**Leitfaden zur Erstellung von ausführlichen englischen Vorhabenbeschreibungen für die**

**„Richtlinie zur Förderung von Translationsprojekten zur Therapie mit gen- und zellbasierten Produkten und assoziierter Diagnostik“**

Stand: Juli 2024

Der vorliegende Leitfaden enthält Informationen für die Erstellung und Einreichung von ausführlichen englischen Vorhabenbeschreibungen und ergänzt die am 15. Juli 2024 veröffentlichte o.g. Förderrichtlinie.

<https://projekttraeger.dlr.de/de/foerderung/foerderangebote-und-programme/translationsprojekte-gen-zelltherapie>

**Was und wer wird gefördert?**

Bitte beachten Sie die Vorgaben und Hinweise in der Förderrichtline unter Punkt 2, Gegen­stand der Förderung, Punkt 3, Zuwendungsempfänger und Punkt 4, Besondere Zuwendungs­voraussetzungen.

In Ergänzung zu den Regelungen unter Punkt 3: Zuwendungsempfänger der Bekanntmachung gilt für Mitarbeitende außeruniversitärer Forschungseinrichtungen (AUFE) folgendes:

Als Forschende, die mit der AUFE affiliiert sind, gelten alle Forschenden, die ihre einzige Affiliation am AUFE haben sowie auch Forschende, die mehrere Affiliationen an unterschiedlichen Instituten oder Institutionen haben, wobei eine Affiliation hiervon mit der AUFE besteht. Als Mitarbeitende, die diesen Forschenden organisatorisch zugeordnet sind, werden sowohl Mitarbeitende mit einem Arbeitsvertrag (und somit einer Affiliation) an der AUFE gewertet als auch Mitarbeitende, die diesen Forschenden im Kontext einer ggfs. vorhandenen weiteren Affiliation zugeordnet sind. Für BIH-Mitarbeitende gelten die gleichen Regeln wie für alle anderen Wissenschaftler\*innen aus außeruniversitären Forschungseinrichtungen (s. auch FAQ-Liste für Antragsteller).

**Allgemeine Hinweise**

Nachfolgende Hinweise sind bei der Planung und Einreichung der ausführlichen englischen Vorhabenbeschreibungen zu beachten.

**Wissenschaftliche Standards**

Die Antragsteller\*innen sind verpflichtet, nationale und internationale Standards zur Qualitätssicherung von präklinischer und klinischer Forschung einzuhalten. Dies gilt insbesondere für Biomaterialbanken, Tierstudien und die Entwicklung von Studienprotokollen für frühe klinische Studien der Phasen I und II. Hierzu sind auch folgende Leitlinien/Prinzipien in der jeweils geltenden Fassung – falls zutreffend - zu berücksichtigen:

* PREPARE Guidelines[[1]](#footnote-1),
* ARRIVE Guidelines[[2]](#footnote-2),
* Leitlinien zur Guten Zellkulturpraxis (Good Cell Culture Practice, GCCP)[[3]](#footnote-3),
* FAIR-Prinzipien[[4]](#footnote-4),
* Deklaration von Helsinki[[5]](#footnote-5).

**Vorgaben für die ausführliche englische Vorhabenbeschreibung**

**Förderanträge, die den Vorgaben der zugrundeliegenden Förderrichtlinie und dieses Leitfadens nicht entsprechen, können ohne weitere Prüfung zurückgewiesen werden.**

