Challenges for Artificially Intelligent Medical Devices in the Nordics and Suggested Strategies to Respond

Linea Holström and Alva Rampe

DIVISION OF INNOVATION ENGINEERING | DEPARTMENT OF DESIGN SCIENCES
FACULTY OF ENGINEERING LTH | LUND UNIVERSITY
2023

MASTER THESIS

triathlon
triathlon group

Challenges for Artificially Intelligent Medical Devices in the Nordics and Suggested Strategies to Respond

A Cross-sectional Study of Challenges when Innovating within Artificially Intelligent Medical Devices and How Companies Can Respond

Linea Holström and Alva Rampe

LUND
UNIVERSITY

Challenges for Artificially Intelligent Medical Devices in the Nordics and Suggested Strategies to Respond

A cross-sectional study of Challenges when Innovating within Artificially Intelligent Medical Devices and How Companies Can Respond

Published by

Department of Design Sciences
Faculty of Engineering LTH, Lund University
P.O. Box 118, SE-221 00 Lund, Sweden

Subject: Innovation Engineering (INTM01),
Division: Innovation
Supervisor: Lars Bengtsson
Co-supervisor: Malin Pfister
Examiner: Kajsa Ahlgren Ode

Abstract

With aging populations, unequal access to care, and shortages of staff, healthcare systems today are facing many challenges. Technology advancements, with artificial intelligence (AI) in particular, have been one of the main drivers of innovation in multiple industries. Although the healthcare sector is moving slower compared to other industries, there is great potential for relieving healthcare workers and improving efficiency with advanced technology and AI. The AI healthcare market is expected to grow at a dramatic speed, and the interest of companies to venture into the field of artificially intelligent medical devices is large.

Although the interest and potential of artificially intelligent medical devices are substantial, there are multiple challenges companies face within the field. This thesis explores the largest challenges companies face and associated strategies companies can use when innovating artificially intelligent medical devices on the Nordic market. The questions are explored through a literary review and interviews with 30 actors from innovating companies, industry organizations, academia, and hospitals. Insights from all sources were compiled, analyzed, and accumulated into a framework with the most challenging areas and corresponding strategies to overcome them.

The identified strategies for successful innovation include strategic regulatory planning, clinical collaboration and evidence generation, agile market entry, and user-centric validation. Furthermore, having efficient data management and model optimization, business viability and reimbursement strategy, and agile development and scalability are noted as key success factors for an artificially intelligent medical device innovation.

Kew Words: Artificial Intelligence, Medical Device, HealthTech, Innovation Barriers

Sammanfattning

Med åldrande befolkningar, ojämn tillgång till vård och brist på personal står dagens sjukvårdssystem inför många utmaningar. Teknologiska framsteg, särskilt inom artificiell intelligens (AI), har varit en av de främsta drivkrafterna för innovation inom flera industrier. Även om hälso- och sjukvårdssektorn utvecklas långsammare jämfört med andra branscher, finns det stor potential att avlasta vårdpersonal och förbättra effektiviteten med avancerad teknik och AI. Marknaden för AI inom hälso- och sjukvården förväntas växa i dramatisk takt, och intresset från företag att satsa på området för artificiellt intelligenta medicintekniska produkter är stort.

Trots det stora intresset och potentialen för artificiellt intelligenta medicintekniska produkter står företag inför flera utmaningar inom området. Detta examensarbete utforskar de största utmaningarna företag möter, och de strategier som företag kan använda vid innovation inom artificiellt intelligenta medicintekniska produkter på den nordiska marknaden. Frågorna undersöks genom en litteraturgenomgång och intervjuer med 30 aktörer från utvecklande företag, branschorganisationer, akademin och sjukhus. Insikter från alla källor sammanställdes, analyserades och mynnade ut i ett ramverk med de mest utmanande områdena och motsvarande strategier för att övervinna dem.

De identifierade strategierna för framgångsrik innovation inkluderar strategisk regulatorisk planering, kliniskt samarbete och bevisframställning, agilt marknadsinträde och användarcentrerad validering. Dessutom noterades effektiv datahantering och modeloptimering, organisationens långsiktighet och ersättningsstrategi, samt smidig utveckling och skalbarhet som framgångsfaktorer för en artificiellt intelligent medicinteknisk innovation.

Nyckelord: Artificiell Intelligens, Medicinteknisk Produkt, Hälsoteknologi, Innovationsutmaningar

Acknowledgments

This Master's thesis was conducted at the Division of Innovation Engineering at Lund University by the Faculty of Engineering and in collaboration with Triathlon Group in Gothenburg. This project has been one of the final steps in completing our Master of Science in Industrial Engineering and Management.

However, this thesis would not have been possible without the support of both the Division of Innovation Engineering and Triathlon Group. We would therefore like to express our gratitude to our supervisors at both organizations. Firstly, we want to thank Malin Pfister, our supervisor at Triathlon Group, for your support and cooperation during the whole process. Also, a special thanks to all other colleagues at Triathlon who have contributed valuable feedback and input.

Secondly, we would like to express our gratitude to our university supervisor Lars Bengtsson for your guidance during all stages of the thesis. Your advice and support along the way have been invaluable.

Lastly, we sincerely want to thank all the actors that have participated in our interviews, for your time and contribution. We could not have done this without you.

Gothenburg, December 2023

Linea Holström and Alva Rampe

Table of contents

Abbreviations

AIMD	artificially intelligent medical device
AI	artificial intelligence
ML	machine learning
MDR	medical device regulation
NPL	natural language processing
QA	quality assurance
RA	regulatory affairs

Definitions

Artificially Intelligent Medical Device

The authors have considered the term Artificially Intelligent Medical Device to be similar to the definition of Machine Learning-enabled Medical Device. The only difference as the authors perceives the word is that an Artificially Intelligent Medical Device also can utilize other subsets of artificial intelligence, such as natural language processing. A machine learning-enabled medical device is a medical device that uses machine learning, in part or in whole, to achieve its intended medical purpose (International Medical Device Regulators Forum 2022). Thus, the authors define artificially intelligent medical devices as a medical device that uses artificial intelligence, in part or in whole, to achieve its intended medical purpose.

HealthTech

HealthTech, short for Health Technology, is defined as a product or service for better delivery, payment, and/or consumption of care (Pruciak 2021). The word HealthTech is often used to refer to prevention and monitoring of patients, rather than diagnostics and treatment, which is included in the term MedTech.

MedTech

The word MedTech, short for Medical Health, includes medical devices, technology used for diagnostics, digital health solutions, and telemedicine platforms (HealthNord n.a.). The purpose of medical technologies is to prevent, diagnose, monitor, treat or provide care for a disease, injury, or other condition (Medtech Europe n.a.)

Introduction

1.1 Background

Today's healthcare system faces major challenges with an aging population, unequal care, and a shortage of staff. Consequently, the waiting times to receive care have grown to record high numbers in many countries – the Nordics included. These trends call for action in the healthcare sector. Technology and digitalization have been the main drivers of change and innovation in most industries, although the healthcare sector is lagging (Stewart 2022).

Today, artificial intelligence (AI) and machine learning (ML) are some of the prime drivers of innovation within MedTech. Although the terms have received a lot of attention recently, not the least due to the introduction of ChatGPT in November 2022, AI in healthcare is not a new phenomenon. AI was coined in the 1950s and was first incorporated into medicine about ten years later (Kaul et al. 2020). The first FDA-approved AI medical device was certified in 1995, yet only 530 approvals had been issued in May 2023 (FDA 2023), as the limitations of the early models prevented any widespread adoption. First, in the early 2000s, many of these limitations were overcome by the start of deep learning, marking the end of the so-called "AI winter" (Kaul et al 2020).

Today the market of AI in healthcare is growing at a dramatic speed. In 2021, the worldwide AI healthcare market was worth about 11 billion USD and is expected to expand to a worth of almost 188 billion USD in 2030. This means an increase of 37 percent annually (Stewart 2022). Thus, there is a growing interest for medical device companies to leverage this potential and venture into the field of artificially intelligent devices.

Despite the mounting interest in AI in healthcare and its potential benefits, a comprehensive understanding of the specific challenges and strategies for implementing AI-driven medical devices in the Nordic context is absent. Kiseleva provided insights on the transparency and accountability aspects of AI in medical devices (Kiseleva 2020), and the regulatory implications of innovations within this field have been investigated by Niemiec et al (2022) among others. However, research on what challenges and related mitigation strategies companies can adopt to reach an efficient and successful innovation phase for artificially intelligent medical devices has not yet been widely investigated.

Innovation within the MedTech industry is nonetheless well needed to reach the global sustainable goal of good health and well-being for all set by the United Nations (United Nations 2022). Thus, the healthcare sector needs to follow other industries and utilize the potential new technology brings, with continued patient safety in focus. Artificial intelligence is already becoming an essential driver of this development. However, there is little research performed on this topic on how to innovate effectively in this field and reach the market with new medical devices. It is therefore interesting to investigate what the main challenges for innovation are for artificially intelligent medical devices and successful strategies to overcome these.

1.2 Problem Formulation

Despite the substantial potential for artificially intelligent medical devices (AIMD) to revolutionize the healthcare industry, there are many challenges to innovate successfully in this field. The market of medical devices in Europe is heavily regulated with time-consuming processes and a limited ability of data collection (Longworth 2023). Therefore, it is interesting to investigate the main reasons for the slow diffusion of innovation and identify strategies to speed up the adoption.

1.3 Triathlon Group

Triathlon Group is a professional service provider to companies and organizations within various industries, among these the HealthTech and MedTech industries. Triathlon has observed artificial intelligence enter the healthcare industry – bringing both challenges and opportunities. To better support clients with the development and commercialization of artificially intelligent medical devices (AIMDs), Triathlon has requested research on the most common challenges for innovation, and associated mitigation strategies.

1.4 Purpose and Research Questions

With consideration of the great potential and substantial challenges artificial intelligence brings to the field of medical devices, the purpose of this master thesis is to increase the knowledge concerning AIMD innovations from an innovating company's perspective. This includes what the largest challenges are for the innovations to succeed, and what associated strategies companies can use to overcome them. By increasing the knowledge within this area, companies

encountering challenges when innovating within AIMDs can leverage the research findings to navigate the innovation process more effectively.

This study aims to investigate the following research questions:

RQ1: What are the most common challenges for companies innovating and introducing artificially intelligent medical devices on the Nordic market?

RQ2: How do these challenges differ depending on

- Product type (image interpretation system, signal interpretation system remote monitoring system, radiology supporting system)
- Product risk class (according to EU MDR)
- Company size

RQ3: Which success factors strategies can be used to overcome the most common challenges?

1.5 Target Audience

The primary audience for this master thesis is stakeholders within the medical device industry in the Nordic countries as they can apply the findings directly to improve the effectiveness when innovating an AIMD. Furthermore, the conclusions made in this report may also apply to other markets beyond the Nordics, and can also be of use to researchers and students.

1.6 Delimitations

In the process of formulating the problem, multiple delimitations were made. Firstly, the scope is limited to Nordic innovating companies and challenges related to the Nordic market structures (Sweden, Norway, Denmark, Finland, and Iceland). However, no variances between the countries are included in the result as only small differences between the nations were observed in the research. Secondly, the medical devices of interest needed to have artificially intelligent features. Within the definitions of Artificial Intelligence, there are several interpretations, and for this thesis, the use of AI needed to be incorporated in the device as either machine

learning, natural language processing, or other systems that incorporate intelligent techniques beyond a set of if-then rules. This excludes the type of AI called rule-based expert systems. More details of the definition of artificial intelligence will be provided in Chapter *4.1 Definition of Artificial Intelligence*.

Further, the analysis takes the perspective of the innovating company's challenges. Other challenges apply to other stakeholders such as distributors and users of the device, and these are considered out of scope in this thesis.

The scope is additionally focused solely on challenges that only appear when artificial intelligence and medical devices are united, and general challenges for only artificially intelligent devices in general or challenges for only medical devices, in general, will be excluded. However, some of the identified challenges might also apply to artificially intelligent devices outside of healthcare practices, or to "unintelligent" medical devices. The targeted overlap is illustrated in Figure 1.1.

Figure 1.1. The scope of challenges investigated in this report is found in the overlap between medical devices and artificial intelligence, where the star in the figure is located.

1.7 Thesis Structure

Table 0.1 Summary of the chapter-by-chapter focus.

Chapter	*Focus*
1 Introduction	Introduces the reader to the relevant background and the problem formulation. Furthermore, the purpose, research questions, target audience, and thesis delimitations are also presented.
2 Methodology	Presents the design of the research, with chosen strategy, methods, and ethics. It also presents how the data collection was performed with a literature study and an interview study.
3 Healthcare in the Nordics	Outlines the supply and demand side of the Nordic healthcare system. This chapter also includes a comparison of the national organization structures, the concepts of medical technology, and applicable regulations.
4 Artificial Intelligence	Introduces the reader to definitions and implications of artificial intelligence, the various types of technologies and how these are being applied in healthcare.
5 Theory	The theory is divided into fundamental models and terms, and previous research. The first section involves definitions and terms of, for example innovation, diffusion, and crossing the valley of death. The second section explores challenges and success factors for artificially intelligent medical devices in previously performed research.
6 Results	The results from the interview study are presented. The first part presents a summary and further elaborations of the identified challenges and success factors. The second part provides a segmentation of challenges based on different attributes. Finally, a framework is presented that concludes the result.
7 Discussion	Firstly, findings are put in relation to literature in a gap analysis, where differences and similarities are emphasized. Secondly, the generalizability of findings is discussed from a Nordic- and European perspective.
8 Conclusion	Concluding results are presented and the research questions are answered briefly. Moreover, research liability and limitations are discussed, as well as future research suggestions.

2 Methodology

This chapter presents the research strategy and method used in this master's thesis, intending to give insight into the research process and explain why certain methods were selected. A seven-step process was used to guarantee the reliability of results.

2.1 Research Approach and Method Design

Research work is defined as a systematic investigation with the overall goal of developing or refining theories, as well as finding solutions to problems (Dresch, A. et al. 2015, pp 14-16). The need for research arises from missing adequate and systematized information to answer some given problems and motivation to conduct research can either arise from a theoretical gap or a practical demand. The latter is referred to as "applied research" and the purpose is for the results to be applied in practice and help professionals in their daily work. As the purpose of this master's thesis is to conclude findings that innovating companies can apply, the project purpose stems from a practical demand primary.

To carry out effective research work, there are certain procedures to follow to guarantee the reliability of results. Dresch et al. (2015) illustrate the methodology by adopting a pendulum including the following parts:

1. Reasons to conduct a study
2. Study's goal
3. Scientific methods
4. Research methods
5. Work methods
6. Techniques for gathering and analyzing data
7. Reliable results

This framework was applied when the structure of the master's thesis was planned and re-evaluated. The following sections go through these seven steps by elaborating on the theory behind the concepts, as well as how they were adopted in this thesis.

2.1.1 Reasons to Conduct a Study

The motives for conducting a study can be many, including having an interesting piece of information to share, having an answer to some important issue, or providing an in-depth understanding of some phenomenon (Dresch, A. et al. 2015, p.16).

The motivation for conducting this master's thesis was to increase the knowledge for effective innovation within the field of AIMDs. Thus, a combination of the reasons elaborated above, with an emphasis on providing an increased understanding of innovating with an AIMD.

2.1.2 Study's Goal

Dresch, A. et al. (2015, p.16) present four different types of research studies, and in this thesis, a descriptive and exploratory approach was used. Previous research and market structure characteristics were used to identify challenges and success factors for AIMD innovations in the Nordics, which is descriptive. Furthermore, a deeper understanding of challenges and success factors was gained through exploring the area in multiple interviews.

2.1.3 Scientific Methods

A scientific method can be either inductive, deductive, or hypothetical-deductive (Dresch, A. et al. 2015, p.16-19). The perspective is based on the premise of how knowledge is constructed. Inductive is based on observation and stems from the process of inferring an idea from previous discoveries or observations. A deductive method has laws and theories as a starting point to propose elements that may explain or predict some given phenomenon. Lastly, a hypothetical-deductive method is characterized by recognizing problems from previous knowledge and suggesting testing hypotheses that result in predictions and explanations.

In this master's thesis, the scientific method was mostly inductive, as knowledge was developed based on findings from interviews and literature, with limited pre-defined hypotheses and theories. Although some assumptions and hypotheses were developed in an early stage, each interview and data collection was based on open-ended questions – and not formulated to test assumed knowledge. However, as new and important areas emerged during the interviews, the literature review was updated to include these topics. Consequently, the method was partly also of a deductive character.

2.1.4 **Research Methods**

Multiple research methods can be used for different purposes depending on the research problem (Dresch, A. et al. 2015, p. 21). In this master's thesis, a cross-sectional study was used. Cross-sectional studies are observational, analyzing data from the same point in time, and this type is useful for establishing initial evidence for future more advanced research (Wang & Cheng 2020). Data was collected through multiple open-ended interviews to allow for elaboration of complex phenomena.

2.1.5 **Work Methods**

A work method describes the order of logical steps the researchers follow to reach the set goals (Dresch, A. et al. 2015, pp. 27-29). The method is based on the defined scientific method, which should be visible in the method design. In its nature, the research method is a methodological guideline.

In this project, the following steps within the work method (Figure 2.1) were used for planning and follow-up purposes. The steps were formed based on the chosen scientific model, as it evolves around inductive exploration of the concepts, challenges, and success factors of AIMDs. Thus, having data collection (interviews) at its core.

Figure 2.1. Research strategy for the master thesis.

2.1.6 **Techniques for Gathering and Analyzing Data**

Before selecting a technique for investigation, the data being sought must be carefully considered (Dresch et al. 2015, pp. 29-31). For data gathering, examples of techniques given by the authors are documentary, bibliographic, interviews, focus groups, questionnaires, and direct observations. For data analysis, the following techniques are stated by the authors: content analysis, discourse analysis, and multivariate statistics.

In this master's thesis, the primary data collection techniques were bibliographic (through a literature review) and interviews. This is further evaluated in the next chapter.

2.1.7 **Reliable Results**

As the reliability of research results depends on how the research was conducted, using scientific methods to come to reliable and objective findings is highly important – not the least for qualitative research. In this master's thesis, quality and trustworthiness were judged by the four criteria of credibility, transferability, dependency, and confirmability, which were introduced by Lincoln and Guba (1985).

Credibility relates to how representative and truthful the data and results of the study are (Korstjens and Moser 2017). The credibility of this thesis was ensured by conducting multiple interviews with companies, clinical users, industry experts, and academia to validate the findings. In addition, multiple interviews were held with actors from various perspectives to ensure rigorous and diverse data.

Transferability concerns the applicability and relevance of the results in other contexts or settings (Korstjens and Moser 2017). Through the cross-sectional study, multiple perspectives were utilized and considered. The aim was for the findings to be applied to more companies than the ones included in this study. The composition of participants and the context of the study are presented in this thesis (chapter *2.2.2 Interview study*) to enable further understanding and evaluation of how the results can be applied in other contexts. Furthermore, a segmented result analysis is presented to enable the reader to get an understanding of how their specific attributes might play out in terms of product type, risk classification, and company size.

Dependability of the research refers to the stability and reliability of research findings and that all recommendations are supported by the data received in the study (Korstjens and Moser 2017). This was achieved by thorough documentation of the methodology from the start and external feedback from supervisors during the full process.

Confirmability evolves from neutrality and interpretations are drawn from data (Korstjens and Moser 2017). A high confirmability would imply the findings of the research study should be confirmed by other researchers (ibid.). This was achieved in the thesis through continuous validation with supervisors – ensuring that findings are based on data from interviews and literature.

