

2020

**Boosting
translational
medicine in
Academia**

S P A R K

— **B I H** —

SPARK-BIH

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SPARK program in Berlin

The **SPARK program in Berlin** was founded in 2015 by Prof. Dr. Craig Garner and Prof. Dr. Ulrich Dirnagl with the support of the Stiftung Charité. The goal was and is **to support academic inventors in translating their research findings** into therapies, products and services, such as novel therapeutics (small molecules, biologics, cellular therapies), medical devices and diagnostics for unmet medical needs.

The program in Berlin was **modeled after the successful SPARK program at Stanford University** which Prof. Dr. Garner was a member of. Since its founding in 2006 SPARK has grown to a global network with programs implemented at more than 50

universities world-wide. The SPARK network serves as a resource for knowledge, advisors and examples of best practice. An annual meeting brings together the leadership of all SPARK programs to discuss global health challenges, strategies to improve translation and how to augment the SPARK educational program. An international workshop on Bio Innovation and Entrepreneurship brings together SPARK participants from all around the globe.

In 2018 the **Berlin Institute of Health (BIH)** decided to perpetuate the program and to include **SPARK-BIH** as part of their **mission to support translational medicine**. SPARK-BIH was successfully

embedded within BIH Innovations, the joint technology transfer of BIH and Charité. Thereby, SPARK in Berlin has grown from supporting about 4 projects per year with 50.000€ each to a program that **currently funds and mentors almost 30 project teams** within the validation fund. Employees from Charité, the Max Delbrück Centre for Molecular Medicine and the BIH can apply **with translational projects from all medical areas**.

Projects are selected for funding by the validation fund in an annual call for proposals with a panel of external experts. Selection criteria include the high of innovation, size of the unmet medical need, competitive advantage over current gold standards, data quality



SPARK Team

and likelihood of translational success. Two funding tracks have been implemented in the validation fund: Earlier projects are supported with up to 50.000€ for one year in track 1 whereas later and more mature projects are supported for two years with a budget of more than 50.000€ as part of track 2. **Funding is strictly milestone-based and projects are closely monitored by members of the SPARK team.**

Teams selected for funding by the validation fund enter the SPARK-BIH program. Here, projects are **supported with mentoring, advice, and an extensive network to accelerate the translation** of their academic invention into a marketable product to the benefit of patients and society. Furthermore,

SPARK educates faculty, students and fellows on topics relevant for translation and business development via their educational series including forums and workshops.

As of 2019, the **Inventors for Health Program** has been implemented at SPARK-BIH to serve as the front-end of innovation and growth **for early-stage ideas**. The Inventors for Health Program has been developed in close cooperation with their partner, **the Stiftung Charité**. The program focuses on developing breakthrough ideas in health and is currently made up of 2 phases – a development and funding phase. Through a series of hands-on bootcamps, inventors identify and elaborate on their ideas, develop entrepreneurial skills,

and develop initial prototypes of their solutions. These teams are augmented by the addition of team-members from other disciplines such as business and design to create truly holistic solutions. In future it is planned that the most promising ideas can apply to be further developed by SPARK-BIH and the validation fund or the Digital Health Accelerator.

Dr. Tanja Rosenmund
Program Manager & Manager
Validation

SPARK-BIH is part of the global SPARK network

Over 50 different institutions have established or are developing their own versions of the SPARK program. The mission is to improve human health by uniting academics and industry experts around the globe to generate an efficient, effective and exciting pathway for translation of academic discoveries and innovative solutions through education and project support.



SPARK-BIH is part of BIH Innovations

SPARK-BIH and the validation fund are part are part of BIH Innovations, the joint technology transfer office of the Charité and the BIH. BIH Innovations consists of four parts enabling the translation and commercialization of academic projects. SPARK-BIH is closely working with the patents & licensing team to in order to protect and exploit innovations.

Patents, licensing, law and startup consulting

Identifying, protecting
and commercializing
assets (with key partner:
Ascenion)

Validation Fund/ SPARK-BIH

Translating medical
inventions (drugs, diag-
nostics, medtech) into
products and solutions
to benefit patients



Strategic cooperations

Forming and managing-
strategic co-operations
with academia and industry

Digital Labs

Translating digital health
solutions to patients/
market (incl. Digital
Health Accelerator)

How do SPARK-BIH and the validation fund work?

SPARK-BIH and the validation fund were created to support academics in translating their inventions into novel therapeutics, medical devices and diagnostics that address unmet medical needs.

SPARK-BIH and the validation fund are part of BIH Innovations, the joint technology transfer of BIH and Charité.

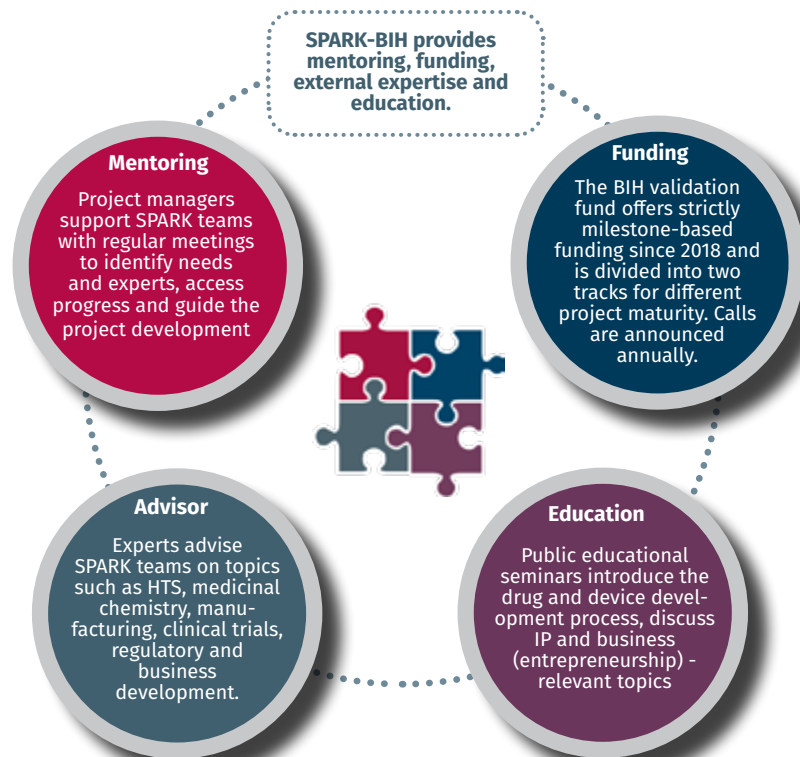
The purpose of SPARK-BIH and the validation fund is to support academic projects with funding, mentoring, advice and education to accelerate their translation for the benefit of patients and society.

Our support is reflected in translationally relevant preclinical data, sound clinical trials, new IP, novel life science startups and industry partnerships as well as licensing agreements.

By applying for funding within the validation fund to enhance the translatability of your project you automatically profit from the SPARK-BIH mentoring and education program.

Project proposals are evaluated on the basis of several aspects, the most important being: (1) addressing an unmet medical need, (2) the potential for translation into the clinics.

Refunding mechanisms (e.g. shares) secure that in case of commercial successes a part of the revenues will be used for future development programs.



How does SPARK-I4H work?

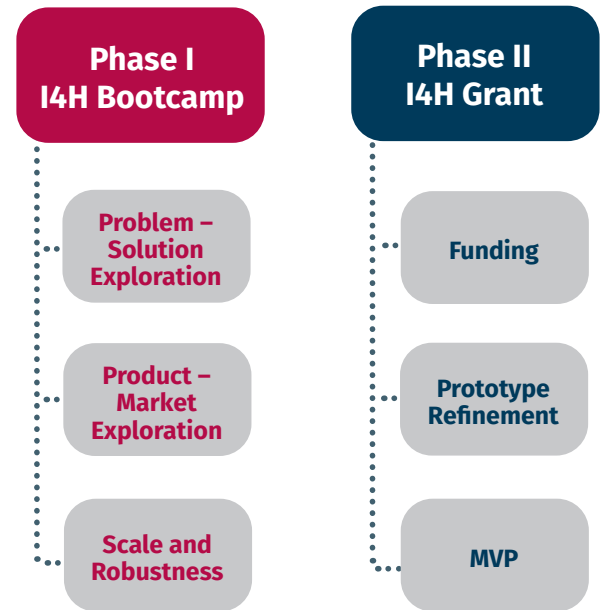
The Inventors for Health (I4H) Program is a pilot program that has been developed together with the Stiftung Charité and addresses scientists with very early projects and ideas.

