of the Sars-CoV-2 outbreak"

This template is designed to give an overview of the entire research consortium. The maximum number of pages used must not exceed three pages including the references provided. In addition to this cover template, the individual research projects within the network, that is a maximum of three subprojects at three institutions, should use the appropriate template for application. In the event that clinical or epidemiological studies are planned, please refer to the templates for a clinical trial and an epidemiological study, respectively. For all other types of research projects foreseen (including ELSI or animal research), please use the template for a research project provided. Please put all documents together into one PDF-file.
When filling out the templates, please note that the entries in italics are intended as information for the application and must be deleted before submitting the application. Please make an entry for each heading. Please prepare your application in English not exceeding three pages (DIN A4, 11 point Arial and 9 point Arial for the synopsis and references, margins of at least 2 cm and single-spaced lines).

SYNOPSIS *(maximum of 1 page)*	
Module (1, 2 or 3)	
Applicant/ Coordinator	*Title Name* *Institute/Clinic/Department* *Institution* *Postal address* *Phone number, e-mail*
Acronym of the Consortium	*Acronym of the consortium*
Structure of the Consortium	*Structure of the consortium*
Summary of the Proposal	*Please briefly summarize the scientific goals of the consortium (max. 1800 characters incl. spaces)*
Requested Funding for the Consortium	*Total funding amount requested (BMBF share excluding project lump sum or overhead costs; for SMEs funding rate 50%) for the entire network for the requested funding period in €*
Requested Funding Period	*The maximum possible funding period is 18 months.*

1 Aims and Structure of the Consortium

1.1 Aim of the consortium

What are the goals of the consortium? Which scientific questions will be addressed? The research hypotheses on which the research concept is based should be clearly formulated. The added value of the joint work should be emphasized.

1.2 Structure of the consortium

What is the structure of the consortium? Which partners are participating in the consortium with which tasks? Please also comment on possible cooperation with partners outside the consortium at a national or international level.

Name	Affiliation	Responsibility/ Role/ Contribution	Sub-

			Project no.

1.3 Work Plan and financial summary

Briefly describe the work plan of the consortium: What should be done specifically? How will the above goals be achieved?
Please also fill out the table provided below:

Sub-Project no.	Method	Material	Aim	Amount of funding requested (excl. overhead)
	Animal study	mice		

2 References

Please list the five most relevant publications for the project in the last five years.

Application for a Clinical Trial within Modules 1 and 2

This template may be used for stand-alone research project or for research projects within a consortium.

The length of the - excluding the appendix – should not exceed 20 pages. Please do not change the formatting of the document or single paragraphs. When filling out the templates, please note that the entries in italics are intended as information for the application and must be deleted before submitting the application. Please make an entry for each heading. Please prepare your application in English (DIN A4, 11 point Arial and 9 point Arial for the synopsis and references, margins of at least 2 cm and single-spaced lines).

PRINCIPAL INVESTIGATOR OF THE TRIAL[4]	*In case of multiple applicants the principal investigator / coordinating investigator of the trial who will assume responsibility for conducting the clinical trial, should be listed first.* • First name, last name, academic title • Institution and department (complete name) • Postal address • Telephone • Fax • E-mail address
Subtype of Covid-19	*Please specify (if applicable) which subtype/course of condition your trial is aiming at (e.g. severe, asymptomatic, moderate form)*
TITLE OF STUDY AND ACRONYM	*Descriptive title identifying the study design, population, and interventions. In case of funding this title shall be quoted in the annual reports of the BMBF.*
OBJECTIVE(S)	*Which principal research questions are to be addressed? Specify clearly the primary hypothesis of the trial that determines sample size calculation.*
INTERVENTION(S)	*Brief description of the experimental and the control treatments or interventions as well as dose and mode of application.* Experimental intervention: Control intervention: Duration of intervention per patient: Follow-up per patient: Accompanying measures: *(e.g. pharmacokinetic analyses)*
KEY INCLUSION AND EXCLUSION CRITERIA	Key inclusion criteria: Key exclusion criteria:
OUTCOME(S)	Primary efficacy endpoint(s): *(e.g. for dose finding and/or for assessment of activity)* Key secondary endpoint(s): Assessment of safety:
STUDY TYPE	*e.g. randomized / non-randomized, type of masking (single, double,*

