Midterm evaluation of BETA.HEALTH

- A national innovation platform sponsored by the Novo Nordisk Foundation

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IRISgroup

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Table of Contents

1. PREFACE

BETA.HEALTH has been introduced as a pilot project running from 2022 to 2026. The long-term goal is to make clinical innovation an integrated part of the Danish healthcare system through the development, implementation and scaling of new solutions – both nationally and internationally. This is achieved through 1) grants for innovation projects, 2) acceleration services including access to mentoring from an experienced team that is well-connected in the ecosystem for clinical innovation, 3) training activities provided through the "BETA.HEALTH Academy".

The total budget for the pilot phase is 129 million DKK, co-financed by the Novo Nordisk Foundation and the five regions.

The purpose of the midterm evaluation is to document how BETA.HEALTH adds value to the Danish healthcare system and to measure the progress of the clinical innovation projects that BETA.HEALTH supports. Furthermore, the evaluation aims to analyse the characteristics of the BETA project portfolio and to map how BETA.HEALTH is integrated into the Danish ecosystem for clinical innovation. Finally, the mandate of the evaluation is to develop recommendations for how BETA.HEALTH can be strengthened in a version 2.0 of the program.

The evaluation report is structured as follows:

- Chapter 2 provides an executive summary and recommendations for BETA.HEALTH 2.0.
- Chapter 3 introduces the data sources and evaluation activities.
- Chapter 4 offers a more detailed introduction to BETA.HEALTH and provides insights into the characteristics of the supported projects, including clinical specialty, innovation focus, team composition, and path to utilisation.
- Chapter 5 evaluates the results and progress of the projects, including the acquisition of further funding and the development according to a new index that measures progress in clinical innovation projects across six dimensions.
- Chapter 6 assesses the value of individual BETA.HEALTH activities, as well as the administration of the programme.
- Chapter 7 presents an analysis of how BETA.HEALTH has been integrated into the ecosystem for clinical innovation. It also provides an overview of the connections between BETA.HEALTH and other programs supporting clinical innovation.
- Finally, chapter 8 contains recommendations on how to strengthen the programme.

Enjoy your reading!

2. EXECUTIVE SUMMARY

This chapter summarises the key findings of the midterm evaluation. Additionally, it presents recommendations on how BETA.HEALTH can be strengthened with a view to a version 2.0 of the programme.

A missing link between clinical innovation and healthcare solutions

The ambition of BETA.HEALTH is to assist researchers and clinicians in transforming clinical research into proven and scalable healthcare solutions.

The evaluation demonstrates that the programme effectively fills a gap in the innovation support system. It allows ideas for new solutions developed in hospitals to mature to a stage where other stakeholders are ready to provide funding and services that support the final phases leading to market and clinical implementation.

Feedback from project leaders and stakeholders in the ecosystem is highly positive. BETA.HEALTH presents a robust and well-designed value proposition for clinical innovation projects.

To date, most project leaders have engaged with BETA.HEALTH primarily for the financial grant. However, it is often the interaction with the BETA.HEALTH team and the content of the acceleration services that deliver the greatest value.

BETA.HEALTH provides hands-on support for projects, which is highly valuable for researchers and clinicians with limited experience in innovation. Additionally, the team has a strong network within the ecosystem, ensuring that projects are matched with qualified experts and companies.

In collaboration with project leaders, the BETA.HEALTH team successfully identifies the most significant challenges facing the projects and brings in expertise to assist with regulatory matters, health economic analyses, design, validation, and more.

An effectful accelerator

As part of the evaluation, we developed a survey-based index to measure progress in clinical innovation projects. The self-assessments made by the project leaders indicate that, on average, the projects achieve significant progress while participating in BETA.HEALTH.

This applies to product development, understanding regulatory issues, crafting a value proposition for future customers, and preparing for implementation and additional funding.

Some projects reach a stage very close to operational practice and/or their first sale during the BETA.HEALTH acceleration phase. Less mature ideas advance to a phase where they, for instance, gain acceptance into other acceleration programmes, such as BII Venture Lab (the BioInnovation Institute).

BETA.HEALTH's success is evident in that six out of ten projects have secured additional funding. Furthermore, two-thirds of the remaining projects anticipate obtaining funding in the near future. A significant majority of the first group indicates that BETA.HEALTH has played a crucial role in attracting this further funding.

Integration in the ecosystem can be further developed

BETA.HEALTH plays a dual role within the ecosystem: filling the gap between clinical research and the development of healthcare solutions, and leveraging the ecosystem to connect clinical innovation projects with the appropriate expertise, partners, and investors.

While the mission has been accomplished in the first area, there is still progress to be made in the

second. On one hand, the BETA.HEALTH team possesses a robust personal network within the ecosystem, enabling the successful matching of projects with experts and potential partners. On the other hand, more systematic relationship-building is needed with stakeholders who can contribute to the projects or serve as partners and investors in the subsequent phases.

For instance, awareness of BETA.HEALTH is patchy among large companies in the healthtech sector and among stakeholders who mobilise private investors. The links to important initiatives such as Health Tech Hub Copenhagen, Medtech Investor Network and Medtech Growth could be strengthened to facilitate the transition to subsequent phases on the path to market and clinical practice.

Broad and robust pipeline, that can be further improved

The evaluation reveals that the BETA.HEALTH project portfolio is diverse, encompassing various fields of expertise. The proportion of projects focused on treatment and diagnostics is nearly equal. Furthermore, while most technologies in the projects target hospitals, a significant number also aim at private homes and general practitioners.

Regarding the geographical distribution and national anchoring of the program, the evaluation indicates a good balance between eastern and western Denmark within the portfolio. However, it also reveals a high concentration of project leaders and participants from Rigshospitalet and Aarhus University Hospital, highlighting the potential for increased participation from other hospitals and regions. Additionally, the evaluation suggests that idea generation could be enhanced through events that bring together hospitals, researchers, the primary sector, and businesses to collaboratively develop solutions for the challenges facing the healthcare sector.

Further development

Although the pilot phase seems successful regarding project progress and impact, there are opportunities to further strengthen BETA.HEALTH.

Chapter 8 gives a thorough introduction to our recommendations, including considerations of which can be implemented quickly and which should be further prepared and included in a version 2.0 of the programme (after completion of the pilot phase).

The bullet points below offer a concise overview of recommendations that suggest significant adjustments to the programme:

- Segmentation of BETA.HEALTH into two grant types – innovation grants and implementation grants – each with distinct onboarding processes.
- Introduction of advisory boards, comprising 2-3 experienced life science leaders, as a resource available to all BETA.HEALTH projects[1].
- Introduction of 1-2 missions as focal areas for future calls to enhance 1) alignment with the major challenges of the healthcare system and 2) collaboration across hospitals in developing fast tracks for implementation.
- Expansion of the BETA.HEALTH Academy, including the development of a comprehensive leadership program in innovation management and a course aimed at researchers and clinicians with little or no experience in innovation projects.
- Development of a revised organisational model that maintains local autonomy and ownership while presenting BETA.HEALTH as a unified organisation with a single leadership structure to stakeholders in the ecosystem.
- A revised composition of the steering group to enhance representation from organisations and sectors that require healthcare solutions.

[1] The offer has already been implemented by the BETA.HEALTH team from call 5 (of the ten calls during the pilot phase).

3. ABOUT THE EVALUATION

This chapter outlines the purpose of the evaluation and provides details on the data sources utilised. It also introduces a new framework for measuring progress in clinical innovation projects, which is applied in the evaluation.

3.1 Purpose of the evaluation

The primary objective of the midterm evaluation is to document how BETA.HEALTH adds value to the Danish healthcare system and to assess the progress of the clinical innovation projects supported by the programme.

The evaluation focuses on the first four BETA.HEALTH calls (see Chapter 4), as most projects from subsequent calls are still in the accelerator or have only just begun.

Given that we are midway through the pilot phase and have only four calls to assess, the extent to which impact can be measured is naturally limited. The successful implementation of healthcare technology solutions requires time, and many projects will likely need follow-up processes and additional funding before they are ready for implementation and scaling.

Consequently, a comprehensive impact evaluation cannot yet be conducted.

The primary focus of the evaluation is to assess whether BETA.HEALTH is effectively designed to unlock the innovation potential in clinical research, and whether the projects are on track to meet the programme's success criteria and KPIs.

Additionally, it aims to provide a detailed overview of the projects supported in Calls 1-4 and to assess how BETA.HEALTH has been integrated into the broader ecosystem for clinical innovation.

Finally, the midterm evaluation serves as a learning tool to guide programme optimisation leading up to 2026, while laying the foundation for the vision and strategic direction of BETA.HEALTH beyond 2026.

3.2 Data sources and activities

The evaluation is based on a variety of independent data sources.

These sources include in-depth interviews, surveys of grant recipients, international case studies, and background material from BETA.HEALTH.

The data underpinning the assessments and recommendations consists of both information collected during the evaluation and pre-existing data, such as project applications.

The following subsections provide an overview of the key data sources used and/or collected in the evaluation.

Interviews

In total, we conducted more than 50 interviews (see Appendix 1 for a full list of interviewees) with project leaders and a diverse range of stakeholders.

Furthermore, we interviewed the BETA.HEALTH teams in Aarhus and Copenhagen to gain a detailed understanding of the programme's organisation and design.

Interviews with project leaders

We conducted 15 in-depth interviews with project leaders (former or current grant holders) to gain a thorough understanding of how BETA.HEALTH how added value to their projects.

A representative selection of interviewees was ensured, taking into account call number, clinical specialty, and regional affiliation.

Interviews with the management of Danish hospitals

Additionally, we conducted six interviews with top management at Danish hospitals and four interviews with department heads at hospitals with significant research activities.

The purpose of these interviews was to gain insights into BETA-HEALTH's integration with individual hospitals' innovation strategies and to gather input on ways to strengthen the program.

Interviews with stakeholders in the ecosystem

We conducted around 25 interviews with stakeholders across the Danish clinical innovation ecosystem, including representatives from investors, foundations, healthtech companies, universities, business organisations, and innovation policy operators.

The purpose was, among other things, to assess BETA.HEALTH's role and integration within the ecosystem, and to evaluate whether the programme addresses gaps in funding opportunities. Additionally, we examined BETA.HEALTH's effectiveness in forming strategic partnerships with key stakeholders in the ecosystem.

Survey

We conducted a survey of all project leaders from Calls 1-4.

The table below provides an overview of the survey population and response count. Overall, a 70 percent response rate was achieved, with minor variations across different calls.

Table 3.1. Applicants and grants, Call 1-4

	Population	*Responses*	*Response rate*
Call 1	12	8	67%
Call 2	15	14	93%
Call 3	15	8	53%
Call 4	11	7	64%
Total	**53**	**37**	**70%**

International case studies

As part of the midterm evaluation, we conducted four international case studies.

The purpose was to gather inspiration for potential adjustments or additions to BETA.HEALTH's activities and organisation.

The international case studies focus on programmes in England, Singapore, the US, and Sweden, selected through desk research on initiatives promoting clinical innovation. Emphasis was placed on regions and countries with experience in areas where BETA.HEALTH expects to increase focus in the coming years, including ecosystem integration, capacity building in clinical innovation, and programmes with a particular emphasis on implementing and scaling health tech solutions.

Material from the BETA.HEALTH team

Finally, the evaluation draws on data regarding project results and progress collected by the BETA.HEALTH secretariat. We had access to existing project materials, including original applications and project-related information from the BETA.HEALTH team's internal database.

The evaluation process has involved close collaboration with the BETA.HEALTH secretariat, including a methodology workshop on measuring development in clinical innovation projects. Regular status meetings have also been held with participation from both the BETA.HEALTH team and the Novo Nordisk Foundation.

4. BETA.HEALTH – AN INTRODUCTION

This chapter introduces BETA.HEALTH and outlines its core activities. It also provides an overview of BETA.HEALTH applicants and grants from Calls 1-4. The profiles of funded projects are examined in greater detail to provide insights into characteristics such as clinical specialty, innovation focus, and team composition.

4.1 What is BETA.HEALTH?

BETA.HEALTH is driven by a vision, shared by the Danish hospitals and Novo Nordisk Foundation, to transform the future of healthcare.

BETA.HEALTH is a pilot program operating from 2022 to 2026, serving as a national health innovation platform and grant initiative that funds and supports high-potential innovation projects derived from clinical research discoveries in Denmark.

The long-term goal is to make clinical innovation an integrated part of the Danish healthcare system through the development, scaling, and implementation of new solutions – both nationally and internationally.

Purpose of BETA.HEALTH

"Clinical research discoveries at Danish Hospitals breeds a flurry of new innovative potential.

BETA.HEALTH focus on the development of these innovation projects for the purpose of more rapidly maturing solutions to the point where they benefit patients and society."

Although Denmark has a strong position in life sciences, with a strong clinical research base and world-leading companies, we struggle to translate research into healthcare solutions that are effectively implemented in clinical practice.

The BETA.HEALTH programme is designed to bridge this gap by combining three tracks that cultivate an environment conducive to successful clinical innovation.

- Designing innovation hubs at hospitals that are closely linked to both research and clinical practice.
- Developing a new approach to innovation funding that combines grants with access to continuous support from innovation experts, as well as specialists from the surrounding life sciences ecosystem.
- Building capacity through seminars, masterclasses and workshops aimed at equipping clinicians with essential skills related to innovation.

Projects can join BETA.HEALTH during their early conceptualisation phase. The programme encompasses innovation stages from MVPs (Minimum Viable Product) and PoC (proof of concept) through to implementation of new solutions.

BETA.HEALTH applies a bottom-up approach and welcomes innovation projects from all clinical fields of research.

Projects accepted into BETA.HEALTH are offered an acceleration track that includes guidance and access to partners and networks, in addition to a monetary grant.

Close support and tailored guidance from the BETA.HEALTH team are key components of the acceleration programme. The team assists grantees in scoping and designing their innovation projects, securing buy-in from decision-makers at hospitals,

identifying relevant partners, and accelerating solutions towards clinical impact.

The purpose is to help remove barriers to innovation and draw on experts and networks to provide appropriate and timely competencies and support to project teams.

The duration of a grant is 6-9 month, and projects are allowed to apply multiple times.

"The programme fills an important gap because the Danish ecosystem in general offers better opportunities for financing drug development than it does for medical devices and health IT. There is a significant funding gap for early-stage innovation projects in these areas."

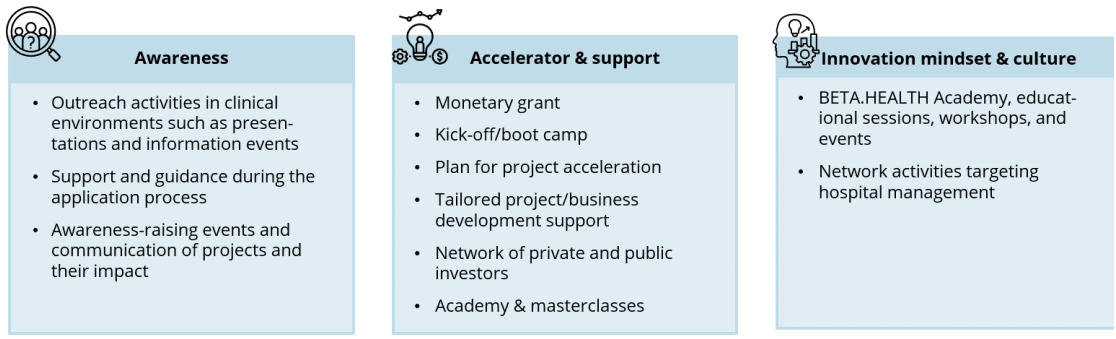
Lars Bech-Jørgensen, Head of Future Healthcare, Danish Industry

4.2 Programme activities

The BETA.HEALTH team is continually focused on enhancing the programme. Several minor changes have been implemented during the first two years of operation, which means that not all funded projects have undergone the same activities. Additionally, the organisation of BETA.HEALTH into two teams (East and West Denmark – see Section 4.3) allows for differentiated activities.

Figure 4.1 provides an overview of the activities that BETA.HEALTH is set up to do.

Figure 4.1. BETA.HEALTH activities



Source: IRIS Group based on material from BETA.HEALTH

Awareness

BETA.HEALTH conducts various outreach activities to raise clinicians' awareness of the programme and to strengthen the pipeline of new projects.

These outreach activities occur in local clinical environments, with the goal of generating new innovation projects and inspiring more clinicians to consider innovation.

Additionally, the BETA.HEALTH team offers individual guidance and support to clinicians considering applying for the programme. The team helps clarify the project's potential and assists clinicians throughout the application process.

Accelerator and support

The accelerator programme is the core activity of BETA.HEALTH, where projects are enrolled for 6-9 months.

New projects are admitted to the accelerator programme twice a year through open application rounds. The selection of projects follows

BETA.HEALTH's impact model, in which projects are evaluated based on:

1. Impact potential in terms of clinical value and benefits to patients.
2. Estimated risk of success.
3. Time required to achieve impact.

Projects admitted to the accelerator programme receive a grant and bespoke support from the BETA.HEALTH-teams. The support is continuous throughout the acceleration period and is tailored to the specific needs of each project. It typically focuses on helping the innovation project teams scope and design development phases that can accelerate the project.

Additionally, the acceleration phase aims to build networks and match projects with relevant experts, mentors, and key contributors, including regulatory and legal specialists.

Finally, BETA.HEALTH also has a strong network within the regions and the healthcare sector, assisting projects in bridging gaps related to trials, testing, demonstrations, and ultimately sales.

Innovation mindset and culture

In addition to supporting innovation projects, BETA.HEALTH has a stated mission of strengthening the competencies necessary to drive clinical innovation and promoting an innovation mindset among clinical researchers.

To support this mission, the "BETA.HEALTH Academy" has been established, under which BETA.HEALTH collaborates with external experts to provide training related to clinical innovation.

To date, the core activities of the Academy have been:

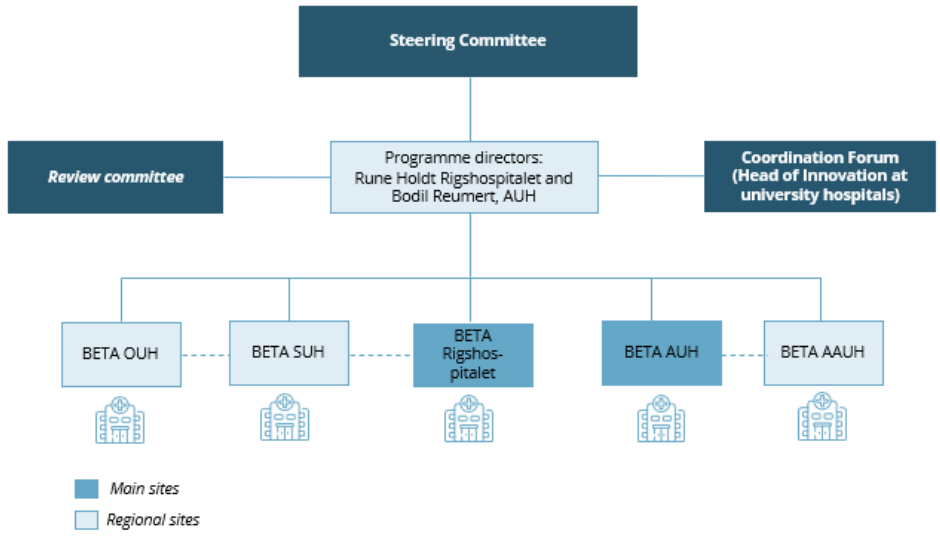
- Boot camps and kick-off meetings for new projects admitted in BETA.HEALTH
- Seminars/workshops aimed at skills development in topics of high relevance to clinical innovation projects (to date, mostly targeting ongoing BETA.HEALTH projects)
- Masterclasses aimed at diffusing knowledge within topics of general relevance to clinical innovation, such as AI in healthcare
- Webinars introducing BETA.HEALTH to clinical researchers
- Engaging the clinical innovation community through networking events and ambassadorship.

4.3 Organisation and governance

The operation of BETA.HEALTH is organisationally divided into two main sites: Rigshospitalet and Aarhus University Hospital. Additionally, there are two regional sites at the university hospitals in Aalborg and Odense. Each regional site is affiliated with one of the main sites, forming what is known as BETA.HEALTH East and BETA.HEALTH West. All four sites are embedded in larger Innovation Units established at all university hospitals.

The organisation and governance of BETA.HEALTH are illustrated in the figure below.

Figure 4.2. BETA.HEALTH organisation and governance



Source: IRIS Group based on material from BETA.HEALTH

The two main sites are responsible for the development and administration of the programme, including overall communication, as well as planning meetings for both the Steering Committee and the Review Committee (see below). They also serve as partners for projects led by clinicians employed at non-university hospitals.

In terms of day-to-day operations and collaboration with or feedback to project holders, the four units operate autonomously.

Additionally, the two main sites are responsible for delivering courses and masterclasses through the BETA.HEALTH Academy and lead the preparation of kick-off activities for new project cohorts.

Each regional site has a full-time equivalent (FTE) position dedicated to supporting BETA.HEALTH projects. The two main sites are staffed with 6,5 FTEs each dedicated to programme management, development, and operation.

BETA.HEALTH is governed by a Steering Committee consisting of hospital directors from the five university hospitals, representatives from the five largest universities, and industry representatives.

The Steering Committee sets the overall strategic direction for BETA.HEALTH and is responsible for coordination with other relevant initiatives in academia, healthcare, and industry.