Traditionally, the barriers-to-entry for medical innovation, research and development have been high. The I4H pilot program is democratizing that process and allowing for citizens and patients to co-develop solutions together with scientists and medical professionals.

Unlike traditional incubation programs focusing purely on later commercialization, the I4H program focuses on developing breakthrough medical innovations by developing the people behind the ideas through skill-building, mindset change, and exposure to a network of innovators and medical change-makers.

Accordingly, the I4H pilot program tests a novel program design. In future it is planned to continue key components of the program as scouting mechanisms to identify and develop early ideas. Subsequent funding might be realized by established funding programs such as SPARK-BIH and the validation fund or the Digital Health Accelerator.

Currently, I4H is made up of two phases: In the first phase, inventors develop their idea(s) rapidly through design-based approaches, with help from experts from other disciplines. In the second phase, funded teams advance their ideas to minimally viable products (MVP) for testing and further development, making use of SPARK-BIH.



SPARK-BIH: Maturity Pipeline of funding opportunities by Stiftung Charité and BIH Validation Fund

Support by **SPARK-BIH** mentoring & education program

BIH Validation Fund by



I4H Incubator of **STIFTUNG CHARITÉ**

PROJECT STATUS

I4H Bootcamp

Phase I with interactive Bootcamps for hands-on skill and mindset development with a focus on entrepreneurial and design-lead approaches.

I4H Grant Stiftung Charité

Outstanding projects which took part in phase I are selected for funding to develop a strong PoC. Selected inventors will receive up to 50% salary support and a maximum of €50.000 in project support.

BIH Validation Fund Track 1

Projects in an early phase of development which are clearly later than pure research projects. Visible, first proof of principle data which need to be validated and completed and are usually used to file a patent. Funding amount is up to €50.000, funding duration is 1 year.

BIH Validation Fund Track 2

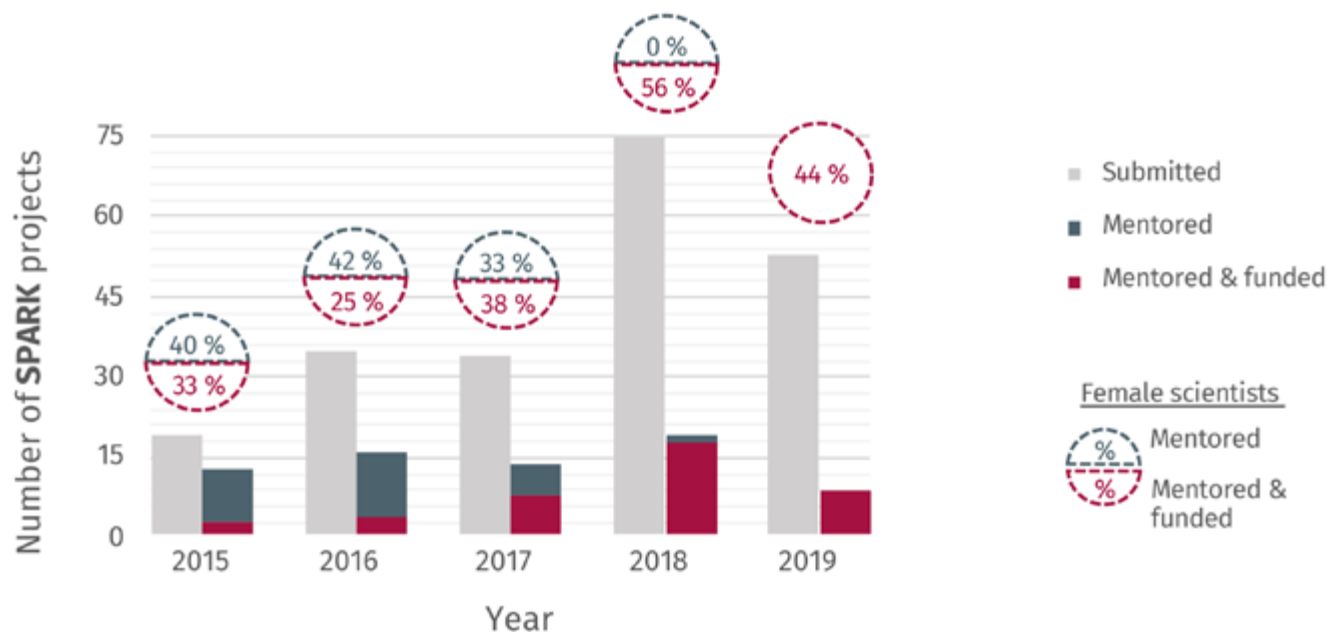
Projects in a more mature phase which are typically patented and need further supporting data and additional development. Examples are safety, dose-finding, medical chemistry, regulatory strategy, clinical trial design and further to be translated into the clinic. Funding above €50.000, with a funding duration is 2 years.


Maturity & translatability of projects

SPARK-BIH in Numbers

SPARK projects from 2015-2019

Number of SPARK projects from 2015-2019



 **216** Project proposals submitted & reviewed

 **42** Projects funded with 5.9 Mio EUR

 **29** Projects mentored, not financed

Translational Success of SPARK projects from 2015-2019

71%

of our **SPARK** teams stated that the **SPARK** program **was crucial** to advance the translational pathway of their project

80%

of our **SPARK** Pharma teams were able to **proceed their preclinical development** program to the next stages

14

Follow-on applied research funding programs were acquired by our **SPARK** teams amounting to **more than 10,5 Mio EUR**

100%

of our **SPARK** medtech and IVD teams were able to **proceed their medical device or IVD development** program to the next stages

All of them also recruited an expert in CE certification or started with the technical documentation and /or QMS 13485 establishment for their product

11

SPARK teams have **filed patents** during or after participation in **SPARK**

3

SPARK teams have **an option contract or term sheet** for potential licensing of their patent ongoing

8

16

Accelerator or Bootcamp programs were started by our **SPARK** teams
Prices or Awards have been won by our **SPARK** teams

7

8

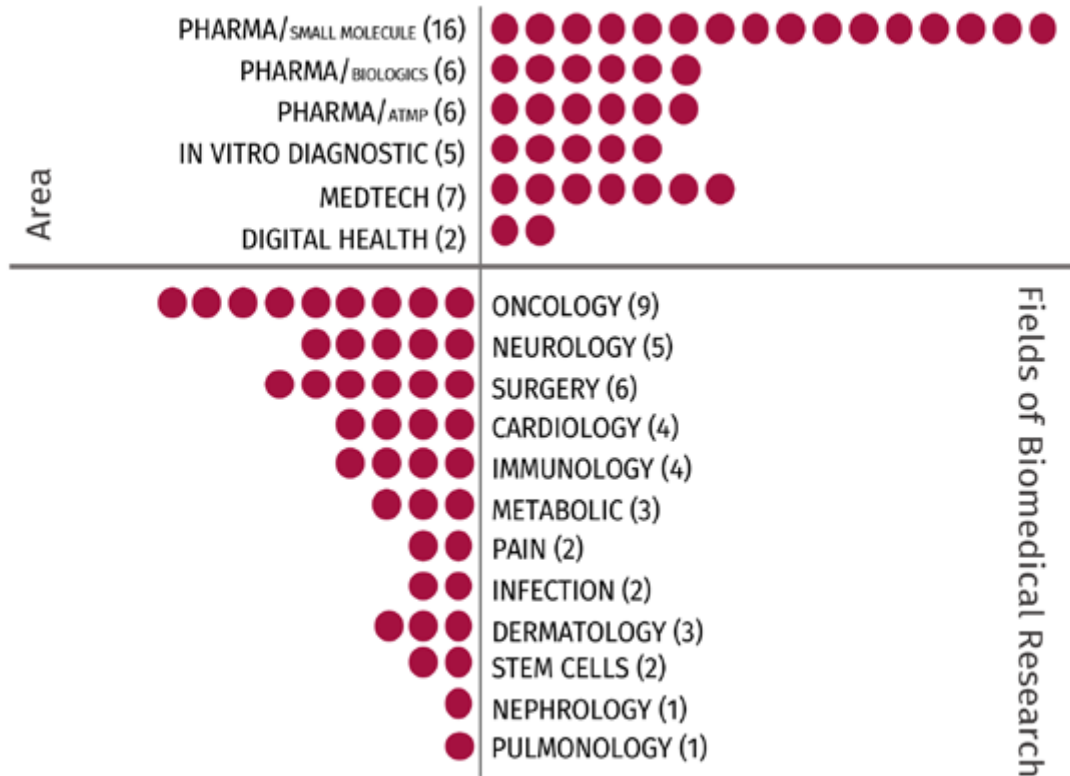
SPARK teams have founded or plan to **found a startup**
SPARK teams have had **cooperations with industry**

