



DCB

Global Center for
Technology Innovation
in Diabetes 



Annual Report 2022/23

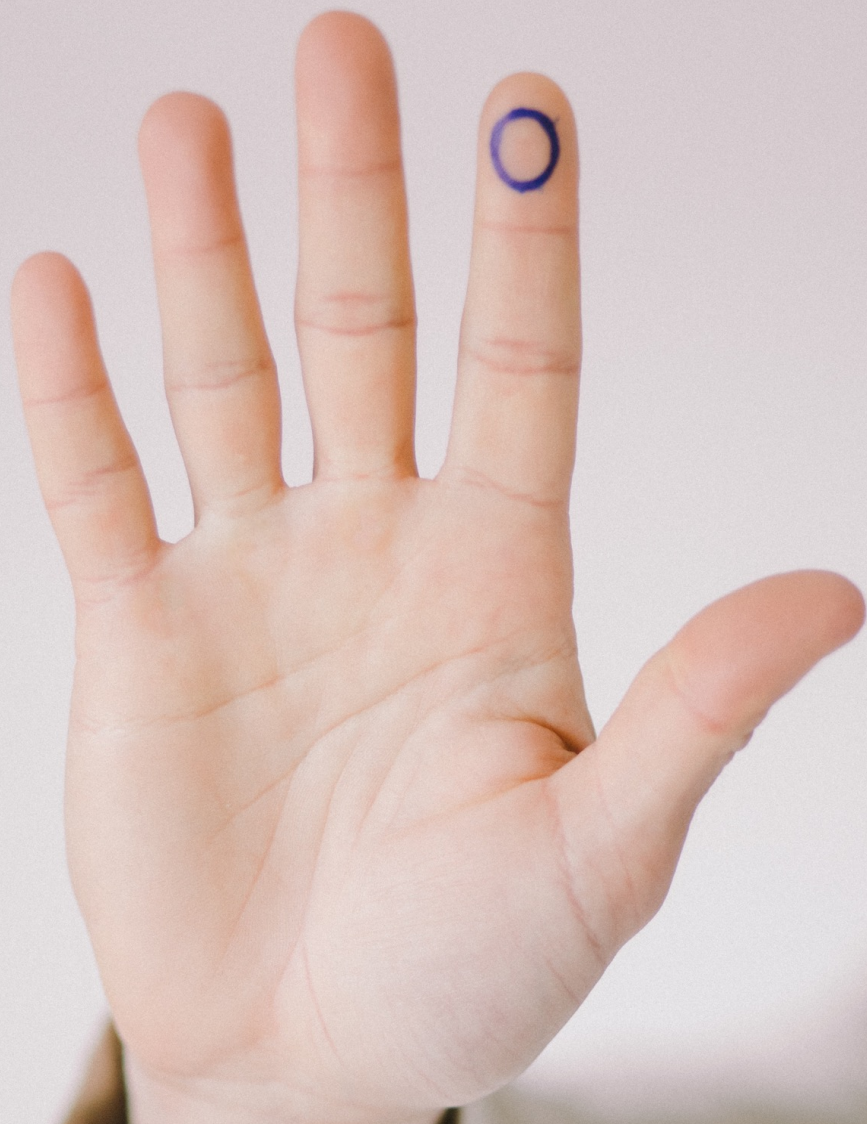


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- SamLab
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DCB Projects

- Smart Start CGM
- T1D1
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- Glucose toujours

Quality

Outlook

In the fiscal year 2022/23, we at DCB have made significant progress towards our strategy and vision thanks to the great commitment of all employees. We have made significant achievements in meeting our 5-year goals. The holocratic structure, in which the individual teams are responsible for their own work and projects and are given the corresponding freedom, has helped us a great deal.

The ongoing support from our board of directors and from Willy Michel as the benefactor has allowed us to further advance our development.

We are now collaborating with around 100 start-ups from more than 30 countries. This number demonstrates that the Diabetes Center Berne has gained recognition beyond national borders and is being perceived internationally as a centre for diabetes technology.

Prof. Dr. Lilian Witthauer and her team in the field of Smart Sensing and Prof. Dr. José Garcia and his team in the field of Closed-Loop Systems have successfully established themselves and are working on specific projects to sustainably improve the lives of people with diabetes.

The close collaboration with these two teams allows the DCB to actively promote and support the translation of research projects into user-oriented and market-oriented solutions.

The whole DCB team is already looking forward to the next Innovation Challenge, which will start in May 2023, as well as to the many new and innovative projects and start-ups we will be working with.

Derek Brandt, May 2023

Our Vision



There are various pieces that make up the puzzle of our vision and mission but it all boils down to one thing:

Making life better for people with diabetes.

Our Vision



TECHNOLOGY

We live diabetes technology.

SOLUTIONS

Together with our professorships, we translate ideas into solutions.

WELL-BEING

We make a positive impact to reduce healthcare costs and improve environmental & social wellbeing.

EXPERTISE

We close gaps by providing expertise, services, funding and a home for people with great ideas, projects and ventures.

COMMUNITY

We identify unmet needs by involving the diabetes community.

INNOVATION

We are the one-stop center to co-create diabetes innovation.

PROFESSIONAL NETWORK

We establish an international and interdisciplinary network of trusted partners to collaborate and co-create the future of diabetes management.

COLLABORATIVE MINDSET

We create an atmosphere of trust, entrepreneurial spirit, and collaborative mindset – a fun team to work with.

Number of DCB employees	22
ISO 9001:2016 certified	23.08.2022 until 22.08.2025
Number mentoring & training sessions	300
Professorships at DCB	3
Supported start-ups	61
In-house clinical studies	3
Ideas in the Innovation Challenge	66
Countries from which ideas originate	26

DCB 5-year Goals (2027)



Leading European Centre for Diabetes Technology

Professorships as a lighthouse for DCB

Established partner for clinical development

Vibrant innovation and start-up environment

DCB-supported products on the market

Great place to work

The DCB Team



We have continued to grow - all open positions have been successfully filled, which means that in 2022, 9 new team members were recruited. In total, the DCB now consists of 22 employees, including the associated research groups of Professors Lilian Witthauer (Sensing & Monitoring Lab), José Garcia-Tirado (PrecisionLab), and Maria Louisa Balmer (TrimLab).

Multiple holocratically organised teams are working together to implement the DCB vision:

- Data Science
- Innovation / Business Development
- Clinical
- Communication
- Operations
- Projects
- Research



Data Team



GOALS / ACTIVITIES / FOCUS AREAS

Building a high-performance data infrastructure and developing smart data products.

- Collaboration with start-ups and industry through statistical support
- Contributing to the development and validation of algorithms through cutting-edge data science
- Enabling the collection of clinical data through the implementation and maintenance of REDCap projects
- Building a data infrastructure to support diabetes technology research and development

The electronic data capture system REDCap (Research Electronic Data Capture) is launched: With the support of iSolutions and the IT department of the Institute of Social and Preventive Medicine at the University of Bern, REDCap, a secure, web-based EDC system, was implemented in a cloud environment (PaaS). The DCB uses REDCap to collect and manage data from various clinical research projects and medical registries.



VINCENT BRAUNACK-MAYER

Senior Data Scientist

Data science and algorithm development
API development for REDCap



MARTINA ROTHENBÜHLER

Project Lead Data Sciences

Data products and clinical data strategy
Clinical development / Regulatory affairs
Data protection

Data Team



ARITZ LIZOAIN

Junior Statistician

Data analysis
Sample size estimation
SAP writing



DOMINIQUE RUBI

Clinical Data Manager / Data Engineer

Creation of clinical research databases
Data management & engineering
REDCap maintenance / IT support

The REDCap software platform offers a flexible and customisable environment for designing online databases, creating forms and surveys, and storing research data. Moreover, REDCap allows for data sharing and exporting.

Initially developed at Vanderbilt University, REDCap is now used by researchers from various disciplines such as clinical studies, epidemiology, and social sciences. In 2022, the Diabetes Center Bern (DCB) became a consortium member of REDCap. As a consortium member, the DCB aims to provide support to partners from industry, start-ups, and universities with a range of services. These services include assistance with study design, data management and analysis, as well as technical support and help with customising and integrating REDCap into other research tools and systems.

The benefits of REDCap include its user-friendly interface, customisable data capture forms and surveys, and flexible data management capabilities.

Researchers can easily design and create their own data capture instruments using REDCap or use pre-built templates for common study designs such as case reports, surveys, and longitudinal studies. The platform also includes a robust audit trail that records all user actions and data changes, ensuring data integrity and compliance with regulatory requirements.

The platform also supports integration with third-party research tools and applications, including electronic health records and clinical study management systems. The goal is to ensure interfaces with the most commonly used diabetes devices in the future, enabling secure and seamless data transfer.

As of March 31, 2023, there were five active studies in REDCap, with two more in development.

Patient ID	Eligibility	Demographics	Diabetes And Medical History	Concomitant Medication	Physical Examination	Laboratory Parameters	Preparation
Moonwalk-02				+			
Moonwalk-03				+			
Moonwalk-04				+			
Moonwalk-05				+			
Moonwalk-06				+			
Moonwalk-07				+			

Collaboration IfDT



The Institute for Diabetes Technology (IfDT) in Ulm is a research institute specialising in clinical research in the field of diabetes mellitus. The goal of IfDT is to support and advance research and development of technologies in the field of diabetes.

