

SAVONIA

University of Applied Sciences

THESIS – MASTER'S DEGREE PROGRAMME
SOCIAL SERVICES, HEALTH AND SPORTS

BUSINESS MODELS IN DIGITAL HEALTH

Challenges and Success Factors of Business Models in Digital Health:

A Narrative Literature Review

AUTHOR/S Ragnar Luur

Field of Study Social Services, Health and Sports	
Degree Programme Master's Degree Programme in Digital Health	
Author(s) Ragnar Luur	
Title of Thesis Business models in digital health: Challenges and Success Factors of Business Models in Digital Health: A Narrative Literature Review	
Date 1.12.2023	Pages/Number of appendices 47/1
Client Organisation /Partners Savonia UAS	
<p>Abstract</p> <p>In recent decades, the number of players in the digital health services sector has exploded, spreading digitalization across all fields. This phenomenon is often referred to as digital transformation, an unavoidable shift. Technological advancements have opened new doors in how healthcare services can be offered, managed, and innovated. Business models in digital healthcare represent the forefront of these changes, enabling and challenging industry players. Digital healthcare is not merely a technological trend but a complex amalgamation of technological innovations, business strategy, patient needs, regulation, and ethics. Therefore, studying digital health sector business models is essential and justified.</p> <p>This thesis aims to investigate the challenges and success factors digital health companies face in their business models, seeking a deeper understanding of these models in the industry.</p> <p>The research was conducted as a narrative literature review. The research questions were: What unique challenges do digital health companies face in their business models? What are the success factors of digital health business models? Literature searches were carried out in databases such as PubMed, Science Direct, and Google Scholar, supplemented by manual searches. Using strict inclusion and exclusion criteria, the search process yielded 17 studies. The data was analyzed through thematic analysis, employing an inductive approach.</p> <p>The results reveal that digital health companies face various unique challenges, including legitimacy, financing and investment, cybersecurity, and assessment challenges. Success factors identified include scalability, collaboration, clinical value, business expertise, the importance of assessment, and disruptive technologies. Based on the results, further research might be necessary, particularly concerning small and medium-sized digital health companies.</p>	
<p>Keywords</p> <p>Digital health, Ehealth, Telehealth, Business model, Enterprise</p>	

CONTENTS

1	INTRODUCTION	5
2	BUSINESS MODELS AND DIGITAL HEALTH	6
2.1	Definitions of Business Model	6
2.2	Osterwalder's Business Model Canvas	7
2.3	Business model framework and value proposition	9
2.4	Modern business models and innovations	10
2.5	Data role in business	11
2.6	Digital health and digitalization	11
3	BACKGROUND OF CHALLENGES AND SUCCESS FACTORS	14
3.1	Challenges in business models	14
3.2	Success factors in business models	16
4	RESEARCH PURPOSE, OBJECTIVES AND RESEARCH QUESTIONS	19
5	METHODS AND ANALYSIS	20
5.1	Narrative literature review	20
5.2	Data collection and selection	21
5.3	Data analysis	23
6	RESULTS	25
6.1	Results of challenges in business models	25
6.2	Legitimacy challenges in business models	25
6.3	Challenges of performance evaluation	25
6.4	Financing and investments	26
6.5	Cybersecurity and information security	27
6.6	Results of success factors	27
6.7	Scalability in digital health	27
6.8	Business competence	28
6.9	The clinical value	28
6.10	Importance of business evaluation	28
6.11	Cooperation with partners	29
6.12	Innovations drive business	29
6.13	Disruptive technologies in business models	30
7	DISCUSSION	31

7.1 Challenges in business models.....	31
7.2 Success factors in business models	32
7.3 Ethical evaluation of the study	34
7.4 Quality assessment of study	35
8 CONCLUSION	36
REFERENCES.....	37
APPENDIX 1: TABLE OF RESEARCH.....	41

LIST OF FIGURES

FIGURE 1. The nine Building Blocks based on Osterwalder et al. (2010)	7
FIGURE 2. Channel types based on Osterwalder et al. (2010, 27)	8
FIGURE 3. Channel phases based on Osterwalder et al. (2010, 27)	8
FIGURE 4. Reflecting the different levels of digitalization adapted from (Sivula et al. 2023, 9)	12

LIST OF TABLES

TABLE 1. Inclusion and Exclusion Criteria Table	22
TABLE 2. Results of the Matrix Overview of Searches Conducted in Databases.....	23
TABLE 3. Example of inductive content analysis about legitimacy challenges	24

1 INTRODUCTION

Information technology has revolutionized the current healthcare industry. The use of healthcare information technologies is expected to increase significantly. Lau, Bartle-Clar & Bliss (2019) state that scientific research, as well as industrial and government support, is needed. Research and support are necessary for the effective implementation of these technologies to build capacity at the regional, global, and national levels.

In the future, digital healthcare is expected to attract significant interest and investment. The market is projected to reach a revenue of \$170.2 billion by 2023, which is anticipated to be just the beginning. The digital fitness and wellness markets are estimated to generate \$96.94 billion in 2023. This suggests that digital health is not solely medically oriented but includes a broader range of consumer services. (Statista Inc. 2023.)

Interest in innovations in digital healthcare has been continuously growing over the past few decades. It can be said that digitalization has penetrated almost all industrial sectors. Technology and data processing development have opened new doors in how healthcare services can be offered, managed, and innovated. Business models in digital healthcare represent the forefront of these changes, offering both challenges and opportunities to industry players. Digital healthcare is not merely a technological trend. It is a complex amalgamation of technological innovations, business strategy, patient needs, regulation, and ethics. Understanding it requires a new approach from both technological and business perspectives. (Oderanti, Li, Cubric, & Shi 2021, 13.)

"Business models matter", states Chesbrough in his article that discusses the possibilities of business innovation for companies. Better-developed business model often trumps superior technology or ideas. Furthermore, not all business models are necessarily the same. From this, it can be assumed that studying business models for different sectors, such as digital healthcare, is essential and justified. (Chesbrough 2007, 12.)

Digital health and the innovation of various business models are crucial due to the rapid development of technology. Business models can adapt to technology and enhance their practical use. The development of business models can create additional value and operational efficiency while also increasing cost savings. Digital health is a multidisciplinary field; thus, integrating different perspectives is essential. (Wahyono 2019, 348.)

The purpose of this thesis is to investigate business models in the digital health sector. The research is carried out as a narrative literature review. This study aims to identify and present the unique challenges and success factors in digital healthcare from a business model perspective. Through the literature review, it is possible to perceive the existing entirety based on previous studies (Johansson, Axelin, Stolt & Ääri 2007, 3).

2 BUSINESS MODELS AND DIGITAL HEALTH

This chapter aims to explain to the reader what business models encompass. Initially, it discusses what the literature describes as a business model, its definition, and what it includes. Subsequently, the concept of digital health and its associated terminology are elucidated. The section highlights business models in digital health based on previous research. This approach helps the reader better understand the context. Simultaneously, the study's theoretical framework is established, through which the content and entirety of our research are formed.

2.1 Definitions of Business Model

A business model is found in every company, regardless of the industry. The term business model is often used, but its definition is unclear. Two essential tasks can be defined within a business model: value capture and creation. In business model can be found six parameters: Revenue mechanism(s), Target market, Value proposition, Value chain, Value proposition, Value network or ecosystem, and Competitive strategy. (Chesbrough 2007, 12.)

A business model can also indicate how a company implements its strategy using the entire organization's resources. It is said to concretize the strategy within the company. The digitalization and electronification of the world have also changed business models, which are now required to be agile and adaptable. A good business model must be logical and modifiable. It combines the company's production processes, customer perspective, cash flows, and partners. It can answer questions such as: What does the potential customer want from us? How do we get the customer interested in us and buying our services? What must be done to ensure our products exceed the customer's needs? (Hesso 2015, 85-86.) The business model explains on a broad scale how a company generates revenue: what it offers, to whom, and how this plan is implemented. In other words, it describes the company's income and service flows, its position in the value chain, and explains the benefits and revenues different stakeholders receive. (Technology Industries of Finland & Pulkkinen 2005, 14-20.)

One key challenge in developing business models is creating value-added services for which customers are willing to pay more than their production costs. There are many reasons for using business models in business development. These include benefits in change management, planning, forecasting the future, analyzing business, developing management, and understanding business. The business model requires testing and development based on feedback to make it sustainable. (Technology Industries of Finland et al. 2005, 14-20; Järvinen et al. 2017, 81.)

A business model is not the same as strategy or tactics. It is rather a narrative of how a company creates value and evolves. (Presnal, Kilpatrick Brathwaite, Salo & Brathwaite 2021, 78.) A company's competitive position depends on how well its business model, based on its strategy, fits into its operating environment. Therefore, understanding business models is valuable for all decision-makers. The more precisely a decision-maker understands and can handle the company's business model, the better they can implement it (Koponen 2019, 117). Business models can emerge, for example, around the same idea or be targeted at a new audience. However, despite its general and established use, the business model has not been clearly defined. (Saarelainen 2013, 18.)

2.2 Osterwalder's Business Model Canvas

The study of business models is still a relatively new field of research. Osterwalder et al. define in their work Business model generation a business model with the help of nine different building blocks (figure 1). A business model describes the rationale of how an organization creates, delivers, and captures value. (Osterwalder, Pigneur & Clark 2010, 15.)



FIGURE 1. The nine Building Blocks based on Osterwalder et al. (2010)

1. Customer segments define all the target groups it aims to reach with its business. They can be, for example, organizations or different groups of people. The company can divide customers into different segments, i.e., customer groups with everyday needs, behavior patterns, or other unifying characteristics. This is particularly important for the company to consider in its business operations, which segments are served, and which are ignored. Customer segments can include the following: Diversified market, mass market, segmented market, multi-sided platforms/markets, niche market. (Osterwalder et al. 2010, 19-77.)

2. Value propositions refer to the service and product selection offered by the company, which produces value for the customer group. This is why the customer chooses the services of that company from among other companies. A value proposition can be, for example: Price, Newness, performance, customization, Design, and accessibility. (Osterwalder et al. 2010, 22-25.)

3. Channels describe how companies find potential customers to sell the product to. Distribution, communication, and sales channels form the contact surface where the company meets the customer. At the same time, they act as essential factors in the customer experience. (Figure 2 and figure 3) show the channel types and their phases best. (Osterwalder et al. 2010, 26.)

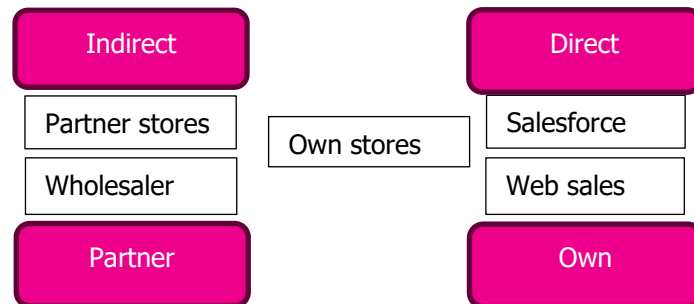


FIGURE 2. Channel types based on Osterwalder et al. (2010, 27)

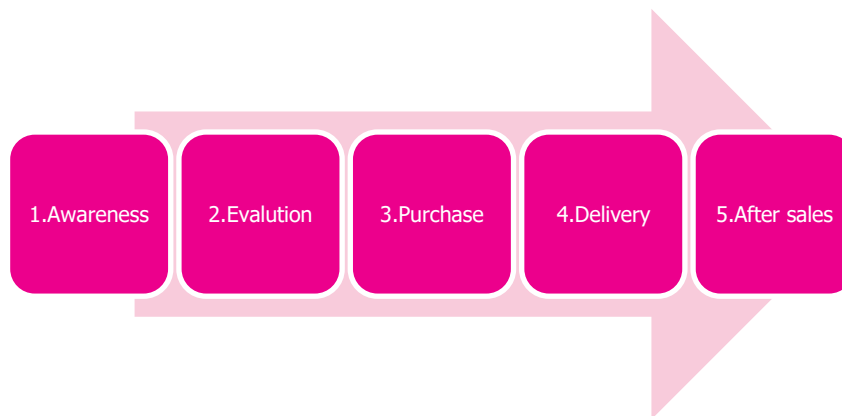


FIGURE 3. Channel phases based on Osterwalder et al. (2010, 27)

4. Customer relationship describes the different customer relationships that the company wants to have with other customer groups. These can include, for example, Customer acquisition, Customer retention, and Boosting sales. Companies have added various partnerships and networks where customers can work together to develop the company's services. (Osterwalder et al. 2010, 28-29.)

5. Revenue Streams are the next most important area after customers. Here, the most important thing for a company is to know the pricing mechanism. They can be, for example, bargaining, auctioning, fixed list prices, market-dependent, volume-dependent, or yield management. The business model can be either transaction revenues or recurring revenues. Income streams can be of many kinds. (Osterwalder et al. 2010, 30-32.)