[4] Zur Definition des "Investigator" siehe “Guideline for Good Clinical Practice” der International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH GCP) (http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf).

	observer blind), type of controls (active / placebo), parallel group / cross-over
STATISTICAL ANALYSIS	Efficacy: Description of the primary efficacy analysis and population: Safety: Secondary endpoints:
SAMPLE SIZE	To be assessed for eligibility (n = …) To be allocated to trial (n = …) To be analysed (n = …)
TRIAL DURATION	Time for preparation of the trial (months): Recruitment period (months): First patient in to last patient out (months): Time for data clearance and analysis (months): Duration of the entire trial (months):
PARTICIPATING CENTERS	To be involved (n): How many centres will be involved? *if applicable* Signed agreement to participate (n)*: How many centres have signed an agreement to participate? Full list under point 12.*
SUMMARY	*Please summarize your proposal in a max. of 300 words.*

1 Innovation and Relevance of the Project

1.1 Objectives/Research Goals

What is the objective? Which results are to be expected?

1.2 Evidence

Set your trial into perspective; substantiate your starting hypothesis. What is the rationale for the intervention? Please describe the existing evidence to support the trial (e.g. proof of principle in a disease specific animal model, relevant systematic review(s) and/or (own) pilot studies, feasibility studies, relevant previous/ongoing trials, case reports/series).

Please note: *Prerequisite for funding of early clinical trials is the provision of relevant and reliable data concerning the potential clinical efficacy of the therapeutic approach in the respective disease area. Therefore, please describe in detail the strengths and weaknesses in the stringency of the previous research and provide evidence for your previous results.*

1.3 Safety

Please provide reliable data on safety and tolerability of the therapy.

1.4 Novel aspects and future impact

What is the novel aspect of the proposed therapy? Describe the innovative approach, development stage of therapeutic concept, prior art/comparison with existing therapies, innovative character. Specify the clinical impact and the therapeutic benefit. What will be the improvement for the patients? Why are the results of the trial important?

Reflect on the socioeconomic impact of the trial (e.g. potential cost reductions for health care, prospective pricing).

1.5 Subsequent Trial(s)

What would be the information gained for a subsequent trial? Define criteria that need to be fulfilled for transferring the proposed approach to a subsequent trial or for dismissing the proposed interventional approach.

1.6 Patient involvement

Please describe how patient involvement is implemented in the planning, conduct and exploitation of results of the trial. Patient involvement can be implemented in different stages of the trial and to a different extent. Please describe your concept for patient involvement.

2 Exploitation concept

Funding is provided in order to accelerate the clinical development and the transfer into clinical practice of new therapies which are of high medical relevance for COVID-19. The following list points out essential features which need to be adjusted according to the development status of your project.

2.1 Intellectual property rights

Please describe the existing freedom to operate of the academic study sponsor in respect to patent and exploitation strategy.

2.2 Assessment of regulatory aspects

Assess the regulatory aspects of your scientific and clinical activities. Describe how regulatory knowledge is represented in your project. Are industrial partners involved who may pursue authorization of the new therapeutic concept, if necessary? Have meetings with regulatory authorities already taken place? Please summarize briefly the results of these meeting(s).

2.3 Next Steps/Milestones

Present necessary next steps and major planned milestones until market entry or introduction into medical practice.

2.4 Expertise for exploitation

Describe skills and expertise of the members of the management team to promote the therapeutic approach and to drive into medical practice. Outline involvement of experts with respect to advice on industrial standards, regulatory aspects, and cooperation with industrial partners.

3 Intervention and Design Aspects

3.1 Intervention Scheme / Trial Flow

Describe the intervention scheme in depth and give a schematic diagram (flow chart) of design, illustrating interventions, procedures and stages. Recommendations for a complete description you may find in the TIDieR checklist and guide.

3.2 Frequency and Scope of study Visits

What is the proposed frequency and scope of study visits and, if applicable, the duration of post-trial follow-up? Please also give a table with time-points of visits and procedures per time-point. Specify items to be recorded on CRF per procedure.

3.3 Control(s) / comparator(s)

Justify the choice of control(s) / comparison(s): Is placebo acceptable? Is there a gold standard? Which previous (animal) studies established efficacy and safety of the chosen control regimen?

3.4 Dose, Mode and Scheme of Intervention

Justify the dose (finding), the mode and the scheme of the intervention. How does the intervention compare to other interventions for the same condition? Will the trial drugs be readily available for the trial?

