SPARK-BIH Information Package

(Last update: March 2025)

Thank you for your interest in the **SPARK Translational Research Program**. Our mission is to advance academic discoveries from the laboratory to patient care. SPARK was created at Stanford University School of Medicine in 2006, to advance academic biomedical research discoveries into promising treatments for patients. Since 2006, SPARK Stanford has supported over 200 projects with advice and funding, resulting in 51 startups (3 are now public companies), 28 licensed IP and 21 investigator-initiated clinical trials. Moreover, hundreds of faculty scientists, postdoctoral scholars, graduate students and medical students have been educated on translation and the concepts of drug development through SPARK's educational program. The weekly meeting at Stanford University routinely brings together 100+ attendees from the Stanford community and outside volunteer advisors from the private sector including industry experts (Kim et al, Nat. Biotechnology, 2024).

The overwhelming success of SPARK Stanford has led to the development of SPARK global, an initiative for the implementation of the SPARK approach at academic institutions worldwide. There are currently over 42 SPARK programs in 21 countries around the globe. SPARK global not only helps as an instrument to replicate the SPARK approach at home institutions, but also allows for exchange of information, advice, mentors and collaboration efforts in clinical trials, and testing of prototypes, among other efforts.

This information package provides general information on SPARK, as well as some frequently asked questions (FAQ). Please contact us with any additional questions that you may have at spark@bih-charite.de.

SPARK-BIH History:

The SPARK program in Berlin was established as the first European SPARK program in 2015 with the support of the Stiftung Charité. Since 2018, we have been part of Charité BIH Innovation (CBI) at the Berlin Institute of Health (BIH) @ Charité.

Berlin Institute of Health´s mission is medical translation with the aim to create impact for patients and society. BIH promotes the transfer of biomedical research findings into clinical application for personalized prediction, prevention, diagnostics and therapy. In parallel, clinical observations are used to develop new research ideas and approaches turning research into health. In addition, BIH is also committed to create a comprehensive translational ecosystem through bundling a variety of competencies and infrastructures in

the vicinity of Charité, placing emphasis on a system-wide understanding of health and disease and that promotes change in the biomedical research culture.

Charité BIH Innovation (CBI) is the joint technology transfer of Charité and BIH and supports scientists and clinicians in the transfer of biomedical research results and inventions into a clinical application. CBI ensures that ideas and inventions not only translate into patents, but that these developments also benefit patients as innovations in the market. CBI is comprised of four teams: IP & Licensing, SPARK-BIH, Digital Labs & Digital Health Accelerator, and Match & Connect.

SPARK-BIH Mission Statement:

At SPARK-BIH we seek to accelerate the translation of academic inventions into clinically relevant therapies, diagnostics and medical devices by offering funding, mentoring and education to:

1) Help academics overcome the obstacles involved in moving their early discoveries from bench to bedside (surviving the "Valley of Death").

2) Educate academic researchers, such as faculty members, postdoctoral fellows and graduate students, on the translational research process and path to clinical application, so that development of promising discoveries becomes second nature to our institution.

3) Promote a translational ecosystem and more cost effective and innovative approaches for the development of novel therapies, including small molecules, vaccines, biologics, gene-and cell therapies, drug-repurposing, diagnostics and medical devices.

What SPARK-BIH Provides:

- Funding

  The SPARK-BIH program offers grants to researchers and clinicians from BIH or Charité via an annual call. Funding is provided for the development of pharmaceuticals/therapeutics (including small molecules, drug repurposing, advanced therapeutic medicinal products (ATMPs), vaccines, biologicals), medical devices, diagnostics and preventives in a milestone-dependent manner. All projects must aim at the transfer of research findings into therapies, products or services to benefit patients and society. The amount of SPARK-BIH funding and the project duration depend on the maturity of the projects.

- Access to specialized knowledge

SPARK's greatest asset is our dedicated group of volunteer advisors, many of whom bring extensive industry experience. Their expertise covers a broad range in areas, including drug development, biologics, ATMP, medical devices, and diagnostics development. Additionally, they offer deep knowledge in high throughput screening, medicinal chemistry, project management, manufacturing, clinical experience and clinical trial design, regulatory affairs, business development, and venture capital.