6. Key Resources reflect the critical resources needed to create the business model. With the help of resources, the company, among other things, reaches markets, offers value proposition, earn revenues, and maintain Customer relationships. Resources can be Human, which is company staff. Intellectual, which includes patents, copyrights, and partnerships. Financial, which are all assets of the

company that can be converted into money. Physical, the company's physical assets such as machines, buildings, etc. (Osterwalder et al. 2010, 33-34.)

7. Key Activities are the essential activities that guide the company's business model. These activities directly affect the company's success. The operational requirements are much the same as for Key resources. Key activities also depend on different business model types. For this reason, they can vary a lot. (Osterwalder et al. 2010, 36-37.)

8. Key Partnerships describe the network of various partners and suppliers. It is said that partnerships form the cornerstones of business operations. Among other things, they optimize business models and reduce risks. (Osterwalder et al. 2010, 38.)

9. Cost Structure includes all the main costs the business model causes for the company. All the functions described in the previous "building blocks" incur costs. They can often be calculated after defining the key functions. The basic idea is always to minimize costs in all business operations. Regarding costs, two different classes of cost structures can be distinguished. (Osterwalder et al. 2010, 39-40.)

2.3 Business model framework and value proposition

Business Model Framework (BMF) is a model that can be used to define business models from the simplest to more advanced models. Companies can use the model to evaluate the opportunities of their current business model in relation to its potential. There are six different types of models distinguished. Type 1 means that a company has an indistinguishable business model from other companies. Today, most companies implement this model. In this model, price competition and availability are emphasized. For example, barbershops and restaurants implement the type 1 model. Companies following the Type 2 model have differentiated their services to some extent. However, they lack resources for investment and stability. The company might have its first successful product, but other products do not achieve the same success. Typically, startup technology companies are like this. In the Type 3 model, the company segments, meaning it investigates markets in its business. In this case, the company can compete for customers in different markets simultaneously. This increases significant profit potential and a broader customer base. Segmentation helps the company to plan its future better with the help of various product and technology maps. Companies implementing the Type 4 model have opened their operations to more external ideas. In this model, companies can utilize technologies to develop and implement their business. The model frees up more resources to develop the company's core business. Customers and partners are often more involved in innovations than in the previous models. In the Type 5 model, we talk about the integrative effect of the business model in core business. In this model, the role of the customer and the supplier is essential for the core operations. This means that customers and suppliers share their roadmaps with the company. A roadmap is intended as a tool for decision-making to improve coordination and resourcing. In this model, it is typical for the company to have more significant investments in various resources than in the previous models. In the Type 6 model, the business model is called an adaptive platform. Companies following this model experiment with several different business models and their variations in many forms. In this model, customers and key suppliers are integrated as

business partners, where there is also a sharing of risks in terms of technology and business. (Kostoff, Schaller & May 2002; Chesbrough 2007, 13-14.)

Business model usually describes a company's operations regarding its results and profits. For example, what the company sells and to whom. The customer is described as a target who pays for various solutions sold to them. The company aims to retain a profit after costs, called the result. When business models are described from the perspectives that combine operations and concepts, it is about defining values. This is referred to as value architecture. When value is created, it results in a value proposition, which describes the method or means by which the company solves the customer's problem. (Hänti 2021, 74-75.)

2.4 Modern business models and innovations

Koponen (2019, 29) states that the platform economy is challenging to define. At the same time, he notes that technological platforms enable interfaces or methods between businesses – strategic technologies. This refers to technologies enabling different companies' business in an entire industry. Platform thinking is acknowledged to have developed through technology platforms.

Now, powerful tools for analyzing the business models of complex platform organizations have become available. Unfortunately, Alexander Osterwalder's widely used 'Business Model Canvas', a valuable tool in designing traditional business models, is not comprehensive enough. Although the Business Model Canvas works well as an essential checklist of different business model components and can be a tool for thinking, it is not flexible enough to describe business models in the platform economy. Since most business model tools are created from the perspective of traditional corporate structures, their practical usefulness is limited when examining platform economy business models, which particularly emphasize internal market interactions and complex feedback loops. Unlike in conventional businesses, where the focus is on internal operations, platform models pay attention to what happens outside the core of the business. Analyzing business models in the platform economy requires three things: first, delineating the business model as a business system - what functions it comprises, and as a revenue model - how it generates income. Secondly, understanding decision-making and its consequences is needed. Thirdly, it is necessary to conceptualize the temporal delays and feedback loops of the consequences. (Koponen 2019, 116-117.)

When an invention or method of operation is commercialized, it can be referred to as an innovation. A challenge for product and service innovations is their rapid replicability. This can cause a company to lose its competitive edge regarding its service. Business Model Innovation (BMI) can be used to address this. BMI can significantly enhance a company's business model. To improve business models through innovation, it is first necessary to understand what it entails. A company must be dynamic and adaptable enough to remain viable. It is suggested that business model innovation can be practically implemented using a navigation map. Companies can approach innovation through experiential and open innovation. The key areas in business model innovation are value proposition, operational value, human capital, and financial value. (Chesbrough 2007,17; Ramdani et al. 2019, 14; Hänti 2021, 83.)

2.5 Data role in business

The role of data in the business world is irreplaceable. It is integrated into a company's operations, and its continuous production is a daily occurrence for most organizations. Often, the potential of data usage remains underutilized in companies. Data is thought to enable, diversify, and improve business in different sectors. It can generate new business opportunities and accelerate existing ones. Understanding the value of data as corporate capital is crucial. Data utilization focuses on creating added value by increasing efficiency or developing new products and services. Data is also a prerequisite for the development and use of artificial intelligence. Data is not useful; it must be refined into value-added support for business. (Sivula, Aho, & Laukkanen 2023, 13.)

Data-driven business refers to activities that utilize data to improve a company's or organization's performance. This starts with business needs and aims to produce added value. It can, for instance, support company management with data products or develop services and products based on data, such as reporting systems or AI applications. Managing data alone is not enough; there needs to be a realistic understanding of the possibilities and limitations of data. Data and platform economies are often discussed side by side. In the platform economy, such as in companies like Wolt and Uber, the focus is on the platform and its associated technologies and business models. In the data economy, the focus is on the data and its benefits. Both are ultimately part of the same economic ecosystem, where data is the core. Utilizing it is crucial, whether optimizing business operations or developing new services and products. Companies should define which business sectors would benefit most from data. Potential uses include increasing a company's efficiency, improving customer experience, or creating new data-based innovations. Developing all these areas requires different expertise, from technological knowledge to renewing business processes and possibly even implementing new operating models. When discussing data, data warehouses, software robotics, artificial intelligence, neural networks, and data analytics are often mentioned. These technologies do not create added value; they are tools that help achieve business objectives. Merely having a large amount of data does not guarantee business success. Data must be turned into useful products or services that add value to the business. Sometimes it is observed that current data reserves have gaps, necessitating the development of strategies for collecting missing information. For instance, data related to customer behavior may need to be gathered over a long period before it can be transformed into valuable data products. (Sivula et al. 2023, 14-20.)

2.6 Digital health and digitalization

This section discusses digitalization and the subject of study, Digital Health. Digitalization affects our society in many ways, from individual factors to the entire community structure. Various technologies and data utilization are changing companies, organizations, and individuals' operating methods. This change is directly reflected in society, including in business models and revenue generation mechanisms of companies. (Figure 4) illustrates how this transformation occurs at different levels (Sivula et al. 2023, 9.)

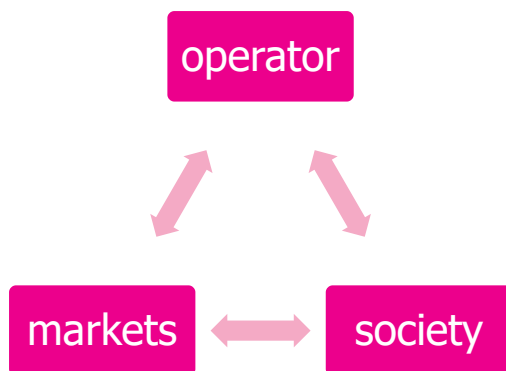


FIGURE 4. Reflecting the different levels of digitalization adapted from (Sivula et al. 2023, 9)

The World Health Organization (WHO) states that digital technology is integral to our daily lives. Through it, the global connection between people is stronger than ever before. Innovations, especially in the digital environment, are occurring at an unprecedented scale and speed. However, the use of technology in enhancing human health is still largely untapped, and there is considerable room for the benefit of digital health applications. (WHO 2023.)

The WHO strategy aims to improve the health of all people worldwide by accelerating the development and deployment of appropriate, easy-to-use, affordable, scalable, and sustainable digital health solutions. It also aims to achieve the health-related Sustainable Development Goals (SDGs). Digital health is valued and widely adopted wherever it is available. The clear idea is to promote fair and equitable access to high-quality health services and increase health systems' efficiency and sustainability by providing quality care at affordable prices and on an equitable basis. All this will be done in a system that protects the privacy and security of patients' health data (WHO 2021, 10.)

The vision also promotes research and development, innovation and multidisciplinary cooperation. It recognises that digital health will be more efficient if there is sufficient investment in governance, institutions and workforce capacity, and if digital systems and information are enabled in education, planning and management, which are essential for the digitalization of health systems and services. WHO emphasizes the importance of digital health on an international level, the significant role of technologies and innovations, the challenges of implementation, and the rapid development of the field. (WHO 2021, 10.)

Digital healthcare has caught up with us and is developing tremendously. It is a specialty that focuses on utilizing digital technology to promote health. It expands the idea of electronic healthcare to include a broader range of digital devices and services consumers use. In versatile healthcare applications, digital health technologies utilize computing platforms, connections, software, and sensors. This includes or is related to artificial intelligence, big data, blockchain technology, healthcare information, health information systems, infodemics, Internet of Things (IoT), interoperability, and telemedicine. The concept of digital healthcare includes digital health (Figure 5), which consists of the aforementioned wearable devices, mobile health using smart devices (mHealth), clinical trials, remote telemedicine (Telehealth-care), well-being, and analytics formed from measured health data

and its visualization. Digital healthcare involves artificial intelligence and cognitive assessment functions in the diagnosis of diseases, as well as predictive healthcare. (FDA 2020; Vähäkainu 2018; WHO 2023.)

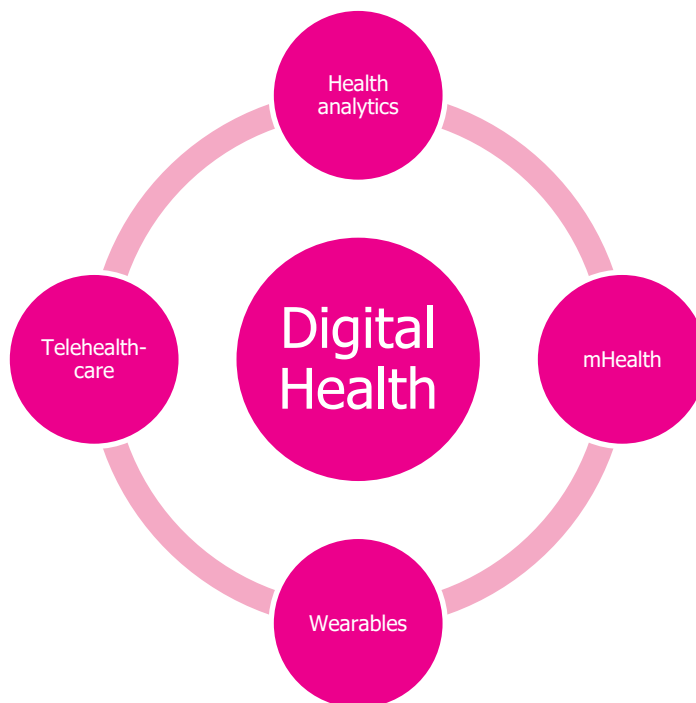


FIGURE 5. What include to digital health adapted from Vähäkainu (2018)

3 BACKGROUND OF CHALLENGES AND SUCCESS FACTORS

In this chapter, previous studies related to the topic are reviewed. By familiarizing oneself with existing theories, they can ideally be improved, and new ones can be created. In science, the principle is to build new knowledge on top of the old, referred to as the accumulation of knowledge. The benefit of this familiarization is that it reveals how issues have been addressed, what types of measures have been used, and what conclusions have been reached. The theoretical foundation of the research must always be based on relevant, appropriate, and up-to-date literature related to the topic. The theoretical framework should be essential and cover aspects relevant to the topic. The theoretical framework can be understood as what has already been written about the subject. Finding theories specifically for a specific problem can be difficult, so the framework can be understood as what is found in the literature and science about the phenomenon. Theories and previous studies are used to support one's research. They are used to strengthen one's research findings. (Kananen 2010, 21; Vilka 2023, 83.)

