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Ecosystem supporting the commercialization of digital health innovations

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Abstract

Digitalization has significantly impacted various industries; however, its full potential in healthcare remains unrealized. Despite the promise of digital health solutions to modernize healthcare and benefit the population at scale, their adoption and scalability lag behind other sectors due to ethical, regulatory, economic, and technological challenges. This article examines the barriers to commercializing digital health solutions and proposes a systematic approach to accelerate growth in this sector, presenting a preliminary commercialization roadmap.

In Finland, numerous wellbeing services counties, higher education institutes, and cities support testbed activities, offering real-world testing environments for health and wellbeing product developers. However, these activities face challenges such as resource uncertainty, funding issues, and lack of a unified national model.

This study utilized thematic interviews and a structured survey to gather insights from stakeholders in the digital health ecosystem. Key challenges identified include the ethical unsustainability of applying agile software development methods in healthcare, the complex and often prohibitive regulatory environment, and the lack of industry-specific funding and competence. The study also highlights the need for interdisciplinary collaboration and effective commercialization pathways.

The findings suggest that national coordination of testbed activities and a comprehensive understanding of the digital health innovation pathway are crucial for fostering innovation. Enhanced funding mechanisms, clear regulatory strategies, and platforms for interdisciplinary dialogue are recommended to support the commercialization of digital health solutions. A preliminary model illustrating the development pathway of digital health innovations is proposed, aiming to address identified challenges and streamline the commercialization process.

Keywords: digital health, agile methods, innovation, ecosystem

Introduction

Digitalization has significantly impacted various industries, but its full potential in healthcare remains unrealized. While healthcare organizations recognize the importance of innovation and digitalization [1], adoption and scalability of digital health solutions have lagged behind other sectors [2]. This slow progress is due to ethical, regulatory, economic, and technological challenges [3], and complexity and fragmentation of healthcare as an innovation context [4]. Primary customers of innovation are healthcare systems while the actual users are usually patients or healthcare professionals [4,5]. Innovations in healthcare are diverse including medical devices, pharmaceutical products and new approaches to patient care, well-being, or illness prevention [4,6,7]. Additionally, knowledge in healthcare is viewed as evidence or research, unlike in management, where it is seen as a strategic asset [8].

In recent years, Finland has made significant steps in enhancing the vitality of digital health sector. The Ministry of Social Affairs and Health has implemented a comprehensive strategy [9] for digitalization and information management in healthcare and social welfare. Initiatives such as HealthHub Finland [10], part of the European Digital Innovation Hub network, have been established to support the development of digital health solutions Additionally, Digital Health Village project [11,12], a collaborative effort among Finnish university hospitals, has created a scalable digital service platform that integrates the best professionals, the latest information, and improved digital and local care for patients.

The complex regulatory environment in healthcare poses challenges for commercializing digital health solutions classified as medical devices [13]. Stringent European regulations [14] lead to delays and increased costs, hindering innovation [15–17]. While regulations ensure safety, they impose financial and time burdens [17]. Still, there is not clear understanding about adverse effects related to implementation of digital health solutions [18]. Clear regulatory strategies are essential for successful market entry.

The transition of the public health care sector to new wellbeing services counties in Finland, coupled with the demand of significant savings, is driving extreme changes. In this constantly changing operational environment, maintaining existing operations is challenging [19]. The successful implementation of digital solutions would require recognizing and describing the current situation, which is challenging in the present, continuously changing environment. Successful implementation of digital solutions requires recognizing and describing the current situation, which is difficult in a continuously changing environment. Additionally, user engagement with digital health solutions is hard to achieve [2,20]. Pilots of digital health solutions are usually very local and have not brought the desired permanent change to healthcare [2].

Agile methodologies are increasingly becoming the norm in software development [21]. Start-ups leveraging digitalization typically follow the minimum viable product (MVP) model, aiming to release a product quickly and improve it based on user feedback. However, in healthcare, deploying an incomplete and untested product is ethically unsustainable [3]. Seasoned software developers in the health tech industry often resort to the straightforward but change-resistant V-model. Combinations of iterative, agile methodologies and the traditional V-model have been introduced [22,23], but a unified view on the development and lifecycle management processes of digital health software has not yet been formed [24].