Box 4.1. Steering committee members

Hospitals:

Søren Pihlkjær Hjortshøj, Medical Director, AAUH (chairman)

Martin Magelund, Center Director, Rigshospitalet

Bjarne Steen Dahler-Eriksen, Medical Director, OUH

Thomas Balle Kristensen, Hospital Director, AUH

Ricco Norman Dyhr, Hospital Director, SUH

Education and Research:

Anne Mette Hvas, Dean, Health, AU

Trine Winterø, Vice Dean for Innovation and Community Relations, Faculty of Health and Medical Sciences, KU

Pascal Madeleine, Vice Dean for Research and Innovation, Faculty of Health Sciences AAU

Uffe Holmskov, Vice Dean for Research and Innovation, Faculty of Health Sciences, SDU

Stine Kruse, Head of Startup Support and Business Development, DTU

Industry:

Marie Lommer Bagger, CEO, Measurelet

Mia Bielecki, Vice President, Global Device Development, Innovation Unit, Ascendis Pharma

Venture/angels:

Shomit Ghose, Start-up advisor, University of California

An additional function of the Steering Committee is to discuss and share knowledge on managing innovation and implementing an innovation culture within hospitals. The committee chair rotates between the regions.

A review committee has also been established, comprising members from clinical departments, academia, industry, and representatives from the university hospitals. The review committee is responsible for awarding grants and determining which projects are accepted into the BETA.HEALTH program.

4.4 Success criteria

The long-term goal of BETA.HEALTH is to make clinical innovation an integrated part of the Danish healthcare system through the development, implementation and scaling of new solutions.

In order to measure how the programme performs on the way to fulfilling this vision, an impact framework with several KPIs has been agreed upon.

In terms of outcomes and impacts, the following key indicators from the framework highlight the ambitions of the pilot phase (2022-26):

- 6 products/services ready for the market
- 40 products/services in the pipeline
- 1 million patients reached
- 15 startups and 16 licence agreements with existing companies
- 4 career/economic incentives for innovation implemented at hospitals at different levels.

Because clinical innovation and implementation of health technologies take time, it is difficult, halfway down the road, to evaluate the extent to which these objectives will be fulfilled.

Instead, the new framework for measuring progress in clinical innovation projects (cf. Chapter 3) constitute an important element in evaluating BETA.HEALTHs journey to create impact.

Finally, the conducted survey provides valuable indications of how BETA.HEALTH will perform in relation to several indicators in the KPI-framework.

4.5 Applicants and grants

This midterm evaluation covers the first four calls for BETA.HEALTH projects. The table below shows the number of applicants and grants awarded in the four calls.

Table 4.1. Applicants and grants, Call 1-4

Call	*Applicants*	*Grants*	*Grant amount in million DKK*
1	50	12	5.5
2	51	16	7.25
3	72	15	5.75
4	74	15	9.5

Source: IRIS Group based on material from BETA.HEALTH

In total, BETA.HEALTH has received 247 applications during the four calls. 58 (or 23 percent) of those were approved for funding.

It is worth noting that the number of applications has grown from around 50 in the first two calls to more than 70 in both Call 3 and Call 4.

BETA.HEALTH offers grants in three sizes:

- **BETA 0.2:** 250,000 DKK in project funding
- **BETA 0.5:** 500,000 DKK in project funding
- **BETA 1.0:** 1,000,000 DKK in project funding

Aside from the size of the grant, the same offers and services are provided to all projects.

In Call 4, the BETA 0.2 grant was discontinued, as it became evident that 250,000 DKK was insufficient to effectively accelerate and mature clinical innovation projects[2].

In addition to the three project grant types, BETA.HEALTH, in collaboration with the pharmaceutical company Roche, awarded the first so-called Industry Partner grant (1,000,000 DKK) in Call 4.

The table below provides an overview of the three types of BETA.HEALTH grants, including the number of applicants and grants awarded.

Table 4.2. Applicants and grants, BETA.HEALTH grants, Call 1-4

Grant type	*Applicants*	*Grants*	*Grant amount, million*
BETA 0.2	56	14	3.5
BETA 0.5	151	38	19.5
BETA 1.0	40	5	5.0
Total	**247**	**58**	**28**

Source: IRIS Group based on material from BETA.HEALTH
Note: BETA Industry Partner is grouped with BETA 1.0

The table shows that BETA 0.5 is the most common grant size. A total of 38 BETA 0.5 grants have been awarded, amounting to a total grant sum of 19.5 million DKK.

Projects that have completed the accelerator program can reapply for a new grant. Additionally, former participants are eligible to apply for grants for new projects. A total of 209 researchers and clinicians (project leaders) have submitted 247 applications to BETA.HEALTH.

4.6 Project characteristics

BETA.HEALTH welcomes innovation projects across all clinical research fields.

To provide a picture of the portfolio, this section characterises BETA.HEALTH projects by clinical specialty, innovation focus, geography, and team composition.

Clinical specialty

In the table below, BETA.HEALTH projects are distributed according to clinical field of expertise.

Table 4.3. BETA.HEALTH projects, Call 1-4

Clinical speciality	Number of projects
Cancer	11
Cardiology	8
Gynaecology & Obstetrics	4
Intensive Care & Emergency Medicine	3
Psychiatry & Psychology	3
Gastroenterology & Hepatology	3
General Medicine	3
Neurology	3
Otolaryngology	2
Clinical Immunology	2
Microbiology & Molecular Medicine	2
Pathology	2
Palliative Care	2
Nephrology	2
Other (e.g. Oftalmologi, Infectious Diseases, Allergies, etc.	8

As shown, the BETA.HEALTH projects are diverse and encompass many fields of expertise.

[2] See Chapter 8 for a further discussion of small grants.

A significant portion of BETA.HEALTH projects focuses on cancer diseases or cardiology.

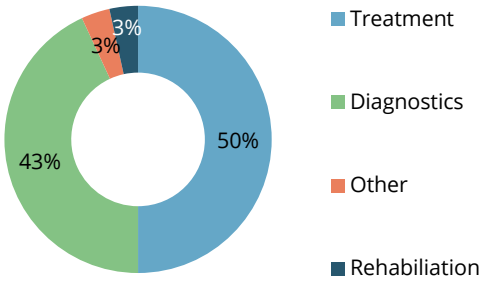
Some projects concentrate on specific diseases, bringing together researchers and clinicians within the same specialty.

However, there are also projects that focus on diagnostics and treatment across various diseases.

Innovation focus

An analysis of the BETA.HEALTH portfolio reveals that 50% of the projects focus on innovative practices in patient treatment, while 43% focus on new solutions in diagnostics. Only few projects have a primary focus on rehabilitation, as shown in the figure below.

Figure 4.3. Primary focus of clinical innovation, call 1-4

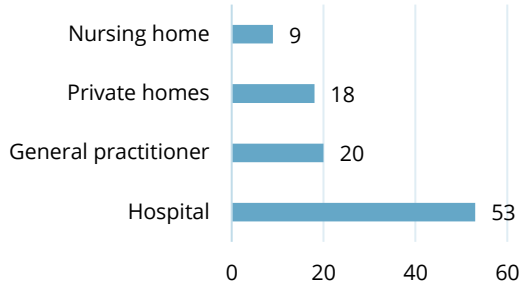


Source: IRIS Group based on material from BETA.HEALTH

Projects in the "other" category have a holistic focus or concentrate on the hospital as a unit. An example of such a project is "Praemostro," which aims to develop a tool that combines historical data with real-time data to predict the number of patients expected to arrive at the emergency ward (see the case study in Chapter 6).

BETA.HEALTH projects also differ in use focus. The programme has the potential to be beneficial in multiple parts of the healthcare sector. Figure 4.4 shows the number of projects applicable to four different sectors. As many projects are developed with more than one sector in focus, a project can count multiple times in the figure.

Figure 4.4. Application focus, Call 1-4



Source: IRIS Group based on material from BETA.HEALTH
Note: Projects can count multiple times.

Almost all BETA.HEALTH projects (53 out of 58) focus on innovations relevant to hospitals. However, several projects appear to have cross-sectoral impacts.

Finally, it is relevant to examine the technological focus of BETA.HEALTH projects.

Recent literature foresees Artificial Intelligence (AI) to revolutionise healthcare[3].

This trend seems also to fuel BETA.HEALTH projects. Approximately 40% of granted projects focus on developing new solutions based on AI and machine learning.

From the project portfolio, it is evident that AI is not confined to specific clinical specialities or areas such as treatment or diagnostics. The Praemostro case also exemplifies a GenAI innovation that is applicable beyond the healthcare system.

Geographical profile of grants

Figure 4.5 reveals the geographic distribution of BETA.HEALTH grants based on the main applicant's hospital affiliation.

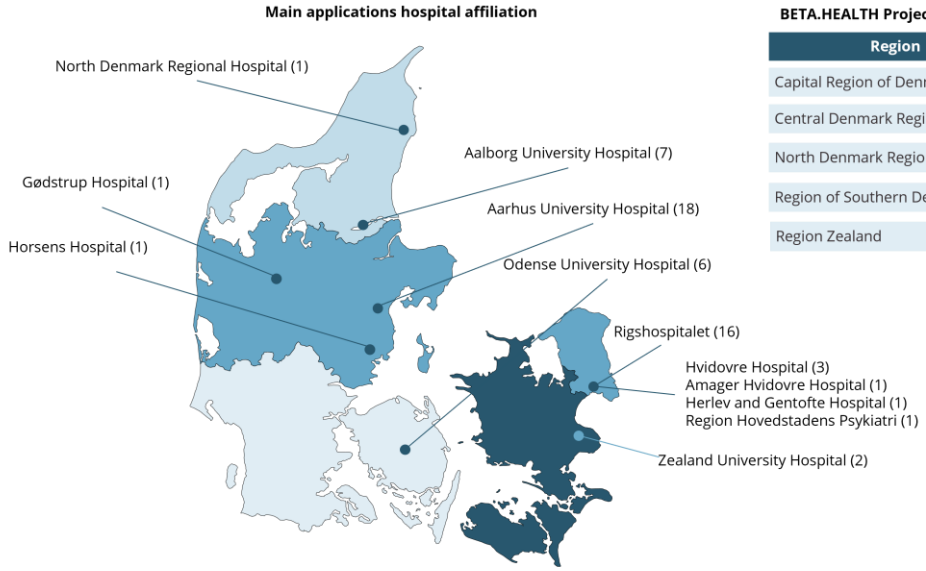
[3] McKinsey (2023): "*Generative AI in healthcare: Adoption trends and what's next*" & Boston Consulting Group (2023)." *Generative AI in health and opportunities for public sector organisations."*

22 grantees, equivalent to 38%, are based in the Capital Region of Denmark. 16 of those are employed at Rigshospitalet.

With 20 grantees, the Central Denmark Region accounts for 34% of the BETA.HEALTH portfolio. Most of the grants in this region are awarded to teams affiliated with Aarhus University Hospital.

The remaining grants are awarded to projects in the other three regions of Denmark. Most grantees in these regions are affiliated with hospitals where BETA.HEALTH has established regional sites.

Figure 4.5. Geographical distribution of BETA.HEALTH projects, Call 1-4



BETA.HEALTH Projects divided by regions

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

Source: IRIS Group based on material from BETA.HEALTH

While there seems to be an appropriate distribution of projects between eastern and western Denmark, reflecting the size and investments in clinical research in the two parts of the country, the figure also suggests that there is room to work towards stronger anchoring in the smaller regions and outside the university hospitals.

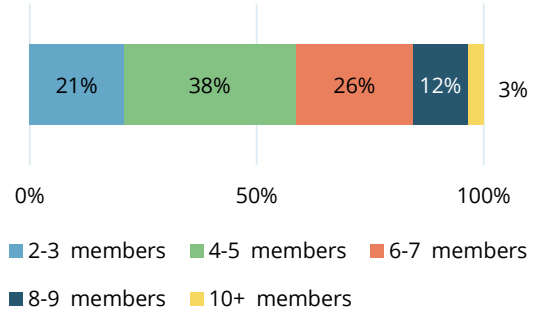
As demonstrated later in the chapter, the same pattern is observed regarding participation in the projects, including departments that do not hold the project leader role.

Members of project teams

Successful innovation relies on the right match of competences, skills and experience. In this subsection, the team composition of BETA.HEALTH projects are explored.

The typical project includes between 4-7 core members, as illustrated in Figure 4.6.

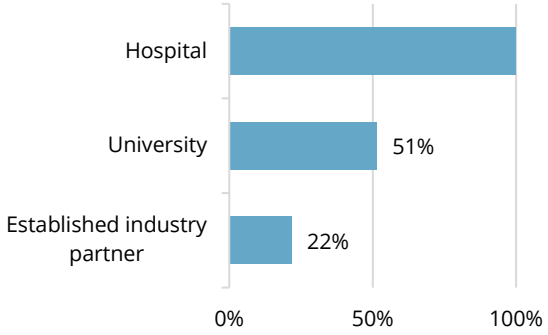
Figure 4.6. Number of core members in BETA.HEALTH projects



Source: IRIS Group based on material from BETA.HEALTH

In the conducted survey, project leaders were also asked to indicate the types of organisations represented by the project team. The answers are summarised in Figure 4.7.

Figure 4.7. Sectors represented in the core project team



Source: IRIS Group, based on a survey targeting project leaders.
Note: N= 37

All projects have at least one core member employed at a hospital, which is a requirement for applying for a grant.

However, the projects vary in terms of the number of hospital departments represented. On average, three hospital wards participate in BETA.HEALTH projects.

Further analysis of the BETA.HEALTH project teams reveals that the proportion of females is 34%. When focusing only on the main applicants, this share decreases to 29%.

Table 4.4 shows the distribution of hospital affiliations among all core team members in the BETA.HEALTH projects who are employed at Danish hospitals.

Table 4.4. Hospital affiliations, core projects members, Call 1-4

Capital Region Denmark	
Rigshospitalet	44
Hvidovre Hospital	7
Herlev and Gentofte Hospital	4
Centre for IT and Medico technology	3
Mental Health Center Ballerup	3
Steno Diabetes Center	2
Bispebjerg Hospital	1
Central Region of Denmark	
Aarhus University Hospital	36
Gødstrup Hospital	4
Horsens Regional Hospital	3
Regionshospitalet Skive	1
Viborg Regional Hospital	1
North Denmark Region	
Aalborg University Hospital	11
North Denmark Regional Hospital	2
Region of Southern Denmark	
Odense University Hospital	9
Regional Zealand	
Zealand University Hospital	6

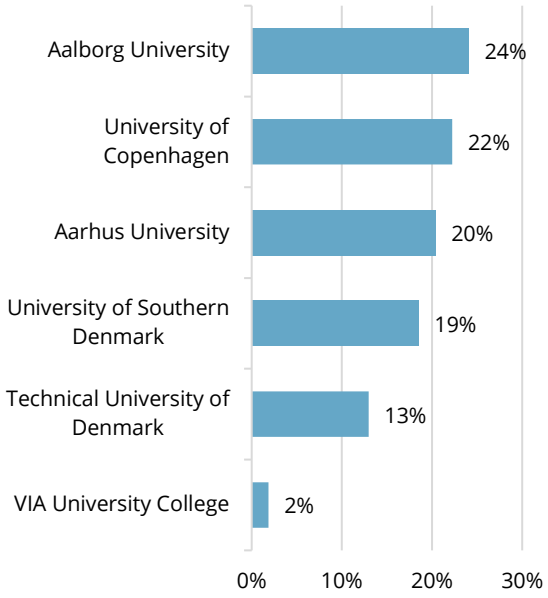
Source: IRIS Group based on material from BETA.HEALTH
Note: The table is based on applications that include institutional information on project members. Not all applicants have provided details about project members

Most of the project members are affiliated with the university hospitals. Rigshospitalet and Aarhus University Hospital account for nearly 60% of the project members.

Almost 80 % of the project members work at one of the five university hospitals.

Figure 4.8 shows the institutional affiliation of project members from the university sector.

Figure 4.8. Affiliation of core members from the university sector

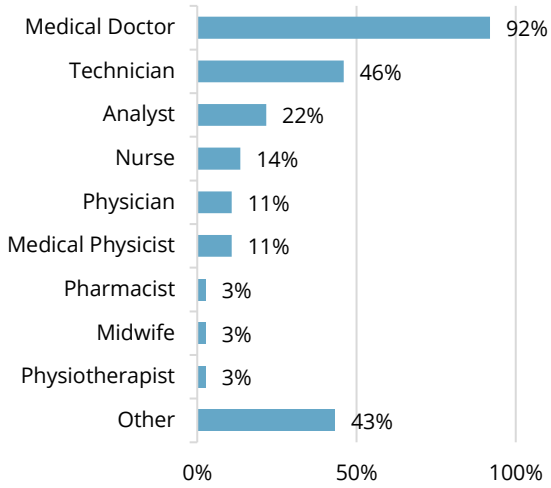


Source: IRIS Group based on material from BETA.HEALTH
Note: The figure is based on applications that include institutional information on project members. Not all applicants have provided details about project members.

The figure reveals that the geographical distribution of participating universities differs significantly from that of the hospitals. Both Aalborg University and the University of Southern Denmark are strongly represented, suggesting that university hospitals focus on collaborating with academic institutions that can provide the necessary expertise.

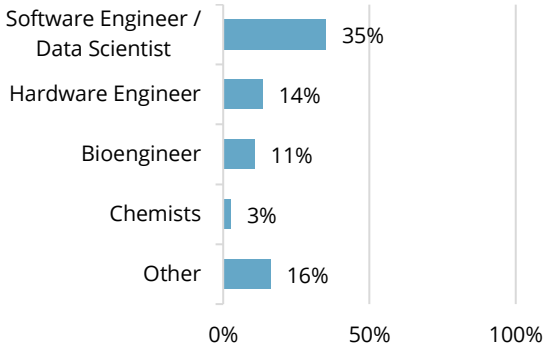
In the survey, project leaders were asked to indicate which health and academic professions were represented in the core team. The results are summarised in Figures 4.9 and 4.10, which display the share of projects that include different professions.

Figure 4.9. Participations of health professions in the core team



Source: IRIS Group based on survey of project leaders.
Note: N= 37

Figure 4.10. Participations of academic professions in the core team



Source: IRIS Group based on survey of project leaders.
Note: N=37

As shown, medical doctors and technicians are the most common professions in the projects. Software engineers and data scientists are by far the most common academic professions reflecting that many projects are dealing with AI and/or health data in a broader sense.

4.7 Motivation for starting a clinical innovation project

To get a better understanding of the motives for applying BETA.HEALTH, project leaders were asked to indicate the main reasons for starting a clinical innovation project. The results are summarised in the figure below.

Overwhelmingly, the project leaders report that the desire to improve patient care and treatment stands out as the main driver for applying BETA.HEALTH.

The results are supported in the interviews where the project leaders highlight patient needs and the desire to improve life quality of patients as main reasons for engaging in innovation.

This underscores that the projects are primarily driven by passionate healthcare professionals.

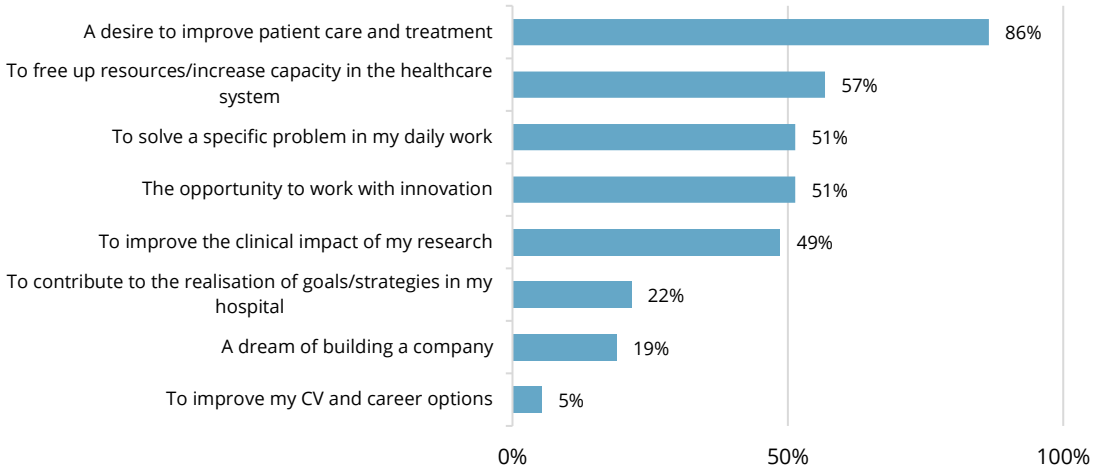
Close to 60% of project leaders identify resource optimisation as a driving force, reflecting the increasing resource challenges within the healthcare system. This indicates that this agenda (related to the so-called double demographic challenge) has also become rooted at a more decentralised level.

Additionally, around half of the project leaders cite the opportunity to improve the clinical impact of their research as a key motivating factor.

Only 22% cite contributing to hospital goals or strategies as a motivating factor. This further supports the idea that the projects are primarily driven by dedicated professionals.

In the interview, some project leaders state that the interest in the projects from department management is modest or even absent. The point is that the focus of daily management remains primarily on operations and treatment, which reflects the goals and incentives set by the regions and individual hospitals. It is challenging to integrate the long-term need to develop new healthcare solutions and free up resources through innovation into the management of specialties.

Figure 4.11. Motivational factors behind the initiation of clinical innovation project



Source: IRIS Group based on survey of project leaders.
Note: N=37. Each respondent could select up to three reasons. The sum of the percentages therefore exceeds 100.

4.8 The path to utilisation

The path or approach to utilisation or implementation of solutions varies across BETA.HEALTH projects. In general terms, there are three main paths to utilising solutions developed in clinical innovation projects:

- **Startup**: The commercialisation process involves the formation of a new company. In some projects, the company is started and led by the inventor at the hospital. In other projects, the founder is an entrepreneur from the private sector who starts the company based on an agreement with the hospital (often with clinical researchers involved in a board of directors or advisory board).
- **Industrial partnership**: The project enters into a collaboration between one or more hospitals and an existing company. In this case, the solution is developed in a public-private partnership, where the company leads the commercialisation process.
- **Internal project**: Development, implementation, and scaling take place within the hospital, often due to a lack of commercialisation potential.

