September 30th 2025

SPARK-BIH
10th Anniversary:
Presenting Teams



SPARK-BIH

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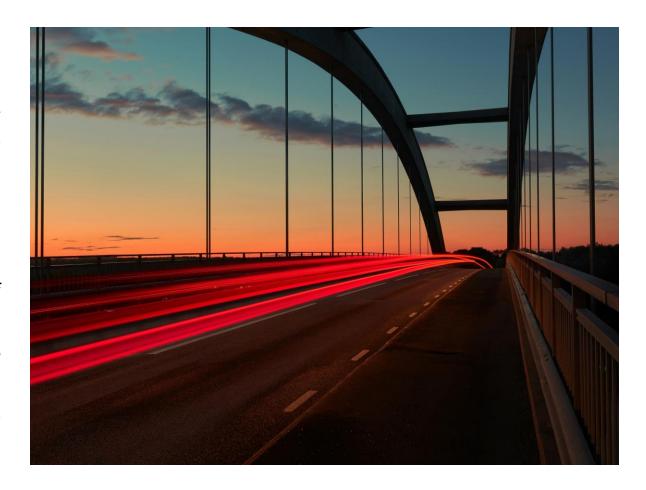
SPARK-BIH Overview

SPARK-BIH: Bridging Biomedical Research and Clinical Application

At the core of biomedical research lies the challenge and necessity of translating scientific discoveries into clinical applications. This process, known as "Medical Transfer", is crucial for transforming innovative research into meaningful benefits for patients, society, and the economy. However, only a small fraction of biomedical discoveries is developed into new products, often due to a lack of funding, expertise, or a transfer-oriented mindset among academic researchers.

The Mission of SPARK-BIH

At SPARK-BIH, our mission is to accelerate the translation of academic research into clinically relevant therapies, diagnostics, and medical devices, addressing unmet medical needs. In order to achieve this, we support researchers and clinicians with milestone-based funding, mentoring and education, fostering a collaborative and supportive environment. Our aim is to turn innovative ideas into impactful solutions that benefit patients and society.



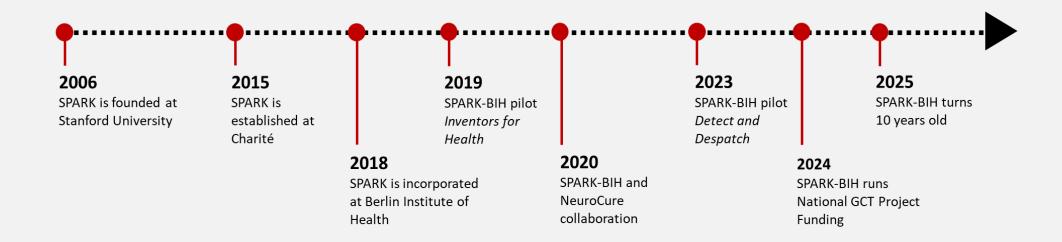
Our Journey

Founded in 2006 at **Stanford University**, SPARK has evolved into a global network comprising over 60 participating institutions worldwide.

SPARK-BIH was established in Berlin in 2015 by Prof. Dr. Craig Garner and Prof. Dr. Ulrich Dirnagl, with the support of **Stiftung Charité**. In 2018, the program became an integral part of the **Berlin Institute of Health** (BIH), which is focused on medical translation. In 2021, the BIH was integrated into the **Charité** - **Universitätsmedizin Berlin**, the joint medical faculty of Freie Universität Berlin and Humboldt-Universität zu Berlin and one of Europe's largest university hospitals.

Today, SPARK-BIH is part of **Charité BIH Innovation** (CBI), the joint technology transfer of BIH and Charité.

Furthermore, SPARK-BIH has established a long-term collaboration with **NeuroCure**, has developed two programs to promote early innovation and, as part of BIH, runs the project funding within the National Strategy for Gene- and Cell-Based Therapies (GCT).



SPARK-BIH and NeuroCure collaboration

In 2020, **NeuroCure** and **SPARK-BIH** joined forces. NeuroCure, a Cluster of Excellence in the neurosciences at Charité, with additional participating institutions. It is dedicated to exploring and understanding the mechanisms of central nervous system diseases to develop novel therapies for neurological and psychiatric disorders.

