2024

BETA-HEALTH®

MIDWAY REPORT RESULTS & IMPACT

IRISgroup

This report is prepared by IRIS Group

IRISgroup

This publication has been prepared by IRIS Group for the Novo Nordisk Foundation and summarises the results of a midterm evaluation of the BETA.HEALTH programme.

It is based on a survey distributed to all project teams that have received grants during the first four calls, as well as in-depth interviews with a large number of stakeholders within the clinical innovation ecosystem.

Moreover, the evaluation makes use of background information in terms of grant applications and statistics gathered by the BETA.HEALTH team during the first two years of the programme.

A more detailed evaluation report can be downloaded from **www.irisgroup.dk.**

Read the report by using this QR code:

November 2024

BETA.HEALTH®

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Why BETA.HEALTH?

Denmark is a global leader in clinical research. Measured in terms of research output and the quality of clinical research, Denmark consistently ranks among the top in the world. Additionally, Denmark is a highly digitalised country with access to unique clinical data sources. The country is also home to a large and thriving life science cluster, supported by a distinctive ecosystem that enables healthtech companies to grow and scale.

Despite these strengths, Denmark has struggled to translate research into healthcare solutions that can be effectively implemented in clinical practice. Many new products have been developed outside of hospitals and with limited input from clinicians and patients, leading to significant challenges when attempting to integrate them into hospital settings.

Moreover, while clinical researchers in Denmark excel at leveraging research potential, they often lack the competences needed to translate their research into real-world innovation. Elsewhere in the sector, healthcare professionals and hospital leaders have been primarily focused on achieving operational excellence and efficiency.

With a healthcare system facing severe challenges with respect to demography and the integration of new treatments (e.g. personalised medicine), accelerating the development and implementation of new solutions is essential. The BETA.HEALTH programme was created to address this need, bridging the gap between research and practical innovation in healthcare.

The programme combines three tracks designed to foster successful clinical innovation:

- Establishing innovation hubs within hospitals, close to both research and clinical practice.
- Introducing a new approach to innovation funding in which grants for innovation are paired with continuous mentorship from innovation experts and experts from the surrounding life science ecosystem.
- Capacity building through ‘Academy’ master-classes and workshops aimed at providing clinicians with critical innovation skills.

BETA.HEALTH is a pilot programme running from 2022 to 2026. The total budget is 129 million DKK. It is organised around two primary teams based at Rigshospitalet and Aarhus University Hospital, and hubs at Odense University Hospital, Zealand University Hospital and Aalborg University Hospital. A national steering committee sets the overall direction, supported by a national review committee responsible for reviewing applications.

The ecosystem for clinical innovation

BETA.HEALTH is a new and crucial brick in the Danish ecosystem for clinical innovation. It bridges research and solutions ready to implement and fills the gap between research and other programmes relevant to healthtech entrepreneurs.

In healthtech, the road from idea to market is often long and costly. This means that BETA.HEALTH must work in synergy with other programmes and initiatives. At the same time, it is crucial for BETA.HEALTH to establish a strong foothold within the clinical innovation ecosystem, including close collaboration and seamless transitions.

The role of BETA.HEALTH in relation to this ecosystem is twofold: 1) to bridge the gap between clinical research and the implementation of new healthcare solutions; and 2) to tap into the ecosystem to match clinical innovation projects with the right expertise, partners and investors.

The illustration on page 9 provides an overview of funds and programmes supporting clinical research and innovation at various stages of the innovation journey. The programmes displayed in the upper part of the illustration are available to all types of projects, while those in the lower part are most relevant for projects involving the formation of a startup.

As indicated, a few programmes specifically target clinical innovation, while most take a broader approach. BETA.HEALTH stands out as the only programme dedicated to healthtech and medtech that covers the early phases of innovation. Moreover, the programme is unique in the sense that it addresses all stages from ideation to implementation.

The figure also illustrates that the ecosystem provides a combination of soft capital (grants), loans, and equity as well as acceleration services – including 1:1 coaching, networking, matchmaking, and access to labs.

