



# ACCESS & ACCELERATION



New momentum for  
the healthcare sector



# Interreg

Deutschland - Danmark



EUROPEAN UNION

This project is supported by Interreg Deutschland-Danmark with funds from the European Regional Development Fund.

## Preface

The aim of the Access & Acceleration project is to provide an overview of the relevant players within the medical innovation sector in the German-Danish border region (*access*), and to signpost ways to speed up the cycle of medical innovation (*acceleration*).

In the last three years, the Access & Acceleration project has examined both the fundamental barriers to market entry and the innovation process in the healthcare sector. The results were integrated into a digital platform where users from the clinical, academic and industrial sectors can find the skills to develop new ideas and to create new products for the healthcare markets in Denmark and Germany.

The partners participated in pilot projects, pursuing the innovation process from the ideation stage to testing and evaluation, right through to the prototype phase. All of the stages were also documented on the platform. The platform also contains examples of good cooperation between research institutions, hospitals and companies. A database linking regional stakeholders offers the opportunity for future cooperation and the further use of the platform even after the end of the project.

**We wish you a pleasant reading**

**Prof. Horst-Günter Rubahn, SDU, lead partner and the Access & Acceleration consortium**

### Project profile

- Seven project partners: Universities, research institutions, companies and clusters
- Running from 2019 to 2022
- Budget: €2.9 million
- Supported by: €1.7 million from Interreg Deutschland-Danmark



## Innovations in healthcare

Changing conditions in the healthcare sector, such as demographic change, rising cost pressures and unmet medical needs, mean we need to develop new, innovative approaches to health technologies. Megatrends such as digitalisation, additive manufacturing, integrated and personalised healthcare and the use of robotics and deep learning in a supporting role, as well as automated medical diagnostics and therapy, all open up opportunities for new solutions.

We can no longer rely on traditional innovation processes for success. Current innovation approaches are often driven by technology and engineering, ignoring the current market requirements. The challenges are becoming increasingly complex when it comes to understanding the expectations, needs and expertise of potential partners in all areas of integrated care. It is also becoming harder to compete with ever-shorter innovation cycles.

Against this backdrop of constantly changing requirements, sharing and exchanging knowledge is increasingly important. Various areas of the healthcare industry, research and new technologies, as well as the field of innovation management, require specialist expertise. Companies are also particularly reliant on support to gain access to professional experts and innovation partners.

“Cross-border cooperation opens up new opportunities, facilitates access to novel research results and increases the speed of innovation. It is important to promote technologies that have been developed with and for patients and ultimately lead to decentralized diagnostics and treatment in our future healthcare system.”

*Anna-Marie Bloch Münster,  
Medical director  
Sydvestjysk Sygehus  
Region Syddanmark*

## Ideation

To create sustainable healthcare innovations that meet actual requirements, we need to involve doctors and other relevant healthcare providers in the innovation process. In an ideation drive across Germany, the Chair of Technology Management at Kiel University examined how the systematic involvement of physiotherapists in the ideation process helps to increase acceptance and willingness to innovate.

The initiative was carried out in collaboration with the German Institute for Therapy Research (DIT) and the Kiel-based company Buchner & Partner (B&P). In addition, the Kiel University has scientifically investigated the use of health innovations among physiotherapists and in hospitals.



The results of the scientific research will be available on the Access & Acceleration project website and will provide a useful basis for improving the involvement of healthcare providers in the innovation process.

[www.accessinnovation.eu/publications.html](http://www.accessinnovation.eu/publications.html)

### 1st phase:

1

Conducting 20 interviews and an online survey of 181 German physiotherapists to determine the effect of including physiotherapists in the ideas process and to identify the current challenges in post-care treatment. This and the following idea drive were promoted by B&P with a newsletter and two articles in the trade journal UP – Unternehmen Praxis. Over 3000 physiotherapists were contacted using the B&P and DIT networks.

### 2nd phase:

2

The 80 registered participants had the opportunity to submit ideas to help with the challenges identified. Submission was to a secure, digital ideas platform (only accessible by registration), which was provided by Nosco.

### 3rd phase:

3

The participants then condensed the ideas they had collected. On the platform, participants had the opportunity to evaluate each idea on the basis of four criteria (innovativeness, feasibility, benefit for patients and benefit for the therapists).