The study aims to investigate business models in the digital health sector. The research aims to uncover and identify the unique challenges and success factors in digital health from a business perspective. The study assumes that digital health companies face specific challenges in their business. In addition, success factors that can be significant in successful business models are identified.

3.1 Challenges in business models

In their study conducted in the United Kingdom, Oderanti et al. (2021,14) observed that despite government and local authority-funded political initiatives and pilot projects, the market for electronic healthcare technology services remained small and highly fragmented. Additionally, the market growth had been significantly slower than previously predicted. Many small and medium-sized technology and service providers dominate the market, including numerous startups with undeveloped products and business models. The study emphasizes the challenge of achieving large-scale economic sustainability in traditional business models. While practical innovations exist, many service providers are small-scale and not commercially viable on a large scale. This raises the question of how innovative solutions can be scaled into profitable business models. Furthermore, it was found that companies depend on other sources of income and their side activities. Regarding the challenges, the study summarizes that many new technologies have reached only a small number of end-users. They are often government-funded, which can limit their commercial exploitation and sustainability. In terms of demand and supply, there is a search for affordable technologies, while service providers often market expensive and complex solutions. This mismatch can lead to inefficiencies and unmet cost savings. Oderanti et al. (2021, 14) also point out that, despite the market potential, many providers of digital healthcare services face challenges in scalability and business sustainability in their traditional business operations.

Silva, F., Silva, E., Neto, E., Lemos, Neto, A., & Esposito (2020, 1) show that in IoT-based digital health solutions, Distributed Denial of Service (DDoS) attacks are now one of the most devastating virtual threats. Combating DDoS attacks is a significant challenge. For example, these attacks can

pose serious risks to patient safety and privacy regarding healthcare hardware and patient data protection.

Companies must understand and adapt to operate in complex business networks, where collaboration with different actors is critical. This requires identifying and exploiting opportunities in the network and aligning the goals and operations of other actors. They add that it is crucial to understand how new technological solutions or components are integrated into broader service offerings. Some technologies may act as value-adding parts without being essential to the core functions of the service. In contrast, others are central to the entire operation and customer value of the service. At the same time, there is a challenge in bringing new technology to market by integrating it into existing business processes and models related to combining technology and services in a way that benefits the customer. The company must identify which technological innovation best fits its current work processes and service offerings. (Laya, Markendahl & Lundberg 2018, 114.)

Favoretto et al. (2022, 749) note that digital transformation requires manufacturing companies to redefine their business logic, leading to necessary changes in organizational structures, business model value systems, and technology infrastructure.

Gomes, Kempainen, Pikkarainen, Koivumäki, & Ahokangas (2019, 27-31) have studied ecosystemic challenges in their research "Ecosystemic business model scenarios for connected health." According to them, business ecosystems are multifaceted by nature, and their boundaries are not clearly defined, which complicates the development of an ecosystemic business model for practical application. While ecosystemic business models continuously evolve throughout the life cycle of the entire business ecosystem, their concrete implementation in practice is tied to negotiations and interactions between stakeholders. Based on the research, those business ecosystems that aim to bring together different actors around a common ecosystemic solution to solve a specific problem require ecosystemic business models. The study has highlighted that actors participating in the ecosystem can identify opportunities for collaboration in their business models by finding synergies and conflicts between the models. Interviews conducted in the study show that a business ecosystem aiming to meet the requirements of hospitals does not need to be limited to a single service platform, which could promote only one industrial partner's business. This might prevent achieving the business ecosystem's common goal and the development of services for a broader customer base.

There have been found challenges of artificial intelligence in healthcare applications. The study revealed several practical challenges in integrating AI into healthcare systems, identifying various pedagogical and technical barriers. The research has also been challenging because the interdisciplinary nature of AI requires a comprehensive approach, taking into account legal dimensions as well as technical aspects. The researchers add that careful adherence to GDPR and privacy protection must be considered. With the increasing significance of AI in health data collection and sharing, the study recommends developing sustainable methods for open-source health data management. Growing concerns about consumer privacy and data protection necessitate the application of national and international regulations and directives. Simultaneously, the importance of deepening understanding of data ownership rights and creating ethical guidelines related to the use of medical AI is emphasized. (Mohammad et al. 2023, 1024-1029.)

3.2 Success factors in business models

Oderanti et al. (2021, 9) highlight effective collaboration and corporate acquisitions; many innovative products and services are developed in small businesses, which lack the infrastructure to deliver them on a large scale. Collaboration, including acquisitions, is essential for achieving growth and sustainability. Additionally, Belfiore, Cuccurullo, & Aria (2022, 3-5) note that most patents in the healthcare IoT sector are privately owned, but public research institutions are in a key position to advance IoT research. Therefore, it is advisable to intensify collaboration between industry and academic circles.

Diversification of the product line: different segments of the eHealth market are often not large enough to achieve sustainability through a single product. Many companies have heavily invested in diversifying their product range. (Oderanti et al. 2021, 9.)

Clear Definition of the eHealth Ecosystem; Identifying key stakeholders, such as service providers, volunteer organizers, insurers, social enterprises, financiers, customers, and users. (Oderanti et al. 2021, 9)

International Orientation and Market Penetration: Success in international markets often relies on acquiring small, specialized companies for new technology and distribution opportunities, as well as exploiting foreign markets through local partners. (Oderanti et al. 2021, 8.)

Management of Financing and Investments: It is reported that companies, such as university spin-outs, have succeeded in maintaining operations after initial funding. Success is also attributed to successful return on investment (ROI) within a certain timeframe and attracting new investors after public financing. (Oderanti et al. 2021, 10.)

Regulatory and Policy Environment; In some international markets, unlike in the UK, the market is dominated by medium-sized and large companies, including multinational corporations. The revenue streams of these companies indicate that most are financially sustainable and have started or planned to expand into a global distribution network. (Oderanti et al. 2021, 10.)

Oderanti et al. state, based on Zott's (2012) study, that value creation often occurs through various business model innovations in a digital context. Innovations happen through changes in planned activities, connections, or active operating systems. They use Osterwalder and Pigneur's (2010) business model framework in their research. Based on the study they found (Hwang and Christensen 2008), it is noted that the lack of innovative business models is the main factor in assessing accessibility and cost issues in healthcare. Digital health is linked to innovative business models, primarily through internet-based innovations. Health technology services include point-of-care (POCT) wearable devices, the Internet of Things (IoT), telemedicine/tile treatment, and online medical consultations. (Oderanti et al. 2021, 2-3.) Developing and applying specific data transmission methods in network infrastructure is necessary to efficiently and broadly implement these wearable healthcare mobile applications, ensuring their performance, network optimization, and system reliability (Garcia-Perez, et al. 2017, 674).

In promoting the use of mobile technology to develop sustainable business models in healthcare, it is essential to comprehensively address areas beyond the technological dimension of the business model, such as value propositions that reflect customer value, organizational structure, and the mechanisms of cash flow formation instead of service platforms. In a sustainable business model enabled by mobile technology in healthcare, value propositions should be formulated according to customer values, generating social benefits. Effective value capture models must be designed to achieve economic benefits. According to the study, telemedicine enables the creation of such value propositions and supports building a sustainable business model. Telemedicine services must offer usability and sustainability, integrating the interests of all different stakeholders into one system. Nosratabadi et al. (2019, 17.)

The ideal forms, goals, and impacts of innovation hubs are still under development, the economic challenges of evolving payment systems and the ability of new digital healthcare technologies to challenge existing service models are tangible. Healthcare sector actors are still tightly focused on meeting regulatory requirements and improving quality, leading to minor adjustments in existing processes. However, this approach may not be sufficient to ensure success in the future environment. Early experiences with innovation hubs show the range of possibilities available to those who want to expand their organization's innovation capacity. In the post-pandemic world, whether innovation hubs can meet the growing clinical, technological, and economic needs remains to be seen. (Bhattacharyya, Shapiro, & Schneider 2022, 2.)

Fürstenau, Klein, Aryn, & Carolin (2021, 822) highlight multi-sided platforms (MSPs) and their business models through care coordination and research models. The study addresses value-based healthcare through patient activity and participation. The alignment of two separate business models enabled the growth and scalability of the platform. Additionally, it is noteworthy that patient-centered care coordination facilitated professionals' collaboration through evidence-based research information enhanced by artificial intelligence algorithms. Multi-sided platforms have been shown to improve the management and coordination of care quality through technology and economic principles. The analysis identified three value-adding stages: efficient coordination, care quality management, and direct patient participation through app-based monitoring (Fürstenau et al. 2021, 823-824).

A literature review related to telehealth conducted by Velayati, Ayatollahi, Hemmat & Dehghan (2022, 2) noted that business models could assist telehealth technology companies. Significant factors include considering stakeholders' and customers' requirements when defining value propositions. This is also the view of Antonio, Petrovskaya & Lau (2020, 2), who recommend reevaluating business models in patient care. Grustam, Vrijhoef, Cordella, Koymans, & Severens (2017,3) state that transaction costs in the telehealth business may be lower in a B2C model compared to a B2B model, which could promote the business of telemonitoring.

Additionally, business models need to be tailored to different contexts. Success can be highly contextual. The same review noted that Osterwalder's business model canvas has been used to gain a more comprehensive overview of the telehealth sector. The research raises the question of how traditional business models can be further refined. It also raised the question of whether a universal

model could be developed specifically for the digital health sector, including elements from traditional and modern business models. (Velayti et al. 2022, 2.)

With technological advancements, all business areas have undergone transformations, particularly the expansion of information availability and the growth in data volumes, which have been key factors in this development. For these reasons, the skill in utilizing information has become an increasingly important competitive edge for companies. Huhtala et al. (2019) states, based on Keen et al. (2006), that a company wanting to break into the market as a new player or develop new business areas must have a business model that clearly describes the company's needs and desires to make changes in its operations. In a digitalizing environment, the versatile utilization of personal data becomes a key company resource. Personal data should be seen as a necessary, readily available, and reusable resource. Companies that are among the first to develop and offer services that support individuals' life management can establish new business models and thus contribute to economic growth. MyData-themed research that commercializing personal data is not straightforward. There are two primary levels in using personal data: individual personal data and combined anonymous or pseudonymous data. As open business models become established and data-related regulations are examined, this aggregation-level data forms a valuable asset for industry players. (Huhtala, Pikkarainen & Saraniemi 2019, 56.)

4 RESEARCH PURPOSE, OBJECTIVES AND RESEARCH QUESTIONS

This chapter introduces the purpose, objective, and research questions of the study. This thesis aims to examine business models in the digital health sector. The research aims to identify and find the unique challenges and success factors of digital health from a business perspective. Digital health companies are assumed to face specific challenges in their business operations. In addition, the possible success factors that may be prerequisites for successful business operations in companies are also explored.

Formulating a research question is a critical phase in the design of a literature review, as, without a clearly defined question, it is impossible to form search terms and criteria for the search process. It can be said that research questions guide the entire research process. For a successful literature review, it is of utmost importance that the researcher identifies a topic within their field that arouses personal interest and is relevant. It is essential to thoroughly consider the questions during the research process, as they guide data collection and enable the discovery of relevant information or tools to solve the issue being developed. The research problem, data acquisition questions, and the why questions that emerge in the analysis phase should form a coherent, logical chain that reflects the core of the phenomenon you are researching or developing. (Kananen 2010, 31; Vilkkä 2021, 105; Vilkkä 2023, 43-44.)

This study formed two research questions. The research questions are detailed below.

1. What unique challenges do digital health companies face in their business models?
2. What are the success factors of digital health companies' business models?

5 METHODS AND ANALYSIS

This chapter discusses the methods used in the research, purpose, objective, research questions, and the steps for searching the research material. The chapter explains to the reader what a narrative literature review means. At the same time, the background and formation of the research questions and the development of data collection are opened. In the research, methods are named as those methods and practices used purposefully to produce observations about the research topic. Various data collection methods provide first- or second-hand information and sources. Different research strategies and approaches are often also considered as research methods. (Vilkka 2021, 59.)

