NeuroCure / SPARK-BIH Call 2022

Questions from the application portal

Please note: This is **NOT** an application form. This document only lists questions as they will be asked in the BIH application portal and is purely meant as a guidance tool for your preparation. **It is mandatory to apply via the BIH application portal.**

To apply for the NeuroCure / SPARK-BIH Call 2022, please submit your proposal **before July 04, 2022 (14:00 CET)** using the BIH application portal. Only complete applications received through the portal will be considered.

GENERAL INFORMATION WHEN WORKING WITH THE APPLICATION PORTAL:

When working on your application using the BIH application portal, we advise you:

- to use Google Chrome. Using other browsers is NOT recommended
- to save your progress regularly (top left hand side)
- not to work on the application with more than one person / from more than one computer at the same time
- to allow for sample time when saving and submitting, especially if you have uploaded documents (saving and submitting may take up to five minutes! Do not close your browser or browse away from the page during this time)
- For questions concerning the BIH application portal, please contact: portal@bih-charite.de

I. Applicant Information

Applicant details *

- Position of applicant *
- Research group of applicant *
- Employer of applicant *
- Clinic/ Facility /Institute (lead) of applicant *
- Campus (lead) of applicant *

Select: CBB, CBF, CCM, CVK, Other

Co-applicant details (if applicable)

- Title of co-applicant

Select: Mr, Ms, Other

- Academic Title of co-applicant

* = this value is required

Select: Dr., Dr. med., Dr. med. dent., Dr. rer. nat., Dr. habil., PD, PD Dr., PD Dr. med., PD Dr. med. dent., PD Dr. rer. nat., Prof., Prof. Dr., Prof. Dr. Dr., Prof. Dr. med., Prof. Dr. med. dent., Prof. Dr. rer. nat.

- Last Name of co-applicant
- First Name of co-applicant
- Position of co-applicant
- Research group of co-applicant
- Employer of co-applicant
- Clinic/ Facility / Institute of co-applicant
- Campus of co-applicant

Select: CBB, CBF, CCM, CVK, Other

- Email Address of co-applicant

Group leader (Kostenstelleninhaber*in) if different from applicant

- Title of group leader

Select: Mr, Ms, Other

- Academic Title of group leader

Select: Dr., Dr. med., Dr. med. dent., Dr. rer. nat., Dr. habil., PD, PD Dr., PD Dr. med., PD Dr. med. dent., PD Dr. rer. nat., Prof., Prof. Dr., Prof. Dr. Dr., Prof. Dr. med., Prof. Dr. med. dent., Prof. Dr. rer. nat.

- Last Name of group leader
- First Name of group leader
- Position of group leader
- Research group of group leader
- Employer of group leader
- Clinic/ Facility / Institute of group leader
- Campus of group leader

Select: CBB, CBF, CCM, CVK, Other

- Email Address of group leader

Description of the team (brief description of the expertise and why the team is suitable to pursue this project)

- Description of the team (max. 1500 characters incl. spaces) *

Provide a brief description of the team that will realize your project. Include each team member's background and experience to demonstrate your credentials. Make sure to include relevant career stages, industry experience etc. List any collaborator(s) who complement your expertise, any service providers you consider contracting and any experts you have consulted concerning your project. Please list any expertise you hope to acquire or gain through the support by SPARK. If applicable, describe any unique infrastructural/facility advantages at your disposal.

* = this value is required

Other BIH Funding

- Other BIH funding (max. 1000 characters incl. spaces) *

Please indicate here if you are currently receiving other BIH funding or if you are currently participating in other BIH selection procedures, if not please enter "no". Please indicate the start and end dates of the funding, the amount of funding and whether the funding is for personnel, consumable or investment costs.

If this information changes during the selection process, please notify the SPARK-BIH management immediately. **Double funding is generally excluded.**

II. Project description

- Non-confidential project title (max. 120 characters incl. spaces) *

Please pick a non-confidential title that catches the essence of your project and that can be used publically.

- Project acronym *

Please pick a 1-word abbreviation for your project.