2.2 Research Methodology Overview

The research method was divided into two phases, firstly a literature review, and secondly an interview study. The first phase aimed to gather knowledge from previous studies within the field of artificial intelligence, healthcare innovation, and related topics, to draw conclusions on the research questions for this study. The second part of the study aimed to gain new knowledge from actors that work with artificially intelligent medical devices in different ways.

2.2.1 **Literature Review**

A literary study was performed to gain knowledge and understanding of the available theories within innovation, artificial intelligence, and other related concepts. Furthermore, existing research were studied within challenges and success factors for artificially intelligent medical devices.

The first step of the literary study was to review academic journals through the university search database, LubSearch, and through Google Scholar. Then, non-academic sources were used to complement the material. The relevant sources were collected in a spreadsheet, including a summary of the main topics, key takeaways, and a mark of relevance (low/medium/high). In the first stage, 25 academic papers and 12 non-academic articles were collected.

The search words used evolved around (but were not limited to):

- Introducing medical AI
- AI in Medtech
- AI AND medicine
- Health technology AND AI
- Medical technology AND AI
- Digital maturity healthcare

This database of relevant literature was used when developing the theory chapter of the thesis. Thereafter, literature was reviewed on an ongoing basis after the initial data-gathering and was added to the research paper by further searches through similar search words and by reviewing references of the sources.

2.2.2 **Interview Study**

The interview study aimed to understand the current challenges that companies and other stakeholders face when developing artificially intelligent medical devices. Furthermore, the interviews aimed to understand common strategies for overcoming innovation challenges and successfully introduce AIMD on the market.

The first phase of the interview study was to determine the relevant actors to contact, and the initial list constituted around 70 stakeholders. In this phase, the actors of interest were categorized into five groups: companies developing medical devices, industry organizations, academia, clinicians, and industry experts. The last four groups were decided to be relevant actors to interview as these actors might have observed challenges or success factors for the medical device companies, that the medical device companies are not aware of.

As a first step, relevant stakeholders were added to a stakeholder list with contact details (when known) and level of priority (low/medium/high) based on their potential contribution to the thesis questions. The stakeholders were found through personal connections, member lists of industry organizations, attendance lists of fairs/seminars, life science reports, LinkedIn, and, google searches. Some companies were also initially contacted through "info-emails" and contact forms on their websites. The actors were then contacted by phone (if available) and by email. The first email included an outline of the project and why the company/person in question was being contacted. After the initial dialogue, interviews were scheduled with the interested actors.

When the interviews were held, all actors were asked for recommendations on which actors should be contacted for further discussions, creating an additional source of contacts. This added to the stakeholder list, which grew to some 121 actors, where 58 stakeholders were contacted, and 30 interviews were held.

About half of the interviews were with developers of medical devices, see Figure 2.2. Some of the interviewed actors belonged to more than one category, for example, a clinical doctor who also conducts research. In these cases, the interview was sorted into the category in which the discussion focused most upon.

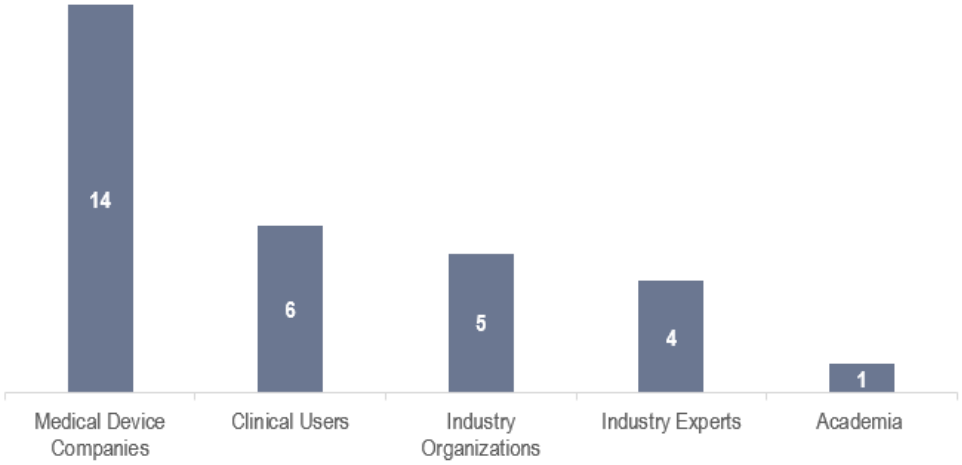

Figure 2.2. Number of interviewed actors per category.

Out of the medical device companies, 9 companies were considered small, while 5 were considered large. The company size was based on the number of employees, where companies with a total number of employees above 200 were considered large. Furthermore, the distribution of product type was fairly equal, whilst the risk class among the interviewed companies was mainly IIA or IIB. See Figure 2.3.

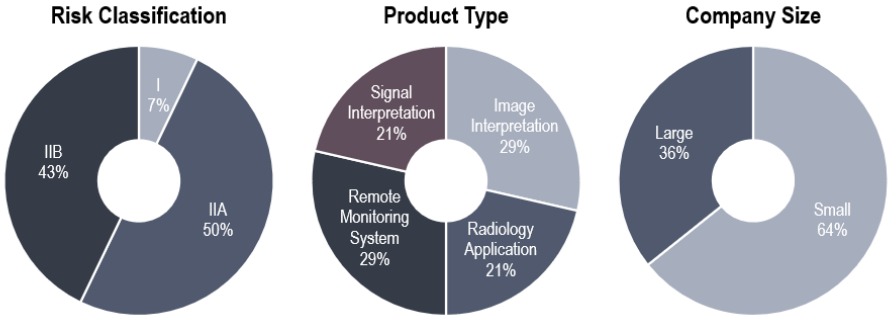

Figure 2.3. Distribution of risk classification based on EU MDR, product type, and company size out of the interviewed medical device companies.

A majority of interviews (24) were held on Zoom, while 6 were held in person. The questions asked were different depending on the perspective and background of the interviewee, to cover different perspectives, see Appendix A.

During the interviews, which typically lasted 30-60 minutes, the interviewees' answers were documented by both interviewers in separate Word documents. After the interview, the documents were crosschecked to ensure all important information was gathered before the challenges and success factors were extracted into an Excel file. Here it was also noted what type of product the company developed, what risk classification the device has, and the size of the company based on the number of employees. When all interviews were completed and all challenges and success factors were lined up in the Excel spreadsheet, the challenges and success factors were summarized with one or two words. Then similar wordings between the interviewees were grouped to form categories.

This allowed for identifying patterns in which challenges were brought up frequently. If common challenges or success factors were found, a category was decided for that challenge, to enable pattern identification. However, there were no pre-determined categories asked about explicitly, rather the categories were determined by the responses of the interviewees. This allowed the answers to be tailored to each actor's biggest challenges and avoided prejudice against previous findings or false hypotheses.

The categories of challenges were compared and grouped one step further into seven themes. These were the topics mentioned most frequently in interviews and became the structure of the Result chapter. Furthermore, the identified mitigation or success strategies were grouped and matched to the applicable themes of challenges. The challenges and mitigation strategies were not always mentioned in the same interview, as actors could portray one specific category as a challenge, while another actor proposed a solution for how to overcome that specific challenge.

To make the results more actionable for innovating companies, a framework was created, describing six identified mitigation strategies to avoid the most common challenges. The framework was created by reviewing the mitigation strategies mentioned in interviews, where some patterns were observed. These patterns formed six strategies that companies can adopt to respond to the identified challenges. The strategies were not explicitly connected to specific challenges but rather aimed to bring a holistic approach to an effective innovation process of AIMDs.

To verify the results, the initial results and framework were shown for two experts. The experts were then asked whether they found the findings reasonable based on their expertise within the area.

2.3 Research Ethics

In the process of conducting this master's thesis, some ethical considerations were discussed and examined. According to Vetenskapsrådet (2023), ethical aspects in research concern the research content and the researcher's relationship to the task. Some fundamental principles that good research practice based on, from "The European Code of Conduct for Research Integrity", are intended to give guidance on practical, ethical, and intellectual problems associated with research. These principles include reliability, honesty, respect, and accountability.

Reliability is safeguarded by using the criteria of credibility, transferability, dependency, and confirmability in Chapter *2.1.1 Reliable Result* to ensure quality and trustworthiness.

Honesty was ensured by fair and open communication with the interviewees by informing each individual about the research background and how the information discussed in the conversation was going to be used in the thesis. Furthermore, notes and results from interviews were extracted and analyzed as objectively as possible. Regular external reviews were additionally valuable to avoid researchers' potential bias by two respective weekly meetings with the two supervisors of this thesis.

Respect was ensured by acknowledging each potential interviewee's right to voluntarily participate or not participate in this study. Each interviewee's right to anonymity was also respected and any potentially sensitive information given in interviews was handled with care.

Regarding the research content, ethical aspects of artificial intelligence and medical devices were discussed both in the literary review and the interview study. In both studies, ethical aspects regarding the risk of bias are elaborated on and discussed. Furthermore, the overall ethical risks of implementing AIMDs are discussed in the context of user acceptance.

3 Healthcare in the Nordics

This section provides an overview of the market structures in the Nordic healthcare system, concepts of medical technology, and applicable regulations. The market structure is explored from a supply and demand approach, and medical technology is described through its definitions and implications. Finally, the regulations on medical devices are described with emphasis on the EU Medical Device Regulation.

3.1 Market Structure

The market structure is studied from a demand side that concludes with a summary of the differences between the Nordic countries, a supply-side that brings global and Nordic trends in the healthcare sector, and challenges in the healthcare sector.

3.1.1 **Demand Side**

The demand for medical devices in the Nordics is largely influenced by how the care sector is structured. Healthcare in the Nordic region is structured similarly between the countries and can be described as universally available and state-covered – offering a cost-efficient and inclusive health model (Vegas & Felman 2023).

There are some differences though, and the following subsection highlights the characteristics of the care sectors in Sweden, Norway, Denmark, Finland, and Iceland.

Sweden

The care system in Sweden is decentralized and organized in three levels: national, regional, and municipal (Janlöv et al. 2023, SKR 2023). Responsibility for care services is mainly delegated to the 21 regions and 290 municipalities. The Ministry of Health and Social Affairs is furthermore responsible for the overall health policies and national governance (Janlöv et al. 2023).

The financing of the healthcare system is largely through taxation, where health expenditure from public sources is described as “quite stable” at 86% of total health

expenditure (Janlöv et al. 2023). This large number is mainly due to outpatient and specialist care constituting around two-thirds of the funding and almost all hospitals are publicly owned.

The 21 regions collaborate in six larger geographical areas, where they are grouped with one to six other regions to ensure full-service coverage (Janlöv et al. 2023). Each of these collaborative healthcare regions has at least one university hospital serving all regions in the area. Furthermore, there are 59 additional regional emergency hospitals and over 1000 specialized clinics operating outside emergency hospitals. The 290 municipalities are operating care mainly carried out in special housing, home care, and in general discharged patients from general hospital care.

Norway

In Norway, the care system is semi-decentralized. Specialist care is the state's responsibility, administered by four Regional Health Authorities and the 357 municipalities are responsible for the primary care and social services (OECD 2022). In 2012, a Coordination reform was introduced to improve coordination of specialist and primary care and in 2019 this was supported by introducing a network of healthcare communities, providing governance structures for joint planning between municipalities and the health trust (owned by the Regional Health Authorities). Furthermore, counties play a role in for example safeguarding access to services and in coordinating care and provision of public health services.

The funding of the Norwegian health system predominantly comes from public sources. Secondary care and partly provision of primary care are financed through national taxes, and municipal taxes are the core source of funding for primary care. In terms of expenditure, public sources account for 85.5% of the current health expenditure and most of the publicly funded health services require a degree of cost-sharing. The out-of-pocket payments constituted nearly 14% of health spending, of which most is spent on pharmaceuticals, dental care, and long-term care. There are, however, cost-sharing-ceilings to protect residents from extreme healthcare spending.

Denmark

In Denmark, the healthcare system is decentralized and operated across three political levels: state, regions, and municipalities (OECD 2021a). Thus, Denmark has national, regional, and local dimensions. The state holds the overall regulatory and supervisory functions for health and elderly care, which has become more centralized gradually. Then five regions hold responsibility for hospital care (emergency care included), psychiatry, general practitioners (GPs), and specialists in private practice. Finally, 98 municipalities are responsible for some social services and primary health services. Examples include elderly care services,

rehabilitation outside hospitals, home nursing, child nursing, child dental treatment, and physiotherapy. Also, regional rehabilitation services and training facilities are co-financed by municipalities. The regional authorities hold the responsibility of organizing and delivering healthcare services in Denmark.

In general, there is a requirement to register with a GP (generally self-employed) that provides primary care and operates as a gatekeeper for accessing hospitals and most specialist care (OECD 2021a). The hospital beds are predominantly publicly owned (94%) and are operated by the regions and outpatient specialist care is delivered at hospital-based ambulatory clinics. The doctors are employed either by public hospitals or by self-employed specialists in privately owned facilities.

The Danish residents are covered by the national health system, where financing primarily comes from taxes on the state level (OECD 2021a). Block grants are allocated to regions and municipalities based on demography and activity levels. Health spending is largely covered by public funding and has remained relatively stable over the last decade, where the share in 2019 was 83%. With expenditure, the out-of-pocket payments are slightly lower in Denmark compared to the EU average, at 14% in 2019 (compared to the EU average of 15%). Co-payments are not required for primary care visits or inpatient hospital care, but apply for dental services, and physiotherapy, among others (OECD 2021a).

Finland

The health system in Finland is centralized from municipal to county level after undergoing a restructuring in 2023. In the reforms, 22 Well-Being Service Countries (WBSC) were introduced, directed by the elected councils, and financed by the state budget (Tynkkynen et al. 2023). Municipalities collaborate with the WSBSCs and remain responsible for public health functions, including environmental health and health protection. On a national level, the legislation and general policy guidelines are prepared. The new structure strengthens the strategic role of the central government by the Ministry of Social Affairs and Health (MSAH). This includes steering the WBSCs in how they organize services by recommendations and support collaboration between nations (Tynkkynen et al. 2023).

The WBSCs hold responsibility for organizing primary and secondary healthcare for their residents, and social and rescue services (Tynkkynen et al. 2023). In addition to the WBSCs, there are five collaborative regions organized around five university hospitals, in which the WBSCs are distributed. These five units centralize the organization of tertiary-level services provided in the university hospitals and distribute responsibilities between the university hospitals for highly specialized care, such as rare disease treatment (Tynkkynen et al. 2023).

In terms of funding, the majority is covered by state taxes. In 2019, 64% percent was covered by the state, 14% through contributions from compulsory national health insurance (NHI), and 22% from private sources (Tynkkynen et al. 2023). The

structural change mainly affects the sources of the state funding, which no longer will come from municipalities' taxes, but instead, WSBSCs will be funded by central government funding. With spending levels, over 79% of health expenditure comes from public sources, 16.4 from out-of-pocket (OOP) payments, and voluntary health insurance constitutes about 4.5% of spending (Tynkkynen et al. 2023).

Iceland

In Iceland, the health system is centralized with a health system that covers all residents (OECD 2021b). The government is largely both a purchaser and provider of most health services. Further, policy, regulation, administration, and financing are centralized nationally. Iceland also has seven healthcare regions with a planning responsibility and no administrative authority or separate revenue streams.

Although most healthcare providers are public, the number of private providers has increased recently. However, most health spending is publicly funded, at 83% of total spending in 2019 (OECD 2021b). The out-of-pocket payments share was 16% of health expenditures the same year, mainly from co-payments of primary care visits, outpatient care, and outpatient pharmaceuticals.

Summary

A summary of the Nordic healthcare organization in terms of organizational centralization, share of public spending from total, and share of out-of-pocket spending of total is provided in Table 3.1 below.

Table 3.1. Summary of the Nordic healthcare organization

Country	***Centralized or decentralized***	***Public expenditure of total***	***OOP spending of total***
Sweden	Decentralized	86%	13%
Norway	Semi-decentralized	86%	14%
Denmark	Decentralized	83%	14%
Finland	Centralized	64%	16%
Iceland	Centralized	83%	16%

3.1.2 **Supply Side**

Global industry trends

The supply side of medical devices consists of the companies and organizations that develop medical technology. In a global context, North America and Europe are leading the market of medical technology with shares of 36% and 29% respectively in 2021 (Statista 2023b). Some of the global titans, with revenues above 20 billion USD in 2022, include Abbot, Medtronic Inc., Johnson & Johnson, and Siemens Healthineers. Mergers and acquisitions have historically been an important growth driver for medical technology companies to gain a broader market and provide investors from smaller and private companies with an exit strategy (Stewart 2023). However, the number of deals has seen a decline in the last decade according to Figure 3.1. below (Statista 2023b). At the same time, the venture capital invested in the US and Europe has experienced growth in the last 15 years according to Figure 3.2 below. This indicates that the average deal within the MedTech industry has become larger.

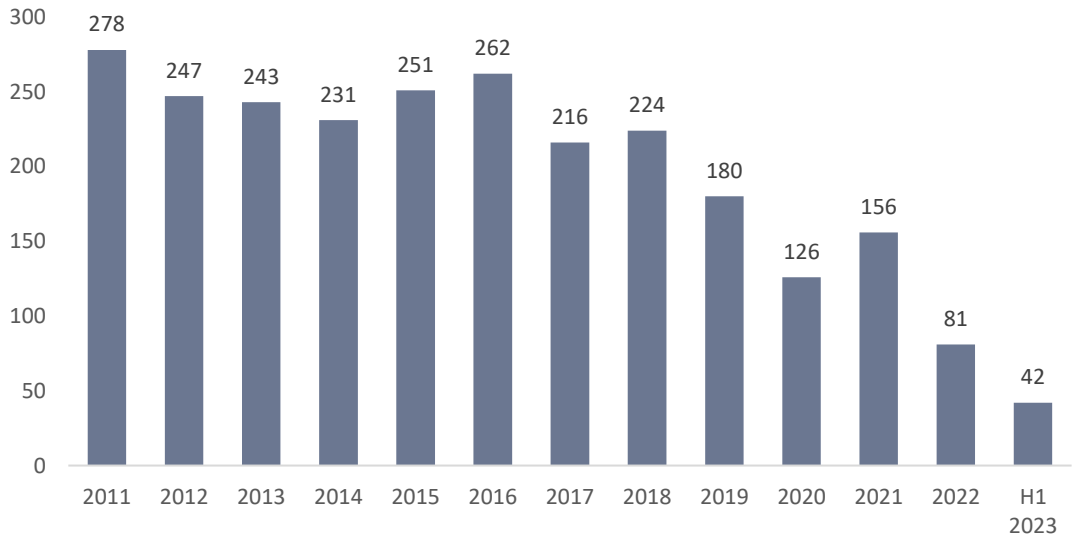

Figure 3.1. Number of merger and acquisition deals in medical technology worldwide from 2011 to 2023. Reworked and adapted from Statista (2023b).