### 4th phase:

4

The participants validated and analysed the feasibility of the top three ideas in a workshop. As an incentive, the participants who created the top three ideas were given the opportunity to further develop the concepts for their ideas, either as part of study projects or as part of another workshop with B&P and Kiel University.

“This cross-border cooperation makes it possible to combine input from two different healthcare systems, to increase the joint potential for innovation and to facilitate cross-border market access. For example, the cooperation between German and Danish players offers a unique opportunity to allow excellent expertise and knowledge to be incorporated into a new value chain, leading in turn to accelerated innovation in both regions that would not be possible if they were to work alone.”

*Carsten Schultz, Kiel University,  
Institute for Innovation Research,  
Chair of Technology Management*

## Gamma4 with ADAPT – product development at Stryker

*Gamma4 with ADAPT* unites partners from universities, clinical practices and the medical technology industry in the German-Danish border region, with the aim of improving the care and clinical practice around geriatric hip fractures.

Stryker Trauma GmbH specialises in the development and production of trauma surgical implants and instruments, for example for treatments using cepha/intramedullary nailing. Medullary nails stabilise broken bones very effectively using a comparatively simple and gentle surgical technique.

The gamma nail has been developed to provide rapid, stable treatment of geriatric hip fractures. Now in its fourth generation, the focus is on innovations that will simplify operational challenges for users. The process uses the ADAPT digital assistance system, which supports the operation and makes it safer, with automated X-ray image analysis and increased position accuracy.

Product safety and quality are paramount in the development of medical devices. All legal and regulatory requirements of the global target markets must be met. This includes a large number of safety and quality-specific verifications that are part of the development process: During the design and phase reviews of the development process, defined in quality management procedures, the evidence is developed, documented and regularly reviewed and approved at each step.

The development of every product is supported by the findings from a continuous innovation process rooted in knowledge.

The product development process follows defined phases, each with several design reviews assigned by topic. A new phase only begins after a phase review has been completed and approved. The project phases ensure that the required framework is completed for optimum product specification, quality control, production, testing (verification and validation), clinical evaluation and regulatory approval procedures.



## Prototype development for Gamma4 and ADAPT 2.1

Cooperation partners from universities and clinical practices were involved in both the innovation and development processes of the project. Two students from the University of Southern Denmark (SDU) contributed to the foundational knowledge for the innovation process with their Master's theses, with a focus on simulation. In total, more than 50 trauma surgeons participated in design reviews and prototype testing in the form of operation simulations on human specimens, and contributed to optimising the designs.

### Elements of the development process

Research phase	Planning	Development	Verification and validation	Launch
Feasibility studies	Design input and performance requirements	Product specifications	Marketing materials	Training modules
Project and development plan	Risk management plan	Product master records	Evidence of usability	Product approvals
Customer and product requirements	Design concepts	Packaging checklist	Evidence of verification and validation for product and process	Logistics approvals
Regulatory plan	Risk assessment	Functional interface analysis	Labelling and instructions for use	Early Product Surveillance
Resource plan and schedule	Investment plan for process design	Finality analysis and design transfer plan	Clinical evaluation	
Financial plan, including order-volume plan	Labelling plan	Verification and validation reports	Technical records	
	Update of documentation from the previous phases	Product and process freeze	Regulatory approval process	
		Update of documentation from the previous phases	Update of documentation from the previous phases	

## Clinical decision support based on health records

Most individuals suffering from Alcohol Use Disorder (AUD) never undergo specialist treatment during their addiction due to the poor performance of conventional AUD identification methods, the lack of systematic screening for alcohol problems, and the stigmatisation associated with harmful drinking. Qualitative studies have shown that hospital staff wishes to be rather sure that alcohol use plays a vital role for the patients' health issues before starting a conversation about alcohol and the benefits of reducing its intake.

The recent availability of Electronic Health Records (EHR) and the advancement of Machine Learning (ML) algorithms have made it easier to offer clinical reasoning when advising patients. The Access & Acceleration partners have developed a data-driven decision support system (AUD-DSS) based on EHR for early detection of patients with AUD, powered by ML algorithms. The currently developed ML models can detect AUD-positive and AUD-negative patients with an accuracy of 93 % using a Random Forest algorithm. Models have further been developed using Neural Network algorithms for early detection (18 months before AUD) of hazardous and harmful drinkers with an overall accuracy of 87 % – 89 %.