5.1 Narrative literature review

The research method used in this study is a literature review. A literature review can be defined as a research method used to examine original research by researchers and scientists. It is conducted to assess, identify, interpret, and synthesize existing knowledge. The method aims to summarize the existing and relevant understanding of the original research in the subject area and to draw critical conclusions to a pre-set research question. The review aims to examine the overall picture or synthesis critically. The nature of a literature review is analytical and multi-methodological. It combines a pre-planned systematic process of searching for studies, critical reading and evaluation of the studies found, selection of studies, note-taking of original studies, analysis of studies, i.e., comparison of data, and synthesis to produce new knowledge. A literature review aims to practice and guide, provide guidance, find tools and methods, or build recommendations, for example. It may also seek to describe what is being researched and known about the subject and, in this context, to identify gaps in the knowledge of the subject. A literature review of research methods is characterized by rigor, regardless of the type of literature review method. This accuracy involves striving for validity, generalizability, and reliability during the research. In practice, it means that the research data are obtained in a deliberate, systematic, limited, and consistent manner, according to pre-established rules, to assist the search process. Transparency means reproducibility, i.e., that the research process discloses, in detail, all the steps taken by the researcher and the reasons for their selection. Transparency requires that the data acquisition and the associated selection criteria are carefully disclosed in the review that is written about the research. The study will describe in detail the search and selection criteria, keywords, databases used and the rationale behind them, and the results of the search in a critically appraised and consistent manner. It is inherent to the literature review that a balance is struck between the selection judged appropriate to the research question and the exactness required by the method. (Vilkka 2023, 11-13.)

In a literature review, according to Vilkka, criticality as a discriminating and structuring activity means that as the process proceeds step by step, the author reflects on what they do and think in the literature review, where the ideas and actions come, and what they imply for the results and conclusions of the literature review. Criticality also means accepting and defining the research challenges presented by the literature review and creatively experimenting and making more observations to find solutions to the problems rather than hiding them. For example, when rejecting or accepting a solution, it should always be done in a reasoned manner. (Vilkka 2023, 14.)

5.2 Data collection and selection

The data for the literature review is usually collected according to a pre-prepared plan. The literature searches for the study were conducted using Savonia's licenses to databases, which the researcher had free access to. A systematic literature review aims to map all significant global research knowledge related to the topic. To achieve this, it is essential to use a comprehensive and carefully planned search strategy. Using relevant databases for the search, from which research on the subject matter is available, is also key. An information specialist is an excellent help in planning the search strategy. (Stolt, Axelin & Suhonen 2016, 25-111.) In this study, the information specialist help was also used.

When choosing search terms, it is essential to select them carefully, as they are crucial in finding studies for the literature review. The search strategy consists of grouping these terms to conduct an effective search. In other words, the search strategy is a method where the selected search words are arranged in a way that helps find relevant material for the literature review. (Vilkka 2023, 56.) The article searches for the literature review were conducted during the summer and autumn of 2023. The specific search dates of individual studies are in the reference list. Based on advice received from Savonia's information specialist, the following databases were selected:

PubMed is a database designed to support searching and processing biomedical and life sciences literature. Its goal is to promote health globally and at the individual level. The database contains over 36 million references and abstracts from biomedical literature. (National Library of Medicine 2023.)

ScienceDirect is a leading database offering peer-reviewed literature from Elsevier's journals and books, containing a wide range of articles. Most articles are available completely free of charge. (Elsevier 2023.)

Google Scholar is a database that enables the simple and extensive search of multidisciplinary scientific literature. Google Scholar allows for the discovery of relevant scientific material from around the world, such as various articles and other publications. (Google Scholar 2023.)

When forming the search terms, Boolean operators were used. The use of Boolean operators is central in database searching to find research material. The operator AND narrows the search so that all search terms must be in the results, thus providing particularly targeted material. On the other hand, the operator OR expands the search by including articles in the results that contain any of the given search terms. The operator NOT should be used cautiously, as it excludes certain words from the results, which may also eliminate relevant material. (Savonia University of Applied Sciences 2023.) Combining search terms with Boolean operators is common in most databases, such as PubMed, Scopus, and Web of Science. Familiarizing oneself with different database guidelines is necessary to ensure good and relevant search results.

Search terms were modified to suit different databases. This was due to different search functionalities, which limited the use of the same search methods. Information retrieval was carried out in the databases above with search terms formed based on the research questions. Savonia's information

specialist guided creating the search terms. With the assistance of the information specialist, developing search terms was more accessible and clarified the initiation of the research.

Studies that correspond to the defined research question are mapped and evaluated when selecting research material (Vilkka 2023, 74). At this stage, the original studies' relevance and ability to answer the posed questions in the context of the literature review are carefully examined. Extensive researcher-specific contemplation and discretion are used in selecting and rejecting studies, adhering to defined criteria. Using predefined methods reduces the possibility of bias in the literature review. (Stolt et al. 2016, 57.) The study's predefined inclusion and exclusion criteria are shown in (table 1)

Inclusion Criteria	Exclusion Criteria
Published in 2015 or later	Published before 2015
Written in English or Finnish	Written in any other language
Material is a scientific publication (peer-reviewed)/other reliable source	other than a scientific article
Available on the internet	Any other form of material
Material accessible for free with student credentials	Access to material is paid
Abstract available	No abstract available

TABLE 1. Inclusion and Exclusion Criteria Table

The search terms used in PubMed were as follows: ("Models, Organizational"[tw] OR "business model*"[tw]) AND (Telemedicine[tw] OR Telenursing[tw] OR telehealth[tw] OR "digital health"[tw] OR ehealth[tw]) AND (challenge* OR difficult* OR barriers OR problems OR limitations). This search was aimed at research question 1, which asked, 'What kind of unique challenges do digital health companies face in their business environment?'. The initial search yielded 243 results. ("Models, Organizational"[tw] OR "business model*"[tw]) AND (Telemedicine[tw] OR Telenursing[tw] OR telehealth[tw] OR "digital health"[tw] OR ehealth[tw]) AND (succes* OR prosperit* OR success factor OR business suc*) were the search terms used for research question 2, which asked, 'What are the success factors of digital health business models, and how do they affect the performance of companies?'. The initial search for this yielded 99 results. The total number of studies from both searches was 342. Following the application of inclusion and exclusion criteria and further refined limitations, see Table 2., this number was narrowed down to 96 studies. Ultimately, 10 articles were selected for analysis in the final study.

The search terms for ScienceDirect were formed based on the PubMed search terms as follows: ("business model") AND (Telemedicine OR telehealth OR "digital health" OR ehealth) AND (succes OR success factor OR business success), ("business model") AND (Telemedicine OR telehealth OR

"digital health" OR ehealth) AND (challenge OR limitations factor OR barriers). The search terms had to be condensed from the previous ones. This is because ScienceDirect's search allows only 8 search terms. The total number of studies from both searches was 1943. After applying the inclusion and exclusion criteria and more specific limitations, see Table 2, this number narrowed down to 146 studies. Finally, 10 articles were selected for analysis in the final study.

The search terms for Google Scholar were formed as follows: ("Models, Organizational" OR "business model*") AND (Telemedicine OR Telenursing OR telehealth OR "digital health" OR ehealth) AND (succes* OR prosperit* OR success factor OR business suc*), ("Models, Organizational" OR "business model*") AND (Telemedicine OR Telenursing OR telehealth OR "digital health" OR ehealth) AND (challenge OR limitations factor OR barriers). The total number of studies from both searches was 17,700. After applying the inclusion and exclusion criteria and more specific limitations, see Table 2, this number narrowed down to 1290 studies. Ultimately, 0 articles were selected for analysis in the final study. The reason for this was that the articles in the database were the same as in the previous databases.

Finally, a manual search was conducted with similar criteria from the databases provided by Savonia UAS. One article was selected for analysis in the study. The total number of studies included in the final literature review amounted to 17. Detailed information about the included articles can be found in Appendix 1.

Database	1st Search Round with Search Terms	2nd Search Round with Refined Criteria	3rd Search Round Based on Title and Abstract	Research Included in the Literature Review
PubMed	243+99= 342	76+20=96	44	10
ScienceDirect	863+1080= 1943	55+91= 146	56	6
Google Scholar	17700	1290	0	0
Manuaalisesti haettu	540	111	18	1

TABLE 2. Results of the Matrix Overview of Searches Conducted in Databases

5.3 Data analysis

The material selected based on literature searches can be analyzed in several ways. In this study, the materials were analyzed using thematic analysis. In thematic analysis, the material is combined by asking how the individual themes defined in different studies relate or whether the studies agree on the subject or have differing views (Vilkka 2023, 88).

The content analysis of the study was approached through inductive reasoning. Inductive reasoning is a process that starts from individual examples or cases and progresses towards more general conclusions. Here, observations and specific points are used to form broader generalizations. Induction

is based on the idea that something available can be deduced from detailed, separate observations. This is typical of data-driven research, where theories and hypotheses are built based on observations. (Kananen 2010, 40.)

The data in this study enabled a holistic approach to the research questions. Initially, the data was read through carefully several times. Preliminary notes were made from these readings, followed by the phase of grouping themes. The final results of the study were shaped after the refined thematization.

Original phrase	Simplified expression	Subcategory	Main category
1. "...the healthcare sector is regulated to address the challenges posed by the rapid digitalization process..."	Healthcare regulation responds to digitalization challenges	Regulation Challenges on DH	Legitimacy Challenges
2. "...The legislator had not foreseen the digital development, particularly not the opportunities that came from combining regulations aimed at resolving different healthcare challenges..."	Unforeseen digital opportunities in healthcare legislation	focus on legitimacy; states shape politics	
3. "...Legitimacy proved to be of central concern for the start-ups and their business formation processes..."	Legitimacy is key in start-up business formation		
4. "...states can normalise and legitimise their political choices, as well as marginalise certain voices..."	States validate politics, marginalizing some voices.		
5. "...new platform business models often face critical legitimacy challenges..."	Platforms struggle with legitimacy		

TABLE 3. Example of inductive content analysis about legitimacy challenges

6 RESULTS

When writing results and conclusions in a thesis, it is essential to present them in a clear and understandable way to the reader (Vilkkä 2021, 151). This chapter deals with the results of the study. The results have been grouped in the most logical order possible for the reader. As a result, the results are easier to follow.

6.1 Results of challenges in business models

Firstly, the results are presented in response to the research question: what unique challenges digital health companies face in their business models.

6.2 Legitimacy challenges in business models

The first challenge highlighted by the results is legitimacy and its associated challenges. Legitimacy, briefly defined, means legality or lawfulness. General legitimacy is defined as actions being socially desirable, appropriate, or purposeful (Bengtson, Morici & Lindholm 2022, 340). The second aspect discussed is sociopolitical legitimacy, where compliance with norms or laws is examined (Essen, Fri-shammar & Cenamor 2023, 3). Lastly, there is cognitive legitimacy, which assesses the general awareness of legitimacy in a broader context. Topics related to legitimacy can be found, from political issues to national questions on using artificial intelligence. (Tucker 2023, 1.)

Essen et al. (2023, 3) highlight legitimacy challenges that companies may face in their business operations. In the study, legitimacy challenges were found, for example, in complex technologies, which were seen as too challenging concerning their value. This is believed to affect stakeholders' perceptions of legitimacy particularly. Another point is that new companies entering the market must adapt their business models proactively to respond to legitimacy challenges. The study also concludes that a business model cannot be considered a unified whole.

Start-up companies strive to build legitimacy and gain approval during the entrepreneurship foundation process by presenting the opportunities and values created by digital technology. The study states that legitimacy challenges are found in service quality, policy, target group variation, complex regulations, and ethical issues. (Bengtson et al. 2022, 341-346.)

Tucker (2023, 1) highlights national strategies for artificial intelligence related to legitimacy in his research on the Nordic countries. They note that adopting AI is inevitable and that the private sector is driving this matter forward. This poses challenges for companies in adapting to the public sector, which has been considered a strong player in healthcare. This creates tensions, for example, in regulation, as the public and private sectors may operate according to different interests and objectives.

6.3 Challenges of performance evaluation

Information about digital healthcare interventions' economic and beneficial impacts is essential for demonstrating economic value and supporting decision-making in the field. The most suitable methods and data collection strategies must be selected for effective and reliable generalization. This ensures that the results obtained are comparable and applicable in different contexts. Information also

serves as the basis for business model design and optimizing payment systems in providing broader services. Suppose reliable evidence of the effects is not available. In that case, efficiency can be questioned by key decision-makers, which in turn can limit investments in digital health services and their long-term integration. Due to the diversity and extent of applications and services, it is impractical to conduct detailed economic evaluations. Instead, it is essential to generalize from some observations to understand how these applications and services impact the economy more broadly. (Bergmo 2015, 2-3)

Kelley et al. (2020, 2) identify a challenge faced by small and medium-sized enterprises (SMEs) in the digital healthcare sector: the lack of formal evaluation. These companies have limited resources and opportunities to conduct comprehensive evaluations, making integrating into healthcare systems difficult.

Lepore et al. (2023, 1) observed that analyzing and processing the acquired information is challenging. A significant challenge is converting large data streams into usable results. This is an aspect that digital healthcare companies must manage to be successful.