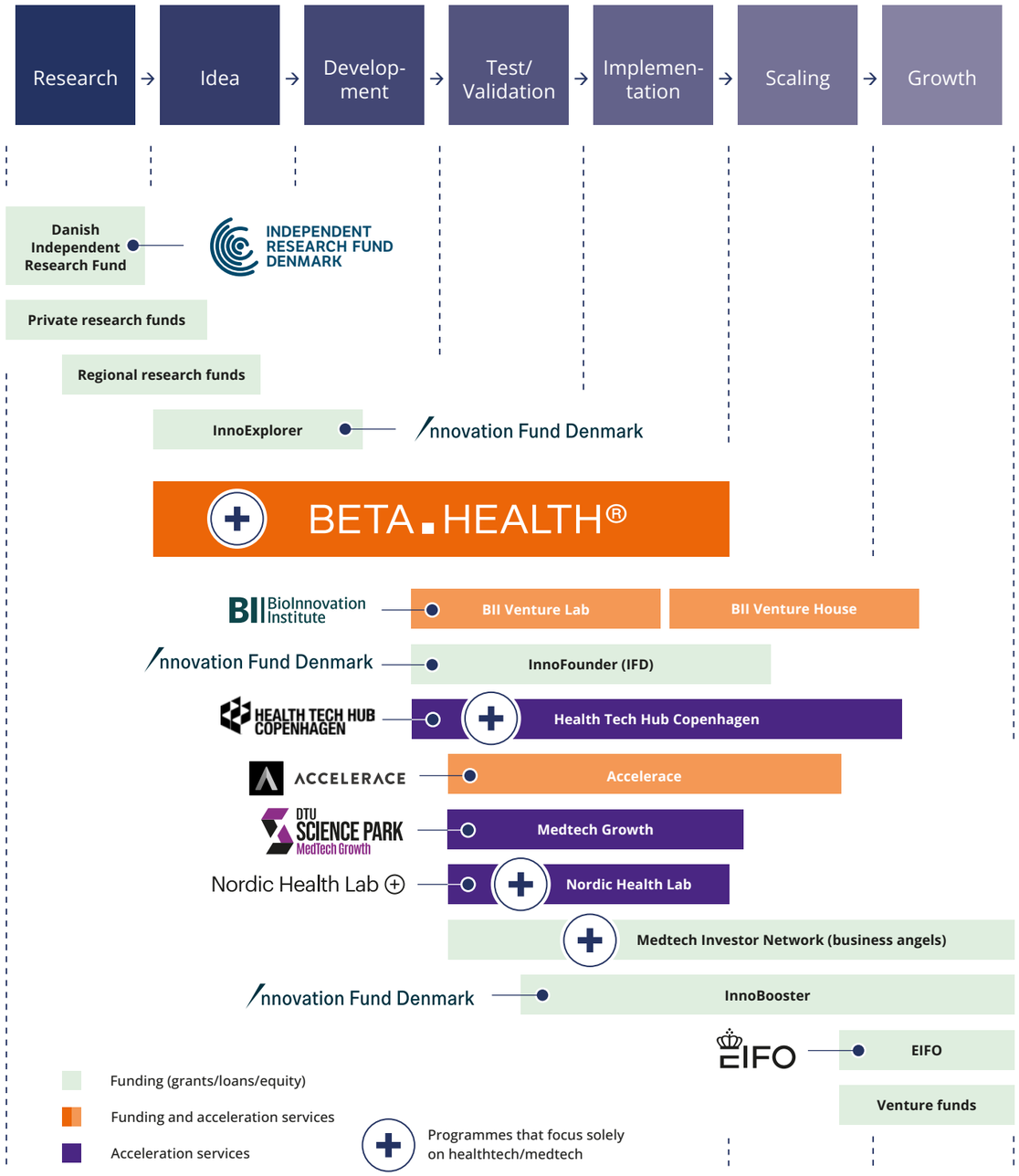
BETA.HEALTH has significantly enhanced the ecosystem's capacity to foster successful innovation. The programme offers access to acceleration services at several stages of the innovation journey. Additionally, clinical innovation projects can now secure early-stage funding much more easily.

For some projects, support from BETA.HEALTH helps advance the solution to a stage where it can be implemented in clinical practice. For other projects, BETA.HEALTH matures the solution and reduces the risk to a degree where other stakeholders are ready to offer grants or risk capital and provide further acceleration services.

