SPARK-BIH 10<sup>th</sup> Anniversary: Presenting Teams



### **SPARK-BIH**

Charité BIH Innovation SPARK-BIH Am Zirkus 1 / Bertolt-Brecht-Platz 3 DE-10117 Berlin

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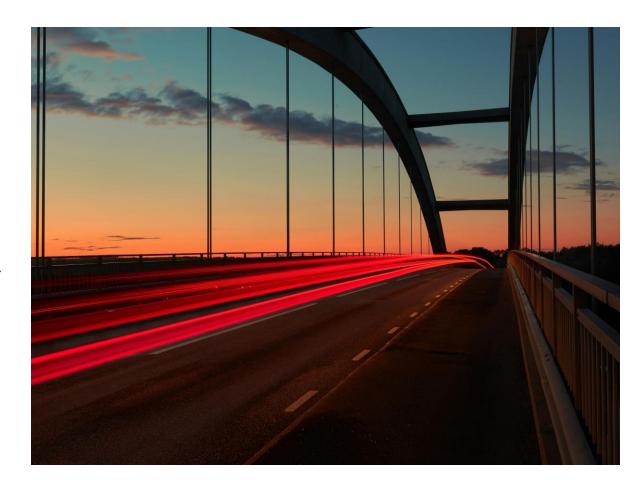
# SPARK-BIH Overviev

# 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 transferoriented 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.



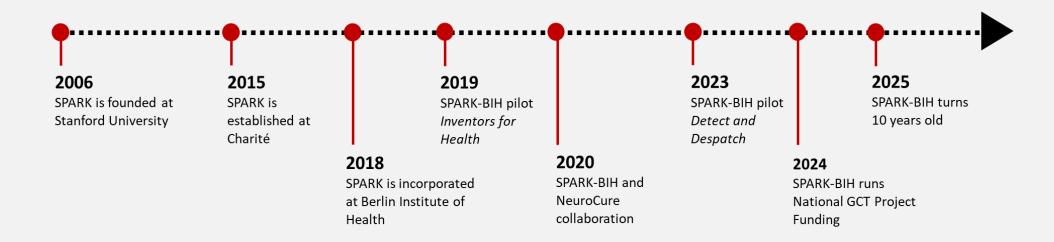
### **Our Journey**

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

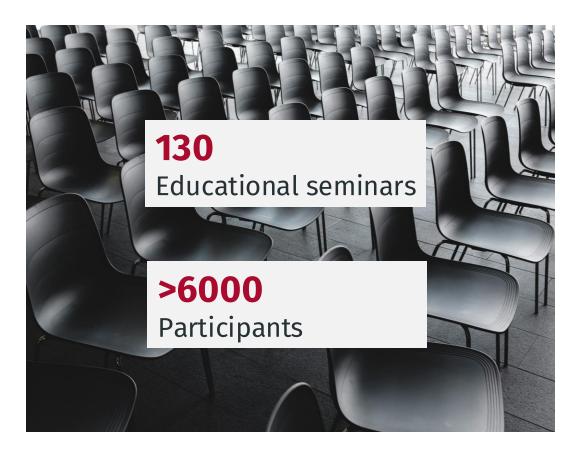
National Strategy
Gene- and Cell-Based Therapies
Project Funding

### **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.

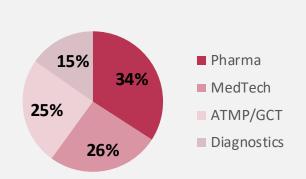
All funding is **milestone-based**, with close monitoring and tailored support from the SPARK team to ensure progress and effective resource use, accelerating the translation of biomedical research into clinical applications.



### **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

Start-ups



**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



clock



Image retrieval tool for MRIs



KernEvo

Cell-stabilization diagnostic platform



**Dr. Tanja Rosenmund**Director SPARK-BIH



**Prof. Craig Garner**Founder SPARK-BIH



**Dr. Anabel Molero Milan**Project Manager



**Dr. Alexander Stumpf**Project Manager



**Dr. Luisa A. Hasam Henderson**Project Manager



**Dr. Sascha Cording**Project Manager



**Rosa Montserrat**Assistant to SPARK-BIH Team



**Katharina Clausnitzer** Assistant to SPARK-BIH Team



**Dr. César Cordero Gómez**Project Manager



**Dr. Josephine Kemna**Project Manager



**Dr. Marialucia Massaro**Project Manager



**Dr. Sharesta Khoenkhoen** Project Manager



**Dr. Stefan Köster** Project Manager

# SPARK-BIH Projects

Lightning Talks

### Gene therapy for the treatment of temporal lobe epilepsy





### PRINCIPLE 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-resistant 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 is setting up a startup and has 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
- Startup EpiBlok Therapeutics founded in 2022

### LONG-TERM GOALS

Clinical trial phase I

### MyoPax: We repair muscle – the human muscle stem cell



### PRINCIPLE 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. The entire muscle can be affected or only single muscles do not function, yet with dramatic impairment of life quality and life-threatening consequences. Muscle diseases are currently untreatable. In Europe alone, over 6 million citizens 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 specimens to treat acquired and inherited muscle diseases. The team has acquired follow-up funding and prepares to set up a startup company to clinically pursue the development of their approach to fight muscle diseases.