The commercialization pathway for digital health innovations involves various public and private service providers (Figure 1). In Finland, wellbeing services counties, higher education institutes, and cities maintain testbed activities, offering collaboration opportunities for developers. These activities aim to enhance cooperation among stakeholders and support research, development, and innovation (RDI) processes within the health technology industry [25]. Testbed activities are typically conducted according to the vision of each organizing entity, with local models established [26], but a unified national operating model is still lacking. Separate interests of different actors in testbed settings makes cooperation challenging leading to the low maturity of the testbed services [27,28]. Challenges for the operation of testbeds include resource uncertainty, unpredictability, funding, quality assurance, and the level of specialization [29,30].

Testbed operations could be seen as a health technology assessment services, encompassing the entire lifecycle of digital health solutions and tailored to the technology's maturity level [31]. Technical readiness levels (TRLs), proposed by NASA in 1973 [32], classify technology development and have been adopted in various sectors, including e-health [33]. Digital health solutions should be thoroughly evaluated from multiple perspectives before being tested in authentic healthcare environments and released to the market. As Jansen-Kosternik et al (2022) proposed, the evaluation should focus on the end-user, health, and societal perspective [31].

The research question guiding this study is: How can public and private RDI resources be better utilized to boost the digital health sector and deliver significant societal benefits? By examining stakeholder experiences and analyzing successful case studies, this study offers insights into addressing the identified barriers and enhancing the utilization of RDI resources.