Ventura, Brovall & Smith (2022, 3) highlight the importance of a business plan for the sustainability and expansion of digital health innovation. The research emphasizes the complexity of complex health interventions, such as DHIs, and their evaluation and implementation challenges. It suggests that the perspectives of various stakeholders and end-users should be considered in the design and evaluation of DHIs. It is also necessary to consider how the complexity of DHIs affects their effectiveness assessment and implementation in the real world.

Chamberlain et al. (2021, 6) note that scaling digital healthcare interventions involves complexities in service pricing and effectiveness. There are also delays and desynchronization of funding flows in public sector procurement. Stahl et al. (2022, 5) also highlighted a challenge in the public healthcare reimbursement mechanisms for using digital services and patients' digital service competencies.

6.4 Financing and investments

Funding is a key challenge for digital healthcare platforms. Since these platforms often operate driven by a "social purpose," their scaling can be slower and less attractive to private investors. Owners and decision-makers of various platforms are encouraged to consider the impacts of the social purpose in financing and scaling. This is particularly important as it can affect a company's ability to acquire funding and thus impact its performance and sustainability. (Pundziene et al. 2023, 13-14.)

In their research, Alami et al. (2023, 2-4) introduce the "Wrong pocket" problem in digital healthcare. It describes a situation where one party bears the costs but does not reap the benefits, while another party gains the benefits but does not bear the costs. This can be particularly detrimental to small and medium-sized digital healthcare companies investing significantly to enter the market. This problem can add complexity to the business models of digital healthcare solutions. This can be especially challenging when healthcare organizations and public entities are involved in the same eco-system, and their goals may not align. This phenomenon primarily benefits larger organizations.

Funding, and its lack, is also seen as a significant challenge when a digital health company is trying to enter the market. Public funding, particularly, was seen as challenging to obtain to support market entry. (Kelley et al. 2020, 2-3.)

6.5 Cybersecurity and information security

Information security and cybersecurity emerge as a central challenge in a digitalizing world. The security of telemedicine systems is a significant challenge that requires interdisciplinary expertise and collaboration between medical and information security professionals. If a cyber attack were to occur, it could, at its worst, endanger human lives. The risk is particularly increased by using outsourced ICT personnel without the appropriate security training. (Kim et al. 2020, 8; Chakraborty et al. 2023, 3-5; Lepore et al. 2023, 3-8.)

Cybersecurity is considered one of the most critical factors in assessing a company's reliability. In addition, other technological infrastructure challenges, such as network connections, must also be considered. Protecting private and personal information is viewed as challenging. This means that companies must adhere to strict privacy laws and standards. (Kim et al. 2020, 8-9; Chakraborty et al. 2023, 3-5; Lepore et al. 2023 3-6.)

6.6 Results of success factors

This chapter presents the results in response to the research question, which asked what are the success factors of digital health companies' business models?

6.7 Scalability in digital health

Scalability was identified as one of the key success factors for companies. Several studies emphasized the importance of scalability as a condition for success in the digital health sector. Regarding scalability, many healthcare systems found it optimal to expand their virtual health services to meet increasing demand rapidly. Various service platforms can be quickly scaled to meet healthcare needs, regardless of how small these platforms originally were. Scalability is considered as important as, for example, financial viability. (Stahl et al. 2022, 3-5; Kelley et al. 2020, 2-4; Chakraborty et al. 2023, 2-5.)

In the current evolving healthcare environment, the development and scalability of virtual healthcare platforms are key operational prerequisites. The COVID-19 pandemic highlighted the significance of these platforms but also revealed their limitations. Globally, healthcare systems are re-assessing their platforms, processes, and strategies with a focus on scalability. This means the ability of platforms to grow and adapt to changing user numbers and needs. The goal is to create flexible, efficient, and scalable solutions that serve patient groups of varying sizes and adapt to changes in healthcare. Scalability is also important from a health equity perspective, ensuring that platforms are accessible and usable by all patients, leveling healthcare disparities. (Stahl et al. 2022, 3-5.)

Technology sector startups have become important players in the health industry, innovating it in many ways. With various technological innovations and increased demand for more personalized and efficient health services, these startups have carved out their own place in the Digital Health industry. They are small and may focus on specific market niches. At the same time, they have signifi-

cant potential to scale in different business environments. Startups are agile, but their failure rate is high, and only a few grow into significant success stories. Their importance is notable as they develop and bring to market complex medical inventions and strive to serve under-served markets by reducing healthcare costs and speeding up service delivery. (Chakraborty et al. 2023, 3-6.)

Scalability in developing and implementing digital health technologies requires structural and financial changes in public healthcare systems. For example, hospital payment systems are based on visit numbers and do not provide incentives to invest in technologies that improve patient care and reduce the number of visits. This limits technologies' scalability potential and ability to affect system-wide outcomes. (Kelley et al. 2020, 4.)

6.8 Business competence

The importance of companies' business expertise emerged next through the analysis of the literature review material. A company must understand the important aspects of its basic business operations in its business model, such as the cost structure of its products, financing, and production. In addition to basic business functions, companies in the digital health sector must also operate in complex environments. Clinical values, such as the effectiveness of the treatment received by the patient, were considered important. (Kelley et al. 2020 3-4; Chakraborty et al. 2023, 3-6; Velayti et al. 2023, 1.)

Velayati et al. (2022, 1) study deals with a multi-dimensional business framework. It emphasizes the importance of different components, both technical and non-technical, in business success. These include financial and organizational components. The study conducted a survey highlighting four main groups a company needs to consider. The critical success factors are cost structure, payments, production, and financing. The most significant components were financial value 52.4%, cost structure 64.3%, human resources 85.7%, traditional marketing 66.7%, and economical pricing 52.4%. The more these components are considered, the more likely the company will succeed.

6.9 The clinical value

Factors influencing a company's success are related to proving clinical value and navigating a complex regulatory environment. Success in publicly funded systems requires a systematic approach considering clinical and financial factors. (Chakraborty et al. 2023, 3-6; Kelley et al. 2020, 3-4.) For example, a company's products must effectively treat diseases, improve patients' quality of life, or enhance healthcare processes. The regulatory environment refers to compliance with various laws and regulations by healthcare companies. Stahl et al. (2022, 4-5) also state that measures of success include patient satisfaction, commitment of healthcare providers, and the use of virtual health solutions among healthcare providers.

6.10 Importance of business evaluation

Digital health (mHealth) companies should invest in evaluation and learning before scaling up their operations. This means that before companies expand their operations, it is beneficial for them to allocate resources to evaluate and learn from their products, services, and business models to gain

insight into how mature and ready their solutions are for broader implementation. (Chamberlain et al. 2021, 2.)

Business development can be monitored using various indicators. Revenue generation capacity, investment efficiency, and the price-quality ratio of services are adequate indicators of a successful business (Kelley et al. 2020, 3-4; Chakraborty et al. 2023, 3-6.)

6.11 Cooperation with partners

Collaboration between digital health service companies is a critical success factor (van Limburg et al. 2015, 1). It requires multi-disciplinary expertise, quick response to market changes, and navigating a complex regulatory environment (Lepore et al. 2023, 3). Through collaboration, companies can achieve more together, create innovative solutions, and improve the quality of patient care (Ventura et al. 2022, 8).

Understanding the operating environment and stakeholders is critical in business. Companies should be able to conduct stakeholder analyses, for instance, to develop their operations. This is a challenging task but necessary for development. This research is significant in the digital healthcare sector, where stakeholders can be intricately inter-connected. Furthermore, the study emphasizes the importance of value creation with stakeholders. Co-creation with stakeholders is essential for the success of a business model. Additionally, involving all stakeholders in the development process is crucial (van Limburg et al. 2015, 1-2.)

The experiences and observations of SMEs when they aim to build sustainable and expandable businesses within the confines of the public healthcare system are essential for developing deeper collaboration between the public and private sectors. (Kelley et al. 2020, 2-4.)

A Digital Health Innovation (DHI)'s business plan should be developed with healthcare services, regulatory bodies, and the industry. It also emphasizes the importance of multidisciplinary collaboration in successfully planning, evaluating, implementing, and maintaining DHIs. (Ventura et al. 2022, 8.)

Bengtson et al. (2022, 341-347) note that the exchange of resources between startups and established players in healthcare is crucial in establishing new digital businesses in the healthcare sector. Lepore et al. (2023, 9) also agree that it is essential for stakeholders to plan their activities to clarify coordination with other players carefully.

Khandelwal, Kolte & Rossi (2022, 529-534) state in their study related to India and its rural areas that partnerships between the public and private sectors can promote better healthcare service delivery. This would improve service availability, especially in rural and impoverished areas. Moreover, collaboration with large and small players enables faster and more cost-effective access to international markets instead of independent business growth.

6.12 Innovations drive business

Innovations also affect the success of companies. The importance of innovations as success factors in business operations is repeated in several pieces of literature selected for the literature review.

They play a central role in bringing new solutions to healthcare challenges. Various novel inventions that shake up the industry's norms and practices can significantly increase a company's chances of success. (Sterling & LeRouge 2019, 2-6.)

Digital healthcare innovations are primarily driven by small and medium-sized enterprises (SMEs) that employ less than 500 people. These companies design digital technologies aimed at solving clinical and administrative challenges. They aim to offer these technologies to healthcare organizations, both public and private healthcare financiers, and directly to consumers in Canada and on international markets. (Kelley et al. 2020, 2-4.)

6.13 Disruptive technologies in business models

In individual business sectors, On-demand telemedicine is on the rise as part of the broader development of digital healthcare. Several success factors underpin this development, making these services attractive to consumers and healthcare organizations. Three key factors stand out: service affordability, easy accessibility, and customer orientation. These factors are often considered the strengths of on-demand telemedicine compared to traditional healthcare services. Moreover, on-demand telemedicine is partly seen as a disruptive technology that can revolutionize traditional healthcare delivery models. Such technology can disrupt old practices, replace outdated products or services, and create new markets. This reflects how digital healthcare challenges old structures and creates new opportunities in healthcare. New business models focusing on these 'disruptive' elements can gain a significant competitive advantage. (Sterling et al. 2019, 2-6.)

Disruptive technologies have improved accessibility and affordability in other sectors, the same cannot be said for the healthcare service sector. This is due to the misalignment between innovation in disruptive technologies and business models. Traditional healthcare institutions are a complex mix of several business models, which requires a renewal of business models. Disruptive technology success is closely linked to its business model. The business model provides an organization with a framework to create and capture value from disruption. Business models can generally be classified into three archetypes: solution shops, value-adding processes, and facilitated user networks. This can be extremely valuable for companies in the digital healthcare sector, especially when trying to understand which business models are most effective with disruptive technologies like telemedicine. It provides insight into how business models and strategies can be designed to leverage best the opportunities offered by disruptive technology. (Sterling et al. 2019, 2-6.)

7 DISCUSSION

This study examined the challenges and success factors in companies' business models. The first research question was: what unique challenges do digital health companies face in their business models? The second research question sought answers: what are the success factors of digital health companies' business models? The literature review's selected material consists of studies that best fit the search criteria. In terms of results, both challenges and success factors were found.

7.1 Challenges in business models

The challenges first raised are those related to legitimacy. Legitimacy challenges were found in technologies, using artificial intelligence between public and private actors, and changing business models. (Bengtson et al. 2022, 341-346; Tucker 2023, 1; Essen et al. 2023, 3.) This is also evident in the back-ground theory. It is noted that healthcare sector actors are increasingly focusing on complying with regulatory requirements and improving quality, leading to minor adjustments in existing processes, as Bhattacharyya et al. (2022, 2) suggest. In Osterwalder's Business Model Canvas (BMC), legitimacy challenges can be seen in connection with the value proposition, for instance, by improving the usability of products for different user groups. Another aspect where legitimacy can be seen is the transparency of the cost structure, which is important to customers. (Osterwalder et al. 2010, 25.) Notably, legitimacy was not easily found in the background theory based on previous studies. Could this be due to the complex definition of the concept and its various meanings?

Next, the results highlight the challenges of operational effectiveness and evaluation. Bergmo (2015, 2-3) emphasize that collecting information on digital health services' economic and beneficial impacts is essential for decision-making and business model design. Kelley et al. (2020, 3-4) note that small and medium-sized enterprises face challenges in evaluation and integration into healthcare systems. Lepore et al. (2023, 3-7) stress the importance of analyzing and utilizing large data volumes for the success of digital healthcare companies. Ventura et al. (2022, 6) emphasize the complexity of implementing and evaluating digital health interventions (DHIs) and the importance of considering the perspectives of various stakeholders and end-users in design and evaluation. In the background research, only Favoretto et al. (2022, 749) state that redefinition is necessary in organizations' business models. Therefore, this part leaves a gap that our research partly addresses.