”We see high potential for BII Venture Lab as a platform to support BETA.HEALTH startups. BETA.HEALTH plays a very important role, as there are no other programs specifically aimed at innovation among clinicians”.

— Tony Cheng-fu Chang
Principal, BioInnovation Institute

Funding and acceleration service



The BETA.HEALTH value proposition

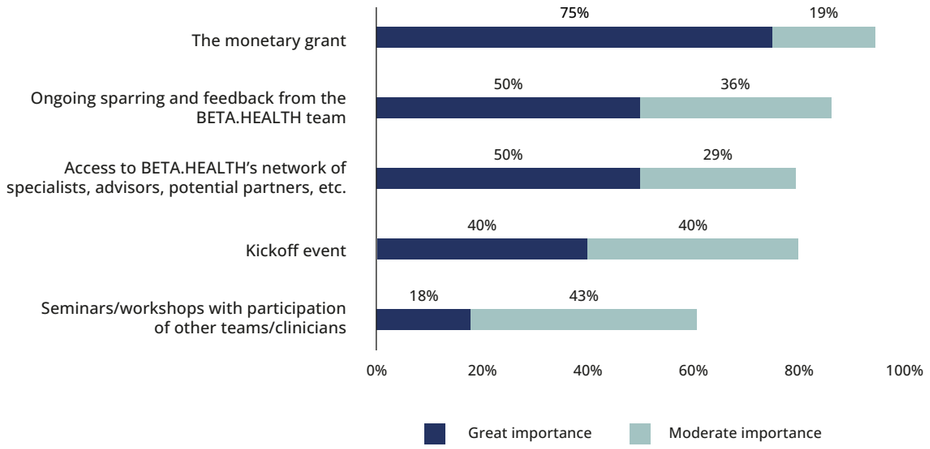
BETA.HEALTH is more than a grant programme. It provides access to a network of experts who can help clinicians to effectively transform their projects into real-world solutions.

The BETA.HEALTH programme is tailor-made for clinicians who have promising projects but little experience with innovation. In addition to a monetary grant, applicants accepted into the BETA.HEALTH undergo a customised 'accelerator programme', which includes guidance from BETA.HEALTH's innovation experts and access to a strong life-science network.

Close support and hands-on coaching are essential elements of the programme, during which the BETA.HEALTH team assists grantees in scoping and designing their innovation projects, securing buy-in from hospital decision-makers, identifying relevant partners, and matchmaking with experts who can help overcome barriers and drive progress.

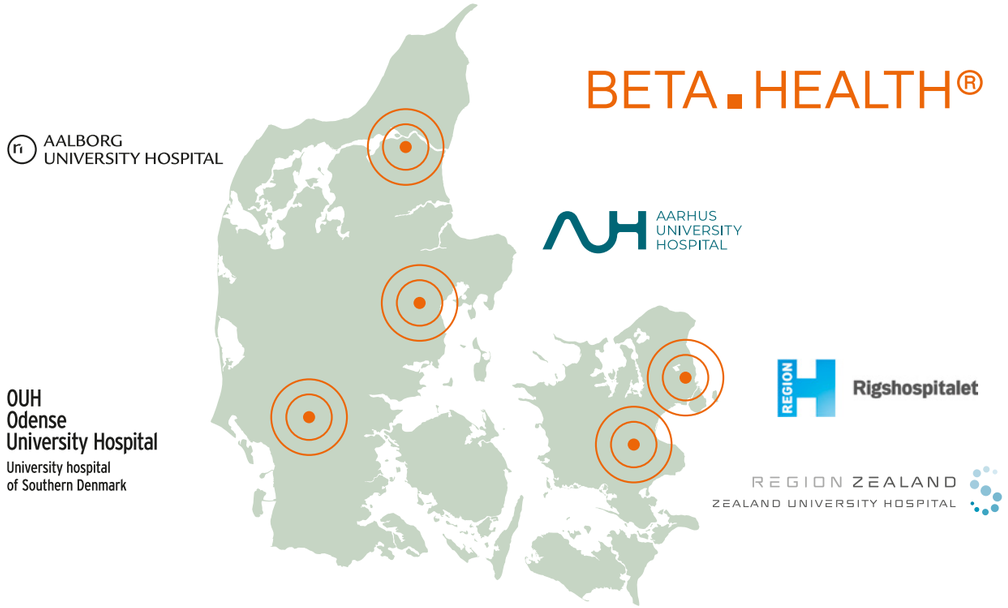
BETA.HEALTH's core services play a crucial role in helping recipients successfully navigate the initial phases of clinical innovation projects. Most agree that the funding, mentorship, and access to BETA.HEALTH's network of experts are equally valuable. The programme also plays a key role in capacity building – an area with potential to create even more value in the future.