### PROJECT ACHIEVMENTS **DURING SPARK**

- Preclinical proof-of-concept, preclinical safety, PEI scientific advice meetings
- Planning of phase I/IIa clinical trial
- Follow-on funding acquired: BMBF 2020 for clinical trial, Helmholtz Enterprise 2018-2019, IBB Coaching Bonus 2019, Translatorik program of the Else Kröner-Fresenius Foundation 2019-2020, Helmholtz Validation Fund 2020-2022, SPOT MDC Spin-Off Support 2020-21
- Science4Life award 2019 for "MyoPax" business concept, Charité Entrepreneur-ship summit award winner 2019
- Pitch contribution at Bio-Europe 2017, World Health Summit 2019, 9th BioM BioAngels Event 2020
- BMBF Funding for clinical study in 2021

### LONG-TERM GOALS

- Founding of a startup company in 2022
- Running the first in human clinical study in 2021

### PREVIOUS SPARK-FUNDING

Track 1 2016

## MyaLink – digital platform to monitor rare diseases



### **PRINCIPLE INVESTIGATORS:**

**Dr. Sophie Lehnerer, Dr. Maike Stein, Dr. Lea Gerischer, Prof. Dr. Andreas Meisel, Prof. Dr. Matthias Endres** Charité



NeuroCure

### **SUMMARY**

Patients with rare diseases require highly individualized therapy by specialists, which is often limited. Myasthenia gravis is a chronic autoimmune disease leading to exercise-dependent muscle weakness. Fluctuations can lead to life-threatening episodes with ICU visits.

This project aims to develop a platform to improve the quality of treatment via enabling the access to specialists and digital symptom tracking to prevent life-threatening episodes and ICU visits.

### **PROJECT GOALS**

- Clinical validation of digital monitoring in Myasthenia gravis patients
- Optimization of software

- Startup foundation or licensing
- Digital monitoring as standard of care

# SPARK-BIH Projects

Showcase

### FiXatas - Ready-to use surgical knots



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



### **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 nonsurgeons 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 field will be 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 startup in early 2020.

### 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
- Started negotiations with medtech
- Startup Clouz founded in 2019

### LONG-TERM GOALS

Track 1 2016

## GrOwnValve – Anchoring mechanism for a personalized, autologous heart valve for children



PRINCIPLE 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 xenogenic 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
- Startup foundation
- CE certification as a medical device

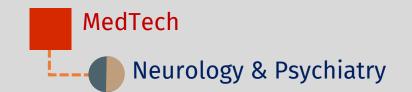
### PREVIOUS SPARK FUNDING

I4H 2019

# Neural mapping using transcranial magnetic temporal interference stimulation



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



NeuroCure

### **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 startup foundation

# Fillable Hybrid Scaffolds for the treatment of critically-sized bone defects



PRINCIPLE INVESTIGATORS:

Jacob Spinnen MD/PhD, Dr. Tilo Dehne,

Dr. Franziska Schmidt, Lennard Shopperly Charité



TRACK 2

### **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
- Start-up or spin-off foundation
- Implementation of new implant in clinical practice

# RACK 2

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



PRINCIPLE 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 – A viral alert realtime monitoring**



PRINCIPLE INVESTIGATORS: Michael Lommel, Dr. Ulrich Kertzscher, Dr. Jens Dernedde Charité



### **SUMMARY**

The COVID-19 pandemic poses a great social and economic burden on individuals and society and the infection with the SARS-CoV-2 virus may lead to severe acute or long-term disease.

An important tool against the COVID-19 pandemic is the early diagnosis of SARS-CoV-2 infected individuals. Tests help to detect and break infection chains more rapidly and can provide additional security in everyday life. In this SPARK project, the team develops a simple, fast and affordable test system that detects the virus with high sensitivity, is cheaper and more accurate than commonly used lateral flow antigen tests and will be particularly suitable for screenings at large events.

### **PROJECT GOALS**

- Build a functional devise prototype
- Pre-clinical validation

- Startup foundation or license to industry
- CE certification as a medical device

### A novel solution for a total artificial heart



### PRINCIPLE INVESTIGATORS: Tim Bierewirtz, Prof. Marcus Granegger, PhD Charité



#### **SUMMARY**

transplantation remains the Heart 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

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

### PREVIOUS SPARK FUNDING

Track 1 2019

# TRACK 1

# BioHeal Eutectic Formula: Therapeutic Deep Eutectic Solvents for Antimicrobial Wound Dressing



PRINCIPLE 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.

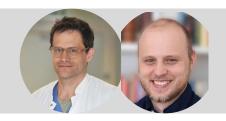
Using therapeutic DES that are derived from natural products can offer several advantages over silver dressings, which are the current standard of care. These benefits include lower production costs, reduced toxicity for patients and the environment, and low risk for antimicrobial resistance.

### **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

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



PRINCIPLE INVESTIGATORS: **PD Dr. Philipp Enghard, Dr. Jan Klocke** 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
- Startup foundation or licensing