Validation Fund / SPARK-BIH Call 2020

+++ Track 2 (more than 50.000€) +++

This is **NOT** an application form. This document only lists questions as they will be asked in the BIH application portal and is purely meant as a guidance tool for your preparation. **It is mandatory to apply via the BIH application portal, only applications received through the portal will be considered. To apply, please use this link.**

To apply for the Validation Fund / SPARK-BIH Call 2020, please submit your Track 2 proposal **before June 18, 2020 (14:00 CET)** using the BIH application portal. Please note that applications will **only** be considered if submitted via the BIH application portal. Below, you find the questions as they will be asked in the BIH application portal to apply for **Track 2**. Make sure you meet the Track 2 eligibility criteria including the ones regarding intellectual property as described in the "Guide for applicants Track 2". In case you do not meet the Track 2 eligibility criteria regarding intellectual property, please consider to apply for Track 1.

Please note that you have to stick to the requirements of this template. Applications that do not follow these requirements will not be considered in the application process.

We suggest working with Google Chrome when using the BIH application portal. Please save your progress regularly.

I. Applicant Information

Applicant details *

- Position of applicant *
- Applicant research group *
- Employer of applicant *

Co-applicant details (if applicable)

- Title of co-applicant
- Academic Title of co-applicant
- Last Name of co-applicant
- First Name of co-applicant
- Position of co-applicant
- Employer of co-applicant
- Research group of co-applicant
- Email Address of co-applicant

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SPARK BIH

BIH Innovations
The Technology Transfer Office of BIH and Charité

Group leader (Kostenstelleninhaber*in) if different from applicant

- Title of group leader
- Academic Title of group leader
- Last Name of group leader
- First Name of group leader
- Position of group leader
- Research group of group leader
- Employer of group leader
- Email Address of group leader

Description of the team (brief description of why the team is suitable to pursue this project)

- Description of the team (max. 1500 characters incl. spaces) *

Provide a brief description of the team that will realize your 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. Please list any expertise you hope to acquire or gain through the support of SPARK. If applicable, describe any unique infrastructural/facility advantages at your disposal.

II. Project description

- Project category *

Select from the following options: Pharma, Medical Devices, Diagnostics

- Indication/Area of research *

Please name the indication/area that your solution addresses. (Multiple choices are possible)

Select from the following options: Cancer/Oncology/Immuno-oncology, Cardiology/Cardiovascular, Chronobiology, Dentistry, Dermatology, Gastroenterology, Hematology, Immunology, Infectious disease, Metabolic Disease/Diabetes, Nephrology, Neurology, Pain, Pulmonology, Regenerative medicine/Stem cells, Surgery, Transfusion, Other

Project description details

- Non-confidential project title (max. 120 characters incl. spaces) *

Please pick a non-confidential title that catches the essence of your project and that can be used publically.

- Project acronym *

Please pick a 1 word abbreviation for your project.

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- Project aim (max. 300 characters incl. spaces) *

Please provide a very short description of what you are planning to accomplish with the project during the funding period. For example: Screen for inhibitor of X, generate data in second mouse model to validate initial results in disease X.

- Description of the "problem"/unmet medical need (max. 1500 characters incl. spaces) *

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

- Description of your new solution/invention (max. 2500 characters incl. spaces) *

Please describe your solution and how it addresses the problem and unmet medical need that you are trying to solve. Please describe both the final product/solution (e.g. a drug, diagnostic assay, implant...) and - if the final solution cannot be achieved within the funding period - the 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. hit identified, prototype developed, GMP-produced substance) and that you are not simply planning further research (e.g. setting up an assay for a high throughput screen, checking the effect of inhibiting a cellular pathway).

- Uniqueness of new solution (max. 1200 characters incl. spaces) *

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 approved and approach the clinic (e.g. greater efficacy, improved safety, increased patient convenience etc.). What are the competitive advantages of your solution?

- Stakeholder involvement (max. 1000 characters incl. spaces)*

Have you included stakeholders already? Have you received input from potential users? Describe how and in which phases of your study relevant stakeholders (e.g. study participants, patient organizations, funding agencies, researchers (including you), enterprises etc...) will be involved and will contribute to your project. Describe the support by other parties. Describe possible conflicts of interest.