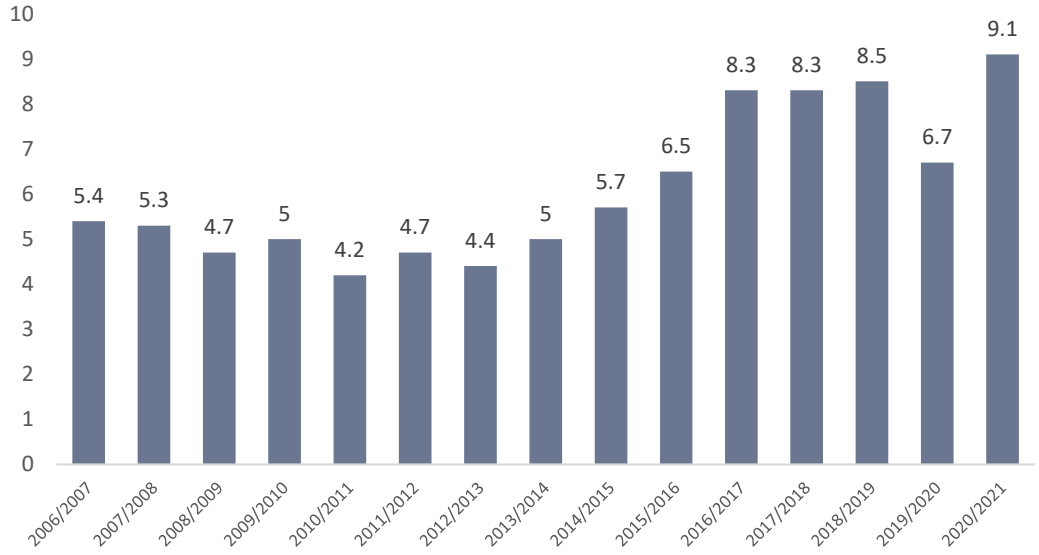

Figure 3.2. MedTech venture capital investment in the U.S. and Europe from 2006 - 2021 (billion USD).

Nordic infrastructure

The Nordic countries have a robust technological infrastructure and advanced healthcare system, and combined with a culture of innovation, well-positioned at the forefront of Global HealthTech, according to Vegas & Felman (2023). The Nordic ecosystem is characterized by a mix of factors contributing to the advancement of HealthTech, including start-ups, established companies, research institutions, and government initiatives. Sweden ranks tenth in the highest exporter of life science on a per capita basis, and Denmark fifth. Some of the titans in the industry are the Danish Novo Nordisk (est. 1923, market cap of almost a trillion dollars), Genab (est. 1999), the Swedish Sobi (est. 1939), and the Finnish Orion Corp (est. 1917). These companies provide a platform for the commercialization of further pioneering technologies and are thus playing an important role in the innovative landscape (Vegas & Felman 2023).

The presence of established companies is supported by a strong education system, where the Swedish Karolinska Institute ranked seventh in the world for Life Science and Medicine by Faculty (Vegas & Felman 2023). Top research in Biochemistry Molecular Biology (top 5 in the world for research), Clinical Neurology, and other fields are performed in the Medicon Village region, which includes Southern Sweden and Eastern Denmark.

The education quality enables the Nordic region to be an important producer of patents in the field. The number of patents for 2021 within life science for each Nordic country is listed in Table 3.2. below.

Table 3.1 Number of Patents by country and category (Vegas & Felman 2023)

Country	***Total***	***Pharma***	***Biotech***	***MedTech***
Sweden	459	133	72	254
Denmark	699	195	241	263
Finland	121	34	24	63
Norway	90	34	24	32
Iceland	42	18	2	22
Total	1 411	414	363	625

Nordic market figures and trends

The turnover of the Nordic Medical Technology market is estimated to be around 7 billion USD in 2023, where the submarket of medical devices has an estimated market volume of over 5.8 billion USD in 2023 (Statista 2023a). Revenue is estimated to experience a growth rate of 3.45% annually. One of the main drivers of stable growth in the Medical Technology market is the aging population – ensuring a sustained capital flow into R&D, production of health services, and implementation of existing technologies. Digitalization is and will be one of the main growth drivers with technological advancements of more tailor-made and data-driven products, although the entrance of new innovative products and thus implementation of new technologies are slowed by the heavy regulations.

Despite a tough-navigated nature, the HealthTech sector has become one of the most important industries for the Nordic Venture Ecosystem, both in terms of venture capital investments and strategic importance for the individual Nordic countries (Vegas & Felman 2023). Considering the healthcare increasing needs and technological advancements, HealthTech offers opportunities for innovation, growth, and investment beneficial for investors. Despite this, the general view of many founders and stakeholders in the Nordic HealthTech sphere is an overall shortage of available capital. By geography, Sweden and Denmark dominate the HealthTech investments in the region, attracting 70-80% of the capital in the Nordics.

By type of investors, specialist investors are concentrating their investments among the areas of Digital Health, MedTech, and BioTech (Vegas & Felman 2023). They are mainly sourcing from universities and Technology Transfer Organizations, incubators, and other investors. Generalists, on the other hand, invest more broadly

among HealthTech sub-sectors. Sourcing from generalists typically comes from entrepreneurial networks, other investors, and startup inquiries.

By geography, investors from Finland and Iceland are investing broadly in health, while Swedish, Danish, and Norwegian investors are more focused on Digital Health and MedTech (Vegas & Felman 2023).

3.1.3 **Challenges in the Healthcare Sector**

A fundamental challenge in digital health is changing systems and work processes. Specifically, the digitalization of services in healthcare (Lee et al. 2023). In response to this issue, models for guidance and support with digital health innovation and utilization could be important (Lee et al. 2023).

The demand for healthcare is pushed by a combination of forces, where the importance of an aging population stands out according to Spatharou et al. (2020). One in four people will be over the age of 65 by 2050, meaning that the healthcare system will be forced to contract with more patients with complex needs, and managing such cases is expensive. It requires a shift in structure from a periodic to a more proactive approach, focusing on long-term care management according to Spatharou et al. (2020). Without such structural changes, healthcare systems will find difficulties in remaining sustainable as stated by the authors. Another aspect is a shortage of staff in the health workforce. With a projected shortfall according to the World Health Organization (2022), there is a need to ensure that the healthcare professionals' time is used where the most value is added: caring for patients.

3.2 Medical Technology

The products included in the market of Medical Technology are devices used for medical purposes such as prevention, diagnosis, and treatment of diseases (Statista 2023a). Well-renowned examples are pacemakers, imaging instruments, dialysis machines, and implants.

A medical device is a product or equipment intended for a medical purpose. In the European Union, a conformity assessment must be conducted on medical devices to demonstrate that they are safe to use and perform as intended (European Medical Agency n.d). The products are regulated at a member state level, but the European Medicine Agency (EMA) is comprised of the regulatory procedure. When passed the applicable assessment, manufacturers can place a CE mark on the device.

A conformity assessment typically involves an audit of the quality system and depending on the device, a review of the technical documentation on safety and performance (European Medical Agency n.d). The member state designates and

accredits so-called *notified bodies* (NBs) to perform the conformity assessments. For high-risk devices, notified bodies need to request the opinion of specific expert panels before issuing a certificate of conformity, and in some instances, they must seek a scientific opinion from EMA to issue the CE certificate.

The Medical Device Regulation (MDR) provides an extensive definition of what is classified as a medical device under Article 2 to determine which products fall under the legislation (Regulation (EU) 2017/745 of the European Parliament). The following part is the first of 71 notes and provides an overview of what is interpreted under the term.

(1) "'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- *a. diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *b. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- *c. investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state,*
- *d. providing information by means of in vitro examination of specimens derived from the human body, including*
- *e. organ, blood and tissue donations,*

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means".

3.3 Regulation and Legislation

For medical devices in Europe, there are several regulations to which manufacturers and innovators must comply to place products on the market. These will be elaborated on in his section.

3.3.1 **Medical Device Regulation**

The most central regulation for medical devices in Europe is the Medical Device Regulation (EU) 2017/745 which applies since May 2021 and must be complied with by manufacturers when placing new medical devices on the European market (European Medicines Agency n.d). The new regulations repeal Directive 93/42/EEC on medical devices and Directive 90/385/EEC on active implementable medical devices. For Vitro Diagnostic Devices (i.e., devices that analyze biological samples outside the body), the new Regulation (2017/746) applies since May 2022 and

repeals Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices. The new regulations changed the legal framework for medical devices in Europe and "introducing new responsibilities for EMA and national competent authorities in the assessment of certain categories of medical device" (European Medicines Agency n.d).

The new regulation strengthens the requirements of a holistic risk approach and therefore provides a stricter classification system, sharper clinical evaluation requirements, and a launched transparency database (Wagner and Schanze 2018). While this ensures higher safety standards on the products that are released to the market, this also places a heavy workload on the companies, that need to provide more evidence for the performance and safety of the product. This implies a large consumption of both time and money, which is something that start-up and scale-up companies might not have.

3.3.2 The Artificial Intelligence Act

Usage of artificial intelligence in the European Union is planned to be regulated by the AI Act; the first comprehensive AI legislation in the world (European Parliament 2023). The motivation for the EU to regulate artificial intelligence is to "ensure better conditions for the development and use of this innovative technology" (European Parliament 2023). The first proposition from the European Commission of a regulatory framework for AI was in April 2021, saying that AI systems for various applications are analyzed and classified by the risk they pose to users. The risk level determined the degree of regulation. Although many AI systems pose minimal risks, they do need to be assessed.

The four risk levels are Unacceptable risk, High risk, Generative AI, and Limited risk (European Parliament 2023). The unacceptable risk AI systems will be banned as they are considered a threat to people. Examples of such systems include cognitive behavior manipulation and social scoring. The high-risk class is AI systems that could affect safety or fundamental rights negatively. All such products will be assessed before placing on the market and during their lifecycle. The generative AI class will have to comply with transparency requirements; stating that the content is AI-generated, prevent the generation of illegal content, and publish summaries of copyrighted data that are used for training. The Limited risk category should comply with minimal transparency requirements, allowing users to make informed decisions (European Parliament 2023).

3.3.3 **Other Legislations**

Although Nordic companies within medical devices primarily are regulated by the EU legislation, there are other legislations relevant for companies aspiring to reach markets outside of Europe. The most attractive market if wanting to reach outside the Nordic region is the United States according to Vegas and Felman (2023), where medical devices are regulated by the FDA.

Food and Drug Administration - FDA

FDA stands for Food and Drug Administration and is a consumer protection government authority. Firms that manufacture, repackage, reliable, and/or import medical devices that are sold in the United States are all regulated by the FDA's Centre for Devices and Radiological Health (FDA 2020). The level of regulatory control is determined by the classification level of the devices, where they are assigned a Class I, II, or III. The level of risk increases from Class I to Class III, and thus also the level of regulation.

Class I devices are mainly exempted from Premarket Notification, most Class II devices require Premarket Notification, and Class III devices generally require Premarket Approval (FDA 2020). Furthermore, is there a list of basic regulatory requirements manufacturers of medical devices distributed in the US need to comply with, such as Establishment Registration, Medical Device Listing, and Quality System Regulation, among others.

GDPR

The General Data Protection Regulation (GDPR) law (Regulation (EU) 2016/679) is a regulation aimed at strengthening the fundamental rights of individuals in the digital age and facilitating business (European Commission n.d). The regulation was entered into force in 2016 and applied in May 2018.

The MDR states that GDPR applies when processing data generated from a medical device, and according to Article 1 (1) in the GDPR, it regards the protection of natural persons involving "the processing of personal data" (Lindstad & Ludvigsen 2023). Using the wording "any information" in the regulation spans a broad scope, where the tipping point evolves around whether the person is identifiable. With anonymous data, the GDPR does not apply, although it is challenging to reach true anonymization in the healthcare sector.

4 Artificial Intelligence

This chapter presents definitions of artificial intelligence, federated learning, and its applications in healthcare. With the definitions, various types of AI are presented, as well as how the term is interpreted in this thesis. Federated learning evolves around training AI algorithms and applications in healthcare including the current use and future outlook.

4.1 Definition of Artificial Intelligence

In general teams, artificial intelligence is the broad science of simulating human abilities (SAS 2019). As this is a rather vague interpretation, many institutions have attempted to define it more specifically, but artificial Intelligence (AI) does not have a single definition that is commonly accepted. Instead, public organs, researchers, and institutions have separate meanings of what should be included in the term. Östberg and Lindsköld are excluding and including separate types of intelligent systems as they see fit for their report *AI for Better Health* (Österberg & Lindsköld 2020).

The interpretation of Östberg and Lindsköld is used as inspiration for the definition used in this master's thesis. However, the traditional expert systems, commonly referred to as rule-based expert systems, are excluded from the interpretation of AI. The motivation goes with the regulatory implications of the AI-Act, where such systems do not fall under the same regulations as more advanced intelligent systems. In addition, the expert systems can be viewed as the older type of artificial intelligence, gradually replaced by machine learning. In this report, the definition of Artificial Intelligence will be limited to Machine learning, Deep learning, and natural language processing systems per Figure 4.1 (the technologies are elaborated on below). Subcategories under these three terms will also be considered. Therefore, simple AI models such as rule-based expert systems are not considered in this report.

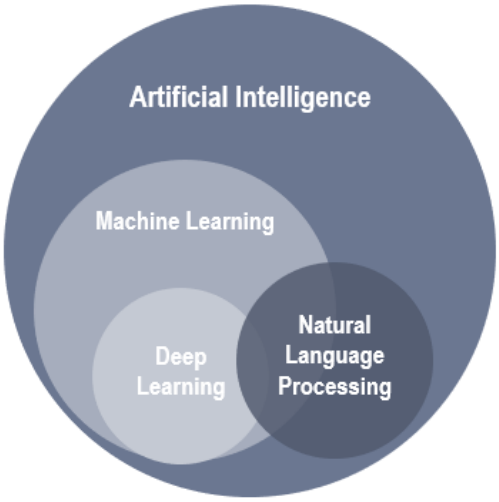

Figure 4.1. Artificial Intelligence and relevant subcategories considered for this report (inspired by Östberg and Lindsköld).

Machine learning

Machine learning is a branch of artificial intelligence that automates analytical model building (SAS 2019). It refers to learning to perform a certain task based on data or from prior experience, for example classifying animal pictures, recognizing handwriting, telling faces apart, or driving a car autonomously (Kalita 2023, p.3). When building a model, it is important to test and measure the performance and a simple way to measure it according to Kalita (2023, p.3) is by accuracy. The use of a metric additionally allows for a comparison between different machine learning programs.

The machine learning used today has evolved from pattern recognition and the theory that computers can learn and perform tasks without being programmed explicitly (SAS 2019). Important are the iterative aspects of machine learning, as models can adapt when being exposed to new data.

An AI algorithm can either be locked or adaptive (Mittermaier et al. 2023). The first type means that once the algorithms are trained, the model will provide the same result each time the same input is employed (Mittermaier et al. 2023). The adaptive type, on the other hand, could be updated constantly as it is trained with new data over time (Mittermaier et al. 2023).

There are several general types of machine learning depending on the type of data used and the approach taken to learn (Kalita 2023, p.4). These are: supervised, unsupervised, and reinforced, where supervised learning is the most popular one. Supervised learning is trained with labeled examples – for example, an input where

the wanted output is known. The model learns by comparing the correct output with the actual output to find errors and correct them accordingly. This type is often used in applications where historical data predicts likely future events (SAS 2019).

With unsupervised learning, the system is not told any "right answer" as there are no labels – instead the algorithm organizes the data by, for example, clustering to find natural groupings (Kalita 2023, p.6). It is hence appropriate for use against data without historical labels as this procedure aims to explore the data and identify some inborn structures. Use cases include finding the main attributes that can separate customer segments from each other, for example, to segment text topics and recommend items (SAS 2019).

Reinforced learning is sometimes referred to as a combination of supervised and unsupervised learning, while others think it is unlike either (Kalita 2023, p.7). In this type of learning, an agent learns to perform a task in an environment. A reinforced learning agent has a collection of basic actions it can perform and can at any given moment assume to "reside" in any of these set states. If the agent learns to go through a maze, these set actions can consist of going right, going left, going up, and going down in a grid representing a maze. When the goal state is reached by the agent, a reward can be given. Usually, most actions are unrewarded, while the last action that accomplishes the task gets rewarded. The agent needs to learn the optimal winning policy, thus which move to make in which state so the agent may win (Kalita 2023, p.8).

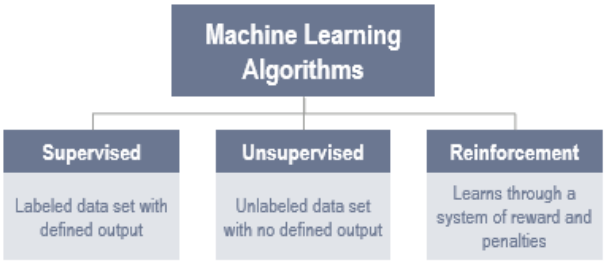

Figure 4.2. Three types of machine learning algorithms. Reworked and adapted from Majumder and Sen (2021).

Artificial Neural Networks (ANN) is according to (Kalita 2023, p.129) an approach to machine learning that has gained more attention in the latest decade as the number of layers has increased from two or three neuronal elements to tens- or even hundreds. A large amount of datasets is generated by different organizations (for-profit, non-profit, and government), and many of these datasets are available for training machine learning algorithms, ANNs included. The use of deep ANNs is what we refer to as Deep Learning. The names and structures of Artificial Neuron

Networks are inspired by the human brain – with the technology mimicking the way that biological neurons signal to one another (Kalita 2023, pp.131-132).

Natural language processing

Natural Language Processing (NPL) is a subset of artificial intelligence that relates to computing the ability to interpret and manipulate human language (Khanmohammadi et al. (2023). By combining rule-based modeling of human language, statistics, machine learning, and deep learning, computers can process human language. It can take the form of text or voice data, and the algorithm can "understand" the full meaning of the message and understand the speaker or writer's intent and sentiment (IBM 2023).

Examples of use cases are programs that translate text, respond to human commands, and summarize large text volumes at speed (IBM 2023, Khanmohammadi et al. 2023). For the computer to make sense of the input, it needs several NPL tasks to break down text and voice data. Examples of these tasks are speech recognition, part of speech tagging, word sense disambiguation, named entity recognition, co-reference solution, sentiment analysis, and natural language generation (IBM 2023).

Early NPL applications were rule-based systems, coded by hand, with the ability to perform certain NPL tasks (IBM 2023). They were difficult to scale to accommodate a large stream of exceptions or increased data volumes of text and voice. The techniques have evolved fast, and today deep learning models enable NPL systems that "learn" as they work and extract progressively more accurate meanings from large volumes of data sets. They are based on conventional neural networks (CNN) and recurrent neural networks (RNN). The process goes by first entering statistical NLP, which combines computer algorithms with machine learning, and deep learning models to automatically extract, classify, and level text- and voice data (IBM 2023, Khanmohammadi et al. 2023). Then a statistical likelihood is assigned to each possible meaning of those elements (IBM 2023).

The use cases of NLP are many, and the development is a "driving force behind machine intelligence in many modern real-world applications" (IBM 2023). Examples of use cases are spam detection, machine translation, virtual agents and chatbots, social media sentiment analysis, and text summarization (IBM 2023).

4.2 Data Federation and Federated Learning

A new concept to train AI models while keeping private data secure is through so-called *federated learning* (Martineau 2022). It was introduced by Google in 2016 and carries a way to unlock information and feed new AI applications. Among the common AI applications, such as chatbots and recommendation tools, a large amount of data was collected and crunched in one place to develop them. Today, however, AI is shifting to a more decentralized style. New AI models are trained in collaboration "on the edge" – on data that does not leave the personal device (mobile phone, laptop, or private server).

Federated learning is becoming the standard for meeting a range of new regulations regarding handling and storing private data (Martineau 2022). Through processing data at their source, federated learning brings a way to tap the raw data streaming from sensors on satellites, machines, and in our bodies, among others.