* Das Projekt soll nachvollziehbar dargestellt werden.
* Es sollen substanzielle Aussagen zu den in der Richtlinie aufgeführten Bewertungskriterien getroffen werden. Die Bewertungskriterien sind unter Punkt 7.2 der Richtlinie zu finden.
* Die Vorhabenbeschreibung ist – je nach Track - für den Projektzeitraum von maximal 1 Jahr (Track 1) oder maximal 2 Jahren (Track 2) zu erstellen.
* Die Vorhabenbeschreibung muss ohne Lektüre der zitierten Literatur oder Hinzuziehung weiterer Literatur verständlich sein.
* Die Vorhabenbeschreibung muss den Vorgaben und der Formatierung der unten folgenden Mustervorlage (DINA4-Format, Schriftart Arial, Schriftgrad 11, Zeilenabstand 1,15 Zeilen, 2,5 cm Seitenrand) entsprechen und in englischer Sprache verfasst werden.
* Die maximalen Seitenanzahlen sind in der Mustervorlage vorgegeben und dürfen nicht überschritten werden.
* Löschen Sie bitte die grau gedruckten Hinweise.
* Bitte nehmen Sie zu jedem (Unter-)Punkt Stellung; sollte ein Punkt nicht zutreffen, kommentieren Sie dies entsprechend.
* Bitte passen Sie die Kopfzeile der Vorhabenbeschreibung jeweils entsprechend der Vorgaben in der Mustervorlage an.
* Der Antragsteller oder – bei Verbünden – der Koordinator erstellt ein einziges PDF Dokument (max. 15 MegaByte), das elektronisch über PT-Outline hochgeladen wird: <https://ptoutline.eu/app/translation_gct>.
* Für weitere Angaben, die sowohl in der ausführlichen Vorhabenbeschreibung und in PT-Outline gemacht werden, gilt: die Angaben in PT-Outline haben Geltung.

Sämtliche Angaben werden vom Berlin Institute of Health at Charité, dem DLR Projektträger und den Begutachtenden strikt vertraulich behandelt.

**Fristen**

|  |  |  |
| --- | --- | --- |
| **Datum, ggf. Uhrzeit** |  | **Durch wen** |
| Bis zum 27. August 2024,13:00 MESZ | Vorlage der englischen Vorhabenbeschreibungen in PT-Outline (PT-Outline wird spätestens ab dem 01. August 2024 zugänglich sein). | Einzelantragsteller\*innen, Verbundkoordinator\*innen |
| Bis 30. September 2024 | Frist für die Vorlage der Absichtserklärung zur Erbringung des Eigenanteils  | Jede antragstellende Institution mit Sitz außerhalb Berlins |
| Bis 30. September 2024 | Vorlage der Formanträge und deutschen Vorhabenbeschreibungen (Kurzversion) über easy online | Jede antragstellende Institution (Einzelantragsteller, Koordinator, Partner) |
| Bis 30.Oktober 2024 | Rechtsverbindlich unterschriebener Nachweis des Eigenanteils an der beantragten Fördersumme | Bei antragstellenden Institutionen mit Sitz außerhalb Berlins: Jede antragstellende Institution bzw. deren Sitzland  |
| Anfang Oktober | E-Mail-Einladung an diejenigen Antragsteller\*innen von Track 2 Projekten, die ihre Vorhaben in der Jurysitzung vorstellen können.  | DLR Projektträger |
| vorauss. 4./ 5. November 2024 | Circa 10-minütiger Vortrag zum geplanten Vorhaben in der Jurysitzung. Genauer Ort und Zeit werden Anfang Oktober bekannt gegeben. | Ausgewählte Antragsteller\*innen von Track 2 Projekten |
| Mitte November 2024 | Information zur Förderentscheidung zu Track 2 Projekten und Nachforderungen mit kurzer Frist durch den DLR-Projektträger via E-Mail | DLR Projektträger |
| Mitte November 2024 | Information zur Förderentscheidung zu Track 1 Projekten und Nachforderungen mit kurzer Frist durch den DLR-Projektträger via E-Mail | DLR Projektträger |

**Mustervorlage für die ausführliche englische Vorhabenbeschreibung**

# General Information

**Funding Track: \_\_ (Track 1 or Track 2)**

**Non-confidential project title** (max. 120 characters incl. spaces)
Please choose a non-confidential title that catches the essence of your project and that can be used publicly.