Through this collaboration, SPARK-BIH supports innovative neuroscience projects and teams, extending its network to include researchers beyond Charité.

Selected teams receive funding from NeuroCure, along with mentoring, education and support from the SPARK-BIH team.

Following the successful implementation of the joint SPARK-BIH/NeuroCure program, the collaboration has been renewed for a third term, with a new call for proposal planned for 2026.



SPARK-BIH supporting early innovation

SPARK-BIH is dedicated to fostering innovation and cultivating an inventive mindset within the BIH / Charité community. In 2019, we launched the "Inventors for Health" (I4H) program to stimulate breakthrough medical innovations and support a new generation of inventors. Through hands-on workshops, such as medical design thinking bootcamps, 10 teams participated, with 6 receiving extended support over 12 to 18 months to further develop their ideas.

Building on the success of I4H, we introduced the "Detect and Dispatch" program in 2023. This initiative connects early-stage innovators with multifaceted scouting activities, educational workshops, and mentoring, supporting them on the initial steps of the translational pathway.

Both programs were made possible through grants from **Stiftung Charité**.





SPARK concept rolls out in Germany in the context of Gene and Cell Therapy

In March 2023, the Federal Ministry for Research, Technology, and Space (BMFTR, formerly BMBF) commissioned the Berlin Institute of Health (BIH) to coordinate the National Strategy for Gene- and Cell-Based Therapies (GCT). The Strategy was developed in a multi-stakeholder approach involving more than 150 experts from science, economy, politics, society, and patients.

It aims to develop safe and effective therapies and diagnostics for severe, currently incurable diseases, enhance collaboration across Germany's strong research landscape, and accelerate the translation of research findings into clinical application. At the same time, it seeks to strengthen Germany's international competitiveness in the field of gene and cell therapies (GCT). One aspect of the National GCT Strategy is Project Funding.

BIH decided to use the SPARK concept — so far established locally for Charité-centric projects — and expand it to a nationwide program in the field of gene- and cell-based therapies as well as associated diagnostics. This decision was driven by SPARK's ability to provide not only financial support but also a wide range of non-monetary services essential for strengthening the gene and cell therapy ecosystem in Germany. Currently, 36 projects from across Germany are participating in the program, benefiting from financial support as well as mentorship, and educational opportunities from GCT experts.

For more details on this program click here or visit this website.















GCT

National Strategy
Gene- and Cell-Based Therapies
Project Funding

Empowering Researchers and Clinicians

The program offers comprehensive support to researchers and clinicians, including **milestone-based funding**, individualized **mentoring**, and access to a broad **network of experts** from industry and academia.



To further cultivate a transfer-oriented mindset, SPARK-BIH offers a diverse range of **educational opportunities**, such as webinars, interactive workshops, and pitch training sessions.



The SPARK-BIH Selection Process

SPARK-BIH invites researchers and clinicians to submit innovative projects for potential funding through an annual call for proposals. A panel of external experts evaluates each submission based on the level of innovation, significance of the unmet medical need, competitive advantage over existing solutions, data quality, and the likelihood of translational success.

The program funding in two tracks:

- Track 1 supports early-stage projects with up to €50,000 for one year.
- Track 2 funds more advanced projects with over €50,000 for two years.

All funding is **milestone-based**, with close monitoring and tailored support from the SPARK team to ensure progress and effective resource use, accelerating the translation of biomedical research into clinical applications.