With federated learning, a single deep learning model is collaboratively trained through multiple people remotely sharing their data and improving on the model iteratively (Martineau 2022). In practice, each party downloads the model from the cloud and then trains it on their private data. Then they summarize and encrypt the new configuration of the model. The new updates are sent back to the cloud, decrypted, averaged, and integrated into the centralized model. Through multiple iterations, the collaborative training goes on until the model is trained fully. The training process can be either horizontal with similar datasets for training, vertical where data are complementary, or transfer learning where a model is trained on similar (but different) tasks than the aimed one. One example is that a model trained to detect cars can be trained to detect cats in transfer learning.

Breaking down data into silos through federated learning comes with great benefits on many occasions (Martineau 2022). In heavily regulated industries, such as healthcare, companies are cautious about taking the risk of using or sharing sensitive data when building an AI model. As deep learning models require tons of training data, federated learning can enable companies to collaboratively train a decentralized model – without sharing confidential medical records. This comes with the potential for the healthcare industry to reap more of the potential that AI brings, while still complying with privacy laws and regulations.

Federated learning comes with great potential, but some risks need to be addressed (Martineau 2022). One challenge is transparency since the training data are kept private, and this puts high demands on the system to test the accuracy, fairness, and potential biases in the models' output (Martineau 2022). Another challenge regards controlling what goes into the model and how to delete material when a host leaves the federation. Since deep learning models are opaque (like a black box), the problem is both finding the host's data and then erasing its influence on the central

model. Finally, an important challenge regards trust. There is a risk that contributors have ill intentions to sabotage the model with phony data or dummy data.

4.3 Artificial Intelligence in Healthcare

Artificial intelligence is described as a "powerful technique that could act as a vehicle to accelerate innovation in healthcare" (Apell & Eriksson 2023). Although there is extensive hype and buzz around AI in healthcare, we are still at the beginning of understanding its full potential. According to Spatharou et al. (2020), three phases of scaling AI in healthcare are expected. The first solutions are likely to address the "low-hanging fruit of routine, repetitive and largely administrative tasks". Tasks that demand significant time from healthcare personnel. This phase includes applications based on imaging that are already used in for example radiology, pathology, and ophthalmology.

The second phase of solutions is expected to drive the shift from bringing more care from the hospitals and into the homes, for instance, remote monitoring, alerting systems, and virtual assistants. This drives the development of patients taking increased ownership of their care (Spatharou et al. 2020). A broader range of Natural Language Processing (NPL) could potentially also be included at this stage, and more use of AI in a broader range of specialties, including oncology, cardiology, or neurology. However, this requires AI to be more embedded into clinical workflows. Additionally, it would require well-designed and integrated solutions to use existing technologies effectively in new contexts. The adoption pace of AI would be determined by a combination of technological advancements organizational culture change and capability building.

The third phase is expected to include more AI solutions as an integral part of the healthcare value chain (Spatharou et al. 2020). Including how we learn, investigate, and deliver care, but also how we improve the health of populations. Some important conditions for AI to reach its full potential in Europe within healthcare concern the integration of broader sets of data across organizations, strong governance to support data quality, and confidence from organizations, practitioners, and patients – both in the actual AI solutions and the ability to manage associated risks (Spatharou et al. 2020).

An application benefit of AI in healthcare is the potential to remove or minimize time used for routine and administrative work. It can take up to 70 percent of the time occupation for a practitioner and this type of benefit is highly welcomed by the healthcare workers, which can speed up adoption. Furthermore, AI can go beyond speeding up time-consuming processes, to augment a range of clinical activities and help access information that can lead to better quality of patient care. Another effect driven by new required skill sets includes the introduction of new professionals.

Spatharou et al. (2020), predict that multiple jobs will emerge in the intersection of medicine and data science.

With AI applications in healthcare, the field of radiology is at the forefront and the hype around it is evident (Kotter & Ranschaert 2021). In 2019, the number of AI-related abstract submissions to Radiology journals and conferences reached 25% of all submissions in Radiology. A large number of publications have shown that AI instruments can recognize patterns in medical imaging with “excellent accuracy”, especially with deep learning (DL).

5 Theory

This chapter consists of theoretical models and terms in the first part, and previous research in the second. Areas of fundamental theory include the diffusion of innovation theory, technology push versus market pull, and crossing the valley of death. Previous research presents the results of the literature review with challenges and success factors for AIMD innovation.

5.1 Fundamental Models and Terms

As a base for the literature study, fundamental theories regarding innovation technology and innovation in healthcare were studied. Furthermore, models and theories regarding innovation characteristics were outlined to better understand the challenges studied in upcoming chapters.

5.1.1 **Defining Innovation**

A starting point to define the phenomenon of innovation is to distinguish it from invention. “Invention is the first occurrence of an idea for a new product or process, while innovation is the first attempt to carry it out in practice" (Dogson et al. 2013, p.4-5). Turning an invention into an innovation, an organization would typically need to combine several different types of knowledge, capabilities, skills, and resources. Furthermore, innovation in most firms depends largely on external sources as a collective achievement from multiple actors both in the public and private sectors. Another dimension of the perquisite for innovation is the national or regional systems, with systematic interdependencies within a given country by political and administrative borders.

It is interesting to study innovation from a systems perspective, as systems may “be locked into a specific path of development that supports certain types of activities and constrains others” (Dogson et al. 2013, p.13). A system more open to impulses from the outside has a reduced risk of being “locked out” from favorable new paths of development emerging outside the system. The “system managers”, often policymakers, thus have an important role in ensuring the openness of the system and preventing innovation activities from becoming unduly constrained by self-

reinforcing path dependency. With a radical innovation, the possibility is higher that it requires extensive infrastructure investments, organizational changes, or social change to succeed. If this is the case; it will be essential to join forces with other actors of change in the private or public sector. To prevent bottlenecks on a system level in skills, research infrastructure, and the broader economic infrastructure, policymakers additionally need to consider different levels of governance (Dogson et al. 2013, p.12-14).

Attempts to define innovation can be found in a range of publications and the general idea of the term centres around "something new". However, a general definition of innovation in science does not exist (Kogabayev 2017). The authors do provide an interpretation, describing innovation as "systematic in nature, leads to a change in all or some elements of the system; is cross-functional in nature, creates a quality leap, 'breaks' the old rules, results in a departure from the system; innovations and inventions after their commercialization (implementation)". By this definition, the term "invention" is again separated in the sense that an invention is a *potential* innovation, in the shape of a new technical solution. McKinsey & Company describes innovation as "the systematic practice of developing and marketing breakthrough products and services for adoption by customers" (2022 a). Thus, an innovation can be referred to both as an output from a process and as a process itself.

5.1.2 **Implications of Innovation**

Successful innovation brings significant new net growth – yet less than 10 percent of established companies report that they are satisfied with their innovation performance according to a McKinsey survey (2022a). In the same study, McKinsey found that companies harnessing the essentials of innovation do see a considerable "performance edge" separating them from their competitors. With a research scope of 183 companies, they saw that mastering innovation can generate an economic profit 2.4 times higher than that of other players. However, it might not be clear how to measure innovation profit in isolation. One way is to look at innovation-driven net new growth, referred to as the "green box" by McKinsey (2022a). The phrase refers to the quantification of growth in revenue or earnings an innovation brings in a set timeframe. The concept can be a tool for clarifying aspirations and influencing choices.

It is a common misconception that innovation is solely about creativity and idea generation. Nevertheless, it is centered on resource allocation; to refocus people, assets, and management attention to the best ideas of the organization (McKinsey 2022 a).

5.1.3 **Diffusion of Innovation**

Rogers' Diffusion of Innovation theory explains how a new idea passes stages of Adoption by different actors in a population (Rogers 1995). When an innovation is adopted in a population, it further develops and the procedure can be described as an intrinsic part of the innovation process (Dogson et al. 2013, p.459-460). Learning, imitating, and feedback effects arising during the spread of a new technology enhance the original innovation (ibid). The benefit received from an innovation is a large driver of the adoption rate. Further, the most important determining factor of the benefit obtained from adopting a new technology is the amount of improvement the new technology offers in relation to a previous technology (Dogson et al. 2013, p.469-470). The level of adoption over time forms an S-curve, illustrated by Figure 5.1. below, where the steepness of the curve can be lower or higher depending on the rate of adoption.

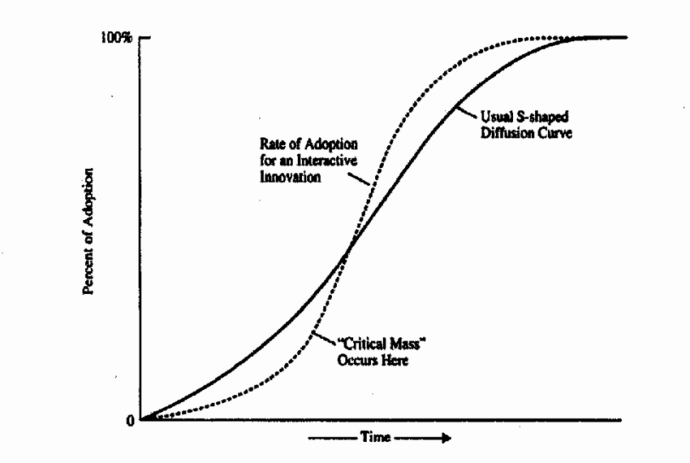

Figure 5.1. Level of adoption of an innovation over time. (Peacock 2007)

The theory was first developed by E.M Rogers in 1962 and explains the passage of a new idea that is passing through stages of adoption by different people and users (Halton 2021). The five groups of people are Innovators, early adopters, early majority, late majority, and laggers. The first two groups are open to taking on the potential risk that comes with trying an innovation, while laggers are risk-averse and begin to use the innovation first when it becomes so conventional that they are forced to use it.

The adoption rate of the innovation is determined by its attributes, where five of the most important ones according to Rogers are: relative advantage, complexity, compatibility, trialability, and observability (Rogers 1995). The chosen communication channel partly determines the likelihood of a successful linkage with the target customers. Further, the type of innovation-decision also impacts the

rate of adoption, where it can be either optional, collective, or authoritarian. The nature of the social system, such as the structure of the network and related norms to the system also affects the rate of adoption. The last factor affecting the rate of adoption presented by Rogers is the extent of change agents' promotion efforts. Although it is mentioned that this relationship might not be direct and linear, there is a greater payoff at certain stages in the innovation's diffusion. All variables determining the rate of adoption of innovations presented by Rogers can be found in Figure 5.2. The rate of adoption is in general measured as the number of individuals that adopt a new idea in a specified time, for example yearly (Rogers 1995). Thus, the adoption rate is a numerical indicator of the steepness of an innovation's adoption curve.

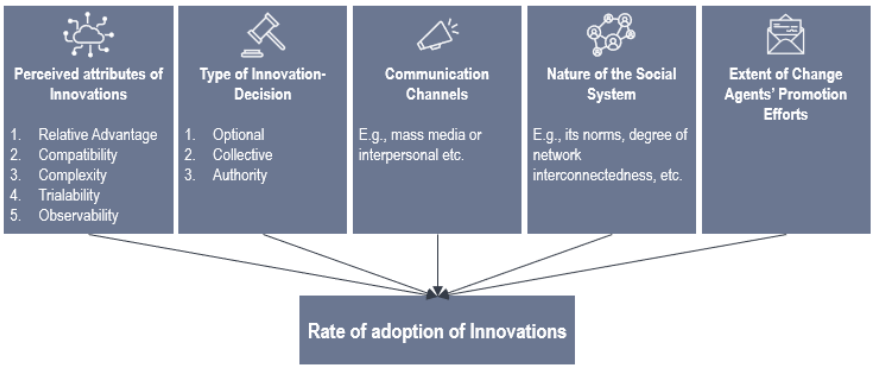

Figure 5.2. Variables determining the rate of adoption of innovations. Reworked and adapted from Rogers (1995).

5.1.4 Diffusion of Innovation in Healthcare

With emerging population needs, healthcare systems have become progressively complex and have experienced difficulties in finding the right solutions (Chaves et al. 2021). Encouraging innovation and creativity in health organizations are described as some of the most important elements in response to rising challenges (Chaves et al. 2021).

Multiple conceptual frameworks have presented ways to analyze factors facilitating or inhabiting the diffusion of innovation in healthcare (Chaves et al. 2021). An environment favoring leadership autonomy has been demonstrated to be one of the most critical elements in favoring creativity, and in contrast, excessive control and intolerance to error are described as a creativity barrier (Chaves et al. 2021).

A challenging exercise for healthcare organizations is to establish a list of criteria to evaluate the innovation before deciding on its incorporation and adaptation. This

is largely performed in two stages. First, local criteria are recognized to assess the relevance of innovations, and second, criteria are established for prioritizing the innovations approved by the first step. Failures can have a severe negative impact, not the least when funded by public money. Therefore, "public organizations must consistently innovate in a responsible, efficient, transparent, and ethical way" (Chaves et al. 2021, p.6).

Administrative, regulatory, and sometimes bureaucratic barriers to innovation are slowing down the process of delivering new solutions to patients and thus prolonging the diffusion process (WHO 2010).

5.1.5 Technology Push versus Market Pull

An innovation can be driven by either advancement in technology, or by identified needs from the market. This is referred to as the *Technology Push versus Market Pull* continuum of product development (Ameka and Dhewanto 2013). In a technology push approach, the innovator finds an interesting technology before efforts are made to identify potential users or markets for the developed technology. When an innovation comes from a market pull approach, the innovator has identified a demand from the market and develops a solution to directly address those needs.

If a technology is developed solely through a technology push approach, it is important to align the innovation with real-world market needs to ensure there is an existing customer base for the product (Brem and Voigt 2009). When developing a technology from a market pull approach, competencies should be acquired within relevant technical areas to not limit the capabilities of the innovation.

The ideal approach is to use a combination of technology push and market pull elements to bring market needs to technology development to increase the chances of successful commercialization and adoption of new technologies (Brem and Voigt 2009). This requires a high level of collaboration between demand and supply, which in healthcare is rather complex as the interaction is controlled by the regulatory environment (Ciani et al. 2016). Ciani et al. describe how in systems where public administrations control the resources available for the healthcare system, this collaboration is further restrained.

5.1.6 **Crossing the Valley of Death**

The *Valley of Death* is recognized as "the gap between the technical invention or market recognition of an idea, and the efforts to commercialize it" (Markham 2002). The term refers to the challenges that occur for innovation in this phase, such as lack of funding, lack of industry interest, regulatory challenges, or uncertainties regarding scalability which often leads to the end of many promising technologies (Ellwood et al. 2022).

Successfully crossing the Valley of Death often requires collaboration between researchers, investors, industry partners, and government agencies to provide the necessary resources, funding, and support to move innovative ideas into successful commercialization (Ellwood et al. 2022).

Ellwood et al. present a framework for the risks companies should consider when developing medical technologies to successfully cross the Valley of Death, presented in Figure 5.3. The *refinement of the narrative for the technology concept* is the first process, and it is explained as the generation of concept ideas in collaboration with other actors, such as researchers or clinicians. The refinement of the narrative aims to validate the process or the product.

The second process highlighted in the framework is the *technical evaluation of lab-scale models*, which aims to assess the robustness of the lab model to different inputs, generate data for a financial pitch, or produce a model for an existing surgical practice (Ellwood et al. 2022).

The lower half of the framework focuses on the user value. The third process in the framework is the process of *understanding how the technology will be used*, which is achieved by collaborating, building partnerships, and reviewing established healthcare pathways. The goal of this process is to understand the initial valuation of the technology (Ellwood et al. 2022).

The fourth process is defined as a *comparative value assessment*, which includes health economics analysis, timing approach to venture capital, and negotiating contributions vs returns of innovation intermediaries (Ellwood et al. 2022).

To achieve an investment-ready proposition, Ellwood et al. suggest the *integration of innovation actor inputs*, through the development of IP strategy and identification of gaps in technical and market competence among others. The wanted outcome of this process is an application for a commercial investment, to support the final crossing of the Valley of Death (Ellwood et al. 2022).

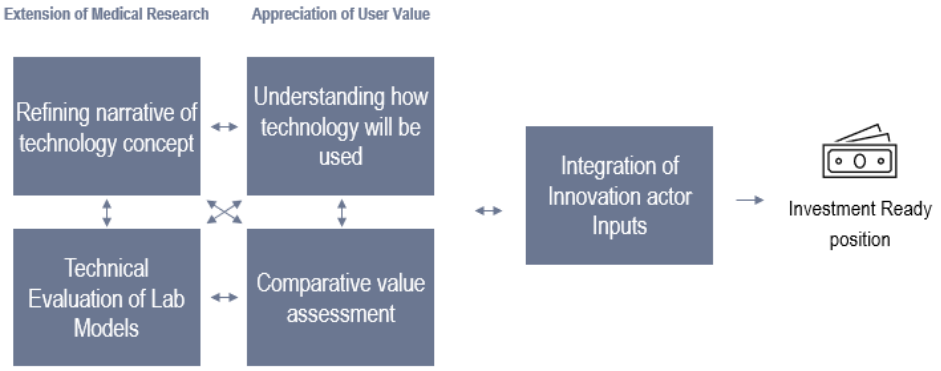

Figure 5.3. Innovation Process Mechanisms during the Valley of Death. Reworked and adapted from Ellwood et al. (2022).

5.2 Previous Research

This chapter presents the identified challenges and success factors in previous research on innovation within AIMD. The sub-chapters are structured based on the most frequent and applicable challenges found in the literature review.

5.2.1 **Access to High-Quality Data**

An obstacle related to data collection necessary to train AI algorithms is the difficulties in using the data because of data liabilities and privacy concerns according to a study by Apell & Eriksson (2023). The study found that re-using patient data from previous clinical trials creates uncertainties regarding data ownership since the consent forms do not allow data originally intended for other research projects to be used for a new purpose. Sweden is known for its developed healthcare quality registers with a great amount of data for a variety of medical procedures, yet all actors do not have access to the data from healthcare databases. For non-academic actors, the restrictions on healthcare data usage were described as a challenge in the study (Apell & Eriksson 2023). Nevertheless, companies founded by medical researchers did not experience these data challenges (Apell & Eriksson 2023).

In another study by Kotter & Ranschaert (2021), the authors find a lack of high-quality annotated datasets for training as a major bottleneck in the introduction of deep learning algorithms for diagnostics and clinical routine functions.

For challenges related to data in the context of AI-driven evidence in health technology assessment, Zemplényi et al. (2023) propose some solutions in an extensive research paper. When there is missing or unstructured data, the recommendation by the authors is to check whether the results can be used without the missing data. If results cannot be used even with curation, it is crucial to assess whether investing in resources to collect data afterward is worth it or how much it would cost to digitalize paper information. With unstructured data, the availability of key variables in text fields should be checked, for example as text bodies in medical reports. If that is the case, text mining methods (such as correction, colocation, and phrase frequency analysis) could be used to extract variables in a structured format. The text mining methods can also be of value to efficiently identify and select studies and extract data from them.

Regarding data sharing between digital systems, Kotter & Ranschaert (2021) express a lack of standards– making it difficult to integrate AI algorithms into clinical workflows.