The DCB and IfDT have a cooperation agreement and carry out joint projects in the field of diabetes technology with a focus on improving the lives of people with diabetes. The collaboration aims to standardise approval studies for continuous glucose monitoring (CGM) systems. The following publications were developed and published in the last year:

Stephan P, Eichenlaub M, Waldenmaier D, et al. A Statistical Approach for Assessing the Compliance of Integrated Continuous Glucose Monitoring Systems with Food and Drug Administration Accuracy Requirements. *Diabetes Technology & Therapeutics* 2023;25(3):212–6.

Eichenlaub M, Stephan P, Waldenmaier D, et al. Continuous Glucose Deviation Interval and Variability Analysis (CG-DIVA): A Novel Approach for the Statistical Accuracy Assessment of Continuous Glucose Monitoring Systems. *Journal of Diabetes Science and Technology* 2022.

Pleus S, Eichenlaub M, Gerber T, et al. Improving the Bias of Comparator Methods in Analytical Performance Assessments Through Recalibration. *Journal of Diabetes Science and Technology* 2022.

For the next year, further collaboration has been initiated for the development and conduct of a study. The study will compare different CGM systems and evaluate the necessary study designs.

Patient Registry

In the spring of 2023, the data team at the DCB is engaged in a feasibility study to integrate the Swiss Diabetes Registry. Furthermore, various possibilities to supplement and refresh the existing patient registry are being evaluated.

CGM Development

We were mandated to contribute to the development and evaluation of a new CGM. DCB's services included data processing through the implementation of automated pipelines, optimisation of the CGM sensor design through visualisations, statistical analysis and testing, characterisation of calibration functions, filtering of sensor signals and evaluation of CGM accuracy.

Influence of the menstrual cycle on insulin sensitivity

As part of a research project, the DCB conducted a systematic literature review and meta-analysis on the influence of the menstrual cycle on insulin sensitivity. The analysis indicated that insulin sensitivity is lower in the second half of the cycle. The results could be presented in an oral presentation at the ATTD conference in February 2023.

Innovation / BD Team



GOALS / ACTIVITIES / FOCUS AREAS

Creating a dynamic innovation and start-up environment

- Awareness, trending, and scouting in Diabetes Technology worldwide
- Building an international network of collaborations and a community
- Identifying unmet needs in collaboration with the community
- Ongoing support for start-ups through expertise, services, and funding
- Conducting the annual Open Innovation Challenge, events, and summer schools

Our Innovation and Business Development team evaluated over 200 ideas, proposals, and applications. Several dozen projects and start-ups were supported by the DCB, providing expertise, access to our network, facilities, and funding. The Open Innovation Challenge 2022 was successfully carried out, with 66 ideas from 22 different countries applying through our Innovation Platform. The winners in the "Diabetes Devices" and "Digital Diabetes" categories were selected during the DCB Start-Up Night on November 30th.



DEREK BRANDT

CEO

Strategy
Mentoring
Team support
Networking



GRETA EHLERS

Business Development

Business scouting & development
Start-up support & Innovation Challenge
Collaboration with SDVF
Branding

Innovation / BD Team



MAREN SCHINZ

Innovation Manager

Innovation strategy development
Connecting start-ups, science and patients
Innovation Challenge & start-up support



SIMON SCHWAIGHOFER

Business Development

Supporting start-ups
Identification and selection of new innovations
Generating partnerships + business for DCB
Collaboration with the SDVF



EMA GRABENWEGER

Innovation Manager

Innovation projects
Events
Start-up support & team support



CORDELIA TRÜMPY

Innovation / Communication

Partnership projects
Network & community
Sparring partner, mentoring

DCB Innovation Ecosystem



SENSING & SMART MONITORING



ARTIFICIAL PANCREAS & BIOLOGICAL FEEDBACK



NON-INVASIVE METHODS



DEVICES



COMMUNITY



OUTREACH



NUTRITION & METABOLISM



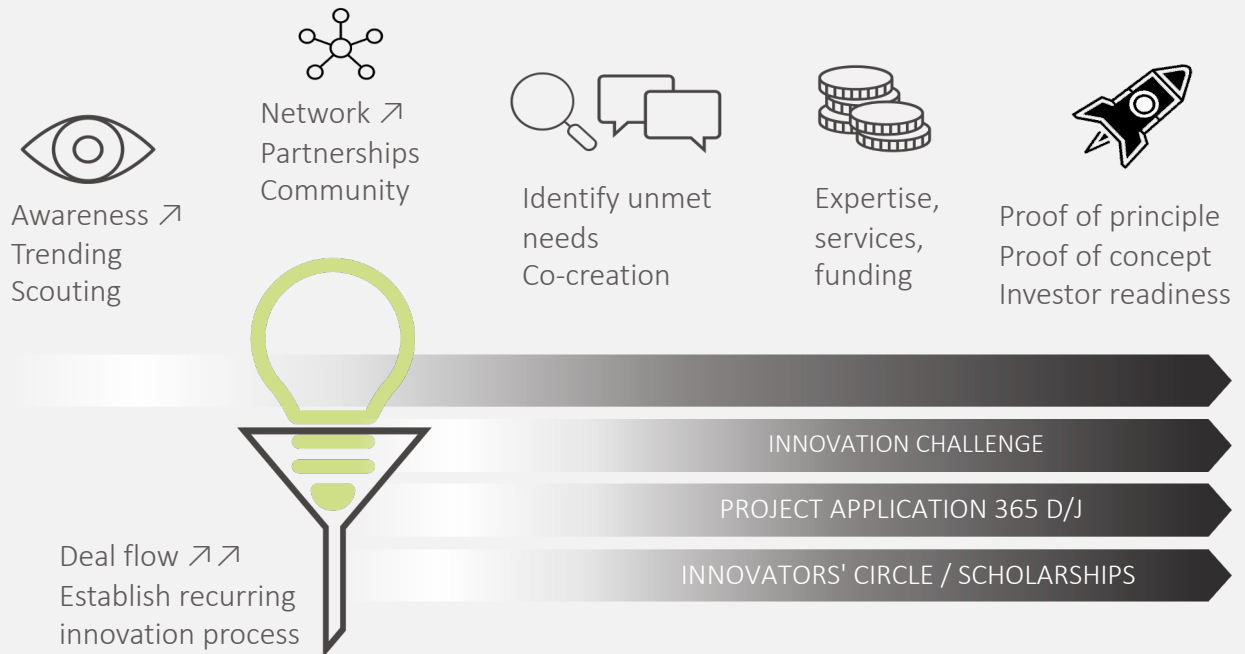
DIGITAL DIABETES



Innovation & Co-Creation



We have continued to work on creating an open innovation environment, expanding collaboration with leading start-up hubs in Switzerland and Germany and creating a strong expert panel.



Swiss Institute for Translational and Entrepreneurial Medicine



Innovation Challenge 22



The DCB Open Innovation Challenge was once again a great success! With 66 applications from 22 different countries, it contributed to expanding the vibrant diabetes tech community. The six final projects from Denmark, France, Australia, Germany, and the USA participated in a week-long bootcamp in Switzerland. The highlight, the DCB Start-Up Night & Award Ceremony, took place on November 30th. The jury selected the following two winners:

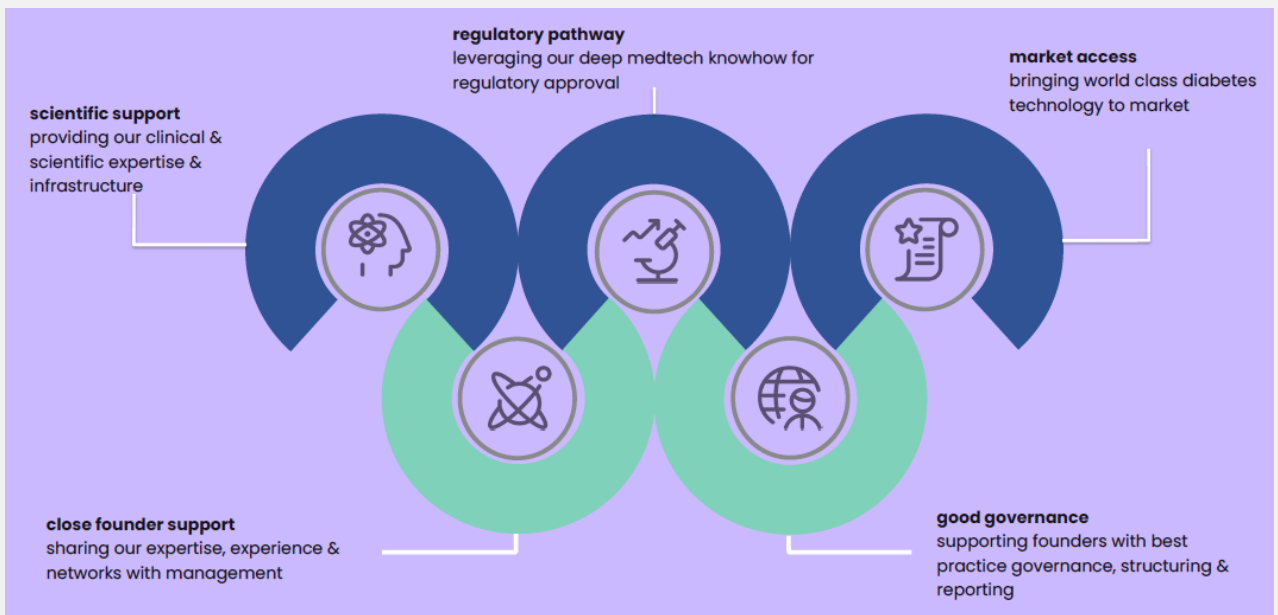
Ole Kjerkegaard Nielsen with GO-Pen ApS (Denmark, Diabetes Devices category): developing an affordable, reliable, and sustainable insulin pen.