3.5 Additional Treatments

Please describe the medication(s) / treatment(s) permitted (including rescue medication) and not permitted before and / or during the trial, if applicable.

3.6 Inclusion / exclusion criteria

Justify the population to be studied, include reflections on generalisability and representativeness, specifically with regard to gender and age.

3.7 Outcome measures

Justify the endpoints chosen: Are there other trials that have utilized this endpoint? Are there any guidelines proposing this endpoint / these endpoints? Patient-relevant endpoints have to be prioritized, if possible. Discuss the clinical relevance and as well the relevance for the patient of the outcome measures for the target population or the patient. Have the measures been validated? Justify appropriateness and limitations of composite endpoints, if applicable.

Determination of primary and secondary measures

How will primary and secondary endpoints be derived from actual measurements, e.g. how is the figure used in the statistical test calculated from the variables initially measured in the subjects?

3.8 Methods against bias

Is randomisation feasible? Which prognostic factors need to be regarded in the randomisation scheme and the analysis? What are the proposed practical arrangements for allocating participants to trial groups? Will trial site effects be considered in randomisation?

Is blinding possible? If blinding is not possible please explain why and give details of alternative methods to avoid biased assessment of results (e.g. blinded assessment of outcome).

3.9 Proposed sample size / power calculations

What is the proposed sample size and what is the justification for the assumptions underlying the power calculations?

Include a comprehensible, checkable description of the power calculations and sample sizes detailing the outcome measures on which these have been based for both control and experimental groups; give event rates, means and medians, the software used for sample size calculation etc., as appropriate. Justify the size of difference that the trial is powered to detect, or in case of a non-inferiority or equivalence study, the size of difference that the trial is powered to exclude. Give evidence / references for the estimated effect size.

If the proposed sample size is not based on statistical calculation, please justify why another approach has been chosen and why the proposed sample size will be adequate to answer the objective of the trial.

Sample size calculations need to take into account anticipated rates of non-compliance and losses to follow up.

Compliance / Rate of loss to follow up

Provide details for assumptions on compliance issues. On what evidence are the compliance figures based?

What is the assumed rate of loss to follow up? On what evidence is the loss to follow up rate based? How will losses to follow up or non-compliance be handled in the statistical analysis?

3.10 Feasibility of Recruitment

What is the evidence that the intended recruitment rate is achievable (i.e. available pilot data, access to patients etc. ?

International collaborations

If the proposed trial includes foreign centres or collaboration with organisations in other countries, please give full details of funding arrangements agreed or under consideration.

3.11 Stopping rules

Please specify the "stopping rules" or "discontinuation criteria"

a) for the individual patient,
b) for participating centers which fail to include the estimated number of patients (if applicable) and
c) for the whole trial.

4 Statistical Analysis

What is the proposed strategy of statistical analysis? What is the strategy for analysing the primary outcome? If applicable, how will multiple primary endpoints be analysed statistically? If interim analyses are planned, please specify. Are there any subgroup analyses? Discuss the robustness of your results e.g. with respect to unavoidable incomplete or missing data.

5 Ethical Considerations

Give a description of ethical considerations relating to the trial (assessment of risks and benefits, care and protection for research participants, protection of research participants' confidentiality, informed consent process).

6 Strategies for Data Storage, Handling and the Dissemination of Results

Describe how data will be collected / generated and how consistency and quality of data will be controlled and documented. Describe how data will be stored, backed-up, managed and curated in the short to medium term. Specify any community agreed or other formal data standard used.

Which metadata is produced about the data generated from the research to enable research data to be used by others outside of your own team (taking into account privacy rules and proprietary data), e.g. documentation of methods used to generate the data, analytical and procedural information, provenance of data and their coding, detailed descriptions for variables, records etc.? Provide plans and place for long-term storage and preservation. Please use existing standards and data repositories where appropriate. Further information can be found under:

http://www.dfg.de/download/pdf/foerderung/antragstellung/forschungsdaten/guidelines_research_data.pdf.

Please provide a data sharing statement, which includes answers to the following questions: Will individual deidentified participant data (including data dictionaries) be shared at all? What data in particular will be shared? Will additional, related documents be available (e.g., study protocol, statistical analysis plan, etc.)? When will the data become available and for how long? By what access criteria will the data be shared (including with whom, for what types of analyses, and by what mechanism)? Further information on the data sharing statement can be found under https://www.nejm.org/doi/full/10.1056/NEJMe1705439.