- Mentorship

  Each team accepted into the SPARK-BIH program is assigned two SPARK-BIH project managers who prepare together with the project team and advisors a detailed work plan with precise milestones, Go/No-Go criteria, as well as a specific budget plan. Project managers meet regularly with the team to identify needs, lower roadblocks, assess progress, provide suggestions and bring in external advice if necessary. Teams present regular progress updates to the whole SPARK-BIH group (SPARK-BIH management team, advisors, and fellow SPARKees), where they receive valuable feedback and advice. In addition, for teams with advanced projects, we create opportunities for pitching their program to investors and support their efforts for funding a start-up.

- Education

  The SPARK-BIH management team meets on a regular basis with all SPARK-BIH project teams. These sessions alternate between project meetings (by invitation only) and public educational/entrepreneurial seminars, lectures and webinars taught by experts in their field. Since 2015, SPARK-BIH has organized more than 145 open events with over 5900 attendees. The educational curriculum includes the development of a Target Product Profile (TPP), information on intellectual property (IP) and regulatory aspects, and pitch training. We also discuss intellectual property early on to ensure that participants understand the importance of a strong patent position to support commercialization efforts. The list of topics discussed annually is included later in this package. In 2020, a Europe-wide Webinar Series on Translation and Entrepreneurship was established, followed by the Innovator's Café in 2021. The latter is an interactive online format to learn from seasoned CEOs and was initiated by SPARK-BIH including all European SPARK sites.

How SPARK-BIH Benefits the Community:

- Our program is designed to enhance institutional knowledge on how to successfully advance an academic discovery or clinical observation into the clinic, a marketable product or a licensing deal by:
    - Scouting activities to identify and develop early-stage transfer projects
    - Identifying and removing roadblocks to translation
    - Increasing access to high quality advice
    - Training researchers and clinicians to become skilled in translational development
    - Instilling translational efforts and entrepreneurship as "second nature" within the research community
    - Fostering a transfer-oriented mindset and strengthening the innovation ecosystem
- SPARK programs are expected to increase the number of investigator-initiated clinical trials.
- Because of the rigor and industry knowledge applied to SPARK projects, teams supported by SPARK have a significantly higher success rate in receiving follow-on grants.
- Participating in SPARK has been reported to enhance the ability of graduate students and postdoctoral fellows to find jobs in industry.

SPARK-BIH Advisors:

External advisors play a crucial role in the success of the SPARK-BIH program. To safeguard newly generated intellectual property, all advisors sign confidentiality agreements to make sure that what is discussed during SPARK meetings remains undisclosed.

At SPARK-BIH, we carefully identify and select suitable advisors who are willing to donate their time and expertise to our program. We seek professionals with the following backgrounds:

- Pharmaceutical and biotech companies, including CROs
- International investment community, ideally with experience in early-stage life science investments
- University network with entrepreneurship or life science experience
- Recent retired professionals from pharma or investing community who

Potential advisors are then invited to meet with the SPARK-BIH program directors before they can attend a SPARK-BIH session. This helps to better understand an advisor's background and areas of expertise, their motivation for participating in SPARK, and a general sense for whether the advisor can adapt their expectations and suggestions to the academic environment. This also can help us to detect any possible conflict of interest between the possible advisor and the SPARK-BIH community.

This process ensures that SPARK-BIH benefits from high-quality, well-aligned advisory support while maintaining a collaborative and secure environment.

SPARK-BIH Successes:

Since 2015, SPARK-BIH has funded over 85 projects. Eight projects have started clinical trials including compassionate use, non-interventional trials, as well as performance evaluation studies. 45 Patent families have been filed, 10 startups have been founded and 10 teams are planning to found a company in the next couple of years.

More Information:

For more information about the SPARK-BIH program, please refer to our website and consider the following publications:
"A Practical Guide to Drug Development in Academia: The SPARK Approach" (SpringerBriefs in Pharmaceutical Science & Drug Development) by Daria Mochly-Rosen and Kevin Grimes, second edition 2023
And SPARKing academic technologies across the valley of death published in Nature Biotechnology, 2024.

Frequently Asked Questions (FAQs):

The following list of questions may help in the understanding of the SPARK method and the SPARK-BIH program.

Why should academic institutions participate in translational research?

There are several compelling arguments for basic science researchers to be interested in translational work:

1. Social responsibility: A significant portion of funding for basic science research comes from public sources. Hence, if translational opportunities evolve it makes sense that researchers use their discoveries to improve public health and give back to society.
2. Foster a culture of innovation: In general, academics are risk-takers and are not afraid to embark on moonshot research questions that potentially have high impact. In contrast, industry tends to be more risk-averse, as companies have to

prioritize investor interests. Given the escalating costs and timelines associated with therapy and product development, academia plays a critical role in driving innovation and addressing unmet medical needs.