Pascal Grimm with Una Health (Germany, Digital Diabetes category): an app for people with type 2 diabetes to understand the causes of their condition and make simple, targeted changes to improve their health sustainably.







The SDVF was launched with the aim of supporting start-ups from the DCB ecosystem and beyond. The SDVF is focused on the topic of diabetes technology and is thus the only fund worldwide that invests exclusively in this topic.

In addition to pure capital, the SDVF brings other important and value-adding aspects into the partnerships with the start-ups:



The experienced operational team, led by Investment Director Craig Cooper, is complemented by three General Partners: Simon Michel, Mike Bauer, and Derek Brandt. They independently assess each investment opportunity and make decisions regarding potential investments.

 <p>Craig Cooper Investment Director Diabetes Fund</p> <ul style="list-style-type: none"> • 25-year global career, 15+ years life sciences • led investment arm of Swiss medtech foundation • mentor/coach at European Institute of Innovation & Technology 	 <p>Derek Brandt CEO, DCB</p> <ul style="list-style-type: none"> • 25+ years experience in life sciences, CHF 350m+ exit • expertise in diabetes, medtech, clinical trials, regulatory affairs, product development 	 <p>Mike Bauer CEO, Swiss Ventures Group</p> <ul style="list-style-type: none"> • 20 years private banking experience with UHNWIs, Swiss private bank senior management • 10 years as startup investor • co-founder Swiss Startup Factory in 2015 	 <p>Simon Michel CEO, Ypsomed</p> <ul style="list-style-type: none"> • chair DCB Research AG • 20 years experience in life sciences • entrepreneurial background, several board memberships, active investor
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Current information on the investments can be found at: <https://diabetesfund.vc/>

SUPERSAPIENS

Supersapiens is a sports performance brand focused on energy management systems that enable athletes to run faster for longer.

With the Libre Sense Glucose Sport Biosensor from Abbott, Supersapiens offers meaningful fuel data through continuous glucose measurement.



Healthcare professionals are often overwhelmed by the amount of CGM data.

OTA is changing this with its AI-powered decision support tool for prioritising and treating patients, transforming data into improved outcomes and quality of life, and reducing costs for healthcare providers.



Due to diabetes and the impact of an ageing population, hard-to-heal wounds continue to be a major challenge for modern healthcare systems.

Piomic Medical has developed the COMS One therapy system to promote wound healing in chronic leg and foot ulcers.



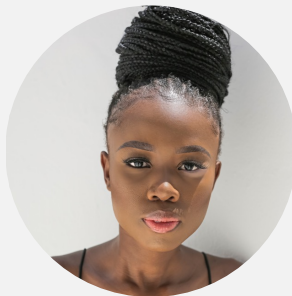
Luna Health wants to fill a big gap - automatic overnight control for people who use insulin pens.

They call it AI - Automated Injections, a way to combine the convenience of insulin pens with the clinical outcomes of automated insulin delivery.

Patient Leader Programme



How do we identify what people with diabetes really need? By involving them of course! That's exactly why we have developed the DCB Patient Leader Programme. By actively listening to the voices of the diabetes community, we want to ensure that the ideas we help develop are truly patient-centric. The DCB Patient Leader Programme now includes nine people with diabetes from seven countries.



THANK YOU VERY MUCH
FOR YOUR PARTICIPATION!



Clinical Team



GOALS / ACTIVITIES / FOCUS AREAS

Conducting clinical trials to support start-ups and research partners in evaluating the performance and safety of their ideas and products

- Conduct studies from the development of the study design to the final report
- Contribute to studies with specific knowledge in the areas of monitoring, data management, study management and/or statistics
- Simplify and improve the efficiency of clinical trial processes regarding regulatory processes and study conduct
- Advise partners on regulatory issues related to clinical evaluation strategy

First clinical trial completed: Our first clinical trial was conducted at the University Department of Diabetology, Endocrinology, Nutritional Medicine & Metabolism (UDEM), Bern, Switzerland and the Institute for Diabetes Technology (IfDT) Ulm, Germany. In this study for an insulin pump manufacturer, we were responsible for the entire clinical process, from the creation of the clinical study plan, the submission of the approval by the ethics committee, the provision of materials, site monitoring, data cleaning and analysis to the preparation of the study report.



MARIE-ALINE GÉRARD

Clinical Research Scientist

Clinical project management
Quality management



STEFANIE HOSSMANN

Clinical Research Scientist

Clinical research management
Regulatory affairs



STEFANIE HOFER

Clinical Research Physician

Clinical strategy development

Clinical trial design

Medical device evaluation / consulting services



REGULA SCHNEIDER

Clinical Research Associate

Monitoring of clinical trials

Enforce clinical trial guidelines and regulations

Support clinical trial set-up

Collaboration with and support of sites



CONSTANCE BISCHOFF

Clinical Research Associate

Monitoring / enforcing clinical trial guidelines and regulations / clinical trial set-up support

Collaboration with and support of sites

Contributing clinical experience



MARTINA ROTHENBÜHLER

Project Lead Data Sciences

Data products and clinical data strategy

Clinical development / regulatory affairs

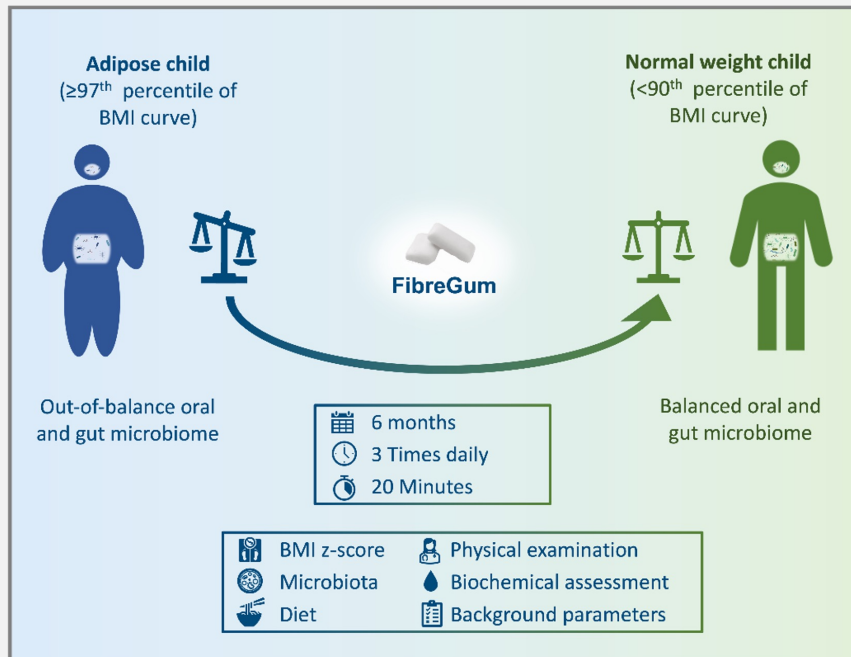
Data protection

Approximately one in six children in Switzerland is affected by overweight or obesity, and the prevalence continues to increase. This rise in obesity and its associated comorbidities represents a significant socio-economic burden, as it leads to increased morbidity and mortality. Obesity is not only a chronic disease but also one of the main risk factors for the most common causes of poor health and premature death worldwide, including cardiovascular diseases, various types of cancer, diabetes, and osteoarthritis.

Preventing obesity in children and adolescents offers a unique opportunity to prevent the path towards an unhealthy adulthood. A low-threshold offering could be the key to success. For this reason, in collaboration with Delica AG, a fiber-enriched chewing gum called "FibreGum" has been developed. The aim of FibreGum is to improve microbial diversity and promote beneficial metabolic products while reducing snacking. To investigate the effectiveness of this chewing gum, a randomized, placebo-controlled clinical trial is being conducted with a cohort of 105 obese children and adolescents.

Project status:

The study was approved by the Cantonal Ethics Committee of Bern on November 18, 2022. The first participant was enrolled on January 9, 2023, and so far, 10 children/adolescents are participating in the study. The results of the study are expected to be available by the end of 2024.



Project team:

Prof. Dr. Maria Luisa Balmer, Inselspital (University Hospital Bern) and University of Bern (Project Lead); Dr. Christoph Saner, Children's Hospital, Inselspital (University Hospital Bern); Dr. Marco Janner, Children's Hospital, Inselspital (University Hospital Bern); Prof. Dominik Meinel, University of Applied Sciences Northwestern Switzerland; Dr. Alexandra Stähli, Dental Clinics Bern (University of Bern); Valentina Huwiler, Inselspital (University Hospital Bern) and University of Basel; Marie-Aline Gérard, Diabetes Center Berne

Project funding:

Diabetes Center Berne (Research Project), Von Tobel Foundation (Research Project), Walter Fuchs Foundation (Research Project), Swiss National Science Foundation

Background

Regular blood glucose measurements are part of the daily life and burden of people with diabetes mellitus. New technologies for measuring blood glucose levels can help reduce the burden of invasive methods of glucose monitoring. One possible solution could be the detection of disease- or metabolism-specific chemical signatures from volatile organic compounds (VOCs) to detect a drop in blood glucose levels. Currently, little is known about the relationship between specific VOCs and glucose metabolism, as well as the potential of such technologies. Sensing low concentrations of VOCs requires sensitive and selective sensors. Chemiresistive sensors, such as metal oxide semiconductor sensors, are already used in clinical settings and show promise for detecting low-concentration VOCs. The sensor we are investigating in the VAARA study changes its resistance properties when it interacts physically or chemically with VOCs or other environmental gases. We are studying the device's measurements of VOC changes in relation to changes in blood glucose levels.