The importance of BETA.HEALTH offerings to project progress



The BETA.HEALTH team

BETA.HEALTH is organised around two primary teams based at Rigshospitalet and Aarhus University Hospital, and BETA.HEALTH consultants at Odense University Hospital, Zealand University Hospital and Aalborg University Hospital.



The BETA.HEALTH programme offers

- Awareness-raising events at Danish hospitals
- Monetary grants
- A kick-off event for each cohort
- Tailored 1:1 coaching and development plans
- Matchmaking with experts, potential partners and investors
- Advisory board with experienced life-science leaders
- Courses and masterclasses in innovation

"In the beginning, we had a hard time understanding the language of innovation and the processes we needed to go through. It was crucial to get help in driving the project towards something that could create value for users. For instance, we didn't know that it was possible to test a solution at such an early stage."

— Lone Winther Lietzen
MD, PhD, Aarhus University Hospital

Purpose of **BETA.HEALTH**

Clinical research discoveries at Danish Hospitals breed a flurry of new innovative potential. BETA.HEALTH focuses on the development of these innovation projects for the purpose of more rapidly maturing solutions to the point where they benefit patients and society.

A unique innovation accelerator

BETA.HEALTH focuses on all aspects of the innovation process – from product development to regulatory issues.

Clinical innovation projects are complex and involve much more than simply developing a unique technical solution. Other dimensions must also be addressed – such as funding, value proposition, regulatory approval and determining how the solution will be integrated with existing IT systems.

The list to the right outlines the six most important dimensions within clinical innovation projects. The figure on the next page shows how a group of selected BETA.HEALTH projects have progressed within these dimensions. A value of 9 represents the highest level of maturity (i.e. the solution has been applied in real-world operations and scaled across regions). Conversely, a value of 1 represents the lowest maturity level (i.e. only an idea exists).

The clinical innovation journey

Product development, testing and validation
From an idea/hypothesis to a complete technology applied in real-world operations.

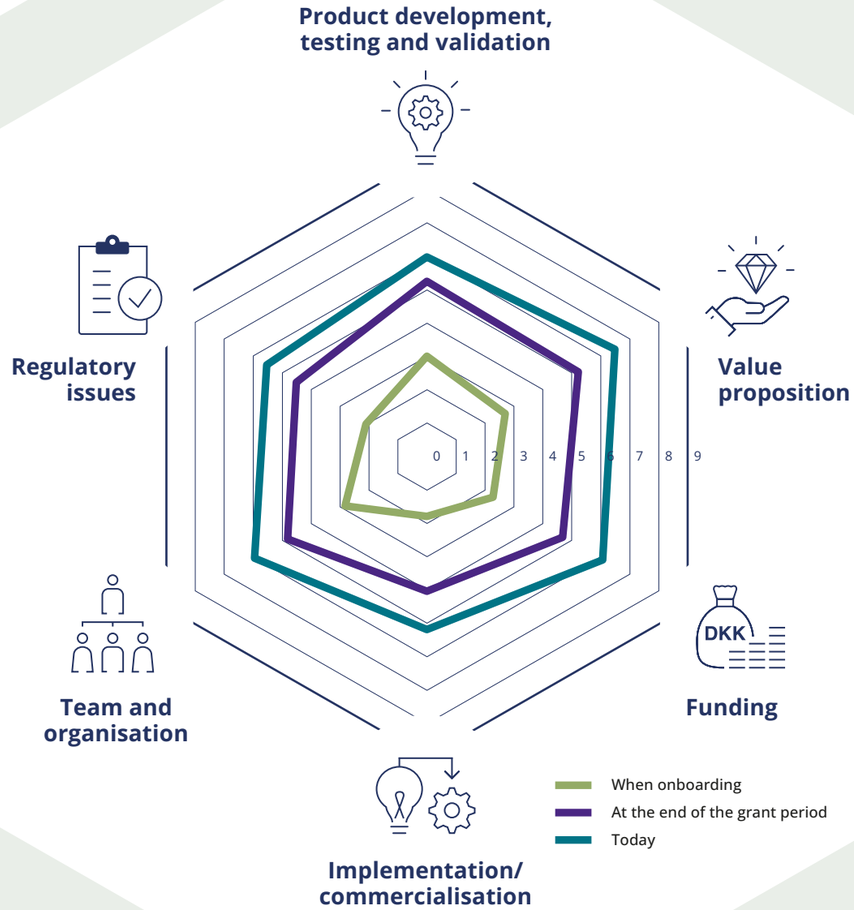
Value proposition
From a limited idea of potential users to a refined value proposition adapted to specific user segments.