Challenges in financing and investment emerged in the study results. According to Pundziene et al. (2023, 13-14), a significant challenge for digital healthcare platforms is obtaining funding, which, for instance, may reduce attractiveness to investors. Alami et al. (2023, 2-4) present the "Wrong pocket" problem, where costs and benefits are unevenly distributed, complicating the development of smaller companies' business. Kelley et al. (2020, 2-4) emphasize that obtaining public funding is challenging for digital health companies trying to enter the market. In previously published research, Oderanti et al. (2021, 2-3) discuss challenges regarding financing. Their study states that companies face challenges in achieving large-scale economic sustainability and often depend on additional income. Osterwalder et al. (2010, 30-34) discuss the importance of revenue streams and key resources, especially financing, including all assets that can be converted into cash.

The final result was the challenges of telemedicine security are raised. The results emphasize the importance of carefully evaluating the information security of telemedicine systems and the risks of cyber-attacks. This includes assessments of operator reliability and customer privacy. (Kim et al. 2020, 8-9; Chakraborty et al. 2023, 3-5; Lepore et al. 2023, 3-6.) The findings of this study align with previous research. Mohammad et al. (2023, 1024-1029) have investigated the challenges of artificial intelligence and especially noted the importance of strict compliance with GDPR and privacy protection. In addition, integrating AI into healthcare systems often poses challenges, according to the study. Silva et al. (2020,1) state that distributed denial-of-service attacks (DDoS) are among the most destructive virtual attacks. Osterwalder (2010, 24-25) identifies risk management as one way of value proposition, creating value for the customer by reducing or managing risks.

7.2 Success factors in business models

This section presents the study's key findings on the success factors of digital healthcare business models. The first success factor to emerge in the results was scalability and its successful management, deemed significant for success in digital health business models. The scalability of various platforms was seen as playing an important role in companies' business models. Scalability was also evaluated from the perspective of equalization. (Stahl et al. 2022 3-6) Chakraborty et al. (2023, 3-5) high-lighted the importance of small, start-up-type companies in scalable markets. Kelley et al. (2020, 2-4) emphasized the agility of public health actors in leveraging companies' full scaling potential. Scalability has also been studied previously. Fürstenau et al. (2021, 822) found that scalability improved professional coordination. Huhtala et al. (2019, 56) emphasized a company's scalability when entering new markets. In Osterwalder et al. (2010)'s Business Model Canvas, scalability is not directly mentioned, but it is included in the value proposition, customer relationships, key activities, and revenue streams. These elements can help a company better design its business models.

Business expertise was emphasized as a success factor. Understanding fundamental business areas, such as product cost structure, finance, and production, is crucial. Digital health companies must operate in complex environments and consider clinical values, such as the effectiveness of patient care. (Kelley et al. 2020, 2-4; Chakraborty et al. 2023, 3-6; Velayti et al. 2023,1) 's re-search high-lights the importance of a multidimensional business approach, where both technical and non-technical components are important. The study identifies critical success factors as financial value, cost structure, human resources, traditional marketing, and economic pricing. Osterwalder et al. (2010, 33-34) also mention that the basic idea of business is to minimize costs. Regarding human resources, they are part of a company's key resources. In section 6, image 1, Osterwalder's BMC also recognizes the rest of the success factors in the results. Oderanti et al. (2021, 10) highlight the management of finances like successful university spinouts. Achieving a triumphant return on investment (ROI) within a specific timeframe and engaging investors during funding rounds were seen as guarantors of success.

Next, clinical value emerged in the results. Clinical value refers to the concrete value produced for the customer. A company's success is affected by its ability to prove clinical value. Success in systems requires considering both clinical and economic factors. (Chakraborty et al. 2023, 3-6; Kelley et al. 2020, 2-4). Also, Stahl et al. (2022, 3-5) state that patient satisfaction, healthcare providers'

commitment, and virtual health solutions' use among healthcare providers are considered measures of success. In Osterwalder et al. 2010's BMC, this theme can be addressed from value proposition to cost structure, Figure 1. Fürstenau et al. (2021, 823-824.) state that effective coordination, quality management, and direct patient involvement enhance clinical value. Antonio et al. (2020, 2) recommends re-evaluating business models in patient care.

Based on the results, a company's own business must be able to be evaluated. Companies should focus on investing in evaluation and learning before scaling their operations. (Chamberlain et al. 2021, 6) Development can be assessed and monitored with various indicators. Business development can be monitored with several indicators (Chakraborty et al. 2023, 3-6; Kelley et al. 2020, 2-4). For evaluation, a company can utilize Osterwalder and Pigneur's business model canvas. Velayti et al. (2022,1) suggest whether a universal model specific to the digital health field can be developed, incorporating elements of traditional and modern business models.

The findings in the literature review's analysis were obtained under the theme of cooperation. (Lepore et al. 2023, 3-6). In the results, inter-company cooperation was perceived as a critical success factor. Through cooperation, companies can achieve more together, create innovative solutions, and improve the quality of patient care (Ventura et al.2022, 8). (van Limburg et al. 2015,1; Kelley et al. 2020, 2-4.) emphasizes developing deeper cooperation between the public and private sectors. Bengtson et al. (2022, 341-347) state that the exchange of resources between start-up companies and established healthcare actors is crucial in the establishment process of new digital businesses in healthcare. Khandelwal et al. (2022, 529-534) state that partnerships between the public and private sectors can promote better healthcare service delivery. Clearly, cooperation is perceived as a significant success factor. The result did not surprise the researcher. According to previous research, the results corresponded to prior studies. Based on previous research, for instance, Oderanti et al. (2021,8) highlight effective cooperation. Cooperation is necessary for achieving growth and sustainability. Additionally, Belfiore et al. (2022, 3-5) recommend intensifying collaboration between industry and academic circles. (Osterwalder et al. 2010, 38.) in the Business Model Canvas states that partnerships form the cornerstones of business, optimizing business models and reducing risks.

Innovations also affect the success of companies. The importance of innovations as success factors in business is justified. They play a central role in bringing new solutions to healthcare challenges. Various new inventions that shake up the field's norms and practices can significantly increase a company's chances of success. (Sterling et al. 2019, 2-6.) Innovations in digital healthcare occur in small and medium-sized enterprises (Kelley et al. 2020, 2-4). Osterwalder et al. (2010, 36-37) mention that problem-solving often involves inventing new solutions. This is found in FIGURE 1, section 7 Key Activities. The results align with the previous theory. Oderanti et al. (2021, 2) state that value creation often occurs through various business model innovations. Garcia-Perez et al. (2017) state in their study that it is necessary to develop and apply business. Bhattacharyya et al. (2022, 2) mention innovation centers, where significant innovations for various needs are hoped to emerge. Huhtala et al. (2019, 56) state that with technological advancements, all business areas have undergone revolutions.

Lastly, the results highlight "disruptive technologies" in the market. This refers to On-Demand telemedicine, or digital remote service, which enables quick access to healthcare professionals and services. According to Sterling et al. (2019, 2-6), success is based on the service's affordability, easy availability, and customer-centricity. It is considered to revolutionize traditional healthcare delivery models. It will shake up old practices, replace products and services, and create entirely new markets. In Osterwalder (2010)'s business model, these disruptive technologies are the same as innovations. Practically, it encompasses the entire business model in FIGURE 1. In their previous study, Fürstenau et al. (2021, 822) discuss multipurpose platforms (MSP) and their scalability to various environments. Koponen (2019, 117) states that a functioning platform economy requires a revenue model, revenue streams, and necessary operations. Bhattacharyya et al. (2022, 2) state that new technologies' ability to challenge prevailing service models is concrete.

7.3 Ethical evaluation of the study

In this section, the ethics of the research are evaluated. In the literature review, the principles of good scientific practice ethically guide the foundations of scientific research (Vilkka 2023, 99). The European Code of Conduct for Research Integrity has recently updated its guidelines on basic ethical research practices. Good research practices are based on the fundamental principles of research integrity, guiding individuals, institutions, and organizations in their research work and addressing practical, ethical, and intellectual challenges. These principles include:

1. Reliability: Ensuring the quality of research in planning, methodology, analysis, and resource use (ALLEA 2023, 6). The reliability of this study has been ensured by careful design. The research plan was clear and coherent and was discussed with the supervising teachers in spring 2023.

2. Respect: Respecting colleagues, researchers, research personnel, society, ecosystems, cultural heritage, and the environment (ALLEA 2023, 6). In this study, the principle of respect was adhered to by appropriately referencing research studies. Similarly, ethical principles were followed through transparency and responsibility.

3. Honesty: Developing, implementing, evaluating, reporting, and communicating research transparently, fairly, completely, and impartially (ALLEA 2023, 6). The researcher has aimed for transparency, particularly regarding the data and results. The reporting of the study has been carried out with an effort to include all essential information. In the research work, an effort has been made to remain impartial and avoid biases and distortions.

4. Accountability: Responsibility for research from concept to publication, its management and organization, training, supervision, mentoring, and its societal impacts (ALLEA 2023, 6). In this research, responsibility is implemented comprehensively, committing to high ethical standards throughout the entire study.

In the literature review, several challenging procedures, such as permit applications or issues related to the handling of personal data, do not burden the research process. The research was carried out during the summer and winter of 2023. This ensured that there was sufficient time for conducting the research. The first version of the research plan was completed at the end of spring 2023. It was recorded in the electronic thesis project guidance and management system Wihi at the same

time. The research does not have a separate commissioner outside the educational institution, but it is commissioned by Savonia University of Applied Sciences (UAS). This study has received guidance from two teachers at Savonia. The teachers are from the degree program. Information retrieval has used the help of Savonia's information specialist. With the help of the information specialist, the correct search criteria for article retrieval have been defined. Transparency in the research has been sought to ensure throughout the entire content to make ethical evaluation easier.

7.4 Quality assessment of study

This literature review aimed to identify success factors and challenges in the business models of digital health companies. Sources for the research were found in international publications and databases in the field. Other publications, such as books, guides, and instructions, have also been included. The material is based solely on written and printed text. For instance, podcasts or video material, which could have diversified the sources of background theories, were not included.

The range of articles contributing to the background theory was broad. Especially Osterwalder's business model in itself almost assembled the necessary framework. It remained for the researcher to consider whether the topic could have been more precisely defined. With a tightly defined topic and research question, it is possible to define key concepts and perspectives accurately (Vilkka 2023, 44).

At the heart of the literature review's evaluation is how the material was selected and how valuable and significant the original studies are concerning the research question (Vilkka 2023, 104). The search process, which was not easy, added complexity to the research. The criteria for selecting the material for this study can be seen in TABLE 1. (Inclusion and exclusion criteria table) and TABLE 2. (Overview matrix results of searches in databases.)

The results of the study were as expected. The researcher was left to wonder whether the results might be due to the broad formulation of the research questions. Could the results be different with a different research method? Could another research method have been needed in addition to the literature review? Alternatively, a survey could have been used here to obtain the results. Could this have possibly changed the direction or even the purpose of the study? How can cultural aspects be taken into account in the results? Angerer, Stahl, Krasniqi & Banning (2022, 1) state that there is still much to be researched in digital healthcare, especially from the perspectives of management and daily operations. The environment of digital healthcare is dynamic. It is both a challenge and an opportunity for companies, as van Limburg et al. (2015, 2) note.

8 CONCLUSION

This narrative literature review has deepened our understanding of the unique challenges and success factors in the business models of digital healthcare companies. The research questions were: What unique challenges do digital health companies face in their business models? What are the success factors of digital health companies' business models? A total of 17 search results were obtained for closer examination.

From the results, we can conclude that digital healthcare companies face significant unique challenges, such as legitimacy, financing, investment, performance evaluation, and cybersecurity. In response to the second question, the importance of collaboration, scalability, market-changing innovations, clinical value, business acumen, and operations self-assessment emerged as success factors.

The study's findings highlight that the digital healthcare sector constantly changes, and companies must adapt quickly to changing conditions. This requires flexibility in business models and the ability to innovate and implement new technologies.

The 9-step Osterwalder business model introduced at the beginning of the study underlies several business models. It helps explain both challenges and success factors. It serves as a background theory and aids in understanding the study's results.

During the research, it was observed that the results corresponded to previously presented theories. The only exceptions were gaps in research regarding legitimacy and effectiveness evaluation, where there was very little background theory for comparison.

In the researcher's view, future attention should be paid to the scalability of digital healthcare platforms and their ability to meet growing needs efficiently. This conclusion is based on the results regarding success factors and disruptive technologies. Additionally, based on the results, it is important to consider ethical and societal aspects, such as patient privacy and information security, which are central to companies' reputation and trustworthiness.

This research can benefit professionals interested in the digital health sector from a business perspective and students in the field. It provides readers with a broad spectrum of business visibility. The rapid development of the digital health sector requires us to understand how the market operates in this field.