The study

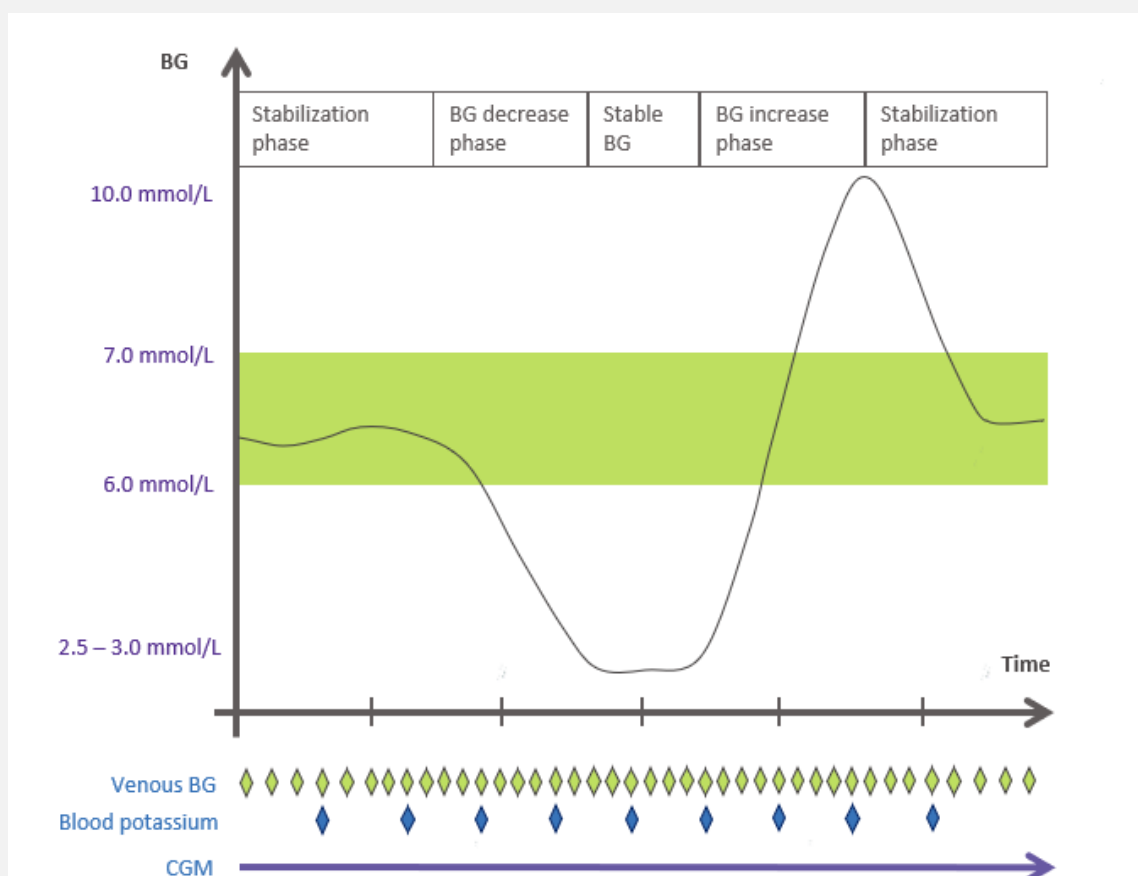
The Sokru device is currently a prototype and is being tested in 10 participants who undergo the study procedure twice. During a study procedure, the blood glucose (BG) of voluntary individuals living with type 1 diabetes is lowered through the injection of insulin to induce hypoglycaemia. The main objective of the clinical study is to determine the signal characteristics of VOCs captured by the Sokru device that are associated with a decrease in blood glucose levels and hypoglycaemia.

Study status

The study was approved by the Ethics Committee and Swissmedic on February 21, 2023. The participants will be recruited and examined in the second quarter of 2023.

Project funding

Diabetes Center Berne (research project) and Lakka Health AG (manufacturer).



Definition of clinical processes

We have developed a set of standard operating procedures (SOPs) for our clinical activities, which are essential. This ensures consistency and compliance with Good Clinical Practice / ISO 14155 and the high quality of research conducted and/or supported by DCB.

Clinical trial advice

We were available to provide start-ups in the Innovation Challenge with support and advice on planning their clinical trials and clinical evaluation of their medical devices. This service was widely used and included detailed advice on how to conduct the study under good clinical practice, as well as identifying an optimal study design to best demonstrate the effectiveness of the medical device.

Advice on regulatory matters

We have been available to various start-ups and other (academic) partners on regulatory issues relating to the marketing authorisation/placing on the market of medical devices.

Communication



GOALS / ACTIVITIES / FOCUS AREAS

Communicative support for the activities and positioning of the DCB, from the conceptual strategic basis to the practical implementation on various communication channels, tailored to the relevant target groups of the DCB.

- Responsibility for the DCB communication strategy, continuous adaptation and implementation via DCB communication channels and stakeholders
- Ensure consistency of the DCB's corporate design, corporate identity and tone of voice
- Providing up-to-date information on the activities of the DCB and in the field of diabetes and diabetes technology through the various communication channels
- Ensure consistent and clear communication across all channels

Communication Team



The new DCB corporate website was launched at the end of January. The DCB newsletter on LinkedIn was continued and published every three weeks. DCB was able to position itself in various media such as newspapers (Sunday newspaper) and magazines (D-Journal).



SUNJOY MATHIEU

Communications Manager

Corporate communications
Communications strategy
Media relations
Content strategy (website, newsletter etc.)
Project management

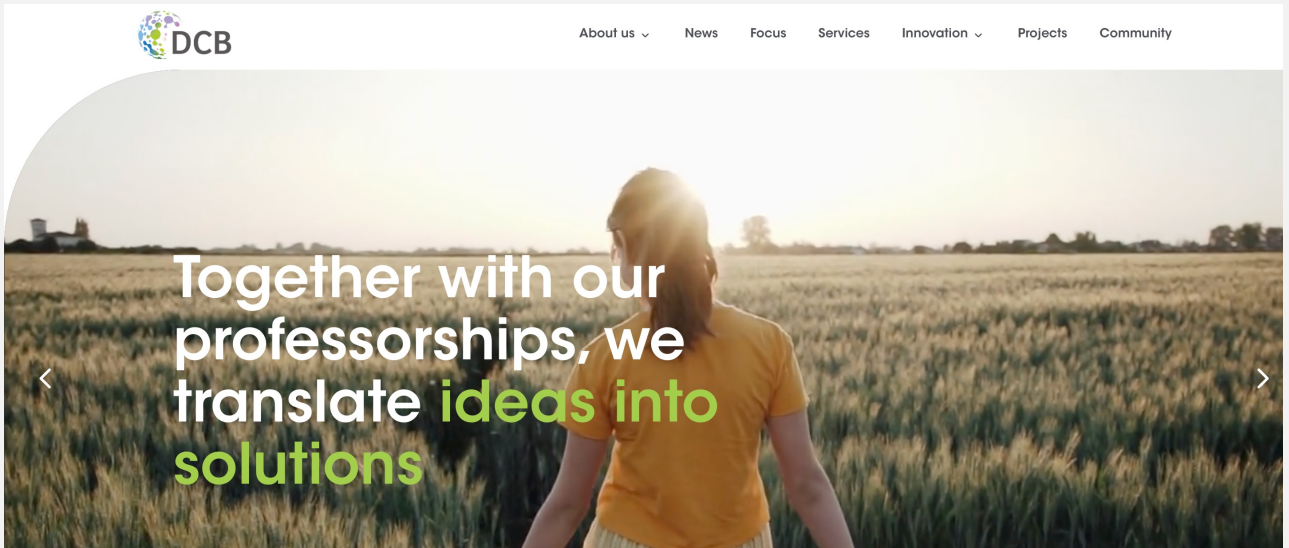
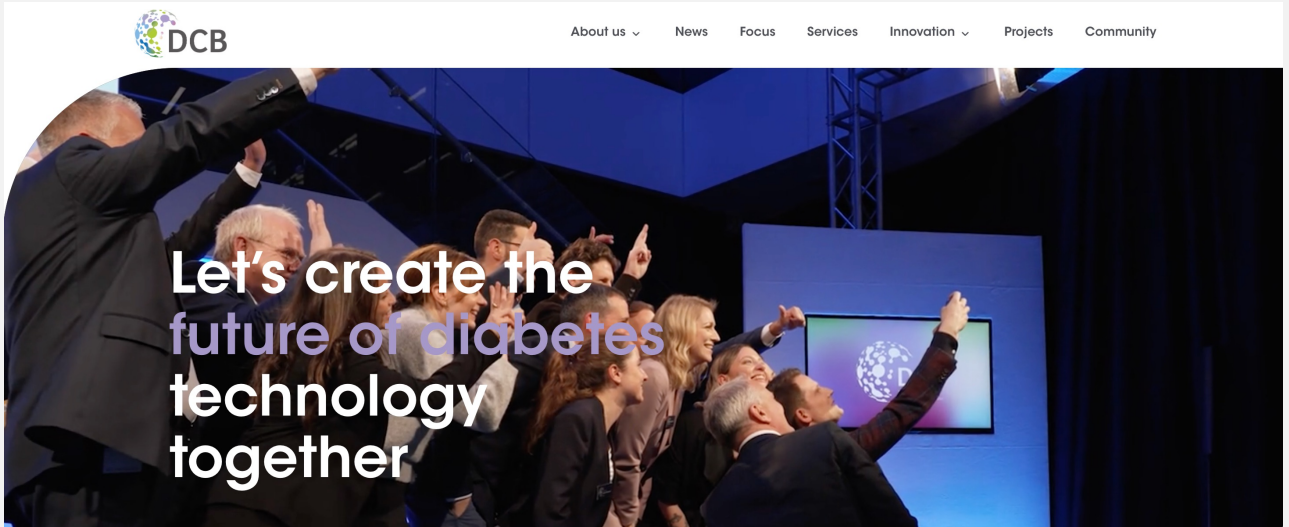


GRETA EHLERS

Business Development

Business scouting & development
Start-up support & Innovation Challenge
Collaboration with SDVF
Branding

Launch Website



DCB About us News Focus Services Innovation Projects Community

Vision & Mission

The Diabetes Center Berne (DCB) is a private, independent Swiss foundation established by Willy Michel in 2017 with the aim of making life with diabetes easier.