- Main goal / product (max. 200 characters incl. spaces) *

Please explain in a short sentence 1) the main goal of the entire project (e.g. develop a cell therapy against breast cancer) and 2) the main goal you want to achieve during the funding period (e.g. select a specific T-cell receptor).

- Project category *

Select from the following options: Pharma, Pharma (ATMP), Pharma (combination therapy), Diagnostic, MedTech, Digital Health, other (e.g. Methods, Platform)

- Indication/Area of research *

Please name the indication/area that your solution is addressing (multiple choices are possible).

Select from the following options: Cancer/Oncology/Immuno-oncology, Cardiology/Cardiovascular, Chronobiology, Dentistry, Dermatology, Gastroenterology, Hematology, Immunology, Infectious disease, Metabolic Disease/Diabetes, Nephrology, Neurology, Psychiatry, Pain, Pulmonology, Regenerative medicine/Stem cells, Surgery, Transfusion, Other

- ICD-11 *

Select from the following options:
01 Certain infectious or parasitic diseases
02 Neoplasms
03 Diseases of the blood or blood-forming organs
04 Diseases of the immune system
05 Endocrine, nutritional or metabolic diseases
06 Mental, behavioural or neurodevelopmental disorders
07 Sleep-wake disorders
08 Diseases of the nervous system
09 Diseases of the visual system
10 Diseases of the ear or mastoid process
11 Diseases of the circulatory system
12 Diseases of the respiratory system
13 Diseases of the digestive system
14 Diseases of the skin
15 Diseases of the musculoskeletal system or connective tissue
16 Diseases of the genitourinary system
17 Conditions related to sexual health
18 Pregnancy, childbirth or the puerperium

* = this value is required

19 Certain conditions originating in the perinatal period
20 Developmental anomalies
21 Symptoms, signs or clinical findings, not elsewhere classified
22 Injury, poisoning or certain other consequences of external causes
23 External causes of morbidity or mortality
24 Factors influencing health status or contact with health services
25 Codes for special purposes, 26 Supplementary Chapter Traditional Medicine Conditions - Module I

Project description details

- Project aim/intended use statement (max. 300 characters incl. spaces) *

Please provide a very short description of what you are planning to accomplish with the project during the funding period. Your description should be understandable to non-experts in your field. For example: Screen for inhibitor of X, generate data in second mouse model to validate initial results in disease X. For medical devices and diagnostics projects, please add the intended use statement.

- Description of the "problem"/unmet medical need (max. 1500 characters incl. spaces) *

Please describe the problem and unmet medical need that your solution addresses. Summarize how you systematically reviewed the existing evidence (e.g. literature, data, expert opinions, registries etc.).

- Description of your new solution/invention (max. 2500 characters incl. spaces) *

Please describe your solution and how it addresses the problem and unmet medical need that you are trying to solve. Please describe both the final product/solution (e.g. a drug, diagnostic assay, implant...) and - if the final solution cannot be achieved within the funding period - the goal you are trying to reach within the funding period. Ensure that you are aiming for a clear developmental goal at the end of the funding period (e.g. hit identified, prototype developed, GMP-produced substance) and that you are not simply planning further research (e.g. setting up an assay for a high throughput screen, checking the effect of inhibiting a cellular pathway).

- Uniqueness of new solution (max. 1200 characters incl. spaces) *

Please describe what makes your solution unique. How does it differ from the current "gold standard"? Please also differentiate your proposed solution from other solutions that are already approved or in development (e.g. greater efficacy, improved safety, increased patient convenience etc.). What are the competitive advantages of your solution?

- Stakeholder involvement (max. 1000 characters incl. spaces) *

Have you included stakeholders already? Have you received input from potential users? Describe how and in which phases of your study relevant stakeholders (e.g. study participants, patient organizations, funding agencies, researchers (including you), enterprises etc...) will be involved and will contribute to your project. Describe the support by other parties. Describe possible conflicts of interest.

