

Guide for Applicants – SPARK-BIH Track 2

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

1. Mission and Aim of Funding

The Berlin Institute of Health (BIH) @ Charité is pleased to announce the **fourth call for proposals** of the **SPARK-BIH program**. SPARK-BIH is part of BIH Innovations – the joint technology transfer office (TTO) of BIH and Charité – Universitätsmedizin Berlin. BIH Innovations supports researchers and clinicians in the development and transfer of technologies and products to patient and market. In addition to consultations and support in the areas of IP, patenting, licensing and law, BIH Innovations offers two funding instruments:

The **SPARK-BIH program** supports projects in **pharmaceuticals, biotechnology, diagnostics and medical devices** to validate research results with the aim of developing them into a therapy or product. The **Digital Health Accelerator** program funds projects in the development of market-ready products and, where appropriate, companies in the field of **digital health**. Our mission 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 and services, which address unmet medical needs and benefit patients. This includes the education of faculty, fellows and students on the translational process. Our program supports 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 or Charité 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 or Charité.

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 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 offers grants for the development of novel therapeutics (small molecule, biologic or cell/gene therapy (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 competitive advantage over the current gold standard.
- Projects must be developed within the academic setting.

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 for 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 or Charité, please contact SPARK 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 SPARK-BIH team before submitting their proposal.

4. Submission Process and Deadline:

Applications must be submitted by **May 31, 2021 before** the call **deadline at 14:00 CET** [via the BIH application portal](#). **Applications will only be considered if submitted via the** BIH application portal and if it contains all required information **including 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).

All questions that are asked in the online application are listed in the document '*Application questions Track 1 – for preparation only!*' Please note that this document is only a guidance tool for your preparation and cannot be used as application form.

It is advisable to use the Google Chrome browser for your online application.
For questions concerning the BIH application portal, please contact: portal@bihealth.de

5. Key dates

Submission deadline: **May 31, 2021 14:00 (CET)**
Project presentations: during the week of **August 16th to 20th, 2021**
Project start: Fall 2021

More detailed information will be communicated in due time.

6. Selection criteria

Proposals will be evaluated based on the following criteria:

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

Selected applicants of Track 2 projects will be invited to pitch their proposals in front of an expert panel during the week of August 16th - 20th, 2021.

Please note: A **substantial data package**, describing the previous findings of the project, is a clear requirement for the 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 including previous data
- Suggested development plan including milestones, Go/No-Go criteria and budget
- Information about the intellectual property situation
- Commercial potential and competitors

In addition to the data package, please **download the project timeline template** from the [BIH website](#), fill it out according to the guideline described in the template and upload it (without instructions) as **combined PDF** with your data package to the “Graphics” section in the BIH portal during the application process.

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, ATMP, medical device and diagnostics applications in all medical areas and other indications of serious unmet medical need.

7. Budget, Duration and Milestone-based Funding

Track 2 is geared towards projects needing **more than 50,000 EUR for a duration of max. 2 years**. We 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 alternative paths towards 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.

At the end of the support by SPARK-BIH, the products and solutions should be able to achieve one of the following:

- Submit a patent application
- Successful out licensing of the patent/technology/product/solution
- Continuation of the project in a spin-out
- Secure additional funding for further development steps in the academic setting (e.g. EXIST, 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 covers personnel costs if it is indispensable to reach the suggested milestones and if the respective personnel already has a contract at your institution (i.e. BIH or Charité).

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 SPARK-BIH management.

8. Mentoring and Expert Advice

Next to financial support, one of the main benefits for supported projects, is guidance and mentorship from a wide range of experts. 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 2 will be continuously supported by external experts, if necessary. Workshop and lecture topics include intellectual property and patent right, regulatory requirements for medical devices, diagnostics or pharma development, clinical trial design, pitching, fundraising and 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 and will receive input from their advisors. Milestones will be reviewed and adjusted, and project teams will receive continued input and advice from experts.

9. Obligations

Please note that applicants or Kostenstelleninhaber*in have to report to the SPARK 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 SPARK-BIH support, a final report (*Verwendungsnachweis*) in a format determined by the SPARK-BIH management must be prepared and delivered by the funding recipients.

10. Questions

For questions please contact:

Dr. Tanja Rosenmund - Teamlead SPARK-BIH
tanja.rosenmund@bihealth.de
030-450-543-056