



## SPARK-BIH Information Packet

*(Last update: May 2022)*

**T**hank 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. After more than 15 selection cycles, [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. Moreover, hundreds of faculty, 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.

The overwhelming success of SPARK Stanford has led to the development of [SPARK global](#), an initiative for implementation of the SPARK approach at academic institutions worldwide. There are currently 60 newly established SPARK programs 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 etc.

This information packet provides general information on SPARK, as well as some frequently asked questions (FAQ). Please contact us with any additional questions that you may have.

### SPARK-BIH Mission Statement:

SPARK was established as the first European SPARK program in 2015 in Berlin with the support of the [Stiftung Charité](#). Since 2018, we are part of Charité [BIH Innovation](#) at the [Berlin Institute of Health @ Charité](#).

The mission of SPARK-BIH is:

- 1) To help academics overcome the obstacles involved in moving their early discoveries from bench to bedside.
- 2) To educate faculty, 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) To develop more cost effective and innovative approaches to drug-, diagnostic and medtech-development.

## What SPARK Provides:

- Access to specialized knowledge

SPARK's greatest asset is our dedicated group of volunteer advisors. The experience of our industry experts spans the range of drug, device and diagnostics development: high throughput screening, medicinal chemistry, project management, manufacturing, clinical experience and clinical trial design, regulatory, business development, and investing.

- Mentorship

Each team accepted into the SPARK program is assigned a project manager who creates 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, make suggestions and bring in external advice. Teams present regular progress updates to the whole SPARK group (SPARK management, advisors, and fellow SPARKees), where they receive valuable feedback and advice, in addition to opportunities of pitching their program to investors.

- Education

SPARK-BIH meets on a regular basis with all SPARK teams. These sessions alternate between project meetings (by invitation only) and public educational/entrepreneurial seminars taught by experts in their field. Between 2015 and 2021, SPARK-BIH has organized more than 100 open events with ~1.500 participants in total. The educational curriculum contains an introduction to the drug development process, and has the new teams prepare a Target Product Profile. 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 packet. In 2020, a Europe-wide Webinar Series on Translation and Entrepreneurship has been established and in 2021 with the Innovator's Café a new interactive online format to learn from seasoned CEOs was set up by SPARK-BIH including all European SPARK sites.

- Funding

The SPARK-BIH program offers grants to researchers and clinicians from the BIH or Charité for the development of novel therapeutics (small molecule, biologic or cell/gene therapy (ATMP)), medical devices and diagnostics for unmet medical needs, as well as repurposing of existing drugs for new indications in a milestone-dependent manner. All projects must aim at the transfer of research findings into therapies, products or services. The amount of SPARK-BIH funding and the project duration depend on the maturity of the projects.

## How SPARK Benefits the Community:

- Our program is designed to increase the institutional memory for how to successfully advance a basic science discovery or clinical observation to a clinical testing, a marketable product or a licensing deal by:
  - Scouting activities to identify and develop early transfer projects
  - Identifying and removing road blocks to translation
  - Increasing access to high quality advice
  - Training development savvy researchers and clinicians
  - Instilling translational efforts as “second nature” within the research community
- Participating in SPARK has been reported to enhance the ability of Graduate Students and Postdoctoral Fellows to find jobs in industry.
- 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.

## SPARK Advisors:

The advisors of SPARK are critical to the success of the SPARK program. They have all signed confidentiality agreements to make sure that what is discussed at SPARK remains undisclosed, and the newly generated intellectual property is assigned to the appropriate inventor and institution.

We at SPARK-BIH, look in the following areas to find advisors who donate their time to our program:

- Local pharmaceutical and biotech companies (including CROs)
- International investment community (better if they have experience in early life science investment)
- University network (entrepreneurship or life science experience)
- Recent retirees from pharma or investing community who now live in the area

Potential advisors are then invited to meet with the SPARK program directors, before they attend a SPARK session, to better understand an advisor’s background and areas of expertise, their motivation

to participate in SPARK, and a general sense for whether the advisor can adapt their expectations and suggestions to the academic environment.

### SPARK-BIH Successes:

Since 2015, SPARK-BIH has funded 56 projects, 30 projects have graduated from the program up until now.

Three projects have started a Phase-I clinical trial including compassionate use non-interventional trials as well as performance evaluation studies. 20 patent families have been filed, three startups have been founded and 5 teams are planning to found a company in 2022.