Current stage of project

- Current stage of the project (max. 1000 characters incl. spaces) *

Please describe what you have achieved. Provide solid, relevant data and evidence supporting the assumption that your solution will be successful and your approach will work (proof-of-concept/technology/principle data). Please show how the data from your previous studies support your description of the new solution. Make sure to include tables/and or graphs including all data points, information on group sizes and the transparent display of the actual data distribution. Please note that supporting graphics and schemes should be uploaded separately (see section "Graphics", max. 4 pages).

- Current Technology Readiness LEVEL of the project *

Select from the following options (reference: https://ncai.nhlbi.nih.gov/ncai/resources/techreadylevels):
TRL1: Review of Scientific Knowledge Base
TRL2: Development of Product Hypothesis
TRL3: Identification and Characterization of Product Candidate
TRL4: Optimization and Initial Demonstration of Safety and Efficacy
TRL5: Advanced Characterization of Product and Initiation of Manufacturing
TRL6: Regulated Production, Regulatory Submission, and Clinical data

* = this value is required

TRL7: Scale-up, Initiation of GMP Process Validation, and Phase 2 Clinical Trial(s)
TRL8: Completion of GMP Validation and Consistency Lot Manufacturing, Clinical Trials Ph3, and FDA Approval or Licensure

Proposed project during funding period

- Description of work plan including work packages, milestones and budget (max. 2500 characters incl. spaces) *

Include structured timelines, milestones and key goal objectives that you suggest for the funding period as well as the associated budget. Please note, a milestone is what you want to have accomplished at the end of a work package. A work package is what you do to reach this milestone (often experiments). Please also include potential pitfalls of the project with sufficient risk assessment and criteria to substantiate continuation of the program at each milestone. The completion of these work packages should not exceed **one year**.

Please describe the work plan as follows: Work package 1 incl. time frame, accompanying description and e.g. statistical analysis 1, accompanying milestone 1, accompanying budget 1, work package 2 incl. time frame, accompanying description and statistical analysis 2, accompanying milestone 2, accompanying budget 2 etc.

Please mention No-Go criteria if applicable

- Data robustness and reproducibility strategies (max. 2500 characters incl. spaces) *

For both your current data and future experiments, please describe which facts support the robustness of your data. Please briefly describe your strategies for **reproducibility of your study methods and results during the funding period.** Which risks of bias can you identify. What are your project specific strategies to reduce the risk of bias.

Please describe how you will/have consider/ed sex (cells, animals, humans) and gender (humans) aspects as a biological variable. In case you are planning an animal study, discuss "replacement" and "reduce" among the 3R principles. How large is your (planned) sample size and how has the sample size been calculated? Did/Do you consider effect size estimates, primary and secondary outcome measures and endpoints as well as possible confounders? Provide a short overview how you conduct(ed) your statistical analyses, e.g. "We use(d) a logistics regression analysis with X as dependent and Y as independent variable. We adjust(ed) for confounder Z".

Explain if and how you already published/shared the current data with the (scientific) community. Did you register or preregister your study. Explain when and how you plan to publish your data or/and (pre-)register your study.

After the end of the funding period

- Future development plan (max. 1200 characters incl. spaces) *

If your project is successful, please describe how you intend to proceed after the support by SPARK-BIH. Which additional steps are necessary to reach patients/market and how can they be realized? Is your intention to license IP to biotech or pharma, to apply for follow-on funding for further development, to found a start-up or partner with industry? When do you think patients will benefit from the product/solution (years from now)? Please be as specific as possible.

* = this value is required

III. Budget overview

Budget details

- Total Budget (Consumables Budget) (in EUR) *

You can apply for a maximum of 50.000 EUR. (Please enter only numbers here)

IV. Intellectual Property

Please provide information on existing IP

- Does one or more invention disclosure(s) and/or patent(s) exist? *

Please indicate if one or more invention disclosure(s) and/or patent(s) exist for the technology you are validating in your project.
Select: Yes, No, Currently being prepared, Not patentable

- If no IP currently exists (max. 500 characters incl. spaces)

Please describe the projected plan to generate new IP.

