Aalto University
School of Electrical
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Master's Programme in Automation and Electrical Engineering

Ideation practices in the health technology industry

Aaro Packalén

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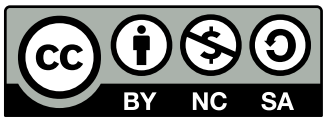

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Abstract The health technology industry has seen steady growth since the late 20th century. The heavy regulation in the field has created an atypical environment for product development, especially challenging for ideation, compared to consumer markets. This thesis explores how ideation is conducted in practice in the health technology industry. Identifying ideation drivers and limiters from the field, and examining the effects of regulations on ideation.

Exploratory semi-structured interviews were conducted with ten interviewees from seven companies, ranging from start-ups to established enterprises and an association. The interviewees ranged from product development team members to project managers and unit leaders. Thematic analysis was used to categorise the findings into four main themes from 422 quotations and 133 individual codes. The main themes are ideation limiters, ideation drivers, facilitation of ideation, and decision-making in ideation. Furthermore, the main themes were divided into 14 sub-categories, giving novel insights into the ideation process in a regulated field.

Comparing the results to existing research reveals common themes emerging from the ideation drivers. User centricity, safety and ownership, and team spirit have been identified as the key drivers of successful ideation in both the existing literature and this research. However, they seem to be implemented more effectively in the health technology industry than in commercial fields. In addition, the use of ideation methods developed by academia, or rather the lack of use, in ideation, aligns well with the recent study by Linsey et al. of a Fortune 500 company. Furthermore, the regulations in the health technology field strongly emphasise the effects of main ideation limiters, money and time, imposing additional restrictions on the ideation process. In addition, the health technology field complicates decision-making with context-specific factors such as insurance reimbursement models and the high cost of design changes.

Understanding the ideation drivers and limiters in a regulated field will help organise ideation phases effectively. Whilst this thesis does not introduce ready-to-implement solutions, it identifies multiple relevant factors for ideation, providing a basis for further research in academia and for reflection among product developers in industry.

Keywords Ideation drivers , Ideation limiters, Health technology industry, Ideation methods, Decision-making in ideation , Regulations

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Tiivistelmä Terveysteknologiateollisuus on kasvanut tasaisesti 1900-luvun lopulta lähtien. Alan tiukka sääntely on luonut kuluttajamarkkinoihin verrattuna epätyypillisen ympäristön tuotekehitykselle ja erityisesti ideoinnille. Tämä diplomityö tarkastelee, miten ideointia käytännössä toteutetaan terveysteknologia-alalla, pyrkien tunnistamaan ideointia ohjaavia ja rajoittavia tekijöitä sekä tutkimaan sääntelyn vaikutuksia.

Tapaustutkimukseen osallistui kymmenen haastateltavaa seitsemästä yrityksestä, jotka vaihtelivat startupeista yrityksiin ja yhdistykseen. Haastattelut suoritettiin teemahaastatteluina, jolloin osallistujat saattoivat ilmaista kokemuksiaan avoimesti. Haastateltavat vaihtelivat tuotekehitystiimin jäsenistä projektipäälliköihin ja yksiköiden johtajiin. Temaattisen analyysin avulla 422 lainausta ja 133 yksittäistä koodia luokiteltiin neljään pääteemaan. Ne ovat ideointia tukevat tekijät, ideointia rajoittavat tekijät, ideoinnin fasilitointi ja päätöksenteko ideoidessa. Lisäksi pääteemat jaettiin 14 alakategoriaan, jotka tarjoavat uusia näkökulmia ideointiprosessiin säädellyllä alalla.

Tulosten vertailu olemassa oleviin tutkimustuloksiin nostaa esiin yhteneviä teemoja. Käyttäjäkeskeisyys, turvallisuus ja omistajuus sekä tiimihenki on tunnistettu onnistuneen ideoinnin keskeisiksi mahdollistajiksi sekä olemassa olevassa kirjallisuudessa että tässä diplomityössä. Lisäksi akateemisesti kehitettyjen ideointimenetelmien käyttö, tai pikemminkin niiden käytön puute, vastaa hyvin tuoretta tutkimusta ideointimenetelmistä Fortune 500 -yrityksissä. Vaikka ideointia rajoittavat tekijät lopulta pelkistyvät rahaan ja aikaan, terveysteknologia-alan säädökset korostavat voimakkaasti näiden vaikutuksia rajoittaen ideointiprosessia entisestään. Lisäksi terveysteknologia-ala hankaloittaa päätöksentekoa kontekstisidonnaisilla tekijöillä, kuten vakuutuskorvausmalleilla ja suunnittelumuutosten korkeilla kustannuksilla.

Ideointitekijöiden ja -rajoittimien ymmärtäminen säännellyllä alalla auttaa ideointivaiheen optimoimisessa. Vaikka tässä diplomityössä ei esitetä valmiita ratkaisuja ideoinnin parantamiseen, se nimeää useita ideointiin vaikuttavia tekijöitä säännellyllä alalla, tarjoten pohjan akateemiselle jatkotutkimukselle sekä pohdinnalle ja prosessien kehitykselle tuotekehityksen ammattilaisille.

Avainsanat Ideointia tukevat tekijät, Ideointia rajoittavat tekijät, Terveysteknologia-ala, Ideointimenetelmät, Päätöksenteko ideoidessa, Sääntely

Preface

I want to express my heartfelt gratitude to my supervisor, associate professor Ivan Vujaklija, and my advisor, university lecturer Vikki Eriksson, for embarking on this adventure with me and for your endless kindness and support. In addition, I would like to thank the associate professor and director of Aalto Design Factory, Tua Björklund, for allowing me to combine my passions for product development and health technology into this Master's thesis.

Finally, I want to thank my partner for making me smile even in the most profound moments of despair, and my lovely colleagues at Aalto Design Factory for keeping me sane throughout this process.

Otaniemi, 24th of November 2025

Aaro Packalén

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Abbreviations

FDA	food and drug administration
510(k)	premarket notification for FDA
PMA	premarket approval for FDA
MDR	medical device regulations in EU
VC	venture capital
R&D&I	research,development, and innovation
IPR	intellectual property rights
NPD	new product development
FEI	front end of innovation
VoC	voice-of-customer
QA	quality assurance
AI	artificial intelligence
R&D	research and development

1 Introduction

From smart wearables to surgical tools and pacemakers, the health technology industry has seen steady growth since the late 20th century [1, 2]. Combined with the ageing population in Western countries [3], the health technology sector continues to attract increased interest from investors, students, and professionals alike. However, strict regulations and standards have created a distinct operating environment within the industry [4] that challenges traditional product development methods by imposing strict constraints and limitations on product development and, subsequently, on ideation.

As such, developing medical devices is a highly regulated process, and depending on their regulatory classification and intended market, they face different regulatory demands [5]. The changing demands might affect development time by years [6], significantly impacting profitability and underscoring the importance of successful ideation, as development costs can reach 10 to 20 million U.S. dollars [6]. Health technology companies cannot afford the 40% failure rate of new products reported by Castellion and Markhan [7]. To highlight the challenges health technology companies face in their development, the process from an innovative idea to an approved product has been investigated, showcasing companies' pain points in the regulatory journey [6], emphasising the challenges of bringing a product to the market with the high cost required by the field, especially impacting start-ups introducing new innovations.

Similarly, ideation practices and management have been studied in less regulated environments. For example, Kornish et al. [8] have examined the influence of organisational hierarchy on ideation effectiveness. Additionally, they illustrated how diversity in group ideation can counteract the tendency for large groups to engage in low-effort ideation, which should be crucial for companies in the health technology field, as successful ideation creates the foundation for product success. Furthermore, they demonstrate that there are no straightforward solutions and that the development context significantly affects the choice of methods.

Moreover, existing research often focuses on group ideation methods, such as brainstorming or brainwriting, despite studies questioning their performative edge over individual ideation [9]. In addition, Reinig et al. [10] have studied different methods for evaluating the success of individual and group ideation, concluding that the evaluation should focus on the quality of ideas rather than on quantity, as traditionally emphasised, as this better matches real-life expectations. Further recommending caution when reviewing research where the evaluation has been conducted based solely on quantity.

Nevertheless, the effect of regulations has been examined from the perspective of public well-being, including performance, safety, and product quality [11]. Additionally, their effects from a business standpoint have also been investigated [12]. However, when the research considers the quality of the end product, user involvement in development, and how regulations can make the development process more rigid and costly, the effects on innovation and ideation are often overlooked. Although the regulatory aspects of the health technology industry have been extensively studied, the impact of these regulations on product development, particularly ideation, has not received the same level of scrutiny. Furthermore, as the development context influences ideation methods, further study of ideation practices within the health

technology industry is needed [13].

This thesis aims to explore ideation practices in the health technology industry to identify drivers and limiters of ideation, and to examine how regulations affect the ideation process. This has been achieved through qualitative research conducted within the health technology industry. The research involved interviews with experts in product development and regulations across a range of health technology companies and an association, ranging from start-ups to established organisations.

The research focused on identifying ideation practices during product development in the health technology industry. The data collection utilised a qualitative research approach, as introduced by Tracy [14]. She describes how qualitative research is often rich and holistic, providing an understanding of sustained processes and focusing on participants' experiences within its context. To support this, the data was collected through semi-structured interviews to allow participants to share their thoughts openly [15]

The remainder of the thesis is organised as follows. Chapter 2 describes the theoretical background of the thesis, explaining the special characteristics of the health technology industry and current research practices on innovation. Chapter 3 presents the methods used to develop and conduct the interviews and explains how the gathered data was analysed. Chapter 4 describes the results of the research. Chapter 5 compares the results of the thesis to existing research, discusses the potential implications and limitations, and presents future research opportunities. Chapter 6 concludes the thesis by highlighting the main learnings.