Funding
From no clear view of funding needs to securing investments that enable scaling of a solution.

Implementation/commercialisation
From an unclear path towards utilisation to successful commercialisation and implementation in clinical practice.

Team and organisation
From a lack of competences/resources to a high-performing, well-structured organisation that is capable of both operating and scaling the solution.

Regulatory issues
From no knowledge of regulatory issues to obtaining regulatory approval.



Innovation readiness level
of BETA.HEALTH projects

The figure illustrates the **average** progression of BETA.HEALTH projects' maturity level from onboarding up until today. It shows that projects mature significantly across all six dimensions during the BETA.HEALTH period – and that progress continues after exiting the programme. The figure includes the 50 percent of BETA.HEALTH projects that have made the most significant progress, as early-stage clinical innovation often involves projects with disappointing results or where the pace must be slowed due to unforeseen factors such as limited resources or regulatory challenges.

BETA.HEALTH shortens time to clinic and market

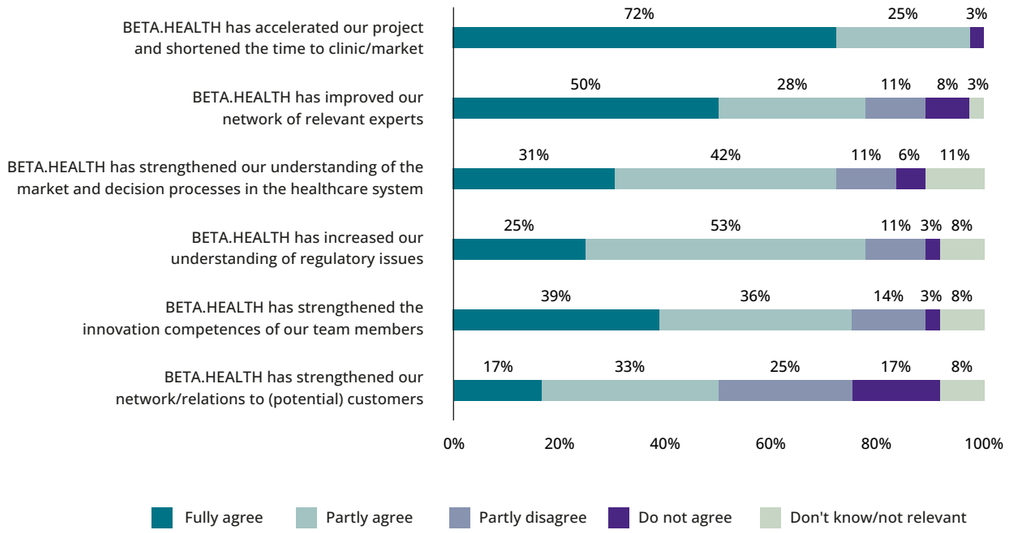
Participation in the BETA.HEALTH programme is pivotal to the progress of the recipient projects. More than 90 percent of the project teams agree that participation in the programme has accelerated their projects and shortened the time to market/clinic.

At the same time, the BETA.HEALTH programme strengthens the recipients' networks of experts and partners, as well as their skills and understanding of regulatory matters – and for many projects, the programme also enhances insights into the procurement and decision-making processes within the healthcare sector.

"A team of researchers like ours requires support to successfully manage innovation projects. The BETA team helped us understand where we were and where to go next. While the funding is essential for driving the project forward, it is the continuous mentoring that truly stands out as the most valuable aspect of BETA.HEALTH."