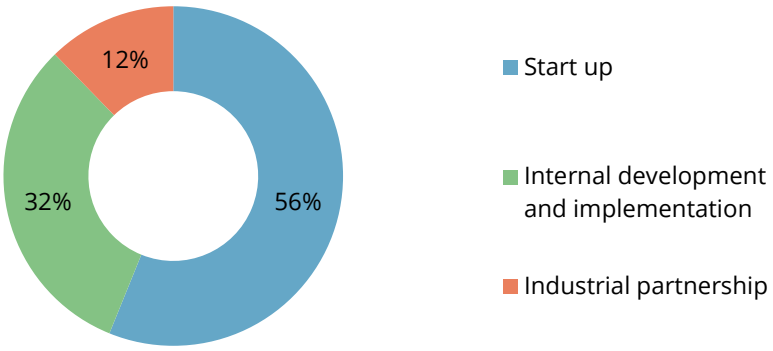
Figure 4.12 shows how BETA.HEALTH projects financed under the first four calls are distributed according to their utilisation path. As indicated, more than 50 percent of the projects involve the formation of a new company.

This reflects, among other factors, that it is easier to attract funding (both soft money from grants and risk capital from private investors) for startups than for projects following other paths to utilisation (see also Chapter 7). Moreover, hospitals often lack the resources to manage time-consuming development processes, testing, etc.

It should also be noted that startups often collaborate with existing companies. Therefore, some projects combine the two paths to utilisation.

Among the 56% who have chosen or expect to commercialise through a startup, a large portion has already established a company. It can therefore be concluded that the KPI goal of at least 15 startups will be met (see Section 4.4).

Figure 4.12. Paths to utilisation for BETA.HEALTH projects, Call 1-4



Source: IRIS Group based on material from BETA.HEALTH
Note: N= 58

Case: ENACT

ENACT is an example of a PhD thesis that has evolved into a clinical innovation project. Two BETA.HEALTH grants have facilitated substantial progress in all areas of clinical innovation, including product development, value proposition, and regulatory issues.

ENACT is an AI-driven solution designed to assist doctors in evaluating endoscopic procedures for patients with ulcerative colitis. Currently, assessments of endoscopy videos are subjective and can vary significantly between clinicians, leading to inconsistencies in treatment decisions. ENACT's AI model addresses this issue by offering a more standardised and reliable method for evaluating these videos.

The solution builds on a promising AI model first demonstrated in a PhD thesis by Bobby Zhao Sheng Lo, who continues to lead the ENACT team. The team also includes his PhD advisors from Hvidovre Hospital, two professors of data science, and a PhD student in data science from the University of Copenhagen.

From research to commercialisation

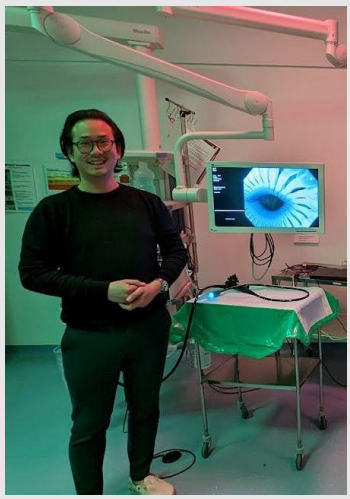
ENACT received its first BETA.HEALTH grant in 2022, which played a key role in advancing the project from a research-focused AI model to a potentially market-ready product. The grant enabled the team to develop a user-friendly interface for clinicians and assess the hardware requirements for hospital deployment. More importantly, BETA.HEALTH provided valuable insights into the commercialisation process, including intellectual property rights (IPR), regulatory challenges, and market entry strategies.

The first grant also helped the team recognise the significance of CE-marking for medical devices. With BETA.HEALTH's guidance, the team clarified the path to CE-certification, which became the primary focus of their second BETA.HEALTH grant in 2023. Since then, the team has achieved internal CE-marking within the Capital Region, allowing the AI model to be implemented without full EU-certification.

The BETA.HEALTH support

With the support of BETA.HEALTH, the ENACT team has made significant progress. They benefited from workshops facilitated by a design consultant, who helped to better understand the needs of clinicians. The feedback was crucial in shaping the user interface and ensuring that the AI results were presented in an intuitive way for doctors. Additionally, BETA.HEALTH introduced the team to regulatory experts who assisted with the CE-marking process, ensuring that the system met the necessary compliance standards.

The team also gained valuable insights into the expectations of investors and clinical stakeholders, particularly regarding the increased willingness to invest in and test the system once CE-certification is achieved. Lastly, BETA.HEALTH helped the team realise that pursuing patents was unnecessary, as the solution's complexity and reliance on proprietary AI make it too difficult to replicate.



"The BETA team pushed us beyond our comfort zone. I was asked to call several key stakeholders to understand what they actually needed. This forced us to focus on the end user."

Bobby Zhao Sheng Lo,
ENACT

5. RESULTS AND IMPACT

In this chapter, the early results and impact of BETA.HEALTH are evaluated. The progress of clinical innovation projects supported by the programme is assessed, and the programme's outputs are examined. Finally, we discuss the barriers to success encountered by BETA.HEALTH projects.

5.1 Introduction

The primary purpose of the midterm evaluation is to document how BETA.HEALTH adds value to the Danish healthcare system and to assess the progress of the clinical innovation projects it supports.

With only four calls (out of ten planned calls in the pilot phase) to review, there are, of course, limitations to what can be measured in terms of impact. Clinical innovation takes time, and as outlined in Chapter 4, the projects supported by BETA.HEALTH vary in maturity and in the time required to reach the clinic or market.

Nevertheless, Sections 5.2–5.5 offer insights into project acceleration and outputs, based on a survey of all grant recipients and interviews with 15 project leaders.

Section 5.6 examines the barriers and challenges to unlocking the full potential of the BETA.HEALTH project portfolio.

5.2 Assessment of project acceleration

Interviews with project leaders clearly indicate that the grants and services provided by BETA.HEALTH accelerate the maturation process of projects and shorten the time to reach the clinic and/or market. But by how much? And in which areas?

To answer these questions, we developed a framework for measuring the progress of clinical innovation projects. This framework is inspired by the internationally recognised KTH Innovation Readiness Level tool[4] and was developed in collaboration with the BETA.HEALTH team to ensure alignment with the specific characteristics of clinical innovation projects.

In its original form, we found the KTH Innovation Readiness Level tool too business-oriented to accommodate the diversity of the BETA.HEALTH project portfolio. The KTH index is primarily designed for startups, whereas BETA.HEALTH also supports projects that follow alternative pathways to utilisation.

Additionally, healthtech projects differ from other tech development projects, particularly due to the critical challenges posed by regulatory issues and the integration into clinical operations. These areas require special consideration when measuring progress.

Therefore, we developed a framework specifically tailored to measure progress in clinical innovation. The framework consists of six complementary dimensions.

[4] See https://kthinnovationreadinesslevel.com

Six key dimensions in clinical innovation

The customised framework allows us to measure the innovation journey of each project, taking into account variations in starting points and pathways to utilisation.

In a survey, project leaders were asked to assess the maturity level of their projects across six dimensions, using a scale from 1 to 9, with 9 representing the highest level of maturity.

Each maturity level was accompanied by a brief explanatory text to guide respondents in selecting the appropriate level on the scale (all indicators and explanatory texts are provided in Appendix 2). Box 5.1 summarises how the different levels can be interpreted.

Box 5.1. Clinical innovation readiness level

The nine levels of maturity for each of the six dimensions are listed in Appendix 2. Across these dimensions, the maturity levels can be summarised as follows:

Level 1-2: Formulation of the idea/hypothesis; initial clarification of users, funding needs, competencies required for successful innovation, and the regulatory framework.

Level 3-4: Initial validation and user feedback; funding pitch prepared and first funding obtained; gaps in competencies identified, and the team for the development phase established; clear understanding of how to achieve regulatory approval.

Level 5-6: Adjusted prototype demonstrated/funded; market segmentation in progress, and implementation strategy developed; strategies for regulatory approval and recruitment in place.

Level 7-8: Technology complete and demonstrated in actual operation; formal organisation in place and funding secured that enables sales/local implementation; value proposition targeting key decision makers.

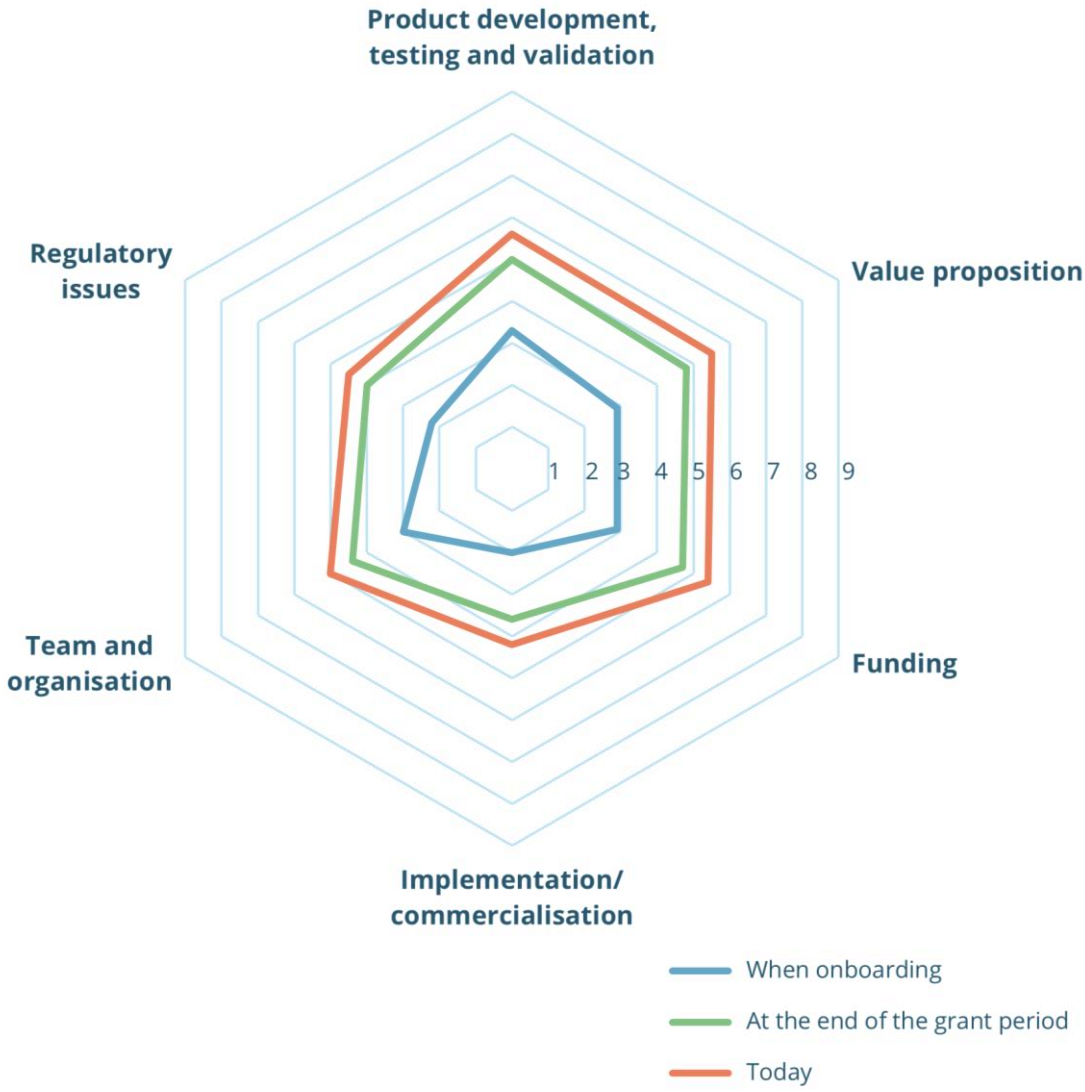
Level 9: Technology applied in actual operations; funding, value proposition and organisation set for scaling; regulatory approval obtained.

In the survey, project leaders were asked to assess the readiness level at three different points in time (as a self-assessment):

1. Upon onboarding BETA.HEALTH
2. At the end of the grant period
3. Today

The responses are summarised in Figure 5.1 on the following page.

Figure 5.1. Average clinical innovation readiness level of BETA.HEALTH projects (Call 1-4)



Source: IRIS Group based on survey of project leaders.
Note: N= 37

The blue line represents the average clinical innovation readiness level of projects at the time of onboarding to BETA.HEALTH.

On average, projects entering BETA.HEALTH seem most mature in terms of team and organisation (according to the self-assessments). With an average score between 3 and 4, the necessary resources and competencies have been identified, and in most cases, the core team is in place. The remaining five dimensions score below 3, indicating that the projects are relatively immature upon entering BETA.HEALTH.

The distance between the blue and green lines illustrates the acceleration of projects during their time in BETA.HEALTH. On average, projects make progress across all dimensions over the 6-9 months they participate in the programme.

Finally, the red line in Figure 5.1 represents the current clinical innovation readiness level of the projects. The somewhat smaller gap between the green and red lines suggests that, on average, BETA.HEALTH projects progress slow down a little after exiting the programme. However, it should be emphasised that a number of projects have

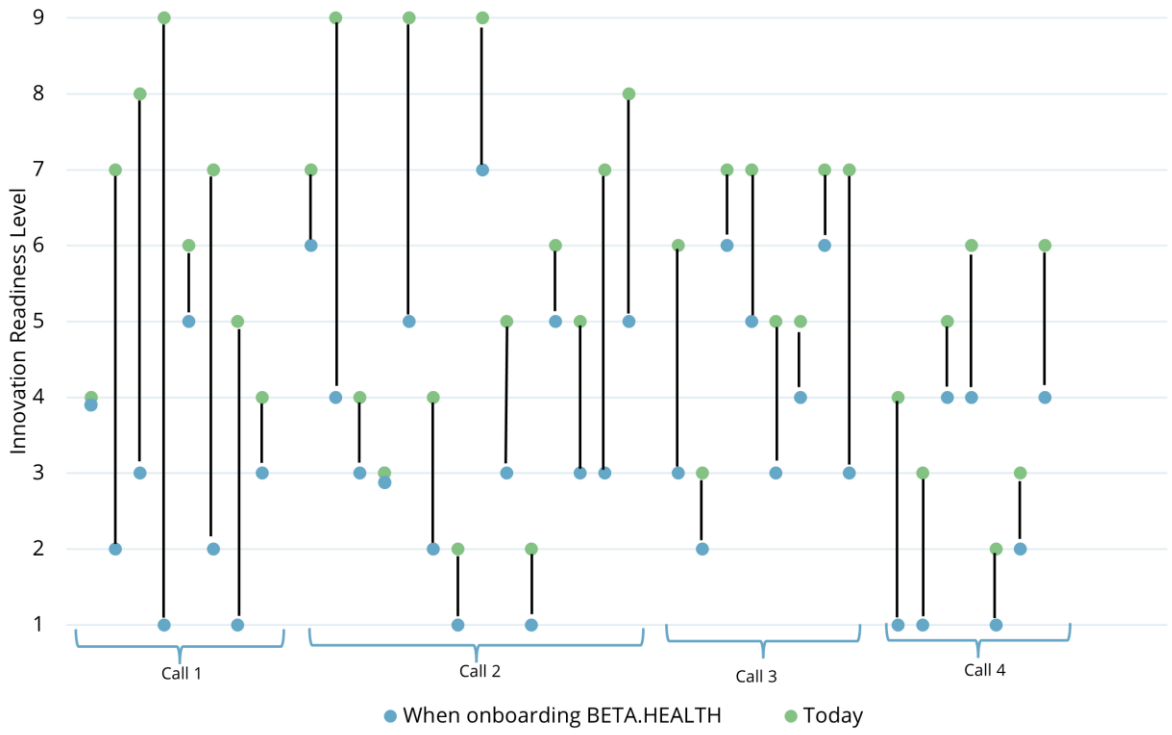
only recently completed their grant period, leaving little time for further development.

The general picture is that progress continues in most projects, but at a somewhat slower pace than during the BETA-acceleration period.

The starting points and acceleration of projects are further explored through interviews with project leaders. Some projects onboard with just an idea and a team, lacking a clear understanding of competencies or funding needs, while others enter the programme with validated technology or even a demonstrated prototype. It is important to note that the average scores presented in Figure 5.1 are based on a very diverse project portfolio.

To illustrate the variation in starting points and acceleration speeds, Figure 5.2 highlights the progress of each project in terms of product development, testing, and validation (one of the six dimensions). The blue dots represent the level when onboarding to BETA.HEALTH, while the green dots indicate the current level.

Figure 5.2 Development in Readiness level of BETA.HEALTH projects (product development)



Source: IRIS Group based on survey of project leaders.
Note: N= 37

Figure 5.2 illustrates the innovation journey of projects granted in Calls 1-4 within one of the six dimensions, namely product development, testing, and validation. The figure shows the diverse maturity levels of projects accepted into the BETA.HEALTH accelerator, and it reveals significant variations in the speed of the innovation journey across projects (including a few projects with no progress).

The figure also reflects logical differences across the calls, with several projects supported under Calls 1-2 now having reached a maturity level where the solutions are either operational or close to it.

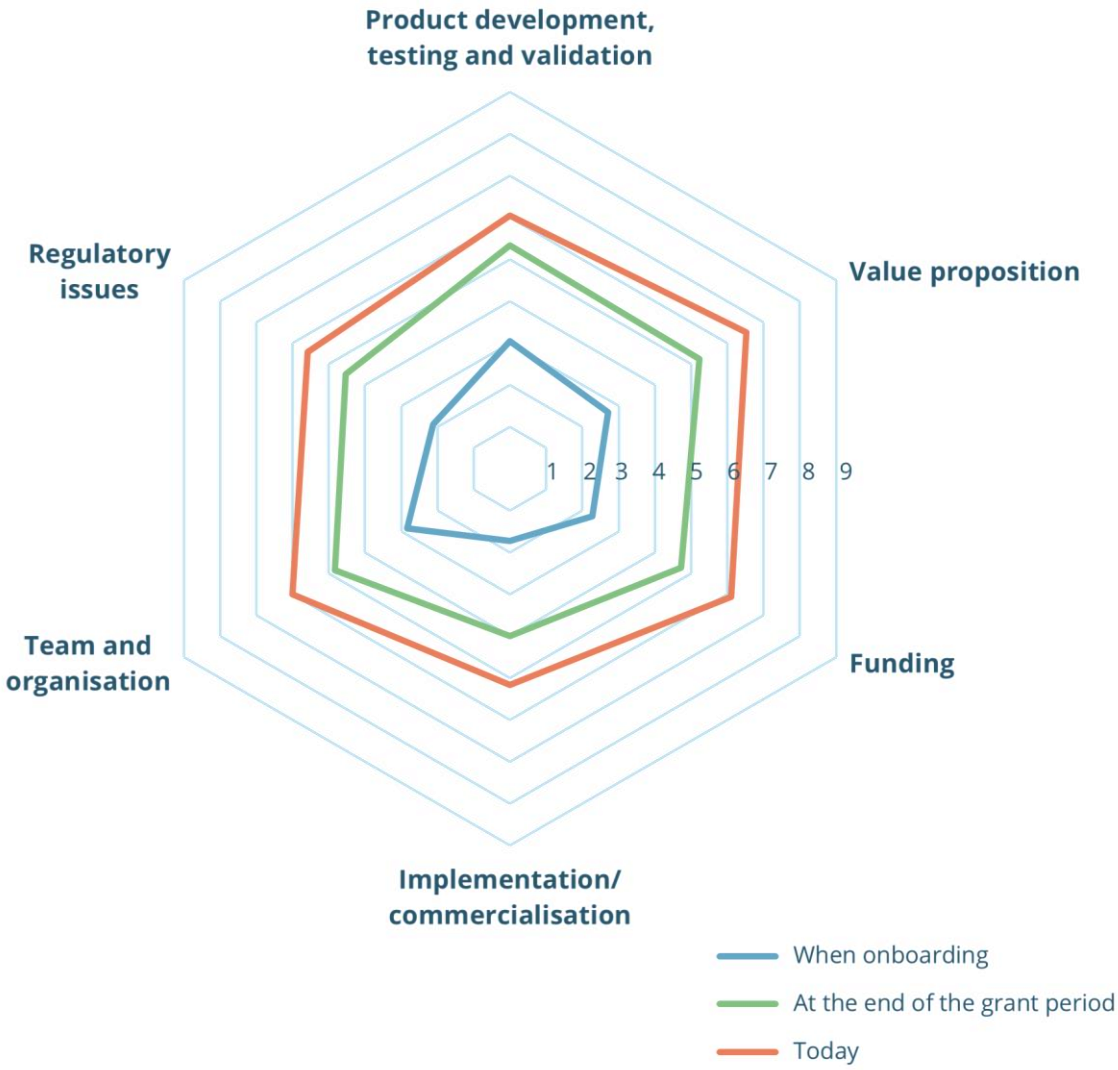
A deeper analysis of the data shows a high degree of correlation across the six dimensions. Projects making significant progress in one dimension typically also succeed in the other dimensions.

In other words, while BETA.HEALTH has been a very strong accelerator for some projects, others have only made minor improvements. This should be expected due to the nature of innovation. A cohort of early-stage clinical innovation will always include projects with disappointing results or where progress must be slowed due to unforeseen factors, such as limited resources or regulatory challenges.

Another contributing factor to the differences in Figure 5.2 is the varying complexity of the projects. For instance, some AI-based projects require relatively modest external funding and can be launched without CE marking, while other projects involve greater regulatory complexity and demand substantial capital for testing and validation.

To illustrate this point, Figure 5.3 reveals the progress for the half of the projects that have made the most significant progress across the six dimensions. The figure shows that the acceleration period has indeed been characterised by rapid maturation for a significant number of projects

Figure 5.3. Clinical innovation readiness level of selected BETA.HEALTH projects (Call 1-4)



Source: IRIS Group based on survey of project leaders.
Note: N= 18

However, the pattern in Figure 5.2 on the previous page also raises the question of whether some projects might lack the necessary resources and competences.