8

of our **SPARK** teams **prepared clinical trials** for their project or were able to **continue and improve the running clinical trials**

*All numbers are based on a survey that was submitted by 21 SPARK teams that started funding until 2018 as well as consultation of the patent team of BIH innovation

Biomedical Fields and Areas of SPARK funded projects from 2015-2019



Statistics on SPARK organized Educational Seminars 2015-2019

"I am here to get or keep in touch with "entrepreneurial" ideas and find inspiration for translation from science to business. It is the first time I participated and very much liked the format." – Attendee in Forum in 2017

50

SPARK organized educational seminars from 2015-2019

33

Different topics on **drug & device development**

97%*

Overall satisfaction with the educational lecture series from 2015- 2019

>1100

Participants in the educational lecture series from 2015- 2019

97

Speakers giving a presentation from 2015 - 2019

*Numbers are based on evaluations submitted by seminar attendees for 79 speakers at 40 different educational seminars in the years 2015-2019



*“In the beginning I considered **SPARK** just another program among all those university-based supporting initiatives. I hoped for some financial support but not more. However, it turned out to provide something much more valuable than money. **SPARK** provides multi-level competence, bringing in the right experts at the right time. In our case, this was not only the critical mind of other **SPARKees**, but also clinicians, advisors and business experienced people, pushing our project to a much higher level. Giving us a special pre-hearing during the Go-Bio application was extremely helpful. The payless support by a team of experts, tailor made to our needs was a so far unique experience for me. Personally, I learned a lot, starting from being a purely academic person, I meanwhile got a sense of how business people think and regulatory boards work. Still there are a lot of things I need to learn to survive in this new environment. I highly appreciate to have **SPARK** on my side on this journey.”*

Prof. Christoph Schwarzer

SPARK-BIH Projects

Our newly funded & mentored **SPARK** Teams of 2019



“The **SPARK** program was instrumental in supporting the MyoPax idea from a basic research project into a solid GMP-compatible product presently under preclinical testing. Without **SPARK**, any translational effort into the clinic would have ceased two years ago.”

Prof. Simone Spuler

A novel peptide to regenerate the central nervous system



PRINCIPAL INVESTIGATOR:
Dr. Sarah-Christin Starossom
Prof. Dr. Friedemann Paul
Charité



Pharma – small molecule



Neurology

SUMMARY

The team has identified a novel mechanism with pro-oligodendrogenic and remyelinating capacity. Based on that mechanism the project aims at developing a novel therapeutic option for multiple sclerosis. Although myelin and oligodendrocytes are thought to be the prime target for autoimmune attacks in multiple sclerosis (MS), there are currently no FDA approved drugs targeting the induction of endogenous remyelination and oligodendrocyte repair. The therapeutic induction of oligodendrogenesis and/or remyelination is a highly unmet need for MS and other diseases of the CNS.

PROJECT GOALS

- Develop a patentable therapeutic agent
- Test *in vitro* dose-response
- Submit invention disclosure

LONG-TERM GOALS

- Novel drug therapy for Multiple sclerosis
- License to Pharma

Validation of anti-cancer agents in patient-derived canceroids



INVESTIGATOR:
Prof. Dr. Reinhold Schäfer
Charité



Pharma – small molecule



Oncology

SUMMARY

The project aims to validate modulators of a transcription factor as agents against cancer. The validation will be conducted in patient-derived canceroids. About 1/3 of all cancers are mutant RAS-driven and cause up to 1 million deaths each year. Novel therapies targeting signaling effector proteins downstream of RAS are already in clinical use, however with uncertain long-term effects. The approach may provide a new avenue for anti-RAS therapies.

PROJECT GOALS

- Validate drug candidates in patient-derived canceroids
- Submit invention disclosure

LONG-TERM GOALS

- Start an investigator initiated trial for cancer patients based on repositioned drugs
- License to Pharma



*“**SPARK** put me on track to focus on the goal to develop a drug and acquire the competencies needed.”*

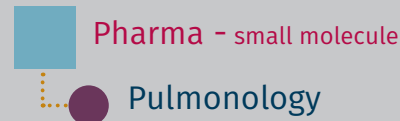
*“**SPARK** helped me to put my exploratory, basic scientist mind to the sideline for a while, to focus on bringing the results of our research to patients and market.”*

Prof. Regine Heilbronn

Exploring a novel therapeutic target in cystic fibrosis



PRINCIPAL INVESTIGATOR:
Dr. Anita Balázs
Charité



SUMMARY

The project aim is to validate and pre-clinically test candidates previously identified as potential modulators of an alternative pathway to circumvent the primary ion transport defect in cystic fibrosis (CF). CF is a life-limiting disease caused by mutations in the CFTR gene. Although highly effective CFTR modulators are emerging, ~10-15% of patients will not benefit from these therapies, while the high price of these drugs prevents access in many countries. There is an unmet need to develop alternative therapy strategies to bypass CFTR dysfunction and to restore epithelial ion transport in CF.

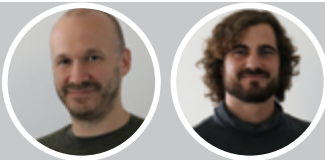
PROJECT GOALS

- Validate and pre-clinically test drug candidates for CF
- Submit invention disclosure

LONG-TERM GOALS

- Novel drug therapy for cystic fibrosis and other muco-obstructive lung diseases
- License to Pharma

A novel solution for a total artificial heart



INVESTIGATORS:
Dr. Marcus Granegger
Tim Bierewirtz
Charité



Medtech



Cardiovascular Devices

SUMMARY

The team aims to develop a functional prototype of an implantable total artificial heart (TAH) for the treatment of end-staged heart failure in pediatric and adult patients. Available TAHs are risk prone regarding reliability, blood damage and thrombus formation. The novel concept promises superior performances by means of reliability, implantability and hemocompatibility.

PROJECT GOALS

- Build a functional model / prototype
- Perform *in vitro* validation
- Submit invention disclosure

LONG-TERM GOALS

- Novel cardiologic medical device for end-staged heart failure
- License to medtech or startup foundation

Development of a stapler for solid organs



PRINCIPAL INVESTIGATOR:
Dr. Panagiotis Fikatas
Charité



SUMMARY

The aim of the project is the final development and validation of a novel surgical stapler that allows the minimal-invasive, wedge-shaped resection of solid organs. Current solutions for solid organ resection are limited and carry the risk for intra- or postoperative bleeding and are associated with a high probability of fistula development. The novel stapler allows to cut solid organs safely and with reduced risk of complications.

PROJECT GOALS

- Build a functional stapler prototype
- Perform validation tests in “dry-lab”

LONG-TERM GOALS

- Startup foundation
- CE certification as a medical device

A novel advanced therapy medicinal product (ATMP) to treat solid tumors



PRINCIPAL INVESTIGATOR:
Prof. Dr. Gabriele Pecher
Charité



SUMMARY

So far, there is no cure for instance for patients with metastatic breast or pancreatic cancer and new therapies are urgently needed. The project aims to develop a novel ATMP for the therapy of solid tumors. The group will use the innovative ATMP in order to generate optimized immune cells to fight the immunosuppressive microenvironment of solid tumors. The ATMP will be validated and preclinical testing will be accomplished.