— Fatemeh Makouei
Biomedical Engineer,
Rigshospitalet

BETA.HEALTH project output according to project team leads



97%

of the project teams agree that participation in BETA.HEALTH has accelerated their projects.

The road to market and clinic

A majority of BETA.HEALTH projects have attracted further funding – and some have already reached the market and clinical operation.

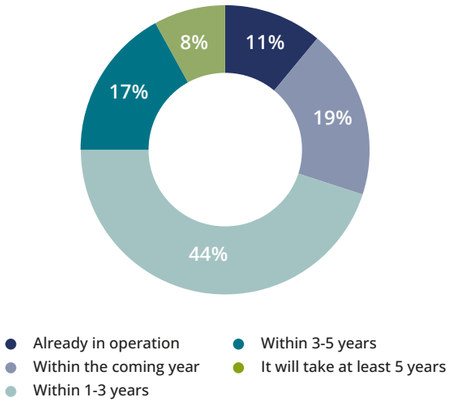
For most BETA.HEALTH projects, there is still a long way to go before reaching the market and operational practice after completing the 'accelerator programme'. Typically, the goal of the accelerator phase is to prepare projects for final testing and validation, and to make them fundable – for example, by foundations or private investors.

Therefore, it is remarkable that three out of ten projects have already reached clinical practice/the sales phase or are estimated to do so within a year. Some projects are even on their way to international markets.

A good example is the Dermloop project and the company Melatech, whose development rapidly accelerated due to participation in the BETA.HEALTH programme.

As regards funding, the BETA.HEALTH team assists the teams in preparing pitch materials, building relations with potential investors, and training clinicians in how to attract capital. It is remarkable that approximately 85 % of the projects have either secured further funding or expect to do so in the near future.

Expected time for clinical solution to be fully operational by the first user(s)



Facts about additional funding

59% of BETA.HEALTH projects have attracted further funding.

9 out of 10 state that the BETA.HEALTH programme played a decisive role in securing further funding.

2/3 of the remaining project teams expect to secure funding soon.

On average, the projects have attracted **3.8 million DKK** in follow-up funding.

Funding sources include national, private and regional funds, venture capital and convertible loans.

Zeta Diagnostics secures funding from two sources

Most middle ear diseases have an underlying cause called 'Eustachian Tube Dysfunction' – marked by dysfunctional pressure regulation of the middle ear, creating negative pressure. No solutions currently exist to directly diagnose this condition. In 2023, Kasper Linde Christensen, an MD from Horsens Regional Hospital, partnered with two business-people with backgrounds in engineering and medical devices to develop a device that can detect this condition early on. Together, they founded the company, Zeta Diagnostics.

Kasper applied for a BETA.HEALTH grant and was accepted into the programme in May 2023. The company also joined the Innofounder programme and was accepted into the Danish Tech Challenge, a DTU-based programme focusing on maturing hardware companies.

The hardware support from the Danish Tech Challenge and the life-science competencies offered by BETA.HEALTH enabled Zeta Diagnostics to create a development plan crucial for the company's progress and the product's maturation.

Building on their results from the BETA.HEALTH programme, Zeta Diagnostics was accepted into the Bioinnovation Institute (BII) and received a convertible loan of 4 million DKK. The team has submitted an application to Innovation Fund Denmark for the Innobooster programme, and has ambitions to continue in the BII Venture Lab and to secure external funding.

Niels Kvorning; MD, PhD, founder of Dermloop

Dermloop reaches the market with success

Dermloop is a digital tool that supports doctors in diagnosing and managing skin diseases. The technology aids general practitioners in distinguishing between benign and malignant skin lesions, substantially reducing the need for physical referrals to dermatologists. In the long term, the goal is to expand the platform's diagnostic capabilities to other medical areas.

The app-based solution captures high-quality images of skin conditions, such as moles, enabling in-platform diagnostics by dermatologists. During image capture, an AI algorithm assists the doctor to ensure optimal image quality. Additionally, the platform includes a learning component designed to improve doctors' ability to detect skin cancer.

The project was accepted into the BETA.HEALTH programme in 2022. The grant was used to further develop the technology, enhance the user interface, and provide documentation related to regulatory compliance. Moreover, the BETA.HEALTH team facilitated a dialogue with the Central Region of Denmark, which became the first customer and eventually resulted in a national tender and procurement. In 2023, private investors injected capital into the startup company Melatech, which is the commercial arm of the Dermloop project.