5.2.2 **Risk of Bias**

A significant challenge of AI-based models in medical applications is related to technical failures and algorithmic bias (Camaradou & Hogg 2023). AI applications have the potential to predict surgical outcomes, assess technical skills, or guide surgeons intraoperatively through computer vision (Mittermaier et al. 2023). Nevertheless, risks evolving from these applications constitute bias, compounding existing inequities in for example socioeconomic status, race, religion, gender, ethnicity, disability, or sexual orientation. Since bias predominantly impacts disadvantaged populations, that can be subject to algorithmic predictions that are less accurate or underestimate the need for care, strategies for detecting and mitigating bias will be pivotal (Mittermaier et al. 2023).

Bias risks can take on many shapes. Mittermaier et al. (2023) outline an example where an AI algorithm trained on hospital data from German patients possibly will not perform as well in the US, where patient populations, medications, or treatment strategies can be different. The biases can arise across the development steps of an AI, from data collection to model development, evaluation, and deployment in clinical settings. Strategies to mitigate bias may involve interventions like pre-screening data through sampling before building a model, incentivizing the model to learn balanced predictions by implementing mathematical methods, and post-processing.

A natural question arising from the development of more advanced AI algorithms is what level of bias is acceptable. The discussion on this topic goes multiple ways by Mittermaier et al. (2023), where one direction is to train the algorithms to become more generalizable to be applied to a broader population, with larger and more diverse data sets. Another approach is training the algorithms to be more localized

and apply only narrowly. In either case, the AI models need to be transparent and explainable for these questions to be studied and debated (Mittermaier et al. 2023).

An adaptive AI, that develops as it acquires data over time, possesses a risk of increasing or adding new bias (Mittermaier et al. 2023). Therefore, routines for consistent bias detection and continuous mitigation will be pivotal in the AI implementation. In medical image analysis, Mittermaier et al. emphasize the importance for radiologists to be actively engaged in developing ethical and regulatory guidelines for using and approving AI tools in Radiology. Especially when it comes to the risk of "built-in bias" (Kotter & Ranschaert 2021) of algorithms as it could lead to unforeseen harm to patients.

The author also expresses the need for radiologists to have some fundamental knowledge of technology to better work in symbiosis with the algorithms (Kotter & Ranschaert 2021). Education in AI that covers both technical and ethical aspects is thus of great value, enabling collaboration with engineers and computer scientists in training and improving algorithms (Kotter & Ranschaert 2021).

Moreover, Zemplényi et al. (2023) propose statistical and analytical approaches to mitigate bias. These include focusing on relative measures (such as effectiveness), using control groups, and investigating whether bias can differ in the groups compared. It can also be an option to use higher-level aggregated data for analysis as well to train the algorithm if sufficient data are available and the result is meaningful for the purpose.

5.2.3 **Access to Funding**

According to the research of Apell & Eriksson (2023), AI experts in academia experienced low financial resources and an unwillingness to invest in AI technology from the corporate side. In medium- and large-sized companies, AI experts were challenged by management to present a return on investment (ROI) for new projects, yet the high uncertainties and lack of evidence often resulted in an unwillingness to invest. For micro- and small-sized companies in the same study, the situation differed. They often attained venture capital for projects in early-stage development. An investor confirmed that local seed investors had a willingness to invest in new projects related to AI technology innovations, although the number of projects and invested capital were low in absolute terms.

Part of this challenge is shared with the overall healthcare industry, where the long time to market and sales cycles increase the risk of investments (Vegas & Felman 2023). Furthermore, investors seek companies with high growth and market potential. As the Nordic markets often are perceived as too small and fragmented, companies launching in one or a few Nordic markets alone might struggle to raise capital.

The approach of investors, according to a study by Nordic Innovation from 2023, is favoring early-stage and tending to invest in companies based in their home countries (Vegas & Felman 2023). The main criteria when assessing investments include team quality, proven demand from the market, and intellectual property (IP) strength. Most investors in the study believe mergers and acquisitions (M&A) are the most viable options to exit deals in Nordic HealthTech.

The US is considered the most attractive market for HealthTech companies by investors according to Vegas & Felman (2023). Recommendations by the authors to attract investments for Nordic companies are to expand their market reach. Through fostering Nordic-US market expansion, Nordic companies can establish themselves in the US and attract capital from US investors, as it is a principal market for growth and investments within HealthTech. By supporting companies with Go-To-Market Strategy development and implementation, HealthTech companies can target markets with the highest growth potential.

5.2.4 **Regulatory Requirements**

Even without AI, MedTech companies have expressed concerns regarding the extensive process of certifying medical devices under MDR. (Medical Device and Diagnostic Industry 2021). According to Kearney and McDermott, clinical evaluation requirements for an MDR certification are posing a great threat to companies, where the cost of pursuing clinical investigations sometimes outweighs the potential return on investment (2023). Kearney and McDermott demonstrate that the skill and knowledge gap among companies is the largest challenge observed, followed by the challenge of sourcing clinical data.

It is unknown how the AI Act will affect the regulation of medical device software using AI, but concerns have already been raised. MedTech Europe (2021) published a response to the proposal of the AI Act where several challenges are published, such as the misalignment between the proposal of the AI Act and MDR which further complicates the understanding of the compliance requirements. Furthermore, the misalignment might imply that companies producing AIMD need to undergo two conformity assessments by notified bodies: one for the AI Act and another one for MDR (Van Raamsdonk 2023)

There is also an identified misalignment between the proposed AI Act and GDPR, as the AI Act requires that training, validation, and testing data sets should be “representative, free of errors and complete” (Van Raamsdonk 2023). This would require complete disclosure of the sensitive and GDPR-protected data.

How the EU parliament, council, and commission will respond to the raised concerns and recommended updates is still undecided, as the regulation has not been adopted yet. The specific challenges that will come with the AI Act are therefore still too early to define.

The head of medical devices and in vitro medical devices at RegSmart Life Science, Mats Högberg (2023), published a chronicle in the MedTech Magazine, where he gives his view on the challenges related to certifying AIMDs under the current regulations. Högberg states that non-static algorithms, such as generative AI, are challenging to certify under the static regulations in the EU, as an installed device might act differently after a certain amount of time. Furthermore, he also expresses concerns regarding responsibility and transparency due to the black-box phenomenon which complicates explainability (i.e., the ability to explain why an algorithm reached a particular decision). Even though Högberg has published a chronicle, which is not a scientific article, his observations are included in the report as Högberg has experienced these challenges firsthand in his professional position.

Artificial Intelligence has been analyzed under the current medical regulatory framework. Müller et al. highlight several requirements that a company developing an AI image interpretation device needs to consider to be approved under the In Vitro Diagnostic Regulation (2022). Firstly, they present that causality must be shown for features in the device, as it needs to be clear what factors affect the algorithm for it to be regulatory approved. Secondly, the analytical and clinical performance of the algorithm must be monitored throughout the use of the device as a part of the post-market surveillance. Thirdly, Müller et al. find that explainability and causality need to be proven to gain certifiability. Therefore, the algorithm needs to be limited to explainable AI according to Müller.

5.2.5 **Understanding and Meeting User Needs**

An important aspect of implementing successful AI technology innovations is to understand and meet the user needs, thus often the requirements of healthcare professionals or patients. However, many companies do not have enough understanding of the user needs, for example, a study from 2023 (Apell and Eriksson) saw that companies experience a lack of guidance from leading healthcare professionals.

As an example, the development of AI algorithms for medical image analysis was initially mostly driven by computer scientists and software developers for research purposes (Kotter & Ranschaert 2021). Hence it did not always result in solutions of value to radiologists and for clinical applications. For this perspective to shift, the authors of the study emphasize the importance of the radiology community to define appropriate use cases based on existing needs and consequently allow for training the algorithms with a clear clinical purpose. Thus, enabling a technology pull from the demand side.

Camaradou and Hogg (2023) also underline the importance of user collaboration but from a patient perspective. As artificially intelligent medical devices are aimed at improving patient health, and not for technology advancement per se, there is a

need to work with patients to enable a product-centric and patient-centric innovation process according to the authors.

According to Camadou & Hogg (2023), many small and medium enterprises (SMEs) already apply user acceptance testing in their product design, particularly for medical devices. However, the input often involves user-friendliness rather than validation (if the device meets the user's needs). Proving impactful knowledge transfer on what matters to patients between diverse patient groups and stakeholders that drive the development of an AIMD, will therefore be of importance.

5.2.6 **User Acceptance**

Clinicians have the potential to improve both the adaptation of an AI tool and the acceptance level by patients, but also the development of the AI tools (Camaradou & Hogg 2023). However, this is challenging as clinicians in general have a limited knowledge of clinical AI and the implications for practice.

In a study of AI-enabled consumer-facing health technology, the authority of AI-based symptom checker (AISC) applications was determined by the reputation of the entities that run behind them (You et al. 2021). Participants in the study chose to use the applications of companies they had trust in – for example, a large and established company. In addition, participants were more likely to attribute authority to AISC apps linked with hospitals or doctors, such as integrated online doctors.

Another success factor in the study of AISC apps is related to data provenance and transparency (You et al. 2021). The participants desired to know where the data, that the diagnosis was based on, originated from. Most participants considered data from established authorities as credible. As an example, highlighted by a respondent, the app can increase credibility by disclosing "some information appropriately, such as how many hospitals, medical records these apps used" (You et al. 2021, p.7). Information can be displayed regarding the AI-enabled healthcare systems' developers, sponsors, and data sources to increase transparency. Additionally, diagnostics information from other sources can be presented for reference to cross-validate medical authority.

In addition to organizational and data credibility, the appearance and interaction interface with the apps also determined the authority assigned to them by the users in the study. How the AISC apps solicited information would impact and when the AISC apps were presenting the right set of symptoms to select from, authority was increased. With probing questions, participants evaluated the AISC app's authority based on whether the questions were comprehensive and in-depth. Improving input flexibility, advancing the presentation of probing questions, and intensifying the knowledge base by mimicking established authorities' diagnostics procedures can increase authority. A future scenario might be for AI-enabled healthcare systems to

provide guidance and warnings to let users notice the potential risks when there is insufficient knowledge to identify a proper diagnosis. Another solution is to introduce doctor-like customer service, so when a user doubts the diagnosis or struggles to describe symptoms, a doctor can be incorporated (You et al. 2021, p.7).

In another study, Camaradou & Hogg (2023) identified a need to make AI more explainable to people from various backgrounds through a UK nationwide survey. Important factors include having effective governance mechanisms in place to address patient concerns related to transparency, accountability, independent oversight, and data protection. Concerns raised by patients around the use of more AI in healthcare evolve around having less interaction with healthcare workers (Camaradou & Hogg 2023).

Recommendations by Zemplényi et al. (2023) in the context of AI-driven evidence in health technology assessment, focus on education of health technology assessment doers and users, establishing collaboration and sharing of best practices (Zemplényi et al. 2023)

5.2.7 **Summary of Challenges and Success Factors in Previous Research**

A summary of the challenges and success factors for AIMD innovations that have been identified in the literary study is presented in Table 5.1.

Table 5.1. Challenges and success factors for AIMD innovation from previous research

Challenge	*Success factor*
Access to high-Quality Data: Challenges in accessing and using health data due to privacy concerns.	**Research and collaboration**: Access data through research projects and clinical collaborations, as well as managing missing- or unstructured data.
Risk of Bias: AI models may perpetuate biases, impacting disadvantaged populations.	**Continuous bias detection and mitigation**: Standardizing data, pre-screening, managing missing data, and bias detection structures.
Access to Funding: Limited resources hinder scalability and innovation.	**Investments:** Prove high team quality, a demand from the market, IP, and capturing a larger market, for example by US expansion.
Access to competence: Difficult to attract AI competence in the industry.	
Regulatory Compliance: Difficult and resource-demanding to certify AIMD under EU legislation	**Explainability:** Limit the algorithm to explainable artificial intelligence to facilitate proof of performance and safety.
Understanding User Needs: Aligning AI development with clinical and patient needs.	**Collaborate with End-Users**: Innovate in close collaboration with potential customers.
Trust and user acceptance: Need to prove compliance and safety.	**Transparency and Accountability**: Ensuring transparency in data sources and decision-making processes and building credibility with established entities.

6 Results

In this chapter, interview findings are summarized from AIMD innovating companies, academia, industry experts, and industry organizations. The first part focuses on the most frequently mentioned challenges and success factors, and how they are related. In the second part, the challenges are divided based on risk class, product type, and company size.

6.1 Challenges and Success Factors

Success factors mentioned in interviews have been coupled with the associated challenges, according to Table 6.1 below. They are ranked according to the number of interviewees who mentioned the area as a challenge. This provides an overview of the result before further exemplifications and elaboration in the remaining part of this sub-chapter.

Table 6.1 Summary of challenges and success factors for AIMD innovation

Challenges	*Detailed description of challenges*	*Success factors*
Regulatory Compliance	▪ Regulatory uncertainties, impeding efficient interpretation of regulatory requirements ▪ Underestimation of work needed, starting too late ▪ Perceived mismatch between new AI technology and regulatory requirements ▪ Developing sufficient – as per the regulatory requirements – clinical evidence	▪ Early planning based on regulatory requirements ▪ Early involvement of regulatory expertise, external or in-house ▪ Performing extensive clinical studies to gather sufficient clinical evidence ▪ Releasing the device on markets with less extensive regulatory requirements
Understanding user needs	▪ Understanding user needs and requirements	▪ Establishing collaboration between the innovating company and clinicians, or having clinicians / clinical background in-house ▪ Involving clinicians early in the development ▪ Performing an early proof-of-concept study to confirm that the device addresses the observed user need

User acceptance	▪ High requirements on sufficient evidence performance and value ▪ Resistance to the change that AIMDs brings ▪ Limited time for clinicians to partake in verification and validation ▪ Requirements from users on transparency and accuracy of training data	▪ Finding ways to show quick results, through e.g., a Pilot ▪ Identifying and engaging KOLs to drive change and acceptance ▪ Having clinical evidence from peer-reviewed independent research ▪ Finding efficiencies in verification and validation planning and execution ▪ Finding a balance in the disclosure of training data using e.g. statistics
Data as the key component	▪ Obtaining access to large amounts of representative data ▪ Avoiding bias ▪ Time-consuming to curate, validate, and process data ▪ Transferring protected and confidential data between the device to the developing company	▪ Finding an effective size of the data set needed to avoid extensive curating ▪ Finding ways to access the needed data without transfer, e.g. through remote access ▪ Collaborating with clinicians or clinical researchers ▪ Initiating research projects in parallel to the product development ▪ Collect data in (several) markets with less stringent requirements ▪ Start with a beta-version, use in-use data to further enhance the AIMD
Systems interoperability	▪ Ensuring interoperability with existing systems	▪ Developing a flexible system (which can in turn be challenging) ▪ Optimizing the model to a selected number of specific conditions, rather than making it generalizable
Access to funding	▪ Long payback time combined with uncertainty regarding AIMD ▪ For small companies: Securing enough money to be able to provide investment pitch data points	▪ Cleary quantifying the benefits in the business case ▪ Developing a scalable product combined with an endurant organization ▪ For small companies: getting access to Vinnova and/or incubator programs
Access to reimbursement	▪ Find reimbursement system for solutions allowing new patient pathways ▪ Inconsistency across reimbursement systems	▪ Ensuring at an early stage that the product is reimbursable ▪ Setting a flexible reimbursement model adapted to the customers' needs ▪ Careful consideration of market suitability based on reimbursement

6.1.1 **Regulatory Compliance**

Ensuring compliance and becoming certified under MDR was described as a challenging task by most interviewees and especially by the smaller companies. Many describe that the regulatory aspect makes the development and innovation process long and more expensive, although it is not described as a full-scale barrier or showstopper. In addition, regulatory requirements are, especially for the smaller companies, challenging to interpret and navigate. With AI included in the device, this becomes even more challenging as there is a limited degree of consensus between regulatory bodies on how to interpret the relatively new MDR for this new technology, and in some cases, health authorities also lack the required competence. In addition to this, the AI Act will most likely be introduced and enter into force in 2024, putting more requirements and pressure on compliance for AIMD innovators. Multiple interviewees highlighted that they underestimated the work needed, and started with the regulatory work, and specifically the technical file, too late impacting the development process.

To mitigate this challenge, several interviewees, both companies and industry organizations, mentioned early planning based on regulatory requirements and early involvement of regulatory expertise. A number of companies having successfully developed and launched AIMDs, stated that they got in contact with specialized QA/RA consultants early, got a few hours with support, and eventually hired the right competencies with assigned QA/RA personnel. This enabled an efficient certification process.

Another key aspect of compliance highlighted in the interviews is related to developing sufficient – *as per the regulatory requirements* – clinical evidence and proving the performance and safety of the AIMD. Required for medical devices by many regulatory authorities, this was described as especially challenging for AIMDs under MDR. One interviewed industry organization explained it as follows:

> *It is challenging for a company to prove that the product is safe to use when the algorithm can't be explained due to the "black box" effect. The surrounding environment of the device will probably affect the performance, but how? If a clinical study is done in one hospital, how can the company ensure it works in the next hospital?*
>
> - *Industry Organization*

To address this challenge, another industry organization highlighted the need for extensive clinical studies. Their recommendation was based on an observation of a Swedish research study where approximately 40 000 patients were involved to prove the clinical safety and performance.

Another approach mentioned during the interviews, to decrease the regulatory requirements and get the product to market faster and with less effort, is to side-track MDR and release the device outside of the EU, on markets with less strict and extensive requirements and regulations. The US frequently came up during interviews as an attractive market in this context. The US FDA was described as "less complicated" than the EU MDR. Other markets, for example, the Middle East, were mentioned in one interview as a potential first market.

An overview of the observed challenges and success factors is shown in Table 6.2.

Table 6.2. Observed challenges and success factors to achieve regulatory compliance.

Challenges	*Success factors*
▪ Regulatory uncertainties, impeding efficient interpretation of regulatory requirements ▪ Underestimation of work needed, starting too late ▪ Perceived mismatch between new AI technology and regulatory requirements ▪ Developing sufficient – as per the regulatory requirements – clinical evidence	▪ Early planning based on regulatory requirements ▪ Early involvement of regulatory expertise, external or in-house ▪ Performing extensive clinical studies to gather sufficient clinical evidence ▪ Releasing the device on markets with less extensive regulatory requirements

6.1.2 **Understanding User Needs**

Understanding the markets' and clinicians' needs and requirements was the second most frequent challenge brought up in interviews. This is also a challenge that can apply to many types of medical devices but becomes especially challenging with AIMDs as AI innovations in many cases are sprung from a technological viewpoint. According to one of the interviewed clinicians, this means that innovators have limited insight into the clinical setting. One of the interviewed industry organizations explained that several companies providing AIMDs are unaware of the misalignment between the device function or performance, and the actual market need. They believed this to be the root cause of why some AIMD companies fail to ramp up sales, get investments, and ultimately succeed.

> *If the user needs are not clearly defined and if the innovation does not solve a clear problem, the innovation is deemed to fail.*
>
> - *Industry Expert*

Evident by both innovating companies and clinicians, is the importance of establishing a collaboration between the innovating company and clinicians and university hospitals. Involving clinicians early in development facilitates innovating solutions that are tailored to the real needs and essentially generates a solution that is desired.

Ultimately, having clinicians or people with a clinical background in-house was considered a success factor by both companies and clinical users. In addition to enabling a robust understanding of the actual clinical need, this strengthens reliability and enables a more focused communication.

Another strategy highlighted during the interviews was to perform a pre-validation, or an early proof-of-concept, in a safe clinical setting to confirm that the device addresses the observed user need, enabling a pivoting of the device functionality or performance and increasing the chances for success.

An overview of the challenges and success factors that were identified during the interview study is presented in Table 6.3.