- If you selected 'not patentable (max. 500 characters incl. spaces)

Please indicate how, when and by whom this was judged. For example, if it has been determined by the technology transfer office that patenting is not and will not be feasible or advisable for this technology/area (e.g. in some cases of drug repurposing etc.).

- If you selected 'not patentable' (max. 1500 characters incl. spaces)

Please describe how you plan to nonetheless reach patients/market/commercialization.

- If one or more invention disclosure(s) and/or patent(s) exist

Please list the invention disclosure reference number(s), or the patent number(s) including patent holder, inventors and any relevant details on the IP status.

Invention disclosure reference number(s): (i.e. CH ____/year (at the Charité)

Patent holder (Charité/other public institution/private company or person). Please list all inventors.

Contact with the Technology Transfer Manager

- Please indicate your contact person at the Technology Transfer Office (TTO) of your institution if available

Select from:, Bettina Büttner, Sven Friedl, Stefanie Grunwald, Anette Schröder, , Sigrun Szepanski, Specify your own value.

V. Commercialization

* = this value is required

Commercialization details

- Does the commercialization of your product solution depend on other patents? (max. 500 characters incl. spaces) *

Does the commercialization of your product/solution depend on other patents? If you do not know, please write "I do not know". Please also describe any repurposing option for the project if applicable.

- Target group (max. 1200 characters incl. spaces) *

Description (quantitative and qualitative) of the targeted user and/or patient group or anticipated target/patient group. How large is the user/patient group? If several users/patient groups/indications are possible, describe the rationale for the current choice of user/patient population/indication. If you have not yet decided on a user/patient population/area of application, please outline ways forward on how to identify the most relevant one/s.

- Commercial potential (max. 1200 characters incl. spaces)

Please describe the market size and market niche that your solution will address. Who are the customers of the solution you are creating (e.g. patients, clinicians, hospitals, insurance companies etc. ...)? Who is going to pay for your solution? What is the added benefit for them? If possible, please estimate how many of the total number of patients/users you might be able to reach. If possible, please estimate the revenue that could be created with this solution (in Germany/worldwide).

- Indicate your potential competitors (max. 1000 characters incl. spaces) *

Please describe alternative or similar solutions that are already on the market or are being developed for the problem you address. Who is or might be your competitor? Please note that it is extremely unlikely that no competition exists. Competition can include similar products or completely different solutions targeting the same problem.

VI. Publications

Publications details

- Key publications (optional)

Please list **up to five** key publications that you feel are important to understand the technology that you are describing. These can relate to previous work you have done and results/data you have gathered that justify your proposed next steps, or publications providing background information to the technology. Please do not include any of your previous publications that are unrelated to the project you are describing in this proposal.

VII. Graphics

Supporting graphics

- Upload PDF file (A4, portrait format) *

Please upload relevant graphics and data that help/support the understanding of your proposal and show key results. Add enough text/figure legend to explain your graphics and label them clearly. Any abbreviations used must be explained. Avoid uploading graphics from publications with lots of background data and graphics of insufficient resolution. Make sure the labeling is readable. Rather, choose graphics that help the reviewers understand the technology and your future plans. **Please upload the graphs as one PDF file, A4, portrait format** (**max. four pages, max. file size 10 MB**).

VIII. Confirmations and signature(s)

* = this value is required

Confirmation and signature(s) required before you can submit. Please upload the signature page that can be downloaded from the SPARK website.

- No alternative funding currently exists for the work applied for in this application (Doppelförderungsverbot) *

[Checkbox]
Please confirm that currently no alternative funding for the work applied for exists.

- Confirmation of change notification *

[Checkbox]

Please confirm that if this changes at any point, you will notify the SPARK-BIH management immediately.

- Upload of signature page *

[Checkbox]

Please upload a PDF scan of the signature page (signed legal compliance / confidentiality document) as provided on the SPARK website (max. file size 2MB).

Please note: the information of your application may be communicated to members of BIH, Charité and BIH Innovations involved in the selection process, members of the technology transfer office of your institution, members of QUEST (Quality|Ethics|Open Science|Translation), of Ascenion GmbH as well as external reviewers who have signed a confidentiality agreement.

* = this value is required