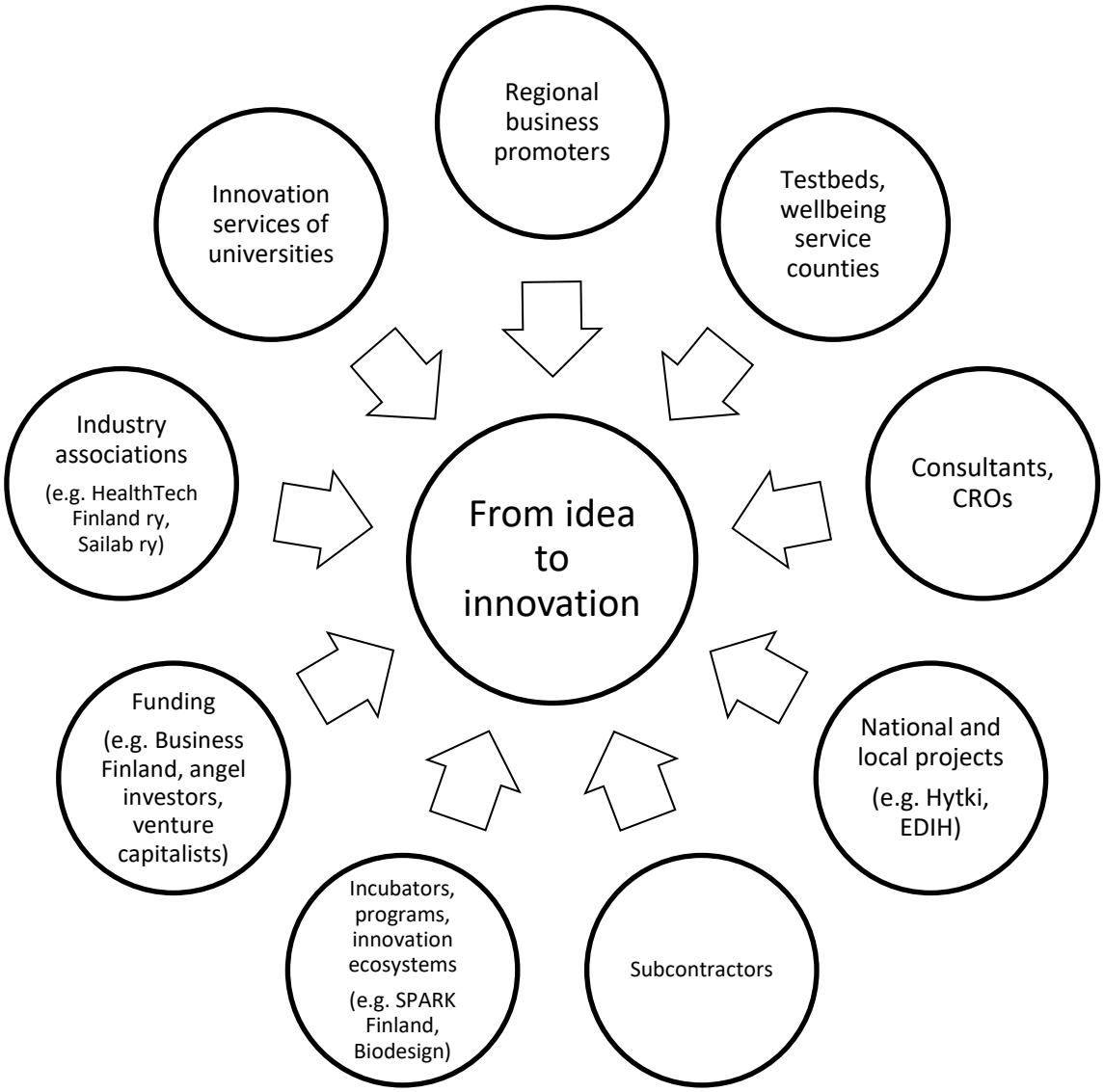

Figure 1. Service providers on the digital health innovation commercialization path.

Material and methods

The data for this study was collected via thematic interviews and a structured survey. The interview requests were sent to all entities listed in the Business Finland brochure titled *World-class testbeds from Finland - Platforms for health innovations of the future* [25]. Personal networks were also used to invite a diverse array of participants (Figure 1). Thematic analysis [34,35] was used as the data analysis method to evaluate the collected data.

Interviews (n=10) were conducted with key actors in the digital health ecosystem, including testbed service coordinators, consulting firms, and industry organizations (such as industry associations and regional development organizations). Interviewees were selected based on their long experience in testbed operations, commercialization of health sector innovations, or industry regulations. The focus was on strategic and operational aspects of digital health innovation and commercialization, excluding end users like healthcare personnel.

The thematic interview framework was prepared in co-operation with Digital Health Knowledge Network project partners. The interviews were conducted via Teams, with consent for automatic transcription obtained. Following questions were included:

1. What operational models could enhance the effective utilization of RDI resources, including funding, expertise, and research infrastructures?
2. What skills will be necessary for the future development of RDI activities in the health sector?
3. Which operational models would promote the utilization of research data in health sector RDI activities, as well as the commercialization of research findings and collaboration with businesses?
4. How can the capabilities of the knowledge network be strengthened to respond to the rapidly changing operational environment?
5. What role could the knowledge network and its actors play in the utilization, commercialization, and marketing of research results?
6. What operational models could enhance collaboration between public and private entities?

The transcribed data was read through multiple times to become familiar with the content. Interesting features of the data were coded across the entire dataset, highlighting significant phrases or sentences. The codes were grouped into themes, capturing broader patterns significant to the research questions.

Analysis revealed a recurring pattern in the interviews, highlighting the reasons behind the healthcare digitalization challenges and their possible solutions. This identified pattern was used as basis for collecting additional data through a Webropol survey (n=10) distributed to participants of testbed network meetings held in Turku (November 2023) and in Tampere (April 2024). Insights from interested parties were gathered by following key questions:

1. *Why?* What challenges are identified in the commercialization of innovations and the development of the digital health sector in Finland, given the increasing competition from other countries?
2. *How?* What strategies could be employed to further enhance product development and commercialization pathways in the digital health sector? Which existing methods are effective, and which are not?
3. *Network Actor?* What operational models for the proposed network actor would facilitate the development of the sector? How would stakeholders involved in supporting commercialization wish to participate in the network's activities?

The main themes were identified from Webropol data and combined with the interview data. The collection and processing data for this study is represented in Figure 2.

The first five themes related to challenges in the digital health industry were clearly identified. However, the theme "The path of digital health innovations from idea to market remains unclear" emerged from interviews with testbed service providers. They noted difficulties in supporting early-stage innovations, premature phases for clinical testing, lack of regulatory awareness, and significant effort required by healthcare professionals. These insights highlight the need for a better understanding of the development path of health technology innovations.