Discuss the dissemination of results of the project, especially beyond regular journal publication. Please state your willingness to share relevant research and project data with other international funding organisations using GloPID-R. Please also indicate which parts of your research contain IP-relevant details and should therefore not be shared.

7 Quality Assurance and Safety

7.1 Quality assurance / monitoring

What are the proposed measures for quality assurance? Which institution will perform the monitoring? Which SOPs will be utilized? Describe and justify the monitoring strategy (percentage of source data verification, number of monitor visits per trial site).

7.2 Safety/ Pharmacovigilance

Describe and justify briefly the proposed strategy for the assessment of patients' safety in the trial (monitoring of adverse events, documentation, reporting procedures, etc).

8 Project Organisation and Management Structure

8.1 Cooperation

Which structure is available, respectively will be implemented for an efficient cooperation within the project? How will the project be managed? What are the contributions of the individual partners?

8.2 Work Programme

Give a short overview of the work programme and the work packages planned with references to section 11. Indicate which tasks will be taken over by whom in the different work packages. Describe the methods you intend to apply.

8.3 Compliance with GLP and GMP

Please indicate how the research will be conducted in compliance with the requirements of GLP (good laboratory practice) and GMP (good manufacturing practice) standards where required.

8.4 Infrastructures

Please describe the facilities available to conduct the clinical trial (e.g. early clinical trial units, GMP facilities, if applicable).

8.5 Management Structure and Procedures

Arrangements for the management of the trials will vary according to the nature of the study proposed. However, all should include an element of expert advice and monitoring, that is ***entirely independent*** *of the principal / coordinating investigator and the medical institutions involved. This will normally take the form of a scientific advisory board / trial steering committee (TSC) and / or an independent DSMB.*

It is recognised that these arrangements may not always be appropriate and the committees needed may vary according to the nature of the study. Thus, the arrangements for supervision should be detailed and justified. The role of these committees can comprise to monitor and supervise the progress of the trial (including the safety data and the critical efficacy endpoints at intervals), to review relevant information from other sources, to ensure adherence to protocol, to consider interim analyses, to advise whether to continue, modify or stop a trial and provide the funding agency with information and advice.

Applicants should submit their proposed arrangements for overseeing of the trial and a suggested ***membership*** *for the committee(s). A minimum of three members should be listed under section 11.*

8.6 Scientific Discipline and Previous Work

Please name your discipline and your special field of work. Describe the major findings of your previous work. Specify your most relevant five publications and indicate the public access links if possible. Ensure that the team of investigators has the necessary range of disciplines and expertise to carry out the study.

9 References

For your references please use the Vancouver style (Further information: International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. NEJM 1997;336:309-15).

10 Project Timeline Flow

As funding by BMBF will critically depend on the project progression according to milestones, please provide a diagram reflecting pre-clinical work packages, GMP production (if applicable), study preparation, pre-study-visits and initiation of centres, recruitment, follow-up and data cleaning/analysis (<u>one page</u> max.).

11 List of Participants

Trial Sponsor				
Trial Management				
#	Name	Affiliation	Responsibility/Role	Scanned signature

Trial statistician *(It is mandatory that a trial statistician is included!)*			
#	Name	Affiliation	Scanned signature

Other major participants				
#	Name	Affiliation	Responsibility/Role	Scanned signature

Subcontractors			
#	Name	Affiliation	Responsibility/Role

Trial Supporting facilities *(reference laboratories, pharmacies etc.)*			
#	Name	Affiliation	Responsibility/Role

Recruiting centres *(please provide signatures on declaration of commitment)*							
#	Name	Affiliation *(only institution and city, no complete address)*	No. of patients with condition relevant to the trial seen in the last 12 months	No. of these patients fulfilling the inclusion criteria	No. of these patients which would approx. agree to participate in the trial per year	Expected no. of patients recruited for the complete trial	Source of these figures
Total sum of recruited patients					Σ =		

Data Safety and Monitoring Board (DSMB)		
#	Name	Affiliation *(only institution and city, no complete address)*

Other participating groups / bodies *(e.g. steering committee in international trials)*			
#	Name	Affiliation	Responsibility/Role

*Include a tabular scientific CV (**two pages**) for the principal/ coordinating investigator. Include also tabular scientific CVs (**one page**) for other participants playing a leading role in section 14 (not separately in the appendix). Please see section 14 for details.*

Recruiting centres must detail their commitment on a separate sheet (cf. appendix) as provided by the funding agency.