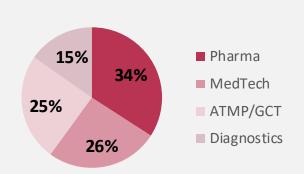


SPARK-BIH in Numbers

Projects

85 Funded Projects

26 Projects in the Program



Progress

402 Applications received

45 Patent families

> **53 Mio €** follow-on funding

Spin-offs



Cancer Therapy
Platform



Gene therapy for Epilepsy



Predicting surgical complications



Pre-tied surgical knot



Telemedicine platform for rare diseases



Muscle Stem Cell Therapy



Assessing circadian rhythm

Software for clinical

documentation



Image retrieval tool

BODYCLOCK

Diagnosis internal

clock



KernEvo

Cell-stabilization diagnostic platform



Dr. Tanja RosenmundDirector SPARK-BIH



Prof. Craig GarnerFounder SPARK-BIH



Dr. Anabel Molero MilanProject Manager



Dr. Alexander StumpfProject Manager



Dr. Luisa A. Hasam HendersonProject Manager



Dr. Sascha CordingProject Manager



Rosa MontserratAssistant to SPARK-BIH Team



Katharina Clausnitzer Assistant to SPARK-BIH Team



Dr. Tanja RosenmundDirector SPARK-BIH



Dr. César Cordero Gómez Project Manager



Dr. Josephine KemnaProject Manager



Dr. Marialucia Massaro Project Manager



Dr. Sharesta KhoenkhoenProject Manager



Dr. Stefan Köster Project Manager

SPARK-BIH Projects

Lightning Talks

EpiBlok Therapeutics: Gene therapy for the treatment of drugrefractory focal epilepsy



PRINCIPAL INVESTIGATORS: **Prof. Dr. Regine Heilbronn, Prof. Dr. Christoph Schwarzer**Charité & Medizinische Universität Innsbruck



SUMMARY

The project aims at developing a gene therapy for the treatment of drug-refractory focal epilepsy. An adenoassociated viral (AAV) vector will be delivered to the epileptic focus, re-expressing a neuropeptide that will be released in an activity-dependent manner, i.e. in periods of high neuronal activity which precedes the onset of a seizure. Suppression of neuronal excitability thereby suppresses the epileptic event. Strong proof of concept data in mice and rats have supported the feasibility of this strategy. The team has set up a spinoff and acquired follow-up funding to further pursue the strategy and develop the gene therapy for the use in patients.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Patents filed in 2016
- Preclinical Proof-of-Concept in vivo and human brain tissue ex vivo in 2016
- Secured GoBio funding of 3.9 Mio. € in 2018 for 3 years
- Science4Life Venture Cup 2021
- GMP production in preparation
- Stpin-off EpiBlok Therapeutics founded in 2022

LONG-TERM GOALS

Clinical trial phase I



MyoPax: Developing cell and gene therapies for muscle disorders

PRINCIPAL INVESTIGATORS: **Dr. Verena Schöwel-Wolf, Dr. Andreas Marg, Prof. Dr. Simone Spuler** MDC & Charité



SUMMARY

Muscle wasting and weakness are leading symptoms of a wide variety of diseases. Major loss of muscle function decreases quality of life and can lead to premature death. Muscle diseases are currently untreatable. In Europe, over 6 million people are affected. The team MyoPax develops an innovative autologous muscle stem cell therapy to treat muscle wasting. The team's technological innovation enables highly standardized manufacturing of pure, native and highly regenerative muscle stem cells from small human muscle tissue to treat acquired and inherited muscle diseases. The team has acquired follow-up funding and has set up a spin-off company to clinically pursue the development of their approach to fight muscle diseases.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Preclinical Proof-of-Concept and preclinical safety
- PEI scientific advice meetings
- Planning of phase I/IIa clinical trial
- Follow-on funding acquired
- Spin-off MyoPax founded in 2022
- Participation in BioInnovation Institute in Copenhagen

LONG-TERM GOALS

 To develop muscle regeneration therapies that restore muscle function

Esostem155: Clinical-grade manufacturing of NY-ESO-1 TCR-modified stem-like T cells overexpressing the pre-miR-155 SNP, rs377265631



PRINCIPAL INVESTIGATOR and project partner(s): **Dr. Dr. Roland Schelker, Prof. Dr. Wolfgang Herr, Prof. Dr. Luca Gattinoni, Prof. Dr. Simone Thomas, Prof. Dr. Matthias Edinger**University Hospital Regensburg & Leibniz Institute for Immunotherapy



SUMMARY

This project focuses on generating stem-like T cells (T_{SCM}) from naive CD8⁺ T cells of patients and equipping them with a NY-ESO-1 TCR and an immunostimulatory microRNA, the miR-155 SNP rs377265631. These T cells are expected to trigger an enhanced and sustained antitumor response in patients with metastatic sarcoma. The project marks an important step towards clinical application and could significantly improve treatment outcomes for patients in the long term.

