**BIH/Charité: RegTherapies Incubator Grant**

**Introductory remarks**

The provided template has been adapted to more clearly delineate the evaluation criteria by which applications will be assessed. This is in accordance with the development of ToMAP (Translation Oriented Means-Model of Assessing Projects).

**Project application form**

Please note that it is your responsibility to submit a complete application and that a formally incorrect application may be excluded from the evaluation procedure. If you have any questions regarding your application, please contact [nicola.brindle@bih-charite.de](mailto:nicola.brindle@bih-charite.de). Please be sure to elaborate a clearly understandable proposal. The proposal should be self-explanatory and not require the reviewers to read the literature that is either quoted or enclosed.

This document must be submitted to [contact@b-crt.de](mailto:contact@b-crt.de) latest by 23:59 h on **29th August 2021**.

**General information**

Please follow the template formatting

Part I, II and II are evaluated with equal weighting.

BIH/Charité – RegTherapies Incubator Grant

*Seed funding to promote Advanced Therapies reaching phase I/IIA clinical trials*

Project Proposal

**<Title>**

Coordinator: <Name>

**Applicant information:**

<Academic degree/title, first name, last name>

<Affiliation>

<Work address>

<Phone number>

<E-mail address>

**Project partner(s):**

<Academic degree/title, first name, last name>

<Affiliation>

<E-mail address>

<Academic degree/title, first name, last name>

<Affiliation>

<E-mail address>

**Total amount of funding requested:** <Sum> €

**Duration of funding:** <one or two years>

**Part I: Description of the Project (evaluation weighting: 33%)**

## **Planned Research Program (Scientific Content)**

Please address the following aspects to describe the research program for your application (max. 1,000 words): The following three sections represent the overall evaluation criteria. The text in grey represent the indicators by which the application will be evaluated. **Please address all points as fully as possible, or indicate why they are not applicable to the application**. Please delete the grey text from the final proposal. Please include a bibliography of references cited at the end of the text (this does not count towards the final word count)

Overall Objectives of the project

1. Medical need and expected impact on patients
   1. What is the impact of the target disease on patient quality of life?
   2. Why are current treatments insufficient?
   3. What are the disease related public expenditures?
   4. Please explain how you consider gender aspects (human) and/or sex as a biological variable (cells, animals, humans) in the context of your research
2. Novelty of of proposed project, how does it fit within the current state of the art?
   1. What is the translational potential for future development of new diagnostic, therapeutic or preventative procedures
   2. Is there any expected competing research from external parties
   3. Preliminary work if available
3. Expected outcomes and project time line (please include a Gantt chart)
   1. Please clearly indicate project milestones (where is the project currently and what is the expected TRL level, see appendix A)
   2. Please clearly indicate distribution of tasks
   3. Describe how the project will create preliminary data for third party funding, if possible please indicate type and source of third party funding.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Example Gantt chart** | **Year 1** | | | | **Year 2** | | | |
| **Work packages/Task Title** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** |
| **WP1: (persons responsible)** | | | | | | | | |
| **Aim:** |  |  |  |  |  |  |  |  |
| Task 1.1: (persons responsible) |  |  |  |  |  |  |  |  |
| Task 1.2: |  |  |  |  |  |  |  |  |
| **Aim:** |  |  |  |  |  |  |  |  |
| Task 1.3: |  |  |  |  |  |  |  |  |
| Task 1.4: |  |  |  |  |  |  |  |  |
| Deliverables and Milestones | D1.1 |  |  |  |  |  |  |  |
|  |  | M1 |  |  |  | M2 |  |  |
| **WP2:** | | | | | | | | |
| **Aim1:** |  |  |  |  |  |  |  |  |
| Task2.1: |  |  |  |  |  |  |  |  |
| Task2.2: |  |  |  |  |  |  |  |  |
| **Aim2:** |  |  |  |  |  |  |  |  |
| Task 2.3: |  |  |  |  |  |  |  |  |
| Task 2.4: |  |  |  |  |  |  |  |  |
| **Aim3:** |  |  |  |  |  |  |  |  |
| Task 2.5 |  |  |  |  |  |  |  |  |
| Task 2.6 |  |  |  |  |  |  |  |  |
| Task 2.7 |  |  |  |  |  |  |  |  |
| Deliverables and Milestones |  |  | D2.1 |  |  |  |  | D2.2 |
|  |  |  |  | M1 |  |  |  | M2 |
| **WP3:** | | | | | | | | |
| **Aim 1:** |  |  |  |  |  |  |  |  |
| Task 3.1: |  |  |  |  |  |  |  |  |
| Task 3.2: |  |  |  |  |  |  |  |  |
| **Aim 2:** |  |  |  |  |  |  |  |  |
| Task 3.3: |  |  |  |  |  |  |  |  |
| Task 3.4: |  |  |  |  |  |  |  |  |
| Deliverables and Milestones |  |  | D3.1 |  |  |  |  | D3.2 |
|  |  |  |  | M1 |  |  |  | M2 |