Current stage of project

- Current stage of the project (max. 1000 characters incl. spaces)*

Please describe what you have achieved. Provide solid, relevant data and evidence supporting the assumption that your solution will be successful and your approach will work (proof-of-concept/technology/principle data). Please show how the data from your previous studies support your description of the new solution. Make sure to include tables/and or graphs including all n, data points and the transparent display of the actual data distribution.

Please note that supporting graphics and schemes should be uploaded separately (see section "Graphics", max. 4 pages)

- Data robustness and reproducibility at current stage of the project (max. 2500 characters incl. spaces)*

Which facts support robustness of your data? Please describe how you considered sex (cells, animals, humans) and gender (humans) aspects as a biological variable.

***** = this value is required

Please briefly describe your strategies for **reproducibility of your study methods and results**. How large is your sample size and how has this been calculated? Briefly discuss effect size estimates, primary and secondary outcome measures and endpoints as well as possible confounders (if applicable). Provide a short overview how you conducted your previous statistical analyses, e.g. "We used a logistics regression analysis with X as dependent and Y as independent variable. We adjusted for confounder Z".

Explain if and how you already published/shared the current data with the (scientific) community. Did you register or preregister your study.

Proposed project during funding period

- Description of work plan including work packages, milestones and budget (max. 2500 characters incl. spaces) *

Include structured timelines, milestones and key goal objectives that you suggest for the funding period as well as the associated budget. Please note, a milestone is what you want to have accomplished at the end of a work package. A work package is what you do to reach this milestone (often experiments). Please also include potential pitfalls of the project with sufficient risk assessment and criteria to substantiate continuation of the program at each milestone. The completion of these work packages should not exceed **2 years**.

Please describe the work plan as follows: Work package 1 incl. time frame, accompanying description and statistical analysis 1, accompanying milestone 1, accompanying budget 1, work package 2 incl. time frame, accompanying description and statistical analysis 2, accompanying milestone 2, accompanying budget 2 etc.

- Data robustness and reproducibility (max. 2500 characters incl. spaces)*

Please briefly describe your strategies for **reproducibility of your study methods and results.** Which risks of bias you can identify. What are your project specific strategies to reduce the risk of bias. Please describe how you plan to consider sex (cells, animals, humans) and gender (humans) aspects as a biological variable. In case you are planning an animal study, discuss "replacement" and "reduce" among the 3R principles.

How large is your planned sample size and how has this been calculated? Provide a short overview how you plan your statistical analyses, e.g. "We will use a logistics regression analysis with X as dependent and Y as independent variable. We will adjust for confounder Z"; "We will report adjusted p-values and confidence intervals". Briefly discuss effect estimates, primary and secondary outcome measures and endpoints as well as possible confounders (if applicable).

Explain when and how you plan to publish your data or/and (pre-)register your study.

After the end of the funding period

- Future development plan (max. 1200 characters incl. spaces) *

If your project is successful, please describe how you intend to proceed after the support by the validation fund? Which additional steps are necessary to reach patients/market and how can they be realized? Is your intention to license 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.

- Description of regulatory requirements (max. 1500 characters incl. spaces)

What are the regulatory requirements that your product/solution/technology needs to meet in order to reach the market? How will you proceed in order to fulfill them?

III. Budget overview

Budget details

- Total Budget (in EUR) *

(please enter only numbers here)

- Consumables and Invest Budget (in EUR) *

(please enter only numbers here)

- Personnel Budget (in EUR) *

(please enter only numbers here)

- Justification of Personnel funding (if applicable). (Max. 500 characters incl. spaces.)

The funding only covers personnel costs in exceptional circumstances. Any personnel funded by the Validation Fund needs to already have a contract at your institution (i.e. BIH, Charité or MDC). No new contracts can be issued (only so-called "Umsetzungen" are possible). Please provide a solid explanation for why personnel is indispensable to reach the suggested milestones. Please note that the Validation Fund will evaluate this aspect carefully.