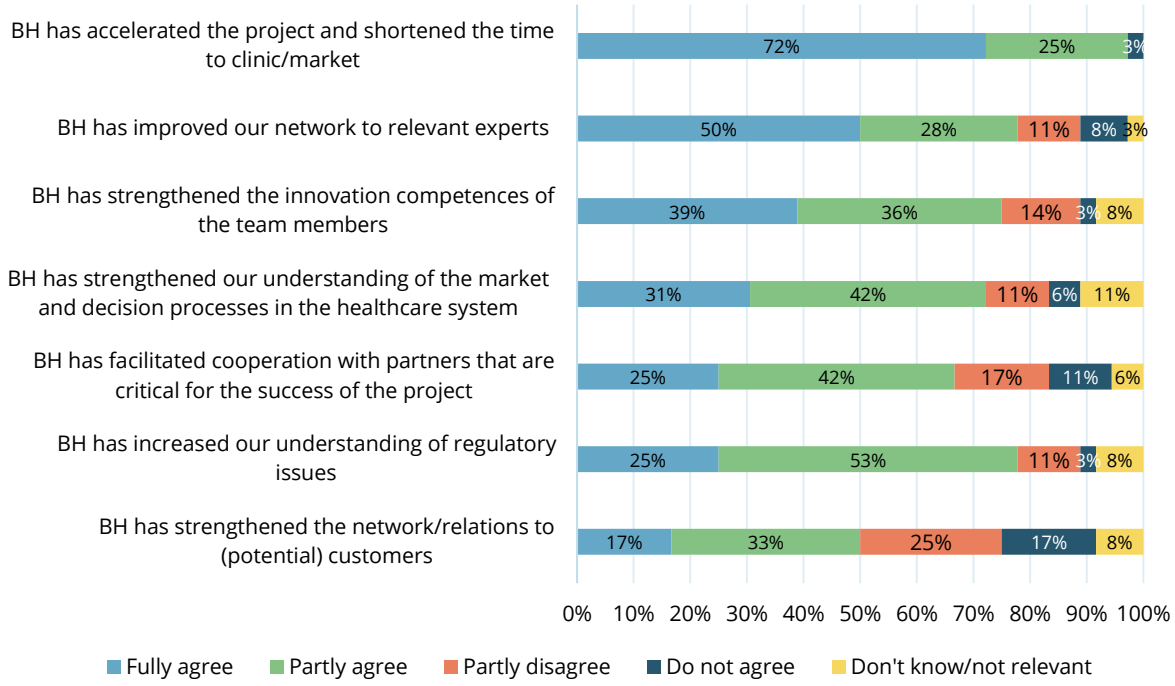
A final point regarding the two figures is that for many projects, there is still a long way to go before reaching the market and clinic after exiting BETA. This means that the success of BETA.HEALTH is largely dependent on having actors in the ecosystem who can assist with follow-up funding and, in many cases, also provide follow-up acceleration services (see Chapter 7). At the same time, the results also highlight the relevance, for some projects, to apply BETA.HEALTH multiple times — for example, during both the development and implementation phases. We will return to this issue in Chapter 8.

5.3 Evaluation of project output

All project leaders interviewed for the midterm evaluation agreed that what makes BETA.HEALTH a unique accelerator is the wide range of services that accompany the grant (see also Chapter 6). The combination of funding and services provided by the BETA.HEALTH team enables projects to accelerate effectively.

Figure 5.4 presents seven statements regarding the output of BETA.HEALTH. Project leaders were asked how they agree with each statement.

Figure 5.4. BETA.HEALTH project output according to project leaders (Call 1-4)



Source: IRIS Group based on survey of project leaders.
Note: N= 36

The first statement in Figure 5.4 reinforces the conclusions from the previous section: BETA.HEALTH accelerates clinical innovation projects and shortens the time to market or clinic. The figure also indicates that in three out of four projects surveyed for the evaluation, BETA.HEALTH has improved access to relevant experts, and in nearly 7 out of 10 projects, the BETA.HEALTH team facilitated cooperation with partners critical to project success.

In interviews, project leaders explained that several features of the programme contribute to the acceleration. In most cases, the BETA team helped to set direction and develop a coherent development plan. It was also emphasised as a key factor that BETA.HEALTH connects the projects with experts in areas where clinicians typically have limited experience or knowledge.

The project Auto Delineation serves as an example. With both a doctor and a medical physicist on the team, all necessary competencies for developing a clinical solution were in place. However, the team lacked connections to innovation partners and experts in regulatory affairs. One of the key outcomes for this project was an improved network, including connections with the innovation unit at Aarhus University Hospital and regulatory experts.

"A team of researchers like ours requires support to successfully manage innovation projects. The BETA team helped us see where we were and where to go next."

Fatemeh Makouei, Biomedical Engineer, Rigshospitalet

Regulatory issues and market insights

It is noteworthy that a significant proportion of surveyed project leaders fully agrees that the BETA.HEALTH project increased their understanding of regulatory issues, as well as decision processes within the healthcare system. Additionally, many project leaders partially agree with these statements.

The interviews provide further insight into these numbers.

In some projects, regulatory issues and the preparation for implementation and sales have been central, as seen in projects like Auto Delineation.

In early-stage projects, these issues have typically been less prominent. However, some interviewees representing this type of project emphasise that further development and progress (after exiting BETA) could have been accelerated if more attention had been given to addressing challenges and planning the next phases. As a result, some project leaders request a stronger focus on the overall innovation journey and better preparation for subsequent steps. This is especially true for internal development projects and startup ventures.

Differences across regions

Splitting the responses by BETA.HEALTH team affiliation (East/West) revealed little change in the results shown in Figure 5.3. The only notable difference was that projects affiliated with the East-team were more likely to agree with the statement that BETA.HEALTH strengthened the innovation competencies of their team members.

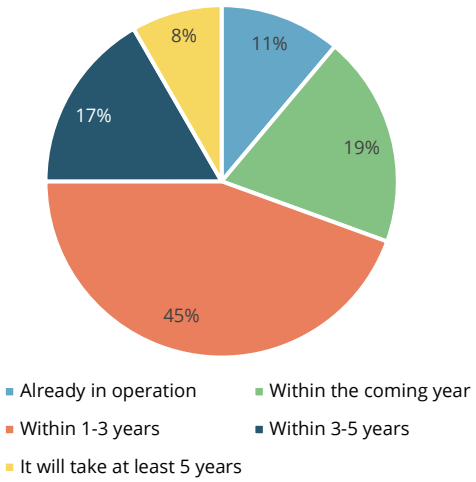
Conversely, projects affiliated with the West-team tended to agree more with the statement that BETA.HEALTH improved their understanding of the market and decision-making processes with-in the healthcare system.

5.4 The road to clinic and patients

The stated purpose of BETA.HEALTH is to support innovation projects in maturing solutions more rapidly so that they can benefit patients and society.

To gauge the time remaining before solutions reach the clinic, project leaders were asked when they expect their solutions to be fully operational for the first users, assuming risks and barriers are overcome. Their responses are shown in Figure 5.5.

Figure 5.5. Expected time for clinical solution to be fully operational by the first user(s)



Source: IRIS Group based on survey of project leaders.
Note: N=36

The figure indicates that 30% of surveyed projects already have a solution in operation or expect to have one within the coming year (corresponding with the pattern in Figure 5.2 above). Of the four projects already in operation (11%, as shown in Figure 5.5), one is running locally (within its own department or hospital), two are operational regionally (across multiple departments or hospitals), and one—a spinout called Ward 24/7—has scaled internationally, with its solution deployed in multiple hospitals abroad.

Halfway through the pilot phase, these results are impressive and demonstrate the initial impact of BETA.HEALTH.

The results in the figure clearly indicate that BETA.HEALTH will fulfil the KPI goal of six solutions in operation at the end of the pilot phase (see Section 4.4).

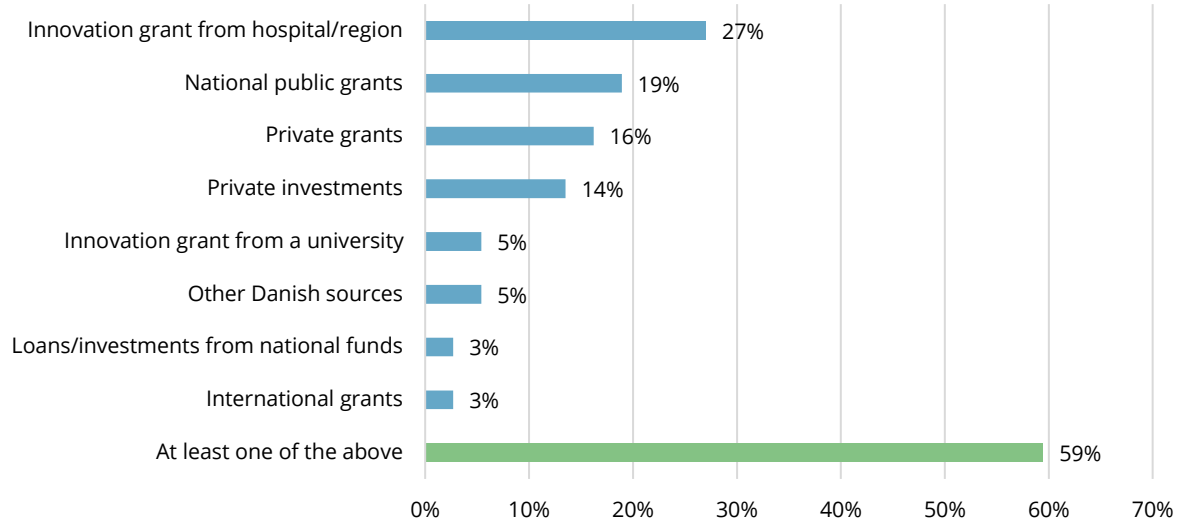
5.5 Ability to attract funding

A BETA.HEALTH grant (during the first four calls) ranged between 250,000 DKK and 1,000,000 DKK in project funding. While the grant size may not be large compared to research grants and other innovation grants, it is often the first innovation grant that projects receive and is intended as seed funding, making the projects fundable for other programmes (see Chapter 6).

In Figure 5.1 above, we learned that, on average, projects progress from a score of 2.8 to 4.5, indicating a shift from initiating dialogue with investors or funds to securing funding.

In the survey, project leaders were also asked how much funding their projects had attracted after onboarding to BETA.HEALTH and from which sources the funding originated. Figure 5.6 shows the proportion of BETA.HEALTH projects that secured further funding during and after the acceleration period.

Figure 5.6. Share of BETA.HEALTH projects that has secured further funding, divided into funding sources (Call 1-4)



Source: IRIS Group based on survey of project leaders.
Note: N= 37

The bottom bar in the figure shows that 6 out of 10 projects have secured further funding. Moreover, the figure reveals a diverse picture, with many sources contributing to the further funding of BETA.HEALTH projects.

The most common source is innovation grants provided by the hospital or region. Additionally, 19% of the projects have obtained national public funds, primarily from programmes like InnoExplorer or InnoBooster (the Innovation Fund Denmark). Private grants and private investments have also been involved in several projects (mostly those at a relatively high maturity level).

On average, projects that have obtained further funding have secured 3.8 million DKK.

For the four out of ten projects that have not yet secured funding, the survey asked whether they expected to receive additional funding in the near future. Two-thirds of these projects confirmed that they do.

The survey also reveals that BETA.HEALTH plays a crucial role and is thus successful as a bridge funding programme. Specifically, 9 out of 10 projects that have attracted further funding indicate that BETA.HEALTH has contributed a great or moderate extent.

"BETA has raised the quality of pitches for our programmes. The clinical innovation projects that have gone through BETA.HEALTH have significantly higher quality and stronger value propositions than other projects within medtech and healthtech."

Troels Jørgensen, Lead Relations Officer, Innovation Fund Denmark

Interviews with some stakeholders in the ecosystem suggest that BETA.HEALTH is on its way to becoming a strong brand. In some programmes and funds, participation in BETA.HEALTH is viewed as a quality seal.

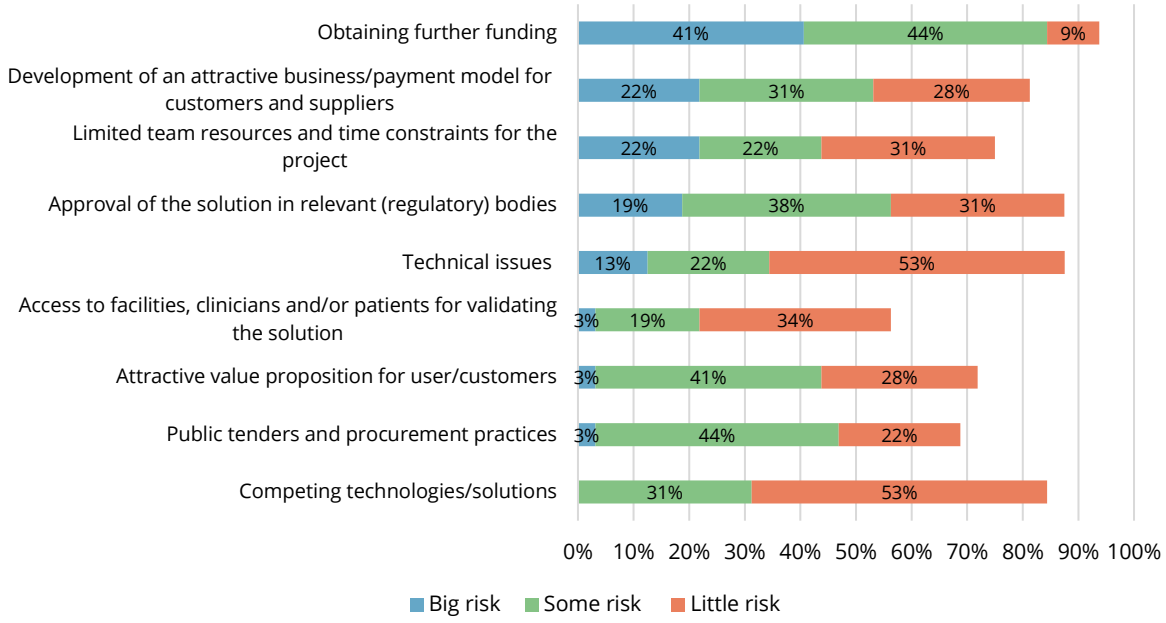
5.6 Barriers to success

As the projects vary in terms of goals, technology, and maturity when entering BETA.HEALTH, they

face different risks related to bringing their solutions to market or clinical practice.

Figure 5.7 illustrates nine potential barriers for BETA.HEALTH projects and the proportion of project leaders who consider them to be a risk.

Figure 5.7. Risk in relation to bringing the solution to market/clinical practice (Call 1-4)



Source: IRIS Group based on survey of project leaders.
Note: N=32. Results only include projects where the solution is not in operation.

Across projects, securing funding for the next steps of the innovation journey constitutes the largest risk followed by the challenge of developing an attractive business and payment model. Limited resources to engage in innovation and regulatory approval also constitute major risk in some projects, while technical risks seem to have been reduced in most projects.

In interviews, project leaders explain that the BETA.HEALTH grant is crucial for kickstarting and accelerating the project, but additional funding is necessary to continue the innovation journey.

Although most projects have succeeded in this matter, further funding is necessary to reach market in many of these projects. And while a number of projects have secured funding from regional or national funds, the challenge of engaging private investors is still something to be solved in the upcoming phases.

As discussed later in Chapter 7, the BETA.HEALTH grant is one of the few funding options available for early-stage clinical innovation. A key focus for most projects is to secure follow-up funding, and in many cases, the BETA.HEALTH team assists by connecting projects to potential funds, refining their value proposition, and training team members in pitching their ideas.

In the interviews, many project leaders also emphasised barriers related to implementing and scaling the solution. Implementing and scaling clinical innovations is a complex task that – apart from requiring the necessary resources in terms of time and money – often involves integration across IT systems, management commitment, and the release of resources in clinical departments.

As many BETA.HEALTH projects are data-driven, implementing solutions at other hospitals depends on access to IT-infrastructure and technical adaptability. With varying systems and practices for providing access to local IT architecture, scaling is foreseen as difficult and time-consuming by a number of project leaders.

According to both project leaders and representatives from hospital management, BETA.HEALTH could serve as a valuable link between projects and key supporting infrastructures at hospitals or within regions (see also Chapter 8).

A more general challenge related to implementation is the need for data and clinical evidence. Once the final prototype or product is in place, the pathway to sales is often linked to large-scale testing (ideally across multiple countries or regions), where the solution is validated as the foundation for a compelling value proposition. This process is resource-intensive for the projects and requires that hospital departments allocate the necessary time for clinical trials. This issue is reflected in Figure 5.7 – almost 45% of the projects assess limited resources as a risk.

Additionally, several of the interviewed projects express that the phase from development to sales is extended due to uncertainty among legal teams regarding the interpretation of procurement regulations. This is especially relevant when considering whether the host institution of a development project is allowed to purchase the solution.

It is expected that an increasing number of projects will encounter implementation challenges as more solutions become fully developed.

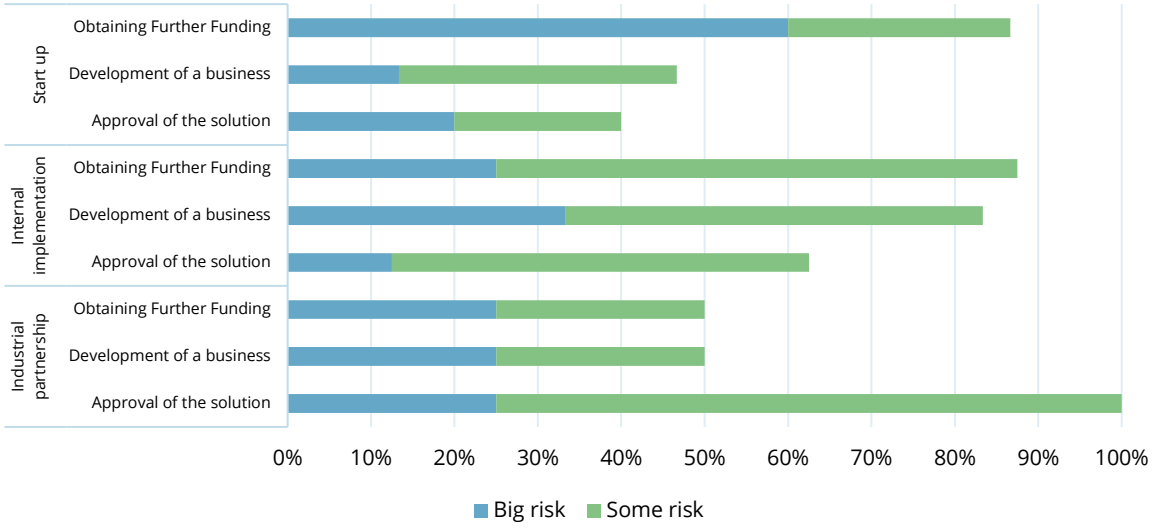
Regulatory affairs represent another challenge for some projects as shown in Figure 5.7. Two out of ten project leaders consider gaining approval from the relevant regulatory bodies to be a big risk. This may reflect uncertainty about the approval process, as well as a lack of skills and resources to obtain, for example, CE marking.

If we look more closely at different types of projects, we find that regulatory issues concern more projects in industrial partnerships than in startups (see Figure 5.8 on the next page)[5].

The figure also suggests that funding is considered a big risk across startups. This result reflects that projects requiring substantial amounts of funding for commercialisation often opt to create a startup (since the supply of programmes is higher for startups and since the formation of a startup makes it possible to attract private investors).

[5] It is important to note that the figure is based on a small number of observations and thus contains uncertainty.

Figure 5.8. Risk in relation to bringing the solution to market/clinical practice, divided into types of projects (Call 1-4)



Source: IRIS Group based on survey of project leaders.
Note: N=32. Results only include projects where the solution is not in operation.

An additional area of significant importance, which is only indirectly covered by the survey, is access to international customers and markets. Few BETA.HEALTH projects have yet reached a stage where international scaling is relevant, but hopefully, this will change in the years to come. Several interviewees emphasise the importance of being able to test and validate solutions in other countries. This could become an even stronger focal area if BETA.HEALTH decides to implement an implementation grant (see Chapter 8).

Moreover, a few interviewees highlight the relevance of establishing partnerships with foreign hospitals that may be interested in following the entire BETA.HEALTH portfolio (for example, those that have reached a certain level on the clinical innovation index). It would be a natural task for the BETA.HEALTH steering committee to coordinate outreach to foreign university hospitals with which the management of Danish hospitals already has strong relationships.

Case: Dermloop

Dermloop is one of the BETA.HEALTH projects already in use in clinical practice. The BETA team played a decisive role in identifying the project's weaknesses and what was needed to make the solution ready for private investments and sales to the regions.

Dermloop is a digital tool designed for aiding doctors in the diagnosis and management of skin diseases. The technology assist general practitioners in distinguishing between benign and malignant skin lesions, significantly reducing the number of physical referrals to dermatologists. In the long term, the ambition is to expand the platform to cover other diagnostic areas.

The solution includes an app that aids general practitioners in the capture of high quality images and a medical history of skin conditions such as moles for in-platform diagnostics by a dermatologist. During image acquisition an AI algorithm assists the doctor, ensuring optimal image quality. Additionally, the platform features a learning component aimed at enhancing doctors' ability to detect skin cancer.