2 Background

The Oxford English Dictionary defines ideation as "The formation of ideas or mental images of things not present to the senses; the creation of new ideas"[16]. In product development, the ideation phase is often considered as a larger entity compared to an individual event of creating a new idea. For example, in design thinking, ideation is considered a crucial phase of the project, as described by Brown [17]. He defines ideation as a "process of generating, developing, and testing ideas that may lead to solutions". Similarly, Cooper and Edgett [18] describe ideation as often including user research and need-finding, testing concept prototypes, and studying existing solutions.

In addition, idea creation does not happen in isolation as highlighted by Mumford and Hunter [19]. They describe how creative efforts, ideas, and innovative products stem from individuals' interactions with their work environment, highlighting the climate, leadership, processes, and group structure as the primary considerations for organisations seeking to develop an innovative environment. Furthermore, hierarchy has a significant impact on innovation and, by extension, ideation. For example, Keum et al. [20] demonstrate that lower hierarchy supports idea generation, and, conversely, that higher hierarchy supports idea selection by combating people's tendency to choose their own ideas.

This thesis examines the broader ideation process and how it is executed in the health technology industry. Focusing on understanding factors driving or limiting the ideation in the product development process. To achieve this, the factors influencing ideation, from the problem definition and idea creation to the selection of the final concept, are investigated. In addition, the effects of regulations in the health technology field on ideation are explored.

The rest of this chapter describes the unique factors of the health technology industry from the context of product development, the research of ideation, and explores the research methods favoured in similar research.

2.1 Health technology industry

The health technology industry, as referred to throughout this thesis, includes the medical device industry and wearable health technology industry, ranging from smart wearables to surgical equipment and implants. The regulations primarily affect the medical device industry, but some wearable health technology solutions are pushing features that are classified as medical devices and require the same approval processes.

In addition, regulatory requirements for the products vary by target market. The United States (U.S.) had the most significant medical device market in 2024 with 46,4% market share, while Europe followed with 26,4% market share as illustrated in the Figure 1 below [2]. This thesis focuses on companies developing products for either or both markets, as they combined share 72,8% of the world's medical device market. Since regulatory processes directly guide the product development, the main regulatory frameworks from the U.S. and the European Union (EU) are explained next.

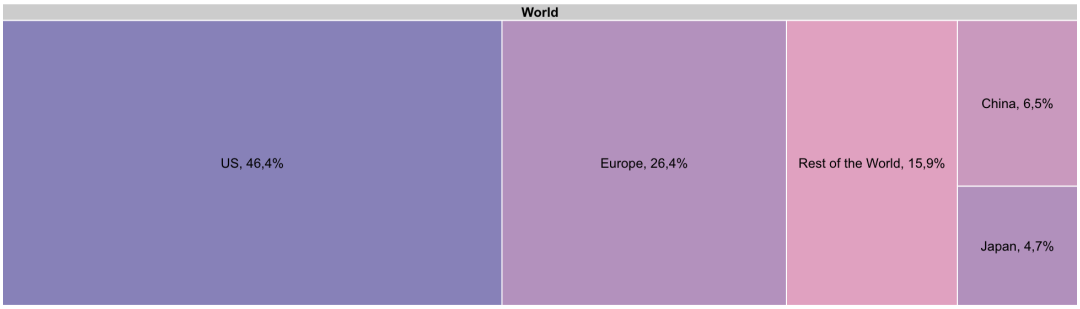

Figure 1: The U.S and European medical markets compared to other medical markets in 2024 [2].

In the U.S., the Food and Drug Administration (FDA) is responsible for medical device regulations, and its two main regulatory frameworks are the Premarket notification (510(k) and Premarket Approval (PMA) pathways [21]. In the European Union (EU), the Medical Device Regulation (MDR) defines the framework for the medical device approval process conducted by notified bodies [22]. In both regions, medical devices can be classified into three categories, which affect regulatory implications.

The classes of FDA and MDR do not match exactly, but for this thesis, they are sufficiently similar. The Class I medical device poses a low potential risk to users, as devices are typically non-invasive and include, for example, electric toothbrushes, manual stethoscopes, and surgical instruments. Class II devices pose a moderate risk to users and are usually surgically invasive, intended for short-term use. Such devices could be catheters and hearing aids. The FDA has only Class II, but MDR has Class IIa, similar to FDA Class II, and a more tightly regulated Class IIb. MDR Class IIb devices pose a higher risk than Class IIa devices, but not as high as Class III devices. The devices can be implantable and long-term surgically invasive, such as surgical lasers and implantable dental devices. Class III devices have a high potential risk. The devices can be active implants, long-term surgically invasive devices, and can support life directly or indirectly. Class III devices include defibrillators and implantable pacemakers, for example. [23, 21, 22]

FDA requires a 510(k) process for Class I and II medical devices [23]. Furthermore, for a Class III medical device, a PMA application is required. The 510(k) process does not require human tests but does mandate laboratory tests [24]. However, it does require a sufficiently similar FDA-approved product, known as a predicate, already on the market. The PMA requires both extensive laboratory and clinical tests and has higher standards than the 510(k) process [25]. In addition to 510(k) and PMA, FDA also has a De Novo classification track to novel class 1 or 2 devices, and a Humanitarian Device Exemption (HDE) track that provides a possible route to market medical devices that may help people with rare diseases or conditions. [26]

The EU's MDR is more detailed in its classification than the FDA's processes. In addition to the risk assessment, the device's position on or in the body and the intended time of use affect the classification. All the classes in the MDR framework share the first two and last two steps of the process. They are the Common Specifications and Post-Market Surveillance (PMS) in the beginning, and the EU declaration of

conformity and CE marking in the end. The Common Specifications include technical documentation requirements and General Safety and Performance Requirements (GSPR). GSPR requires companies to evaluate clinical data, but the data can come from similar devices already on the market, mirroring the FDA's predicate system. Class I devices must comply with the four steps outlined. Classes IIa, IIb, and III must comply with the Periodic Safety Update Report (PSUR). PSUR require the companies to summarise the results and conclusions from the PMS. It also has to inform of preventive and corrective steps taken based on the results of PMS. Finally, Class IIb and III devices must undergo additional clinical evaluation, during which the risk-benefit factors of the devices are analysed. The different types of clinical evidence required for medical devices under the MDR are presented in Figure 2, starting with clinical data for the GSPR evaluation that all products must comply with. The clinical evaluation is used to inform the extent of PMS after market launch. In addition, Class IIb and III devices must undergo clinical investigation and post-market clinical follow-up to comply with the MDR. [22, 27]

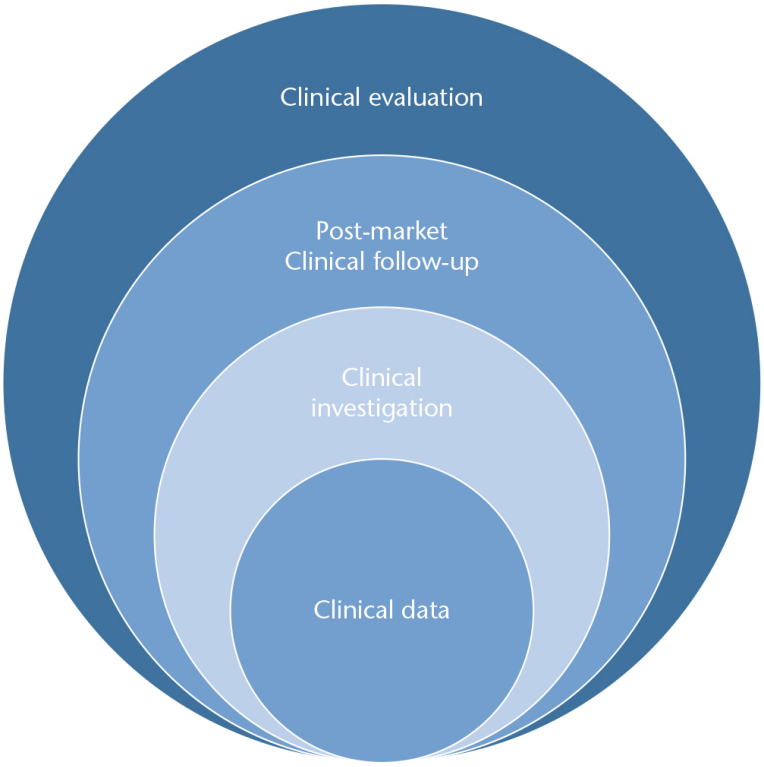

Figure 2: Clinical data and clinical evaluation are required from all products under the MDR, while clinical investigation and post-market clinical follow-up are mandatory for Class IIb and III devices [27].

The insurance reimbursement policy in the U.S. introduces another difference from the EU market. Centers for Medicare & Medicaid Services (CMS) controls which products can gain the reimbursement codes. The process for obtaining this reimbursement code can be done in parallel with the FDA approval process. To obtain

the reimbursement code, the developers must clearly demonstrate the device's clinical impact, supported by clinical evidence, and how the costs can be covered. Additionally, greater clinical evidence may be required than for FDA approval. Furthermore, it can be challenging to obtain the code for innovative devices, since applying for a new reimbursement code might be required. [28]

The regulations and reimbursement policies create an atypical product development environment compared to other commercial fields. The different markets and regulations mean companies may have to develop solutions tailored to each market, which is not unheard of in other fields either. In addition, the U.S. insurance reimbursement policy makes it much harder to sell a product to customers if it lacks the reimbursement code. Furthermore, the regulations add requirements to the development process. In combination, this creates a quite guided product development path. Next, the effect of this environment on ideation and development is further explored.