DCB supports ideas and projects in the field of diabetes technology worldwide by providing expertise, access to clinical research facilities and its own laboratories, as well as financial resources. The goal is to bring these ideas closer to market entry in a collaborative partnership. The work of the DCB is non-profit: the goals are new insights and innovations around diabetes management as well as a vibrant community.

DCB About us News Focus Services Innovation Projects Community

Focus areas

DCB specifically focuses on supporting the following highly innovative, but not yet fully academically established research areas. These are areas that are developing rapidly and thus have a correspondingly high academic, translational and industrial potential.

- Artificial Pancreas & Biological Feedback**
This highly innovative research area strives to develop systems that can take on the role of the human pancreas.
- Sensing & Smart Monitoring**
The research area Sensing & Smart Monitoring aims to improve the management of diabetes with the help of new innovative sensor solutions.

DCB About us News Focus Services Innovation Projects Community

Our projects

From idea to implementation, DCB supports and funds project activities and innovations with partners and researchers that are blazing new trails in the area of diabetes.

- APPLIED CLINICAL DIABETES RESEARCH**
 - CLINICAL STUDIES
 - IN PROGRESS
 - CLINICAL TRIALS
 - RESEARCH PROJECTS
- APPLIED CLINICAL DIABETES RESEARCH**
 - CLINICAL STUDIES
 - IN PROGRESS
 - CLINICAL TRIALS
 - RESEARCH PROJECTS
- APPLIED CLINICAL DIABETES RESEARCH**
 - CLINICAL STUDIES
 - IN PROGRESS
 - CLINICAL TRIALS
 - RESEARCH PROJECTS

The FibroScan study - Changing the course of obesity
The goal of our study is to assess weight reduction in obese children and adolescents by demanding the gut.

SmartStart Health: Unlocking life-changing benefits of CGM in diabetes
DCB and SmartStart Health collaborate to identify and address a world-first patient education mobile app to increase.

SGI12 inhibitor therapy for type 1 diabetes—the effect of dapagliflozin on...
Analysis of SGI12 leads to increased insulin-independent elimination of glucose in the kidneys. In the use.

FACHBEITRAG

Diabetes-Technologie: Mehr Lebensqualität durch Innovation

Am Diabetes Center Berne (DCB) wird an neuen Technologien zur Behandlung von Diabetes geforscht und Ideen zur Marktreife verholfen. Wie kann dies das Leben von Menschen mit Diabetes verbessern?

Weltweit leben über 537 Millionen Menschen mit Diabetes, was für die Betroffenen eine stetige Herausforderung im Alltag bedeutet. Technologische Innovationen leisten hier einen wichtigen Beitrag, das Leben mit Diabetes zu erleichtern. Sei es zur Messung des Glukosespiegels oder zur Planung der benötigten Insulinmenge über eine App. Doch trotz der enormen Fortschritte in der Diabetestechnologie besteht immer noch ein grosser ungedeckter Bedarf an innovativen, technischen Lösungen. Ziel ist es dabei, dass Menschen mit Diabetes die täglichen Herausforderungen besser meistern können und dies zu einer nachhaltigen gesundheitlichen Verbesserung führt.

Mit dieser Vision wurde 2017 das Diabetes Center Berne (DCB) von Willy Michel, dem Gründer von Ypsomed, ins Leben gerufen und durch 50 Millionen Franken aus seinem privaten Vermögen finanziert. Über drei Professuren, in Kooperation mit der Universität Bern und dem Inselspital, sollen Forschungsgebiete im Bereich der Diabetestechnologie gefördert werden. Im Fokus stehen die Entwicklung von Systemen, welche die Funktion der menschlichen Bauchspeicheldrüse übernehmen können und die Erforschung der kontinuierlichen, verzögerungsfreien und präzisen Messung von Glukose.

Für diesen Forschungsschwerpunkt konnte mit Prof. Dr. phil. Lilian Witthauer die erste Professorin an der Universität Bern besetzt werden. In ihrem Sensing & Monitoring Lab, kurz samlab, entwickeln Witthauer und ihre Forschungsgruppe neue Sensoren, die unter anderem den Blutzuckergehalt in Echtzeit messen. Die Sensoren basieren auf verschiedenen optischen Technologien. «Mit unserer Forschung zu Echttzeit-Glukosesensoren streben wir

eine verbesserte Kontrolle der Blutzuckerwerte an zu erreichen, um die Gesundheit von Menschen mit Diabetes positiv zu beeinflussen», so Witthauer. Neben der Sensorentwicklung befasst sich das samlab auch mit der Auswertung von Sensordaten, die durch intelligente Algorithmen das Leben von Menschen mit Diabetes verbessern sollen.

GEZIELTE START-UP FÖRDERUNG

Mit seinen Aktivitäten hat das DCB bereits internationale Ausstrahlung erlangt. Dies zeigte sich bei den Teilnehmenden und Gewinnern der jährlich stattfindenden Open Innovation Challenge aus über 35 Ländern. Ziel der Challenge ist, innovative

Projekte auf schweizerischer und internationaler Ebene im Bereich Diabetesmanagement gezielt zu fördern.

Die teilnehmenden Start-ups profitieren von Experten-Feedback. Die besten Projekte in den Kategorien Diabetes Devices und Digital Diabetes werden in eine Trainingswoche eingeladen, in der sie ihre Lösungen mit persönlichen Coaches weiterentwickeln können. Den Finalisten winkt ein Preisgeld von bis zu 100'000 US-Dollar. Die DCB Innovation Challenge gehört zu den weltweit grössten Awards im Bereich Diabetes.

Der diesjährige Gewinner in der Kategorie Diabetes Devices ist GO-Pen, ein Start-up aus

Dänemark, das spezielle und kostenoptimierte Insulin-Pens entwickelt. Während in der Schweiz Insulin-Pens als kostengünstige und sichere Geräte weit verbreitet sind, müssen sich weltweit 13 Millionen Menschen mit Diabetes immer noch jeden Tag Insulin über Einwegspritzen verabreichen. Genau hier setzt «Go-Pen» mit seiner Innovation an und verbessert den Zugang für eine grössere Anzahl an Betroffenen.

In der Kategorie «Digital Diabetes» gewann das Start-up Una Health, das sich zur Aufgabe gemacht hat, die Gesundheit von Menschen mit Typ-2-Diabetes nachhaltig zu verbessern. Mit Una Health lernen Menschen mit Typ 2 Diabetes, wie Ernährung und Bewegung ihren Blutzuckerspiegel beeinflussen. Spielerisch wird gezeigt, wie sie mit einfachen Mitteln ihre Gewohnheiten positiv und nachhaltig beeinflussen können.

INNOVATIVE PROJEKTIDEEN GESUCHT

Haben Sie ein Anliegen oder die Idee im Bereich Diabetes-Technologie? Teilen Sie diese mit dem Diabetes Center Berne (DCB)! Egal, ob Sie eine Privatperson, ein Start-up oder eine Fachperson aus dem Gesundheitswesen oder der Forschung sind. Entscheidend ist, dass es im Leben von Menschen mit Diabetes einen Unterschied macht.



Die diesjährige DCB Start-up Night der Open Innovation Challenge 2022, inklusive Gewinner GO-Pen und Una Health.

KONTAKT
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3010 Bern
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www.dcberne.com



16 | Forschung

Menschen mit Diabetes im Mittelpunkt

Diabetesforschung soll sich an Patientenbedürfnissen orientieren. Deshalb involviert das Diabetes Center Berne (DCB) möglichst viele Menschen mit Diabetes in seine Aktivitäten und sucht weltweit nach innovativen Projekten und neuen Erkenntnissen, die das Leben mit Diabetes erleichtern.

Autoren: Sunjoo Mathieu

Das futuristisch anmutende Gebäude, in welchem sich das Diabetes Center Berne (DCB) befindet, spricht für dessen zukunftsorientierte Aktivitäten. Hinter langen Glasfassaden führen offene Treppenhäuser zu Räumlichkeiten, in denen sich verschiedene Teams für eine Forschung einsetzen, die für Diabetesbetroffene transparent und zugänglich sein soll. Anders gesagt: Gearbeitet wird nach dem translatonalen Forschungsansatz, was bedeutet, dass Forschungsergebnisse und neu entwickelte Produkte sowie Technologien auf direktem Weg in die (klinische) Anwendung und zu den Diabetesbetroffenen gelangen.

