Guide for Applicants – Validation Fund/SPARK-BIH Track 1

This guide addresses **Track 1 only**. Please be aware of the separate "Guide for Applicants Track 2".

1. Mission and Aim of Funding

The Berlin Institute of Health (BIH) and BIH Innovations – the joint technology transfer office (TTO) of the BIH and Charité – Universitätsmedizin Berlin (Charité) – together with SPARK-BIH are pleased to announce **their third call for proposals**.

The mission of BIH Innovations and this funding line is to accelerate the translational process from academic invention to marketable product. We aim to foster an environment that supports innovative research and the development of novel therapies, products or services, which address unmet medical needs and benefit patients. This includes the education of faculty, fellows and students on the translational process. In the context of this funding line, we support the development of novel treatment options, diagnostics and medical devices as well as repurposing projects through financing critical next validation steps and by supporting teams with mentoring and through education. It is the aim of the funding program to advance translation towards solutions and products with medical impact. Advanced development steps are expected to be realized via licensing IP to industrial partners or dedicated start-ups with equity held by home institutions, BIH or third parties designated by them.

2. Eligibility

Exclusively, researchers or clinicians from the BIH, Charité or MDC are eligible for funding, including principal investigators, postdoctoral researchers, and graduate students. However, each application must be signed or co-signed by a principal investigator (Arbeitsgruppenleiter*in/Kostenstelleninhaber*in) who needs to be an employee of BIH, Charité or MDC.

In order to ensure the successful completion of each project, the principal investigator needs to confirm that the duration of his/her employment contract at BIH/Charité/MDC covers at least the duration of the proposed project and that currently no alternative funding for the work applied for exists.

The BIH seeks to increase the diversity of its funding programs. Women, individuals from underrepresented racial and ethnic groups, as well as individuals with disabilities are especially encouraged to apply for BIH programs.

3. Project Requirements

The funding program supports the development of novel therapeutics (small molecule, biologic or ATMP), medical devices and diagnostics for unmet medical needs, as well as repurposing of existing drugs for new indications. Any clinical indication will be considered.
All projects (Track 1 AND Track 2) must aim at the **validation** of research findings with the goal of translating these into therapies, products or services. **Basic research will not be funded**. The following are the project requirements for projects in **Track 1 AND Track 2**:

- Projects must be translational; basic (DFG-like) research projects are NOT eligible.
- Projects must address a significant unmet medical need.
- The described solution must be innovative and novel (no "me too" solutions).
- Projects must be based on solid data, which demonstrate proof-of-principle (depending on the projects this can be *in vitro*, *in vivo*, proof-of-technology etc.) and justify the described next steps.
- Described solutions must exhibit a strong (significant) competitive advantage over the current gold standard.

In order to ensure project alignment with the requirements of the call, all applicants who are unsure of which track (Track 1 or Track 2) is most suitable for their project are encouraged to contact the Validation Fund/SPARK-BIH team before submitting their proposal.

4. Deadline and Selection Procedure

Eligible applicants for **Track 1** are invited to submit their project proposal by **June 18, 2020, 14:00 CET** via the BIH application portal. Selected applicants of Track 1 projects will be invited to pitch their proposals in front of an expert panel on 7 or 8 September, 2020. Project starts are planned for January 2021.

5. Selection criteria

A substantial data package, describing the previous findings of the project, is a clear requirement for application. Next to basic information about the applicants, information to be supplied in the application includes but is not limited to brief descriptions of:

- Applicant credentials
- Problem and unmet medical need
- Solution/invention, how it is unique and how it addresses the unmet medical need
- Current stage of the project, previous data and future development plan
- Suggested work plan, milestones and budget
- Information about the intellectual property situation
- Commercial potential and competitors

Proposals will be evaluated on the basis of:

- Scope of unmet medical need
- Novelty of approach
- Fit of proposed solution to unmet medical need
- Quality, validity and robustness of data
- IP status/suggested alternative path to patient/market
- Feasibility of developmental path (budget and time)
- Suitability of team
- Marketability/probability of commercialization

Some examples of past projects include unmet medical needs in pediatric, neglected or orphan diseases, cardiovascular, oncology, inflammatory, respiratory, neurological, autoimmune indications and infectious disease. We will consider small molecule, biologics, ATPM, medical device and diagnostics applications in all medical areas and other indications of serious unmet medical need.