In developing the preliminary, iterative model of digital health product development (Figure 3),

researchers incorporated learnings from testbed projects, regulatory requirements, standards, and methods related to medical device development [14,36,37], and an article on innovation maturity and testbed services [31].

The study did not require formal ethics approval as it did not involve sensitive personal data or interventions. Participants received a privacy notice explaining the study's purpose, their involvement, and data usage. Participation was voluntary, and informed consent was obtained. Data was stored on the research team's server without personal identifiers.

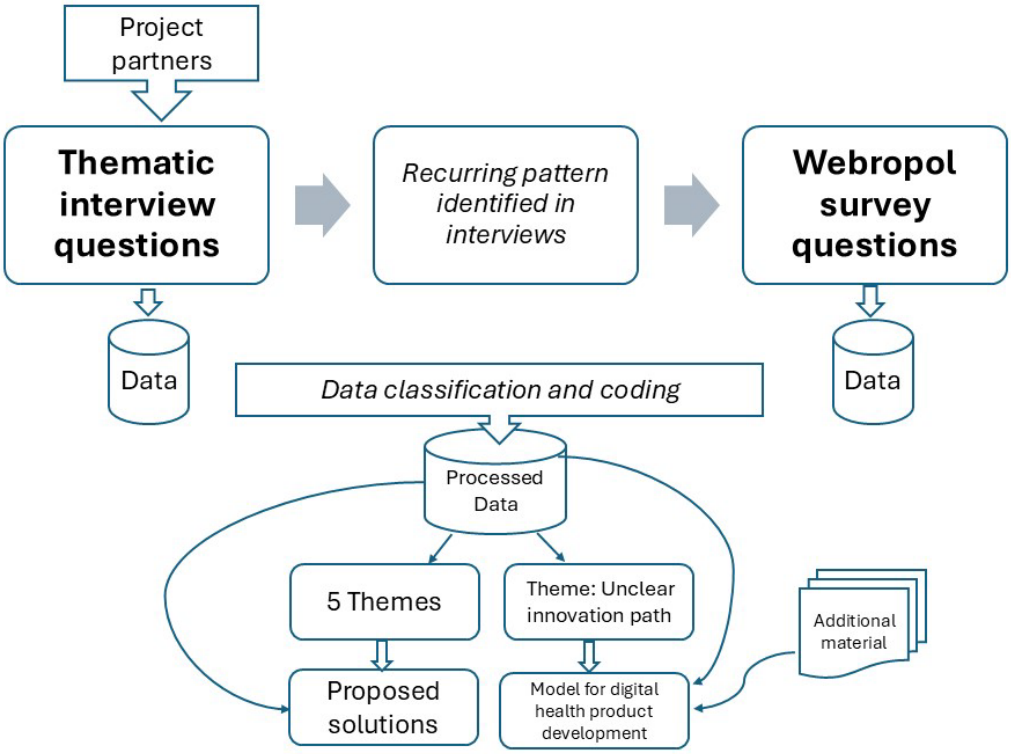

Figure 2. Data processing.

Results

The following analysis presents an overview of the key challenges and development needs identified in the digital health sector. Drawing from interviews and survey responses, this paper highlights critical issues such as procurement processes, resource limitations, regulatory complexities, and the need for enhanced collaboration and communication. Diverse array of parties promoting the commercialization of digital health innovations are shown in Figure 1.

There was a clear consensus in the interviews that the digital health sector is expected to grow significantly faster than what has been seen so far. More coordinated national cooperation was viewed positively, and concrete actions were particularly needed to overcome the challenges in the sector instead of reports and studies.