3. Champion the science: Even the most promising therapies require dedicated advocates to promote their development across the challenging path from discovery to application—a journey often referred to as the "Valley of Death", described by Elias Zerhouni, former director of the National Institutes of Health (NIH): "*If researchers don't champion their own discoveries, who will?*"

Why do academic researchers want to participate in SPARK?

Your science can make the difference:

Surveys of SPARK participants reveal that the most frequently cited benefit of SPARK is access to an expert advisor network. Many participants also report that SPARK funding has been crucial to keep their projects moving towards the next value point; highlighting the funding gap for experiments in the so-called "Valley of Death." Additionally, SPARK serves as a bridge between projects and potential investors while facilitating the addition of new team members. Overall, SPARK plays a vital role in reducing the barriers of translational research and accelerating the path from discovery to application for the benefit of patients and society

Has the view of researchers about SPARK participation changed over time?

While funding may have been the initial incentive for participants for joining SPARK, access to education, hands-on experience, and expert advice has increasingly become the primary motivation and most valuable benefit of participating in the SPARK program.

Does SPARK track licensing terms and patents issued?

The IP&L team of Charité BIH innovation, the joint technology transfer office (TTO) of Charité and BIH negotiates all licenses and decides what patents to file. SPARK-BIH does not receive any fraction of royalties generated from SPARK-supported teams.

At what stage of development does SPARK accept projects?

SPARK has a range of projects at different levels of development, from exciting new targets with some validated biology that need more screening effort to identify a hit compound, to repurposing programs that are poised to enter the clinic. SPARK-BIH also accepts projects for biologics, vaccines, new chemical entities, gene and cell therapy (ATMP), diagnostics, medical devices, technologies, as well as repurposing projects. Projects can be from all medical fields.

Why focus on unmet medical needs?

SPARK is driven to address unmet medical needs to create patient and societal benefit, not to generate money. As such, the potential market earnings for a project are not the major factor for the project selection.

How many advisors does SPARK have?

SPARK Stanford now has over 150 advisors, ~30 who attend any given SPARK session, but they started with only 5 advisors. SPARK-BIH also started with a few advisors and is adding advisors continuously as the program matures and currently has over 50 active advisors.

Does SPARK-BIH market its projects?

The IP and licensing team (IP&L) of Charité BIH Innovation together with their service provider Ascenion GmbH is supporting marketing projects and patents. SPARK-BIH might support this activity via its network in agreement with the project leaders and colleagues from the IP&L team. We do, however, create opportunities for SPARKees to pitch their project to investors and support efforts for funding a start-up or licensing.

What fraction of SPARK projects result in startups vs. are licensed by existing companies?

SPARK Stanford has to date supported nearly 110 projects with advice and funding, which has led to 30 startups, 48 licensed IP and 25 clinical trials.
At SPARK-BIH most patents generated and enabled through SPARK support are offered for licensing. Since 2015, SPARK projects resulted in 45 filed patents, founding of 10 startups and other 10 teams are planning to found a startup.

Does SPARK have an investment fund to further incubate its start-up companies?

Not at the moment.

How does SPARK handle collaborations with industry?

The IP and licensing team of CBI together with their service provider Ascenion GmbH establishes initial contacts with pharma, biotech or Venture Capital (VC) groups to match SPARK projects to potential licensees. In close exchange with their colleagues, SPARK-BIH supports and helps with these activities. SPARK-initiated discussions are always done as an initial contact without full disclosure of the project.

Do any big pharma companies help fund SPARK-BIH?

No, SPARK-BIH does not receive industry funding to support the SPARK program or fund certain teams.

SPARK Seminar Topics:

Regular SPARK-BIH sessions offered to funded teams include project updates and educational seminars taught by experts in their field. The annual curriculum may be adapted according to the needs of the SPARK-BIH community. Examples of topics addressed are outlined below.

- SPARK introduction/ welcome seminar
- Target Product Profile
- Intellectual property and introduction of CBI
- Drug development
- Diagnostics/ device development
- Reproducibility of research and ethics
- High throughput screening and medicinal chemistry
- Lead optimization and pharmacophore modelling Clinical trial design
- Regulatory considerations
- Pharmacokinetics and preclinical pharmacology
- Drug repurposing
- Market analysis/ How to structure a VC pitch
- Legal aspects of founding and venture capital
- How to raise money
- Partnering and funding
- Value assessment
- Business model development
- Women in leadership
- Pitching