**Part II: Team Bulding and Project Management (evaluation weighting: 33%)**

Please address the following aspects to describe the project management for the research program for your application (max. 1,000 words): The following four sections represent the overall evaluation criteria. The text in grey represent the indicators by which the application will be evaluated. **Please address all points as fully as possible, or indicate why they are not applicable to the application**. Please delete the grey text from the final proposal. If applicable, include a bibliography of references cited at the end of the text (this does not count towards the final word count).

1. Competence and composition of the research team
   1. How does your project establish a new scientific network or interdisciplinary collaboration? (e.g., between junior and senior researchers, basic and clinician scientists, different fields of research)
   2. Are all relevant expertise/competences included? How will the proposed team support the project?
   3. How will your experience enable the success of the project (with you as PI)
2. Availability of required infrastructure
   1. Is access to required infrastructure guaranteed?
   2. Is access to patients and/or involvement of patient organisations guaranteed?
3. Opportunity and risk assessment with accompany mitigation strategy
   1. Estimation of risk: Is risk High, Medium or Low?
      1. A risk is a plausible event or issue that could have a high adverse impact on the ability of the project to achieve its objectives. Level of likelihood to occur (Low/medium/high): The likelihood is the estimated probability that the risk will materialise even after taking account of the mitigating measures put in place. Level of severity (Low/medium/high): The relative seriousness of the risk and the significance of its effect (EU Grants: HE Programme Guide: V1.1 – 19.07.2021).
   2. Do you have Freedom to Operate (no legal boundaries)
4. Document and data management
   1. If relevant: how do you organise the data-management

**Part III: Commercialisation (evaluation weighting: 33%)**

Please address the following aspects to describe the possibilities for commercialization/exploitation of the research program for your application (max. 1,000 words): The following four sections represent the overall evaluation criteria. The text in grey represent the indicators by which the application will be evaluated. **Please address all points as fully as possible, or indicate why they are not applicable to the application**. Please delete the grey text from the final proposal. If applicable, include a bibliography of references cited at the end of the text (this does not count towards the final word count).

1. Investigation of possible partners
   1. Please list the discussed and/or even contacted relevant partners (internal or external e.g., academic, industry, patient organization etc)
2. Commercialisation and exploitation strategy
   1. Please describe commercialisation potential and your timeline for developing a commercialisation strategy
   2. Please describe the probability of market launch (very low/high) and the duration
   3. Did you add an idea (eg pitchdeck) for a (concept)-businessplan (as a possible) start-up?
3. Intellectual property (IP) strategy and regulatory aspects
   1. What is the patent status (from no patent planned – objection period ended)
   2. If relevant please indicate the status of the application for ethical approval? Please attach the application and/or the vote of the ethics committee as a separate file.
4. Dissemination strategy and open science
   1. Please describe your strategy for dissemination and adherence to open science.

**Part IV: Budget plan**

Please use the table below to provide information on the planned use of funds: **Total amount of funding requested:** <Sum> €. Please specify personnel (with exact names if possible), consumables, investments or other.

|  |  |  |
| --- | --- | --- |
| **Budget item** | **Description** | **Estimated costs** |
| **PostDoc** | E13 100% on WP1 | € xx.xxx,xx |
| **PhD student** | E13 65% on WP2 |  |
| **Consumables** |  |  |
| **Subcontract** |  |  |
| **Other** |  |  |