

Application Questions Track 1 – for preparation only

SPARK-BIH Call 2024

+++ Track 1 (up to 50.000€) +++

Please note: This is **NOT** an application form. This document only lists questions that will be asked in the BIH application portal if you apply for **Track 1** and is purely meant as a guidance tool for your preparation.

It is mandatory to apply via the BIH application portal, only complete applications received through the portal will be considered. The application must be provided in English. **To apply please submit your Track 1 proposal before the deadline on Monday July 8th, 2024 (14:00 CET). Please [use this link](#).**

Please make sure you meet the Track 1 eligibility criteria as described in the “Guide for Applicants Track 1” ([use this link for Guide Track 1](#)) before applying. Furthermore, please print and sign the signature page provided on the [SPARK website](#) to upload it as a PDF scan during the application process.

GENERAL INFORMATION WHEN WORKING WITH THE APPLICATION PORTAL:

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

- 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 from more than one computer at the same time
- to allow for ample 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 move 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 *

- Applicant Name*
- Applicant Address*
- Applicant City*
- Applicant ZIP/Postal Code*
- Applicant Phone*
- Applicant Mobile Number*
- Applicant Email Address*

- 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)

- Co-applicant Name
- 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

- 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

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

Provide a brief description of the team that will work on this project, and why the team is suitable to pursue this 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.

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 BIH funding, the amount, 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

Project description details

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

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

- Project acronym *

Please choose a 1-word abbreviation for your project.

- Final product *

Please explain in ONE short sentence the main goal of the entire project: The product/service that should reach patient/market (e.g. develop a cell therapy against breast cancer)

- Main project goal *

Please explain in ONE short sentence 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 (SMOLs, biologics), ATMP (e.g. gene therapy, somatic cell-therapy, tissue engineered medicines), Diagnostic, MedTech

- Indication/Area of research *

Please name the indication/area that your solution is addressing (max. of two choices).

Select from the following options: Autoimmunity, Cardiology, Dermatology, Infectious Disease, Metabolism, Methods/Platform, Muscle Disease, Nephrology, Neurology, Ophthalmology, Oncology, Pediatrics, Psychiatry, Radiology, Surgery, 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
- 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

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

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

- **Description of your new solution / intended use statement (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 the final product/solution you envision (e.g. a drug, diagnostic assay, implant...). For medical devices and diagnostics projects, please add the intended use statement. For example: A medical device to be used in X patients in order to XYZ

- **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?

- **Project aim during funding period (max. 2500 characters incl. spaces)**

Please describe 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). Please identify and describe technical and commercial challenges.

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

Please describe how and at what phases of your study relevant stakeholders (e.g. study participants, patient organizations, funding agencies, researchers -including you-, enterprises etc...) are or will be involved and contribute to your project (e.g. have you already involved stakeholders and/or received input from potential users?). Please describe any support received or required by other parties and 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 so far. 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. Descriptions of TRL ranging from TRL₁ through TRL₈ for different categories of research can be found here <https://ncai.nhlbi.nih.gov/ncai/resources/techreadylevels> :

- TRL₁
- TRL₂
- TRL₃

TRL4
TRL5
TRL6
TRL7
TRL8

Proposed project during funding period

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

Please describe the **key goal objectives** that you aim to achieve during the funding period and structure them according to appropriate work packages, including structured **timelines and milestones** and indicate the associated budget. .

Please note, a work package describes the group of related tasks/sequence of activities (often experiments) as smallest unit within the overall project that leads to achieving a milestone (usually a deliverable). A milestone specifies an important stage of the project progress and marks what you want to accomplish within each work package.

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 Go/No-Go criteria in the appropriate section (max. 1500 characters incl. spaces)

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

Please describe what methods and approaches have been used and will be applied for the generation of your data (both past and future experiments) and indicate how they support the robustness of your data. Please add the information that is relevant to your project

1. Have relevant confounding variables and risks of bias been defined? Please name the confounding variables, explain how they were considered and your strategies to reduce the risk of bias.
2. Are sex (cells, animals, humans) and gender (humans) considered as a biological variable in your study? Please describe how you implemented this in your study design.
3. Please explain how you have implemented the 4 Landis Criteria (<https://www.nature.com/articles/nature11556>; a)blinding b)randomization c)inclusion/exclusion criteria d)sample size calculation) in your study design
4. How large is your (planned) sample size and how was the sample size calculated? Was a power calculation conducted (at the level of experimental unit)? Was the effect size defined for the power calculation? Provide a short overview on 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".
5. Please describe which critical control conditions, such as positive and negative controls, were and will be included in your experimental designs.
6. Have primary (and secondary) outcome measures and endpoints been defined (further information: <https://arriveguidelines.org/arrive-guidelines/outcome-measures/6b/explanation>)?
7. Please describe if you have already published/shared the data you included in this application 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. Please keep the '**First patent then publish**' approach in mind and talk to CBI about your project before you publicly disclose any of your data.

After the end of the funding period

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

If your funded project is successful, please briefly 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 reached? Is your intention to license Intellectual Property (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.

III. Budget overview

Budget details

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

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

IV. Commercialization

Commercialization details

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

If you do not know, please write "I do not know". Please also describe any repurposing option for the project if applicable.

- Commercial potential and business strategy (max. 1200 characters incl. spaces) *

Please briefly 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/become 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.

- 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.

V. Publications & Abbreviations

Publications details

- Key publications (optional, max. 500 characters incl. spaces.)

Please list up to five key publications that you think are important to understand the technology/solution 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.

Abbreviations

- Abbreviations *

Please explain all abbreviations used in your application.

VI. 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 one or more invention disclosure(s) and/or patent(s) exist, please add the corresponding Charité invention disclosure reference number(s)

CH ____/year at the Charité (e.g. CH001/2023)

- If one or more patent(s) exist:

Please list the patent number(s) including patent holder (Charité/ other public institution/private company or person), all inventors and any relevant details on the IP status.

Please note that in case an entity other than Charité (partially) holds the patent rights, it is mandatory that you contact the SPARK-BIH team before submitting this application.

- 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.

Contact with the Technology Transfer Manager

- Please indicate the technology transfer manager that you are in contact with for this project at Charité BIH Innovation, the joint technology transfer office of Charité and BIH *

Select from: Bettina Büttner, Sven Friedl, Stefanie Grunwald, Bettina Otto, Anette Schröder, Sigrun Szepanski, Thomas Wallach, no contact yet, Other please specify

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 10MB).

VIII Confirmations and signature(s)

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

- The proposed work in this application is currently NOT funded by alternative funding/sources (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 Charité BIH Innovation involved in the selection process, members of the technology transfer office of your institution, members of QUEST (Quality|Ethics|Open Science|Translation), Ascenion GmbH, as well as external reviewers who have signed a confidentiality agreement.