Guidelines for Applicants - Project description

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**Guidelines for Applicants – Project description**

Version vom 14.06.2021

Note: The structure of this template must be followed when preparing your proposal. It has been designed to ensure that the important aspects of your planned work are presented in a way that will enable the experts to make an effective assessment against the evaluation criteria.

Please make sure to present clear preclinical evidence including efficacy data, e.g. in vivo results, for your molecule of interest. This evidence is a pre-requisite for funding. Alternatively, comparable in vivo models within a different setting, e.g. sepsis models, can be presented. Additionally, please make sure to consult the regulatory authorities beforehand, even if your molecule of interest is well known to them within a non-COVID setting. Also, provide a clear rationale why your molecule of interest is superior compared to state-of-the-art approaches. Finally, please include work related to variants of concern in the project description.

Page limit: The project description should not be longer than 60 pages. It is in your interest to keep your text as concise as possible, since reviewers rarely view unnecessarily long proposals in a positive light. The reference font is Arial, the minimum font size allowed is 11 point. Standard character spacing and a minimum of 1,5 line spacing is to be used. The page size is A4, and all margins (top, bottom, left, right) should be at least 20 mm (not including any footers or headers).

General Information (Cover Sheet)

|  |  |
| --- | --- |
| **Project title** | *maximum of 150 characters* |
| **Acronym** | *maximum of 15 characters, may contain numbers, letters or hyphens* |
| **Project duration** | *in months* |
| **Total costs of the project** |  |
| **Requested funding** |  |
| **Short description** *maximum of 1000 characters* |

***List of co-operation partners***

|  |  |  |  |
| --- | --- | --- | --- |
| ***No.*** | ***Partner*** | ***Company/institution name and address*** | ***Name and contact details (telephone, email address) of the project manager*** |
| ***1*** | *(Coordinator)* |  |  |
| ***2 (if necessary)*** |  |  |  |
| ***…(if necessary)*** |  |  |  |

1. Introduction
	1. Brief description of the coordinating company (0,5 page)
	2. Executive Summary in tabular form (1 page max.)

|  |  |
| --- | --- |
| Type of therapeutics | *Therapeutics against SARS-CoV-2 or Therapeutics for treatment of COVID-19* |
| Type of technology | *e.g. small molecule, monoclonal antibody* |
| Mode of action | *Please indicate the mode of action here (short description).* |
| Status of development (max. 100 words) | *in particular, remaining steps and timeline for the approval of clinical trials* |
| Major milestones with timelines |  |
| MS1 |  |
| MS2 |  |
| MS3 |  |
| MS4 |  |
| Variants of concern | *in particular, planned activities* |

1. Objectives (2 page max.)
	1. Overall objectives of the project

Describe the overall objectives for the project, which should be clear, measurable, realistic and achievable within the duration of the project. Objectives should be consistent with the expected exploitation of the project. In addition, describe and explain the overall concept and methodology of the project.

* 1. Scientific and/or technical objectives of the project

Please state your specific objectives regarding e.g. clinical development, CMC (chemistry, manufacturing and control) and GMP production.

1. State of the art; development stage and innovation (5 page max.)
	1. State of the art

Briefly describe the international state of the art regarding the underlying type of therapeutics and technology against SARS-CoV-2 and/or treatment of COVID-19.

* 1. Development stage of the project

Please provide a detailed description of the current development stage. Please provide information on relevant preclinical data (mode of action, *in vitro* and *in vivo* efficacy, safety and ADME in relevant in vivo models) and estimated dose range for clinical use. Please attach relevant documents from scientific advice consultations with responsible regulatory authorities (see also 5.3.2). The same applies if the approval for a phase I or I/II clinical trial has already been granted (see also 5.3.1).

Please provide an overview of the CMC process and describe the development stage of the GMP production, the need for upscaling for further clinical trial phases and the cooperation with third parties (Contract Manufacturing Organisation, CMO) for production and/or filling.

* 1. Innovation

Describe the advance your project would provide beyond the state-of-the-art and/or the standard-of-care and the extent the proposed work is ambitious. Describe the target product profile and the intended use of your product in clinical practice after market approval (i.e. hospital or outpatient use). To describe the innovation potential, please provide a brief comparative analysis to other approaches in the global therapeutics pipeline (with a special focus on development stage, efficacy, safety, ease/costs/volume of manufacturing) or the standard-of-care, preferably in table form.