Dermloop has been implemented by 10% of Denmark's general practitioners and is set to be rolled out to 80% of all general practitioners in Denmark over the next two years. Melatech has also partnered with a company in the United States to expand the technology to healthcare organisations nationwide, covering 4.5 million residents.

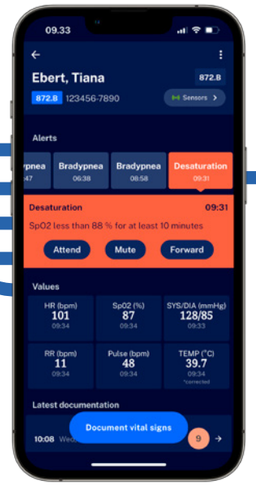
WARD 24/7

WARD 24/7 monitors patient condition in real time – and saves lives.

Data from Danish hospitals shows that 30 percent of patients experience severe complications, such as wound infections or blood clots, during hospitalisation after major surgery or severe illness. This leads to an average of four additional days of hospitalisation – or in the worst cases, death.

An estimated 40 percent of these complications could be prevented if their warning signs were detected in time. The team behind WARD has developed a solution aimed at detecting early warning signs to reduce complications and improve outcomes. With this solution, algorithm-based software installed as an app wirelessly monitors patients' vital signs in real time and alerts nurses to intervene if there are critical changes in key parameters such as heart rate, blood pressure and oxygen saturation.

WARD 24/7 became a spinout in 2019, following years of successful development and testing within the Danish healthcare system. The project attracted significant funding early on, with its first major boost coming in 2018 through a Grand Solutions grant from Innovation Fund Denmark.



Clinically validated app uses algorithms to monitor patients' vital signs. Continuous wireless monitoring has great potential to predict complications and reduce ICU transfers.

WARD 24|7

Successful scaling

WARD 24/7 obtained CE marking in November 2023, and the system is already implemented in 13 hospital departments across five European countries, either in commercial contracts or as pilot operations.

FDA approval is expected in early 2025, and with the close research collaboration with hospitals in Cleveland and Boston, there are high expectations for sales in the United States market.

Clinical studies abroad

The BETA.HEALTH grant played a pivotal role in supporting clinical implementation abroad. When onboarding with BETA.HEALTH, WARD 24/7 had a working prototype but was lacking experience with hospitals in other countries.

With support from BETA.HEALTH, the project team conducted trials in Norway, Netherlands, United Kingdom, Germany, and the United States. Partnerships in the United States with the Cleveland Clinic and Massachusetts General Hospital have been particularly significant in commercialisation efforts.

The strong international profile of the clinical implementation projects paved the way for additional funding. In 2023, WARD 24/7 secured 20 million DKK in bridge funding from its group of investors, as well as a new Grand Solution grant of 30 million DKK.

2023

WARD 24/7 secured **20 million DKK** in bridge funding and a Grand Solution grant of **30 million DKK.**

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The first two years

309 Applications received (Calls 1–5)

71 Projects accepted

197 Clinicians & researchers have participated in accepted projects

34.1 Awarded in grants Million DKK

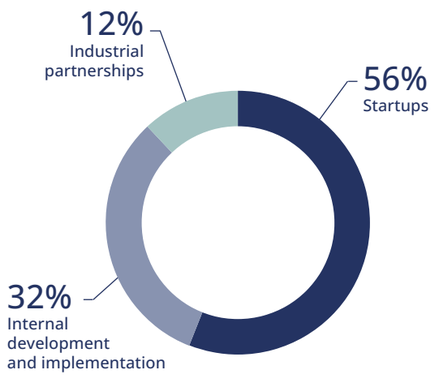
Profile of BETA.HEALTH projects

BETA.HEALTH has a broad project portfolio that reflects commitment across regions, sectors, hospitals and clinical specialities.

A positive side effect is the formation of new companies.

The most common path to utilisation is the formation of a new company. This reflects the fact that attracting funding is often easier for startups than for projects following other routes to utilisation. Furthermore, hospitals often lack the resources to manage time-consuming development processes, testing and validation.

