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Guide for Applicants – BHI Validation Fund Track 2

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

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.

In addition to the above requirements (requirements for Track 1 AND Track 2), a positive review by the technology transfer office (TTO) of your institution is required in Track 2. This review must result in **one of the following**:

1. A granted patent. If any background intellectual property exists regarding the proposed project that is not held (solely) by BIH, Charité and/or MDC, please contact the fund management in order to determine whether your project qualifies for funding.
2. Patent application submitted (*Patentanmeldung eingereicht*).
3. Invention claimed but patent application not yet submitted (*Inanspruchnahme mit geplanter Patentanmeldung*).
4. Invention disclosed to TTO with confirmed intention to claim. The future patent application is subject to additional data and future IP situation/medical need (*erfolgte Erfindungsmeldung mit positiver Einschätzung durch TT in Abhängigkeit von zukünftigen Daten und zukünftiger IP-Situation/Medical need*). This case can occur either if the invention disclosure is incomplete and patenting is not yet possible or if patenting is possible but not yet advisable. In case of the latter, the inventor must agree to postpone the patent submission.
5. In cases where patenting is not feasible or advisable, a detailed description of an alternative path to patient/market is required. Please note that in order to determine the IP situation, a consultation with the TTO is nonetheless mandatory in these cases. This option is only acceptable if the TTO determines that patenting is truly not feasible or advisable in this area (e.g. in some cases of

software development, some cases of drug repurposing etc.), not if the invention has simply not been developed far enough yet.

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 team before submitting their proposal.

4. Deadline and Selection Procedure

Eligible applicants for Track 2 are invited to submit their project pre-proposal by **January 16, 2018, 15:00 CET**. Pre-proposals will be screened for eligibility, and selected applicants of Track 2 projects will be invited to submit full proposals detailing their proposed project plans. These invitations will be sent out in February 2018 and applicants are given approximately 4 weeks to prepare full proposals. Providing a positive review by external experts, projects are then invited to pitch their projects in front of an external expert panel in April 2018 (exact dates will be announced in due time). Project starts are planned for May/June 2018.

5. Selection criteria

Next to basic information about the applicants, information to be supplied in the pre-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 of developmental path (budget and time)
- Quality of data
- Suitability of team
- Marketability/probability of commercialization
- IP status/suggested alternative path to patient/market

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, Duration and Milestone-based Funding

Track 2 is geared towards projects needing more than 50,000 EUR. There is no limit to the amount of funds per project. However, keep in mind that since limited funds are available, projects with high financial demands will be evaluated especially carefully. 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.

If you are in principle eligible for Track 2 (i.e. meet the IP requirements) but require less than 50,000 EUR for the completion of your project, please apply for Track 1.

In Track 2, 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 2 years.

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

- Successful outlicensing 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)

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 the milestones will be evaluated 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.

Please note that project funding is strictly milestone-based, and only the budget for one consecutive milestone will be released at a time.

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. In addition, projects in Track 2 will be continuously supported by external experts if necessary.

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 pre-proposals Track 2: January 16, 2018
Invitations for full proposals: February 2018
Submission deadline full proposals: March 2018
Project presentations: Late April 2018
Funding decision: May 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.