Table 6.3. Observed challenges and success factors to understand the user needs.

Challenges	***Success factors***
▪ Understanding user needs and requirements	▪ Establishing collaboration between the innovating company and clinicians, or having clinicians / clinical background in-house ▪ Involving clinicians early in the development ▪ Performing an early proof-of-concept study to confirm that the device addresses the observed user need

6.1.3 **User Acceptance**

As with most medical devices, the target users for AIMDs are either physicians or patients. During the interviews, it was highlighted that physicians often place high requirements on sufficient evidence that the product works as intended and that it brings significant value to the user to accept a specific AIMD. One interviewee highlighted that – as AI is a new emerging technology and the healthcare system in general is change resistant – it is key to be able to show *quick* results to ensure acceptance. The interviewee further suggested that this could be performed through one or more pilots of the device in clinical settings.

As the adoption of AIMD in many cases requires updates to processes, engaging Key Opinion Leaders (KOLs) that support the acceptance and drive the change was also brought up as a strategy. Interviewed clinicians suggested that acceptance could be achieved utilizing a site-specific validation in which they were able to perform a quick validation at their clinical based on their specific patient population, also continuously as the device is updated. Other interviewees mentioned the acceptance hurdle could be overcome by using clinical data and evidence from peer-reviewed independent research.

Another challenge frequently mentioned by interviewees is that clinicians have limited time to partake in the verification and validation testing of new AIMDs, as required to gain acceptance. A general success factor is hence to ensure *efficient* verification and validation planning and processes. One interviewed company solved the dilemma by employing a general practitioner whose only focus was to use the company's AIMD on patients in the clinic (with consent to take part in the testing). By doing this, they managed to show the product's performance and safety by gathering data in the right clinical setting, without requiring extensive efforts from hospital employees.

In addition, users also place unique requirements on AIMDs related to training data transparency and accuracy. Clinicians request to see what data the model has been trained on, to understand whether it applies to their specific patient population. However, this data is the developing company's secret as to why the algorithm performs the way it does. Finding a balance in how much information regarding the training data of the model that should be displayed, posed a great dilemma for many of the interviewed developing companies. One way to overcome this dilemma is to provide statistics on the data that is used for the training to show that the data represents the patient population.

All identified challenges and success factors to gain user acceptance are summarized in Table 6.4.

Table 6.4. Observed challenges and success factors to gain user acceptance.

Challenges	***Success factors***
▪ High requirements on sufficient evidence performance and value ▪ Resistance to the change that AIMDs brings ▪ Limited time for clinicians to partake in verification and validation ▪ Requirements from users on transparency and accuracy of training data	▪ Finding ways to show quick results, through e.g., a Pilot ▪ Identifying and engaging KOLs to drive change and acceptance ▪ Having clinical evidence from peer-reviewed independent research ▪ Finding efficiencies in verification and validation planning and execution ▪ Finding a balance in the disclosure of training data using e.g. statistics

6.1.4 **Data as the Key Component**

Several challenges related to data were highlighted during the interviews, and it regards accessing large amounts of representative data, the risk for bias, curating data, and transferring data.

Access to large amounts of representative data and bias mitigation

Obtaining access to relevant and representative clinical data poses a significant hurdle for AIMD-developing companies. The main reason for this is said to be that the system is designed to protect individual patients, and the data is often confidential and protected. The dataset needed when developing AI algorithms for medical devices needs not only to be large, but moreover, it must represent the patient population. Finding a balance between data on healthy subjects versus data on subjects with specific diseases poses a great challenge for many of the interviewed companies. One interviewed company developing a device for real-time image interpretation further explained this challenge:

> *The initial data gathering was done on our employees, which gave us data on healthy measurements. This data was used to perform an initial proof-of-concept study, but we needed data from sick patients as well. We managed to get approval for conducting research in an emergency room in Sweden, but all the patients that were scanned were light-skinned, which is why we couldn't use only this data to train the model, or we would get a biased algorithm. The next step is to collect data from a more diverse population.*
>
> *– Medical Device Company*

To overcome this hurdle, several companies collaborate with clinicians or clinical researchers to access the data needed to develop the model. One company set up agreements with several hospitals to access the data for free but paid only a licensing fee if the data was used in the AI model, as a cost-efficient strategy to access data.

Conducting research as a part of product development was also noted as a strategy to retrieve data. By initiating a research project, companies could more successfully collaborate with hospitals, and these companies also had the competence and know-how to curate and synthesize data effectively to mitigate bias in the algorithm.

Another strategy applied by a company without a network of clinicians in the Nordics was to collect data overseas, to move forward in product development despite lacking data. The company further explained that some countries have lower requirements for collecting clinical data and performing clinical trials, and in some

cases, this can be exploited. To avoid bias, collecting data from multiple countries was also considered a success factor by some actors.

The last strategy mentioned by the interviewees is starting with a beta version of the device that is "good enough" to be used, but not as good as ultimately desired. The purpose of this strategy is to get the product out on the market to collect data while the product is in use. The target is to use the collected data to further improve the algorithm so the device can be updated with, for example, higher accuracy or additional claims. The interviewed company also mentioned that there are certain risks associated with this strategy, such as not gaining reliability from the customer if the product does not have the optimal function, and that there are certain challenges with obtaining the data that the device has collected in clinical settings due to regulations.

Data curation and transfer

Processing of obtained data is a time-consuming task, involving cleaning and anonymization of data to meet regulatory requirements and to control what the AI reacts upon. One of the interviewed companies working with image interpretation for the detection of skin cancer mentioned that they noticed during data curation that some of the collected images contained band-aids, and by chance all images containing band-aids had cancerous lesions. Therefore, they had to modify (crop) the images manually to exclude the band-aid from the picture, or else the model would assume that a band-aid in the images was an indication of cancer.

While data curation is not a showstopper, underestimating the time required for processing data can affect the development timeline and impact the algorithm and device performance. An AI researcher from academia emphasized that collecting extensive information around a smaller data set and curating smaller qualities is more effective than accessing larger and unstructured data sets.

To transfer collected data from the device to the developing company, and to transfer new data into the device while it is in clinical use, was also highlighted as a challenge from multiple actors. This is mainly due to data transfer restrictive cloud usage and data protection laws in healthcare. One of the large companies interviewed, highlighted data transfer as one of their major challenges currently, as they wanted to be able to update their algorithm when needed, but also monitor the device performance remotely.

A strategy to overcome this challenge is to let the developing company access the collected data remotely without essentially transferring it. Another small company had adapted to their customer's local data storage solution and delivered a physical hard drive when updates were made. The company acknowledged the ineffectiveness of this strategy but explained that it was the only way to make the transfer as of now.

The identified challenges and success factors related to data as the main component are shown in Table 6.5.

Table 6.5. Observed challenges and success factors related to data.

Challenges	*Success factors*
▪ Obtaining access to large amounts of representative data ▪ Avoiding bias ▪ Time-consuming to curate, validate, and process data ▪ Transferring protected and confidential data between the device to the developing company	▪ Finding an effective size of the data set needed to avoid extensive curating ▪ Finding ways to access the needed data without transfer, e.g. through remote access ▪ Collaborating with clinicians or clinical researchers ▪ Initiating research projects in parallel to the product development ▪ Collect data in (several) markets with less stringent requirements ▪ Start with a beta-version, use in-use data to further enhance the AIMD

6.1.5 Systems Interoperability

Integrating new solutions and systems into the already existing ones is in many cases how AIMDs are implemented. However, this was described as challenging by both small and larger companies since different systems are used in healthcare and clinical settings. This makes it difficult, or even impossible, for companies to create one solution that can be implemented everywhere.

Some interviewed clinicians mentioned that successful strategies for effective AIMD implementation include having a whole-system perspective and paying attention to the full system, rather than the specific process the device operates in. In this sense, it is important to have a flexible system that can fit into the larger system. However, this is no easy task as developing a flexible system was expressed as challenging by both innovating companies and industry organizations. According to an AI researcher, a better strategy can be to optimize the model to specific conditions on one or a few sites, rather than trying to develop a generalizable product for multiple occasions.

The observed challenges and success factors for system interoperability are presented in Table 6.6.

Table 6.6. Observed challenges and success factors related to system interoperability.

Challenges	*Success factors*
▪ Ensuring interoperability with existing systems	▪ Developing a flexible system (which can in turn be challenging) ▪ Optimizing the model to a selected number of specific conditions, rather than making it generalizable

6.1.6 Access to Funding

Getting investments was described as a common challenge for most of the interviewed companies. One of the industry actors explained that investments are challenging for medical device companies, as the payback time usually is long due to the extensive development cycles. However, the industry actor had observed even further challenges for AIMD companies attempting to secure funding. The actor mentioned that as the use of AI in healthcare is relatively limited, there is a larger uncertainty from the investors' side as to whether the product will succeed or not.

For smaller companies, this is specifically challenging as investors often want to see some revenue, prototypes, certifications, or IP before investing, while funding is needed to come to that stage for a startup company. This catch-22 is partly expressed in the quote below by the CEO of an early-stage AIMD innovating company.

> *Funding is the most challenging part and our biggest pain. The investors want to see revenues to invest, but we need money to develop, test, and launch the product.*
>
> *– Medical Device Company*

Evidently, no interviewee provided an easy solution to the funding problem, but some strategies were mentioned to mitigate the hurdle and improve the odds of receiving investment. Several actors mentioned that it is important that the business case is proven and quantified through e.g., health economy calculations. There must be economic gains for the user by implementing the AIMD, and this should be shown to the investor, and it can also be used at a later stage to attract customers.

Furthermore, having a scalable product was also explained as a success factor by one of the larger companies. However, this actor mentioned that even though the product needs to be scalable, it is important to be endurable and not grow too fast. It was considered more important to have a few successful implementations in the beginning to ensure long-term viability.

Several actors also mentioned the Swedish Innovation Agency Vinnova as a potential source of early investments for start-up companies, and incubator projects were mentioned as ways to get support in the early funding process.

The identified challenges and success factors to access funding are shown in Table 6.7.

Table 6.7 Observed challenges and success factors to access funding.

Challenges	*Success factors*
▪ Long payback time combined with uncertainty regarding AIMD ▪ For small companies: Securing enough money to be able to provide investment pitch data points	▪ Cleary quantifying the benefits in the business case ▪ Developing a scalable product combined with an endurant organization ▪ For small companies: getting access to Vinnova and/or incubator programs

6.1.7 **Access to Reimbursement**

As AI allows for healthcare outside the traditional patient flows (e.g. remote care), several actors mentioned a challenge to find a reimbursement model for the product that was accepted by the targeted customers. Three of the four actors that highlighted reimbursement as a challenge developed a remote monitoring system, and the fourth actor represented an industry organization. The developing companies emphasized that it is important to ensure reimbursement possibilities for the product early on, or else the product offering needs to be adjusted to allow for sales.

According to one interviewee, the Nordic healthcare structure with primary regional responsibilities for healthcare further complicates access to reimbursement. The interviewee suggested that since there is no clear national guideline on how regions should use and reimburse remote solutions, separate reimbursement solutions are sometimes needed for different regions. Therefore, it was suggested to pay special attention to how the business case can be structured around the product, to secure a flexible set of reimbursement possibilities for different regions.

The most frequent success factor mentioned in interviews was to launch the device in the US market, where they have a more beneficial reimbursement model for remote patient monitoring, specifically. In addition, the US was described as more unified with terms and conditions compared to the more fragmented Nordic and EU markets. However, it was also highlighted by an AIMD company that there are benefits to launching in the home market over the US due to more personal connection in the home market and a broader understanding of the market dynamics.

Therefore, careful consideration of what market suits the company and its product should be made.

A summary of all identified challenges and success factors mentioned during the interviews connected to access to reimbursement is presented in Table 6.8.

Table 6.8 Observed challenges and success factors to access reimbursement.

Challenges	*Success factors*
▪ Find reimbursement system for solutions allowing new patient pathways ▪ Inconsistency across reimbursement systems	▪ Ensuring at an early stage that the product is reimbursable ▪ Setting a flexible reimbursement model adapted to the customers' needs ▪ Careful consideration of market suitability based on reimbursement

6.2 Segmented Challenges

To get a deeper understanding of how different characteristics of the product and the company impact the challenges, this analysis aims to find patterns based on risk classification, product type, and company size. In this part, only the innovating companies are part of the results, which excludes the 16 interviews from academia, industry organizations, and clinicians.

6.2.1 **Risk Classification**

With challenges divided on risk classification, data, and regulatory aspects are represented in all categories. However, the company developing a medical device in risk classification I did not experience the same magnitude of regulatory challenges as most of the other companies in higher risk classes. The interviewee who developed a class I device stated that this might be because class I device manufacturers can self-certify, in opposite to higher risk classifications. This person stated that the technical documentation needs to be updated and provided to regulatory bodies on request, which is why the regulatory aspect was still considered as a challenge. Understanding the requirements and providing extensive documentation were noted as the main challenges under the regulatory aspect for the classification of I company.

Moreover, user acceptance was only described as challenging for companies with products in risk class IIB. One company developing in that risk classification

expressed a need to explain the accuracy of performance to clinicians to prove product safety. This was explained by the higher level of risk that the patient is exposed to, thus the higher risk classification. As the clinician wants to mitigate the risk that the patient is exposed to, he or she requires to see more evidence of the risk-mitigating actions. User acceptance was challenging to gain as artificial intelligence is unfamiliar to many, and there was no standard way of examining the risk in the hospital according to one of the interviewed actors.

Systems interoperability was identified as a challenge for classification IIA and IIB, but not I. This can be explained by the fact that the interviewed class I company provided a system directly to the patient and did not need to integrate the device into clinical practice. Therefore, the financial barrier to release the product, was not as high for the company in classification I as for the higher risk classifications, as the cost of certifying through a notified body and providing evidence for user acceptance was not needed. However, finding a suitable reimbursement system was noted as a challenge for this company.

Note that there was only one company in risk class I, but the observations have been supported by three industry organizations.

A segmentation of challenges depending on the risk classification of the device is presented in Table 6.9.

Table 6.9. Challenges segmented by risk classification according to EU MDR

Challenge (# interviews)	*Risk classification I (1)*	*Risk classification IIA (7)*	*Risk classification IIB (4)*
Regulatory Compliance	x	x	x
Understanding User Needs		x	
User Acceptance			x
Data as the Key Component (incl. bias mitigation)	x	x	x
Systems Interoperability		x	x
Access to Funding		x	x
Access to Reimbursement	x	x	

6.2.2 **Product Type**

With the challenges divided on product type, all categories expressed data and regulatory aspects as challenging. Data curation was only emphasized as a challenge by radiology companies and image interpretation companies. In interviews, it was elaborated on the extensive curation work needed for these images.

All product types raised concern regarding the challenge of understanding user needs and access to funding, except for companies providing devices within the radiology area. Several of the interviewees mentioned that AI has come furthest within radiology applications in healthcare, and one of the interviewed actors claimed that this was due to the improvements that AI provides within the area. It is unclear whether the evident need for AI is the reason why these companies are the only ones that have not stated access to funding as a challenge.

Furthermore, reimbursement was only highlighted with remote monitoring. The CEO of a remote monitoring company expressed that there currently are no proper

reimbursement systems for digital preventive care. All challenges identified for each of the studied product types are presented in Table 6.10.

Table 6.10. Challenges segmented by product type

Challenge (# interviews)	*Image interpretation (4)*	*Radiology applications (3)*	*Remote monitoring (4)*	*Signal interpretation (3)*
Regulatory Compliance	x	x	x	x
Understanding User Needs	x		x	x
User Acceptance	x			
Data as the Key Component (incl. bias mitigation)	x	x	x	x
Systems Interoperability	x	x		x
Access to Funding	x		x	x
Access to Reimbursement			x	

6.2.3 **Company Size**

With differences in challenges based on company size, the small-sized companies represent all challenges, while the larger companies did not mention user acceptance, access to funding, and reimbursement as challenging. For many of the smaller companies, however, funding was described as the largest barrier to overcome. One of the large companies that was interviewed described that since they have a well-known brand name, the company has a reputation which makes other actors want to collaborate. Thus, the brand name enables easier user acceptance.

Furthermore, the fact that reimbursement was not stated as a challenge by the large companies can be explained by the fact that only one of the five large companies developed remote monitoring devices. This company developed a remote medical device to monitor patients participating in clinical trials, and therefore the plan was to reimburse the device with the company's budget and thus avoid the challenge of

getting external reimbursement. See Table 6.11. for segmentation of challenges dependent on company size.

Table 6.11. Challenges segmented by company size

Challenge (# interviews)	*Small (9)*	*Large (5)*
Regulatory Compliance	x	x
Understanding User Needs	x	x
User Acceptance	x	
Data as the Key Component (incl. bias mitigation)	x	x
Systems Interoperability	x	x
Access to Funding	x	
Access to Reimbursement	x	

7 Discussion

This chapter consists of a discussion of the research findings in this thesis in relation to previous research, as well as the generalizability of the research in a Nordic and European context. The research findings and literature are compared in a gap analysis to find similarities and identify differences. The generalizability provides a comparison between the Nordic countries concerning market structures and whether the result can be applied broader in Europe.

7.1 Gap Analysis

After conducting a literary review and interviews, some similarities and differences have been observed regarding challenges and success factors for artificially intelligent medical devices. In general, most challenges found in the literary review were also brought up during the interviews, although some found in the literature were not mentioned in the interviews and some brought up in interviews were not found in the literature.

7.1.1 **Regulatory Compliance**

Regulatory compliance is shown to be a challenge in both literature (Medical Device and Diagnostic Industry 2021) and during interviews. Both studies show that the regulatory process is both time-consuming and expensive, and it is evident that companies struggle to interpret what the regulatory requirements are. Furthermore, the challenge of developing sufficient clinical evidence due to the black-box effect is also agreed upon by both studies.

The perceived mismatch between AI and the regulatory requirements was highlighted in the chronicle by Mats Högberg (2023) but was not mentioned in any research studies. Nevertheless, the mismatch was also highlighted during the interviews.

However, separate approaches on how to become regulatory compliant were found in literature and interviews. The reviewed literature suggests limiting the complexity of the AI to be able to provide explainability and causality to show how and why

the algorithm makes a certain decision, to enable a more traditional certification process. The interviewers did not portray this solution, but rather emphasized the importance of early planning and early involvement of regulatory expertise, which the literature did not highlight.

Whether the regulatory threshold is lower in other jurisdictions compared to the European is not confirmed in the reviewed literature but is however a statement that was brought to light during interviews.

7.1.2 Understanding and Meeting User Needs

It was highlighted in both literature and through interviews that understanding the needs of the users or "market knowledge" is of high importance. In the literature, companies that did not come from a medical research background experienced a lack of guidance from healthcare professionals which made it challenging to develop tailored solutions (Apell and Eriksson 2023).

To address this, both literature and interviews agree that collaboration is needed between the developing company and clinicians. In interviews, it was clarified that collaboration can also happen in-house if clinical expertise is acquired in the company. The purpose of the collaboration was to exchange information to understand the needs and requirements of the user side, and to ensure that the developed product answered the identified needs.

In interviews, it was suggested to perform an early proof-of-concept study to confirm that the device addresses the identified user needs. This was, however, not an observed strategy in literature.

7.1.3 User Acceptance

When comparing the challenge observed in literature and interviews, one difference was identified regarding the targeted user. In the literature, emphasis was put on getting acceptance from the patient (You et al. 2021), while interviews focused on getting acceptance from the clinicians. This might be a result of the product type that is considered if the device is sold directly to patients or clinicians.

