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## Guide for Applicants – BHI Validation Fund Track 1

Note: This guide addresses Track 1 only. Please be aware of the separate “Guide for Applicants – BHI Validation Fund Track 2”.

### 1. Mission and Aim of Funding

The Berlin Institute of Health (BIH) and Berlin Health Innovations (BHI) – the joint technology transfer office (TTO) of the BIH and Charité – Universitätsmedizin Berlin (Charité) – together with SPARK-Berlin are pleased to announce their first call for proposals in the newly established validation fund.

The mission of Berlin Health 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, devices and digital health solutions through financing critical next validation steps and by supporting teams through education.

### 2. Eligibility

Every researcher or clinician at the BIH, Charité or MDC is 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.

The BIH seeks to increase the diversity of its funding programs. Women scientists, 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 validation fund supports the development of novel therapeutics (small molecule or biologic), medical devices, diagnostics and digital solutions for unmet medical needs, as well as repurposing of existing drugs for new indications. Any clinical indication will be considered. All projects in the validation fund (Track 1 AND Track 2) must aim at the validation of research findings with the goal of translating these into therapies, products or services. 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.

Project teams that apply for Track 1 are not required to have filed a patent, but are strongly encouraged to contact the technology transfer office (TTO) with regard to their invention prior to the application.

In order to ensure project alignment with the requirements of the call, all applicants who are unsure which track is most suitable for their project are encouraged to contact the validation fund team before submitting their proposal.

### 4. Deadline and Selection Procedure

Eligible applicants for Track 1 are invited to submit their project proposal by **January 16, 2018, 15:00 CET**. Selected applicants of Track 1 projects will be invited to pitch their proposals in front of an expert panel in early March 2018 (exact dates will be announced in due time). Project starts are planned for March/April 2018.

### 5. Selection Criteria

Next to basic information about the applicants, information to be supplied in the proposal includes but is not limited to brief descriptions of:

- Applicant credentials
- Problem and clinical need
- Solution/invention and how it is unique

- Current stage of the project and future development plans
- 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 clinical need
- Novelty of approach
- Feasibility (budget and time)
- Quality of data
- 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, medical device, diagnostics applications as well as digital health solutions in these areas and other indications of serious unmet medical need.

## 6. Budget and Duration

Track 1 covers projects of up to 1 year with a budget of up to 50,000 EUR, based on the accomplishment of milestones. Highly successful projects may be chosen by the fund management for additional funding in a second year (again up to 50,000 EUR).

Please note that project funding is milestone-based. If it is determined at any point during the project that the project goals cannot be met anymore, the project and funding will be terminated.

Please describe the goal you hope to achieve with the help of the BHI Validation Fund and all steps that you consider vital in order to achieve this goal. Please include an estimated budget for each step and 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 the milestones will be reviewed together with you 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.

## 7. Mentoring and Expert Advice

Next to financial support, one of the main benefits for supported projects is guidance and mentoring. Eligible projects will be chosen to become part of the SPARK-Berlin

program (see [SPARK-Berlin website](#)) and will be expected to participate in all SPARK project meetings and lectures.

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 6 months from the project's start 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 **January 16, 2018** via the [BIH online application portal](#). Please note that applications must be submitted before the call **deadline at 15:00 CET**.

Fill out the application and sign the signature page on the [BIH website](#) (in cases where the applicant is not the PI, we need the PI/Kostenstelleninhaber\*in to co-sign your application). Briefly describe your proposed therapy, medical device, diagnostic, or digital solution, which must address an unmet medical need and utilize a novel approach in any indication by answering the questions in the form. Please submit your application electronically via the BIH online portal.

## 9. Key dates

Submission deadline Track 1: January 16, 2018

Project presentations: Early March 2018

Funding decision: Early March 2018

The exact dates will be communicated in due time.

## 10. Questions

For questions please contact:

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Info events will be hosted throughout December 2017. Please check the [BIH website](#) for dates and locations.