# Application Questions Track 2 – for preparation only

**SPARK-BIH Call 2024**

# +++ Track 2 (more than 50.000€) +++

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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 2** 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 2 proposal **before the deadline on Monday, July 8th, 2024 (14:00 CET). Please use this link.**

Please make sure you meet the Track 2 eligibility criteria including the ones regarding intellectual property as described in the "Guide for applicants Track 2" ( use this link for Guide Track 2) before applying. In case you do not meet the Track 2 eligibility criteria regarding intellectual property, please consider applying for Track 1. 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 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 move away from the page during this time to avoid losing the added information)
- 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*



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- 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 of SPARK. If applicable, describe any unique infrastructural/facility advantages at your disposal.



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## 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



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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.

- Description of regulatory requirements (max. 1500 characters incl. spaces) *

What are the regulatory requirements that your product/solution/technology needs to meet in order to reach the market? How will you proceed in order to fulfill them? Briefly describe the status of your project related to the regulatory approval process (e.g. preclinical evaluation, meetings with PEI or other regulatory authorities). Are there any plans for a pre-scientific or advisory meeting with PEI or other discussion with regulatory authorities within the funding period? Have you received input from Stabsstelle Regulatorik at BIH or other regulatory support groups at Charite or BIH?

## Current stage of project

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

To qualify for track 2 funding, the proof-of-concept/technology/principle data needs to be achieved prior to your application. Please describe achievements and provide solid, relevant data and evidence supporting the assumption that



* = this value is required

your solution will be successful, and your approach will work .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 TLR8 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 **two years**.

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

- Description of Go/No-Go criteria (max. 1500 characters incl. spaces) *

Please describe Go/No-Go criteria for each work package. Go/No-Go testing refers to a pass/check test principle and is an essential part of drug / product development. Please use Go/No-Go decision criteria that are precise, well-defined and as little as possible subject to interpretation.

- Upload of project timeline *

Please download the "Project Timeline Template" from the SPARK website, fill it out according to the guideline described in the template and upload it as combined PDF with your data package in the "graphics" section.

**Select: Yes, I have uploaded my project timeline in the "Graphics" section**

- 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.



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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 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 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 (in EUR) *

Please enter only numbers here

- Consumables (in EUR) *

Please enter only numbers here

- Personnel Budget (in EUR) *

Please enter only numbers here

- Justification of Personnel funding (if applicable). (Max. 500 characters incl. spaces.)

The funding covers personnel costs if indispensable to reach the suggested milestones and if the respective personnel already has a contract at your institution (i.e. BIH or Charité). **No new contracts can be issued, only so-called "Umsetzungen" are possible**. **Please note: the majority of the position (at least 50% for a full-time position) has to be covered by the existing contract.** Please provide a solid explanation for why personnel is indispensable to reach the suggested milestones.

## IV. Commercialization

### Commercialization details

- 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



* = this value is required

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 and business strategy (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? Please estimate how many of the total number of patients/users you might be able to reach. 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 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.

- 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? Please also describe any repurposing option for the project if applicable.

# 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/solutions 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 (Max. 500 characters incl. spaces.) *

Please explain all abbreviations used in your application.

# VI. Intellectual Property

Please note, eligibility for **Track 2** requires at least a positively evaluated invention disclosure (*positiv bewertete Erfindungsmeldung*), for a complete explanation please refer to Guide for Applicants Track 2. If you do not have a positively evaluated invention disclosure (or your solution has not yet reached the stage at which an invention disclosing is feasible), **you do not qualify for Track 2 (yet). Please consider applying for Track 1 instead.**

## 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



* = this value is required

- 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. 1500 characters incl. spaces)

Please describe why it has been determined by the technology transfer office that patenting is and will not be feasible or advisable for this technology/area (e.g. in some cases of drug repurposing etc.).

Please note: if you simply have not yet reached the stage at which disclosing an invention is feasible, **you do not qualify for Track 2 (yet). Please consider applying for Track 1 instead**.

- 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 and project timeline

- Upload combined PDF file (A4, portrait format)*

Please upload a **combined PDF of your project timeline** (template downloaded from the SPARK website) **as well as 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.**



* = this value is required

- 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 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.



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