6. Budget, Duration and Milestone-based Funding

Track 1 is geared towards projects needing up to 50,000 EUR. We therefore urge you to carefully evaluate your project and to include only work packages and expenses in your proposal, which are critically important for the successful validation and completion of your project.

Please describe the specific steps needed to commercialize your product or otherwise move it towards the market and/or patient. These steps may vary widely depending on the area of the product or solution you are working on and its current developmental stage. In general, you should limit the overall time frame to 1 year.

At the end of the support by the Validation Fund, the products and solutions should be able to achieve one of the following:

- Successful out licensing of the technology/product/solution
- Continuation of the project in a spin-out
- Secure additional funding for further development steps in the academic setting (e.g. GO-Bio, BMBF)

Please describe all steps (including budget) that you consider vital in order to achieve one of these outcomes. Suggest critical milestones at which the project can be evaluated regarding its continuation. **Please note that before a final funding decision is made, the entire project plan as well as milestones and budget will be evaluated together with you by external experts and may be adjusted**.

Funding support is aimed at research consumables, investments or contract services (high-throughput screening, regulatory services, animal studies, consulting etc.). The funding only covers personnel costs in exceptional circumstances.

Please note that project funding is strictly milestone-based. The budget will be released consecutively in a milestone-dependent manner and project progress will be monitored continuously. If it is determined at any point during the project that the project goals cannot be met anymore, the project and funding will be discontinued. Only those costs will be covered, which are directly related to the project, which will be agreed to in a Milestone Funding Agreement and which will be detailed in a corresponding budget table. Any future changes to work packages and/or milestones must be discussed with and agreed to by the Validation Fund management.

7. Mentoring and Expert Advice

Next to financial support, one of the main benefits for supported projects, is guidance and mentoring. Eligible projects will become part of the SPARK-BIH program (see 'SPARK-BIH Website') and will be expected to participate in all SPARK activities (regular project meetings, workshops and lectures). In addition, projects in Track 1 will be continuously supported by external experts if necessary. Workshop and lecture topic examples are intellectual property and patent right, regulatory requirements for medical devices, diagnostics or pharma development, clinical trial design, pitching, fundraising or GLP. The workshops will be tailored to the needs of the supported SPARK projects to ensure education on aspects of the translational process.

Each project selected for funding will work according to milestones and progress metrics to ensure the project's steady progress. A project progress presentation and meeting will be held approximately every 6 months where investigators will report on progress and challenges. Milestones will be reviewed and adjusted, and project teams will receive continued input and advice from the Consultant Panel.

8. Submission Process

Please apply by **June 18, 2020**. Applications must be submitted before the call **deadline at 14:00 CET. Applications will only be considered if submitted via the** BIH application portal and do include all required information including the signature page.

Fill out the online application form and sign the signature page that can be downloaded from the BIH website (in cases where the applicant is not the PI, we need the PI/Kostenstelleninhaber*in to co-sign your application).
It is advisable to use the Google Chrome browser for you online application.
For questions concerning the BIH application portal, please contact: portal@bihealth.de
Please note that the document '*Application questions Track 1 – for preparation only!*' lists all questions as they will be asked during the online application. This document is only a guidance tool for your preparation and cannot be used as application form.

9. Key dates

Submission deadline: **June 18, 2020 14:00 (CET)**
Project presentations: September 7 or 8, 2020
Project start: planned for January 2021

More detailed information will be communicated in due time.

10. Obligations

Please note that applicants or Kostenstelleninhaber*in have to report to the Validation Fund management if deviations from the information given in the application occur during the application process and (for funded projects) during the entire funding period. This applies to but is not limited to changes concerning the team (e.g. contracts), changes regarding the IP situation or resources for the project (e.g. funding).
After project completion, and/or after discontinuation of the Validation Fund / SPARK-BIH support, a final report (*Verwendungsnachweis*) in a format determined by the Validation Fund management must be prepared and delivered by the funding recipients.

11. Questions

For questions please contact:

Dr. Tanja Rosenmund - Manager Validation Fund / SPARK Program Manager
tanja.rosenmund@bihealth.de
030-450-543-056