Themes that are slowing down the progress of the digital health sector emerged prominently from the data. The themes and concrete proposals collected through interviews and a survey for overcoming the challenges in the digital health sector (Table 1):

*Public Procurement Procedures and Technology Adoption. "*Wellbeing services counties should have standardized procurement processes, allowing suppliers to use the same documentation across all of them. This requires leadership from the ministries*"*

The adoption of new innovations in the public sector is perceived as challenging. Success in public procurement is particularly difficult, if not impossible, for small software companies. The study identified, that while testbed activities are robust in many areas, companies often express disappointment when successful pilot projects do not lead to actual procurement. Additionally, the public sector's capability to procure innovative solutions is seen as inadequate and innovative public procurement procedure is not sufficiently utilized. Furthermore, it was highlighted in the interviews that the implementation of procured technology solutions may be inadequate; insufficient resources are allocated, staff training on new technology usage is incomplete, and sometimes, the healthcare unit does not utilize the acquired technology at all. The public sector's procurement expertise of innovative solutions is lacking, and the procurement processes are complex and not uniform nationwide, which complicates the adoption of new innovations. Procurements were also seen fragmented, leading for partial optimization instead of effective procurement of overall solutions. Additionally, Finland's wellbeing services counties are currently burdened with massive savings targets, which are pursued on a tight schedule by cutting costs, reflecting also on procurements. Technology is unfortunately not seen as a means of achieving savings.

Impact Data. "The impact of technology, for example on working hours or working conditions and consequently on sick leave, is difficult to demonstrate."

The lack of impact data was perceived in the interviews as a significant barrier to demonstrating the benefits of technology. This issue is also related to the previous theme; public procurement should better consider cost-effectiveness, and this expertise needs to be enhanced. Designing impact studies is challenging, and companies rarely have sufficient research expertise to design them.

Complex regulatory environment. Regulatory challenges especially related to Medical Devices and AI solutions, were a key issue in all interviews. The European regulatory environment has become extremely challenging, if not impossible, for small companies. Numerous regulations, both European as well as national, especially those targeting digital

health solutions, were mentioned to promote the consulting industry rather than the digital health sector.

Lack of industry-specific funding. "Proof-of-concept funding is available in very limited quantities." The journey of health sector innovations from idea to market is longer than in many other industries, and there is a lack of funding instruments that consider the specific characteristics of the sector. Enhanced funding mechanisms, particularly for early-stage innovations, were seen as crucial for the industry. Angel investors and venture capitalists were seen very welcomed to participate in the network. While there is a growing understanding among investors regarding the unique challenges of health technology development, many companies still enter the market with insufficient resources.

Lack of industry-specific competence and effective collaboration models. "Instead of looking for super individuals, we should focus on building good and diverse teams." The healthcare sector is complex with its various operational models and extensive regulations and their interpretations. The research data indicated a significant need for interdisciplinary collaboration and expertise in the development and commercialization of digital health solutions. The interviews also highlighted that companies still need support in sales and communication skills to better communicate their products to customers. Educational institutions were seen as crucial links between professionals and technology. The future demands new professionals who understand both technology and the needs of the health and social care sector. Students were also seen as change agents in their future workplaces.

The path of digital health innovations from idea to markets remains unclear. The interviews revealed that companies developing medical devices are rarely able to receive support from testbed operations due to the heavy regulations involved. Companies also often attempt to test their products in clinical environments too early. Additionally, research permit practices and general research expertise related to clinical studies are particularly lacking in small companies, which complicates the implementation of testbed operations. As a result, some testbed operators have faced challenges in co-developing early-stage innovations with companies.

Unlike other themes, this was processed further by the researchers, reflecting the interview results and experiences from other testbed projects, on the regulations related to medical device development and existing literature. Particularly, the view presented by Jansen-Kosternik et al. (2022) in their article [31], where testbed operations should be seen primarily as continuous evaluation of innovation and tied to its TRL (Technological Readiness Levels) maturity influenced the preliminary model presented in Figure 3. The created model aims to describe the incremental development of innovation from different maturity perspectives towards a mature, commercial product. The model suggests that co-development with end-users and health care professionals of early-stage innovations should occur in laboratory or simulation environments rather than clinical environments and testing in clinical environments should only commence when the innovation is sufficiently mature from various perspectives. The model is hoped to encourage different testbed operators to develop co-creating and evaluation methods especially for early-stage innovations.