Das DCB ist eine private, unabhängige Schweizer Stiftung, die 2017 mit dem Ziel gegründet wurde, Menschen mit Diabetes das Leben zu erleichtern. Das DCB unterstützt in der Schweiz und weltweit innovative Ideen und Projekte im Bereich der Diabetestechnologie, indem es das bestehende Fachwissen, den Zugang zu klinischen Forschungseinrichtungen und eigenen Labors sowie finanzielle Mittel bereitstellt. Die Projekte sollen in partnerschaftlicher Zusammenarbeit auf dem Weg zum Markteintritt unterstützt werden.

Eine eng wissenschaftliche Partnerschaft besteht zwischen dem DCB und der Universitätsklinik für Diabetologie, Endokrinologie, Ernährungsmedizin und Metabolismus (EDEM) des Inselspitals Bern sowie mit dem Institut für Diabetes-Technologie (IDT) in Ulm. Zudem sind mit der Universität Bern drei neue Professuren im Bereich Diabetestechnologie geplant. Eine erste Professorin konnte mit Prof. Dr. phil. Lilian Witthauer (Schwerpunkt Sensortechnologie) bereits erfolgreich besetzt werden.

Die Arbeit des DCB ist nicht gewinnorientiert. Das ist wichtig für die unabhängigen Aktivitäten zur Entwicklung neuer Erkenntnisse und Produkte rund um das Diabetesmanagement. Dazu gehört die Förderung einer lebendigen Community (Gemeinschaft) zum Thema Diabetes und Technologie. Das DCB gründete ein eigenes «Patient Leader»-Programm (patientenorientiertes Programm) zur direkten Einbindung, Unterstützung und Vernetzung von Menschen mit Diabetes. Somit stellt das DCB sicher, dass die umgesetzten Ideen den Patientenbedürfnissen entsprechen. Zusätzlich erhalten die «Patient Leaders» die Möglichkeit, neue Technologien in einer frühen Entwicklungsphase zu testen und Feedback zu geben. Sie sind auf den Kommunikationskanälen des DCB präsent, werden in ihren eigenen Aktivitäten unterstützt und mit einem interdisziplinären Netzwerk in Kontakt gebracht.

Durch das DCB unterstützte Projekte

Neue Erkenntnisse, die das Leben von Menschen mit Diabetes erleichtern, stehen auch im Zentrum der vom DCB aktuell unterstützten Projekte, wie die folgenden Beispiele zeigen.

SmartStart Health: Patientenaufklärung zur kontinuierlichen Glukosemessung (CGM)

Mit der kontinuierlichen Glukosemessung (CGM) entfällt zwar das häufige kapilläre Messen des Blutzuckerspiegels, aber die CGM kann zu einer Überforderung führen. Plötzlich ist man täglich konfrontiert mit unabhigen Daten, Trendpfeilen und Alarmeinstellungen, die nicht immer intuitiv verständlich sind. Die Betroffenen sind



Blick in das Diabetes Center Berne: Eine Studentinlehramt wird zu Forschungszwecken in eine Hypoglykämie (Unterzuckerung) versetzt.

sich bewusst, dass ihnen die CGM hilft, zu hohe und zu niedrige Blutzuckerwerte zu vermeiden. Es herrscht aber eine grosse Verunsicherung darüber, wie man die guten Ergebnisse erreichen kann. Dank Schulungen können Menschen mit Diabetes die Daten der CGM-Systeme gut verstehen und nutzen. Somit können sie in Absprache mit der Ärztin oder dem Arzt die richtigen Behandlungseinsparungen treffen.

Die CGM-App von SmartStart Health informiert und unterstützt Diabetesbetroffene mit interaktiven, kleinen Lerneinheiten, die auf realen Lebenssituationen basieren. Die App wurde unabhängig von Sensorherstellern entwickelt und funktioniert mit verschiedenen Marken von Sensoren. Geplant

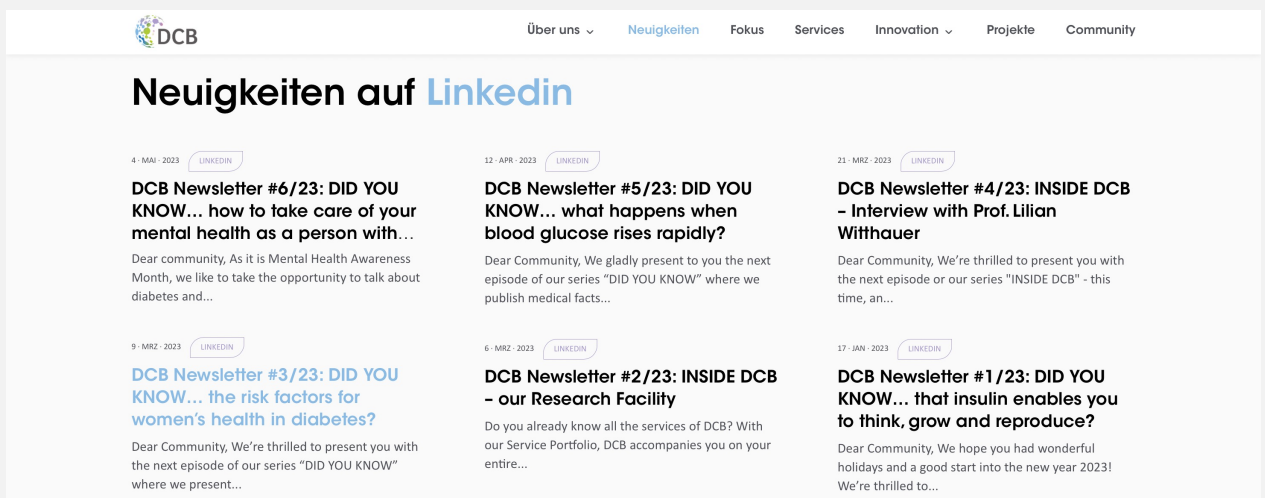
ist zudem ein Telemedizin-Portal für medizinische Fachpersonen, damit sie die Patientinnen und Patienten im Alltag optimal unterstützen können.

Das Unternehmen SmartStart Health wurde von Melissa Hoffmann, selbst auch Diabetikerin, gegründet. Die benutzerfreundliche Smartphone-App wird aktuell getestet und perfektioniert. Diabeteszentren in den USA und in der Schweiz evaluieren die App mit Unterstützung des DCB. Die Ergebnisse der Evaluation sollen bis Mitte 2023 veröffentlicht werden. Danach wird die CGM-App in diversen Sprachen, auch in Deutsch, zum Herunterladen bereitgestellt.

Mehr zu SmartStart Health und ein CGM-Quiz finden Sie unter: <https://smartstart.health>

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The DCB LinkedIn newsletter continues to be published regularly and counted almost 1000 subscribers in March 2023. The newsletter is published every three weeks on both LinkedIn and the website and provides information on current topics in research and diabetes technology as well as DCB activities.



Neuigkeiten auf LinkedIn

- 4. MAI - 2023** **DCB Newsletter #6/23: DID YOU KNOW... how to take care of your mental health as a person with...**
Dear Community, As it is Mental Health Awareness Month, we like to take the opportunity to talk about diabetes and...
- 12. APR - 2023** **DCB Newsletter #5/23: DID YOU KNOW... what happens when blood glucose rises rapidly?**
Dear Community, We gladly present to you the next episode of our series "DID YOU KNOW" where we publish medical facts...
- 21. MRZ - 2023** **DCB Newsletter #4/23: INSIDE DCB – Interview with Prof. Lilian Witthauer**
Dear Community, We're thrilled to present you with the next episode of our series "INSIDE DCB" - this time, an...
- 9. MRZ - 2023** **DCB Newsletter #3/23: DID YOU KNOW... the risk factors for women's health in diabetes?**
Dear Community, We're thrilled to present you with the next episode of our series "DID YOU KNOW" where we present...
- 6. MRZ - 2023** **DCB Newsletter #2/23: INSIDE DCB – our Research Facility**
Do you already know all the services of DCB? With our Service Portfolio, DCB accompanies you on your entire...
- 17. JAN - 2023** **DCB Newsletter #1/23: DID YOU KNOW... that insulin enables you to think, grow and reproduce?**
Dear Community, We hope you had wonderful holidays and a good start into the new year 2023! We're thrilled to...

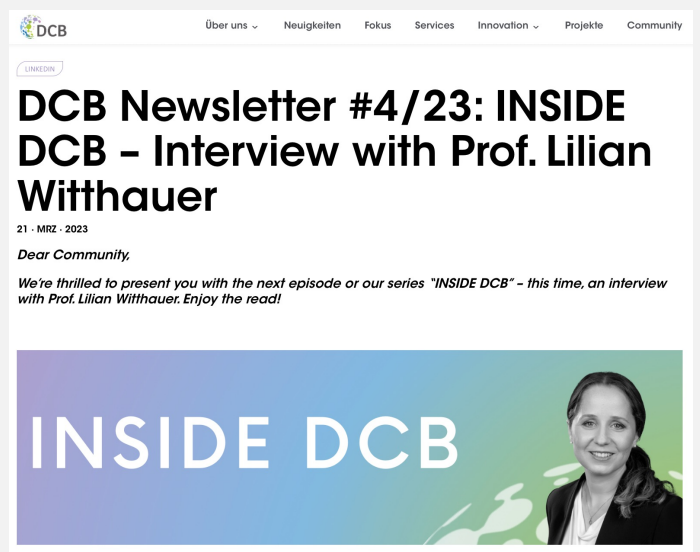


DID YOU KNOW?