The AUD-DSS enables hospital staff to become aware that excessive alcohol use might be a complicating factor and encourages them to have a conversation with the patient and offer help if needed.

### Innovation collaboration

- Partners involved from computer engineering, clinical research, and the hospital data centre
- Propose and develop novel approaches based on ML algorithms that aids in the early detection of patients with AUD
- 6 scientific publications and 3 conference talks

### In a nutshell

- **Output:** Data-driven decision support system for early detection of patients with AUD
- **Outcome:** Statement on AUD probability
- **Impact:** Security for hospital staff to address and advise hazardous and harmful drinkers resulting in an expected increase of AUD treatments

"The main pitfall we faced was within data collection. It proved well to closely collaborate with OUH data centre. However, difficulties remain in transferring the predictive model to other hospitals as well as feeding in a broader data base in order to improve accuracy."

*Ali Ebrahimi,  
Mærsk Mc-Kinney Møller Institute,  
University of Southern Denmark*



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## Market access

### Barriers to accessing the Danish and German healthcare markets

To successfully enter the healthcare market, it is important for both Danish and German companies to understand the healthcare sector of the other country and to pursue clear strategies. We identified three significant barriers to market access for companies:

1. Compliance with European and national regulations and laws (e.g. MDR)
2. Lack of knowledge of the underlying structure of the foreign healthcare system
3. Lack of knowledge about financing opportunities to support companies

### The road to a roadmap

- › Two online surveys with 51 participants
- › Two workshops with 29 participants
- › Qualitative interviews with ten participants with contributions from a wide range of companies, institutions and research institutions

### A roadmap to overcoming the barriers to market entry

The *Roadmap to market* was developed to support companies that want to supply the Danish and German healthcare markets with their innovative products. This is an online, interactive instrument that provides:

- Relevant information on the Danish and German healthcare markets
- Strategic proposals to overcome barriers to market entry
- Background information and a library of links for successful market entry



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## An innovation platform for the healthcare sector

This project yielded results which could facilitate innovations in the healthcare sector. It also collected useful information from other healthcare-based projects, as well as contacts and practical examples. We have developed an online platform to make all this data available to as many players in the healthcare sector as possible.

It provides information on expertise, background information and case studies for interdisciplinary and cross-sector cooperation throughout the innovation process, and is aimed at small and medium enterprises, scientists in hospitals and public institutions, as well as advisory institutions within the healthcare sector.

### The platform in brief

- › Ideation including user engagement
- › Database of expertise in the region
- › Advertisements for matchmaking events
- › Information on financing options
- › Background information on regulatory framework conditions
- › Tips for accessing the Scandinavian or German healthcare market
- › Case studies for innovation partnerships



WWW.ACCESS-PLATFORM.EU

## How to network with us

The results of the Access & Acceleration project were achieved through interdisciplinary, cross-sectoral and cross-border cooperation. Our partners have outstanding competencies and are open to new innovation partnerships.

- › Research projects
- › Student projects
- › Educational projects
- › Development partnerships
- › Consulting projects

