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# Guide for Applicants – NeuroCure / SPARK-BIH Call for Translational Proposals

This guide addresses the NeuroCure/SPARK-BIH Call **only**.

## 1. Mission and Aim of Funding

We are pleased to announce the first joint NeuroCure / SPARK-BIH call for proposals.

The mission of SPARK-BIH 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 steps and by supporting teams with mentoring and education. It is the aim of the funding program to advance translation towards solutions and products with medical impact.

## 2. Eligibility

Researchers and clinicians from the Neuroscience community are eligible for funding, including PIs, postdoctoral researchers and graduate students. Applications need to be co-signed by a NeuroCure PI who will hold the financial responsibility. Collaborative applications including two, or more PIs are highly encouraged.

## 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 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**. We highly encourage you to also submit your proposals for very early projects, as we offer the possibility to support you with mentoring only in order to help advance your ideas further towards translation. Please find below the project requirements:

- 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.

If you are unsure whether your project is suitable for the program, if you need support in identifying a translational aspect, if you have an idea for a pharma-, diagnostics- medtech- or digital health project or if you have developed a special technique or tool that might benefit a wider community please contact us. A team including Craig Garner will be available for specific advice. Please contact Katharina Grauel ([katharina.grauel@charite.de](mailto:katharina.grauel@charite.de)) who will coordinate appointments.

For all other questions, please contact Tanja Rosenmund ([tanja.rosenmund@bihealth.de](mailto:tanja.rosenmund@bihealth.de)), program manager Validation Fund / SPARK-BIH

## 4. Deadline and Selection Procedure

Eligible applicants are invited to submit their project proposal by **June 24, 2020, 14:00 CET** via the [BIH application portal](#). Selected applicants will be invited to pitch their proposals in front of an expert panel between September 7<sup>th</sup> and 11<sup>th</sup>, 2020. Projects are planned to start in Fall 2020. In case of technical problems with the application portal, please contact: [portal@bihealth.de](mailto:portal@bihealth.de)

## 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

An overview of questions as they will be asked in the BIH application portal is provided in the document “Application questions NeuroCure/SPARK-BIH Call”.

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

## 6. Budget, Duration and Milestone-based Funding

Projects will be supported with up 50.000 EUR for one year. You can apply invest and consumables. For very early projects, we offer mentoring without monetary support.

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 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 NeuroCure / SPARK-BIH Fund, the products and solutions should be able to achieve one of the following:

- Secure additional funding for further development steps in the academic setting (e.g. GO-Bio initial, BMBF etc.)
- Submitting an invention disclosure (Erfindungsmeldung) to your respective institution
- Applying for a patent
- Successful out licensing of the technology/product/solution
- Continuation of the project in a spin-out

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.).

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 by a SPARK-BIH project manager. 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 program 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 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 24, 2020**. Applications must be submitted before the application **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 NeuroCure website (in cases where the applicant is not the PI, we need the NeuroCure principal investigator /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](mailto:portal@bihealth.de)

Please note that the document '*Application questions NeuroCure/SPARK-BIH Call – is for preparation only!*' It 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 24, 2020 14:00 (CET)**

Project presentations: planned for September 7<sup>th</sup> to 11<sup>th</sup> 2020

Project start: planned for Fall 2020

More detailed information will be communicated in due time.

## 10. Obligations

Please note that applicants or Kostenstelleninhaber\*in have to report to the NeuroCure Management Office 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 NeuroCure Management Office must be prepared and delivered by the funding recipients.

## 11. Advice and Questions

- If you are unsure whether your project is suitable for the program
- if you need support in identifying a translational aspect in your research
- if you have an idea for a pharma-, diagnostics-, or medtech- project
- if you have an idea for digital health project
- or if you have developed a special technique or tool that might benefit a wider community

please contact us. A team including Craig Garner will be available to discuss your idea/project with you and to give specific advice. Please contact Katharina Grauel ([katharina.grauel@charite.de](mailto:katharina.grauel@charite.de)) who will coordinate appointments.

For all other questions please contact:

Dr. Tanja Rosenmund – program manager Validation Fund / SPARK-BIH

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