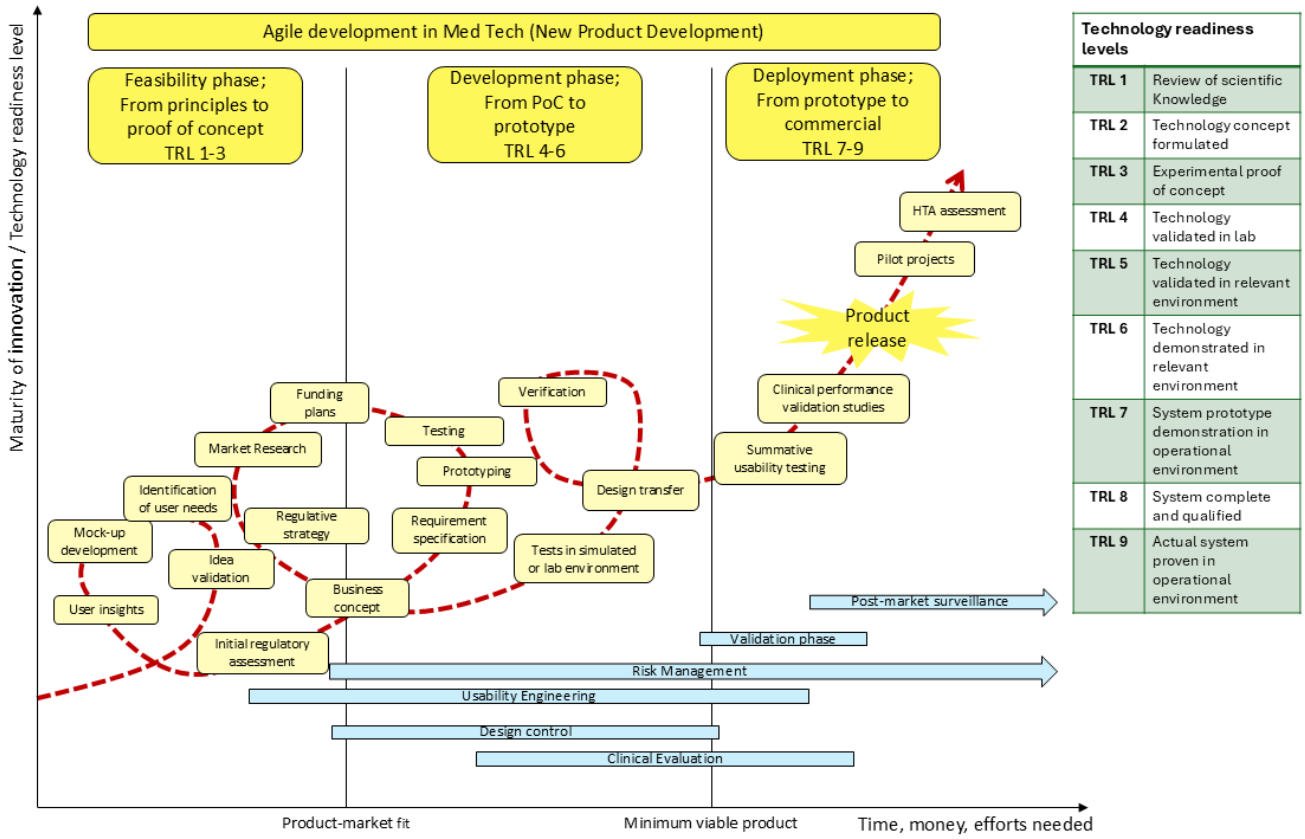

Figure 3. Preliminary, iterative model for digital health product development.

Table 1. Themes and proposals for overcoming digital health challenges.

Theme	Activity
Public procurement and implementation	Harmonization of procurement processes of wellbeing services counties Increasing the use of innovative public procurement procedure Creating a link between pilot projects and the procurement process
Impact data	Allocating more support and resources to conducting impact studies. This may include training, funding, and expert assistance. Developing standardized methods and processes for impact studies can facilitate their implementation and improve the comparability of results. Better consideration impacts in public procurement Collaboration with educational institutions, research institutes and the public sector can help companies conduct impact studies for their solution. This can also improve the quality and reliability of the studies.
Complex regulatory environment	Developing clear interpretations of regulations and common methods to gain regulatory compliance Establishing more support services for SMEs offering early-stages regulatory advice and assistance Encouraging closer collaboration between companies and regulatory bodies
Lack of industry-specific funding	Involving funding bodies (business angels and venture capitalists) in the industry network Increasing proof-of-concept funding More support and advisory services for companies and innovators to utilize funding opportunities.