* 1. Intellectual property rights

Please make a statement on intellectual property rights, which are or may be affected by the implementation of the project.

*Text example if all property rights are held by the applicant: We have established the state of the art in the fields of activity affected by this project by means of current information research. To the best of our knowledge, the project is not already the subject of other research, developments, investigations or patents and there are no industrial property rights or applications for industrial property rights that would prevent the project from being carried out and the results from being exploited at a later date.*

*If third-party property rights are affected by the project, please list them separately (in table form, if applicable) and confirm that the rights owners have given their consent to the implementation of the project (freedom-to-operate).*

1. Previous work of the applicant(s) and cooperation with third parties (3 page max.)

If applicable, describe the structure of the consortium and the contribution and competences of involved partners.

For each partner, describe briefly the preliminary work that has contributed to achieving the above-mentioned level of development and justify, in general terms, which previous work and which structural and financial requirements qualify the partner to carry out the project applied for. Please also include experiences concerning market approval for therapeutics.

Please describe also any cooperation with third parties, especially with subcontractors (name, task in the project, any previous experience).

1. Information on clinical trial(s)

Clinical trials have a number of methodological and regulatory specificities. Information on these issues is crucial for evaluators to assess the scientific quality of the proposal. The following structure should help applicants to provide this essential information. For each clinical trial performed within the project, information on the issues listed below should be provided. Each section must be shortly and concisely described. In case one or more issues do not apply to a particular trial, please briefly explain/justify. In case the requested information is currently not available (e.g. a clinical trial is planned for a later stage of the project and will be based on data from prior studies) the source of this data and/or the applied methodology should be described.

* 1. Study title

Study title, short title or unique identifier.

* 1. Study design and endpoints
		1. Study design

Brief description of the objectives or hypotheses and concise description of the selected study design (study type, estimated enrolment, allocation of participants, intervention model etc.).

* + 1. Primary and secondary endpoint(s)

Description and justification of the primary and secondary endpoints/outcome measures (and how these relate to the objectives).

* 1. Regulatory status and activities
		1. Regulatory / ethics status

Clearly define the regulatory/ethics status for the study according to national and EU regulations. Please include any requested or granted approvals of clinical study applications.

List treatment guidelines (e.g. addressing best practice of treatments) and methodological guidelines (e.g. Good Clinical Practice) that are applied in study design and execution.

* + 1. Scientific advice

Summarise the activities achieved in the context of regulatory scientific advice. For previous advice in context of clinical development, provide a summary of the current status and the answer(s) of the authority (please also attach the scientific advice report/response).

* 1. Subjects/population(s)

Definition of study population(s) by inclusion and exclusion criteria. Please discuss appropriate inclusion of women and special populations, such as children and elderly (with defined age groups). If there are populations specifically excluded, please justify.

Definition of sub-populations if subgroup analysis is intended.

* 1. Statistic analysis plan

Definition and justification (power calculation) of sample size, definition of statistical methods and planning of statistical analysis (including stopping guidelines and/or procedures to control sources of bias and their influence on results, if relevant).

* 1. Cumulative safety and efficacy information
		1. Cumulative safety information

Concise information on safety and tolerability of study interventions: e.g. pre-clinical data from in vitro or in vivo studies; data from any previous clinical studies; data from (pharmaco‑)vigilance systems or other sources (or reference to section 3.2). Use relevant sections (or a summary) of the Investigational Medicinal Product Dossier (IMPD).

* + 1. Cumulative efficacy information

Concise information on efficacy of study interventions based on (pre-)clinical data (or reference to section 3.2). Use relevant sections (or a summary) of the Investigational Medicinal Product Dossier (IMPD).

* 1. Conduct
		1. Schedule for study conduct including timelines for key study milestones

Include a realistic planning of the schedule for the study conduct (including key milestones like first patient first visit, last patient last visit, end of study (including data analysis), including provisions and timelines for ethics and other administrative approvals. Dates are defined relative to the starting date of the project (i.e. month 1, month 6 etc.).

