Guide for Applicants – 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 at Charité (BIH) is pleased to announce the **fifth call for proposals** of the **SPARK-BIH program**.

SPARK-BIH is part of Charité BIH Innovation (CBI) – the joint technology transfer office (TTO) of BIH and Charité – Universitätsmedizin Berlin. CBI 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, Charité BIH Innovation offers two funding instruments, one of which is the SPARK-BIH program:

The **SPARK-BIH program** supports academic inventors with high-impact projects that address unmet medical needs. Projects from **all medical disciplines** that develop **novel therapies** (small molecules, biologics, ATMPs), **diagnostic assays**, **medical devices** as well as **repurposing projects** will be considered. We provide milestone-based funding, coaching, mentoring, project management, and target education on translation and entrepreneurship. Our goal is to accelerate the translational process from academic invention to marketable product that benefits patients and society. 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 program 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.

A positive review of an invention disclosure by the technology transfer office (TTO), as required for Track 2, is **not** needed for Track 1. 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 Dr. Tanja Rosenmund. before submitting their proposal.

4. Submission Process and Deadline:

Applications must be submitted in English by **July 04, 2022 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 SPARK 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.

We strongly suggest to use the Google Chrome browser for your online application. Using other browsers is NOT recommended.
For questions concerning the BIH application portal, please contact: portal@bih-charite.de

5. Key dates

Submission deadline: **July 04, 2022 14:00 (CET)**
Project presentations: Furing the week of **September 12 to 16, 2022**

Project start: Fall 2022

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 / level of innovation
- Fit of proposed solution to unmet medical need
- Quality, validity and robustness of data
- Marketability/probability of commercialization/path to patient
- Feasibility of development (budget and time)
- Expertise of the team

Selected applicants of Track 1 projects will be invited to pitch their proposals in front of an expert panel during the week of September 12 to 16, 2022.

Please note: A **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

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 1 projects are funded with **up to 50,000 EUR for a duration of max. one year.** 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 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 funding period, the products and solutions should be able to achieve one of the following:

- Positive review of the invention disclosure by the technology transfer office (TTO)
- Patent application submitted
- Secure additional funding for further development steps in the academic setting (e.g. GO-Bio *initial*, 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 assessed for 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 or contract services (high-throughput screening, regulatory services, animal studies, consulting etc.).

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 Website') and will be expected to participate in 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 topics may 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 at least every 6 months where investigators receive input on their progress and challenges. 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 SPARK-BIH 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:

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