PROJECT GOALS

- Develop large-scale manufacturing process
- Develop comprehensive quality control tests to ensure that the product meets the required clinical standard

LONG-TERM GOALS

Prepare for Phase I trial

FrontEar: Clinical Translation of Optogenetic Gene Therapy for Hearing Restoration



PRINCIPLE INVESTIGATOR: **Prof. Dr. med. Tobias Moser**University Medical Center Göttingen



SUMMARY

FrontEar aims to translate pioneering research on optogenetic cochlear implant systems (OCIS) into clinical application to restore hearing in people with severe hearing loss or deafness. By combining optogenetic gene therapy with an optical cochlear implant, OCIS promises more natural hearing and improved speech understanding compared to current electrical implants. FrontEar will ensure clinical trial readiness through GMPcompliant manufacturing and completion of preclinical toxicity and efficacy studies.

PROJECT GOALS

- Establishing GMP-compliant manufacturing process
- Evaluate safety through regulatorycompliant preclinical studies

LONG-TERM GOALS

 Advancing optogenetic gene therapy towards pivotal trials, in combination with the oCI

Track 1

CureMILS: Sildenafil - from a blockbuster to an orphan drug



PRINCIPLE INVESTIGATORS:

Prof. Dr. Markus Schülke-Gerstenfeld Charité **Prof. Dr. Alessandro Prigione** University Düsseldorf



SUMMARY

The team has developed a novel assay system based on patient-derived induced pluripotent stem cells (iPSCs) to identify compounds for treating Leigh syndrome. Using this assay, a class of drugs applicable for repurposing that restore the cellular disease phenotype has been identified. The team has initiated a compassionate use treatment for a terminal ill patient using Sildenafil. The patient has recovered significantly. Based on these results a clinical study is planned. Leigh syndrome is a rare severe mitochondrial disease affecting children where treatment options are lacking.

PROJECT GOALS

- Identified and validated compound class for treatment of Leigh syndrome
- Performed compassionate treatment
- Plan to prepare phase 1/2 orphan drug repurposing trial

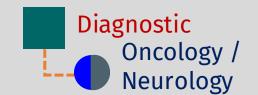
- Run a multicentric clinical study
- Approval of Sildenafil to treat MILS under the orphan drug designation in 2024

NeuroCalm: Chemotherapy, Adverse effects, Lithium, and Biomarkers



PRINCIPLE INVESTIGATORS:

Prof. Dr. Matthias Endres, PD Dr. Petra Hühnchen, PD Dr. Wolfgang Böhmerle, Charité



SUMMARY

Neuropathies are among the most common side effects of cytotoxic chemotherapy. These impairments affect the quality of life and represent a dose-limiting factor for treatment of cancer patients.

This team has discovered that neuronal damage can be reduced by coadministration of a marketed drug and initiated a phase II clinical trial to prove this effect. In addition, the team has identified potential prognostic biomarkers that will enable prediction of chemotherapy induced polyneuropathies and might prevent neurotoxicity by preselecting patients at risk.

PROJECT GOALS

- Initiate and complete clinical trial
- Identify and validate biomarker profiles
- Patent submission (biomarker)

- Establish co-administration as standard of care
- Clinical validation of biomarker set
- License to Biotech or spin-off foundation

SPARK-BIH Projects

Showcase

FiXatas: Ready-to use surgical knots



PRINCIPAL INVESTIGATOR: **Dr. Panagiotis Fikatas** Charité



TRACK 2

SUMMARY

In the project a device and method for the generation of extra corporally pre-tied surgical knots has been developed. The device consists of a yarn carrier with a pre-tied but still open knot ready to use during surgery. It is easy to use even by non-surgeons without special training. Knots produced are stronger and more stable than other sliding knots and tying is faster. Potential user groups have been extended. The first use will be in endoscopic surgery where tying knots is very challenging due to limitations in space and the visual field. Several patents and designs have been filed. The team has founded a spin-off and achieved CE certification for their product.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Patent granted in 2018
- Project developed from invention to marketable product
- Winner of the Ethicon Future Award 2016
- 3rd Place of PROFUND "Research to Market Challenge 2017", 2nd Place at BPW 2018 contest, 2nd Place at YES! Delft Pitching 2019
- Spin-off Clouz founded in 2019
- CE certification for OneKnot