DCB Newsletter #3/23: DID YOU KNOW... the risk factors for women's health in Diabetes?

 **Diabetes Center Berne**
2,710 followers

March 8, 2023




DCB Newsletter #4/23: INSIDE DCB – Interview with Prof. Lilian Witthauer

21 - MRZ - 2023

Dear Community,

We're thrilled to present you with the next episode of our series "INSIDE DCB" - this time, an interview with Prof. Lilian Witthauer. Enjoy the read!

INSIDE DCB



Operations Team



GOALS / ACTIVITIES / FOCUS AREAS

Finances / HR

Implementation of the strategy and business plan and ensuring accounting and financial reporting in compliance with laws and regulations

Facility and Laboratory Management / EHS

Ensure the smooth operation of the DCB facility and its equipment, ensure health and safety and provide project implementation services

Quality Management

Ensure compliance with ISO 9001 requirements and support effective and efficient workflows

Operations Team



LORENZ BURKHALTER

CFO / COO

Finance
HR
Operations



REBEKKA HIRSCHI

Team Assistant

Team assistance
HR and Finance assistance
Training manager



CORINNE NYDEGGER

Finance / Operations Assistant

Finance assistance
Facility management
Safety Officer

Project Team



GOALS / ACTIVITIES / FOCUS AREAS

- Development of the QARBS app
- CE approval according to ISO 13485
- Validated food database



Project Team



MYRIAM TINNER

Product Manager

Project management QARBS
Regulatory and product development
support for start-ups



MELANIE STOLL

Nutrition Specialist

Responsible for food database and
nutrition topics

Research



Associated research groups:

- **SamLab** (Sensing & Monitoring Lab) led by Prof. Dr. phil. Lilian Witthauer
- **PrecisionLab** led by Prof. Dr. José Garcia-Tirado
- **TrimLab** led by Prof. Dr. Maria Louisa Balmer



PROF. DR. PHIL. LILIAN WITTHAUER
Tenure Track Professor



DR. EHSAN HASSANPOUR YESAGHI
Postdoc



CAMILO MENDEZ SCHNEIDER
Research Fellow



MAHSA NASEHI
Research Fellow

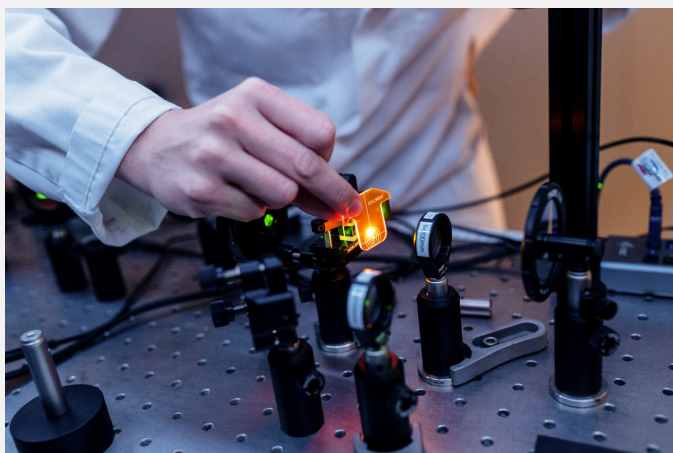


CLEO NICOLIER
Research Associate

The first project to be successfully initiated was the Moonwalk pilot study, which investigates the relationship between blood glucose levels and hypoglycaemic symptoms during sleep.



Another project is focused on the development of a sensor that measures the glucose level in the blood continuously and without delay. The instantaneous measurement is of special interest when the blood glucose level changes rapidly, during meals, sports or stress. The glucose sensor is based on a light-based measurement method and therefore uses the physical properties of the glucose molecule.





PROF. DR. JOSÉ GARCIA-TIRADO
Tenure Track Professor



MARIA CAROLINA FRAGOZO-RAMOS
PhD Student GCB



CLARA ESCORIHUELA ALTABA
PhD Student

DR. VIHANGKUMAR NAIK
Postdoc



PROF. DR. MARIA LUISA BALMER
SNSF-Eccellenza Professor, Group Leader



MELANIE SCALISE
PhD Student



VALENTINA HUWILER
PhD Student



ANNINA FELDER
Master student



DR. DISHA TANDON

Postdoc



JASMIN VILLARS

Bachelor student



GABRIELA BLEUER

Bachelor student

DCB Projects

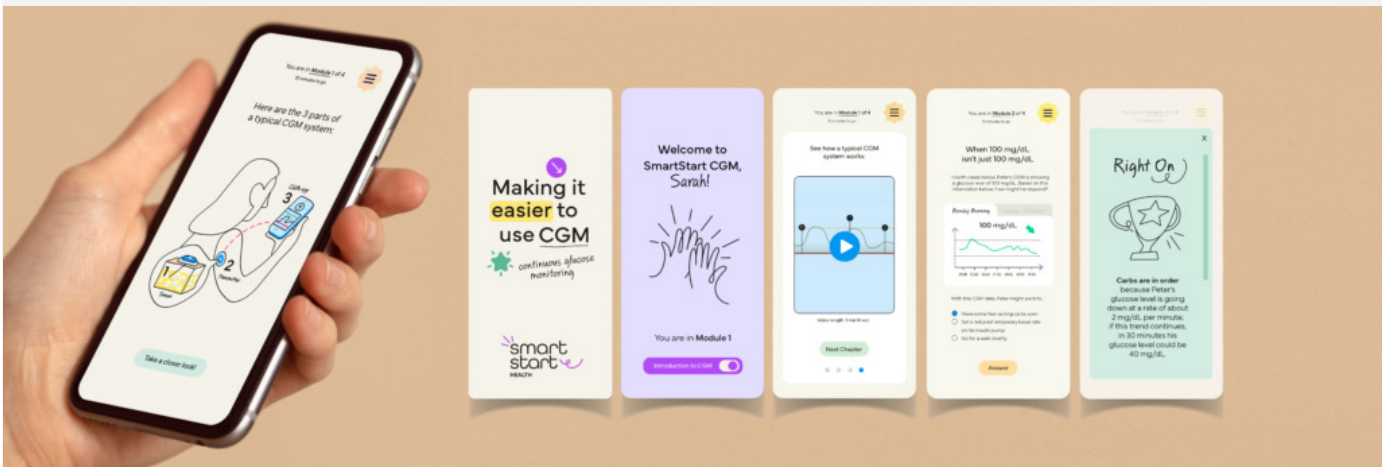


- SmartStart CGM
- T1D1 (Type 1 From Day 1)
- Enhance-D
- CarbVis & Qarbs APP
- Glucose toujours

DCB and SmartStart Health collaborate to develop and validate a world-first patient education mobile app to increase knowledge and improve outcomes among people with diabetes using continuous glucose monitoring (CGM). The aim of the app is to improve the know-how of people with diabetes who use continuously measuring glucose sensors (CGM) and thus improve therapy results.

Overwhelming amount of CGM data

When people with diabetes/caregivers start using CGM to gain tighter diabetes control, they face a steep learning curve, regardless of how many years they have lived with diabetes. They're overwhelmed by hundreds of data points per day, trend arrows and fine-tuning settings for alerts and alarms. They are aware that CGM can be a powerful tool for minimising high and low blood glucose levels and improving their quality of life, but they aren't sure how to achieve these outcomes. Without timely support to use CGM effectively, people with diabetes/caregivers may see CGM data as clear documentation of diabetes management challenges they feel they cannot overcome.



SmartStart CGM as an innovative solution for CGM education

Education is important for people using CGM to be able to understand and use CGM data to make appropriate treatment decisions that lead to quality of life benefits as well as improvements in diabetes outcomes. SmartStart Health is rising to the challenge of CGM-specific patient education with SmartStart CGM, a user-friendly smartphone app. Supported by DCB, diabetes centres in the US and Switzerland will evaluate the new scalable solution in a proof-of-concept study. The partnership aims to analyse the results in Q3 2022 and publish by mid-2023.

The SmartStart CGM app is designed to inform and empower users with interactive micro-learning based on real-world scenarios that reflect the reality of living with diabetes. A telehealth portal for healthcare professionals will enable clinicians to assess patient engagement with the programme.

Project team:

Melissa Holloway (Founder & CEO), Kieron Heath (Operations), Effra Digital (Technology consultant), Will Hargreaves (Business development), Jamie Welsh (Content development)

Funding:

DCB supports SmartStart Health with 100k CHF funding

T1D1 – an app by the youngest participant of the Open Innovation Challenge

When Drew Mendelow from Washington D.C. was diagnosed with type 1 diabetes in 2020, he began searching for a suitable app for his diabetes management. Realising that there was no existing solution in the market that met all his needs, the 13-year-old at the time decided to take matters into his own hands and program his own app: T1D1 (Type 1 from Day 1).

The DCB is supporting the project with expertise and funding to prepare the necessary documentation for the T1D1 app to be approved by the FDA (USA) and the European Union under the Medical Device Regulation (MDR).

The app currently has over 45,000 downloads and many thousands of users daily. The approval is necessary for the continued use of the app and to be able to offer an adequate app solution to more people with diabetes in the future - both in the USA and in Europe.