The literature suggested that one major challenge for user acceptance was that the patient had limited comprehension of the algorithm. Therefore, the suggested solution in the literature was to use explainable algorithms to gain acceptance (Camaradou & Hogg 2023). Another concern by patients found in the literature was the perception that AI in healthcare would lead to fewer human interactions. However, it was evident by all experts in interviews that AI in contrast will be essential to improve the efficiency of care and be able to meet the increased need

and pressure on healthcare personnel. By automating routine tasks, clinicians will be able to spend more of their time with direct human interaction.

In interviews, the focus was on getting acceptance from the clinicians. One of the main identified challenges was the high requirements for sufficient evidence of performance and added value. In interviews, it was understood that if doctors trust the product and recommend it to a patient, the patient will rarely have concerns regarding the decision.

However, it was apparent that the CE marking is not enough for clinicians to trust an AIMD innovation, but transparency regarding the accuracy of training data is needed. The transparency concern is also touched upon in the literary review in the context of symptom checkers (You et al. 2021). Although the study was based only on consumer-facing health technology, the responses were similar to the interview study. Participants in the study wanted to know some information about where the data that determines the diagnosis originates from. The transparency information could include statistics of how many hospitals, or medical records the application in this case used, for example.

The same issue was formulated in the interview study, along with some associated mitigation strategies. The concern expressed was largely related to how the algorithm was trained and its accuracy. To meet these concerns, strategies communicated were to provide some transparency and disclosure of the training data, have accuracy metrics of the diagnosis or recommendations, and have independent and peer-reviewed research that supports the claims.

Through interviews with regional hospitals in Sweden, it was also understood that clinicians and doctors have limited time to test and validate innovations. No explicit strategies were found in the literature for companies to overcome this, but in interviews with clinicians, the main message was to lower the threshold. This includes enabling hospital personnel to easily test and collaborate with new products, as well as showing clearly how the product would create immediate value. Approaching clinicians in an early stage with a complex product that is non-intuitive to test might be difficult as time is a limited resource. One strategy mentioned by a company in this situation was to fund a clinical nurse for testing and therefore not create an extra workload. If applicable, this could be a useful strategy.

7.1.4 Data as a Key Component

The first part of the discussion regarding data concerns accessing high-quality data, the second part regards curation and transfer of the accessed data, and the third part discusses the risk of bias and how to mitigate it.

Access to high-quality data

With data access, the challenges were formulated similarly in literature and by most interviewees, with data liabilities and privacy concerns at the core, but also since data for one purpose cannot be "re-used" for a different purpose. In the literature, it was evident that companies founded by medical researchers did not experience the same challenges concerning data access (Apell & Eriksson 2023). This was also found in the interviews, where innovators from a medical research background demonstrated far less concern regarding data access. A successful strategy to access data can therefore be to collaborate closely with medical researchers.

Curation and transfer of data

Furthermore, data sharing was also found to be a challenge in literature with few standards for data sharing between systems, which makes it difficult to integrate AI algorithms in workflows (radiology workflow in the literature example, Kotter & Ranschaert 2021). In interviews, the aspect of data sharing was described as an issue by some actors and the concerns stem from the same privacy concerns as with data access. This is making it difficult for hospitals and clinicians to use remote cloud solutions, which is putting higher demands on AIMD companies to find local solutions where the data does not leave the physical hospital walls. In practice, this can imply a need to develop and integrate separate systems for each hospital with a local data storage and transfer solution.

Regarding data curation, some recommendations were found in the literature study on how to manage missing and unstructured data. These include assessing whether results can be used without missing data if possible and if results cannot be used even with curation, an assessment should be made to determine if an investment to collect new data afterward is motivated (Zemplényi et al. 2023). These strategies were found in a broader health technology context, and not explicitly for medical devices, but the findings might still be applicable. These specific strategies were not mentioned in interviews, where no strategies were found except having a realistic view of how much time and effort data curation work usually requires.

Risk of Bias

The risk of bias in AI-based models is well documented in the literature and is highly connected to data (Mittermaier et al. 2023). The data a model is trained on will be the basis of what comes out of it, and therefore accessing high-quality data, transferring, and curating it effectively will be pivotal. It is also important to be aware of what potential bias an algorithm can have built in to mitigate the effect, which was apparent both in the literature and in interviews with AI experts. In literature, mitigation strategies include pre-screening data through sampling before building the model and incentivizing it to learn balanced predictions through implementing mathematical methods (Mittermaier et al 2023). These strategies were not mentioned explicitly in the interviews, where the mitigation strategies evolved around collecting high-quality and diverse data, and actively working to access data from underrepresented groups.

7.1.5 System Interoperability

The discussion of training the algorithm to become generalizable and applied broadly versus using more specific training data for a slim application was found in interviews, but not in the reviewed literature in the context of interoperability. Although there are no direct answers to this question, interviews with clinical personnel displayed the importance of interoperability, where it is principal to optimize the model to fit specific conditions on each site. As IT systems and routines can look very different in different hospitals and clinical settings, having an algorithm that can be targeted to these specific conditions will essentially be important.

7.1.6 Access to Funding

Access to funding was evident in both the literature review by Apell & Eriksson (2023) and with most actors interviewed, especially the innovating companies. Some actors described that funding is the absolute largest challenge that determines the success or failure of the company. Expressed both in literature by Vegas & Felman (2023) and by interviewees, is that the unwillingness to invest in AIMD projects is related to the high uncertainties and lack of evidence, but also the long time to market that characterizes the overall MedTech industry. Some success factors were identified in the literature and the interviews. In the literature, different criteria were found which investors assess when considering an investment. The criteria include team quality, proven demand from the market, and intellectual property (Vegas & Felman 2023). Meeting these criteria can be identified as a success factor. These criteria were not stated in interviews however, where the success factors highlighted were to quantify the benefits in the business case,

develop a scalable product for smaller companies, and get access to early funding through innovation agencies and/ or incubator programs.

The literature regarding investments comes from an investor perspective while the success factor in interviews comes from a company perspective, which naturally explains the different angles. Combined, the investor perspective, with for example proving a real demand, can be a reason some companies struggle with investments. Thus, a problem receiving investment can be rooted in a problem of understanding the real needs and it might therefore not be solved with a funding plan. Therefore, a success factor for companies struggling with investments in an early stage can be to tailor the innovation more to proven market demands and communicate how the product will meet the needs.

Expanding to the US was also evident in literature by Vegas & Felman (2023) but for a different reason. From an investment perspective, the US was described as the most attractive market for HealthTech companies, and that market expansion to the US for Nordic companies benefits attraction of investments. In the interview study, a CEO of an innovating company in an early stage mentioned that they were having discussions with collaborative partners in the US. He stated that the high valuations investors have there are lucrative. However, the team decided to launch in the Swedish market nonetheless as they know their home market better which for example enables closer collaboration.

7.1.7 Access to Reimbursement

Reimbursement was regarded as a challenge by four interviewed companies but was not found in the reviewed literature. This challenge was explained to be especially evident when AIMDs change the workflow and the existing reimbursement system cannot be used, for example with digital preventive care. Since system changes take a long time and collaborating with the public sector can be difficult in a decentralized system, one success factor mentioned in interviews was to launch in markets outside the Nordics. The United States was frequently brought up by companies and industry organizations as a promising market with more favorable reimbursement systems, especially for remote monitoring.

7.1.8 Challenges to the Diffusion of Innovation

Innovation can be studied from a systems perspective, where Dogson et al. (2013) state that a system can be “locked” into a certain path of development. Policymakers and other actors that affect the path have important roles in enabling innovation and this can be seen as especially important with artificially intelligent medical devices. As the medical device industry is heavily regulated in the EU, and new regulations for AI are expected to be put on top of this with the AI Act, finding paths to introduce

more beneficial innovations will be pivotal. This also goes for the user side, where systems need to be put in place to find settings where innovations can be tested, and collaborations can be established. In interviews with clinicians, the need to find structures to test, validate, and implement AIMD innovations was evident. In some Swedish regions, competence centers are being established to enable this collaboration and similar initiatives would most likely be needed to speed up the adoption rate.

Among the variables that determine the rate of adoption, according to Rogers' famous innovation theories (Rogers 1995), AIMD characteristics can be perceived as relatively disadvantageous for a high rate of adoption. Among the perceived attributes, the relative advantage can be high since AI technology enables more time- and cost-efficient care, although the compatibility with existing systems can be low with regards to challenges with interoperability. Furthermore, the devices are often complex, and trialability and observability can therefore be difficult. This puts a higher demand for innovators to strengthen these perceived attributes, for example by enabling compatibility with existing systems by having a whole-system approach and not viewing the product in isolation. To lower the perceived complexity, there is a need to make the product more intuitive, and by performing early proof-of-concept, the trialability and observability can be improved.

Moreover, the adoption rate is also impacted by the type of innovation decision. With a collective or authority innovation-decision, for example, when a whole region or nation determines to procure a medical device, this will speed up a fast innovation rate. The S-curve will then get a very steep curve. If the decision is optional, for example when adopted by individual private actors, the diffusion might become easier to start, as attracting single private actors can often be easier than agreements with an entire region through public procurement. However, the s-curve will most likely not become as steep as with a collective decision to adopt an innovation, since there will be only one deal at a time.

7.1.9 **Segmented Challenges**

The segmented challenges showed some differences regarding product types, risk, classification, and company size. However, the patterns were not very distinct, and it can therefore be difficult to make any distinct conclusions.

The main differences with risk class were only evident when accounting for how pressing the regulatory challenge was, and not only whether it was a challenge or not. For the company with the lowest risk classification (IA), the regulatory aspect was considered a challenge, but it was not considered a very pressing one and it did not act as a bottleneck for further development. For the innovations in the

highest risk classification (IIB) on the other hand, the regulatory aspect was described as an absolute bottleneck that would determine success or failure by multiple interviewees.

Regarding product type, the most distinctive difference between the categories was that reimbursement only was described as a challenge for remote monitoring. This can be explained by the change in workflow that comes with remote monitoring solutions, where the compensation system is adopted for patient listings or patient visits. Although AI solutions can bring disruptions to the current systems with the other types as well, this challenge might be most apparent when the patient and the care provider do not need to be in the same location, which remote monitoring enables.

When dividing the result based on company size, the findings were that the larger companies did not experience the same difficulties with funding or user acceptance. This was expected as the larger companies have extensive internal capabilities and financial resources, and often long-term collaborations with research hospitals. The latter implies that they might not have to go through the difficult process of getting initial contact for collaboration with clinicians. However, understanding user needs was still mentioned as a challenge even for the larger companies, which implies that a closer partnership might be desired, nonetheless.

7.2 Suggested Framework to Overcome Challenges

Based on the findings from the analyzed literature and the interview study, a framework was crafted to guide companies to mitigate the most common challenges when innovating an AIMD. The concluded framework is shown in Figure 7.1. The framework is divided into six focus areas, where the headline concludes with a success factor that can be used to mitigate the mentioned challenges. The success factors in the figure are strategic regulatory planning, clinical collaboration, and evidence generation, agile market entry and user-centric validation, efficient data management and model optimization, business viability and reimbursement strategy, and agile development and scalability. The sub-strategies provided under each category were found to be the most effective ones to address the identified challenges from the research.

Figure 7.1. Framework on strategies to respond to the most commonly identified challenges that occur for companies that innovate AIMD.

Innovating companies can apply this knowledge to mitigate some of the most pressing challenges within AIMD innovation. By applying strategic regulatory planning, interpretation can be supported, as well as gaining a realistic time plan. It can also support in developing a sufficient plan for how to collect the regulatory required clinical evidence, which was also highlighted as a challenge.

By collaborating with clinicians during the whole process of development, from early need identification to implementation, the user needs are possible to understand, and sufficient evidence will be generated more easily.

Moreover, the market entry needs to be done strategically. The primary market needs to be decided upon by consideration of market-related requirements, and knowledge or network in the market. Furthermore, the targeted user in the market needs to be the center of the validation process to understand how the proposed device solves the problem for the user.

The data needs to be handled efficiently to optimize the model. This implies obtaining an optimal amount of representative data for targeted conditions to be able to mitigate bias without spending extensive time on curating unusable data. The data management also needs to consider data access and transfer solutions that are suitable for the product and the system.

The business perspective and connected reimbursement strategy are also important to highlight. The benefits of the device should be quantified, and a reimbursement strategy should be adopted early in relation to the targeted market.

Lastly, the development needs to be agile, with a flexible and scalable product. The product development should be iterative, and the company can consider launching an initial beta version to gather market opinions and data before the complete product is finished.

By following these six recommendations, the most common challenges can more easily be mitigated.

7.3 Generalizability

7.3.1 **Differences in the Nordics**

The results derived from the interview study with innovating companies do not show any distinct differences between the Nordic countries. In addition, industry experts could tell only a few vague differences. As all markets go under the same EU regulations and have similar structures with mostly public spending, this is expected. However, some differences were found in terms of investors' focus when investigating the market structures in chapter *3.1.1 Demand Side*, where Swedish, Norwegian, and Danish investors were found to invest more focused on digital health and MedTech, compared to investors in Finland and Iceland that were found to invest more broadly in health. From this investment perspective, Sweden, Denmark, and Norway seem to be the most advantageous countries to attract funding for AIMD innovations.

Furthermore, some differences in the respective countries' healthcare systems could potentially favor some markets over others, and this has to do with the type of innovation decision in relation to the diffusion of innovation. For example, Finland and Iceland are found to be more centralized than Sweden and Denmark, with Norway between. A more centralized healthcare system could potentially favor a more collective innovation decision, thus enabling more harmonized integration. Another benefit would be easier optimization of the model for more conditions, rather than adopting separate integrations for each site. Nevertheless, a larger market is favorable for a faster scaling and therefore Iceland might be less attractive than Sweden despite the more centralized structure.

Moreover, it has been evident in interviews that public procurement processes are demanding, and therefore targeting private actors can be beneficial for faster diffusion. This would be related to an optional innovation decision. Between the Nordic countries, the different potentials for privately funded care can be demonstrated in the share of "out of pocket" (OOP) spending and the share of public spending, which are summarized at the end of chapter *3.1.1 Demand Side*. Between the countries, Finland and Iceland have the largest shares of OOP spending at 16%,

whereas Sweden has the lowest at 13%. With public spending as a share of the total, Sweden and Norway have the highest rates at 86% with Finland at the lowest at 64%.

With the discussed market characteristics combined, Finland seems to be the most promising Nordic country in terms of market structure. With a centralized system, a substantially lower share of public spending, and a relatively high OOP spending, Finland theoretically seems like a more promising market compared to Sweden which is one of the most decentralized markets with the highest public expenditure and lowest OOP spending. However, this difference was not apparent in interviews where little distinction was made between the counties. Therefore, it is difficult to say how these structural differences affect the diffusion of medical devices in practice.

7.3.2 General Applicability in Europe

Although the study was performed in a Nordic context with mostly Swedish companies, the same regulations apply in the whole EU and therefore some findings from this master's thesis could potentially be applied in a broader EU context. In particular, the findings related to the regulatory aspect, but also challenges related to market knowledge and data. However, more studies of organizational structures and market differences would have to be made to draw any conclusions evolving the whole EU.

8 Conclusion

This final section presents the concluding results and answers the research questions. Further, the reliability and limitations of the results are presented, as well as suggestions for future research.

8.1 Concluding Results

The goal of the thesis was to answer the four questions presented in Chapter *1.4 Purpose and Research Questions*. These questions have largely been answered along with the results and are summarized in this part.

RQ1: What are the most common challenges for companies developing and introducing artificially intelligent medical devices on the Nordic market?

The main challenges identified in this study are regulatory compliance, understanding user needs, user acceptance, and data as the key component. Other challenges are systems interoperability, access to funding, bias, and reimbursement.

RQ2: How do these challenges differ depending on

- Product type (image interpretation system, signal interpretation system remote monitoring system, radiology supporting system)
- Product risk classification (following EU MDR)
- Company size

The segmented study of how challenges differ depending on product type, risk class, and company size shows smaller differences between the categories. The most distinct difference regards company size, where the larger companies did not express funding and user acceptance as barriers, whereas the smaller companies saw these attributes as major bottlenecks.

RQ3: Which success factors strategies can be used to overcome the most common challenges?

The concluding result is the proposed framework, consisting of the success factors divided into six areas according to Figure 8.1. below. The areas of success factors are divided into strategic regulatory planning, clinical collaboration, and evidence generation, agile market entry and user-centric validation, efficient data management and model optimization, business viability and reimbursement strategy, and agile development and scalability.

Figure 8.1. Framework on success factors that can be used to respond to the most commonly identified challenges that occur for companies that innovate AIMD.

8.2 Reliability and Limitations

The described procedures taken to ensure good research quality are described in section *2.1.1 Reliable Results* and are based on the criteria *credibility*, *transferability*, *dependability*, and *confirmability*. Nonetheless, research work always has its limitations, and this also applies to this thesis. The limitations of the conclusions are discussed in this section.

The *credibility* of the conclusions can be discussed in the context of data collection and scope. In this thesis, a relatively large scope was analyzed with a limited number of interviews, which could lower the credibility. If a larger number of interviews

were conducted, or if the scope was reduced, more precise conclusions could have been drawn from the material. Furthermore, the results of segmented challenges were uneven in some categories (for example risk classification) which lowers the credibility of conclusions drawn from that material.

In terms of *transferability*, the aim for the researchers was to include a wide range of companies, experts, industry organizations, and clinicians in a Nordic context for the results to be applied to multiple companies. Even though the distribution between the different interviewees was representative of the study with emphasis on the innovating companies, the distribution between nations became uneven. An overwhelming majority of interviews were with Swedish companies and most interviewees only had experience from working in Sweden. Therefore, the uneven distribution among the Nordic countries might have an impact on the conclusions and pose a risk that they cannot transfer as well to the other Nordic countries. For more representative data collection, more interviews should have been held with representatives from other Nordic countries.

Another aspect of transferability evolves how the research results can be transferred to actors outside the target audience and provide value. In this thesis, the target audience was stakeholders in the medical device industry, primarily the innovators of artificially intelligent medical devices. However, other parties in the industry might make use of the findings. For example, some challenges are related to industry structures with different interpretations of legislation and difficulties connecting with clinicians. These findings can be further studied and addressed from a systems perspective, to promote innovation within medical devices tailored to the needs of the healthcare sector. Additionally, some challenges and success factors discussed are relevant to a broader range of medical devices without an AI feature. Therefore, innovating companies within non-AI medical devices can make use of some of the findings.

Concerning *dependability* and *confirmability*, a weakness regards some degree of subjectivity in the analysis. For example, the qualitative interview responses were subject to interpretation by researchers and a weakness therefore relates to researchers' misinterpretations and potential bias. To mitigate this subjectivity, conclusions were based on several sources and validated with the supervisors. Despite this, other researchers might have come to different conclusions. Another weakness regards the potential biased view on AI from the interviewees given that all actors interviewed are working with AI technology with a genuine interest. Therefore, this group might have an overly positive view that does not reflect the general views. Although this aspect is difficult to mitigate since all interviewees volunteered to take part in this project, it can be important to bear in mind.

8.3 Contribution to Research and Future Research

This master's thesis has focused on challenges and success factors for innovating within the field of artificially intelligent medical devices, from the perspective of an innovating company. Since this is a relatively new area, only limited research is available, especially from the perspective of an innovating company in a Nordic context. Additionally, some gaps were identified in research on how to mitigate some of the pressing challenges that could be answered in this study. Therefore, this thesis contributes to increasing the knowledge within this field.