GrOwnValve: Anchoring mechanism for a personalized, autologous heart valve



PRINCIPAL INVESTIGATOR: **PD Dr. Boris Schmitt** Charité



SUMMARY

The aim of the project is the production and testing of an anchoring mechanism of a personalized, autologous heart valve for children enabling growth in a once-in-a-lifetime point-of-care minimally invasive implantation. The novel anchoring mechanism facilitates placement of the valve without hindering growth of valve and vessel. For babies born with a congenital heart valve defect there is no dedicated child valve on the market. Instead, they often receive animal valves which degrade over the following years urging for risky open-heart re-surgery.

PROJECT GOALS

- Perform preclinical testing of anchoring mechanism together with the valve
- Prepare phase II clinical trial in children

LONG-TERM GOALS

- Perform phase II clinical trial in children
- CE certification as a medical device

PREVIOUS SPARK FUNDING

I4H 2019

NEMATIS: Neural mapping using transcranial magnetic temporal interference stimulation







PRINCIPAL INVESTIGATORS: Khaled Nasr, Prof. Dr. Surjo Soekadar, Prof. Dr. Andreas Heinz Charité



SUMMARY

Deep brain stimulation has provided dramatic benefit for a variety of clinical conditions. However, current noninvasive

technology allows only superficial stimulation of the brain. The only possible ways of reaching deeper brain regions require invasive approaches.

This project aims at developing a medical device that enables non-invasive stimulation of deep brain areas at millimeter precision to enable the treatment of neurological and psychiatric disorders such as depression or OCD.

PROJECT GOALS

- Develop and build prototype
- *In vivo* testing
- Preparation for CE certification

- Phase I clinical study
- Implementation of the solution in the clinical workflow by licensing to Medtech company or spinoff foundation

Osseolith: Fillable hybrid scaffolds for the treatment of critically-sized bone defects







PRINCIPAL INVESTIGATORS: Jacob Spinnen MD/PhD, Dr. Tilo Dehne, Dr. Franziska Schmidt, Lennard Shopperly Charité



SUMMARY

Critical bone defects caused by trauma, surgery, or destructive bone diseases are usually treated by either autologous bone grafting or synthetic bone substitutes. While autologous bone grafting means removing part of intact bone tissue and carries risks of complications, synthetic bone structures remain inferior to autologous bone in terms of tissue healing.

Our solution comprises a new form of bone substitute that enables tissue regeneration of large bone defects with load-bearing capacities, thus providing reliable bone healing without losing rehabilitation potential.

PROJECT GOALS

- Identify and select most suitable material combination for the implant
- Develop the ideal implant structure
- Fabricate prototype for in vivo proof-of-concept (PoC) of the bone substitute
- Validate the implant functionality in vivo

- Validation of the prototype in vivo with large animals
- Spin-off foundation
- Implementation of new implant in clinical practice

Puringe: Pure syringe system for contamination-free storage, transport and injection of therapeutics



PRINCIPAL INVESTIGATORS: Felix Hehnen, Dr. Paul Geus, Tim Bierewirtz Charité



SUMMARY

200 million people are affected by macular degeneration leading to 20 million intravitreal injections per year. Silicone oil is the most prevalent lubricant in syringe systems and can lead to floaters in the eye. The team is developing Puringe, a syringe system designed to address two major challenges for intravitreal injections: accurate small dosing and contamination-free injections.

The key element of the system is a highly innovative membrane that allows precise dosing and contamination free application.