[Please insert text here using Arial, size 11]

**Project acronym**
Please choose a 1-word abbreviation for your project.

[Please insert text here using Arial, size 11]

**Project duration**

(max. 12 months for Track 1, max 24 months for Track 2)

Xx months

**Total requested funding of the project (all partners)**

Xx Euros

**Applicant (Einzelvorhaben) or consortium coordinator (for Track 2, only; required in case of “Verbundvorhaben”)**

Please note the criteria for applicants in paragraph 3 (Zuwendungsempfänger) of the “Förderrichtlinie” and on page 2 of this document.

|  |  |
| --- | --- |
| **Last Name** |  |
| **First Name** |  |
| **Academic title** |  |
| **Institution** *(in English)* |  |
| **Department** *(in English)* |  |

**Project partners (for Track 2, only; information mandatory in case of “Verbundvorhaben”)**
Please complete one table per partner, delete for “Einzelvorhaben”.

|  |  |
| --- | --- |
| **Last Name** |  |
| **First Name** |  |
| **Academic title** |  |
| **Institution/ Company** *(in English)* |  |
| **Department** *(in English)* |  |

**Description of the team** (max. ½ page for single applicants, up to 1 page for consortia)
Provide a brief description of the team that will work on this project and why the team is suitable to pursue this project. Include each team member’s background and experience to demonstrate your credentials. Make sure to include relevant career stages, industry experience etc. List any collaborator(s) who complement your expertise, any service providers you consider contracting and any experts you have consulted concerning your project. If applicable, describe any unique infrastructural/facility advantages at your disposal.

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

# Project description

## Project description details

### Final product/ process

Please explain in ONE short sentence the main goal of the entire project: The product/process that should reach patient/market (e.g. develop a cell therapy against breast cancer)

### Main project goal

Please explain in ONE short sentence the main goal you want to achieve during the funding period (e.g. select a specific T-cell receptor).

### Project category

Select from the following options: ATMP (e.g. gene therapy, somatic cell therapy, tissue engineered product), Diagnostic, other (e.g. Exosomes, mRNA-based therapy)

### Indication/Area of research

### Please name the indication/area that your solution is addressing (max. of two choices).

Select from the following options: Autoimmunity, Cardiology, Dermatology, Infectious Disease, Metabolism, Muscle Disease, Nephrology, Neurology, Ophthalmology, Oncology, Pediatrics, Psychiatry, Pulmonology, other.

## 2. Description of the project (For the whole chapter 2 (2.1 – 2.7) max. 5 pages Arial font, size 11, 1.15 lines-spaced. Subheadings have to be kept. Please delete the instructions/grey text)

### 2.1 Description of the "problem"/unmet medical need (ca. ½ page)

Please describe the problem you are trying to solve and the unmet medical need that your solution addresses. Summarize how you systematically reviewed the existing evidence (e.g. literature, data, expert opinion, registries etc.)

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

### 2.2 Description of your new solution (ca. 1 page)

### Please describe your solution and how it will address the problem and unmet medical need that you are trying to solve. Please describe the final product/solution you envision (e.g. cell therapeutic, gene therapeutic, tissue engineering product, diagnostic assay).

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

### 2.3 Uniqueness of new solution (ca. 1/3 page)

Please describe what makes your solution unique. How does it differ from the current "gold standard"? Please also differentiate your proposed solution from other solutions that are already approved or in development (e.g. greater efficacy, improved safety, increased patient convenience etc.). What are the competitive advantages of your solution?

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

### 2.4 Project aim during funding period (ca. 1 page)

Please describe the project goal you are trying to reach within the funding period. Ensure that you are aiming for a clear developmental goal at the end of the funding period (e.g. GMP-produced cellular therapeutic) and that you are NOT simply planning further research.

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

### 2.5 Current stage and proof-of-concept of project (ca. 1/3 page)

Please note the criteria for Track 1 und Track 2 in the „Förderrichtline“ in paragraph 2 „Gegenstand der Förderung“ and 4 „Besondere Zuwendungsvoraussetzungen“.

