



SPARK-BIH Information Packet

Thank you for your interest in the SPARK Translational Research Program. SPARK began at Stanford University School of Medicine in 2006 (<http://sparkmed.stanford.edu/>). After more than ten selection cycles, SPARK Stanford has to date supported nearly 130 projects with advice and funding, which has led to 25 startups, 10 licensing and 30 clinical trials. Moreover, hundreds of faculty, postdoctoral scholars, graduate students and medical students have been educated on the science and concepts of drug development through SPARK's educational program. The weekly meeting at Stanford University routinely brings together 80+ attendees from the Stanford community and outside volunteer advisors from the private sector.

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 ~ 40 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 and collaboration efforts in clinical trials and testing 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-BIH was created in 2015 to support the academic efforts of translating discoveries into therapeutics, medical devices, diagnostics and digital health products that address unmet medical needs.

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 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, diagnostics and digital health 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 meets regularly with the team to identify needs, lower roadblocks, assess progress and make suggestions. Teams also 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 Tuesday evenings from 5:00 - 7:00pm. These sessions alternate between project meetings and public educational/entrepreneurial seminars taught by SPARK experts in their field. 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.
- Funding

SPARK-BIH funding is integrated within the Berlin Health Innovations Validation fund

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 clinical testing or a licensing event by:
 - Identifying and removing stumbling 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 projects 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 or assignee.

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)
- Local investment community (better if they have experience in 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.

More Information:

For more information on the SPARK, 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 they 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 acts as a matchmaker between projects and interested investors. 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.

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 as the program matures.

Does SPARK track licensing terms and patents issued?

Because the technology transfer office (TTO) negotiates all licenses and decides what patents to file, 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 programs.

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](#).

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, diagnostics, medical devices and digital health.

Why focus on unmet medical need? Wouldn't second in class be commercially viable?

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 does SPARK handle collaborations with industry?

SPARK will often speak with contacts at pharma, biotech or Venture Capital (VC) groups to try to match SPARK projects to potential licensees. These 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.

What fraction of SPARK Stanford projects form startups vs. licensed by existing companies?

Of the 20 projects currently licensed, 9 were to established companies, and the other 11 were to primary investigator (PI) startups.

Does SPARK market it's projects?

Yes, but only with the consent of the team leader. SPARK-BIH will maintain a list of non-confidential two--line summaries for all unlicensed projects, which we share with interested potential licensees. When a project has reached a new value point, we will also schedule phone calls with venture capital groups and pharma partners to promote the technology.

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

Not at the moment.

SPARK Seminar Topics:

Evening SPARK-BIH sessions alternate between educational seminars taught by experts in their field (1 -- 2 presentations/night) and project updates (2 teams/night). 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 Working with Tech Transfer Office
- Drug Development
- Diagnostics/ device development
- Software commercialization
- Reproducibility of Research and Ethics
- High Throughput Screening and Medicinal Chemistry
- Lead optimization and pharmacophore modelling
- Clinical Trial Design
- Selection of Animal Models
- Regulatory considerations
- Pharmacokinetics and preclinical pharmacology
- Drug repurposing
- Market analysis/ How to structure a VC pitch
- Legal aspects of founding and venture capital
- Partnering and funding
- Value assessment
- Bootstrapping and lean approaches
- ATMP (Advanced Therapeutic Medicinal Products)
- Business model development
- Women in leadership and pitching