This study has provided valuable information for developing business models in digital healthcare. There is a great need for further research in digital healthcare. Based on the results, further research might be necessary, particularly concerning small and medium-sized digital health companies. Such research can better understand how these companies can overcome challenges and leverage success factors in developing their business. In light of the results, companies of this size are the most scalable and innovative actors that can contribute to the sector's development.

REFERENCES

- ALLEA (2023) The European Code of Conduct for Research Integrity – Revised Edition 2023. Berlin. <https://allea.org/wp-content/uploads/2023/06/European-Code-of-Conduct-Revised-Edition-2023.pdf> Accessed 18.11.2023.
- Alami, H., Shaw, S. E., Fortin, J. P., Savoldelli, M., Fleet, R., & Têtu, B. (2023). The 'wrong pocket' problem as a barrier to the integration of telehealth in health organisations and systems. *Digital health*, 9, 20552076231169835. <https://doi-org.ezproxy.savonia.fi/10.1177/20552076231169835> Accessed 31.8.2023.
- Angerer, A., Stahl, J., Krasniqi, E., & Banning, S. (2022). The Management Perspective in Digital Health Literature: Systematic Review. *JMIR mHealth and uHealth*, 10(11), e37624. <https://doi-org.ezproxy.savonia.fi/10.2196/37624> Accessed 9.9.2023.
- Antonio, M. G., Petrovskaya, O., & Lau, F. (2020). The State of Evidence in Patient Portals: Umbrella Review. *Journal of medical Internet research*, 22(11), e23851. <https://doi-org.ezproxy.savonia.fi/10.2196/23851> Accessed 31.8.2023.
- Belfiore, A., Cuccurullo, C., & Aria, M. (2022). IoT in healthcare: A scientometric analysis. *Technological Forecasting and Social Change*, 184, 122001. <https://doi.org/10.1016/j.techfore.2022.122001> Accessed 1.9.2023.
- Bengtson, A., Casales Morici, B., & Lindholm, C. (2022). Becoming a public sector insider - A case study of Swedish digital healthcare start-ups' entrepreneurial business formation processes. *Industrial Marketing Management*, 105, 340-350. <https://doi.org/10.1016/j.indmarman.2022.06.013> Accessed 1.9.2023.
- Bergmo T. S. (2015). How to Measure Costs and Benefits of eHealth Interventions: An Overview of Methods and Frameworks. *Journal of medical Internet research*, 17(11), e254. <https://doi-org.ezproxy.savonia.fi/10.2196/jmir.4521> Accessed 15.8.2023.
- Bhattacharyya, O., Shapiro, J., & Schneider, E. C. (2022). Innovation Centers in Health Care Delivery Systems: Structures for Success. *Journal of medical Internet research*, 24(2), e33961. <https://doi-org.ezproxy.savonia.fi/10.2196/33961> Accessed 28.8.2023.
- Chakraborty, I., Ilavarasan, P. V., & Edirippulige, S. (2023). Critical success factors of startups in the e-health domain. *Health Policy and Technology*, 12(3), 100773. <https://doi.org/10.1016/j.hlpt.2023.100773> Accessed 28.8.2023.
- Chamberlain, S., Dutt, P., Godfrey, A., Mitra, R., LeFevre, A. E., Scott, K., Mendiratta, J., Chauhan, V., & Arora, S. (2021). Ten lessons learnt: scaling and transitioning one of the largest mobile health communication programmes in the world to a national government. *BMJ global health*, 6(Suppl 5), e005341. <https://doi-org.ezproxy.savonia.fi/10.1136/bmjgh-2021-005341> Accessed 28.8.2023.
- Chesbrough, H. (2007), "Business model innovation: it's not just about technology anymore", *Strategy & Leadership*, Vol. 35 No. 6, pp. 12-17. <https://doi-org.ezproxy.savonia.fi/10.1108/10878570710833714> Accessed 21.8.2023
- Elsevier (2023). Science direct. Internet page. <https://www.elsevier.com/solutions/sciencedirect> Accessed 1.9.2023.
- Essen, A., Frishammar, J., & Cenamor, J. (2023). Entering non-platformized sectors: The Co-evolution of legitimacy debates and platform business models in digital health care. *Technovation*, 121, 102597. <https://doi.org/10.1016/j.technovation.2022.102597> Accessed 1.9.2023.
- Favoretto, C., Glauco Henrique de, S. M., Moacir, G. F., Maicon Gouvea, d. O., & Gilberto Miller Devós Ganga. (2022). Digital transformation of business model in manufacturing companies: Challenges and research agenda. *The Journal of Business & Industrial Marketing*, 37(4), 748-767. [doi:https://doi.org/10.1108/JBIM-10-2020-0477](https://doi.org/10.1108/JBIM-10-2020-0477) Accessed 4.9.2023.
- FDA. U.S. Food & Drug administration (2020). What is Digital Health? Internet page. <https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health> Accessed 15.7.2023.

- Fürstenau, D., Klein, S., Aryn, V., & Carolin, A. (2021). Multi-sided platform and data-driven care research. *Electronic Markets*, 31(4), 811-828. doi:<https://doi.org/10.1007/s12525-021-00461-8> Accessed 20.8.2023.
- Garcia-Perez, C., Diaz-Zayas, A., Rios, A., Merino, P., Katsalis, K., Chang, C.-Y., Shariat, S., Nikaiein, N., Rodriguez, P., & Morris, D. (2017). Improving the efficiency and reliability of wearable based mobile eHealth applications. *Pervasive and Mobile Computing*, 40, 674-691. <https://doi.org/10.1016/j.pmcj.2017.06.021> Accessed 1.9.2023.
- Gomes, J. F., Kemppainen, L., Pikkarainen, M., Koivumäki, T., & Ahokangas, P. (2019). Ecosystemic business model scenarios for connected health. *Journal of Business Models*, 7(4), 27-33. Retrieved from <https://www.proquest.com/scholarly-journals/ecosystemic-business-model-scenarios-connected/docview/2407766206/se-2> Accessed 4.9.2023.
- Google Scholar (2023). Stand on the shoulders of giants. Internet page. <https://scholar.google.com/intl/en/scholar/about.html> Accessed 1.9.2023.
- Grustam, A. S., Vrijhoef, H., Cordella, A., Koymans, R., & Severens, J. L. (2017). Care coordination in a business-to-business and a business-to-consumer model for telemonitoring patients with chronic diseases. *International journal of care coordination*, 20(4), 135-147. <https://doi-org.ezproxy.savonia.fi/10.1177/2053434517747908> Accessed 31.8.2023.
- Hesso, J. (2015). Hyvä liiketoimintasuunnitelma. Kauppakamari.
- Huhtala, T., Pikkarainen, M., & Saraniemi, S. (2019). Exploring potential changes in the business model: The impacts of using human-centered personal data as A resource. *Journal of Business Models*, 7(2), 53-63. Retrieved from <https://www.proquest.com/scholarly-journals/exploring-potential-changes-business-model/docview/2407765783/se-2> Accessed 02.09.2023.
- Hänti, S. (2021). Asiakkaista ansaintaan: Asiakaskeskeinen liiketoimintamalli. Alma Talent.
- Johansson, K., Axelin, A., Stolt, M., & Ääri, R-L. (2007). Systemaattinen kirjallisuuskatsaus ja sen tekeminen. Turun yliopisto.
- Järvinen, M., & Kari, M. (2017). Yritä, erehdy, onnistu: Helppo opas yrittäjyyteen. Kustannusosakeyhtiö Otava.
- Kananen, J. (2010). Opinnäytetyön kirjoittamisen käytännön opas. Jyväskylän ammattikorkeakoulun julkaisuja-sarja. Tampereen Yliopistopaino Oy-Juvenes print.
- Kelley, L. T., Fujioka, J., Liang, K., Cooper, M., Jamieson, T., & Desveaux, L. (2020). Barriers to Creating Scalable Business Models for Digital Health Innovation in Public Systems: Qualitative Case Study. *JMIR public health and surveillance*, 6(4), e20579. <https://doi-org.ezproxy.savonia.fi/10.2196/20579> Accessed 31.8.2023.
- Khandelwal, R., Kolte, A., & Rossi, M. (2022). A study on entrepreneurial opportunities in digital health-care post-Covid-19 from the perspective of developing countries. *Foresight (Cambridge)*, 24(3/4), 527-544. doi:10.1108/FS-02-2021-0043 Accessed 31.8.2023.
- Kim, D. W., Choi, J. Y., & Han, K. H. (2020). Risk management-based security evaluation model for telemedicine systems. *BMC medical informatics and decision making*, 20(1), 106. <https://doi-org.ezproxy.savonia.fi/10.1186/s12911-020-01145-7> Accessed 8.9.2023.
- Koponen, J. (2019). Alustatalous ja uudet liiketoimintamallit: Kuinka muodonmuutos tehdään. Alma Talent.
- Kostoff R. N. & Schaller R. R., May (2002). Science and technology roadmaps, in *IEEE Transactions on Engineering Management*, vol. 48, no. 2, pp. 132-143, doi: 10.1109/17.922473. Accessed 18.08.2023.
- Lau, F., Bartle-Clar, J. A., & Bliss, G. (Eds.). (2019). Improving usability, safety and patient outcomes with health information technology: From research to practice. IOS Press, Incorporated. https://books.google.fi/books/about/Improving_Usability_Safety_and_Patient_O.html?id=MUp-swgEACAAJ&redir_esc=y Accessed 20.8.2023.
- Laya, A., Markendahl, J., & Lundberg, S. (2018). Network-centric business models for health, social care and wellbeing solutions in the internet of things. *Scandinavian Journal of Management*, 34(2), 103-116. <https://doi.org/10.1016/j.scaman.2018.02.004> Accessed 1.9.2023.

- Lepore, D., Dolui, K., Tomashchuk, O., Shim, H., Puri, C., Li, Y., Chen, N., & Spigarelli, F. (2023). Interdisciplinary research unlocking innovative solutions in healthcare. *Technovation*, 120, 102511. <https://doi.org/10.1016/j.technovation.2022.102511> Accessed 1.9.2023.
- Mohammad, M. A., Jesus, M., Davood, F. S., Alves, P., Aliakbar, H. B., & Hariri, F. (2023). Artificial intelligence ethics and challenges in healthcare applications: A comprehensive review in the context of the european GDPR mandate. *Machine Learning and Knowledge Extraction*, 5(3), 1023. doi:<https://doi.org/10.3390/make5030053> Accessed 9.9.2023.
- National Library of Medicine (2023). National Center for Biotechnology Information. PubMen Overview. <https://pubmed.ncbi.nlm.nih.gov/about/> Accessed 1.9.2023.
- Nosratabadi, S., Mosavi, A., Shamshirband, S., Zavadskas, E. K., Rakotonirainy, A., & Chau, K. W. (2019). Sustainable business models: A review. *Sustainability*, 11(6), 1663. <https://doi.org/10.3390/su11061663> Accessed 4.9.2023.
- Oderanti, F. O., Li, F., Cubric, M., & Shi, X. (2021). Business models for sustainable commercialisation of digital healthcare (eHealth) innovations for an increasingly ageing population. *Technological forecasting & social change*, 171, 120969. <https://doi.org/10.1016/j.techfore.2021.120969> Accessed 7.5.2023.
- Osterwalder, A., Pigneur, Y., & Clark, T. t. (2010). *Business model generation: A handbook for visionaries, game changers, and challengers*. Wiley.
- Presnal, K., Kilpatrick Brathwaite, C., Salo, M., & Brathwaite, C. K. (2021). *Big rich money: Miten tehdä yrittäjän unelmista kannattavaa liiketoimintaa*. Basam Books.
- Pundziene, A., Gerulaitiene, N., Bez, S. M., Georgescu, I., Mathieu, C., Carrabina-Bordoll, J., Rialp-Criado, J., Nieminen, H., Varri, A., Boethius, S., van Gils, M., Giménez-García, V., Narbón-Perpiñá, I., Prior-Jiménez, D., & Vilutiene, L. (2023). Value capture and embeddedness in social-purpose-driven ecosystems. A multiple-case study of European digital healthcare platforms. *Technovation*, 124, 102748. <https://doi.org/10.1016/j.technovation.2023.102748> Accessed 1.9.2023.
- Ramdani, B., Binsaif, A., & Boukrami, E. (2019). Business model innovation: A review and research agenda. *New England Journal of Entrepreneurship*, 22(2), 89-108,89A. doi:<https://doi.org/10.1108/NEJE-06-2019-0030> Accessed 9.9.2023.
- Saarelainen, E. (2013). *Kohti menestyvää liiketoimintamallia*. Suomen Liikekirjat.
- Savonia ammattikorkeakoulu (2023). *Tiedonhaun perusteet: Tiedonhaku*. Internet page. <https://libguides.savonia.fi/c.php?g=360558&p=2443743> Accessed 2.9.2023.
- Silva, F. S. D., Silva, E., Neto, E. P., Lemos, M., Neto, A. J. V., & Esposito, F. (2020). A Taxonomy of DDoS Attack Mitigation Approaches Featured by SDN Technologies in IoT Scenarios. *Sensors (Basel, Switzerland)*, 20(11), 3078. <https://doi-org.ezproxy.savonia.fi/10.3390/s20113078> Accessed 31.8.2023.
- Sivula, A., Aho, M., & Laukkanen, M. (2023). *Datasta liiketoimintaan: 10 tehokasta työkalua*. Alma Talent.
- Stahl, M., Cheung, J., Post, K., Valin, J. P., & Jacobs, I. (2022). Accelerating Virtual Health Implementation Following the COVID-19 Pandemic: Questionnaire Study. *JMIR formative research*, 6(5), e32819. <https://doi-org.ezproxy.savonia.fi/10.2196/32819> Accessed 3.9.2023.
- Statista Inc. (2023) *Digital Health – Worldwide*. Internet page. <https://www.statista.com/outlook/dmo/digital-health/worldwide> Accessed 24.9.2023.
- Sterling, R., & LeRouge, C. (2019). On-Demand Telemedicine as a Disruptive Health Technology: Qualitative Study Exploring Emerging Business Models and Strategies Among Early Adopter Organizations in the United States. *Journal of medical Internet research*, 21(11), e14304. <https://doi-org.ezproxy.savonia.fi/10.2196/14304> Accessed 23.08.2023.
- Stolt, M., Axelin, A., & Suhonen, R. (2016). *Kirjallisuuskatsaus hoitotieteessä (2. korjattu painos.)*. Turun yliopisto.