Please note that supporting graphics and schemes can be added at the end of the project description (see section "**Graphics**" below, max. 4 pages)

Please categorize the current status of your project into the most appropriate TRL. Descriptions of TRL1-8 for different categories of research can be found here: <https://ncai.nhlbi.nih.gov/ncai/resources/techreadylevels>:

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

### 2.6 Description of regulatory status of your project (ca. ½ page)

### If possible, please provide information regarding the following aspects: What is the regulatory status of your project? Please indicate which scientific steps are needed for your product to meet the requirements for a Clinical Trial Application (CTA)/ in order to reach the market? How do you plan to proceed in order to fulfill them (e.g. preclinical evaluation, GMP development, meetings with PEI or other regulatory authorities)? Have you already received regulatory support, e.g. by the Regulatory Support Unit https://www.bihealth.org/de/translation/nationales-netzwerkbuero-fuer-gen-und-zelltherapien/regulatory-support-unit

###

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

### 2.7 Patient and stakeholder involvement (ca. 1/3 page)Please describe how patient involvement is implemented in the project. Patient involvement can be implemented in different stages of the project and to a different extent[[6]](#footnote-6). Please justify why your concept is adequate for the planned project. If no patients/patient organizations are involved, please explain why.If applicable, please describe how and at what phases of your study other relevant stakeholders (e.g. payers, healthcare professionals...) are or will be involved and contribute to your project (e.g. have you already involved stakeholders and/or received input from potential users?).

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

## 3. Proposed project during funding period

## (max. 1 page per work package)

### Description of work plan including work packages, milestones and budget

Please describe the **key goal objectives** that you aim to achieve during the funding period and structure them in appropriate work packages. Please provide the information as outlined below. Total time frame for Track 1: max. 12 months, for Track 2: max. 24 months.

Please also include potential pitfalls of the project with sufficient risk assessment and criteria to substantiate continuation of the program at each milestone.

**Work package 1 (time frame: [insert no.] months, responsible partner and other project partners involved: [insert names])**

Please note, a work package describes the group of related tasks/sequence of activities (often experiments) as smallest unit within the overall project that leads to achieving a milestone (usually a deliverable). A milestone specifies an important stage of the project progress and marks what you want to accomplish within each work package.

***Key objective 1***: Text

***Description***: Text

(incl. statistical analysis, if applicable; if more than one partner is involved in the work package, it must be clearly outlined which partner will perform which tasks within the work package. If necessary different milestones can be defined for the tasks of each partner involved)

***Milestone 1 ….***: Text

***Total funds for milestone***: xx Euros

***Technical risks 1****:* [Please insert text here using Arial, size 11, 1.15 lines-spaced]

***Mitigation plan/alternative scenarios 1****:* [Please insert text here using Arial, size 11, 1.15 lines-spaced]

***Go/No-Go criteria 1***:

Please describe Go/No-Go criteria for each work package. Go/No-Go testing refers to a pass/check test principle and is an essential part of product/process development. Please use Go/No-Go decision criteria that are precise, well-defined and as little as possible subject to interpretation.

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

**Work package 2 etc.**

Same information as for WP1

## 4. Project timeline

Please adjust as needed according to the work packages (WP) and milestones (MS) you defined above.