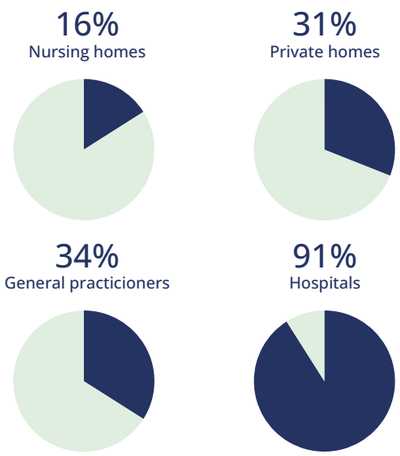
Path to utilisation for BETA.HEALTH projects



The entire healthcare sector benefits from BETA.HEALTH.

BETA.HEALTH projects differ in use focus, and the programme benefits multiple parts of the healthcare sector. As many projects are developed with more than one sector in focus, a project can count multiple times in the figure below.

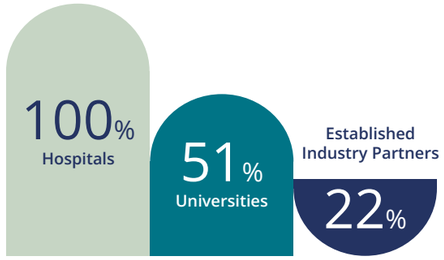
Application focus of BETA.HEALTH projects



The university sector participates in one out of every two projects.

Most BETA.HEALTH project teams consist of 4–7 core members. Often, multiple clinical departments participate, frequently alongside a university researcher. Universities typically contribute deep technological expertise to the projects, particularly in areas such as artificial intelligence (AI).

Sectors represented in the core team



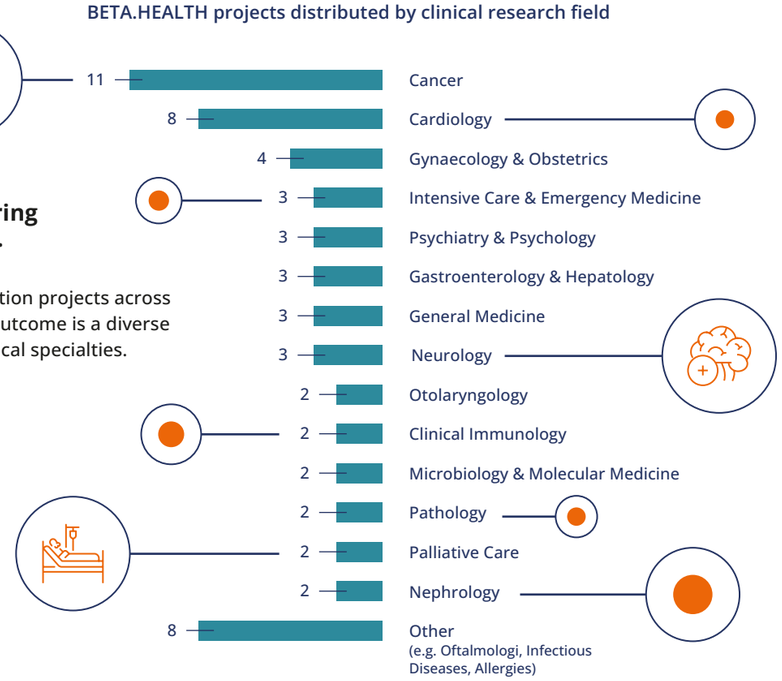
All regions are represented in BETA.HEALTH projects.

BETA.HEALTH stands out as a national initiative that is supported and utilised by all major hospitals. The decentralised model, with BETA.HEALTH team members based at every university hospital, fosters local engagement and provides close proximity to researchers and clinicians with promising innovation ideas.

Geographic distribution of BETA.HEALTH projects

Region	Share
Capital Region of Denmark	38%
Central Denmark Region	34%
North Denmark Region	14%
Region of Southern Denmark	10%
Region Zealand	3%

BETA.HEALTH projects distributed by clinical research field



A diverse portfolio covering many fields of expertise.

BETA.HEALTH welcomes innovation projects across all clinical research fields. The outcome is a diverse portfolio covering all major clinical specialties.

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BETA.HEALTH®

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