A final version of the trial protocol has to be submitted to the funding agency together with the statement by the ethics committee after the review process. While funding for a preparatory phase might be provided upon the general funding decision, funding of the actual trial can only be provided if all necessary formal and legal requirements are met.

12 Information on Financial Aspects

Funds can only be granted for research activities. Do not include patient care costs.

12.1 Financial Summary

Please fill out the financial summary below.

	Organizational Segment	Institution/ Participant / Trial Site	No of items/ Kind of equipment / Explanation	Qualification of staff	TV-ÖD TV-L TV-Ä	Total months	Mittel in Euro
1	**Clinical Project Management**						
2	**Project Management**						
4	**Data Management**						
5	**Biometry**						
6	**Quality Assurance / Monitoring**						
7	**Safety / Pharmaco-vigilance**						
8	**Trial Committees**						
9	**Meetings / Travel**						
10	**Case Payment**						
11	**Reference Centers**						
12	**Materials**						
13	**Trial Drug**						
14	**Insurance**						
15	**Fees**						
16	**Equipment**						
17	**Publications**						
18	**Other**						
	TOTAL (without overhead / „Projektpauschale“)						

12.2 Co-financing by industry or other parties is possible if

Co-financing by industry or other third parties is possible if

- *the independence of investigators is ensured and*
- *if terms and conditions of the financial commitment are disclosed.*

If co-financing is intended, please describe the type and volume of the intended co-financing, indicating the respective company or other third party.

> ***Please don't make any legally binding agreements before notion of award has been made; please contact the project management agency (DLR-PT) first!*** *Appropriate agreements on intellectual property, confidentiality, publication of results, property rights should be concluded between all those playing a leading part in the conduct of the trial.*

12.3 Other Funding

In case you have already submitted parts of the same request to other institutions or the BMBF, please mention this here. Indicate other sources which will provide funds, free services or consumables.

If this is not the case, please declare: "A request for funding of this project has not been submitted to any other addressee. In case I submit such a request I will inform the DLR Projektträger immediately."

13 CVs of Major Participants

13.1 Principal / Coordinating Investigator

Include a tabular scientific CV (max. two pages) for the principal / coordinating investigator containing a list of the last five clinical trials by him/her and their reporting status with regard to registration of the trial, publication of the trial protocol and of major results. Explain where trials have remained unreported.

13.2 Other participants with Leading Role

Include tabular scientific CVs (<u>one</u> page) for other participants playing a leading role (e.g. co-applicants, members of trial management, trial statistician; <u>not</u> all collaborating partners at all trial centres) including a list of a maximum of 5 publications on the most relevant projects related to this project's topic by him/her that have appeared during the last five years.

APPENDIX

DECLARATIONS OF COMMITMENT OF PARTICIPATING CENTRES

Please use the template provided to declare the commitment of each participating center (including the center of the principal investigator). The template is to be signed personally by the investigator at the respective site (as named in the list of participants involved in the trail; see heading 11 of the proposal). Do not submit facsimiles.

Name of investigator:
Institution:

Information on the clinical trial *(according to the proposal)*[1]

Trial title:	
Inclusion criteria:	
Exclusion criteria:	
recruitment period (months):	

Strategy for the determination of recruitment figures

How many patients with the condition specified above have you seen in your institution during the last 3 months?	
How many patients do you estimate to see in the course of the next year	
How many of these patients would fulfil the inclusion criteria of the above mentioned trial?	
How many of these patients would approximately agree to participate in the above named clinical trial per year?	
How many patients will approximately be recruited during the entire trial?	

Which source/assumptions did you use for the estimation of potential participants in the above named clinical trial?

☐ Individual estimation
☐ Hospital data management system
☐ Patient registry
☐ Others

If others: please specify

Are there any other ongoing clinical trials/ projects competing for the same patients? ☐ yes ☐ no

If yes: How will this affect recruitment for the above-named clinical trial?

Commitment to participate

I hereby agree to participate in the above-named clinical trial and support the trial by recruiting patients.