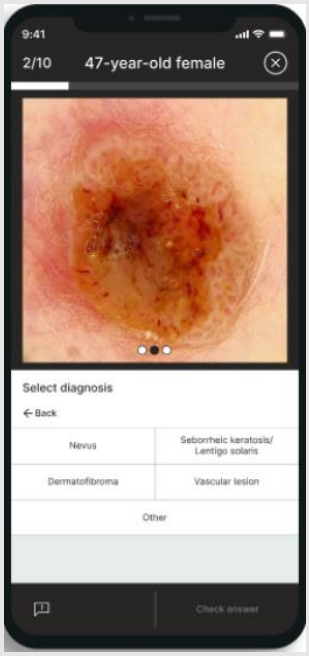
The idea for Dermloop was fostered by Niels Kvorning, a doctor and postdoctoral researcher at Herlev and Gentofte Hospital, in 2018. However, it wasn't until 2020, with funding from the Innovation Fund, that product development gained momentum. During this phase, it became evident that the greatest potential lay in general practice, where simple and fast access to a specialist could help address resource challenges across the healthcare sector.

The project was accepted into the BETA.HEALTH programme in 2022, which became a crucial factor in making the solution attractive to private investors. The BETA.HEALTH grant was utilised to further develop the technology, enhance the user interface, and provide legal documentation. In the latter area, the expertise of the BETA.HEALTH team in regulatory matters was leveraged to confirm and document that the product did not require CE marking. Additionally, the BETA team assisted in finding an expert who could explain and document why the images taken in general practice could be considered anonymous, thus avoiding GDPR issues.

In 2023, private investors injected capital into the startup company Melatech, which serves as the commercial arm of Dermloop. BETA.HEALTH's strong network was instrumental in connecting Melatech with the Central Denmark Region, which subsequently purchased the solution.

Dermloop is implemented by 10% of the country's general practitioners and is set to be rolled to 80% of all general practitioners over the next two years. Simultaneously, Melatech has partnered with a company in the United States to expand the technology healthcare organisations across the US that in total covers 4.5 million residents.

Revenue in 2024 is projected to reach 6 million DKK, and Melatech already employs 14 full-time staff members.



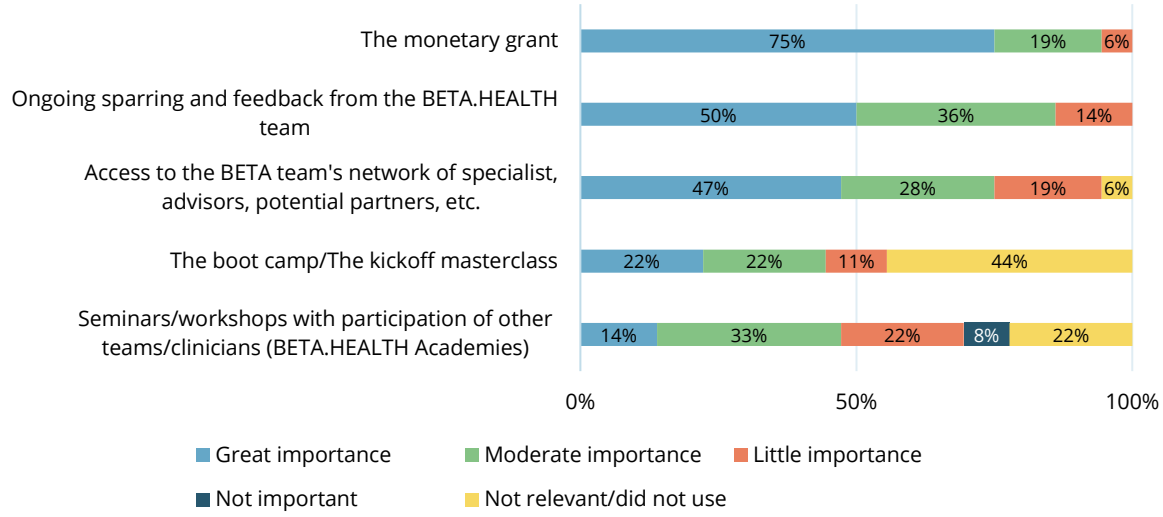
6. EVALUATION OF BETA.HEALTH ACTIVITIES AND SERVICES

This chapter evaluates the services provided by BETA.HEALTH to clinical innovation projects adopted in the acceleration programme. Moreover, it assesses the administration of the programme based on feedback from project leaders.

6.1 Introduction

Among the participants in BETA.HEALTH, there is generally a very high level of satisfaction with the overall programme design, the individual services, and the competencies of the two BETA teams. This is reflected in the survey, where respondents were asked to indicate the value they attribute to the programme's services for the progress of their projects (see Figure 6.1).

Figure 6.1. The importance of BETA.HEALTH offers for the progress of projects



Source: IRIS Group based on survey of project leaders.
Note: N=36. The kick-off masterclass was introduced in West from call 4. This explains the high number answering "not relevant/not use" to this specific question.

Of course, it is not very surprising that 95% indicate that the funding itself has a significant or moderate impact on progress. Clinical innovation projects are highly dependent on funding if they are to reach the market or clinical practice. However, it is notable that 86 % state that the feedback they received from the BETA team is important, with 50 % attributing great importance to it. This underscores the fact that BETA.HEALTH is more than just a funding opportunity. At the same time, interviews also show that, in many projects, the feedback significantly enhances the value that the grant brings to the projects.

It is also evident that BETA.HEALTH's network adds value to the projects. Many clinicians have a limited network of consultants, industry contacts, and experts. BETA.HEALTH's finely tuned network ensures that the projects are matched with

individuals and companies that can help them tackle the biggest challenges during the acceleration phase.

Finally, the figure indicates that the BETA.HEALTH Academy has had a more moderate impact on the specific projects so far. In this regard, it should be noted that kick-off masterclasses were only introduced in Call 4 in the West. This explains why a high percentage of respondents answered "not relevant/did not use" to this question.

The following sections (6.2–6.4) elaborate on how project leaders assess and evaluate their participation in BETA.HEALTH, distinguishing between the different stages: kick-off, acceleration, and finally, exit. Section 6.5 evaluates the value of the BETA.HEALTH Academy activities, while Section 6.6 provides feedback on the administration of the programme.

6.2 Kick-off

When projects onboard BETA.HEALTH, they are invited to a boot camp (East) or a kick-off masterclass (West). However, projects from West Denmark that were granted funding in the first three calls were offered individual sparring instead of a kick-off masterclass. Nevertheless, all events had the same focus: to help projects scope their ideas and plan their time with BETA.HEALTH.

In interviews, project leaders explain how consultants from the BETA.HEALTH teams challenge them to work intensively on their idea, value proposition, market plan, etc., in the initial phase of the grant. Project team members are generally impressed with the innovation professionals they meet at the first meetings and workshops.

The boot camp in the East is described by multiple project leaders as a tough but valuable event. The value is achieved through a combination of meeting other clinical innovation projects, learning from successful innovation journeys, and –most importantly – being challenged on aspects of innovation that the teams had not considered prior to BETA.HEALTH. A project member interviewed for the midterm evaluation stated that she initially provided feedback to BETA.HEALTH that the boot camp was too intense. However, with some distance from the event, she changed her mind and now believes the intensive first two days were extremely valuable to the project.

The boot camp forces team members to spend two days together off-site, away from their clinics and desks. For some projects, these two days represent the most concentrated time they have spent together on the innovation project. Working full-time in a clinic or part-time with research on the side leaves few consecutive days for their innovation work.

The intensive initial phase – whether it be a boot camp, kick-off masterclass, or individual sparring – seems to be a successful way to challenge project teams to identify the most important next steps and draw up a plan to realise them.

All projects receive tailored guidance, and the steps planned in the initial phase are specifically designed to accommodate the acceleration of each innovation project.

"The strength of BETA.HEALTH is its flexibility and focus on helping projects where it creates the most value. We don't have to fit into specific boxes like in other incubation programmes."

Kasper Linde, CSO and Founder, ZETA Diagnostics

If projects realise, during the initial phase, a need to adjust the scope and activities outlined in their application, BETA.HEALTH is helpful and open to changes in scope or budget items. It is evident from the midterm evaluation that BETA.HEALTH, compared to other innovation grants, is a highly flexible grant, allowing a wide range of activities and budget adjustments along the way.

However, some projects found the boot camp (East) and kick-off masterclass (West) to be a little too rigid, not fully accounting for the wide

variation in clinical innovation readiness levels across projects. Additionally, in cases where projects received a follow-up grant from BETA.HEALTH, the boot camp for the second grant did not seem as relevant to the projects as the first meeting with the programme. Only three project leaders interviewed for the midterm evaluation had applied for and received a second grant. Nevertheless, all reported that the second boot camp was essentially a copy of the first one they attended, focusing on teams new to clinical innovation.

If BETA.HEALTH plans to offer more follow-up grants in the future, there appears to be room for improving the initial phase for follow-up projects.

6.3 Acceleration

Most BETA.HEALTH projects are managed by clinicians with little or no experience in clinical innovation. For that reason, individual sparring is an important part of the programme and distinguishes it from other funding options, such as the InnoExplorer offered by the Innovation Fund Denmark (see Chapter 7).

Across projects, project leaders agree that the professional sparring received from the BETA.HEALTH team throughout the grant period is what makes BETA.HEALTH a unique programme.

The BETA team members are characterised as experienced, accessible, and eager to help make the solution a success. Most project leaders interviewed for the midterm evaluation did not expect the high level of mentoring offered.

BETA.HEALTH consultants bring real-world experience from the medical industry or the healthtech startup scene. They understand the challenges that project members face and are familiar with the structures that clinical innovation projects must navigate.

Project leaders also emphasise the value of BETA.HEALTH consultants being proactive, energetic, and closely involved with the projects.

"BETA.HEALTH is a unique programme. The essence is not the money but the support you receive from the team in terms of knowledge and networking. These are experienced innovation professionals who know how to guide projects in the right direction and connect you with the right experts."

Jasper Nijkamp, Associate Professor, Aarhus University Hospital

During the acceleration phase, many projects benefit from the extensive network provided by the collective BETA.HEALTH consultants. Key network contacts include regulatory and technical specialists, as well as funding sources, innovation units, and end users.

There are many examples of how the BETA.HEALTH network benefits projects. In one case, a BETA.HEALTH consultant used her network at Aarhus University to arrange a project presentation in front of 40-50 medical doctors attending a course. The feedback and input received from this large group of end users was invaluable for the acceleration of the project. In another case, a BETA.HEALTH consultant helped connect a project to key decision-makers in the Central Denmark Region, who ultimately decided to purchase the solution.

Projects' use of external consulting is often a result of advice and networking from BETA.HEALTH consultants. Several projects have accelerated their innovation journeys based on a health economic impact analysis of their solution provided by a specialised consultancy. Prior to BETA.HEALTH, few projects had solid knowledge of the health economic impact of their solution, which is essential for attracting future funding.

Regulatory issues and design of innovation journeys are two other areas where both internal and external consultants help projects accelerate.

CE marking is an example of a dimension of innovation that few clinicians are aware of before starting an innovation project. CE marking documents

that a medical device complies with applicable EU legislation and is necessary to freely market medical devices in the EU. The road to CE marking can be challenging, but the evaluation finds that projects are in good hands with BETA.HEALTH. During their acceleration phase, many projects obtain a clear understanding of the steps towards CE marking and receive professional help to set up a Quality Management System (QMS), which is required for documentation.

Assistance with designing user interfaces and branding for startups is another valuable service offered by BETA.HEALTH, which multiple project leaders have emphasised as crucial for accelerating their projects.

There are, however, areas where adjustments to the programme could potentially accelerate projects even further. One area is legal and practical assistance with implementing solutions in the health sector. Project teams are often well-connected within their clinical domain, but their relationships with legal and executive departments at hospitals are often less established. According to a number of interviewees, BETA.HEALTH could serve as a link between projects and key stakeholders at hospitals.

Another area is early consideration of international scaling. BETA.HEALTH could to a greater extent establish connections with experienced business professionals to help projects gain an understanding of interest and key structures such as standards, IT systems, and procurement practices in health sectors abroad.

"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 toward something that could create value for clinicians. 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

6.4 Exit of BETA.HEALTH

When exiting BETA.HEALTH, projects need a clear vision of the next steps in their innovation journey. BETA.HEALTH can support clinical innovation projects from idea to implementation. However, as we learned in Chapter 5, the portfolio of BETA.HEALTH projects varies significantly in terms of clinical innovation readiness when onboarding to BETA.HEALTH and when exiting the programme. Consequently, the next steps for projects exiting BETA.HEALTH are rarely identical.

At the time of interviewing project leaders, some projects were just about to exit due to an extended grant period, while others had onboarded a second grant. Among the projects that have officially exited the programme, several project leaders keep in touch with their BETA.HEALTH consultant and report that BETA.HEALTH is happy to spend time answering questions or giving advice even though the team is no longer part of the portfolio.

However, whether projects keep in touch with BETA.HEALTH or not, some projects feel that the road to the clinic and patients is still unclear when they leave the accelerator.

Despite project leaders reporting great satisfaction with project acceleration thanks to BETA.HEALTH, some projects still have not decided how to utilise their technology or clarified their intellectual property rights (IPR) when exiting the programme.

Another challenge, according to project leaders, is that they see a gap to the next funding step and do not know how to bridge it.

In most cases, BETA.HEALTH has strengthened the innovation competencies of the team members (see Figure 5.3 in Chapter 5), but some projects still need help in drawing up a roadmap for the next steps, including a realistic timeline and estimates of the resources needed to reach each step.

6.5 BETA.HEALTH Academy

As shown in Figure 6.1 in the beginning of the chapter, there is significant variation in the project leaders' assessment of how BETA.HEALTH Academy has impacted the progress of their projects. This finding is supported in the conducted interviews. Some projects have greatly benefited from the courses, while others have not prioritised participation or have gained limited value from them.

The reasons for these differences can be summarised as follows:

- Some of the more mature projects find most of the courses too general and have prioritised work packages in their own projects.
- For some clinicians, it has been difficult to prioritise time to attend courses, as many have been scheduled during periods when they had pre-assigned operational duties.
- In some workshops, project leaders found that there was too wide a variation in participants' backgrounds and in the focus of BETA projects. This made it difficult to establish a strong connection between theory and practice in the workshops.
- When BETA.HEALTH have identified challenges that cut across projects and has designed courses accordingly, the value of the Academy has been high.

The project on Eustachian Tube Dysfunction (commercialised through the startup Zeta Diagnostics – see the case in Chapter 7) is an example of a project that has successfully tapped into the BETA.HEALTH Academy:

- The project team participated in a workshop on regulatory issues arranged together with two external experts. The workshop provided an important overview of regulatory challenges and how to proceed with development to obtain CE marking.
- The project team participated in a masterclass focused on communicating value propositions to regional procurement officers. This experience strengthened their value proposition and stress-tested the validity of the project's health economic calculations.

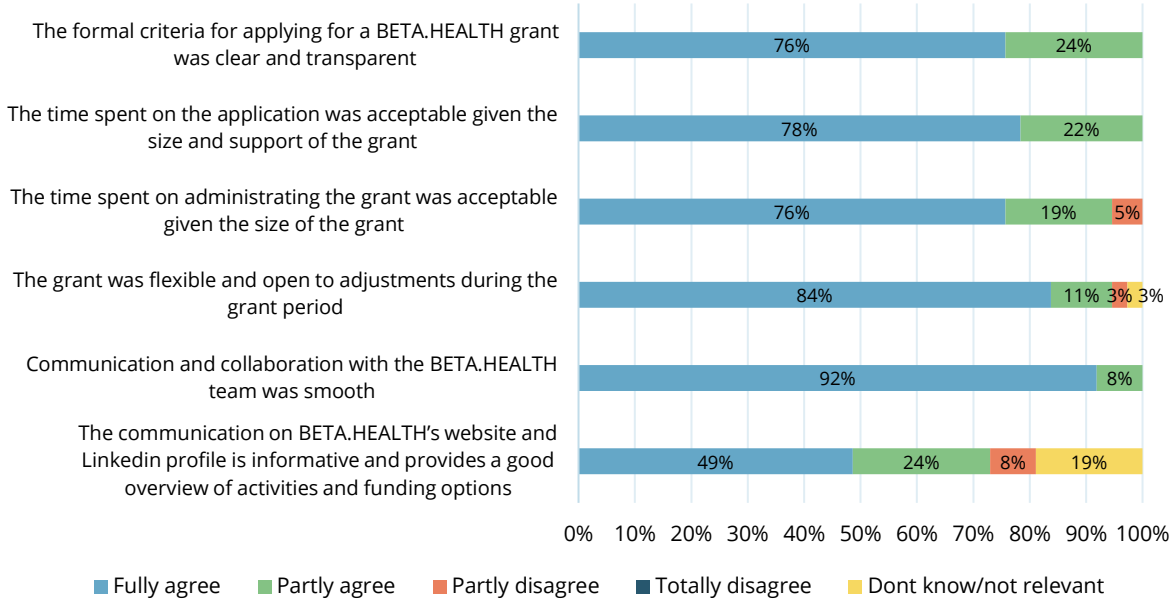
Some interviewees also emphasised that the Academy has provided informative events on current issues such as AI in the health sector. While these courses might have a small impact on ongoing projects, they could be important for the development of future ideas and projects.

Despite these differences in participation and impact, the interviews indicated strong support for BETA.HEALTH and a desire to broaden the scope and target group. There is a common understanding that innovation competencies and culture need to be strengthened at all levels in the health sector, and that BETA.HEALTH Academy can be a key actor in this regard. We will return to this in the recommendations in Chapter 8.

6.6 Administration of BETA.HEALTH

There is a high level of satisfaction with the administration of BETA.HEALTH. This is reflected in the figure below, which provides an overview of the agreement levels with statements related to both the application and project phases, as well as the communication efforts of BETA.HEALTH.

Figure 6.2. Project leaders' assessment of the administration of BETA.HEALTH (Call 1-4)



Source: IRIS Group based on survey of project leaders.
Note: N=37

The project leaders express the highest degree of dissatisfaction regarding the communication on BETA.HEALTH's website and LinkedIn profile. The feedback indicates that the website, in particular, is difficult to navigate when they search for information about BETA.HEALTH, including the grant procedures and the value proposition offered to projects. Moreover, some researchers with no prior experience with innovation projects found the terminology challenging to understand and struggled to determine whether their ideas or projects were eligible for BETA funding.

Thus, the feedback indicates that researchers perceive the website more as a branding tool for BETA.HEALTH directed at stakeholders, rather than as a platform that provides clear user journeys for those interested in applying for a grant.

Despite the high rating of the administrative services provided by BETA.HEALTH, the interviewees also pointed to issues that call for improvement:

- Some terms in the application form are difficult to understand for researchers with no prior experience in innovation (digital guidance is requested).
- BETA.HEALTH allows multiple grants for projects, but the criteria for accessing subsequent grants are unclear (including whether adoption in other funding programmes disqualifies a project from receiving a new BETA grant).
- Feedback to rejected projects/applicants could be improved, including guidance regarding 1) other funding options and 2) the relevance of applying for a BETA.HEALTH grant in future calls (and what elements need improvement).

One service not yet mentioned in this report is access to advice for researchers before applying for BETA.HEALTH. Several project leaders have utilised the BETA.HEALTH team to assess the relevance of their ideas, and in some cases, the team has also played a crucial role in encouraging teams to apply for BETA.HEALTH.

6.7 Final remarks

Finally, it is relevant to note that BETA.HEALTH has been operational for just over two years, and that the two main teams had very little time to establish the programme. As the evaluation indicates, supporting clinical innovation is a complex endeavour, and effectively communicating the value proposition to clinicians without prior experience in innovation and acceleration programmes has posed a significant challenge.

In this context, it is impressive that the BETA.HEALTH team has achieved so much, and that the programme receives such positive feedback from clinicians who have utilised BETA.HEALTH's services (as revealed in the survey data).

It should also be emphasised that the ability to deliver results in a programme like BETA.HEALTH is significantly influenced by the framework within which it operates. Several interviewees pointed out that the increasing focus on innovation from hospital senior management has been a critical prerequisite for BETA.HEALTH's success.

Conversely, many department heads remain focused on operational matters, which, in some projects, may weaken the conditions for reaching clinical practice, as indicated by the barriers outlined in Chapter 5. It is therefore important to foster a stronger innovation culture within hospitals and to equip leaders with the skills needed to support the development and implementation of new technologies (see Chapter 8).

Additionally, the long-term impact of BETA.HEALTH relies on how the regions prioritise innovation and new technology. Many respondents noted the need for closer collaboration on initiatives that facilitate the implementation and testing of new technologies in pilot operations.

Finally, the success of BETA.HEALTH is also heavily dependent on other stakeholders in the ecosystem prioritising and funding clinical innovation, a topic we will explore further in Chapter 7.

Case: Praemostro

Praemostro is an example of an innovative AI-driven solution developed by a team of researchers with no prior commercial experience. Two BETA.HEALTH grants have significantly impacted the scaling of the solution and helped set a commercial direction.

Praemostro is an AI-driven solution aimed at improving staffing accuracy in hospital emergency departments. Emergency departments often face unpredictable fluctuations in patient inflow, leading to staffing challenges that impact both patient care and hospital efficiency. Praemostro's system utilises machine learning to forecast patient inflow 12 hours ahead.

The core team consists of Mikkel Brabrand, a physician, and Troels Martin Range, a mathematical economist, both researchers based at the Department of Emergency Medicine at Odense University Hospital (OUH). Their idea stemmed from an article they read about how individuals with chronic obstructive pulmonary disease were more likely to be hospitalised during bad weather.

From a research-driven project to a commercially viable product

The core team had the clinical knowledge and technical skills to build a successful prototype. In fact, an early prototype was in operation at OUH for one years prior to onboarding BETA.HEALTH. But the team initially lacked experience in commercialising healthcare innovations.

Two BETA.HEALTH grants allowed the team to reprogram their system for scalability, test it in other hospitals with different IT setups, and develop a comprehensive user interface and visual identity.

The team also benefitted from BETA's expert guidance on commercial and business strategy, including counselling on establishing a spinout company and advice regarding pricing structure. This support helped the team accelerate Praemostro towards a commercially viable product.