PROJECT GOALS

- Complete the preclinical development of the ATMP
- Prepare phase I / II clinical trial
- File novel patent

LONG-TERM GOALS

- Perform phase I / II clinical trial
- License to Pharma or startup foundation

A novel gene therapy for treatment of aggressive B cell lymphoma



PRINCIPAL INVESTIGATOR:
Prof. Dr. Antonio Pezzutto
PD Dr. Antonia Busse
Charité



SUMMARY

The project seeks to complete the preclinical characterization of a human-derived T cell receptor (TCR) that selectively recognizes a specific point mutation of the protein MyD88. This specific mutation is a key oncogenic driver event in around 20% of patients with an aggressive variant of Diffuse Large B cell lymphoma, and in around 50% of patients with Primary CNS lymphoma. Both patient populations have a poor prognosis, and only limited therapies are available especially for the elderly and patients with severe comorbidities. Adoptive T cell therapy with MyD88-specific T cells would represent a truly tumor-specific therapy, being much more selective than CAR T cells or immune checkpoint inhibitors.

PROJECT GOALS

- Complete the preclinical development of the ATMP
- Prepare phase I clinical trial
- Establish industry partnership

LONG-TERM GOALS

- Perform phase I clinical trial
- License to Pharma

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



PRINCIPAL INVESTIGATOR:
PD Dr. Boris Schmitt
Charité



Medtech



Cardiology

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

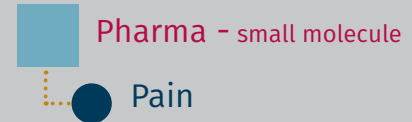
LONG-TERM GOALS

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

In vivo validation of a novel class of pain medication



PRINCIPAL INVESTIGATOR:
Dr. Viola Seitz
Prof. Dr. Christoph Stein
Charité



SUMMARY

The project seeks to complete external validation of *in vivo* data on NFEPP, a novel compound that has demonstrated potent pain relief without addiction potential in initial experiments. A patent has been filed and results were published in Science in 2017. Although pain research has identified a plethora of targets, no truly innovative analgesics have reached the market in the past years, mostly due to low efficacy or severe side effects. This leaves a significant unmet medical need for novel, safe and effective compounds with reduced side effect burden and abuse liability.

PROJECT GOALS

- External validation of preclinical *in vivo* studies
- Secure follow-on applied research funding

LONG-TERM GOALS

- Further develop under CMC and GMP conditions
- Test safety & toxicity of NFEPP
- Perform phase I/IIa clinical trials
- License to Pharma

SPARK-BIH Projects

Our **SPARK** Teams that started funding & mentoring
in **2015 - 2018**

Development of a platform for the isolation of T cell receptors for cancer immunotherapy



PRINCIPAL INVESTIGATOR:
Dr. Felix Lorenz, Dr. Julian Clauss, Dr. Inan Edes, Prof. Dr. Wolfgang Uckert
Max Delbrück Center for Molecular Medicine



Pharma - ATP



Oncology

SUMMARY

The project is designed to develop a high throughput platform to identify T cell receptors (TCRs) specific for cancer antigens to target new patient groups with TCR immunotherapy. Preliminary studies not only demonstrated the feasibility of the strategy, but also identified two novel TCRs. Patents covering these TCRs and the platform were previously filed at the European Patent Office. The team is setting up a startup (called Captain T Cell) and has acquired follow-up funding to further pursue the strategy and develop TCRs for the use in patients as well as increasing the output of this novel and unique platform. A service lab (Helmholtz Innovation Lab) has been established in parallel at the Max-Delbrück-Center.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Robust platform established to develop >30 isolated TCRs
- Multiple patents filed from 2015-2019
- Winner at life sciences and healthcare startup accelerator OneStart in 2016
- Jury price at BioVaria showcasing event for life science technologies in 2017
- Total follow-on pre-seed funding of 4 Mio. € until 2020
- Startup planned for 2020



*“**SPARK** was the starting point for my whole team to start thinking how we can translate our research results in developing drugs for patients.”*

*“I was so excited to participate in the **SPARK** mentoring program, because it provides a completely new perspective on the clinical translation of projects. For scientists it is so important to get insights into the process of translating basic research findings into treatments. These insights provided by the **SPARK** program definitely shaped my way of thinking about current and future scientific projects.”*

Dr. Felix Lorenz



*“**SPARK** enabled us to translate an initial mechanistic idea into a successful preclinical drug development project.”*

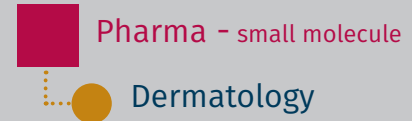
*“**SPARK** is a great initiative to de-risk innovative projects and to enhance translational research from bench to bedside. **SPARK** provided us with excellent partners, pushed our project and helped a lot in making decisions and focusing on the next steps.”*

PD Dr. Karoline Krause

New treatment strategies by targeting the inflammasome



PRINCIPAL INVESTIGATOR:
PD Dr. Karoline Krause
Charité



SUMMARY

The project has identified several inhibitors of inflammasome activation in a high-content screen. Inflammasome activation is a hallmark of several monogenic and complex systemic auto-inflammatory diseases for which only few standard therapies exist. In addition, inflammasome activation plays a central role in the pathogenesis of additional diseases such as contact dermatitis. The identified inhibitors are evaluated for their use in the different indications. One compound has the potential to be repurposed.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Identified several lead candidates
- Extended indication & initiated collaboration
- Preclinical proof of concept in human skin models
- Patent filing planned for 2020
- Started writing Investigator's brochure
- Started partnering with Pharma concerning novel chemical entity

2015

Gene therapy for the treatment of temporal lobe epilepsy



PRINCIPAL INVESTIGATOR:

Prof. Regine Heilbronn

Prof. Christoph Schwarzer

Charité & Medizinische Universität Innsbruck



Pharma - small molecule



Neurology

SUMMARY

The project aims at developing a gene therapy for the treatment of drug-resistant focal epilepsy. An adeno-associated 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
- GMP production in preparation
- Startup planned for 2021



“When first invited, I came for money. Now I come for priceless expertise and multi-level support.”

Prof. Christoph Schwarzer

FiXatas - Ready-to use surgical knots



PRINCIPAL 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 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 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 founded in 2020

Lead optimization of STOML3 inhibitors for the treatment of neuropathic pain



PRINCIPAL INVESTIGATOR:

**Prof. Dr. Gary Lewin,
Dr. Christiane Wetzel**

Max Delbrück Center for Molecular Medicine



Pharma - small molecule



Pain

SUMMARY

In this project a small molecule inhibitor for STOML3 will be developed to treat neuropathic pain. The protein is required for the transduction of pain signals in peripheral pain receptors. STOML3 expression is upregulated after nerve injury in sensory fibers making it a great target. In a high throughput screen several inhibitors of STOML3 oligomerization and thus (mechano)transduction were identified. In vivo proof of concept has been achieved in two mouse models for neuropathic pain. Neuropathic pain is a condition caused by nerve damage or disease affecting the nervous system. In half of the patients pain relief cannot be achieved by current treatment options.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Preclinical proof-of-concept in 2016
- Patent filed in 2016
- Publication: 2017
- Secured Helmholtz Validation Fund in 2016 for further development and optimization of lead compounds candidates

2015

Validation study for cervical HPV and dysplasia screening test



PRINCIPAL INVESTIGATOR:
PD Dr. Andreas Kaufmann
Charité



SUMMARY

The team has developed a diagnostic test for cervical HPV infection and dysplasia detection with high sensitivity, specificity as well as a high positive predictive value. The initial use is in triaging of equivocal screening findings. Current tests like cytology and PCR-based HPV testing either lack diagnostic accuracy or require a biopsy in follow up. After patenting, the team is currently performing a clinical study. In the future, CE certification of the test and accreditation of a service lab are planned to bring the test to the patients. Cervical cancer is the second most common cancer in women living in low and middle income countries with more than half a million new cases in 2018. Due to lack in standard screening procedures the test could be used there as a screening tool.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Developed a multiplexed quantitative mRNA-based test combining HPV and biomarker expression
- Developed algorithm to predict disease stage
- Patent filed in 2019
- Study planned and initiated



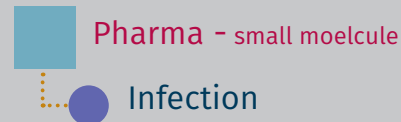
“SPARK has fostered an outside view on our IVD product helping to consider critical aspects of development and marketing.”