IV. Intellectual Property

Please note, eligibility for **Track 2** requires at least a positively evaluated invention disclosure. If you do not have a positively evaluated invention disclosure (*positive bewertete Erfindungsmeldung*) or you solution has not yet reached the stage at which an invention disclosing is feasible **and you do not qualify for Track 2 (yet). Please consider applying for Track 1 instead.**

Please provide information on existing IP

- Please indicate if one or more invention disclosure(s) and/or patent(s) exist for the technology you are validating in your project *

Select: Yes, No, Currently being prepared, Not patentable

***** = this value is required

- If no IP currently exists, has it been determined by the TTO that patenting is and will not be feasible or advisable for this technology/area (e.g. in some cases of drug repurposing etc.).

[Select: Yes, No]

Please note: if you simply have not yet reached the stage at which disclosing an invention is feasible, **you do not qualify for Track 2 (yet). Please consider applying for Track 1 instead**.

- If you selected 'Not patentable', please describe how you plan to nonetheless reach patients/market/commercialization (max. 1500 characters incl. spaces)

- If one or more invention disclosure(s) and/or patent(s) exist, please list the invention disclosure reference number(s), or the patent number(s) including patent holder and any relevant details on the IP status.

Invention disclosure reference number(s): (i.e. CH ____/year (at the Charité) and MDCyear/___ (at the MDC)

Patent holder (Charité/MDC/other public institution/private company or person)

Please note that in case an entity other than Charité or MDC (partially) holds the patent rights, it is mandatory that you contact the Validation Fund team before submitting this application.

Contact with the Technology Transfer Office (TTO)

- Please indicate your contact person at the Technology Transfer Office (TTO) of your institution (BIH/Charité: BIH Innovations, MDC: MDC-TTO)

Select from: Xenia Boergen, Bettina Büttner, Sven Friedl, Stefanie Grunwald, Anette Schröder, Frank Stief, Sigrun Szepanski, Gerd Müller, Vera Martos Riano, Dr. Daniel Romaker, Other please specify

+++ Only fill out the section below, if you have indicated any invention disclosures or patents above. If not, please skip to the next section +++

<u>INVENTION 1</u>

- Invention 1. Invention disclosure reference number

The invention disclosure (Aktenzeichen der Erfindungsmeldung) number starts with CH____/year (at the Charité) and MDCyear/___ (at the MDC)

- Invention 1. Patent number

- Invention 1. Patent holder

Who is the patent holder (Charité/MDC/other public institution/private company or private person)? Please note that in case an entity other than Charité or MDC (partially) holds the patent rights, it is mandatory that you contact the Validation Fund team before submitting this application

- Invention 1. Additional comments (500 character limit incl. spaces)

Please provide any relevant details on the IP status of the technology you are planning to validate in this project.

INVENTION 2

- Invention 2. Invention disclosure reference number

The invention disclosure (Aktenzeichen der Erfindungsmeldung) number starts with CH____/year (at the Charité) and MDCyear/___ (at the MDC)

- Invention 2. Patent number

- Invention 2. Patent holder

Who is the patent holder (Charité/MDC/other public institution/private company or private person)? Please note that in case an entity other than Charité or MDC (partially) holds the patent rights, it is mandatory that you contact the Validation Fund team before submitting this application

- Invention 2. Additional comments (500 character limit incl. spaces)

Please provide any relevant details on the IP status of the technology you are planning to validate in this project.

V. Commercialization

Commercialization details

- Does the commercialization of your product solution depend on other patents?

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

- Target group (max. 1200 characters incl. spaces) *

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.

- Commercial potential (max. 1200 characters incl. spaces) *

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).

- Indicate your potential competitors (max. 1000 characters incl. spaces) *

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 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.

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VI. Publications

Publications details

- Key publications (optional)

*Please list **up to 5** key publications that you feel are important to understand the technology 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.*

VII. Graphics

Supporting graphics

- Upload PDF file*

*Please upload 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. Please upload the graphs as 1 PDF file (**max. 4 pages, max. file size 10MB**).*

VIII. Confirmations and signature(s)

Confirmation and signature(s) required before you can submit via upload of the signature page that can be downloaded from the call website.

- No alternative funding currently exists for the work applied for in this application (Doppelförderungsverbot) *

[Checkbox]

Please confirm that currently no alternative funding for the work applied for exists.

- Confirmation of change notification *

[Checkbox]

Please confirm that if this changes at any point, you will notify the Validation Fund management immediately.

- Upload of signature page *

[Checkbox]

Please upload a PDF scan of the signed legal compliance / confidentiality document as provided on the BIH website (max. file size 2MB).

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