Commercial potential beyond healthcare

While Praemostro is primarily focused on the healthcare sector, particularly in emergency departments, its predictive AI system has broader potential applications. The team has already begun testing the technology in other high-variability environments, such as food production facilities. The ability to forecast demand with high accuracy could also optimise staffing and resource management in other industries.

7. BETA.HEALTH'S INTEGRATION IN THE ECO-SYSTEM FOR CLINICAL INNOVATION

BETA.HEALTH is an important brick in the comprehensive Danish ecosystem for clinical innovation and healthtech. This chapter focuses on how BETA.HEALTH has been integrated and adopted in the ecosystem. It also provides an overview of the links to other programmes supporting research, innovation and scaling of healthtech solutions.

7.1 BETA.HEALTH and the ecosystem

Denmark hosts a very strong and vibrant ecosystem for clinical innovation and life science in a broader sense. We have world leading companies, numerous startups and scaleups, a very strong clinical research base, advanced hospitals, private fonds investing heavily in research and innovation, as well as a number of incubators (such as COBIS, Incuba Science Park Skejby and DTU Science Park). Moreover, a digitalised healthcare system and access to a unique data infrastructure creates strong preconditions for innovation.

The role of BETA.HEALTH in relation to the ecosystem is twofold: to fill a gap between clinical research and the development of health care solutions; and to tap into the ecosystem in order to match clinical innovation projects with the right expertise, partners and investors.

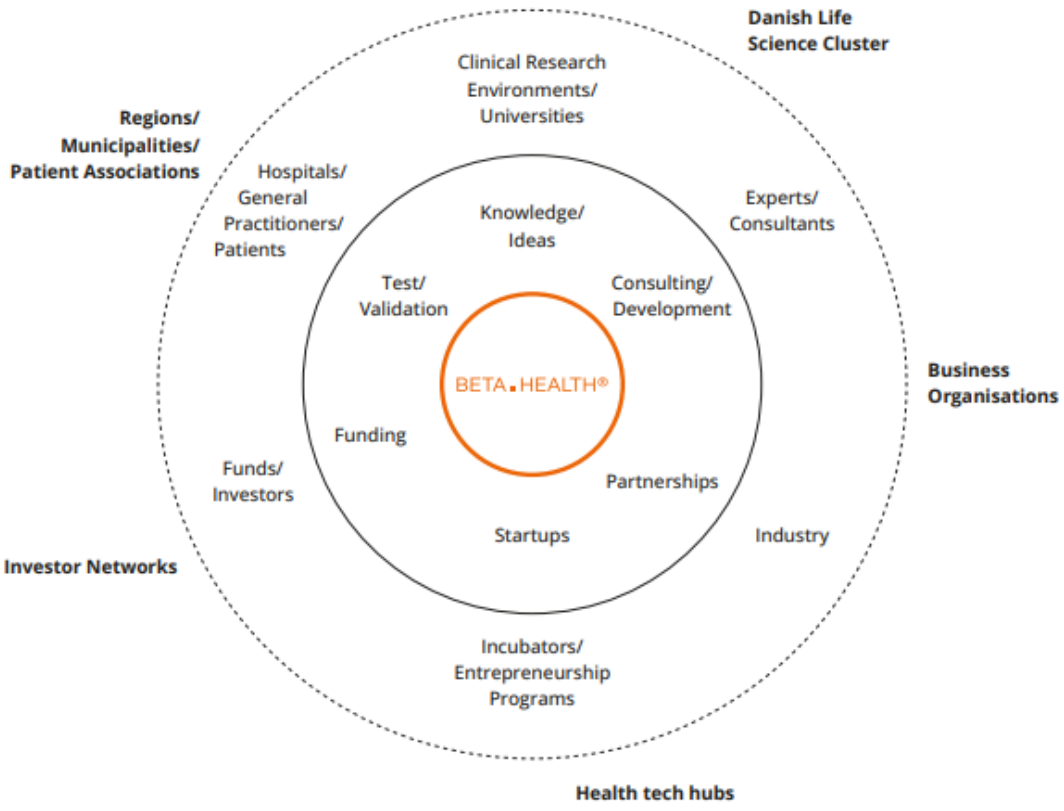
Figure 7.1 on the next page summarises the ecosystem for clinical innovation and healthtech, as well as key stakeholders, from a BETA.HEALTH perspective. The inner circle divides innovation activities into six headlines – 1) knowledge and new ideas, 2) development and access to expertise, 3) formation of partnerships, 4) startup activities (if formation of a startup is part of the commercialisation process), 5) funding of innovation and 6) test and validation. The outer circle provides an overview of the key actors in the ecosystem and where they typically play important roles in the innovation circle.

Outside the circles, the figure shows key stakeholders that organise and represent actors in the outer circle. These stakeholders constitute important partners to BETA.HEALTH, since they can ease access to relevant actors in the outer circle. Thus, it is important for an innovation accelerator like BETA.HEALTH to develop a strong network with organisations, that can facilitate access to experts, industrial partners, relevant universities, test environments and investors.

7.2 Knowledge of BETA.HEALTH in the ecosystem

To effectively tap into the ecosystem, it is important that BETA.HEALTH is well-known among the various stakeholders (and vice versa) and that BETA.HEALTH effectively collaborates to match the projects with the right companies, environments, investors, and other relevant partners.

Figure 7.1. The ecosystem of clinical innovation seen from a BETA.HEALTH perspective



Kilde: IRIS Group

To shed light on this issue, we have interviewed approximately 30 leading individuals in different parts of the ecosystem. The following sections summarise the inputs from the stakeholders, starting with clinical research environments and universities.

7.2.1 Clinical research and universities

A crucial task for BETA.HEALTH has, of course, been to become well-known at hospital departments that carries out clinical research. A high information level at the hospitals is decisive in securing a strong pipeline of innovation projects, and to fulfil the purpose of BETA.HEALTH to become a unifying national platform for clinical innovation.

BETA.HEALTH has invested significant resources in informing and communicating about the programme across hospitals and hospital environments. This has been done through presentations in departments and research networks, webinars, newsletters, and by building a large mailing list to inform about new calls and BETA.HEALTH Academy activities.

There is considerable recognition of this effort across university hospitals, and the interviews with stakeholders at the hospitals indicate a good awareness of BETA.HEALTH in the relevant environments. However, the assessment outside of university hospitals is that awareness of the programme and its value proposition for innovation projects could be further expanded.

When it comes to universities, BETA.HEALTH's primary task has been to help projects identify relevant researchers who can enrich the projects with knowledge about new technologies or assist by providing access to facilities (see Chapter 4).

As shown in Chapter 4, a relatively large number of BETA projects involve researchers from universities. The interviews reveal that awareness of BETA.HEALTH at universities is limited today, but the BETA team is effective at leveraging university connections to identify relevant research environments.

However, in the interviews both universities and companies indicate that universities could play a larger role in developing new project ideas that might enhance BETA.HEALTH's pipeline. Until now, universities have only come into play once projects have been formulated and development work had begun.

A point raised in the interviews is that Denmark has a significant potential to develop health technologies with a major impact if clinical knowledge and user needs expertise from hospitals are combined with the universities' knowledge of new technologies and the business sector's knowledge of the market and foreign healthcare systems. In this context, several interviewees suggest that BETA.HEALTH should focus more on idea generation within selected themes (see Chapter 8), and that increasing awareness of BETA.HEALTH within relevant research environments would be beneficial.

Finally, the relations to Danish Life Science Cluster (DLSC)[6] are weak according to DLSC. The purpose of DLSC is to connect partners, drive innovation projects, and create networks between companies, research institutions, and organisations within life science and welfare technology. According to DLSC, the collaboration could be developed in areas where BETA.HEALTH can benefit from leveraging DLSC's core services, such as:

- Matchmaking – DLSC organise events where companies, researchers and clinicians are matched to develop ideas that could solve clinical needs.
- Implementation – DLSC finance and facilitate projects aiming at implementing solutions in the health sector.
- Partnerships – as a cluster organisation, DLSC has deep knowledge of the innovation agenda in many companies. This knowledge could be relevant to BETA.HEALTH in their efforts to link selected projects with external partners (see Chapter 8).

7.2.2 Experts, consultants and industry

The right side of Figure 7.1 covers the business sector and includes sectors such as it, healthtech, medtech, pharma, and consultancy. First, a core task for BETA.HEALTH is to match projects with experts who have specialised knowledge in areas such as product development, IT architecture, user-driven innovation, regulatory issues, etc. (See Chapter 6). A large share of the grants is spent on these services, and since clinicians' networks to experts are often poor, the quality to a great extent depends on the ability of BETA.HEALTH to identify relevant suppliers.

Second, the best route to commercialisation and scaling for some projects is to form partnerships with existing companies that have the resources and expertise to develop and scale new solutions. It is often important to establish these partnerships early (during the acceleration process), as market insight can be crucial for success. Thus, helping BETA.HEALTH project leaders identify relevant partners and informing life science companies about the BETA pipeline are important tasks for the BETA.HEALTH team.

Third, existing companies and leaders in the life science industry can act as sparring partners for innovation projects. The interviews revealed a strong interest and willingness among established

[6] The national cluster organisation for life science.

companies to contribute to BETA.HEALTH. For the interviewed companies, the BETA.HEALTH program creates an opportunity to gain an overview of the pipeline of new ideas and technologies emerging from the hospitals. Thus, BETA.HEALTH can create a win-win situation, where companies, on one hand, increase their insight into early technologies, and on the other hand, enrich the projects with their knowledge of business models, market issues, and preconditions for scaling new technologies.

There is no doubt that BETA.HEALTH has been successful in connecting projects with relevant experts (see Chapters 5-6). It is also evident that several projects have been linked with appropriate industrial partners.

The interviews clearly indicate that the success is based on strong personal networks among members of the BETA.HEALTH team, combined with skills and experience in searching experts in the ecosystem where personal networks may have gaps.

This approach has worked thus far, but it also misses opportunities in all three mentioned tracks and may lead to some degree of sub-optimisation. Both the interviewed business organisations and companies advocate for a more systematic approach, where organisations and networks outside the circles in Figure 7.1 help identify relevant actors interested in contributing to the different parts of the innovation circle. Moreover, as BETA.HEALTH grows and more projects exit, it may be relevant to build a database or CRM system that collects data and evaluations of experts, partners, and consultants who have contributed to BETA.HEALTH projects.

7.2.3 Incubators and entrepreneurship programmes

In more than 50 percent of the BETA-projects, the path to utilisation involves the formation of a startup, cf. Chapter 4. Thus, it is of great importance that BETA.HEALTH projects manage to benefit from programmes and services available to tech startups in the ecosystem.

Most university hospitals host incubators that offer tech startups office space, access to labs and meeting rooms, as well as various administrative services and business support. Aarhus, Copenhagen, and Aalborg each host incubators with a specific focus on life sciences. Moreover, BII and Health Tech Hub Copenhagen (see next section) offer access to office space for early-stage startups.

A significant proportion of BETA startups utilise these facilities and services, and interviewees report a high level of information regarding relevant office spaces, labs, and programs.

The project leaders interviewed who have chosen the entrepreneurial path also express satisfaction with how BETA.HEALTH keeps them informed about relevant startup programs such as Inno-Founder (Innovation Fund Denmark) and BII.

7.2.4 Fonds and investors

As indicated in Chapter 5, all BETA projects rely on additional funding to reach the market and clinical practice. Given that most project leaders have limited experience with innovation funding and lack connections to potential investors, it is essential for BETA.HEALTH to build relationships with potential funding sources.

This is particularly important for projects where the path to utilisation occurs through startups. Internal implementation projects may have better opportunities to obtain funding through regional funds, while projects with industrial partners can secure funding from the partner.

The interviews present a mixed picture. On one hand, there is a strong and ongoing dialogue with central organisations in the funding ecosystem. BETA.HEALTH considers the BioInnovation Institute (BII) and the Innovation Fund Denmark (IFD) as important stakeholders and a natural next step for several projects. Feedback from these

organisations suggests that BETA.HEALTH is well-known, that its cases are of high quality, and that the BETA.HEALTH team has excelled in communicating about the program and relevant projects.

On the other hand, there is limited awareness of BETA.HEALTH among actors in the private part of the ecosystem. The interviews suggest that the program is not well-known among private investors or networks that connect investors in the medtech and healthtech fields. The same applies to Health Tech Hub Copenhagen, a private cluster organisation focused on the startup segment. In addition to offering mentoring and office space in the hub's premises, Health Tech Hub Copenhagen also organises a large international investor network interested in early-stage startups.

7.2.5 Hospitals, general practitioners and patients

The last group of stakeholders consists of actors who are important collaborators when the solutions need to be tested and validated in trials and operational settings. These include, among others, departments of general medicine at hospitals, clinical staff at hospitals, general practitioners, nursing homes, and patients.

In these groups, there is predominantly a need to inform about relevant projects, while it seems less relevant to keep a high information level about BETA.HEALTH in general.

However, to ease access to clinical environments and patients, it is important for some BETA projects to establish connections with organisations that represent these stakeholders. This includes management teams from departments of general medicine, municipalities, the General Practitioners' Organization (PLO), and patient associations. With a growing focus on implementation anticipated (see Chapter 8), it seems crucial to enhance communication with these groups in the future.

The interviews suggest that the efforts in the first two years of the program have been directed towards stakeholders in the health sector who are important for securing proposals for new innovation projects.

7.3 The value chain for clinical innovation

The journey from idea to market and clinical practice is long, complicated, and expensive. While project holders can reapply for a BETA grant, it typically requires much more funding and effort to make healthtech solutions ready for clinical use.

The success of BETA.HEALTH is therefore largely dependent on the availability of other grants and acceleration services. Fortunately, a key conclusion from the interview round is that the ecosystem and funding opportunities have significantly improved over the last 3-4 years, thanks to both BETA.HEALTH and other important initiatives. The following initiatives represent major improvements in the ecosystem for clinical innovation projects:

- BII launched the BII Venture Lab in 2021—a 12-month incubation programme for life science companies that offers access to BII's offices and labs, a risk-free convertible loan of 500,000 Euro, advisory services including business development and scientific sparring, a team coach, and a structured approach to testing and validating new products.
- In 2022, BII furthermore launched its Venture House programme as a follow-up to Venture Lab. The programme supports maturing of technologies in startups and offers the same kind of services as Venture Lab, as well as a convertible loan off Euro 1,3 mill.
- EIFO has established a team dedicated to healthtech and medtech. Since 2019, the fund's direct investments in the sector have increased fivefold, and health tech is recognised as a key focus area in EIFO's strategy.
- Financed by the Novo Nordisk Foundation, DTU Science Park and DTU established the Medtech Investor Network in 2024, focusing on healthtech, medtech, and biotech. The network

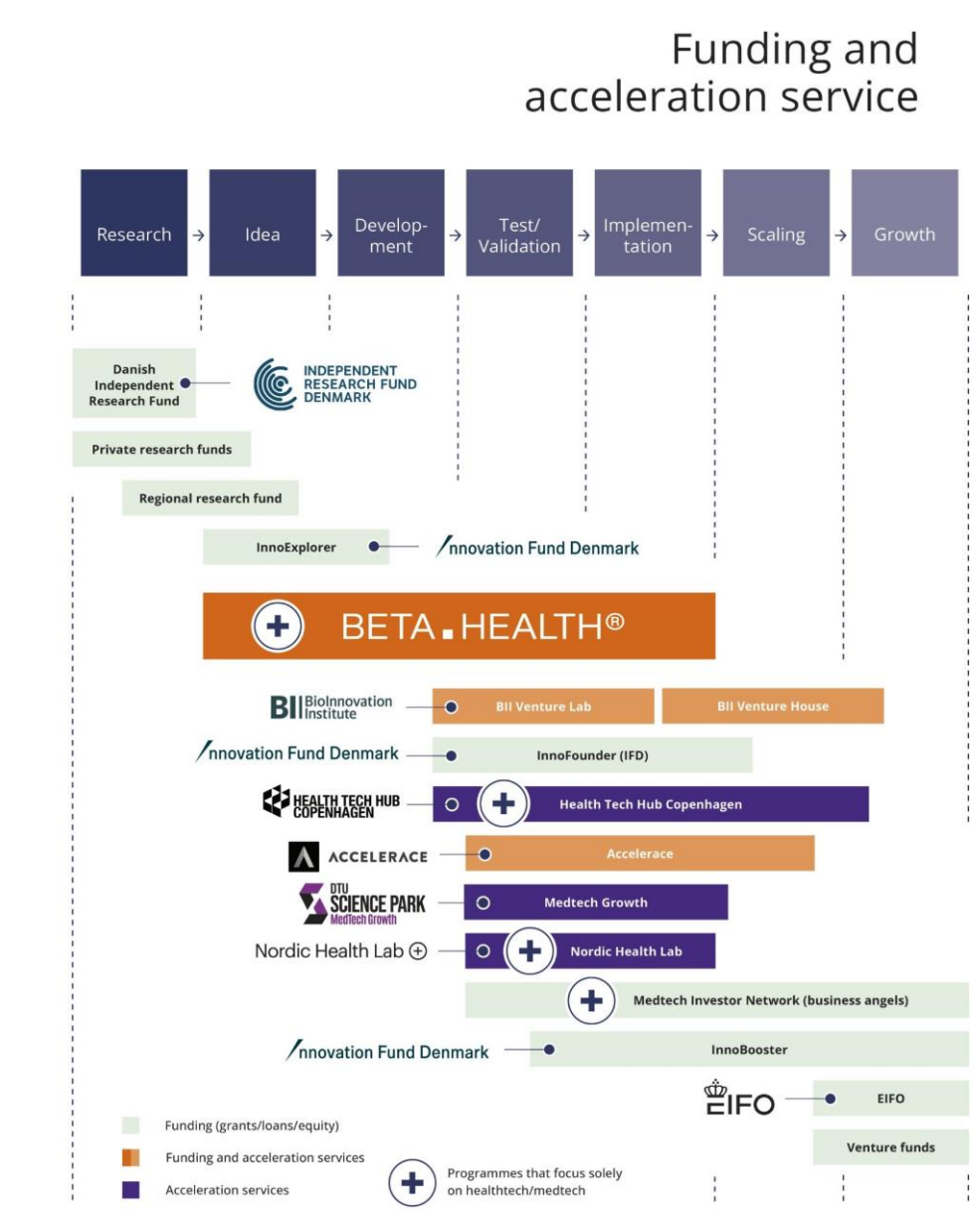
organises various events across Denmark to introduce angel investors to startups. Additionally, the initiative offers capacity building and training for business angels interested in investing in life science startups.

- Supported by the Industrial Fund, Health Tech Cluster Copenhagen has developed several acceleration services for startups, including office space, business support, and connections to potential test environments in Europe. Established in 2019, the Hub also features an international network of investors interested in early-phase startups.
- In 2024, DTU Science Park launched a new "Medtech Growth" program, financed by the Industrial Fund. This program includes a comprehensive 360-degree analysis of the business plan and provides access to leading experts (e.g. in regulatory issues and funding), mentors, office space, and labs. Spanning 12 months, the program is organised around several boot camps and sprints.
- In 2023, life science, health, and welfare technology were selected as one of the three focal areas for the Innovation Fund as part of a political agreement. This decision means that a large share of the investments in the Inno-Founder and Innobooster programmes will be directed toward life science projects.

Figure 7.2 on the next page creates an overview of the current national programmes, and how they are related to the different phases of the typical innovation journey from research to market. The programmes in the upper part of the figure are accessible for all kinds of projects, while the programmes in the lower part are accessible only for those projects that imply formation of a startup.

As indicated, some programmes are dedicated specifically to healthtech and medtech, while others take a broader approach.

Figure 7.2. Programmes supporting clinical innovation projects and healthtech companies



Source: IRIS Group

The figure reveals that BETA.HEALTH fills a crucial gap in the value chain for clinical innovation. Without BETA.HEALTH, InnoExplorer would be the only programme available for clinical innovation projects in the early phases. Moreover, although the BETA grants are relatively small compared to later financing rounds for healthtech projects, BETA.HEALTH supports several phases of development. This reflects the reality that expenditures often increase significantly during the implement-tation and scaling phases of healthtech solutions. As shown, one important feature of BETA.HEALTH is that the program offers both funding and acceleration services, as described in Chapter 5. The same

is true for the major BII programs and, to some degree, for Health Tech Hub Copenhagen[7]. This means that healthtech projects receive high-quality acceleration services throughout the entire journey, from idea to scaling and growth phases.

BII, Health Tech Hub Copenhagen, and the new Medtech Growth program can be viewed as complementary pathways for healthtech startups. The needle eye in BII is relatively small since the Venture Lab only accepts 20 company each year, with a significant portion of those slots allocated to biotech and therapeutics. In contrast, Health Tech Hub Copenhagen and Medtech Growth are open to more companies and specialise in the same areas of the life science sector as BETA.HEALTH.

As indicated, EIFO focuses on the growth phase and does not yet have experience investing in BETA cases. EIFO's engagement typically begins with providing convertible loans of approximately 5 million DKK to healthtech companies that have raised seed capital through a couple of rounds. These companies usually reach a stage comparable to BII's Venture House. Subsequently, EIFO invests equity in collaboration with European venture funds. For instance, in recent years, EIFO has made significant investments in Danish healthtech companies (such as Dawn Health and Corti) alongside major European funds like Atomico and Prosus.

[7] The Hub does not offer grants but helps members to develop pitches & decks and to connect them with investors and soft money opportunities.

Case: ZETA Diagnostics

ZETA Diagnostics is an example of a company that has benefited from a cohesive ecosystem with strong funding opportunities from idea to market. BETA.HEALTH made the company fundable for other programmes and investors.

Most middle ear diseases have an underlying cause called Eustachian Tube Dysfunction (dysfunctional pressure regulation of the middle ear, creating negative pressure).

Kasper Linde Christensen, a medical doctor, participated in the Biomedical Design programme in 2019, where it was identified that there is a significant unmet clinical need and that no solutions currently existed to diagnose the condition.