PD Dr. Andreas Kaufmann

Inhibitors of ribosome assembly



PRINCIPAL INVESTIGATOR:
Dr. Rainer Nikolay
Charité



SUMMARY

In this project it is planned to develop a new class of antibiotics, based on the inhibition of prokaryotic ribosome assembly. According to the WHO antibiotic resistance is a global threat. The team has developed an *in-vivo* screening assay based on reporter strains, where large and small ribosomal subunits have been tagged with red or green fluorescent proteins. A disturbance in subunit assembly can be detected via the fluorescent ratio. Based on this fluorescence-based reporter assay, a high throughput screen was performed to identify small molecule inhibitors that specifically interfere with the assembly of either the large or the small ribosomal subunit and thereby inhibit bacterial growth.

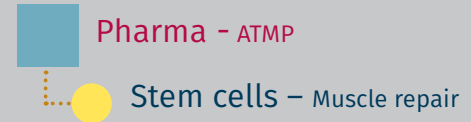
PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- HTS was performed at the FMP
- Due to low specificity of the screening assay hit candidates could not be identified
- Advise to improve the screening assay & evaluate alternative approaches (e.g. structure-based design)
- Identified hit compounds in in-silico structure-based design methods in collaboration with AG-Wolber (FU Berlin)
- Hit compounds are being tested in several assays.

We build muscles– the human muscle stem cell



PRINCIPAL INVESTIGATOR:
Prof. Dr. Simone Spuler
Dr. Verena Schöwel
MDC & Charité



SUMMARY

Muscle wasting and weakness are leading symptoms of a wide variety of diseases. The entire muscle is affected or only single muscles do not function, yet with dramatic impairment of life quality and life-threatening consequences. Muscle diseases are 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 cell populations out of small human muscle tissue specimens. This enables the team to set up multiple treatment algorithms for 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 ACHIEVEMENTS DURING & AFTER SPARK

- Preclinical Proof-of-concept, preclinical safety ongoing, PEI scientific advice meetings
- Planning of phase I/IIa clinical trial
- Follow-on funding acquired: Helmholtz Enterprise 2018-2019, IBB Coaching Bonus 2019, Translatorik program of the Else Kröner-Fresenius Foundation 2019-2020
- Science4Life award 2019 for “MyoPax” business concept
- Charité Entrepreneurship Summit pitch award winner 2019
- Pitch contribution at Bio-Europe 2017 and World Health Summit 2019

2016

matrix for antigen-specific secretion of plasma cells secreting pathogenic autoantibodies



PRINCIPAL INVESTIGATOR:
Prof. Dr. Falk Hiepe
Charité



Pharma - small molecule



Immunology

SUMMARY

Long-lived memory plasma cells secreting pathogenic antibodies have emerged as a promising therapeutic target since these cells are resistant to conventional immunosuppressive drugs and therapies targeting B cells. Current therapies targeting plasma cells such as proteasome inhibitors deplete all plasma cells including those contributing to humoral immunity that may result in immuno-deficiency. Therefore, the group developed a concept that is able to deplete plasma cells based on the specificity of their secreted antibodies. The group aims to use deplete autoantibody-secreting plasma cells in a murine autoimmune model in order to demonstrate functionality of the technique. The project recently gained interest and support by industry.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Completed the SPARK funding period successfully
- Winner of the Sanofi iAward 2018 & 2020
- Project projected to reach preclinical proof of concept by 2025



“The **SPARK** program was absolutely decisive to change our mindset in planning and thinking of experiments and research, from being limited to basic research to a holistic understanding of the requirements of translational research.”

Dr. Philipp Enghard



“**SPARK** is fundamental for researchers from any field to bring an idea from research to what needs to be done in the business field.”

Dr. Alessandro Faragli

Flurinocyte - urine flow cytometry as biomarker for renal diseases



PRINCIPAL INVESTIGATOR:
Dr. Philipp Enghard
Charité



In vitro Diagnostic



Nephrology

SUMMARY

The project aims at developing a diagnostic assay to quantify cellular components present in human urine via flow cytometry. Cells identified and quantified allow the differential diagnosis of several renal diseases. The presence or absence of specific cell types correlated to disease activity and disease severity. This simple urine test could be used as a diagnostic tool, to screen patients who need a renal biopsy, monitor treatment and predict outcome. The assay could become a helpful tool in the clinic when a quick primary assessment is required to define subsequent clinical workup and may enable a more personalized treatment.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Data validation in different patient groups
- Established an easy-to-use sample conservation protocol to simplify the test logistics
- Currently validating marker and sample logistics in two multi-center studies on renal diseases

Prediction and prevention of congestive events in heart failure patients



INVESTIGATOR:
Dr. Alessandro Faragli
Charité



SUMMARY

Heart failure (HF) represents the leading cause of hospitalization worldwide. Because of the difficulty in treating this chronic disease, re-hospitalizations are associated with high cost for the healthcare systems, accounting for €28 billion per year in Europe only. The team aims at building an algorithm to predict and prevent congestive events in heart failure patients. They have identified risk predictors and created an algorithm. At the moment, the team is performing a database analysis on existing cohorts of HF patients to build the first risk prediction model.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Risk predictors identified
- First algorithm designed

LONG-TERM GOALS

- Perform clinical study to determine accuracy of prediction algorithm
- Submit invention disclosure
- License to medtech or startup foundation

Novel drugs strengthening endogenous immuno-regulatory processes



PRINCIPAL INVESTIGATOR:

Dr. Stefan Frischbutter

Charité & German Rheumatism Research Center



Pharma - small molecule



Immunology

SUMMARY

The balance in the immune system between suppression or activation of immune responses is highly complex, very tightly regulated and fine-tuned with multiple cell types orchestrated. If this fine-tuning is out of balance, diseases such as autoimmunity occur. In this project the team is focusing on the suppressive capacity of the immune system and is evaluating the use of drugs to bring this arm back in balance. The team has developed a high-throughput-screening platform and identified already several bioactive molecules with re-balancing capacity. The team has validated these drug candidates in primary human immune cells and assessed the resulting immune reaction and potential impact on disease.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Hits from drug screen have been validated and immune responses were partially dissected
- Target validation and drug development under way
- Major hurdles have been identified in pursuing the idea into the clinic

BodyTime - A new diagnostic tool to assess the internal clock



PRINCIPAL INVESTIGATOR:
Prof. Dr. Achim Kramer
Charité



In vitro Diagnostic



Other

SUMMARY

The circadian clock is a biological program that structures physiology and behaviour according to the time of day. It is active in practically all cells of our bodies. The circadian clock is thus a cell-based program that is essential to health and well-being. The team has developed a new diagnostic tool to probe human internal time and rhythm using a single blood sample. It has utility in defining the correct time of day for drug dosing, in order to achieve the least adverse effects. Of note, >50% of the top selling drugs target clock-controlled genes and thus likely have specific time of day effectiveness. This solution can therefore offer value in reducing side effects as well as helping with sleep disorders or work performance.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Identified core set of time-telling genes
- Patent filed in 2018
- Developed a robust assay and predictive algorithm with 30 min accuracy
- Follow-on applied research funding by BIH Digital Health Accelerator
- Started beta-testing with different patient cohorts in 2019
- Startup foundation planned in late 2020

2017



*“Before entering the **SPARK** program, we had many translational paths in mind. Now we have found the most promising one.”*

Dr. Stefan Frischbutter



*“We are very thankful to **SPARK** for laying in front of us the whole spectrum of expertise in the field of drug development and giving us access to role-models in the field conveying that “we can do it” as well.”*

Prof. Dr. Markus Schülke



“Through the educational and entrepreneurial forum I profited from experts and was trained in bringing therapy into clinic. I also got insights into hurdles, developmental processes, regulations that other **SPARK** projects are dealing with. The financial support allowed us to carry on the translational process of our project. Brainstorming for solving unexpected reactivity of our reagent was finally crucial to save the whole project.”