_____
Date / Signature [2]

[1] Delete italic text at completion of the template.

[2] Note: This document is to be signed personally by the investigator at the respective site (as named in the list of participants involved in the trial; see 11. in the proposal), do not submit facsimiles.

Application for a Research Project within Modules 2 and 3

This template may be used for stand-alone research projects or for research projects within a consortium.

Please describe your research project. Please fill out the relevant section 8 for animal studies, if applicable. Please highlight the contribution of this research project to the entire consortium, if applicable. For research projects with and without animal studies the length of the application is limited to 9 and 6 pages, respectively and excluding the appendix. Please prepare your application in English (DIN A4, 11 point Arial, margins of at least 2 cm and single-spaced lines).

Title and Acronym	
Principal Investigator	*Name, Institution*
Abstract	*max. 300 words*

1 Working hypothesis and research question(s)

Please state your working hypothesis and the underlying scientific question in this proposal. What are the objectives and the research goals? Please highlight the novel aspects of this proposal and the future impact of the research results. Please also comment on existing evidence and the current state of research.

2 Methodological approach

Give a short explanation for the chosen methods and the procedure of analysis. What is the impact of the chosen method for your data? Which instruments will be used?
For quantitative data analyses: Please provide examples of statistical models and assumptions that will be used. Justify clearly the sample size necessary for the planned analyses.

***3* Own previous work and publications**

Please describe your previous work related to this topic and include a maximum of 5 relevant publications in the last 5 years as a reference.

4 Work plan including milestones

Please provide details on your working plan and milestones in this project.
If the subproject has Dual Use Research of Concern (DURC) potential, please comment on it.

Applicable only if this research project is part of a consortium:

***5* Contribution to the consortium**

If applicable, please describe how this research project is embedded into the consortium. Please outline the added-value of the research project in the consortium.

6 Quality assurance, standardization, data sharing

Please describe measures taken to ensure high quality of data, standardization and the sharing of data. These may include precautions to secure validity of test procedures (also across labs), authentication of biological resources (animals, cells, antibodies, media etc.), skills needed, standardized protocols, data management, (pre)registration, reporting guidelines

Please state your willingness to share relevant research and project data with other international funding organizations using GloPID-R. Please also indicate which parts of your research contain details relevant to intellectual property and should therefore not be shared.

7 Ethical and legal considerations

A short list of any ethical and legal aspects (e.g. ethics votes, animal experiment approval, data protection), which must be regulated before the project begins.

If you plan to conduct animal studies in your research project, please comment on the points made in the ARRIVE Guidelines[5] listed under section 8 or argue why these points do not apply.

8 Animal studies

Background and objectives:
Explain the experimental approach and rationale; and how the animal model being used can address the scientific objectives, explain the study's relevance to human biology. Discuss briefly the acceptability of the harm incurred by the animals versus the potential benefit for the patient.

8.1 Methods:

a. *Study design (number of experimental and control groups, steps to minimize the effects of subjective bias, experimental unit).*
b. *Experimental procedures (drug formulation and dose, anesthetic and surgical procedures, equipment – How, When, Where, Why);*
c. *Experimental animals (species, strain, sex, developmental stage, age, weight, source of the animals, genetic modification status, etc.);*
d. *Housing and husbandry (type of facility e.g. specific pathogen free [SPF]; type of cage or housing; bedding material; number of cage companions, type of food, access to food and water, environmental enrichment etc.)*
e. *sample size*
   - *specify the total number of animals used in each experiment, and the number of animals in each experimental group;*
   - *provide details of any sample size calculation used. Indicate the number of independent replications of each experiment, if relevant.*
f. *Allocating animals to experimental groups (details of how animals were allocated to experimental groups, including randomization or matching if done; order of treatment and assessment)*
g. *Experimental outcomes (define the primary and secondary experimental outcomes assessed e.g. cell death, molecular markers, behavioral changes)*
h. *Statistical methods*
   - *provide details of the statistical methods used for each analysis.*
   - *specify the unit of analysis for each dataset (e.g. single animal, group of animals).*
   - *describe any methods used to assess whether the data met the assumptions of the statistical approach*
   - *Brief outline of the statistical analyses including handling of missing data or clustering/hierarchical structures within the data*
   - *Assumed effect sizes (should be justified by effect sizes from previous studies)*
   - *Description of the primary efficacy analysis and population*

8.2 Relevance of the Model

[5] The ARRIVE Guidelines: Animal Research: Reporting of In Vivo Experiments. Originally published in PLOS Biology, June 2010 (http://www.nc3rs.org.uk/arrive-guidelines)

Which model/models is/are to be used: Please provide details for animal species /cell model, strain, sex, age (developmental stage), weight. Provide source of animals or cells, international nomenclature, genetic modification status, genotype, health/immune status, drug or test naïve, cell line, authentication and characterization, age and sex of donor, nature of tissue specimen, storage and banking.