2.1.1 Innovation in the health technology industry

The development of a medical device from an idea to an approved medical product is a slow and expensive process. It is affected by the device's regulatory category and the geographical market. Traditionally, big companies focus on incremental improvements to their current products, while start-ups develop breakthrough innovations. To get through the long regulatory process, start-ups require external funding from either a Venture Capitalist (VC) or from a bigger company that decides to partner with them or buy them out. The market is especially tough for start-up companies, since their survival often depends on getting to the market quickly. This could lead to rushed ideation and prototyping, resulting in the release of sub-optimal but working designs to market. [6]

The regulations affect development from the beginning, as the preclinical tests that all medical devices, unless exempt, must undergo to reach the market typically take two to three years. In addition, the development cost before clinical testing may range from 10 to 20 million U.S. dollars. If the devices require clinical studies, the time frame is largely expanded. In addition, to perform preclinical or clinical tests, device manufacturers, including subcontractors, should be registered and approved, adding another layer of complexity to the development. As such, the development process differs significantly from that in commercial fields. [6]

As regulations impact the entire development and innovation cycle, they must be taken into account from the beginning. Furthermore, emphasising the importance of the relationship between regulatory bodies and the developers [29]. The four primary records important for documenting the process are the Design history file (DHF), Device master record (DMR), Device history record (DHR), and Technical documentation file (TDF), as presented by King et al. [30]. DHF contains the product's design history, including all design activities used to develop the product and its major components and accessories. DMR contains the different specifications and procedures for the design currently in production and on the market. DHR contains the device's production information, including process and test plans, and update instructions. TDF offers a list of relevant data confirming that the device complies

with the GSPR.

As can be seen, the documentation process must start at the beginning of the innovation process. Guerra-Bretaña et al. [31] showcase the Quality Management System in Figure 3, visualising the internal and external factors affecting the research, development, and innovation (R&D&I) process. The tool is introduced as an internal framework for the medical device R&D&I to ensure the proper documentation and communication throughout development. The framework visualises the crucial role of risk- and quality management systems in development, emphasising the importance of including them from the outset. Furthermore, they argue that the barriers to medical product innovation must be overcome through coordinated efforts involving stakeholders, emphasising the importance of collaboration among users, developers, and regulatory personnel.

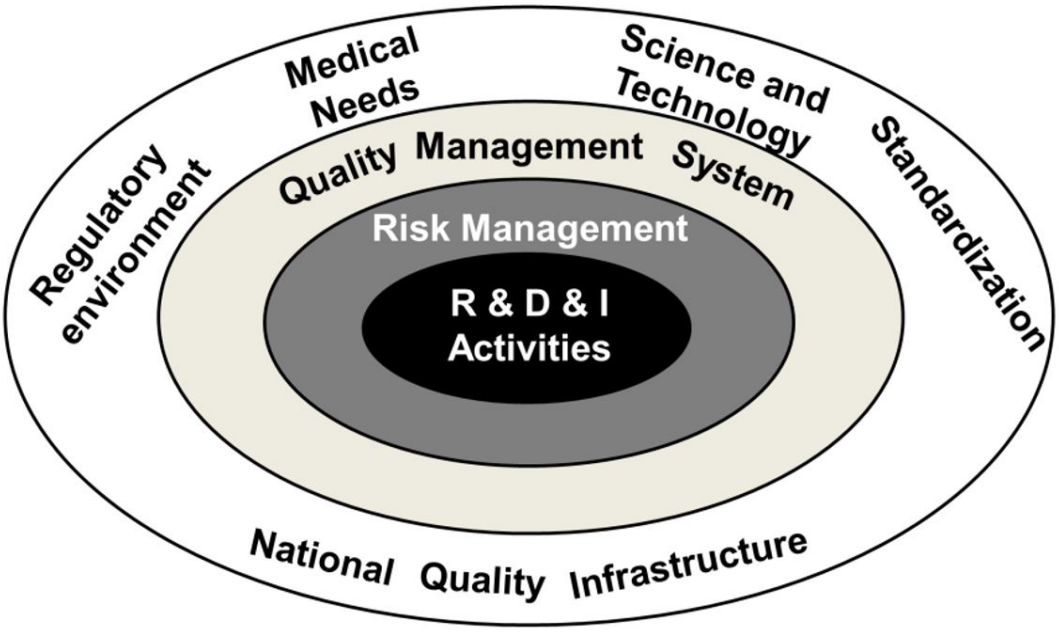

Figure 3: Visualisation of external and internal factors affecting the R&D&I of medical devices by Guerra-Bretaña et al. [31].

Despite medical practices and markets changing rapidly, the inherent conservatism in the field, which favours existing solutions, was recognised as early as the early 19th century [32]. Furthermore, Bergsland et al. [33] highlight how, after new products reach the market, it might still take years before a device or procedure is widely utilised. In addition, they discuss how the high-profit window for a new product can be short, reducing the advantage of being the first out with the new technology since others can then use it as a predicate for similar developments. Moreover, after a product reaches the market, introducing the technology into a hospital is not always straightforward, as Greer [34] describes. She explains how it can be complicated to reach consensus between the physicians who actually use the products and the administration that manages purchases—furthermore, emphasising the importance of understanding the

field and the distinction between a user and a buyer during development.

New innovations in the field often come from collaborations with academia and commercial interests [35]. There are differing views on which small or large companies bring innovations to the market. Stern [36] argues that because smaller companies often lack financial backing, they are less likely to pioneer innovations for the market. However, Kaplan et al. [6] argue that most new device categories originate with start-ups, backed by VC or larger companies. They continue to argue that larger companies would rather focus on developing successive iterations than on groundbreaking technologies.

As innovations often come from collaborations with academia and commercial interests, it is worrying that the lack of exchange of ideas between engineering and medical communities is slowing the field's development. However, some institutions have initiated programs to bring new products to market faster [37]. In addition, Bergsland et al. [33] hypothesise that the poor protection of academics' Intellectual Property Rights (IPR) has slowed the field's development. They continue to describe how IPR rights are important for motivating innovation and development, but also challenge the innovativeness of smaller companies, as patents often raise device costs. In addition, larger companies can try to dispute them through extensive legal action.

Research on the effect of regulations on the innovation process is limited and often focuses on higher levels of the process, as shown above. Supporting this, Blind [13] states that there has been little empirical research on the impact of the regulations on innovation. There have been new research developments following Blind's exploration, but they too mostly remain at higher levels of innovation [36, 38, 39]. This leaves a gap for researching the ideation process in the field and how the regulations affect it compared to commercial fields. This thesis aims to help fill that void. To support this, the following section explores existing research on ideation and methods.

2.2 Ideation research

Typically, the ideation research focuses on the New Product Development (NPD). Idea generation and concepting are often called the "fuzzy front end" [40] or Front End of Innovation (FEI) [41] of the NPD. Previous research has highlighted that up to 75% to 80% of the manufacturing and marketing costs are locked in during the fuzzy front end [42]. Emphasising the importance of understanding and utilising the factors affecting it.

Ideation and creativity research has its origins in cognitive psychology, where researchers generally agree that creating a new idea involves repurposing elements from existing knowledge bases in novel ways, as shown by Dahl and Moreau [40]. A good example of this is the "Scotch tape" method for isolating a graphene layer for the first time in history [43]. Dahl et al. describe analogical thinking as a basic mechanism underlying creative tasks, in which people use information from familiar categories to construct new ideas. For example, a product design company uses formal brainstorming sessions to encourage development team members to draw on each other's knowledge bases, thereby expanding the combined knowledge base and enabling the development of more original product ideas [44, 45].

Dahl et al. [40] examined the effectiveness of the analogies in the ideation. They found a positive correlation between the number of analogues used and the originality of the resulting concept. In addition, they showed how using multiple knowledge bases increased the number of analogies used. Furthermore, they learned that when external benchmarks were introduced, fixation reduced the number of original ideas produced. This research has been influential in the field of ideation research, and parallels can be seen in many ideation methods developed, such as brainstorming and method 635 brainwriting.

One of the core measures for the ideation research is the ideation quality. It has a significant impact on the methods used and developed for the ideation process. Traditionally, ideation success has often been measured in the quantity of the ideas [46]. However, Reinig et al. [10] argue that the quantity of ideas is not a sufficient measure of ideation success. Furthermore, they suggest using the good-idea-count to measure ideation success, as it more accurately reflects what is expected in workplaces. In addition, studies show that group ideation does not necessarily produce better ideas than individual ideation [9].

2.2.1 Ideation practices

Ideation in product development often follows a design funnel, in which the number of ideas considered decreases as development progresses. Kagan et al. [47] has studied how the transition from idea to implementation affects the success of the ideation process and who should make the decision. They found that imposing constraints, such as a transition time from ideation to implementation or a concrete deliverable at a transition point, outperformed giving the development team decision-making autonomy. Interestingly, they did not find any differences in outcomes between shorter and longer ideation times; rather, the risk-return trade-off increased as the ideation phase lengthened, since there was less time to iterate the final prototype. However, there was a correlation between delayed first idea, test, and failure with poor design performance, supporting the "get physical fast" and "fail fast, succeed sooner" recommendations.

To proceed to the implementation phase, ideation must be completed successfully first. Herring et al. [48] have explored the idea-generation techniques used by creative professionals. They highlight that existing research has focused on formalised idea-generation techniques used during group sessions, such as brainstorming, while overlooking other strategies, including free association, mind-mapping, divergent thinking, and sketching. Based on their research, they identified 19 idea-generation techniques favoured by professionals, including role-playing, brainstorming, collaboration, critique, expert opinion, user research, forced analogy, passive searching, prototyping, sketching, and socialising.