In interviews, significant interest from the clinical side to adopt this technology was identified to offer more efficient and safe care to patients. However, structural and organizational barriers are partly preventing the development. Further research could have this clinical perspective and explore how health providers can incentivize the development and deployment of AIMDs from a systems perspective.

Additionally, the new EU regulation on AI (called the AI Act) is expected to come into effect in 2024 which will impact AIMD innovating companies. Today, the implications of this regulation are unclear and therefore, further research could study how this will impact medical device companies and how to mitigate potential negative impacts.

References

Ameka, I. & Dhewanto, W. (2013). Technology Push vs. Market Pull in Technology University Innovation: Commercialization case study: ITB. *Information Management and Business Review*, 5(7), 337–341. doi: 10.22610/imbr.v5i7.1060.

Apell, P. & Eriksson, H. (2023). Artificial Intelligence (AI) Healthcare Technology Innovations: The Current State and Challenges from a Life Science Industry Perspective, *Technology Analysis and Strategic Management*, 35(2), pp. 179–193. doi:10.1080/09537325.2021.1971188.

Brem, A. & Voigt, K.-I. (2009). Integration of market pull and technology push in the corporate front end and innovation management—Insights from the German software industry, *Technovation*, 29(5), pp. 351–367. doi:10.1016/j.technovation.2008.06.003.

Camaradou, J.C.L. & Hogg, H.D.J. (2023). Commentary: Patient Perspectives on Artificial Intelligence; What have We Learned and How Should We Move Forward?, *Advances in Therapy*, 40(6), pp. 2563–2572. doi:10.1007/s12325-023-02511-3.

Chaves, B., Briand, C & Bouabida, K. (2021). Innovation in Healthcare Organizations: Concepts and Challenges to Consider. *International Journal of Health Research and Innovation*. doi:10.47260/ijhri/911

Ciani, O., Armeni, P., Boscolo, PR., Cavazza, M., Jommi, C., Tarricone, R. (2016). De innovatione: The concept of innovation for medical technologies and its implications for healthcare policy-making, *Health Policy and Technology*, 5(1), pp. 47–64. doi:10.1016/j.hlpt.2015.10.005.

Dodgson, M., Gann, D. M., & Phillips, N. (Eds.). (2013). *The Oxford handbook of innovation management*. OUP Oxford.

Dresch, A., Lacerda, DP., Antunes Jr, JA. (2015). *Design Science Research. [Elektronic resours] A Method for Science and Technology Advancement*. Springer International Publishing. ISBN: 9783319073736.

Ellwood, P., Williams, C. and Egan, J. (2022). Crossing the valley of death: Five underlying innovation processes, *Technovation*, 109. doi:10.1016/j.technovation.2020.102162.

European Comission (n.d). *Data protection in the EU.* Available at: https://commission.europa.eu/law/law-topic/data-protection/data-protection-eu_en [Accessed 2023-11-03]

European Medicines Agency (n.d). *Medical devices*. Available at: https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices [Accessed 2023-10-17]

European Parlament (2023). *EU AI Act: first regulation on artificial intelligence*. Available at: https://www.europarl.europa.eu/news/en/headlines/society/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence [Accessed 2023-10-24]

FDA (2020). *Overview of Device Regulation*. Available at: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation [Accessed 2023-10-31]

FDA (2023). *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices.* Available at: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices [Accessed 2023-11-03]

Halton, C. (2021). Diffusion Of Innovations Theory Definition. *Investopedia*. Available at: https://www.investopedia.com/terms/d/diffusion-of-innovations-theory.asp. [Accessed 2023-10-26]

HealthNord (n.a.). *What is MedTech?.* Available at: https://www.healthnord.com/en-us/education/what-is-medtech/ [Accessed 2023-12-20]

Högberg, M. (2023). Mats Högberg ”Kan regelverken hantera AI inom vården?”, *Medtech Magazine*, 7 December, Available Online: https://www.medtechmagazine.se/article/view/1069391/mats_hogberg_kan_regelverken_hantera_ai_inom_varden [Accessed 2023-12-09]

IBM (2023). *What is Natural Language Processing?*. Available at: https://www.ibm.com/topics/natural-language-processing [Accessed 2023-09-28].

IBM (2021). *What are Neural Networks?*. Available at: https://www.ibm.com/topics/neural-networks [Accessed 2023-09-28]

International Medical Device Regulators Forum (2022). Machine Learning-enabled Medical Devices: Key Terms and Definitions. Available at: https://www.imdrf.org/documents/machine-learning-enabled-medical-devices-key-terms-and-definitions [Accessed 2023-12-20]

Janlöv, N., Blume, S., Glenngård, AH., Hanspers, K., Anell, A., Merkur, S. (2023*).* Sweden: Health system review. *Health Systems in Transition*, 2023; 25(4): i–198. Web ISSN 1817-6127. (pp. 15-25).

Kalita, J.K. (2023). *Machine Learning Theory and Practice*. First edition. Chapman & Hall/CRC Press.

Kaul, V., Enslin, S. and Gross, S.A. (2020). History of artificial intelligence in medicine, *Gastrointestinal Endoscopy*, 92(4), pp. 807–812. doi:10.1016/j.gie.2020.06.040.

Kearney, B., and McDermott, O. (2023). Challenges faced by manufacturers with clinical evaluation under the new European Medical Device Regulations, *Cogent Engineering*, 10(2). doi:10.1080/23311916.2023.2261236.

Kelly, C J., & Young, AJ. (2017). Promoting innovation in healthcare. *Future healthcare journal*, 4(2), 121–125. doi:10.7861/futurehosp.4-2-121

Khanmohammadi, R. et al. (2023). 'An Introduction to Natural Language Processing Techniques and Framework for Clinical Implementation in Radiation Oncology'. *ArXiv*. doi.org:10.48550/arXiv.2311.02205

Kiseleva, A. (2020). AI as a Medical Device: Is it Enough to Ensure Performance Transparency and Accountability?, *European Pharmaceutical Law Review*, 4(1), pp. 5–16. doi:10.21552/eplr/2020/1/4.

Klitsie, J.B., Price, R.A. and De Lille, C.S.H. (2019). Overcoming the Valley of Death: A Design Innovation Perspective. *Design Manag J*, 14: 28-41. doi:10.1111/dmj.12052

Kogabayev, T., & Maziliauskas, A. (2017). The definition and classification of innovation, *Holistica*, 8(1), pp. 59–72. doi:10.1515/hjbpa-2017-0005.

Korstjens, I., & Moser, A. (2017). Series: Practical guidance to qualitative research. Part 4: Trustworthiness and publishing. *European Journal of General Practice* 24(1): 120-124.

Kotter, E. & Ranschaert, E. (2021). Challenges and solutions for introducing artificial intelligence (AI) in daily clinical workflow, *European Radiology*, 31(1), pp. 5–7. doi:10.1007/s00330-020-07148-2.

Lee, E., Sjöqvist, B., Hagiwara, M. et al. (2023). Development of Verified Innovation Process for Healthcare Solutions (VIPHS): A Stepwise Model for Digital Health. *Studies in health technology and informatics*, 302: 736-740. doi.org/10.3233/SHTI230250

LifeInDenmark (2023). *How the Danish Healthcare System Works*. Available at: https://lifeindenmark.borger.dk/healthcare/the-danish-healthcare-system/how-the-danish-healthcare-system-works [Accessed 2023-10-17].

Lincoln, Y.S. & Guba, E.G. (1985). Naturalistic inquiry. Beverly Hills, California: Sage.

Lindstad, S. & Ludvigsen, K.R. (2023). When is the processing of data from medical implants lawful? The legal grounds for processing health-related personal data from ICT implantable medical devices for treatment purposes under EU data protection law, *Medical Law Review*, 31(3), pp. 317–339. doi:10.1093/medlaw/fwac038.

Longworth, C. (2023). Is EU MDR harming medical device innovation? *Medical Device Netowrk*. 1 March. https://www.medicaldevice-network.com/news/is-eu-mdr-harming-medical-device-innovation/?cf-view&cf-closed [Accessed 2023-12-07]

Majumder, A. & Sen, D. (2021). Artificial intelligence in cancer diagnostics and therapy: current perspectives, *Indian Journal of Cancer*, 58(4), pp. 481–492. doi:10.4103/ijc.IJC_399_20.

Martineau, K. (2022). What is federated learning? *IBM Blogg*. [Blogg]. 24 August. https://research.ibm.com/blog/what-is-federated-learning [Accessed 2023-11-15]

McKinsey & Company (2022). *What is innovation?*. https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-innovation [Accessed 2023-10-02].

Medical Device and Diagnostic Industry (2021). *One year after EU MDR Delay, Plenty of Barriers to Compliance Remain*. https://www.mddionline.com/medical-device-regulations/one-year-after-eu-mdr-delay-plenty-of-barriers-to-compliance-remain [Accessed 2023-11-27]

MedTech Europe (2021). *MedTech Europe response to the open public consultation on the proposal for an Artificial Intelligence Act*. Available at: https://www.medtecheurope.org/wp-content/uploads/2021/08/medtech-europe-response-to-the-open-public-consultation-on-the-proposal-for-an-artificial-intelligence-act-6-august-2021-1.pdf

MedTech Europe (n.a.). *What is Medical Technology?*. Available at: https://www.medtecheurope.org/about-the-industry/what-is-medical-technology/ [Accessed 2023-12-20]

Mittermaier, M., Raza, M.M. & Kvedar, J.C. (2023). Bias in AI-based models for medical applications: challenges and mitigation strategies, *NPJ Digital Medicine*, 6(1), pp. 1–3. doi:10.1038/s41746-023-00858-z.

Müller, H., Holzinger, A., Plass, M., Brcic, L., Stumptner, C., Katloukal, K. (2022). Explainability and causability for artificial intelligence-supported medical image analysis in the context of the European In Vitro Diagnostic Regulation, *New BIOTECHNOLOGY*, 70, pp. 67–72. doi:10.1016/j.nbt.2022.05.002.

Niemiec, E. (2022). Will the EU Medical Device Regulation help to improve the safety and performance of medical AI devices? *Digital Health*. 2022;8. doi:10.1177/20552076221089079.

OECD/European Observatory on Health Systems and Policies (2021a). *Denmark: Country Health Profile 2021, State of Health in the EU*, OECD Publishing, Paris/European Observatory on Health. Systems and Policies, Brussels. ISBN 9789264963412

OECD/European Observatory on Health Systems and Policies (2021b*), Iceland: Country Health Profile 2021, State of Health in the EU*, OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels. ISBN 9789264425026

OECD/European Observatory on Health Systems and Policies (2022). *Norway: Health System Summary*. WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, Copenhagen. ISBN 9789289059053

Peacock, S.E. (2007). Challenges to modernity: the digital divide die digitale Spaltung. Available at: https://search.ebscohost.com/login.aspx?direct=true&AuthType=ip,uid&db=edsndl&AN=edsndl.OCLC.oai.xtcat.oclc.org.OCLCNo.246688789&site=eds-live&scope=site [Accessed 2023-10-10]

Pruciak, M. (2021). MedTech vs HealthTech vs BioTech: What Are The Differences?. *Ideamotive*. Available at: https://www.ideamotive.co/blog/medtech-vs-healthtech-vs-biotech-what-are-the-differences [Accessed 2023-12-20]

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)' (2017) *Official Journal L* 117, 1-175. http://data.europa.eu/eli/reg/2017/745/oj

Ringard, Å., Sagan, A., Sperre Saunes, I., Lindahl, AK. (2013). Norway: health system review. *Health Systems in Transition*. 15(8):1-162.

Rogers, E.M. (1995). Diffusion of Innovations. 4th edition. The Free Press. ISBN 0-02-874074-2.

SAS (2019). *Machine Learning: What it is and why it matters.* Available at: https://www.sas.com/en_us/insights/analytics/machine-learning.html [Accessed 2023-10-15]

SKR (2023). *SÅ styrs sjukvården i Sverige*. Available at: https://skr.se/skr/halsasjukvard/vardochbehandling/ansvarsfordelningsjukvard.64151.html [Accessed 2023-10-16].

Socialstyrelsen (2021). *Pandemin har förstärkt vårdens tidigare utmaningar*. [online] Available at: https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/pandemin-har-forstarkt-vardens-tidigare-utmaningar/ [Accessed 2023-09-21].

Spatharou, A., Hieronimus, S. and Jenkins, J. (2020). Transforming healthcare with AI: The impact on the workforce and organizations. *McKinesy & Company*. Available

at: https://www.mckinsey.com/industries/healthcare/our-insights/transforming-healthcare-with-ai [Accessed 2023-10-01].

Statista (2023a). *Medical Technology - Nordics*. Available at: https://www-statista-com.ludwig.lub.lu.se/outlook/hmo/medical-technology/nordics (Accessed 2023-10-31).

Statista (2023b). *Medical technology insustry*. Article ID: did-18123-1. Available at: https://www-statista-com.ludwig.lub.lu.se/study/18123/medical-technology-industry--statista-dossier/ [Accessed 2023-11-03].

Stewart, C. (2022). AI in healthcare market size worldwide 2030. *Statista*. Available at: https://www.statista.com/statistics/1334826/ai-in-healthcare-market-size-worldwide/ [Accessed 2023-09-22].

Stewart, C. (2023). Value of M&A medical technology company deals worldwide 2011-2023. *Statista*. Available at: https://www-statista-com.ludwig.lub.lu.se/statistics/331774/value-of-medtech-merger-and-acquisition-deals-globally/ [Accessed 2023-11-03].

Tynkkynen, LK., Keskimäki, I., Karanikolos, M., Litvinova, Y (2023). *Finland: Health system summary*, 2023. ISSN 2958-9193 [online].

United Nations (2022). Goal 3: Good health and well-being. [online] *The Global Goals.* Available at: https://www.globalgoals.org/goals/3-good-health-and-well-being/ [Accessed 2023-09-20].

Van Raamsdonk, A. (2023). The effect of Europe's Artificial Intelligence Act on the Medical Device Industry. *Emergo*, Available at: https://www.emergobyul.com/news/effect-europes-artificial-intelligence-act-medical-device-industry

Vegas, E., & Felman, A, (2023). Investor approaches and perspectives on Nordic Health Tech. *Nordic Innovation*, Available at: https://pub.norden.org/us2023-455/index.html

Vetenskapsrådet (2023). *Conducting ethical research*. https://www.vr.se/english/applying-for-funding/requirements-terms-and-conditions/conducting-ethical-research.html [Accessed 2023-12-20].

Wang, X. & Cheng, Z. (2020). Cross-Sectional Studies: Strengths, Weaknesses, and Recommendations. *Chest*, 158(1), pp. S65–S71. doi:10.1016/j.chest.2020.03.012.

Wagner, M. & Schanze, T. (2018). Challenges of Medical Device Regulation for Small and Medium sized Enterprises. *Current Directions in Biomedical Engineering*, Vol. 4 (Issue 1), pp. 653-656. https://doi.org/10.1515/cdbme-2018-0157 [Accessed 2023-10-05]

Wigand, RT. Electronic Commerce. (2003). Encyclopedia of International Media and Communications. *Elsevier*, PP 489-503, ISBN 9780123876706, doi.org/10.1016/B0-12-387670-2/00077-7.

World Health Organization (2022). *Global Strategy on Human Resources for Health: Workforce 2030: Reporting at Seventy-fifth World Health Assembly.* Available at: https://www.who.int/news/item/02-06-2022-global-strategy-on-human-resources-for-health--workforce-2030 [Accessed 2023-09-21]

You, Y., Kou, Y., Ding, X., Gui, X. (2021). The Medical Authority of AI: A Study of AI-enabled Consumer-facing Health Technology. doi:10.13140/RG.2.2.33097.98403.

Zemplényi, A., et al. (2023). Recommendations to overcome barriers to the use of artificial intelligence-driven evidence in health technology assessment, *Frontiers in Public Health*, 11. doi:10.3389/fpubh.2023.1088121.

Österberg, M. & Lindsköld, L. (2020). AI for better health: A report on the present situation for competitive Swedish AI in the life sciences sector. *Swelife and Vinnova Innovation Agency*. Available at: https://docslib.org/doc/6895819/ai-for-better-health-a-report-on-the-present-situation-for-competitive-swedish-ai-in-the-life-sciences-sector [Accessed 2023-10-01]

Appendix A Interviews

A.1 Interview Guide, Innovating Companies

Introduction

1. Tell us more about yourself.
2. What is your background?
3. Can you tell us more about your company?
4. Are you currently working with AI? In what ways?

About AIMD

1. What kind of AI is used?
2. What types of products are using AI?
3. What risk classification does the product have?
4. What have been the biggest challenges in your development process?
    a. Were there any challenges when developing the hardware and/or software of the physical product?
    b. Did you face any challenges before going to market that were not related to the physical product?
    c. Were there any challenges when you decided to go to market with your product?
    d. Did you face any challenges after selling your device?
5. What strategies have you found to navigate these barriers?
6. What "key factors" do you think have been most important (or become most important) to succeed with your AI innovation?
7. If you had the chance to do it all over again, would you have done anything differently? What advice would you have given yourself?
8. Is there anything that we haven't discussed yet that you think we should know about?

A.2 Interview Guide, Industry Organizations and Industry Experts

Introduction

1. Tell us about yourself and what role you have in the organization.
2. Tell us more about the organization.
    a. How do you support innovation in the region?
    b. What is your role in the development of new products?
    c. Which actors do you support? Is it always a company or can it be individual researchers/projects?

About AIMD

1. Do you see any trend linked to AI in new innovations? Is it common to use?
2. What does it look like in medical technology? Are there companies that work with AI that seek support from you?
    a. In what stage/phase are the companies that work with AI in MedTech?
    b. What kind of AI is used?
3. Are there any common challenges that you see the companies working on?
    a. Any of these that seem particularly difficult to overcome?
4. Do you see any differences between different Nordic countries regarding the challenges that AIMD companies face?
5. What do the companies that manage to overcome these challenges do differently?
6. What factors do you think are most important for companies to consider to be at the forefront of development?
7. Is there anything that we haven't discussed yet that you think we should know about?

A.3 Interview Guide, Academia

Introduction

1. Tell us about yourself and the field in which you conduct research or work.
2. How closely are you connected to healthcare (to understand healthcare needs)?
3. What is your contact/proximity to the industry?

About AI research

3. What do you see as the major barriers in the development of AI-based innovations (in the Nordic region)?
4. Are there any technical challenges for AI when used in Medical Technology that don't exist for other AI products?
5. What do you think companies need to invest in or work on to navigate these barriers?
6. What do successful companies do differently?
7. What success factors have you observed for establishing AI-based healthcare innovations?
8. Do you have any recommendations for individuals in healthcare, academia, or business that we should contact?
9. Is there anything we haven't discussed today that you believe would be beneficial for us to know?

A.4 Interview Guide, Clinical Users

Introduction

1. Tell us more about yourself.
2. What is your background?

About AI in clinical settings

1. How far have you come with AI applications in your region/hospital?
2. What is the general view on AI in healthcare?
3. How do you usually get in contact with innovative companies?
    a. Can they contact you directly?
    b. What can you do with a direct proposal?
4. What are the most important criteria for you to consider using an AI-based product?
5. What are the common reasons for you to use AI-based products? What demands do you have for the products?
6. What can be the reasons for your decision not to use AI-based innovations?
7. How do you evaluate new potential medical devices?
8. Is there anything we haven't discussed today that you believe would be beneficial for us to know?