Please provide sound scientific reasoning how and why the chosen model can address the scientific objectives and the study's relevance to human biology.
Consideration of external validity: age, sex of animals or samples, comorbidities, lab variety (number of labs participating in the study).

9 Other funding

In case you have already submitted the same request for financial support or parts hereof to other funding organizations, please mention this here.
If this is not the case please declare:
"A request for funding this project has not been submitted to any other addressee. In case I submit such a request, I will inform the DLR Projektträger immediately".

10 Financial details of the project

10.1 Commercial interest

Please describe any potential commercial interest of a company in the results of the study. Please pay particular attention to "Freedom to operate" concerning exploitation of the results of the study.

10.2 Financial summary

Personnel for a maximum of 18 months			
Position / Salary Group	Total Budget	Duration (months)	Tasks / Justification
Other resources for a maximum of 18 months			
Type	Total Budget	Specification / Justification	
Consumables			
Animal costs			
Equipment			
Travel			
Other			
Sum: Total Budget:			
Institutional Overhead, „Projektpauschale":			
Sum: Requested Budget (50% BMBF-share for SME)			

11 References

For your references please use the Vancouver style (Further information: International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. NEJM 1997;336:309-15).

APPENDIX

1 CVS OF THE PRINCIPAL / COORDINATING INVESTIGATOR

Include a tabular scientific CV (max.one page) for the principal / coordinating investigator.

2 CVS OF OTHER PARTICIPANTS WITH LEADING ROLE

Include tabular scientific CVs (<u>one</u> page) for other participants playing a leading role including a list of a maximum of 5 publications on the most relevant projects related to this project's topic by him/her that have appeared during the last five years.

Application for an Epidemiological Study within Module 3

This template may be used for stand-alone research project or for research projects within a consortium.

Please prepare your application in English not exceeding 15 pages (DIN A4, 11 point Arial and 9 point Arial for the synopsis and references, margins of at least 2 cm and single-spaced lines).

Coordinating Investigator	
Title of the Study	
Subtype of Covid-19	*Please specify (if applicable) which subtype/course of condition your trial is aiming at (e.g. severe, asymptomatic, moderate form)*
Objective(s)	
Need for the Study	
Significance for the Consortium	
Study Type	
Target Population & Inclusion / Exclusion Criteria	*Key inclusion criteria:* *Key exclusion criteria:*
Sample Size	*To be assessed for eligibility (n = …)* *To be allocated to study (n = …)* *Expected to be analyzed (n = ….)*
Data Collection	
Data / Statistical Analysis	
Duration	*first study subject in to last study subject out* *requested duration of funding (months)*
Participating Centers	*If applicable: How many recruiting centers will be involved? (n)*

1 Working hypothesis and research questions

Please state your working hypothesis and the underlying scientific question in this proposal. What are the objectives and the research goals? Please highlight the novel aspects of this proposal and the future impact of the research results. Please also comment on existing evidence and the current state of research.

2 Epidemiological and Economical Relevance of the study and Impact on Health Care

Please elaborate on the impact the proposed research will have on health care systems in general and on the understanding of the current COVID-19 outbreak in particular. Please comment on the epidemiological and economical relevance of the study proposed.

3 Justification of the Design Aspects

Please comment on each of the aspects listed below. Please elaborate on the methods against bias used, give detailed information about number of probands/patients and anticipated non-response and missing data.

3.1 Reasons for the Study Design

3.2 Target / Study Population, Sampling

3.3 Feasibility

3.4 Data collection

3.5 Methods against Bias

4 Statistical Analysis

Give a short explanation for the chosen methods and the procedure of analysis. What is the impact of the chosen method for your data? Which instruments will be used?
For quantitative data analyses: Please provide examples of statistical models and assumptions that will be used. Justify clearly the sample size necessary for the planned analyses.