The positive impact of user research and Voice-of-Customer (VoC) methods on ideation has been well documented [18, 17, 41, 49]. The market-driven approach to ideation aligns with VoC, emphasising the importance of understanding customer needs and wants, as stated by Cooper [49]. He further states that this is supported by virtually every study of product success factors. In addition, he highlights that

fact-based product definition should be conducted with precision, as it may otherwise lead to project scope creep and unstable product specs, slowing down the process. To facilitate effective ideation, he suggests customer visits, lead user analysis (in which the innovative user is identified and brought into the development process), observing customers in their natural interactions at work, focus groups, and design thinking.

Another way to involve users in the development is crowdsourcing, as explained by Schemann et al. [41]. They describe crowdsourcing as another potential solution for generating commercially valuable ideas, highlighting the importance of tackling the problem, since, despite existing research, the failure rate of newly introduced products remains around 40 per cent [7]. Furthermore, Schemann et al. investigated the feasibility of online crowdsourcing and the frequency with which ideas turn into actual products. They found that when ideators paid attention to ideas from others, it increased the likelihood that their own ideas would be implemented. In addition, they showed that popularity based on simple likes or dislikes helped companies identify innovative ideas from a pool of hundreds to thousands. The research shows that the usefulness of crowdsourcing extends beyond improving a company's public image with customers.

In addition, prototyping has been shown to support communication and decision-making among the development team, users, and other stakeholders, especially rough prototyping or concepting during ideation [50]. However, Kirjavainen et al. [51] found that engineering design professionals mostly discussed testing final prototypes, rarely mentioning prototyping as part of early steps in idea development. They continued to discuss how this implies a gap between what is regarded as prototyping in the literature and what practitioners do. In addition, it has been argued that less prototyping can lead to missed opportunities in idea generation, as prototyping can foster new idea generation.

As product development and ideation are often team efforts and the ideas are not created in a vacuum, creating the right environment for innovation and ideation has been deemed one of the top three success factors for new product development by Cooper [49]. He identifies factors as senior management passionately supporting innovation, encouraging internal entrepreneurs, risk tolerance among management, recognising team efforts, management refraining from micromanaging, the whole team participating in project review meetings, time allowed for people to work on their creative side projects, and on unofficial projects. Cooper states that most businesses include less than a third of these elements in their business practices.

Another factor affecting the development environment and ideation is decision-making. As discussed above, it can affect team spirit, and, additionally, decision-making during the ideation process, as well as the hierarchy of decision-making, can affect the results of ideation [8]. Kornish et al. [8] argue that when decisions are made in a more decentralised manner, they can draw on specialised knowledge from experts in the relevant field. In addition, they add that when decision-making is centralised, it is more likely to take into account the bigger picture. A quality that larger organisations can find intriguing.

However, different ideation methods can be counted in the hundreds [52], and studying the effectiveness of them all is not feasible. Kirjavainen and Hölttä-Otto [53]

analysed 88 well-documented ideation methods to identify the underlying elements that positively affect ideation. Their results suggested that ideation methods consist of two types of mechanisms: implementation and idea-promoting mechanisms. The mechanisms and their underlying elements are shown in Figure 4 below. As shown in the figure, the implementation mechanisms include elements that describe how sessions should be run, while the idea-promoting mechanisms include elements that support idea creation. Kirjavainen et al. explain how breaking down ideation methods into mechanisms makes comparison easier, highlighting the building blocks behind them.

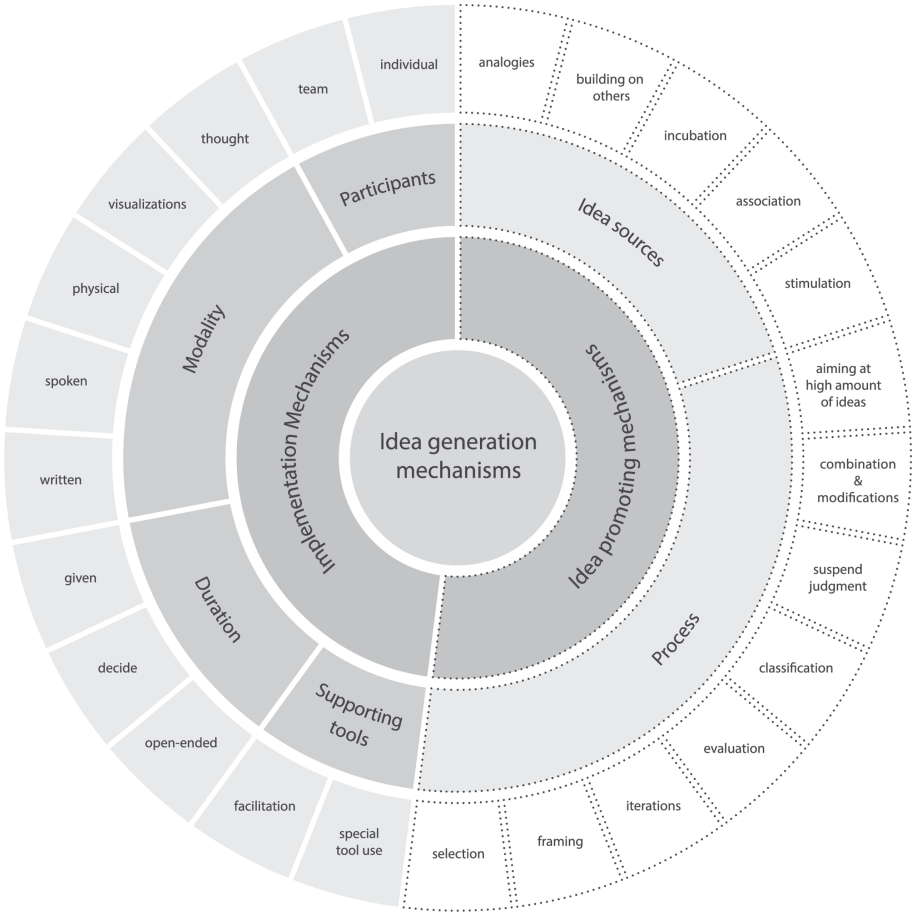

Figure 4: The creativity mechanism and the underlying elements found from 88 ideation methods, enabling easier comparison across methods [53].

However, as academics develop new ideation methods, their implementation in industry is far from certain. The gap between the development of design methods and their use in practice has been noted [54]. In a recent study, Linsey et al. [55] studied the adaptation of the methods in a Fortune 500 company. Based on their research, they noted that companies were adopting methods suited to the current products and practices. Conversely, if the method did not suit the field, they were seen as challenging to use and could introduce tension in the workplace. They also highlighted that management played a significant role in implementing methods, such

as allocating time for training and support, and that the tool was seen as beneficial for implementation. In addition, they hypothesised that students might adopt methods more readily if they gained a clear advantage from them in class projects, and that they would transfer the methods to companies in time.

2.2.2 Typical research methods

Ideation research can be conducted in many different ways. For example, analysing public datasets [41], conducting literature reviews [8], or by qualitative research [51]. Qualitative research is often favoured as it supports understanding the experiences of individual participants as they interact with methods, tools, and processes for design [56, 57]. In qualitative research, case studies have been found to be well-suited for explorations that require a detailed understanding of social or organisational processes, since the data collected is often rich in context [58]. Additionally, case studies' unique characteristic of drawing on multiple data sources supports the formation of new theories [59].

In addition, when the aim of a research project requires a qualitative approach and the exploration of participants' experiences, semi-structured interviews are often used to collect data [15, 60, 61, 51, 62]. Interest in semi-structured interviews stems from the expectation that interview subjects' perspectives are more likely to be conveyed freely in an open-ended interview setting than in a standardised interview or questionnaire. [15]. To analyse the data gathered from the interviews, thematic analysis has been widely used as a qualitative analytical method [63]. It has been noted as the foundational method for qualitative analysis, and the first one that researchers should learn [64]. Thematic analysis is a method for analysing, identifying, and reporting emerging patterns in data, as described by Braun and Clarke [64]. In addition, they note that it often extends beyond the research topic, encompassing a range of aspects. However, they add that thematic analysis fails to retain a sense of continuity and contradiction across individual accounts.

3 Research material and methods

This thesis utilises qualitative research through semi-structured interviews with the health technology industry to identify ideation practices and the factors that affect them in a regulated field. The participants' positions ranged from product development team members to project managers and unit leads. Qualitative research is a suitable approach for examining data characteristics such as interactions, experiences, and the process environment [65].

The interview data were coded with open coding and analysed using thematic analysis to develop the main themes. The interviews were conducted in a semi-structured manner, as the method helps explore experiences about poorly understood topics [14]. This chapter describes the methods used and the collection and analysis of the research data.

3.1 Data collection

A qualitative research approach was selected, as it supports understanding of the individual participants' experiences with methods, tools, and processes [56, 57]. Furthermore, utilising the semi-structured interview in the research allowed participants to express their experiences openly and to develop themes without pre-existing hypotheses, thereby enabling the discovery of unexpected insights and causal factors [15, 55].

The data were gathered from 10 individuals from seven companies and an association. The original list of companies to be contacted was compiled with the help of the thesis advisor, supervisor, and the Aalto Design Factory research group. Snowball sampling [66] was utilised at the end of interviews to recruit additional participants, which proved to be an effective strategy. In total, 15 invitations were sent for the interviews.

Table 1 lists the unique identifiers of the participants, the type of their company, and their general role. The s, e, or a after the participant number indicates the type of company the interviewee works for, providing context as studying the results of the thesis.

Interview participants		
Participant identifier	Company type	Role
p1s	Start-up	Team member
p2e	Established	Manager
p3s	Start-up	Manager
p4e	Established	Team member
p5a	Association	Legal
p6s	Start-up	Manager
p7e	Established	Manager
p8e	Established	Manager
p9e	Established	Manager
p10e	Established	Manager

Table 1: Unique identifiers and background information of the participants.