SAFE becomes Enhance-D

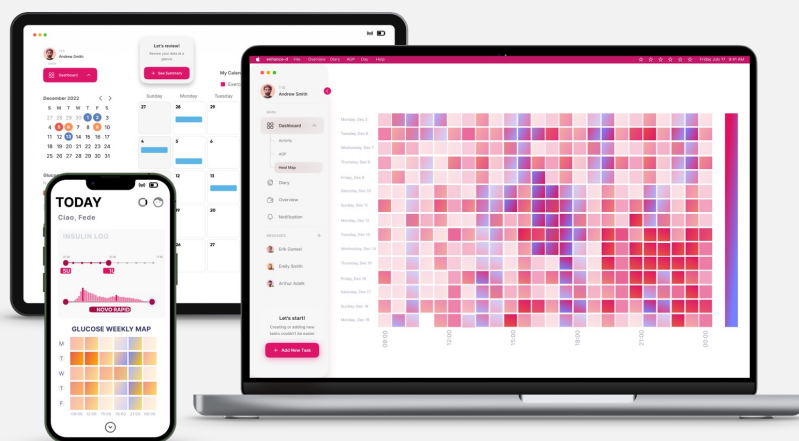
In autumn 2021, two dedicated scientists contacted the DCB and requested support. Their goal was to consolidate and present all available activity, nutrition, and therapy data (CGM, insulin, etc.) collected in one app, providing a clear overview and simple analysis.

It is well-known and scientifically proven that nutrition and exercise have a significant impact on blood sugar levels or glucose levels in interstitial fluid. Currently, if one wants to know how exercise or food intake affects their current glucose levels, it must be done manually. In the best case, one would enter their meals or exercise sessions into the CGM and/or insulin pump app. However, more detailed information about nutrition values or the intensity of exercise sessions is lost. Additionally, the overview reports from CGM apps become very cluttered (line graphs) when they span more than one day.

Based on their previous experience working with professional athletes with diabetes, they are familiar with the challenge of creating optimal training plans considering all influencing factors. They wanted to develop a solution that could generate a simplified overview for everyone, whether professional athletes or individuals simply starting regular exercise.

The app should be designed in a way that both people with diabetes and medical professionals can quickly identify opportunities for therapy adjustments, optimize dietary habits and training times, or identify the influence of other events.

After the corporate design and identity had been defined and the customer needs had been integrated into the app, the beta version was delivered for testing. Enhance-D stands for improved self-management for people with diabetes using a simple digital solution.



Today, Enhance-D is a recognised Innosuisse project, one of the first start-ups for the T1D moonshot programme, part of Start-Up Health and supported by the Helmsley Charitable Trust.

Project team: Federico Fontana (Founder & CEO), Sam Scott (Founder & CSO), Fabio Saviozzi (Founder & CCO), Felipe Mattioni Maturana (Founder & CTO).

Project support: DCB supports Enhance-D financially with 150'000 CHF as well as with access to our network of experts and our knowledge in product development.

The past 12 months were dedicated to implementing the new computer vision pipeline and improving usability. Through various expert interviews, the user interface was enhanced and adjusted to meet the needs of the users.

To generate optimal images for volume calculation, different concepts were explored to achieve an ideal user experience. With the current concept, it is now possible to capture an accurate image without the need for a depth sensor on the smartphone (starting from iPhone 12 Pro). The captured images can then be processed by the network for volume calculation.

Our own validated food database currently includes over 750 different food items and can be expanded as needed. The integrated localized search function allows users to find foods that may have different names in different language regions (e.g., the word for beetroot in Swiss German “Rande” vs. “Rote Beete” in German). Where official density values are not available, we conducted our own measurements to make the database as comprehensive as possible.

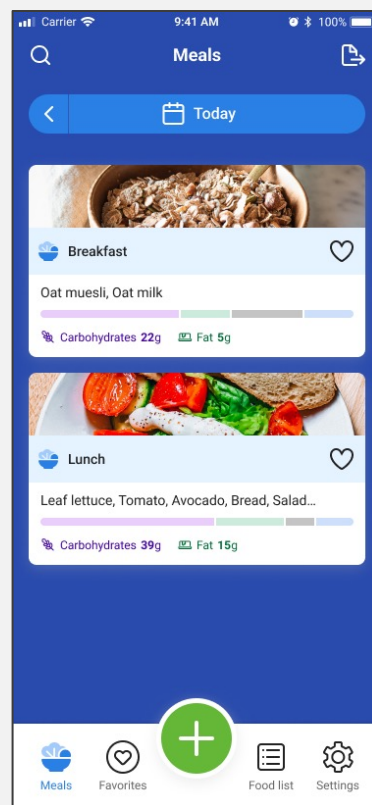
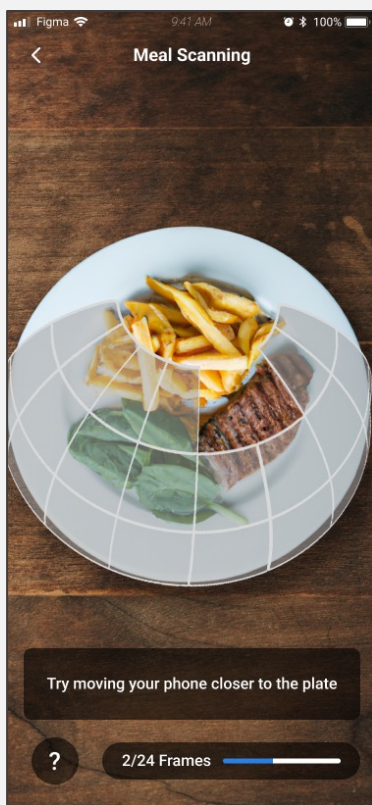
In the performance study, a total of 525 scans were conducted, and all of them fully met our requirements. These scans were performed by 11 different individuals who were unfamiliar with the app. After successfully completing the performance tests, we proceeded with the usability testing as required by regulations. One of the critical tasks was repeated in a new version.

CarbVis & Qarbs APP



The first quarter of 2023 was dedicated to documentation. The final documents, such as the Clinical Evaluation, Risk Analysis, and Validation and Verification Summary Report, were prepared, and Version 2 is now ready to obtain MDD Clearance and subsequently achieve MDR Clearance. The dossier will be submitted in calendar week 19.

Project team: Simon Schwaighofer (CEO of CarbVis), Melanie Stoll (DCB, Nutrition Scientist), Myriam Tinner (DCB, Product Manager), Egemen Vardar (comerge AG, Project Manager), Andreas Pedroni (comerge AG, Regulatory), and other employees at comerge AG.



Glucose toujours is an independent, dedicated, and entertaining media platform providing information about diabetes. Each week, a team of journalists, authors, and artists "decodes" diabetes news from around the world. The platform is supported by the DCB as both institutions are committed to innovations in the field of diabetes and support the latest diabetes technology projects.

Through original contributions, research, and interviews, Glucose toujours challenges the conventional coverage of diabetes and changes the way diabetes is discussed in the press. Glucose toujours is funded by its readership, who can subscribe to support the work of the editorial team. For the DCB, this collaboration is the perfect complement to support new approaches and innovative content about diabetes.

Glucose toujours

le media qui en dit long
sur le diabète

L'info de la semaine

L'histoire d'un des premiers patients à prendre du teplizumab pour retarder l'apparition du diabète de type 1.

En couverture

Guy Fagherazzi : "La boucle fermée ne fait pas disparaître le



Quality

DCB is ISO 9001 certified:

The certification body, SQS, conducted the certification audit on August 16, 2022. We successfully passed the audit without any findings, and the certification was granted.

The certification is valid until August 2025, with an annual maintenance audit required. The first audit is scheduled for the second quarter of 2023.

Quality Management System:

Since April 2022, DCB has implemented a flexible, process-oriented, and electronic Quality Management System (QMS) based on ISO 9001:2015. It incorporates general quality processes as well as clinical core processes based on ICH-GCP. Various functions, such as review and approval processes, can now be carried out electronically, making training processes more manageable and improving the competence level of employees.





At DCB, we work focused on our long-term goals within the framework of our vision. Only by successfully implementing the numerous initiatives and projects and bringing them to the market can we create value for those affected by diabetes through diabetes technologies. Specifically, this means the following:

The DCB Innovation Challenge is on its way to becoming one of the most renowned awards in the field of diabetes technology internationally. We will continue and further optimize this challenge in the coming years to support innovators and start-ups in bringing their products and solutions to the market, thereby achieving a positive impact for people with diabetes.


Conducting clinical studies forms the backbone of our work in translational research. Our goal is to "translate" technologies into development and the market, supported by efficient clinical studies starting from the research and ideation phase, to generate value for people with diabetes. Therefore, we will also work intensively in this area to expand our expertise and broaden our international network.



We will also continue to strengthen and develop partnerships with established medical technology companies, researchers and start-ups internationally. This is an important element in promoting the networking of innovators with partners who can implement these ideas on the market. We see a great opportunity here, because established companies are always looking for creative approaches and start-ups need strong partners to bring them to market; for us, this is another way of translating, of building bridges.

The whole world is talking about artificial intelligence (AI/CI). But this can only be implemented if the corresponding database is consistent and of high quality. We are working with our data team and in various initiatives to create and further expand this database, so that the advantages of artificial intelligence can be fully used for the benefit of people with diabetes. For example, in the form of suggestions and advice in daily life and in the more than 100 additional decisions that a person with diabetes has to make every day as part of diabetes management.



A close-up photograph of a hand with a blue circle drawn on the index finger. The hand is positioned against a light, blurred background. The blue circle is a simple, thin-lined ring, representing the universal symbol for diabetes.

The blue circle is the universal symbol for diabetes. It was introduced in 2006 to give diabetes a common identity. The symbol is intended to:

- Support efforts that raise awareness of diabetes
- Raise awareness of diabetes among the general public
- Show support in the fight against diabetes