- Sujan M. (2018). Managing health IT risks: reflections and recommendations. *Journal of innovation in health informatics*, 25(1), 952. <https://doi-org.ezproxy.savonia.fi/10.14236/jhi.v25i1.952> Accessed 25.8.2023.
- Teknoliateollisuus (yhdistys) & Pulkkinen, M. (2005). *Liiketoimintamallit arvonluojina: Ketjut, pajat ja verkot*. Teknologiainfo Teknova.
- Tucker, J. (2023). The future vision(s) of AI health in the Nordics: Comparing the national AI strategies. *Futures*, 149, 103154. <https://doi.org/10.1016/j.futures.2023.103154> Accessed 25.2023.
- van der Burg, R., Ahaus, K., Wortmann, H., & Huitema, G. B. (2019). Investigating the on-demand service characteristics: An empirical study. *International journal of service industry management*, 30(6), 739-765. <https://doi.org/10.1108/JOSM-01-2019-0025> Accessed 28.8.2023.
- van Limburg, M., Wentzel, J., Sanderman, R., & van Gemert-Pijnen, L. (2015). Business Modeling to Implement an eHealth Portal for Infection Control: A Reflection on Co-Creation With Stakeholders. *JMIR research protocols*, 4(3), e104. <https://doi-org.ezproxy.savonia.fi/10.2196/resprot.4519> Accessed 23.8.2023.
- Velayati, F., Ayatollahi, H., Hemmat, M., & Dehghan, R. (2022). Telehealth Business Models and Their Components: Systematic Review. *Journal of medical Internet research*, 24(3), e33128. <https://doi-org.ezproxy.savonia.fi/10.2196/33128> Accessed 2.9.2023.
- Velayati, F., Ayatollahi, H., Hemmat, M., & Dehghan, R. (2022). The 4P telehealth business framework for Iran. *BMC medical informatics and decision making*, 22(1), 266. <https://doi-org.ezproxy.savonia.fi/10.1186/s12911-022-02011-4> 3.9.2023.
- Ventura, F., Brovall, M., & Smith, F. (2022). Beyond effectiveness evaluation: Contributing to the discussion on complexity of digital health interventions with examples from cancer care. *Frontiers in public health*, 10, 883315. <https://doi-org.ezproxy.savonia.fi/10.3389/fpubh.2022.883315> Accessed 3.9.2023.
- Vilkka, H. (2021). Näin onnistut opinnäytetyössä: Ratkaisut tutkimuksen umpikujiiin. PS-kustannus.
- Vilkka, H. (2023). Kirjallisuuskatsaus metodina, opinnäytetyön osana ja tekstilajina. Art House.
- Vähäkainu P, (2018). Digitaalinen terveys ja älykäs terveydenhuollon teknologia. Informaatioteknologian tiedekunnan julkaisuja No.43/2018. Jyväskylän yliopisto. Pdf-file. <https://www.jyu.fi/it/fi/tutkimus/julkaisut/tekes-raportteja/digitaalinen-terveys-ja-alykas-terveydenhuollon-teknologia.pdf> Accessed 16.7.2023.
- Wahyono, W. (2019). Business model innovation: A review and research agenda. *Journal of Indian Business Research*, 11(4), 348-369. doi:<https://doi.org/10.1108/JIBR-12-2017-0251> Accessed 01.09.2023.
- WHO, World Health Organization (2021). *Global strategy on digital health 2020-2025*. Geneva: World Health Organization; Licence: CC BY-NC-SA 3.0 IGO.. <https://apps.who.int/iris/bitstream/handle/10665/344249/9789240020924-eng.pdf> Accessed 01.09.2023.
- WHO, World Health Organization (2023). *Digital health*. Internet publication. https://www.who.int/europe/health-topics/digital-health#tab=tab_1 Accessed 15.07.2023.
- WHO, World Health Organization (2023). *Digital health. Overview*. Internet publication. https://www.who.int/health-topics/digital-health#tab=tab_1 Accessed 01.09.2023.

APPENDIX 1: TABLE OF RESEARCH

Author(s) and year of publication, database	Article/Study title	Research method	The purpose of the study/Objective	Research results related to the research questions/Findings
Bergmo 2015. PubMed	How to Measure Costs and Benefits of eHealth Interventions: An Overview of Methods and Frameworks	Economic evaluation method, cost-benefit analysis. Collected in two ways: alongside trials and observational studies, and from the existing literature	The purpose of the study is to enhance understanding and application in the field of economic evaluation in eHealth, offering various practical insights and guidance for professionals, decision-makers, and other stakeholders.	The challenge in digital healthcare is to effectively demonstrate the economic and beneficial effects of interventions, which is essential for investments and integration. Another challenge is to develop methods for generalizing and transferring outcomes.
Kelley et al. 2020. PubMed	Barriers to Creating Scalable Business Models for Digital Health Innovation in Public Systems: Qualitative Case Study	Case study	The aim of the study is to determine how healthcare systems can optimize their operations to promote the integration of digital health innovations produced by small and me-	The challenge is the lack of formal evaluation due to limited funding and the absence of clinical incentives. The key to success is seen in the collaboration between the public and private sectors, along with special financing

			diem-sized enterprises (SMEs).	
Velayati et al. 2022. Pubmed	The 4P telehealth business framework for Iran	Mixed methods	The study develops a new business model for telehealth services in Iran. Using a multi-method approach and expert panel evaluation, the model identifies key factors, such as the expertise of partners and required capital, that influence the commercialization and sustainability of telehealth services.	The study reveals the most critical success factors: cost structure, payments, production, and financing. The most important components identified were economic value, cost structure, human resources, traditional marketing, and financial pricing.
Stahl et al. 2022. Pubmed	Accelerating Virtual Health Implementation Following the COVID-19 Pandemic: Questionnaire Study	Questionnaire Study	The article discusses the impact of the COVID-19 pandemic on the adoption of virtual health in the United States. The study evaluates the strategies and	The study highlights challenges such as reimbursement mechanisms and patients' understanding of the service. Measures of success include scalability, patient satisfaction, healthcare providers' engagement,

			business models of large healthcare systems in virtual health.	and the utilization of virtual health solutions.
Kim et al. 2020. Pubmed	Risk management-based security evaluation model for telemedicine systems	on-site surveys	The study focuses on the security risks of telemedicine. It analyzes security threats and risks in seven service areas.	Cybersecurity and cyber attacks are a major challenge for digital health companies.
Alami et al. 2023. Pubmed	The 'wrong pocket' problem as a barrier to the integration of telehealth in health organisations and systems	Perspective analysis, qualitative research.	The study addresses a specific challenge related to the implementation and sustainability of telehealth services, known as the "wrong pocket" problem.	The "wrong pocket" problem in digital healthcare describes a situation where investments and benefits are unevenly distributed among different parties, creating challenges especially for small businesses.
Sterling, R., & LeRouge, C. (2019). Pubmed	On-Demand Telemedicine as a Disruptive Health Technology: Qualitative Study Exploring Emerging Business Models and Strategies Among Early Adopter Organizations in the United States	semistructured phone interviews	The study addresses the business models and strategies of on-demand telemedicine services from the perspective of virtual urgent	On-demand telemedicine (disruptive technologies) challenges old structures. Consumer-centricity and flexible, easily accessible services are key success factors that provide a competitive

			care clinics (VCCs).	advantage in the market.
van Limburg et al. (2015). Pubmed	Business Modeling to Implement an eHealth Portal for Infection Control: A Reflection on Co-Creation With Stakeholders	mixed methods	The study presents an approach to business modeling in the context of e-health, with a particular focus on the importance of stakeholder engagement in the development and implementation process.	The study emphasizes value creation and collaboration (co-creation) with stakeholders as crucial for the success of the business model. Involving stakeholders in the development processes is a key success factor.
Ventura et al. 2022. Pubmed	Beyond effectiveness evaluation: Contributing to the discussion on complexity of digital health interventions with examples from cancer care	Case study	The study addresses the challenges of complexity related to the development and testing of digital health interventions (DHI).	Business plans for digital health interventions (DHIs) should be developed in collaboration with healthcare, regulatory bodies, and industry, emphasizing the importance of interdisciplinary collaboration at all stages.
Chamberlain et al. 2021. Pubmed	Ten lessons learnt: scaling and transitioning one of the largest mobile health communication programmes in the	"Lessons learned" type.	The study focuses on scaling one of the world's largest mobile health programs in India.	Challenges in scaling digital healthcare interventions include the complexity and efficiency of pricing the service, as well as

	world to a national government			delays in public sector procurement and the lack of synchronization of financial flows.
Essen et al. 2023. Science Direct	Entering non-platformized sectors: The Co-evolution of legitimacy debates and platform business models in digital health care	Case study	The study addresses the development of digital healthcare platforms in Sweden between 2013 and 2020, focusing on legitimacy challenges.	In the study, legitimacy is examined from three perspectives, and it is concluded that digital health companies must adapt their business models to address the challenges of complex technologies and evolving norms to achieve legitimacy.
Chakraborty et al. 2023. Science Direct	Critical success factors of startups in the e-health domain	Interview research and thematic analysis	The study investigates healthcare technology startups that aim to improve healthcare accessibility, affordability, and quality through innovative solutions.	The success of a digital health company depends on its ability to demonstrate clinical value, navigate a complex regulatory environment, and consider financial factors such as profitability and scalability, as well as revenue-generating capacity and the price-quality ratio of its services.
Pundziene et al.2023.	Value capture and embeddedness in social-purpose-driven	Multi-case study	The study focuses on the value creation of digital	The financing and scaling of digital healthcare plat-

Science Direct	ecosystems. A multiple-case study of European digital healthcare platforms		healthcare platforms in the context of a socially driven ecosystem.	forms can be challenging, which may reduce their attractiveness to investors.
Bengtson et al. 2022. Science Direct	Becoming a public sector insider -A case study of Swedish digital healthcare startups' entrepreneurial business formation processes	Case Study	The study delves into the business formation processes of emerging companies in Sweden.	In the study, challenges related to legitimacy are identified in various areas for startup companies. Success factors include resource exchange between startup companies and established players in healthcare.
Lepore et al. 2023. Science Direct	Interdisciplinary research unlocking innovative solutions in healthcare	Action research	The study investigates the integration of Internet of Things (IoT) devices and machine learning (ML) into healthcare.	The study presents cybersecurity and data flow as challenges. The importance of stakeholder collaboration emerges as a success factor.
Tucker 2023. Science Direct	The future vision(s) of AI health in the Nordics: Comparing the national AI strategies.	Comparative case study	The study discusses the growing significance of artificial intelligence in healthcare and emphasizes that future visions are driven and	The study highlights legitimacy challenges related to the adoption of artificial intelligence in the Nordic countries, particularly from the perspective of differing interests and regulatory

			implemented by the private sector.	tensions between the public and private sectors.
Khandelwal et al. 2022. Emerald insight	A study on entrepreneurial opportunities in digital health-care post-Covid-19 from the perspective of developing countries	Archival research	The study addresses the challenges and opportunities of digital healthcare in both developing and developed countries in the context of the COVID-19 pandemic.	Collaboration with specialized actors promotes faster and more cost-effective access to international markets.