All interview data has been anonymised, including participants' companies, the products they work with, and their names. Instead, anonymised unique identifiers are used to differentiate between them. Although the type of company they work for and their general position are shared to provide context for the findings. The company types were divided into two, since defining start-ups and medium- and large-sized health technology companies proved infeasible. In addition, it helps protect participants' anonymity. The companies were classified according to their own descriptions. The participating companies range from Finnish start-ups to multinational companies with development units in Finland to international companies in the EU and the U.S. The size of the companies varies from tens of personnel to thousands, and at the time of data collection, all companies were developing products for the global market. The data were gathered through individual interviews.

The research process followed the guidelines set by the Finnish Advisory Board on Research Integrity (TENK) and those of Aalto University. In addition, the General Data Protection Regulation (GDPR) guidelines regarding the collection of personal information, as well as the management, storage, and access to data, were considered to protect the privacy of the interviewees. All participants were informed of these practices and agreed to them. Implementing these practices enabled the participants to share their experiences freely.

The data collection was conducted through individual semi-structured exploratory interviews. Semi-structured interviews allow participants to voice their experiences openly [15]. In addition, this method enables the creation of datasets and themes without the need for pre-existing theory or hypothesis, allowing the discovery of unexpected insights and causal factors. [55]. Furthermore, conducting the interviews in a semi-structured format allowed the interviewer to explore additional interesting topics while using the interview guide to ensure all necessary topics were discussed [57]. A total of ten participants were interviewed from seven companies and an association. Two participants were interviewed from two companies. The participants' and companies' varying backgrounds provided a broad perspective for the research.

The semi-structured interviews consist of predefined questions without predefined

answers, directing the discussion towards the research topic [67]. To conduct the interviews, a semi-structured interview guide was developed based on examples from literature and similar studies done in the research group. The interviews focused on the ideation methods, drivers, and limiters in product development and lasted approximately 60 minutes.

The questions were divided into six sections to provide a comprehensive understanding of interviewees' experiences of the ideation process. The sections are:

1. Setup
2. Role and background
3. Warm-up to the theme
4. Ideation success criteria and evaluation "case examples"
5. Future
6. Wrap-up

The first section, Setup, included introductions, discussing the purpose of the study, and ensuring that the interviewees understood the confidentiality and GDPR practices. In addition, the interview structure was introduced, and consent to record was confirmed. Five minutes were reserved for this section.

In the second section, Role and background, basic information about participants' positions, tasks, companies, and backgrounds was collected. In addition, participants' typical resources and limitations were discussed. The questions in this section focused on understanding the environment in which participants work. Five minutes were reserved for this section.

The third section, Warm-up to the theme, included direct questions about ideation methods and tools, as well as the people participating in the ideation and decision-making. Participants often shared case examples unprompted in this section. These questions provided insights into the organisation and management of the ideation sessions and the phase as a whole. Ten minutes were reserved for this section, although it was often exceeded.

In the fourth section, Ideation success criteria and evaluation "case examples", the interviewees were asked to describe their typical ideation flow from idea to selection. Then they were asked to share if it was a typical ideation flow in their organisation and if they had an example of a flow that had gone wrong. In addition, decision-making and organisation were further discussed, as was the effect of team dynamics. The interviewees were asked to provide concrete examples for each question, enabling exploration of their processes. Prompts were prepared for all the idea cases, and 5 x 6 minutes were reserved for this section.

The fifth section, Future, included questions about wished future directions and what the participants would like to change or keep as is. This section helped to boil down the most and least important factors of their ideation process. Five minutes were reserved for this section.

Finally, in the sixth section, Wrap-up, the interviewees could add anything they deemed relevant that had not yet been discussed and ask questions in turn. In addition, they were asked to recommend suitable participants for the research. Five minutes were reserved for this section.

The interview guide was tested with two volunteers during the development. The volunteers did not have experience in the health technology field, but they had backgrounds in product development. Based on the interviewer's notes and volunteers' feedback, the interview guide was adjusted. A few questions were adjusted or removed due to overlap, and the number of questions for the sections was adapted to match the intended timing. The testing provided valuable experience in conducting the interview and in anticipating what to expect before the actual research interviews. In addition, during the first interview, team dynamics were brought up. It was such an interesting point that the same question about the effects of team dynamics and how to support it was asked in all of the subsequent interviews. The complete interview guide is presented in Appendix A.

Data collection was conducted in person and via video calls. This was done to provide more flexibility in interview times and locations. For video calls, Microsoft Teams was utilised. The interviews were conducted in either English or Finnish, depending on the interviewee's preference. One hour was reserved for each interview, while the actual durations ranged from 42 to 74 minutes, with an average duration of 62 minutes. The interviews were conducted between April and June in 2025. All of the interviews were conducted by the author alone. All interviews were audio-recorded with two purpose-built recorders and later transcribed verbatim by Aalto University's transcribing partner in accordance with the GDPR. Personal or detailed information of participants was not shared outside the Aalto Design Factory research group. The original interview transcripts have been archived by the research team in compliance with Aalto University regulations.

3.2 Data analysis

The data analysis was conducted using open coding and thematic analysis methods. An open coding approach was selected, as it enables categorising a wide variety of factors and concepts without prejudice [68]. To provide structure for the coding process, the research questions were used as a top-level parent codes [61]. In addition, a parent code "Other" was used for interesting findings that did not fit the original research questions.

Once the coding was completed, the codes were analysed and grouped using thematic analysis. A thematic analysis approach was selected, as it enables the identification, categorisation, and development of insights into common themes across the dataset, facilitating the identification of collective and shared experiences. In addition, thematic analysis is effective for highlighting patterns in the interviews and examining the interview data as a whole. [69]

The coding was conducted using ATLAS.ti [70] through open coding in three passes. The complete dataset was coded once initially, followed by two additional coding rounds to ensure uniformity and thoroughness of the work. The author

carried out the coding alone. In addition, the interviewees were categorised into document groups based on their gender, role, company, and target market to enable future comparisons between the found themes and backgrounds. After coding was completed, the individual codes were exported to an Excel file, which was imported into Miro [71] to enable visual mapping of the codes. The codes were colour-coded by their original research question to maintain clarity about the results' origins. The codes were first analysed and theme groups formed within their respective research questions, followed by a second round of analysis across the top-level codes. After which, the resulting themes and subthemes were brought back into ATLAS.ti. The process is visualised in the flowchart presented in Figure 5.

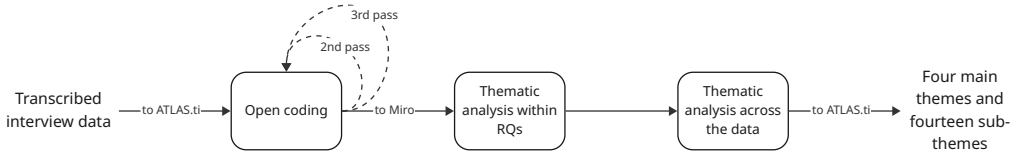

Figure 5: The process used for the data analysis.

Importantly, the second round of analysis across the data allowed for exploration without the limitations of the original assumptions, resulting in more in-depth analysis and revealing information that would have otherwise gone overlooked. For example, it enabled better incorporation of findings under the "Other" parent code. An important development, since most findings related to ideation limiters came from that parent group.

4 Results

The results present the findings from the analysis of 10 ideation practice interviews in the health technology field. One hundred thirty-three factors influencing ideation were identified from 422 quotes. Four main themes were discovered using the methods described in the previous chapter. They are ideation drives, ideation limiters, facilitation of ideation, and decision-making in ideation. This chapter introduces the factors found to drive or limit ideation. In addition, the findings on facilitated and non-facilitated ideation methods are presented. Finally, the different decision-making patterns and their effects are described.

The results are framed through the ideation limiters and drivers, as shown in the Figure 6 below. They provide the core of the findings on factors supporting or hindering ideation. At the same time, facilitation and decision-making are examined within the same context, as they can contribute to either depending on the implementation. The results do not offer a straightforward solution to ideation practices in the health technology field. However, it presents the practices identified, their experienced benefits and limitations, and the underlying factors that mould the processes. The "n" represents the number of participants mentioning the factor discussed.

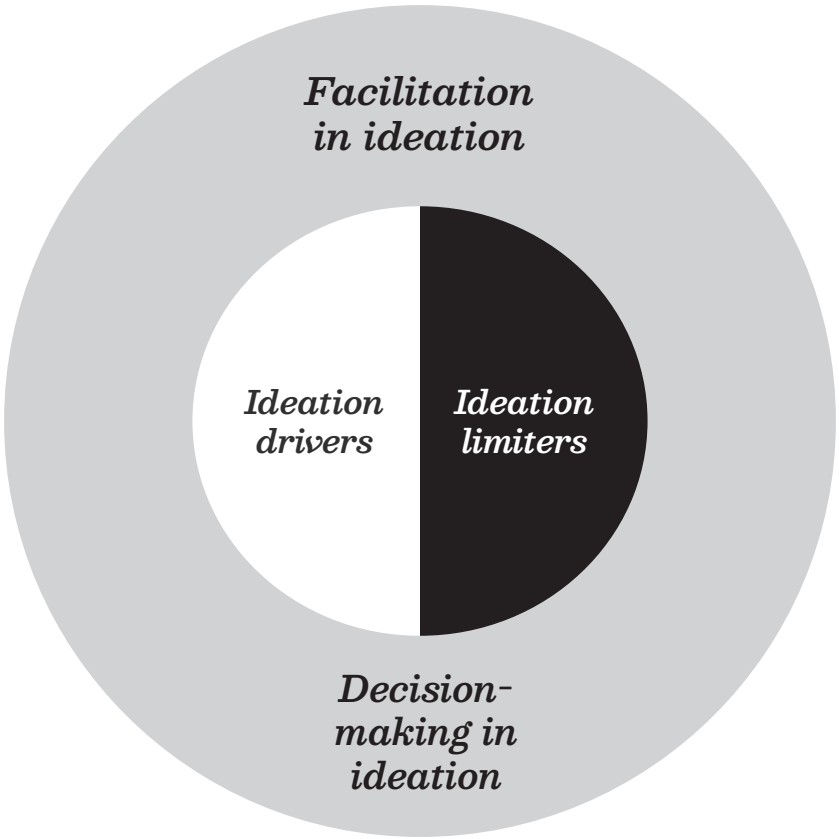

Figure 6: Ideation drivers and limiters support or hinder the ideation process, providing the core of the results, while facilitation and decision-making can contribute to either, depending on the implementation.