Dr. Simone Rhein

TCR gene therapy of CD22-positive B cell malignancies



PRINCIPAL INVESTIGATOR:
Dr. Simone Rhein
Prof. Antonio Pezzutto
Charité



SUMMARY

In this project, the goal is to generate a TCR for gene therapy of B cell malignancies by targeting the B cell antigen CD22. CD22 is a good alternative target to CD19- and CD20-directed therapies as these therapies often lead to downregulation or loss of the antigen. CD22-targeted CAR T cells induce remission in B-ALL that is naive or resistant to CD19-targeted CAR immunotherapy. The clinical success however is hampered by downregulation of surface CD22 expression upon CAR treatment, which greatly reduces efficacy. Since TCRs do not depend on antigen surface expression, these patients could benefit from TCR T cell therapy. A newly generated TCR candidate is being tested for off-target toxicity and will be compared to CD22 CAR T cells. A patent has been filed on the CD22-specific TCR.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- novel CD22-specific TCRs identified
- patent filed in 2018 (second TCR added in 2019)

LONG-TERM GOALS

- Demonstration of superiority over CD22 CAR T cells
- Perform phase I clinical trial
- License to Pharma

Drug discovery for mitochondrially inherited Leigh syndrome (MILS)



PRINCIPAL INVESTIGATORS:
Prof. Dr. Alessandro Prigione
Prof. Dr. Markus Schülke
MDC & Charité



Pharma – small molecule



Neurology

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. 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 ACHIEVEMENTS DURING & AFTER SPARK

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

2018



*“**SPARK** is a great platform to learn about the drug development process and to think as a translational researcher. It exposed us to topics which we as basic scientists typically do not have on our daily agenda but which are vital for translation, such as intellectual property and requirements for clinical trial design. Advice from other **SPARKEes** was helpful in streamlining the way towards a drug and to identify important checkpoints within preclinical validation.”*

Prof. Dr. Chiara Romagnani

Peptide-based vaccination targeting innate responses against viral infection and cancer



PRINCIPAL INVESTIGATOR:

Prof. Dr. Chiara Romagnani

Charité & German Rheumatism Research Centre



Pharma – small molecule



Oncology

SUMMARY

The immune system has evolved different strategies to prevent and fight cancer and infections. Natural Killer (NK) cells are an innate immune cell type able to kill tumor and/or infected cells. The team has identified a specific peptide whose expression is shared by cytomegalovirus and certain tumors. The project aims to exploit this immunological phenomenon by using the peptide as a vaccine directed against tumors and cytomegalovirus, simultaneously. The advantage of this approach is that cancer patients can benefit from this boost for the immune system that is ready not only to fight cytomegalovirus but also relapsing tumors.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Co-stimulants assessed for vaccine development
- Partners for development of vaccine identified
- Clinical indication and potential clinical partners identified
- *In-vivo* proof-of-concept ongoing

2018

Molecular imaging of biofilm infections - Validation of FISH controls for automated endocarditis diagnostics



PRINCIPAL INVESTIGATORS:

PD Dr. Annette Moter

Dr. Judith Kikhney

Charité



In Vitro Diagnostic



Infection

SUMMARY

Fluorescence in situ hybridization (FISH) is a molecular technique, which allows identification and visualization of microorganisms within tissues. Currently, the daily diagnostic use of FISH is restricted to highly specialized laboratories because it involves not only high-level of expertise, but also many hands-on steps, time-consuming microscopy, laborious annotation and documentation of FISH images and is lacking standard high quality controls. In this project diagnostic use of FISH in daily routine for endocarditis diagnostics is tested by automating the full process of this technique. The group is focusing on multiple aspects of this diagnostic procedure – with one emphasis on the generation of solid and validated routine positive controls.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Design and validation of controls
- Developed a sample tracking software
- Currently developing semi-automated digital image analysis for detection of bacteria in histological sections
- Developed an intelligent image handling archiving and documentation system
- Currently testing entire platform in routine diagnostic and comparing the ‘hands-on’ with the automated FISH (within the BMBF-funded iSOLID consortium)



*“Without financial support, the project would not have been possible and the fantastic **SPARK** team helped us to achieve tremendous progress in a structured and well-focues way.”*

Dr. Kostja Renko

Image-based Support of Minimal-Invasive Mitral Valve Repair



PRINCIPAL INVESTIGATOR:
Prof. Dr. Anja Hennemuth
Charité & German Rheumatism Research Centre



SUMMARY

About 7000 isolated mitral valve surgeries are performed in Germany every year. Mitral valve repair (MVR) is superior to valve replacement. Successful repair does not only lead to better survival but also better quality of life and avoidance of anticoagulants. However MVR success rates strongly correlate with the experience of the surgeon as MVR is difficult to learn due to differences in pre-OP images of the moving heart and during the operation (or during surgery). This indicates the need for a better intraoperative decision support. The team works on the application of image-based surgery planning and image-based navigation with different modalities. This could help the surgeon to accurately consider anatomical and dynamic properties of the valve during surgery.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Started development of software modules for image fusion and integrated visualization and interaction
- Started setting up quality management and documentation system
- Initiated collaborations to specify user needs and interface questions
- Initiated industry collaborations for clinical integration
- Acquired BMBF funding together with industry partner

Predicting post-operative complications in real-time



PRINCIPAL INVESTIGATOR:
Dr. Alexander Meyer
Prof. Dr. Volkmar Falk
Charité & DHZB



SUMMARY

The large number of concurrent patient data in critical care units goes well beyond the capacity of the intensive care physician and may lead to treatment delays or clinical errors. The team applies deep machine learning methods in a critical care scenario to provide timely and highly accurate decision support to the clinical staff. They have developed a set of forward-facing real-time prediction models for severe post-cardiothoracic surgery complications. Primary focus is the prediction of postoperative bleeding.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Prototype ready including user interface and client-server infrastructure
- Business plan completed
- Collected first user feedback
- Completed team
- Started recruiting partner hospitals
- Further refined and improved bleeding model
- Started to work towards regulatory approval with experts

2018

Inhibition of thyroid hormone inactivation for cancer treatment



PRINCIPAL INVESTIGATOR:

Dr. Kostja Renko

Prof. Dr. Lutz Schomburg

Charité



Pharma – small molecule



Oncology

SUMMARY

An initial compound library screen led to a preliminary list of hormone modulators. The compound target reportedly plays a role in different cancer entities. During the SPARK funding period, drug candidates were characterized for specificity, potency and on-cell effects. Furthermore, in silico drug design was started to predict improved candidates. Experimental approaches to verify the reported beneficial effects in a cancer cell line completed the overall strategy. Future plans include strategic cooperation with oncology experts.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Verification and characterization of >50 compounds from an HTS approach
- Further testing of selected, specific candidates on intact cells
- Ongoing validation of candidates in cancer cell lines
- Plan of strategic cooperations with oncologists

Prevention of paclitaxel-related Neurotoxicity



PRINCIPAL INVESTIGATOR:
Dr. Wolfgang Böhmerle
Prof. Dr. Matthias Endres
Charité



Pharma – small molecule



Neurology

SUMMARY

Polyneuropathy is a common, potentially long lasting and debilitating neurological side effect for cancer patients treated with paclitaxel. It has been shown, that paclitaxel binds the neuronal-calcium sensor 1 protein which causes calcium dyhomeostasis in neurons. This process contributes to the development of paclitaxel-induced neuropathy and can be selectively blocked by an approved on-the-market drug that can be readily repositioned. In this project, the potential of co-administration of this drug with paclitaxel to prevent neurological side effects is being exploited. Currently the team has designed a clinical study, consulted the BfARM for scientific advice and is recruiting funding for executing the study to assess the potential of the repositioned drug to reduce paclitaxel-induced neurotoxicity.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Assessment and compilation of available pre-clinical data
- Completion of GAP analysis
- Consultation of BfArM on design of clinical study
- Recruitment of clinical partners
- Assembly of trial infrastructure
- Preparation of documentation and design for phase II study
- Funding recruitment in progress for phase II repurposing trial

2018



“**SPARK** support was essential to continue and to improve our translational research project. Additionally it opened new horizons to evaluate new alternative peptides for our target protein.”