Kasper Linde therefore initiated the development of a device able to diagnose the condition. As part of the Biomedical Design programme, he received a small grant in 2022 to develop a functional prototype yielding proof of principle.

Kasper simultaneously applied for a BETA.HEALTH grant, and the was accepted into the programme in May 2023. Following this, he founded the company Zeta Diagnostics alongside two co-founders with backgrounds in engineering and medical devices.

The company also became part of the Inno-Founder programme and was accepted into Danish Tech Challenge – a DTU based programme focusing on maturing hardware companies.

The combination of hardware-support from Danish Tech Challenge and the life science competencies in the BETA.HEALTH-team, allowed Zeta to create a development plan that was crucial for the company's progress and the product's maturation.

The BETA.HEALTH funds were channelled into product development, preparation of a patent application, and regulatory work. At the same time, Zeta Diagnostics received assistance in conducting health economic calculations to document the clinical potential.

A key element in the collaboration with BETA.HEALTH was the participation in a regulatory workshop. The workshop provided insight into regulatory challenges and how to obtain CE-marking and emphasised practical strategies for successful compliance.

Further funding obtained from multiple sources

Building on the results and progress from the BETA.HEALTH project, Zeta Diagnostics was accepted into BII and received a convertible loan of 4 million DKK.

It is expected that further funding needs before reaching the market will be around 15 million DKK. An application for the Innobooster programme has been submitted to the Innovation Fund Denmark, and there is also an ambition to continue in the BII Venture Lab and to secure outside funding.

"The BETA team helped us create a development plan that ultimately made ZETA Diagnostics fundable. The value of the programme largely lies in its flexibility to adapt the use of funds to the needs of the projects".

Kasper Linde Christensen, ZETA Diagnostics

8. BETA.HEALTH 2.0 – RECOMMENDATIONS FOR FURTHER DEVELOPMENT

Even though the pilot phase appears to be a success in terms of impact, BETA.HEALTH can be further strengthened. This section proposes adjustments to the programme's design, organisation, and governance.

8.1 Introduction

This concluding chapter offers suggestions on how BETA.HEALTH can be strengthened moving forward. Based on the analyses and conclusions in the previous chapters, the ambition is to provide a comprehensive proposal for what a BETA.HEALTH 2.0 could look like. That is, how the programme can be designed after the pilot period from 2022-2026. However, several of the recommendations can be implemented quickly and would be natural elements of what could be called BETA.HEALTH 1.5 – an adjusted programme design for the remaining part of the pilot period.

The chapter even includes recommendations that BETA.HEALTH is already in the process of implementing. In other words, the intention is to outline how the programme as a whole can be strengthened in relation to the first two years of the pilot period, without specifically addressing the timing of the various ideas and recommendations.

However, it should be emphasised that some of the recommendations imply major adjustments in program design. This includes the proposed changes in organisation and governance, as well as the recommendations regarding mission-driven calls and the division of grants into innovation grants and implementation grants.

We suggest that these recommendations be implemented as part of a new application and plan for BETA.HEALTH 2.0. It is important that the remaining part of the pilot phase is not disrupted by adjustments that would require significant resources for communication and development.

The chapter also presents examples of good practice from the international case studies.

8.2 Grant structure

Although DKK 500,000 is not a large amount when it comes to healthtech innovation, the eva-luation reveals that the grant enables projects to advance and become more fundable.

A large share of the projects has secured additional funding, and BETA.HEALTH also allows projects to apply for a new BETA grant.

However, some project leaders argue that the grant amount is insufficient for clinical innovation projects and that the time to market or clinical application could be shortened further if a higher grant limit were introduced.

While this argument holds for some projects, larger grants would also result in a smaller needle eye for applicants/new projects if the total budget is not adjusted. When the high degree of success in obtaining further funding is taken into consideration, we do not find strong arguments for a considerable higher grant limit for innovation projects.

More grant types?

Another important issue is whether it makes sense to treat early-stage projects and later-stage projects under the same umbrella. The following challenges should be addressed in a BETA.HEALTH 2.0 version:

- The risk-impact balance varies significantly between early-stage and later-stage projects,

making it non-optimal to evaluate them using the same criteria.

- The key parameters for evaluating applications for BETA support differ between early innovation projects and those focusing more on testing and validation. It does not seem clear that experts in evaluating innovation projects are also experts in evaluat ing implementation projects.

As more BETA.HEALTH projects mature and advance in their readiness levels (see Chapter 5), the demand for implementation support is expected to increase. Consequently, a growing number of applications are anticipated from projects that have already participated in the program or completed the development phase.

According to BETA.HEALTH's website, the overall purpose of BETA.HEALTH is to support and accelerate innovation projects. However, it remains unclear to several stakeholders and clinicians whether purely implementation-focused projects are eligible for funding. The evaluation clearly indicates that significant barriers to realising the potential of clinical innovation projects are associated with this phase.

Additionally, consideration should be given to whether grant limits and funding criteria should differ between early-stage and later-stage projects. For instance, some interviewees emphasise that the need for funding to free up resources within hospitals and project teams is often greater in implementation projects.

Finally, according to several interviewees, early ideas for clinical innovation projects often needs more clarification (including expenditures for preliminary tests) before it makes sense to apply for a larger grant.

This aligns with feedback from the BETA.HEALTH team, who explained that they have had to reject several promising ideas due to their immaturity. The assessment indicates that more of these projects could be considered for a BETA.HEALTH grant if it were possible to apply for smaller funds for activities that could help advance ideas from level 1 to level 2 on the clinical innovation index presented in Chapter 5.

In the light of these observations, we propose the following adjustments of the programme:

- Introductions of small and easily accessible grants up to 50.000 DKK that can be used initial tests and experiments, workshops, etc.
- Segmentation of BETA.HEALTH in two grant types – innovation grants and implementation grants.
- Separate application forms and selection procedures for each grant type.
- Onboarding of implementation competencies within both the BETA.HEALTH team and the review committee.
- Separate onboarding processes for the two types of grants with more focus on inter-project events, such as bootcamps, for innovation projects.

Segmenting BETA.HEALTH into two types of grants would align with the structure of clinical innovation programs in other countries.

A new initiative has recently been launched in Singapore, focusing on supporting the adoption and implementation of clinical innovations (see Box 8.1).

Box 8.1. Clinical Innovation and Adoption Initiative in Singapore

Since its inception in 2014, the National Health Innovation Centre Singapore (NHIC) has supported clinical innovation projects that develop and implement medical technologies and services, offering financial assistance and strategic guidance. The NHIC offers grants of up to $ 300,000 per project, providing essential financial support to drive the development and commercialisation of innovative healthcare solutions.

Challenges in implementation across hospitals

Many of the projects has encountered several barriers when it comes to implementing innovations across Singapore's healthcare system. Although successful in their initial phases, several projects faced challenges in securing additional funding to support broader adoption within hospitals. Another barrier was the demand for robust clinical validation and additional real-world data to convince other hospitals, both in Singapore and internationally, to adopt these new solutions. The need for additional funding and implementation and extensive validation often slowed the adoption process.

Grant for Clinical Innovation Adoption and implementation

Recognising these challenges, the NHIC introduced a new grant in 2023: the "*Clinical Innovation and Adoption Initiative*." This grant focuses not on the development of new technologies, but on scaling and integrating existing innovations across Singapore's healthcare clusters. Selected projects are eligible for up to $1 mill. in funding, which facilitates commercialisation and integration into hospital systems. In addition, NHIC provides guidance to ensure successful implementation.

Promising results from targeted funding

Although the Clinical Innovation and Adoption Initiative has been active for only 1.5 years, it is already demonstrating promising results. Several projects have used the funding to adopt their solutions across different hospital wards, integrating them into clinical practice. Furthermore, the initiative has made it easier for projects to secure additional funding. The grant acts as a mark of quality, giving credibility to the innovations and increasing their attractiveness to external investors.

Finally, consideration should be given to allowing more flexibility in the use of grants. Some interviewees argue that resource limitations often pose a significant barrier to progress, especially in implementation projects and internal development projects. In some cases, progress could be enhanced if more than the current limit of 20 percent could be allocated for resource buyouts. This is particularly relevant for projects involving development work related to integration with critical IT infrastructure, which external consultants often cannot access.

8.3 Value proposition

The value proposition of BETA.HEALTH to clinical innovation projects is already strong and attractive, as indicated in Chapter 6. However, the interviews also reveal that the BETA concept can be further developed.

Most importantly, it should be kept in mind that BETA.HEALTH only constitutes the first steps in a long journey from idea to operational practise.

Thus, the ability to prepare the projects for the next steps and to strengthen their ability to tap into the ecosystem (after exiting BETA) is instrumental for the success of BETA.HEALTH.

The survey revealed that obtaining further funding, business model development and regulatory issues are some of the biggest challenges after BETA-exit. Many of the interviewed project leaders also emphasised a lack of understanding of decision-making processes among public purchasers as a barrier to success.

As mentioned in Chapter 7, this is contrasted by an established life science sector and investor environments with significant interest in BETA's pipeline and a willingness to contribute with resources.

Based on these observations, we propose the following adjustments of the programme:

- Introduction of advisory boards (consisting of 2-3 experienced life science leaders) as an offer to BETA.HEALTH-projects[8]. The boards could meet 2-3 times during the BETA-

[8] This option has already been introduced (from Call 5).

acceleration phase with an option to continue after BETA-exit.

- Matchmaking sessions where BETA-startups pitches their projects to interested investors. The service can be developed in collaboration with the current programmes: Medtech Investor Network and Health Tech Hub Copenhagen.
- Introduction of a road map to market/clinical practise as an exit-product to BETA-projects. The road map could emphasise likely funding options, entry points to the health sector, relevant test environments, etc. – dependent on the needs of each project.

8.4 Themes, ideation and selection

In their original applications to the Novo Nordisk Foundation, the applicants proposed that BETA.HEALTH should focus on specific areas, aligned with key challenges in the healthcare sector and local research strengths.

However, following the release of the Novo Nordisk Foundation grant, initial discussions with clinical research environments revealed a wide range of ideas and projects. As a result, in consultation with the steering committee, BETA.HEALTH decided to open applications to all clinical environments and specialties. This approach has effectively made BETA.HEALTH a bottom-up programme, despite the definition of three broad focus areas (as outlined on the program's website).

Since the start of the programme, key challenges (such as capacity issues) in the healthcare sector have only increased. In the interviews with both hospital managements and actors in the ecosystem, a majority argue for a more mission-driven or challenge-driven approach.

This refers to a top-down approach in which leaders in the healthcare sector (see also Section 8.6) define key challenges that require innovation and new solutions. Interviewees particularly highlighted themes such as capacity and resource scarcity, home-based patient care, and early detection. However, they also emphasised that the mission themes should not be too broad; instead, they should focus on areas where the challenges are most pressing and where new solutions are likely to have the most significant impact.

The main arguments for a more missions-driven approach are (according to the interviews):

- Currently, most ideas for innovation arise within clinical specialties in hospitals, while few projects address the overall functioning of the healthcare system and cross-sectoral challenges – issues that would be natural focal points in a mission-driven approach.
- The biggest challenge in turning innovation into impact is the lack of will and resources for implementation (see Chapter 6). By focusing more on specific issues, hospital management can better ensure the necessary capacity for implementation, as well as facilitate collaboration among departments across hospitals.
- Too many clinical innovation projects fail to reach clinical practice because they do not address critical problems in the healthcare sector.

"Currently, much innovation and idea generation occur within individual specialties, while few ideas address the overall healthcare system and cross-sectoral collaboration. This, coupled with the need to free up resources in the healthcare sector, supports a more mission-driven approach, where challenges are defined from a macro perspective to develop solutions that effectively address these challenges."

Adam Wolf, Director, Danish Regions

On the other hand, there are also interviewees who warn against turning BETA.HEALTH into a top-down programme. The arguments are:

- If the ambition is to change the mindset at the hospitals, it is not recommendable to focus on specific issues and themes.
- If the goal is to change the mindset at hospitals, it is not advisable to focus solely on specific issues and themes.
- Successful innovation projects are often driven by passionate individuals with a strong commitment to improving clinical practice within their specialty (see Chapter 4). These types of projects and solutions are also generally easier to scale internationally.

The logical solution, considering these opposing viewpoints, is to find a balance between a mission-driven approach and a bottom-up approach. This entails reserving part of the funding for specific missions.

Regarding mission-driven projects, several informants also argue that BETA.HEALTH could experiment with supporting projects that utilise *innovative procurement methods*.

This would involve providing grants to projects in which one or more regions or hospitals commit in advance to purchasing the final solution, provided it meets predetermined requirements and expectations. By involving users and procurement departments earlier in the projects, implementation could become easier. For example, the grant committee could take on an advisory role, while the decision to initiate and potentially select a project idea would be made by the purchasing regions, hospitals, or municipalities.

The use of innovative procurement methods in BETA.HEALTH projects could align well with a new implementation grant, where the goal would be for one or more stakeholders to commit to purchasing a solution if the final tests meet specific requirements that the stakeholders help define.

Ideation and screening

It is also important to consider whether BETA.HEALTH should continue as a reactive program that supports good ideas and projects as they arise, or whether it should also encourage or even facilitate idea generation. As mentioned in Chapter 7, several interviewees suggest increasing the focus on bringing clinicians, researchers, and companies together to generate ideas based on clinical needs. The argument is that formalised matchmaking in the early phases could lead to better ideas and more impactful solutions.

Several interviewees also argue that a stronger focus on ideation is essential for BETA.HEALTH to succeed with a mission-driven approach. A key argument is that missions will create a demand for solutions that address challenges across sectors and function within the health system. Moreover, it becomes essential to bring together actors who can link challenges and user needs with technological opportunities.

Some interviewees suggest that BETA.HEALTH should facilitate idea generation itself. Others emphasise that this role fits more naturally with other organisations, such as the Danish Life Science Cluster, but that BETA.HEALTH could collaborate with these stakeholders on specific events focused on developing project ideas within the missions BETA.HEALTH is working on.

Another issue the need for more thorough screening of ideas and new technical solutions. To ensure investment in projects with high potential impact, more resources should be allocated to screening for existing market solutions.

According to some of the interviewed companies and business organisations, BETA.HEALTH has, in its initial calls, funded the development of some AI-based solutions that already exist on the market – or that could be developed by companies with minor adjustments to existing technologies.

Based on the discussion above, recommendations could be:

- Introduction of 1-2 missions/challenges (defined by the steering committee) as focus areas each covering for example 3-4 calls, while still

leaving a share of the means for bottom-up ideas.[9]

- Collaboration with key stakeholders in the ecosystem on idea generation events focusing on the missions.
- Introduction of "intelligent public demand" tools as an effort to ease implementation challenges in BETA.HEALTH projects.
- Collaboration with TTO-offices on more effective screening when evaluating ideas and their risk/potential (including potential crowding out of existing private solutions).

Box 8.2 and Box 8.3 provide examples of international life science initiatives supporting idea generation across sectors.

Box 8.2. MESH Incubator

The MESH Incubator, founded in 2016, is a pioneering innovation hub situated in Mass General Brigham and developed in collaboration with Harvard Medical School. The incubator focuses on developing and supporting entrepreneurial and innovative solutions healthcare challenges.

Interdisciplinary collaboration to solve health issues

At the core of MESH's innovation efforts is the Innovation Teams Biodesign Programme, a yearlong interdisciplinary collaboration that addresses critical healthcare challenges.

The goal is to develop innovative solutions to the challenges through interdisciplinary collaboration.

Once a year, MESH Incubator host a "Problem Day" where multidisciplinary teams of clinicians, engineers, and MBA candidates come together to present solutions to a series of health care issues.

Each year, a specific theme is chosen for MESH Incubator's Problem Day, which serves as the focal point of the event. The theme guides the projects presented, and how the participants work across teams and disciplines throughout the day.

Recent themes have included AI-based diagnostic tools, augmented reality for surgical guidance, advanced drug delivery systems. Team formation happens during and after Problem Day.

Teams are composed of clinicians, researchers, engineers and business professionals, ensuring a multidisciplinary approach. The teams then receive entrepreneurship training, access to venture capital networks, and bespoke business development support.

Since its launch, the Innovation Teams Biodesign Programme has supported the formation of nine startups.

Box 8.3. Karolinska Innovations

Karolinska Innovations is the Karolinska Institute's innovation office. Since its establishment in 1996, the office has offered support to researchers and clinicians through early-stage funding, business guidance, commercialisation services, as well as access to office space.

Idea formulation and collaboration

Karolinska Innovations hosts several peer learning sessions, where researchers and clinicians gather to exchange ideas, share challenges, and discuss potential innovations.

They also facilitate an online community for clinicians that enables healthcare professionals to connect, share experiences, and explore innovation opportunities.

To enhance engagement among the research community, Karolinska Innovations has developed the "*Inreach Programme*." This initiative provides a range of support services such as seminars, workshops, personalised guidance, and one-on-one coaching targeted at clinical researchers.

[9] We did not ask for specific examples of missions in the interviews. It is, of course, important that they lead to a more focused project portfolio and create incentives for solutions that provide benefits across the entire sector. Very broad missions such as "release of resources in the health sector" are unlikely to prompt changes in the project portfolio.

Research groups can schedule a business coach to visit and discuss the available opportunities for pursuing innovations, providing tailored guidance on how to move forward with their ideas. As part of the programme, they also facilitate inspirational lectures to help fostering innovation within research teams.

Finally, they host a yearly Investor Days with the purpose of matching startups that are ready for commercialisation with venture capitalists, angel investors, and corporate partners. This event serves as a platform for innovators to pitch their validated solutions, secure funding, and accelerate market entry.

8.5 BETA.HEALTH Academy

BETA.HEALTH Academy is an umbrella for courses, masterclasses, and webinars aimed at strengthening innovation competencies and building innovation capacity within hospitals.

The mission of the academy is to develop the competencies necessary to drive clinical innovation and to foster an innovation mindset, culture, and leadership among clinical researchers and hospital management.

According to the BETA.HEALTH team, the users of the academy in its first two years have primarily been BETA project participants. The academy has largely focused on developing courses relevant to researchers and clinicians involved in current innovation projects, although it has also offered more general courses, such as an introduction to AI in the healthcare system and an overview of BETA.HEALTH grant rules and criteria.

Interviews with top managers from the university hospitals, in particular, indicate an ambition to broaden the scope of the academy.

First, there is growing recognition that innovation (including the development and implementation of new technology) is becoming an increasingly important management task in hospitals.

For BETA.HEALTH to succeed in developing better healthcare solutions, and for hospitals to effectively implement them, it requires managerial focus and the ability to organise and promote innovation.

"The challenge at the management level is to find the right balance between the daily clinical tasks and development of treatments of higher quality and efficiency."

Ditte Sloth Møller, Associate Professor, Aarhus University Hospital

"It is important that clinical management understands what innovation can do for Rigshospitalet. We need to develop a common language around innovation. Today, we have an organisation for research and treatment but no structures for innovation. BETA.HEALTH should aim to strengthen leaders' understanding of how innovation can benefit daily operations and the need to structure this in each unit. It is crucial that implementation doesn't rely solely on persistent enthusiasts."

Martin Magelund, Deputy CEO, Rigshospitalet

Second, hospital managers and other stakeholders in the ecosystem believe it is important to build stronger competencies among researchers and clinicians regarding innovation. This can encourage more hospital staff to engage in idea development and propose innovation projects, while also equipping teams in future projects to achieve impact. Introductory programs for a broader audience in hospitals can include elements such as an overview of the different phases of an innovation journey, funding for innovation, regulatory issues, and essential tools.

Third, it is essential to continue developing courses where projects facing similar challenges can acquire expert knowledge and work on applying this knowledge to their own initiatives.

According to the interviews, it is especially important to strengthen the availability of courses related to implementation and how projects can incorporate aspects such as IT architecture, procurement processes, and training into their initiatives and value propositions.

It is also suggested that BETA.HEALTH could more actively reach out to other actors in the ecosystem to provide access to the courses for startups outside of BETA.HEALTH (potentially for a fee). This could enhance the quality of the courses and improve opportunities for matching projects with similar challenges.

Finally, it is important to design the course offerings so that they are accessible to clinicians across the country and in a way that allows for flexible planning in relation to their operational duties. Therefore, it is crucial to develop digital tracks and offer courses in a hybrid format, without compromising quality.

Based on these inputs, we propose the following adjustments of the programme:

- Development of a general educational programme in innovation management targeted at department heads and unit managers at Danish hospitals.
- Development of an introductory course in innovation aimed at researchers and clinicians with no prior experience in innovation projects.
- Continued efforts to develop courses on themes relevant to active innovation projects, where teaching by experts is combined with practical exercises based on issues from the projects. These courses should also focus on challenges expected in upcoming phases of the projects.
- Development of digital course formats.

Box 8.4 and Box 8.5 highlight international examples of how to boost innovation skills at hospitals.

Box 8.4. Clinical Entrepreneur Programme

The NHS Clinical Entrepreneur Programme in the UK is a free initiative aimed at developing the entrepreneurial skills of both clinical and non-clinical NHS staff. Launched in 2016, the program is designed to foster innovation within the healthcare system and empower staff to become innovators and entrepreneurs who can drive the development of new healthcare solutions. It has grown to support over 1,300 healthcare professionals to date.

The programme covers six modules that teach participants essential business skills needed to bring clinical innovations to market. These modules include topics such as team formation, value proposition, communication, and funding strategies. It targets NHS staff at various levels, from doctors and nurses to pharmacists and allied health professionals, focusing on personnel with little or no prior experience in innovation projects.

An evaluation shows that the programme has boosted clinicians' innovation skills, enabling them to develop solutions and drive change within healthcare.

This programme also encourages collaboration, idea-sharing, and ongoing professional growth, helping clinicians better integrate innovation into their daily practice and enhance patient care.

Box 8.5. MESH Core Bootcamp

The MESH Core Healthcare Bootcamp, launched by the MESH Incubator at Mass General Brigham in 2016, is a course designed for clinicians and medical students to enhance innovation skills.