The research questions this research aimed to answer were 1) How do the regulations affect the ideation, 2) How is the ideation phase and decision making organised, 3) How is the ideation conducted in the health technology industry, and 4) How does the team spirit affect the development. During coding, an additional field called "Other" was created to capture interesting points that did not fit the original research questions. The division of quotes under the research questions, in correlation with the identified themes, is presented in Table 2, which visualises the weight of origins in the findings. In addition, it shows that, for the most part, the research questions have produced answers within the expected domain. However, the limitations had not necessarily been adequately considered during the development of the interview guide.

Interview impact matrix				
	Ideation drivers	Ideation limiters	Facilitation	Decision-making
RQ1	-	6	1	9
RQ2	4	11	-	18
RQ3	7	2	28	-
RQ4	14	1	-	-
O	-	21	4	3

Table 2: Correlation between the research questions and the identified themes.

The interviews conducted gave insights in an even manner for the research. Table 3 below shows the number of quotes shared in this thesis per participant. Between the companies, the insights are divided evenly. The low number of quotes from the association interview stems from the interviewees' position within the legal department. However, the interview provided important information about the regulations and processes companies face, and how they affect the development path.

Interview participants			
Participant identifier	Company type	Role	No. of quotes
p1s	Start-up	Team member	5
p2e	Established	Manager	4
p3s	Start-up	Manager	4
p4e	Established	Team member	6
p5l	Association	Legal	1
p6s	Start-up	Manager	6
p7e	Established	Manager	5
p8e	Established	Manager	6
p9e	Established	Manager	2
p10e	Established	Manager	3

Table 3: Number of quotes used from each participant.

4.1 Ideation drivers

Ideation drivers describe the factors that nine participants (90%) felt helped the ideation process and creating a fruitful atmosphere for ideation. Three main drivers for ideation were identified from the interviews during the analysis. They are User insight (n=8, 80%), Safety and ownership (n=8, 80%), and Team spirits (n=8, 80%).

4.1.1 User insight

User insights describe how participants interacted with users and involved them in their ideation processes, from need definition to idea generation and feedback sources. Eight (80%) participants emphasised the importance of user insight. The participants mentioned using users as an inspiration source, to help evaluate ideas against user needs, as well as a direct source of ideas. The participants involved the users in the ideation process as much as possible.

Six participants (n=6, 60%) highlighted the importance of clearly defining user requirements early on, based on real user data. They used observing, interviews, and existing predicates to define the user needs. A participant described their process, where defining the user needs is one of the first steps:

> "One is very, very early or even one of the first steps in the process, which is defining the user needs. You have to prepare a document where you have documented your user needs. There is a process to that. There should be a minimum number of surgeons or nurses that you interview, and then you compile their input into that document and define that these are the user needs." (p3s)

Similarly, another participant described how they created their product and company around the user needs:

> "We spent three weeks at a clinic. We had decided to establish a medtech company [...] We attended doctors' receptions, sat in and observed, got to watch surgeries, sat and waited there, and had the opportunity to interview nurses, doctors, and professors. We simply noted observations on the various needs identified there. We compiled a list of about 700 items, drawing information from the real world." [1] (p6s)

Closely connected to user needs in the ideation, all eight (80%) participants emphasised the importance of a more general user-centrism in the ideation process. They involved users in ideation, gathering feedback on ideas and concepts, testing prototypes, and defining improvement opportunities for existing products. In addition, understanding the operational realities and environment for the products was important for them. One participant described how their development engineers visit hospitals at least once a month:

> "At least once a month, product development engineers go to a hospital to observe surgeries and see how the products are used. The aim is to

> specifically identify the types of problems encountered in operating rooms, where staff may not even realise they are spending a lot of time. This often succeeds, especially in the U.S., if you are from a well-recognised company. Surgeons are usually quite keen to genuinely talk with product development staff. They don't want to talk to salespeople, but they do want to engage with product development engineers and discuss products, without feeling pressured by sales pitches. [...]"[1] (p7e)

In addition to studying potential users' needs, requirements, and validation, five participants (50%) mentioned using users as a direct source of ideas. Ideas were gathered through prototype feedback sessions and interviews, or through ideation sessions organised with specialists. In addition, it was highlighted that larger companies can utilise groups like medical advisory boards, which are compiled from esteemed doctors and specialists, as one participant describes:

> "[...] we typically involve the search and design team or the medical advisory board to review the case. We might say, "Okay, we would like to develop this kind of product," and then listen to their ideas and brainstorm a bit. Often in these sessions, we go into a cadaver lab and work on things, experimenting with other products that are somewhat in the same field. They are often prepared with their own slide sets and bring them into the discussion to contribute." [1] (p9e)

Overall, the eight (80%) participants emphasised that users are at the centre of development, ideation, and decision-making, supporting and focusing the ideation process. User centricity serves as the foundation for ideation, with other drivers, such as safety and ownership and team spirits, helping bring the concepts to life.

4.1.2 Safety and ownership

Safety and ownership highlight the importance of psychological trust for ideation, creating space for tinkering and innovation. In general, eight participants (80%) highlighted the importance of safety and ownership for the ideation process. Creating a trusting, open atmosphere is considered crucial for successful ideation and development. Participants mentioned the importance of psychological safety, understanding the people around them, having enough time, having the freedom to test, and a low hierarchy in supporting ideation.

Many participants (n=7, 70%) emphasised the importance of psychological safety and trust and described how the work culture contributes to the willingness to share ideas freely. In addition, they highlighted the importance of trusting their own work, and the team helps build an atmosphere where open conversation and idea exchange are possible. A participant highlighted the importance of a safe atmosphere:

> "If you feel like you can throw out silly ideas or ask stupid questions without being negatively judged, that is important. Quite often, what

people think are silly questions are actually quite sensible ones. So a trusting atmosphere is, in my opinion, absolutely essential." [1] (p4e)

Closely connected to the trust, five (50%) participants emphasised the impact of understanding and knowing the people around you on a deeper level, including their strengths and weaknesses. They mentioned how it is often easier to ideate with people that they know well. In addition, the participants at the manager level also highlighted the importance of knowing team members on a more personal level. Helping create a safe space and leading team members to support them. A participant also described how this helps them to discuss the worries more constructively:

> "And then everyone is highly motivated, gets along well, and knows how to express concerns in a constructive manner." [1] (p6s)

In addition to the personal side of ideation, half of the participants (n=5, 50%) highlighted the need for sufficient time to ideate and be creative. They expressed hope for time and freedom to continue researching and prototyping, along with their typical work tasks. Furthermore, they described how a low hierarchy fosters ownership and internal motivation, thereby encouraging ideation and the development of concepts and projects. The importance of having time was highlighted as follows by a manager:

> "In our company, and I'm sure in many others, the challenge is that time is limited. If you want to get people into a creative state to come up with something new, they should also have time to do nothing. For instance, when they can read articles from the field more extensively and similar activities, it helps develop their understanding of the domain and potentially sparks ideas. And maybe, when you have time to simply stare out of the window, you can come up with good ideas." [1] (p7e)

Supporting safety and ownership is closely tied to supporting the team spirit. The following section presents the most important aspects of the team spirit demonstrated by the participants.

4.1.3 Team spirits

Eight participants (80%) described how team spirit can affect the ideation. They highlighted the impact of team dynamics, communication, diversity, and team formation. Most of the participants (n=5, 50%) emphasised the importance of the team dynamics and good communication, describing how the team dynamics can make an ideation session succeed or fail, as one participant put it:

> "I have put three people in a room and told them to come up with ideas, and I end up with 150 new ideas. I can take three different people from the same team, put them in a room and tell them to come up with ideas, and they will not have a single idea after an hour and a half. It is all about the chemistry between the people, how they complement each other, and how it all works." [1] (p2e)

[1] Translated from Finnish

Especially the managers focused on understanding their team members and how to interact with them to make the most of team dynamics.

Five people (50%) emphasised how diversity in the development team supports the ideation. They described how different kinds of people help develop ideas further, for example, when a "visionaire" paints a big picture, and a realistic person then ideates an executable version. They also discussed the importance of having people who can do many things, rather than everyone focusing on their own niche. One participant describes how people from different backgrounds can contribute:

> "[...] bit better is involving more and more new people, even at the engineering team level, bringing more ideas to the room in a way or activating more people to kind of work on it. Even in the same approach, they come up with an idea on their own." (p3s)

Building a successful team with good team dynamics is not always easy. Four people (40%) described how challenging it can be to build a well-functioning team. They highlighted how difficult it is to acquire people with the right mindset and dynamics for the team, especially when they are not involved in the recruitment process. The importance of well-defined, matching values was also emphasised, as not everything can be learned. In addition, celebrating victories together and conducting team-building activities outside the office were highlighted as effective ways to support teams and keep them motivated. Especially celebrating small victories was deemed important, since in the health technology industry, the big wins are often far and few between. It was also mentioned that recruiting the better innovator is not always the best option for the team:

> "[...] You might find it is better, or you are in a situation where you would prefer to have the more socially skilled team player rather than the extremely talented innovator who is just impossible to manage. In the end, the innovator alone does not achieve anything; it is ultimately about teamwork. I have witnessed and seen many cases [laughs] where the innovator just throws the entire organisation into chaos and is stubborn, not recognising that while they have their excellence, there are others whose excellence is also needed and not accepting or appreciating the necessity and value of others' contributions. The team is extremely important." [1] (p8e)

4.2 Ideation limiters

Ideation limiters identify the factors participants described as challenging their ideation processes. Nine participants (90%) recognised limiting factors in their ideation processes. Four main limiters for ideation were identified. They are resources (n=7, 70%), regulations (n=9, 90%), conservativeness (n=9, 90%), and knowledge concentration (n=3, 30%).