Timeline example:

|  |  |
| --- | --- |
|  | **Year 1** |
| Short title of work package and mile stones  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| WP1: [short title] |  |  |  |  |  |  |  |  |  |  |  |  |
| MS1: [short title] |  |  |  |  |  |  |  |  |  |  |  |  |
| WP2: [short title] |  |  |  |  |  |  |  |  |  |  |  |  |
| MS2: [short title] |  |  |  |  |  |  |  |  |  |  |  |  |
| Etc. |  |  |  |  |  |  |  |  |  |  |  |  |

Year 2, for Track 2 projects, only:

|  |  |
| --- | --- |
|  | **Year 2** |
| Short title of work package and mile stones  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| WP1: [short title] |  |  |  |  |  |  |  |  |  |  |  |  |
| MS1: [short title] |  |  |  |  |  |  |  |  |  |  |  |  |
| WP2: [short title] |  |  |  |  |  |  |  |  |  |  |  |  |
| MS2: [short title] |  |  |  |  |  |  |  |  |  |  |  |  |
| Etc. |  |  |  |  |  |  |  |  |  |  |  |  |

## Data robustness and reproducibility strategies (max. ½ page)

Please describe what methods and approaches have been used and will be applied for the generation of your data (both past and future experiments) and indicate how they support the robustness of your data. Please add the information that is relevant to your project

1. Have relevant confounding variables and risks of bias been defined? Please name the confounding variables, explain how they were considered and your strategies to reduce the risk of bias.
2. Are sex (cells, animals, humans) and gender (humans) considered as a biological variable in your study? Please describe how you implemented this in your study design.

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

## After the end of the funding period

**Future development plan (max. ½ page)**
If your project is successful, please describe how you intend to proceed after the funding period. Which additional steps are necessary to reach patients/market and how can they be reached? Is your intention to license Intellectual Property (IP) to biotech or pharma, to apply for follow-on funding for further development, to found a start-up or partner with industry? When do you think patients will benefit from the product/solution (years from now)? Please be as specific as possible and provide a timeline of the next steps including an estimation of within how many years the product/solution can be available on the market**...)**

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

# Budget overview

### a) Displayed by work package

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | ***WP 1*** | ***WP 2*** | ***WP 3*** | ***…*** |  |
| *WP lead (partner no., name)* |  |  |  |  |  |
| *Other partners involved* |  |  |  |  |  |
| ***Budget*** |  |  |  |  | ***Total for the Consortium*** |
| *Personnel* |  |  |  |  |  |
| *Consumables* |  |  |  |  |  |
| *Equipment* |  |  |  |  |  |
| *Travel* |  |  |  |  |  |
| *Other Costs* |  |  |  |  |  |
| *Overhead* |  |  |  |  |  |
| ***Total Budget\*****(incl. own contribution)* |  |  |  |  |  |

\* Please, double-check that the total requested budget is equal to the sum of the tables under III b.

### Displayed by partner (for consortia (Verbundvorhaben) one table per partner)

|  |  |  |
| --- | --- | --- |
|  | ***Coordinator (Partner 1)*** | ***Justification of budget*** |
| *Name of the PI, Institution* |  |  |
| *Involved in work packages no.* |  |  |
| *Personnel\*\** | *e.g.* *1 Sci, 24 PM* | *Person Months, position of employment, and role/tasks* |
| *Consumables* |  | *Detailed list of lab consumables needed by this partner* |
| *Equipment* |  | *In case new equipment is required to reach a certain milestone. Please note details in the “Förderrichtlinie”.* |
| *Travel* |  | *Travel required for the project, e.g. project team meetings.* |
| *Other Costs* |  |  |
| *Overhead* |  |  |
| ***Total budget for partner*** |  |  |
| ***Requested budget*** |  |  |
| ***Funding rate (%)\*\*\**** |  |  |

\*\*Sci = Scientist, Grad = Graduate student, Eng = Engineer, T = Technician, O = Other, PM = PersonMonths; Please use your local institutional salaries for calculation.
\*\*\*Funding rate is 90% of total budget for state-financed institutions except for state-financed institutions of the state of Berlin (see call for proposals, 4. Prerequisites)

# IV. Commercialization (max 2 pages)

### Target group (ca. 1/3 page)

Description (quantitative and qualitative) of the targeted user and/or patient group or anticipated target/patient group. How large is the user/patient group? If several users/patient groups/indications are possible, describe the rationale for the current choice of user/patient population/indication. If you have not yet decided on a user/patient population/area of application, please outline ways forward on how to identify the most relevant one/s.