* + 1. Description of recruitment strategy

Description of the recruitment strategy, including realistic estimates of the expected recruitment rate (subjects per month/per centre) based on available data.

Ensure that efficient contingency measures are included (see also section 7) so that any potential delays during the recruitment phase can be compensated.

* + 1. Description and assignment of intervention

Please describe the intervention(s) tested (dose, mode and scheme) and methods for allocation and blinding.

* 1. Study management, study monitoring, data and sample management

Please include a description of

* Planned strategy for study management,
* Study monitoring plan (monitoring visits, level of source data verification, etc.),
* Adverse event reporting,
* Data collection and management (including mechanisms to ensure data quality, completeness and integrity),
* Sample management.
	1. Sponsor and committees

Please specify the trial sponsor. Specify the role of the different committees (e.g. Data Safety Monitoring Board, Independent Data Monitoring Committee, etc.).

* 1. Study medication

Please provide information on manufacturing and / or labelling of the study medication and which plans and / or commitments are in place for this.

* 1. Clinical centres

Specification of criteria for site selection and indicative list of clinical centres / recruitment centres planned to be involved in the clinical study.

* 1. 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).

1. Detailed work description

Please provide a brief overview of the overall structure of the work plan and a timing of the work packages (GANTT Chart including all work packages and sub work packages, their duration in project months, milestones, see Annex).

Please provide a detailed work description and use the following table for the work plan (where appropriate the work packages have to be broken down into further sub work packages):

|  |  |  |  |
| --- | --- | --- | --- |
| [work package no.] | [work package title] | [total person months (PM)] | [start month Mx – end month My] |
| **Mainly responsible:** [partner] |
| **Involved parties:** [partner, subcontractors etc.] |
| [partner 1] | [partner 2, if necessary] | [partner 3, if necessary] |
| [PM for partner 1] | [PM for partner 2] | [PM for partner 3] |
| **Objectives:** |
| ***Description of work:*** *Please provide a detailed work description including the division of work between the partners/subcontractors.**You should give enough detail in each work package to justify the proposed person months and other resources to be allocated.* |
| ***Expected results/deliverables:****What is the output of the work package? For clinical studies, major results are e.g. final version of study protocol as approved by regulatory bodies or ethics committee, registration number of study, approval for clinical study, 50% of the study population recruited.* |
| ***Resources:*** *costs for consumables (if applicable: type and amount), travel, equipment, subcontracts* |

* 1. List of milestones

Please define (normal and major) milestones, i.e. important interim goals representing project progress or critical decision points. Please consider all important activities relevant to the implementation of the project, e.g. for conducting the clinical trials (e.g. finalized study documents, approval from ethics committee(s) and regulatory bodies, first patient first visit, last patient last visit, 25%/50%/75% of patients recruited, end of study (including data analysis) and preparation of GMP material (e.g. completed GMP manufacturing of drug substance, completed filling of drug product, completed stability study). Note, that achievements of milestones must be measurable. For this purpose, list the indicators of success for each milestone to show how you will confirm that the milestone has been achieved. The due date is measured in months from the project start date.

Please foresee major milestones (not more than 4), which are relevant for the payment of the grant (see 12) and reporting schedules. Major milestones may be: completed GMP manufacturing for clinical trial(s), successful completion of Phase I/IIa/IIb trial. Please indicate the major milestones in bold and indicate them as MS1-MS4.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Milestone Number | Milestone name *(is it a major milestone?)* | Related work package | Due date (month) | Indicators of success |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

* 1. Risk assessment, mitigation and avoidance

Please describe any critical risks, that project’s objectives or milestones may not be achieved. Detail the risk avoidance or mitigation strategies and any contingency plans (see table below).

|  |  |  |  |
| --- | --- | --- | --- |
| Description of risk | Level of likelihood (low, medium, high) | Related work package | Proposed risk mitigation measures/contingency plans |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. Exploitation plan and impact (4 pages max.)
	1. Economic, scientific and technical exploitation of results

Please describe the economic exploitation of project results, the business strategy and how you will address the next steps after successful completion of the project towards market approval and use in medical practice (taking into account the regulatory framework and health technology assessment, possible industrial partners for commercialisation, potential users of the project results, timelines, market conditions). In case of cooperation projects, describe how each partner will benefit from the project results (as regulated in the consortium agreement).