4.2.1 Resources

This chapter described the resource limitations the participants identified, primarily time and money. Seven participants (70%)reported that resource limitations hindered the ideation process. Four (40%) of the participants agree that the main limiting factors are money and time. The more prominent of the two was time. For example, a participant described their ideation timeline as follows when asked if they had as much time as they needed:

> "We do not have the luxury to ideate like that.[...] for this part of the project, you have these two weeks, whatever ideation is needed, you do it, you test it, you implement it. If it does not work, you ideate more, or you reiterate, but there is always a time limit like that." (p1s)

In addition, another participant highlighted the impact of money, and how they can spend as much time as they want to work on an idea alone, but when they try to take it forward, the limitations appear:

> "In practice, I can use my time as much as I want, but when we are making physical products, especially medical products, we always need, let's say, some sort of funding to move things forward. And that is when restrictions start to appear as soon as money starts moving. Creativity is essentially the only limit to what we can propose, but the reality is, when doing business, the biggest reality is money." [1] (p2e)

As shown, time and money were perceived as having a significant impact on ideation. The limitations are derived from market pressure and the drive to turn innovations into profit. In addition, a few participants (n=2, 20%) highlighted that innovation does not always translate into a pricing advantage. Furthermore, elaborating that even if it transfers to a competitive advantage, the possible benefits and development costs have to be weighed from a profit perspective. Four participants (40%) identified that the pressure to get the solution to market and profitability constraints limited their creativity.

> "The biggest challenge is dealing with development schedules. Very often, I do not quite understand why, but in these companies there often seem to be managers who perhaps do not easily grasp how long it takes to design medical devices." [1] (p4e)

Resource limitations are often exacerbated by regulations, as compliance requires additional documentation and QA tasks in parallel with development.

4.2.2 Regulations

Nine participants (90%) strongly emphasised that regulations and, subsequently, predicates limit ideation. They highlighted the United States 510(k) system as

[1] Translated from Finnish

especially limiting, as possible ideas are compared to existing predicates to avoid the lengthy PMA process. They also described the high cost of completing the lengthy PMA process. Interestingly, the 510(k) was more popular than the European MDR process because the latter had longer waiting times and too few notified bodies exist. Therefore, especially smaller companies focus on the 510(k) track, as described by a participant:

> "However, this requirement for such a predicate often also somewhat limits the types of features that are desired. Nothing too unusual is wanted because the aim is to follow the 510(k) process, which includes the predicate." [1] (p4e)

In addition, two of the participants (20%) said they consciously avoid the regulations. Trying to avoid more regulated medical classes or the medical classification altogether, making the development and approval processes lighter and shorter. One participant describes:

> "For example, if the device itself initiates the hearing test, then it is classified as a Class 2 medical device, because it is automatically controlling a Class 2 medical device. However, if our software prompts the user or operator to start the test, then it is considered an operator-initiated test and not automatically initiated, allowing it to be classified as non-medical software." [1] (p6s)

Developing in the health technology domain requires strict documentation of both the development process and the work itself. Many participants (n=4, 40%) described how the QA department becomes involved in the ideation as soon as it gains some traction. QA also makes sure that all of the regulations are followed, giving limited space to ideate freely:

> "If some sort of positive indication is received, then it starts to delve deeper, and regulations and standards are examined to understand how this can be achieved." [1] (p2e)

Furthermore, a participant (n=1, 10%) highlighted that it is often not sensible to develop a new ideal component for the system if a good-enough solution exists on the market. The cost and time to get the new component approved counter the benefits of the bespoke part.

Finally, a few participants (n=2, 20%) stated that the United States' 510(k) and PMA processes are more straightforward than the European MDR process. In addition, they mentioned that the different regulatory requirements across markets guide their ideation when deciding which market to target first, often leading to European innovations entering the U.S. market first or, in some cases, only.

> "But it was the same for us even before we were sold; we made the decision not to seek approval from the EU but to go to the FDA, as it is an easier path." [1] (p7e)

In addition, another participant (n=1, 10%) reported that AI regulation in the medical sector is lower than in other sectors in the EU and the U.S. Interestingly, China currently has the highest AI regulation in the health technology domain.

The strict regulations and quality standards can contribute to the field's resistance to change. This conservativeness can often pose its own challenges for ideation.

4.2.3 Conservativeness

The conservatism of the health technology field and its effects on ideation were mentioned by almost all participants (n=9, 90%). Based on the interviews, the conservativeness in the field materialises mainly as selective adoption of ideas, small, safe iterations, and hierarchical organisations.

Few participants (n=2, 20%) noted that their companies prefer small, safe, incremental iterations over a single, big, innovative leap. They attributed this to limited resources and aim to avoid catastrophic failures:

> "So we take a very small step instead of a bigger leap that might have a catastrophic failure. We take small, calculated steps towards the goal." (p1s)

Similarly, two (20%) participants mentioned that their companies are very selective about the ideas. To get the idea to market might take from a few years to five or even more. This has to be taken into account while ideating, so the teams have to look quite far into the future to evaluate whether the idea will still be relevant. This can limit the ideation, as one participant voiced:

> "In this way, it actually hampers innovation quite a bit, as you have to filter through so much and look so far to the future, that hey, has the world already moved on when you reach the finish line in four years." [1] (p10e)

Half (n=5, 50%) of the participants mentioned the impact of hierarchy on innovation. The development teams were seen to have low hierarchy, while three members (30%) highlighted that their company's overall hierarchy is high. This manifests as uncertainty about why an idea is selected over others. The development team might not even be part of the decision-making, as described by one participant:

> "So the commercial side, the one that looks at the numbers and examines the portfolio while considering the sales strategy, should communicate more closely with the product development side. [...] But if product development were somehow involved in the evaluation before the project is selected, they might suggest solving the issue in a completely different way." [1] (p4e)

Few participants (n=2, 20%) highlighted the importance of reputation in the conservative field. If the doctors are trained and have used specific equipment throughout their careers, it can be challenging to get them to try something new. Even when it is objectively better performing. At the same time, there are doctors whose

opinions are highly valued among colleagues, and they act as influencers who can help a solution gain traction. Finally, they concluded that reliability is critical; the product has to be available and robust, as described by an interviewee:

> "This is quite an exceptional field in the sense that customers are very, very conservative. If they are accustomed to a product they have found reliable and that works reliably, that is a significant factor. Another aspect that I believe is underestimated is the availability of these products. In this industry, customers are extremely sensitive to delivery difficulties, because if, for example, there is a surgery underway and a product is needed, it is an extremely unfortunate situation if the company cannot deliver the products the customer has purchased." [1] (p8e)

Finding and convincing the right doctors is not the only human-related challenge in the industry. As the field is highly specialised, only a few people have a deep understanding of both the regulations and the technology and its possibilities. This can introduce knowledge concentration challenges to the ideation, as described in the next section.

4.2.4 Knowledge concentration

Three professionals (n=3, 30%) reported knowledge concentration-related challenges, due to the high development and specialised knowledge requirements in the health technology field. It was noted that these challenges contribute to an entry barrier to the field:

> "Because you come as a fresh engineer with a lot of ideas, you want to change the world. [...] you realise there are so many obstacles, regulations, these tests, sample size, deviation process, change process, nonconformity, this and that. [...] do not want to be here, and you are killing my ideas and innovativeness. [...]" (p3s)

In addition, the professionals felt that a strong understanding of the field and its specific requirements is necessary for fruitful ideation. As highly knowledgeable people are rare and siloing happens easily, when different teams do not communicate well, the importance of information structure is highlighted. It was described to help avoid overlaps and unnecessary work:

> "Precisely so that if any information is generated, you know where to find it or how it can be shared more broadly. If you start doing something and need those parameters and the initial information, you should know where to find it, ensure it is up-to-date and relevant, and if there are questions, know whom to ask." [1] (p6s)

Many of the challenges originating from the knowledge concentration could be addressed through facilitation. The following section introduces the findings about this subject.

4.3 Facilitation in ideation

Facilitation in ideation describes how nine participants (90%) understand their ideation process and which facilitation tools they might or might not use and why. Based on the interviews, both facilitated and non-facilitated methods can drive or hinder ideation. In addition, the participants tended to prefer non-facilitated methods over the facilitated methods. First, the facilitated ideation methods (n=5, 50%) are presented, followed by how structure in ideation was seen by four (40%) participants. Lastly, the non-facilitated ideation methods favoured by eight (80%) participants are described.

4.3.1 Facilitated ideation methods

This section describes the facilitation methods used by the participants. Five participants (50%) reported having a framework for ideation. However, they did not share any tools with each other. Furthermore, three (30%) participants mentioned dividing ideation and decision-making into separate sessions, preferably on different days, to support pressure-free ideation.