The programme covers key topics such as patents, prototyping, AI in healthcare and business planning. The goal is to equipe participants with the necessary skills to navigate healthcare innovation. It offers workshops in both online and in-person formats and has attracted over 400 participants since its launch

Innovation as an integrated part of medical education

The MESH Core Healthcare Bootcamp is the first of its kind to be recognised by the Accreditation Council for Graduate Medical Education (ACGME).

The accreditation allows the Bootcamp to be part of residency programmes, providing a structured pathway for participants to gain essential skills in healthcare innovation while fulfilling their medical training requirement.

The programme enjoys strong institutional support from the top management of Mass General Brigham. The support has been pivotal in strengthening clinicians' innovation competencies and fostering a culture of entrepreneurship.

It should be emphasised that realising the recommendations for further developing the BETA.HEALTH Academy will require significant development efforts. Additionally, a substantial effort is needed to mobilise leaders and staff at the hospitals to participate, and the activities must be scheduled in a way that avoids conflicts with operational tasks. Therefore, it would be wise to establish a long-term plan and implement the recommendations over several years.

8.6 Organisation and governance

As described in Chapter 4, BETA.HEALTH is organisationally divided into two main units: East Denmark (Rigshospitalet) and West Denmark (Aarhus University Hospital), each with its own programme manager. Additionally, three regional entities, each equipped with one FTE and integrated into local innovation units, are located at Aalborg University Hospital, Zealand University Hospital, and Odense University Hospital. The first entity refers to the Aarhus team, while the other two refer to the Copenhagen team.

The two main units operate largely as independent entities. They are responsible for information dissemination, evaluation of applications, project support, and academy activities in their respective regions.

They collaborate on the preparation of meetings for the steering committee and the review committee. Furthermore, call procedures are coordinated and communicated through the common BETA.HEALTH website.

According to interviews with hospital managers and project leaders, the division of BETA.HEALTH into two independent teams has offered several advantages during the initial phases of the programme:

- Extensive knowledge of local clinical research environments and local culture.
- Knowledge of local frameworks in relation to it-architecture, procurement procedures, and regional funding options.
- Proximity and availability for advice and guidance to clinical researchers regarding potential participation in BETA.HEALTH.
- Knowledge of relevant experts and collaborators with geographical proximity to the projects.
- Early acceptance of BETA.HEALTH as a national programme.
- Agility in responding to local needs for communication, Academy activities, etc.

Moreover, a number of interviewees also emphasise the importance of proximity in motivating the clinicians to engage in innovation projects.

A few project leaders have expressed some confusion regarding the differences in approaches and terminology between East and West Denmark. However, this issue, which is more common outside of Aarhus and Copenhagen, has only been a minor concern and could be addressed through a programme adjustment.

However, the question remains whether the current organisational structure is optimal for a BETA.HEALTH 2.0 version.

Towards a unified organisation?

The need to strengthen the implementation of BETA.HEALTH in the ecosystem, and to broaden the value proposition with regard to the academy and implementation services, calls for organisational considerations.

In the interviews, companies and businesses organisations emphasised a need for one point of contact and for BETA.HEALTH to act as one organisation. Investors, potential participants in advisory boards, cluster organisations, etc. would rather look at BETA.HEALTH as one pipeline of innovation projects than two.

Regarding BETA.HEALTH Academy 2.0, significant development work is also required. The development of a broader academy programme will require coordination and collaboration with other actors offering courses for health tech startups. It seems appropriate for this work to be carried out under a single leadership.

The same applies to the ambition of strengthening BETA.HEALTH's focus on implementation projects, including what services and activities the programme should offer in terms of preparing projects for the implementation and scaling of their solutions. This development work should also be closely coordinated, and it is important that the services appear consistent in terms of how far BETA.HEALTH should go in supporting projects in implementation.

However, it is also important that the operational task of helping projects in this area remains decentralised, as there are significant local differences in areas such as it-architecture and procurement practices.

In conclusion, the task is to develop an organisational model where local autonomy and ownership are maintained, while BETA.HEALTH at the same time presents itself as a unified organisation under one leadership in relation to stakeholders in the ecosystem.

BETA.HEALTH could draw inspiration from the collaboration of Danish universities in the field of innovation. For instance, the eight universities in the joint programme 'Open Entrepreneurship' have developed a model with a single programme leadership and local hubs, which has both generated strong results and is associated with local autonomy and ownership. A similar approach is seen in some smaller incubation programmes such as ESA BIC Denmark (space technology).

With the ambitious recommendations and the complexity of the programme in mind, it seems appropriate to elect a management team (e.g. a director and a deputy director) each responsible for different task and parts of the programme.

Whether it is best to centralise the management physically, or if it is better to anchor the management team at two hospitals, depends on factors that we, as external evaluators, find difficult to assess satisfactorily. Both models have advantages and disadvantages, and the choice fundamentally depends on which model that is supported by the hospitals.

BETA.HEALTH's anchoring in existing innovation units could argue in favour of a combined East/West management model to maintain close collaboration and coordination with the hospitals' other efforts in the field of innovation.

Moreover, it is important to assess whether the distribution of team resources across hospitals is appropriately balanced.

The uneven distribution of projects across hospitals (cf. Chapter 4) and the critical importance of

local, one-on-one support for projects could justify an upgrade in Aalborg, Odense, and Slagelse. This could potentially be achieved by strengthening the staffing of the overall team, especially considering the substantial development tasks ahead and the likelihood that implementation projects will demand more resources from the BETA.HEALTH team than most innovation projects have done so far.

A new composition of the steering committee?

Finally, it is relevant to consider whether the steering committee has the right composition.

The interviews clearly indicate that, in addition to setting the direction of the programme, the committee has been valuable for fostering cross-hospital dialogue on innovation issues. All university hospitals are in the process of investing more resources and commitment into the innovation agenda. Having a forum where experiences are shared and key issues, such as implementation and scaling, are discussed is regarded as a significant benefit of BETA.HEALTH.

In light of the conclusions and recommendations from this evaluation, it is evident that the steering committee should assume a stronger role in the following areas:

- Defining missions.
- Developing common initiatives for the faster implementation and scaling of BETA.HEALTH projects, possibly focusing on selected areas.
- Sharing experiences related to the implementation of new technology within hospitals and the healthcare sector as a whole.
- Serving as a sparring partner for the BETA.HEALTH team regarding the use of intelligent demand approaches.
- Collaborating to identify foreign hospitals and regions that can serve as partners for BETA.HEALTH in testing solutions abroad (see Chapter 6).

As indicated in the first point, both hospital managements and ecosystem actors argue that the responsibility for defining missions should lie with the steering committee, which is tasked with setting the direction for BETA.HEALTH.

This also means that the steering committee will take on a more board-like role and should more prominently represent the organisations that procure and use innovations. A number of interviewees argue in this context that the primary sector should also be represented in the steering committee, just as hospitals with large general medicine departments are important users.

Conversely, it seems less critical that all major universities are represented in the steering committee. Universities are key partners primarily in idea generation and at the project level.

Finally, it would be relevant to expand the steering committee to include a representative from the Danish investor community within health technology, as there is, as described in Chapter 7, an unrealised potential to connect BETA.HEALTH's project portfolio with private investors.

Thus, a revised composition of the steering committee could be:

- Five representatives from top management of the university hospitals (as currently).
- Two representatives from top management of hospitals with large departments for general medicine.
- The CEO of Danish Regions.
- 1-2 representatives from the primary sector.
- 1-2 representatives from the universities.
- Two representatives from the healthtech industry (as now).
- One representative from the investor side.

Based on these considerations, we propose the following adjustments to the programme:

- Merging the two teams into one organisation with a single management team.
- Keeping a decentralised organisation with strong representation at all university hospitals, and with a strong autonomy in relation to operational issues.
- Defining a new and broader mandate for the steering committee.
- Changing the composition of the steering committee.

Case: Ward 24/7

Ward 24/7 is well-positioned to become a major player in global healthcare, transforming how patient care is managed. BETA.HEALTH played a pivotal role in supporting clinical trials and implementation abroad, paving the way for international scaling.

Ward 24/7 is an AI-powered clinical support system designed to improve patient safety by providing continuous, wireless monitoring of vital signs in high-risk patients. Using advanced sensors and real-time machine learning algorithms, the system alerts healthcare professionals to physiological deteriorations, enabling timely interventions and potentially life-saving treatment.

Founded in 2016 by two medical doctors, Ward 24/7 was developed in response to inefficiencies in traditional, manual monitoring practices. By continuously tracking parameters such as oxygen saturation, heart rate, and blood pressure, the system transforms how hospitals manage postoperative care and acute medical conditions.

Ward 24/7 became a formal 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, which enabled the move from concept to clinical application.

Clinical studies abroad

The BETA.HEALTH played a pivotal role in supporting clinical implementation abroad. When Ward 24/7 joined BETA.HEALTH, the company had a working prototype but lacked experience with hospitals in other countries.

With support from BETA.HEALTH, trials are conducted in five countries. Of particular significance are the partnerships with the Cleveland Clinic and Massachusetts General Hospital in the United States. These collaborations provided critical validation for the project and significantly raised its international profile.

The strong international profile helped pave the way for additional funding. In 2023, Ward 24/7 secured DKK 20 million in bridge funding from its group of investors, as well as a new Grand Solutions grant of DKK 30 million.

Successful scaling

Ward 24/7 obtained CE marking in November 2023, and the system is already in use in 13 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 the aforementioned high-profile hospitals in Cleveland and Boston, there are high expectations for strong sales in the U.S. market.

APPENDIX 1. INTERVIEWEES

1. Project leaders

Name	Title	Organisation
Bobby Zhao Sheng Lo	Postdoctoral Researcher	Amager and Hvidovre Hospital
Fatemeh Makouei	Biomedical Engineer	Department of Clinical Medicine, University of Copenhagen & Rigshospitalet, Department of Otolaryngology and Audiology
Kasper Linde	CSO and Founder	ZETA Diagnostics
Katja Kjær Grønbæk	PhD Student	Department of Clinical Medicine, University of Copenhagen & Rigshospitalet
Kristian Bach Laursen	Clinical Research Assistant, Cardiological Research Unit, Cardiology Department	Odense University Hospital
Lise Bech Jellesmark Thorsen & Ditte Sloth Møller	Clinical Associate Professor Associate professor of Medical Physics	Aarhus University Hospital
Lone Winther Lietzen	Clinical Lecturer, Department of Clinical Medicine	Aarhus University Hospital
Martin G. Tolsgaard	Professor of Medical Education	Rigshospitalet
Martin Hylleholt Sillesen	Clinical Research Associate Professor of Surgery	Rigshospitalet
Mikkel Brabrand	Head of Research, Research unit of Emergency Medicine (Odense)	Department of Clinical Research, University of Southern Denmark
Niels Kvorning	Postdoctoral researcher	Herlev and Gentofte Hospital
Ole Köhler-Forsberg	Associate Professor	Aarhus University Hospital
Sam Riahi	Clinical Professor	Aalborg University Hospital
Samuel Levi Svendsen	Postdoctoral Researcher at the Department of Biomedicine	Aarhus University Hospital
Tejs Jansen	Clinical Specialist	Rigshospitalet

2. Hospital management

Name	Title	Organisation
Bjarne Dahler-Eriksen	Medical Director	Odense University Hospital
Ditte Sloth Møller	Chief Physicist, Danish Centre for Particle Therapy	Aarhus University Hospital
Henning Weihrauch Voss	Hospital Director	Gødstrup Regional Hospital
Inge Nordgaard-Lassen	Chief Physician in the Gastroenterology Unit	Hvidovre Hospital
Jasper Nijkamp	Associate Professor, Oncology Department	Aarhus University Hospital
Martin Magelund	Deputy Director	Rigshospitalet
Morten Breindahl	Head of the Neonatal Clinic	Rigshospitalet
Søren Pihlkjær Hjortshøj	Chief Medical Officer	Aalborg University Hospital
Thomas Balle Kristensen	Hospital Director	Aarhus University Hospital

3. The broader ecosystem

Name	Title	Organisation
Adam Wolf	Director	Danish Regions
Anne Bach Stisen	Head of Unit	Health Innovation Centre of Southern Denmark
Anne Mette Hvas	Dean	Aarhus University
Frederik Knud Nielsen	Healthcare Partnership director	Novartis
Freja Bertelsen	Managing Partner	Danish Life Science Cluster (Aarhus)
Jacob Ravn	Head of Innovation	Innovation Clinic, Region North
Jesper Grønbæk	CEO	Health Tech Hub Copenhagen
Jonas Flintegård	Theme Leader, Health Innovation	Region Midtjylland
Klaus Veng	Director	Emento A/S
Lars Albert Beck Thomsen	Managing partner (CMO)	Trustworks

Lars Allerup	Senior Advisor	Rud Petersen
Lars Bech-Jørgensen	Head of Future Healthcare	Danish Industry
Mads Lacoppidan	Managing Director, Life Science	EIFO
Marie Smed	Chief Consultant	Capital Region of Denmark
Rasmus Hother le Fevre	CEO	Ferrosan
Rasmus Thomsen	Strategic Partnership Lead	Roche
René Hauge Sørensen	Consulting Director	Trifork
Steen Donner	CEO	DTU Science Park
Sys Zoffmann Glud	CEO	Biomedical Design
Søren Møller	Associate Professor	Novo Seeds
Thomas Kofoed	Partner	Netcompany
Thomas Kielsgaard Kristensen	Innovationschef	Odense Universitetshospital
Tony Cheng-fu Chang	Senior Business Developer	BII
Trine Winterø	Vice Dean Innovation and External Relations	University of Copenhagen
Troels Jørgensen	Lead Relations Officer	Innovation Fund Denmark

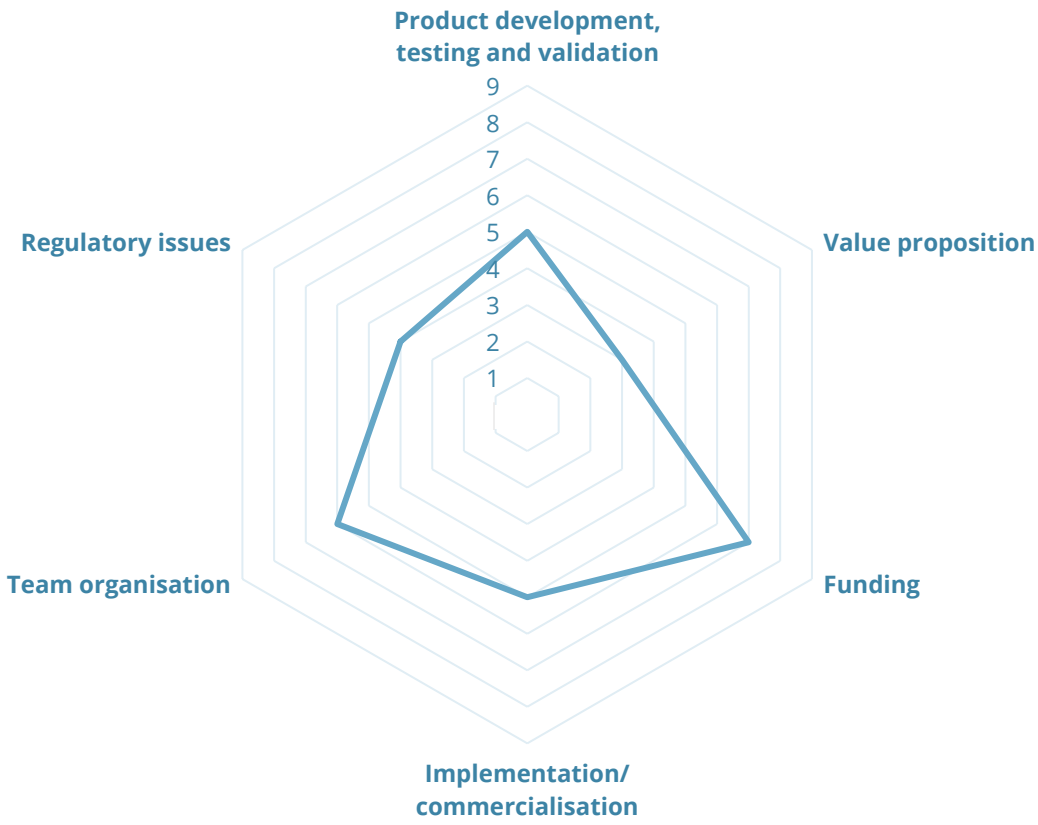
4. International cases

Name	Title	Organisation
Chris Coburn	Chief Innovation Officer	MASS General Brigham, US
Johan Weigelt	CEO	KI Innovations, Sweden
Marc Succi	Director	MESH Incubator, US
Pauline Tay	Director	National Health Innovation Centre, Singapore
Polly Sullivan	Programme Lead, NHS Clinical Entrepreneur Programme	NHS Innovation Accelerator, United Kingdom

5. BETA.HEALTH team

Name	Title	Organisation
Anne Aavad	Project Manager	Aarhus University
Bodil Christine Reumert	Head of Strategic Innovation	Aarhus University
Diana Riknagel	Chief Innovation Officer & Head of International Affairs	Aarhus University
Ditte Thøgersen	Academy Lead	Rigshospitalet
Rasmus Fält	Accelerator Lead	Rigshospitalet
Rune Holdt	Chief of Staff	Rigshospitalet
Susanne Svendsen	Senior Project Manager	Aarhus University

APPENDIX 2. CLINICAL INNOVATION INDEX



1. Product development, testing and validation

1	Idea formulated and hypothesis of clinical needs
2	Technology concept and potential use areas have been formulated
3	A proof-of-concept has been developed for critical functions, and idea of end user requirements
4	Technology validated in a simulated environment – first test results received
5	Technology validated in a relevant health environment – end user feedback integrated in first prototype/model
6	Adjusted prototype/model demonstrated in a relevant health environment – feedback received that enables development of the final version
7	Final prototype/model demonstrated in an operational environment – end-user specifications in place
8	Technology completed and successfully demonstrated in real-world operations by the first users
9	Technology completed, sold to customers and applied in real-world operations

2. Value proposition of the solution

1	No or limited understanding of potential users and customers/key decision-makers responsible for procurement/implementation
2	Preliminary identification of users and key decision-makers responsible for procurement and implementation
3	Initial mapping of users and key decision-makers in place; some segmentation of customers/users
4	Initial interaction with/feedback from users and/or key decision-makers – criteria for implementation/procurement identified among users in key segments
5	First pitch presentation targeting users and key decision-makers in place, including calculations of clinical impact
6	Refined pitch presentations developed, highlighting both clinical and economic value for users/customers – market segmentation in progress
7	Sales/pitch material updated based on feedback from key decision-makers and results of final tests – ongoing dialogue with several key decision-makers
8	Final value proposition in place that describes the clinical and economic benefits to key decision-makers
9	Value proposition refined and adapted to specific users/segments as part of scaling efforts

3. Funding

1	No clear view of funding needs and of how to fund the innovation activities (besides BETA.HEALTH)
2	Funding needs for further development defined – no funding yet obtained besides BETA.HEALTH, but funding options identified
3	Dialogue with funds/potential investors begun – pitch presentation or application to funds in progress
4	Funding secured (besides BETA.HEALTH) for further development and testing
5	Further funding secured enabling validation in real-world environment
6	Plan for funding of the remainder of the development phase in place – ongoing dialogue with investors or funds
7	Funding for activities leading up to test of final prototype/model secured
8	Funding for all phases leading up to the first sale/use in actual operation has been secured
9	Funding in place that enables scaling of the solution

4. Implementation/commercialisation

1	Path towards implementation/commercialisation unclear/undecided
2	Path towards implementation/commercialisation decided (startup, partnership with existing company or internal implementation projects)
3	First plan with milestones for the implementation/commercialisation process in place, including IPR-strategy
4	Important milestones achieved – organisation and/or partnerships under construction that enable implementation/commercialisation
5	Formal organisation and/or partnerships in place that enable implementation/commercialisation of the solution
6	First go to market/implementation strategy developed, e.g. plans for validation in pilot operation, technical integration, training of clinicians, payment model, etc.
7	Key milestones in go to market/implementation strategy achieved; solution ready for use in pilot operation and business/payment model in place
8	Formal organisation in place to provide operational support; preconditions for one national use and scaling have been addressed properly (technical integration, development of training programmes for clinicians, etc.)
9	Organisation finetuned in order to reap the full potential in strategy/value proposition (e.g. exports, dissemination to other hospitals/healthcare organisations in DK)

5. Team and organisation

1	Lack of necessary competences/resources to develop/verify the solution
2	Limited competencies and/or capacity present – first idea of the competences and resources needed in the development phase
3	Most resources and competencies in place that enable development of the solution – gaps in competences/resources identified
4	Team in place (with clearly defined roles) that enables development and first test of the solution
5	Initial mapping of the necessary competences and partnerships required to bring the solution to the market/clinical practise
6	Clear strategy for recruitment and/or partnerships to secure onboarding of competencies/resources required to bring the solution to the market/clinical practise
7	Most competencies in place, and resources committed in order to make the solution ready for operation/sales
8	Professional/efficient organisation in place that enables first sale or local implementation
9	High performing, well-structured organisation that enables operation and/or scaling of the solution (including governance structure)

6. Regulatory issues

1	No or limited knowledge of regulatory issues in relation to the product/technology
2	Relevant regulatory regime related to the solution identified – no or limited knowledge of processes leading to regulatory approval
3	Some knowledge of MDR and processes leading to CE-marking – dialogue with regulatory experts initiated/planned
4	Definition of intended use and risk classification of the solution – clear understanding of how to achieve CE-marking
5	Regulatory strategy and plan for documentation in place, reflecting intended use of the solution
6	Clinical evaluation plan in progress – market claims integrated
7	Documentation for notified body in progress – quality management system implemented or close to implementation
8	Contact to notified body – documentation ready
9	CE labelling obtained or audit from notified body

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