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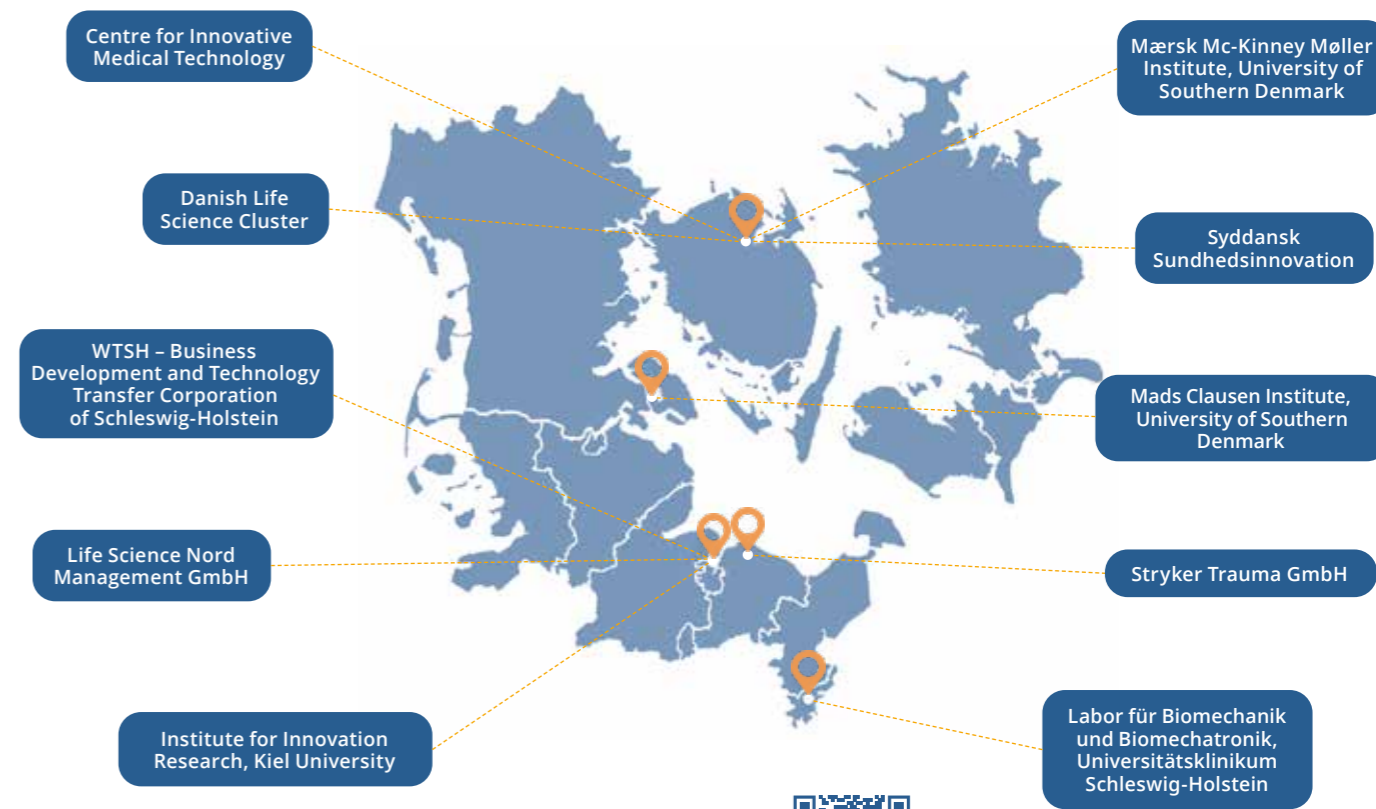
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## Competences in the region



More companies and institutions in the database of our platform. Scan me



## Competences in the region

### Centre for Innovative Medical Technology

- Development, test, evaluation and implementation of innovative medical technologies
- Organisation and implementation of medicorelated research projects
- Documentation for investments in innovative medical technologies by use of Health Technology Assessment (HTA)

### Danish Life Science Cluster

- Networking nationally and internationally with focus on welfare and medical technology, pharma, biotech and life sciences
- Health data and digitalisation
- Personalised medicine

### Kiel University, Institute for Innovation Research, Chair of Technology Management

- Innovation management in healthcare
- User innovation and acceptance
- Management of open innovation eHealth, telemedicine and AI applications in healthcare

### Labor für Biomechanik und Biomechatronik, UKSH

- Test facilities for medical devices, (implants, endoprotheses)
- dynamic and quasi-static testing of biotechnical materials

### Life Science Nord Management GmbH

- Systematic networking between business and science in the life sciences
- Consultations: start-ups, techtrans, strategy development, fundraising

### Mads Clausen Institute, University of Southern Denmark

- Biomedical imaging
- Sensortechnology
- Centre for Materials Analysis and Characterisation
- Photonics engineering

### Mærsk Mc-Kinney Møller Institute, University of Southern Denmark

- Centre for Clinical Robotics
- Centre for Artificial Intelligence
- Robots and drones
- artificial intelligence, software engineering and energy informatics
- health informatics

### Stryker Trauma GmbH

- Production of medical devices
- Services for medical care

### Syddansk Sundhedsinnovation

- PPO Innovation and cooperation
- Knowledge centre
- Participatory assessment for new technologies

### WTSH – Business Development and Technology Transfer Corporation of Schleswig-Holstein

- Regional bio- and medicoinnovation consultancy
- Startup funding and financing

## Imprint

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### Project management

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