### More Information:

For more information on the SPARK program, please have a look at our [website](#) and consider the [following publication](#):

"A Practical Guide to Drug Development in Academia: The SPARK Approach" (SpringerBriefs in Pharmaceutical Science & Drug Development) by Daria Mochly-Rosen and Kevin Grimes.

### Frequently Asked Questions (FAQs):

The following list of questions may help in the understanding of the SPARK process.

#### **Why should academic institutions participate in drug development?**

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

1. Social obligation: Much of the money to fund basic science research comes from public funds, so it makes sense for researchers to try to help their discoveries improve public health if translational opportunities exist.
2. Foster culture of innovation: Academics are risk takers in that are not afraid to embark on big high-risk research questions if they have potential for a high impact. Industry tends to be more risk averse, as corporate heads have investors to please. Given the escalating costs and timelines associated with drug development, the field needs more innovative people tackling challenges in order to meet medical needs.
3. Champion the science: Even promising therapies need champions to promote their development across the "Valley of Death" described by Elias Zerhouni, former director of the National Institutes of Health. "If not you, then who?"

#### **Why do academic researchers want to participate in SPARK?**

In surveys of SPARK participants, the most cited benefit of SPARK is access to the expert advisors. Many participants also report that SPARK funding was critical to keep the project moving towards the next value point; highlighting the gap in available funding for experiments in this "Valley of Death." SPARK can also act as a matchmaker between projects and interested investors and support

the addition of new team members. Overall, SPARK's efforts help reduce the barriers to translational research.

### **Meeting in person is inconvenient. Can I do teleconferences?**

While geographical spread may force some virtual meetings, in-person meetings are very important. Advisors are more invested when they can look researchers in the eye and see the excitement. The informal networking before and after SPARK meetings helps build the sense of community and has resulted in multiple collaborations between SPARK scholars. In-person meetings hold everyone accountable and engaged — if a researcher hears a great presentation from another team, they are driven to make their own presentation just as impressive. The same goes for advisors — everyone wants to make the great suggestion that gets the team over the next hurdle. During the recent Covid pandemic we have also made good experiences with online formats and will keep offering those in cases where in-person meetings are difficult to schedule.

### **Have researchers' views on SPARK participation changed over time?**

Although, the funding may initially have drawn participants to SPARK, the access to education, experience and advice has grown to be the biggest motivations for participation in SPARK. Please find testimonials of our SPARKees [here](#).

### **Does SPARK track licensing terms and patents issued?**

The technology transfer office (TTO) negotiates all licenses and decides what patents to file, hence, SPARK does not track royalty revenues or patents filed as metrics of our success. SPARK also does not receive any fraction of royalties generated from SPARK-supported teams.

### **At what stage does SPARK take projects in?**

SPARK has a range of projects in each class, from exciting new targets with some validated biology that need a screening effort to identify a hit compound, to repurposing programs that are poised to enter the clinic. SPARK-BIH also accepts projects for biologics, new chemical entities, cell/gene therapy (ATMP), diagnostics, medical devices as well as repurposing projects. Projects can come from all medical fields.

### **Why focus on unmet medical needs?**

SPARK is driven to address unmet medical needs, not to generate money. As such, the potential market earnings for a project do not factor heavily into project selection. Also, we feel the best way to utilize the innovation occurring in academia is to focus on novel approaches to treat disease.

### **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 has also started with few advisors and is adding advisors continuously as the program matures. At the moment, SPARK-BIH has over 56 active advisors.

### **Does SPARK market its projects?**

The patents and licensing team of Charité BIH Innovation is marketing projects/patents. SPARK-BIH might support this activity via its network in agreement with the project leaders and colleagues from the patents and licensing team.

### **What fraction of SPARK projects form 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 filed 41 patents, 10 teams have founded or plan 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 patents and licensing team of CBI will speak with contacts at pharma, biotech or Venture Capital (VC) groups to try to match SPARK projects to potential licensees. In close exchange with their colleagues, SPARK supports and helps with these activities. SPARK-initiated discussions are always done as an initial contact without project full disclosure.

### **Do any big pharma companies help fund SPARK?**

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

### **SPARK Seminar Topics:**

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

- SPARK introduction/ welcome seminar
- 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
- ATMP (Advanced Therapeutic Medicinal Products)
- Business model development
- Women in leadership
- Pitching