Outline the strategy for knowledge management and protection. Include measures to provide open access to peer-reviewed scientific publications which might result from the project.

For each partner, describe the scientific and technical exploitation of results, i.e. gain in knowledge, publications (note that publication of clinical study results is mandatory), sharing of data, use of results for other projects, etc.

* 1. Impact

In case of successful completion of the project and further development steps, describe the impact on health care and treatment of SARS-CoV-2 and COVID-19.

Please address also the following issues:

* Consideration of public support in pricing. With the grant applied for, your therapeutics development will be largely financed by public funds. Please describe how you intend to take this into account in your pricing strategy and how you intend to make this transparent to the sponsor and the public.
* Licensing policy in a European context. Please note that the relevant European Commission State Aid Communication (Amendment C(2020) 2215 final) requires that “Aid for coronavirus relevant R&D can only be granted, if beneficiaries commit to grant non-exclusive licences under non-discriminatory market conditions to third parties in the European Economic Area.” Please explicitly declare that you have taken note of this regulation and that you will comply with it.
* Please explain how you will ensure, that an appropriate proportion of the production of an approved therapeutic supported by this funding measure will be made accessible for the German population.
1. Financing of the project

The legally binding budget plans are part of the formal application (AZK/AZA/AZAP). In the following, information is requested which is necessary for the assessment of the overall financing and the (milestone-related) payment modalities.

Please ensure that the statements made below do not contradict the budget statements indicated in the AZK/AZA/AZAP-application form.

For each partner, please break down the total costs of the project, your own contribution and the requested BMBF funding on the basis of the milestone planning.

|  |
| --- |
| Partner 1 – Financial means |
| Cost category | Milestone 1 | Milestone 2 | Milestone 3 | Milestone 4 | **Total** |
| Personnel plus Overhead[[1]](#footnote-1) |  |  |  |  |  |
| Consumables |  |  |  |  |  |
| Equipment |  |  |  |  |  |
| Subcontracts |  |  |  |  |  |
| Travel |  |  |  |  |  |
| Other |  |  |  |  |  |
| Total costs |  |  |  |  |  |
| Funding rate (%) |  |  |  |  |  |
| Allowance[[2]](#footnote-2) |  |  |  |  |  |
| Own contribution |  |  |  |  |  |
| Requested funding (including allowance) |  |  |  |  |  |

Please specify the nature of the costs in the following table for each partner:

|  |
| --- |
| Partner 1 - Justification of costs |
| Explanations | Milestone 1  | Milestone 2 | Milestone 3 | Milestone 4  |
| PersonnelPlease specify (e.g. clinical trial manager clinician scientists, clinical trial assistant and the number of person months) |  |  |  |  |
| Consumables |  |  |  |  |
| Equipment |  |  |  |  |
| Subcontracts |  |  |  |  |
| Travel |  |  |  |  |
| Other |  |  |  |  |

If applicable (cooperation projects), provide a table for the overall project costs (cumulative costs for all partners):

|  |
| --- |
| All Partners - Cumulative project costs |
| Cost category | Milestone 1 | Milestone 2 | Milestone 3 | Milestone 4 | **Total** |
| Personnel plus Overhead[[3]](#footnote-3) |  |  |  |  |  |
| Consumables |  |  |  |  |  |
| Equipment |  |  |  |  |  |
| Subcontracts |  |  |  |  |  |
| Travel |  |  |  |  |  |
| Other |  |  |  |  |  |
| Total costs |  |  |  |  |  |
| Funding rate (%) |  |  |  |  |  |
| Allowance[[4]](#footnote-4) |  |  |  |  |  |
| Own contribution |  |  |  |  |  |
| Requested funding (including allowance) |  |  |  |  |  |

Annex I – GANTT Chart and milestone planning

1. overhead funding according to BMBF funding body regulations [↑](#footnote-ref-1)
2. „Projektpauschale“, for universities only (20%). [↑](#footnote-ref-2)
3. overhead funding according to BMBF funding body regulations [↑](#footnote-ref-3)
4. „Projektpauschale“, for universities only (20%). [↑](#footnote-ref-4)