PROJECT GOALS

- Develop a functional prototype
- Prepare prototypes designed for manufacturing and mass-production

- Develop a first-in-class product
- Get certified and approved for medical use
- Enter the market

ALARM: Development of a non-invasive and fast screening method for tuberculosis in exhaled breath.







PRINCIPAL INVESTIGATORS:

Michael Lommel, Dr. Matthias Groeschel, Jan Schroer
Charité



SUMMARY

Tuberculosis (TB), the leading cause of infectious disease-related deaths worldwide, is spread via aerosols. Missed or delayed diagnosis are a major barrier to achieving WHO TB eradication goals. The development of rapid diagnostic and screening techniques is crucial.

The team aims to develop a rapid, sensitive, low-cost, and easy-to-use point-of care diagnostic for TB detection in breath that is based on the system they developed for the detection of SARS-CoV-2.

PROJECT GOALS

 Proof-of-Concept for the development of a highly sensitive, non-invasive and low-cost diagnostic test for tuberculosis in exhaled breath.

- Clinical validation in different cohorts and settings
- To establish a platform technology for detection of a variety of disease-causing agents that can be measured in exhaled breath

ShuttlePump: A novel solution for a total artificial heart





PRINCIPAL INVESTIGATORS: **Tim Bierewirtz, Prof. Marcus Granegger, PhD** Charité



SUMMARY

Heart transplantation remains the life-saving therapeutic option for patients with end-stage heart disease. However, the large heart transplant waiting list is the reflection of a severe and persistent shortage of donor hearts. Total artificial heart (TAH) is an artificial organ that mimics the native heart. It is designed to replace the heart in patients with end-stage heart failure as a bridge to heart transplantation. There are very few TAH solutions on the market and the one available are nonetheless risk prone regarding reliability, blood damage and thrombus formation. Hence, the aim of the project is to develop a functional prototype of an implantable, pulsatile TAH with superior performances by means of reliability, implantability and hemocompatibilty.

PROJECT GOALS

- Manufacturing and assembly of fully functional prototypes
- Perform virtual and physical fitting studies
- Perform acute/chronic in vivo validation study within large animals

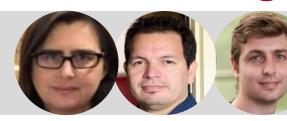
LONG-TERM GOALS

- Spin-off foundation or license to MedTech company
- CE certification as a medical device

PREVIOUS SPARK FUNDING

Track 1 2019

LiquiDress: Therapeutic deep eutectic solvents for antimicrobial wound dressing



PRINCIPAL INVESTIGATORS:

PD Dr. Fiorenza Rancan Charité

Prof. Marcelo Calderon and Dr. Matias Picchio Polymat



SUMMARY

The goal of the project is to develop an antimicrobial and anti-inflammatory dressing for treating infected chronic and complex wounds. To achieve this, the team uses deep eutectic solvents (DES), which are mixtures of two or more components that together have a lower melting point than the individual substances. Using therapeutic DES that are derived from natural products can offer several advantages over silver dressings, which are the current standard of care. These benefits include lower production costs, reduced toxicity for patients and the environment, and low risk for antimicrobial resistance.

PROJECT GOALS

- Evaluate the efficacy and toxicity of identified DES in human ex vivo wound models.
- Identify the best performing DES and perform the first pre-clinical test in vivo

- Preclinical study and validation
- Develop an efficacious medical product

Urikon: Single-cell sequencing of urine cells as transformative diagnostic for kidney diseases



PRINCIPAL INVESTIGATORS: **PD Dr. Philipp Enghard, Dr. med. Simon Ronicke**Charité



SUMMARY

Kidney diseases affect about one in ten people and is associated with significant morbidity and mortality. At present, there are no biomarkers based on liquid biopsies and nephrologists are dependent on kidney biopsy to get a meaningful diagnosis. Our vision is to establish single-cell RNA sequencing of urine cells as a completely new and non-invasive approach to diagnosing kidney diseases.

PROJECT GOALS

- Proof-of-Principle
- Analyze urine samples of patients with different kidney disease indications

- Patenting disease-specific diagnostic signatures as well as AI-based algorithm for diagnosing kidney diseases
- Spin-off foundation or licensing