Prof. Peter Kühnen

MC4R agonist treatment of patients with monogenic obesity



PRINCIPAL INVESTIGATOR:
PD Dr. Peter Kühnen
Charité



Pharma – small molecule



Metabolic Disease

SUMMARY

Obesity is an increasing problem with immense socioeconomic burden and personal suffering for the individual patients. In this project the team has identified a novel intracellular pathway via a known receptor, how satiety is mediated in the cells. When this signaling pathway is disturbed, the patients experience a constant hunger feeling irrespective of how much they eat. The goal is to identify patients that can benefit from modulating the signal with a known drug and change their hunger feeling thus reducing the weight naturally. The team has identified patients with several mutations at respective receptor signaling pathways as well as epigenetic changes and are able to include these patients in an investigator-initiated clinical trial.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

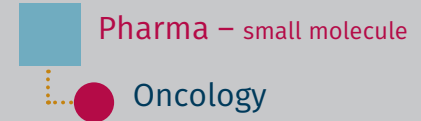
- Patent filed
- Diagnostic screen established
- Identified several mutations and epigenetic modifications within the MC4R pathway which might identify patients for MC4R agonist treatment
- Enrolled several patients in the ongoing Phase 2 investigator-initiated clinical trial

2018

Combinatorial treatment for metastatic colorectal cancer



PRINCIPAL INVESTIGATOR:
Prof. Dr. Ulrike Stein
Prof. Dr. Wolfgang Walther
MDC & Charité



SUMMARY

Colorectal cancer is the third most diagnosed cancer and fourth most common cause of death world wide, metastasis being the cause of about 90% of deaths. Team Stein has identified two FDA approved drugs that combined robustly inhibit the metastasis of colon cancer. They have initiated a first phase II clinical trial for one of the drugs – and are aiming at initiating a second phase II clinical trial for combinatorial therapies for colorectal cancer (CRC). An option contract has been negotiated with a biotech company, which also includes an option for an industry partnership with the Stein Team.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- One patent granted, several patents pending
- First preclinical developmental steps & POC completed
- Phase II mono-therapy clinical study is running
- Ongoing licensing negotiations & planned industry partnership



“SPARK was most crucial:

- because of the entire networking for scientific and regulatory advice to accelerate project translation into clinical application*
- financial support to perform in vitro and in vivo experiments to accumulate the essential data sets for approval by authorities to enter clinical phase I/II trial*
- these data are also crucial to attract sponsors/investors for the*
***post-SPARK phase**“*

Prof. Ulrike Stein



“The input from **SPARK** was crucial to realize that a structure-based design of small molecule inhibitors would be a more direct and most probably more promising approach. Following this suggestion, a collaboration with a structure-based modelling group (AG Wolber, FU Berlin) was established.”

Dr. Rainer Nikolay

SPARK-BIH Projects

Mentored-only **SPARK** Teams

Cairo against Chaos: A novel eHealth system for enhanced transfusion and medication safety



PRINCIPAL INVESTIGATOR:
Dr. Michael Notter
Charité



Digital Health



Transfusion medicine

SUMMARY

Blood Transfusion requires a maximum level of security and precision, because, if performed inappropriately, it can kill patients. This is why a paper-based security and documentation system is legally mandatory and implemented in every single hospital that prevents errors from occurring. In this project, the entire transfusion process is digitally captured. This is achieved by combining a proprietary infusion catheter for automatic pre-transfusion blood sampling with a software- and radiofrequency (RFID)-based identification system. An app has been developed to maintain a high level of patient security and a seamless documentation of the whole process. A prototype system is currently being tested in the Charité.

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Value proposition and business model tested
- Team composition evaluated and experts identified
- Clinical testing initiated at Charité in 2014 – 2018
- 2019 collaboration with “Inter-disziplinäre Arbeitsgemeinschaft für Klinische Hämotherapie (IAKH)” aiming at supra-regional implementation of Cairo

Development of a liposome-based delivery system for Langerhans cells



PRINCIPAL INVESTIGATOR:
Dr. Christoph Rademacher
Dr. Robert Wawrzinek
MPI of Colloids and Interfaces



Pharma – Small molecule



Other

SUMMARY

The team identified a small molecule ligand to Langerin that can be used for targeted delivery of antigen to Langerhans cells. What renders them very special is that they are one of the few dendritic cells residing in the epidermis, the uppermost layer of the skin, and therefore a very attractive target for immune modulation attempts.

The team showed that decorating liposomes and other nanoparticles with their small molecule ligand leads to highly specific uptake by Langerhans cells *in vitro*, *in vivo* and in human skin explant models. The team currently translates the technology for the delivery of novel vaccines and anti-cancer treatment

PROJECT ACHIEVEMENTS DURING & AFTER SPARK

- Risk predictors identified
- First algorithm designed

LONG-TERM GOALS

- Startup foundation of Cutanos (planned for mid 2020)
- Preclinical and first-in-human-studies

2015



“With the help of the **SPARK** program we could refocus our priorities and were able to advance our project from an idea to a finished trial protocol.”

Dr. Wolfgang Böhmerle

SPARK-BIH Projects

Our newly funded & mentored **I4H** Teams of 2019



PRINCIPAL INVESTIGATOR:
PD Dr. Boris Schmitt
Charité



SUMMARY

GrOwnValve is part of Dr. Schmitt's vision to create the first heart valve for children with congenital heart defects grown of autologous tissue. No valve is yet on the market which is specifically suited for use in children. To achieve this, the GrOwnValve project will make use of an anchor, making sure that once in place the valve will not need to be replaced, but can remodel in the patient.

Dr. Schmitt and his team are targeting the 1% of newborn children per year which are born with congenital heart defects – this represents around 1.35 million children and could permanently impact their ability to lead healthy, full lives.

PROJECT GOALS

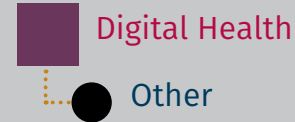
- Design and manufacture anchor
- Perform preclinical testing of anchor

LONG-TERM GOALS

- Startup foundation
- CE certification as a medical device



PRINCIPAL INVESTIGATOR:
PD Dr. Angela Religio
Charité



SUMMARY

The team is working at the cutting edge of chronotherapy to deliver a solution which might alter the way cancer is treated conventionally. Mastering the ability to determine when gene-targeting drugs are delivered can make the difference between successful and unsuccessful treatment regimens and reduce side-effects. In addition to cancer, the TimeTeller system might be able to help determine optimal treatment times for a variety of indications. The associated costs of cancer treatments yearly substantially exceed \$1 trillion. Should the number of cases with successful management of the disease increase this cost will plummet. TimeTeller and systems like it help reduce this cost.

PROJECT GOALS

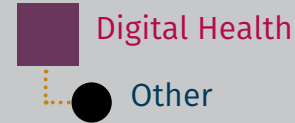
- Develop TimeTeller into an innovative & useful tool
- Treatment optimization

LONG-TERM GOALS

- Provide personalized recommendations for optimal activity times
- Introduce TT into clinics worldwide



PRINCIPAL INVESTIGATOR:
Dr. Jessica Olschewski
Charité



SUMMARY

Medu+ aims to enable the patient to inform themselves with audited information about diagnosis, treatment and additional care programs through access to a digital platform before, during and after their clinical pathway.

Whether it's the initial consultation, a post-operative session, or something else, the clinical environment for many patients can represent an unknown and unsure place, where information sources are varied and sometimes inconsistent. Medu+ is helping to close the loop on patient information sources starting with the gynecological clinic at the Charité and moving outwards from there.

PROJECT GOALS

- Develop an initial proof of concept and audited information pathway for the gynecological clinic at the Charité

LONG-TERM GOALS

- Enter into cooperation with additional clinics
- Represent the number one resources for audited treatment information for a given clinical pathway



“The **SPARK** team provided us with crucial critical questions, complementary expertise and a very friendly dynamic team.”