5 Ethical and Legal Considerations

A short list of any ethical and legal aspects (e.g. ethics votes, data protection), which must be regulated before the project begins.

6 Data Handling and Dissemination

Please describe measures taken to ensure high quality of data, standardization and the sharing of data. Please state your willingness to share relevant research and project data with other international funding organizations using GloPID-R. Please also indicate which parts of your research contain IP-relevant details and should therefore not be shared.

7 Study Management

7.1 Major participants

#	Name	Affiliation	Responsibility/Role
			Principal/Coordinating Investigator
			Responsible for Special Methodological Aspects / Statistics
			Recruiting centres (e.g. hospitals, nursing homes, network of health care providers)
			Study supporting facilities / institutions (e.g. sickness funds, central laboratories)
			Responsible for Quality Assurance / Data Management
			Self-help, support and advocacy organizations of patients (if applicable)

7.2 Recruiting Centres / Study-supporting Facilities, Secondary Data Sources

8 References

- For your references please use the Vancouver style (Further information: International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. NEJM 1997;336:309-15).

9 Financial and Time Plan

9.1 Financial Plan

Item	Months	Salary Group	Detailed Description	Requested Resources
Personnel				€
Scientific				€
Non- Scientific				€
Other				€
Consumables	*n.a.*			€
Subcontracts	*n.a.*			€
Travel	*n.a.*			€
			Total	€
			Overhead („Projektpauschale“)	€
			Requested Resources (incl. overhead)	€

Co-financing of the study by a company (yes/no):

Commercial interest:
Please describe any potential commercial interest of a company in the results of the study. Please pay particular attention to “Freedom to operate” concerning exploitation of the results of the study.

9.2 Work Plan including milestones

Please provide details on your working plan and milestones in this project.
Describe the work program with a timeline and milestones.

9.3 Other Funding

In case you have already submitted the same request for financial support or parts hereof to other funding organisations, please mention this here.
If this is not the case please declare:
“A request for funding this project has not been submitted to any other addressee. In case I submit such a request, I will inform the DLR Projektträger immediately”.

10 CVs of the Principal / coordinating investigator

Include a tabular scientific CV (max.one page) for the principal / coordinating investigator.

11 APPENDIX

Declarations of Commitment of the Participating Centers

Name of investigator:
Institution:

Information on the study

Study title:	
Inclusion criteria:	
Exclusion criteria:	
recruitment period (months):	

Strategy for the determination of recruitment figures

How many subjects/patients with the condition specified above have you seen in your institution during the last 3 months?	
How many subjects/patients do you estimate to see in the course of the next year	
How many of these subjects/patients would fulfil the inclusion criteria of the above mentioned study?	
How many of these subjects/patients would approximately agree to participate in the above named study per year?	
How many subjects/patients will approximately be recruited during the entire study?	

Which source/assumption did you use for the estimation of potential participants in the above named study?
☐ *Individual estimation*
☐ *Hospital data management system*
☐ *Patient registry*
☐ *Others*
If others: please specify

Are there any other ongoing clinical studies/ projects competing for the same subjects / patients? ☐ *yes* ☐ *no*

If yes: How will this affect recruitment for the above-named study?

Commitment to participate

I hereby agree to participate in the above-named study and support the study by recruiting subjects / patients.

_____
Date/ Signature

Conflicts of Interest
I hereby declare that I have no conflict of private, economical or financial interests with regard to the above mentioned study and the investigational drugs that will be used. I have no patents, whether planned, pending or issued, broadly relevant to the work.

_____
Date/ Signature

Declarations of commitment of other institutions providing data / secondary data sources

If data from any other institutions is used for the study, the access to data needs to be clarified and documented.

Contact Person:
Institution:
Name of registry:

Information on the study

Study title:	
Inclusion criteria:	
Exclusion criteria:	
Number of Patients:	

Information on Data provided

Secondary data source	
Data provided:	
Data protection:	

Commitment to participate
I hereby agree to participate in the above-named study and support the study by providing data, etc.

_____
Date / Signature

Conflicts of Interest
I hereby declare that I have no conflict of private, economical or financial interests with regard to the above mentioned study. I have no patents, whether planned, pending or issued, broadly relevant to the work.

_____
Date / Signature