Theme	Activity
Lack of industry-specific competence and effective collaboration models	Increasing training: regulation, sales and communications, general product development skills Establishing platforms for dialogue among experts from various fields could facilitate the sharing of best practices and enhance innovation Increasing cooperation between students and companies and training of new experts
The path of digital health innovations from idea to markets remains unclear	Preliminary, iterative model for digital health product development (Figure 3) was formed based on the interview results, experiences from health technology testbed-projects and regulations, standards and methods related to the medical device design and development.

Discussion

The findings from this study highlight several key aspects of the commercialization of digital health innovations, focusing on the supporting ecosystem, commercialization pathways, and identified challenges along with potential solutions. These findings closely align with the previous research regarding the challenges and potential of digital health industry [1,3].

Success in the market typically requires solutions that are demonstrably superior to existing options, necessitating early identification of innovations with the highest potential for further development. Testbed operators could assist in systematically increasing the maturity of digital health solutions. The focus of activities could be shifted more towards supporting very early-stage product development work and aim for testing in an authentic healthcare environment only when the product's maturity has proved to be sufficient, and product is to be released soon. This approach would simultaneously enhance the maturity of the testbeds themselves which has been seen as a challenge in previous studies. [27]

A clear need for impact studies and their utilization in the technology procurement process emerged strongly in the results.

The significant renewal and increase of regulations in the industry require joint efforts to form unified interpretations of the legislation and openly communicate these operational models, thereby enhancing industry consensus and cooperation between different stakeholders. Interpretations should also consider the capability of small companies to implement the heavy processes required by the legislation.

To better coordinate the digital health sector, the path of digital health innovations from idea to commercial product needs to be understood [38], so that support measures (e.g., testbed activities) can be more effectively targeted at identified bottlenecks. This should also consider available commercial services to avoid unnecessary competition between the public and private sectors. Supporting digital health innovations could be seen as a systematic assessment process based on technology maturity [31,39], in which the solution being evaluated is examined from different perspectives. This can provide a perspective for testbed organizations to develop their services to better meet the needs of digital health innovators.

Despite the challenges identified in the commercialization of health tech innovations, the study also highlighted successful examples of testbed operations. One notable case involved a therapy-focused educational institution that established a productive partnership with a company, providing expert

testing service for products in company's development path. This collaboration allowed for a seamless integration of the testbed services into the company's product development process, demonstrating the potential for effective joint development efforts. The maturity of the product being evaluated was considered in the process. However, this test platform had already found evaluations of digital products challenging, which indicates that the model still needs further development for digital health.

The study's limitations include the broad scope of the research question, the relatively small number of interviews and survey responses, and the absence of health technology end-users and healthcare personnel among the interviewees. Despite these limitations, the study presents a novel approach to the development of testbed operations, which may benefit innovators, testbed operators, companies, and ultimately healthcare and patients

Conclusions

The health technology sector is characterized by its diversity and rapid evolution. Effective collaboration among various stakeholders is essential for fostering innovation. The study suggests that national coordination of testbed activities could enhance the effectiveness of these initiatives.

The significant renewal and increase of regulations in the industry require joint efforts to form unified interpretations of the legislation and openly communicate these operational models, thereby enhancing industry consensus and cooperation between different stakeholders. Interpretations should also consider the capability of small companies to implement the heavy processes required by the legislation.

A more comprehensive understanding of the industry and consideration of different perspectives would enhance and streamline collaboration between various stakeholders in the field. Bringing health solutions to market requires diverse expertise, including technical, clinical, regulatory, and research knowledge, and understanding the path of digital health innovations from idea to market is essential for all stakeholders.

In conclusion, fostering innovation in the digital health sector requires a coordinated effort to address regulatory, funding, and collaboration challenges. By enhancing national coordination of testbed activities, providing clear regulatory strategies, and establishing platforms for interdisciplinary dialogue, the commercialization of digital health solutions can be significantly accelerated. This holistic approach will not only benefit innovators but also contribute to the overall improvement of healthcare services.

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Conflict of interest

The authors declare no conflicts of interest.

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