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

### Commercial potential and business strategy (ca. 1/3 page)

Please describe the market size and market niche that your solution will address. Who are the customers of the solution you are creating (e.g. patients, clinicians, hospitals, insurance companies etc. ...)? Who is going to pay for your solution? What is the added benefit for them? Please estimate how many of the total number of patients/users you might be able to reach. Please estimate the revenue that could be created with this solution (in Germany/worldwide).

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

### Indicate your potential competitors (ca. 1/3 page)

Please describe alternative or similar solutions that are already on the market or being developed for the problem you address. Who is or might be/become your competitor? Please note that it is extremely unlikely that no competition exists. Competition can include similar products or completely different solutions targeting the same problem.

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

### Does the commercialization of your product/solution depend on other patents? (ca. 1/4 page)

Does the commercialization of your product/solution depend on other patents? Please also describe any repurposing option for the project if applicable.

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

### Risk assessment and management (ca. 1/2 page)

Please identify and describe challenges and describe the risk management (e.g. alternative scenarios).

[Please insert text here using Arial, size 11, 1.15 lines-spaced]

# V. Publications & Abbreviations

### Key publications

Please list **up to five** key publications that you think are important to understand the technology/solutions that you are describing. These can relate to previous work you have done and results/data you have gathered that justify your proposed next steps, or publications providing background information to the technology. Please do not include any of your previous publications that are unrelated to the project you are describing in this proposal.

## Abbreviations

Please explain all abbreviations used in your application.

# VI. Intellectual Property

Please note that eligibility for **Track 2** requires one of the following scenarios (see also the Förderrichtlinie)

• patent granted (Patent erteilt),

• patent filed (Patentanmeldung eingereicht),

• invention disclosure claimed, patent application planned (Inanspruchnahme mit geplanter Patentanmeldung).

**If you do not qualify for Track 2 (yet). Please consider applying for Track 1 instead.**

**Please provide information on existing IP (mandatory for Track 2, only)**

Please list the patent number(s) including patent holder (public institution/private company or person), all inventors and any relevant details on the IP status.

**Please note that in case a private company or person (partially) holds (or will hold) the patent rights, it is mandatory that an academic institution holds the majority of IP rights**

**VII. Graphics**

## Supporting graphics (max. 4 pages, including legends)

## Please add relevant graphics and data that help/support the understanding of your proposal and show key results. Add enough text/figure legend to explain your graphics and label them clearly. Any abbreviations used must be explained. Avoid uploading graphics from publications with lots of background data and graphics of insufficient resolution. Make sure the labeling is readable. Rather, choose graphics that help the reviewers understand the technology and your future plans.

**VIII. Confirmations and signature(s)**

## Der englischen Vorhabenbeschreibung muss ein Unterschriftenblatt angefügt werden, auf dem alle Projektpartner (in der Regel die Projektleiter\*innen) mittels Unterschrift die Kenntnisnahme sowie die Richtigkeit der in der Vorhabenbeschreibung gemachten Angaben bestätigen müssen.

Please note: the information of your application may be communicated to members of DLR Projektträger, BIH and external experts involved in the selection process who have signed a confidentiality agreement.

1. https://journals.sagepub.com/doi/pdf/10.1177/0023677217724823 [↑](#footnote-ref-1)
2. https://arriveguidelines.org/arrive-guidelines [↑](#footnote-ref-2)
3. e. g. Guidance on Good Cell Culture Practice, Coecke et al., 2005 sowie ergänzende, aktualisierte Dokumente dazu [↑](#footnote-ref-3)
4. https://www.forschungsdaten.org/index.php/FAIR\_data\_principles [↑](#footnote-ref-4)
5. Deklaration von Helsinki: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> [↑](#footnote-ref-5)
6. More information available e.g. from INVOLVE [↑](#footnote-ref-6)