Prof. Dr. Anja Hennemuth

SPARK-BIH Project Glossar – Team Affiliations (I)

Dr. Anita **Balázs**, Charité, Department of Pediatric Pulmonology, Immunology and Intensive Care Medicine, Head of Department: Prof. Dr. Marcus Mall

“Exploring a novel therapeutic target in cystic fibrosis”

PD Dr. Wolfgang **Böhmerle**, Charité, Department of Experimental Neurology

“Prevention of paclitaxel-related Neurotoxicity”

Dr. Philipp **Enghard**, Charité, Medical Department, Division of Nephrology and Internal Intensive Care Medicine

“Flurinocyte - urine flow cytometry as biomarker for renal diseases”

Dr. Alessandro **Faragli**, Charité, Medical Department, Experimental Cardiology, AG Post/Alogna, Head of laboratory: Dr. Alessio Alogna (BIH Junior Clinical Scientist)

“Prediction and prevention of congestive events in heart failure patients”

Dr. Panagiotis **Fikatas**, Charité Department of Surgery, Experimental Surgery, Head of department: Prof. Dr. Igor M. Sauer

“Development of a stapler for solid organs”

Dr. Panagiotis **Fikatas**, Charité Department of Surgery, Experimental Surgery, Head of department: Prof. Dr. Igor M. Sauer

“FiXatas - Ready-to use surgical knots”

Dr. Stefan **Frischbutter**, Charité, Comprehensive Allergy Center Charité & German Rheumatism Research Center

“Novel drugs strengthening endogenous immuno-regulatory processes”

Dr. Marcus **Granegger** & Tim **Bierewitz**, Charité, Institute for Imaging Science and Computational Modelling in Cardiovascular Medicine, Biofluid Mechanics Laboratory, Group leader: PD Dr. Ulrich Kertzscher

„ShuttlePump - A pulsatile valveless total artificial heart”

Prof. Dr. Regine **Heilbronn** & Prof. Dr. Christoph **Schwarzer**, Charité, Institute of Virology & Innsbruck Medical University, Department of Pharmacology

“Gene therapy for the treatment of temporal lobe epilepsy”

Prof. Dr. Anja **Hennemuth**, Charité, Institute for Imaging Science and Computational Modelling in Cardiovascular Medicine (ICM) & Member Of Management Board at Fraunhofer Institute for Digital Medicine (MEVIS)

“Image-based Support of Minimal-Invasive Mitral Valve Repair”

SPARK-BIH Project Glossar – Team Affiliations (II)

Prof. Dr. Falk **Hiepe**, Charité, Department of Rheumatology and Clinical Immunology (including working area of Physical Medicine), Rheumatologic Research lab, AG Hiepe - Development of Therapeutic Strategies for Autoimmune Diseases

“Affinity matrix for antigen-specific depletion of plasma cells secreting pathogenic autoantibodies”

PD Dr. Andreas **Kaufmann**, Charité, Department of Gynecology, Gynecological tumor immunology lab

“Validation Study for Cervical HPV and Dysplasia Screening Test”

Prof. Dr. Achim **Kramer**, Charité, Institute of Medical Immunology, Department of Chronobiology

“BodyTime - A new diagnostic tool to assess the internal clock”

PD Dr. Karoline **Krause**, Charité, Department of Dermatology, Venereology and Allergology, Dermatologic Allergology (AG Maurer) & Comprehensive Allergy Center Charité

“New treatment strategies by targeting the inflammasome”

PD Dr. Peter **Kühnen** & Prof. Dr. Heike **Biebermann**, Institute for Experimental Pediatric Endocrinology, Director of Institute: Prof. Dr. Heiko Krude

“MC4R agonist treatment of patients with monogenic obesity”

Prof. Dr. Gary **Lewin**, Dr. Christiane **Wetzel**, Max Delbrück Center for Molecular Medicine, Lewin Lab - Molecular Physiology of Somatic Sensation

“Development and optimization of novel small molecules to treat metabolic syndrome”

Dr. Felix **Lorenz**, Julian **Clauss**, Dr. Inan **Edes**, Prof. Dr. Wolfgang **Uckert**, Max Delbrück Center for Molecular Medicine, Uckert Lab - Molecular Cell Biology and Gene Therapy

“Development of a platform for the isolation of T cell receptors for cancer immunotherapy”

Dr. Alexander **Meyer** & Prof. Dr. Volkmar **Falk**, Charité, Department of Cardiovascular Surgery, Medical Data Science Group

“Predicting post-operative complications in real-time”

PD Dr. Annette **Moter**, Dr. Judith **Kikhney**, Charité, Institute of Microbiology, Infectious Diseases and Immunology, Group leader “biofilm” & Biofilm Center of the German Heart Center Berlin

“Molecular imaging of biofilm infections - Validation of FISH controls for automated endocarditis diagnostics”

SPARK-BIH Project Glossar – Team Affiliations (III)

Dr. Rainer **Nikolay**, Charité, Institute of Medical Physics and Biophysics, Spahn Lab - Cryo-Electron Microscopy of Macromolecular Machines
“Inhibitors of ribosome assembly”

Dr. Michael **Notter**, Charité, Medical Department, Division of Hematology, w and Tumor Immunology, Clinical Research and Digital Medicine, Notter Group – Engineering patient safety
“Cairos against Chaos: A novel eHealth system for enhanced transfusion and medication safety”

Dr. Jessica **Olschewski**, Charité, Department of Gynecology
“Medu+”

Prof. Dr. Gabriele **Pecher**, Charité Berlin, Medical Clinic of Oncology and Hematology, Department of Molecular Gene- and Immunotherapy
“A novel therapy medicinal product for the therapy of solid tumors”

Prof. Dr. Antonio **Pezzutto** & PD Dr. Antonia **Busse**, Charité, Medical Clinic of Oncology and Hematology, Charité Medical School, and MDC, Department of Molecular Immunotherapy
“A novel gene therapy for treatment of aggressive B cell lymphoma”

Prof. Dr. Alessandro **Prigione**, Max Delbrück Center for Molecular Medicine, AG Prigione - Mitochondria and cell fate reprogramming
Prof. Dr. Markus **Schülke**, Charité, Department of Neuropediatrics, NeuroCure Clinical Research Center, AG Schuelke – Translational Genomics
“iPSC-based drug discovery of mitochondrially inherited Leigh syndrome (MILS)”

Dr. Christoph **Rademacher**/Dr. Robert **Wawrzinek**, Max Planck Institute of Colloids and Interfaces, Biomolecular Systems, Research Group
“Structural Glycobiology”
“Development of a liposome-based delivery system for Langerhans cells”

Dr. Angela **Religio**, Charité, Institute for Theoretical Biology (ITB), Molecular Cancer Research Center (MKFZ), Systems Biology of Cancer
“TimeTeller”

Dr. Kostja **Renko**, Charité, Institute of Experimental Endocrinology, AG Renko
Prof. Dr. Lutz Schomburg, Deputy director of Institute of Experimental Endocrinology, AG Schomburg
“New thyroid hormone enzyme inhibitor for cancer treatment”

Prof. Dr. Chiara **Romagnani**, Charité, Medical Department, Division of Gastroenterology, Infectiology and Rheumatology, Berlin Center for Advanced Therapies (BeCAT) & German Rheumatism Research Centre Berlin (DRFZ), Romagnani lab – Innate immunity
“Peptide-based vaccination targeting innate responses against viral infection and cancer”

SPARK-BIH Project Glossar – Team Affiliations (IV)

Prof. Dr. Reinhold **Schäfer**, Deputy Director (Translational Research) of the Charité Comprehensive Cancer Center, Molecular Tumor Pathology
Director: Prof. Dr. med. Ulrich **Keilholz**

„Validation of anti-cancer agents in patient-derived canceroids”

PD Dr. Boris **Schmitt**, Charité, Department of Pediatric Cardiology, Group leader KidCathLab
“GrOwnValve”

PD Dr. Boris **Schmitt**, Charité, Department of Pediatric Cardiology, Group leader KidCathLab
“GrOwnValve - Bioresorbable Stent as anchor for a personalized, autologous heart valve for children”

Dr. Viola **Seitz** & Prof. Dr. Christoph **Stein**, Charité, Institute of Experimental Anesthesiology
“In vivo validation of a novel class of pain medication”

Prof. Dr. Simone **Spuler** & Dr. Verena **Schöwel**, Max Delbrück Center for Molecular Medicine, Experimental and Clinical Research Center and Charité, Spuler Lab – Myology, Muscle Research Unit
“We build muscles– the human muscle stem cell”

Dr. Sarah-Christin **Starossom**, Charité, Institute of Medical Immunology, Junior Group Leader AG Starossom
Prof. Dr. Friedemann Paul, Charité, Clinical Neuroimmunology Group, Group Leader Experimental and Clinical Research Center
„A novel peptide to regenerate the central nervous system “

Prof. Dr. Ulrike **Stein** & Prof. Dr. Wolfgang **Walther**, Max Delbrück Center for Molecular Medicine and Charité, Stein Lab - Translational Oncology of Solid Tumors
“Combinatorial treatment for metastatic colorectal cancer”

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Dr. Philipp Enghard: © **Simone Baar** | Charité – Universitätsmedizin Berlin

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