In addition, two (20%) out of the three participants reported using brainstorming as an ideation method. They highlighted the importance of the brainstorming rules and good facilitation to make sure that the sessions succeed, as a participant described their experience:

> "Another approach, of course, is team brainstorming sessions where everyone "throws up" their ideas. I have created a groundwork or best practices for brainstorming. It is important to have a solid owner and facilitator for the session. It is crucial that the owner genuinely owns what they are doing. They need to do a good job defining the problem and what outcomes are desired; otherwise, it becomes a meaningless exercise. The owner must thoroughly research the background to present the context effectively to others. If the context can be sent in advance, that is better, as it prevents people from just aimlessly banging their heads against the wall. Sessions should ideally be between half an hour and an hour and a half maximum to be beneficial. Lots of paper and other materials are important, which I usually provide, along with various sticky notes and other tools. Key rules include recording all ideas without dismissing any, and banning phones and other distractions—things like that." [1] (p9e)

Other facilitated methods were specific for each team (n=1, 10%). The used ideation methods included constraining ideation by scrutinising ideas to determine whether they were executable, imposing tight time limits on ideation or creating other forms of pressure, and narrowing the problem space to limit solutions to available options. Although the approaches differ, all methods aim to restrict ideation in some way.

In addition, a few other processes were introduced. A participant mentioned using agile sprints to develop ideas and solutions to well-defined problems. Another participant described using the jobs-to-be-done method to better understand how to

create value for customers, and then using a morphological box to turn the ideas into a functioning product. One project manager also used pushing against the ideas as a way to help the team members develop their ideas further.

Overall, no shared favoured methods from the industry could be defined. Participants had mixed thoughts about the facilitation and structure of the ideation sessions. This will be examined further next.

4.3.2 Structure in ideation

Four participants (40%) described how structure and facilitation in very early ideation could help address the still-abstract problem space. They mentioned that they like concepting together for early ideas, that structure helps approach early problems systematically, and that systematic tools help when venturing into new domains. A participant describes:

> "We have had sessions where we have sat down, thought things through, and prototyped. When we have been looking for very rough conceptual directions, it has worked well." [1] (p6s)

In addition, individual participants (n=1, 10%) highlighted a need for systematic problem-solving during development and for more early R&D to support better end products. The four participants (40%) felt that the structure and facilitation could help in the very early stages of the ideation. However, most participants (n=8, 80%) preferred the non-structured and facilitated ideation methods, which are explored in the next section.

4.3.3 Non-facilitated ideation methods

Non-facilitated ideation methods were preferred by eight (80%) participants. Six (60%) of them mentioned not using any formal ideation methods. They described how the ideas do not come when forced, and one participant even opposed ideation methods where there is a set problem, time, and space for ideation:

> "I somewhat oppose forced ideation, where a problem arises, and we gather everyone in a room to put ideas on post-it notes." [1] (p2e)

Furthermore, the same six (60%) participants highlighted the importance of organic discussion and encounters for their ideation. They described two primary methods. First, when encountering people in the workplace and starting discussions, ideas may arise, be shared, and bounced around, and if they evolve well, a separate meeting can be organised. The second case involves someone coming up with an idea, which can come from reading related materials or just being bored, for example, then the person might think and develop the idea further. Afterwards, they find relevant experts from their team or from other teams, with whom they bounce the idea and develop it further. As a participant put it:

> "Occasionally, when I am bored, I just go and chat with people. If we receive some directive from above to think about something specific, I can casually throw the idea to someone else, saying, "What do you think about this?" I might initially think about it at my desk, wondering if it could be a good idea, then show some scribble to someone, and they might respond, "Hey, yes, but it could be done this way." A really good idea might emerge from that." [1] (p4e)

In addition, seven (70%) participants preferred rough prototyping, visualisation, and concepting to support the ideation process. Rough prototyping, especially 3D-printed parts, was used by all seven (70%) participants to better understand the ideas and mechanics, troubleshoot, and study scaled versions of the small components.

Furthermore, the prototyping and drawing were highlighted as a universal language between different origins and backgrounds. Low-hierarchy concepts were also deemed helpful for understanding how to validate potential ideas. In addition, physical prototypes and other materials were crucial for the participants' feedback sessions with surgeons and other users. One participant described how a rough prototype can help the communication with people outside the company:

> "Yeah, these actually 3D printed models have been very useful. One for the sales team because it is a lot easier to show them how this works and try to convince the surgeons with these, and for us as well, because we are trying to explain something mid-air like this, I just go grab one here, I mean this one." (p1s)

In addition, rough prototyping and visualisation support continuing iteration. As mentioned in the ideation limiters, the field's conservativeness favours small, safe iterations over ambitious leaps. Three participants (30%) preferred taking small steps and going back and forth between ideation and concepting to ensure they accounted for all user needs. This was also found to help learning from the ideation. Furthermore, it can also help to solve complex problems, as one participant mentioned:

> "You can generally see how the physics work, whether our locking mechanism engages and stays in place, and so on. In this case, the first 3D prints were probably done in a fairly simple, flat manner, and then eventually it evolved into the rotational symmetry that we needed." [1] (p7e)

Overall, the freedom to ideate alone, in pairs, or in small groups was seen as beneficial. The importance of unexpected encounters and coffee table talks was highlighted. Concepting and drawing were found important for internal communication and idea development, as well as for external communication and feedback gathering. The non-facilitated methods were favoured over the structured and facilitated ideation methods.

4.4 Decision-making in ideation

Decision-making plays a key role in the successful ideation process, and a clearly defined decision-making process can help facilitate ideation drivers, such as safety,

ownership, and team spirit. Four main drivers for decisions were identified from the insights from all participants (n=10, 100%). They are data driven decisions n=9, 90%, contex driven decisions (n=9, 90%), market driven decisions (n=6, 60%), and opinion driven decisions (n=6, 60%)

4.4.1 Data driven decisions

Nine (90%) participants shared experiences with data-driven decision-making methods. Six participants (60%) described the business case as a first step in validating the idea. They are trying to understand whether there is a market gap and a product gap in their product line-up, and how much money could be made from it. In addition, profiling the product to the market was seen as important by a participant:

> "However, profiling the product for the market is always very important. This is true across all industries, but it is particularly relevant here; you need to determine what you want to achieve with the product in the specific market. Are you aiming to create a more budget-friendly product or something that is more high-end technology?"[1] (p4e)

If the business analysis is passed, the ideas are then analysed through the predefined product requirements (n=5, 50%) and feasibility (n=5, 50%). Based on the interviews (n=5, 50%), the product requirements are defined at the beginning of the project based on user and company needs. They help define what features should or should not be in the product, as described by a participant:

> "I have created all sorts of feature listings, ranked them, and tried to categorise them into different boxes—these belong to one category, and those to another—so you end up with a structure you can live with moving forward. Because ultimately, the requirements specification is key; no feature should be included in the product unless there is a requirement for it." [1] (p8e)

After matching the requirements, the potential ideas are analysed for feasibility as described by five (50%) participants. During the feasibility analysis, the participants studied which ideas can be profitable, which can be brought to the market during the time frame, and if the teams or companies have the capability to develop the ideas into products, as described by the participant:

> "We have actually had multiple designs for the product or ways of assembly. We had multiple ideas, but we chose one first that did not work, so we started focusing on others. So selection happens again through the filter of feasibility, do-ability, costs and those kinds of things." (p1s)

In addition, one participant highlighted how it can be hard for companies to bring new innovative products to market outside their core competencies. Highlighting the challenge that the health technology field poses to the development:

> "And perhaps most importantly, one major challenge with innovative products—those that by definition might deviate from the company's usual product portfolio—is that having the technical expertise to develop such a product is not enough. It requires many other skills within the company for it to have any chance of commercial success." [1] (p8e)

Three participants (30%) also mentioned using prototyping as a validation tool. Showcasing and testing the functionality and vision in reality was seen as helpful during the decision-making. With the prototypes, the discussion around the subject was easier and convincing decision makers with a functioning prototype was seen as a must by a participant:

> "[...]We conducted work on a product in the research department, and I saw prototypes that looked exactly right, with nearly final functionality. The proof of concept had to be developed to the point where it demonstrated that it was a functional system." [1] (p10e)

While data-driven decision-making provides a quite clear decision pipeline, decisions are not made in isolation. The industry and company contexts affect decision-making, as explained in the next section.

4.4.2 Context-driven decisions

Context-driven decision-making was described by nine (90%) participants. The context in the health technology field primarily comes from regulations. The decision factors can be divided into two subcategories, stemming from the regulations: long development times and associated expenses.

Seven participants (70%) reported that regulations slow down their development. They mentioned that they need production completely set up, from subcontractors to QA, to test their prototypes. In addition, the lead times for samples and high-quality prototypes could be months. In general, the development projects were described as lasting years, in some cases even 10 or more. The tightening of regulations and the small number of notified bodies further slow the process. In some cases, the turnaround might even be half a year, as described by one participant:

> "So we had performance efficiency issues with the prototype, and it would take one year to see the result of the changes. That is not good." (p1s)

Since development and testing take so long, implementing product changes is also found challenging, as highlighted by four (40%) participants. They describe how small changes can be processed internally, but when redesigning or removing a component, or changing the supplier, revalidating the affected parts is required. This was felt to slow or limit many improvement ideas. As a participant put it:

> "Well, it is indeed a heavy process when you have determined your product is ready to proceed to verification and validation testing. After that point, any changes become very challenging to implement. It is not that they are

> difficult to execute, but you always have to consider whether the existing testing remains valid or whether everything needs to be redone. Since we are dealing with expensive samples, significant quantities, and long lead times, it is always a balancing act to decide when to dare to make changes." [1] (p7e)

As can be seen from the interviews, the regulations create expenses in the form of documentation and testing. This was further discussed by two participants (20%). They highlight how it can be hard for smaller companies to secure funding to continue development. Especially since documenting well from the beginning is crucial for the projects, as described by one of them:

> "[...]They have done things well, but have not documented anything. Without documentation, there is no evidence of how it was done, so you have to start nearly from scratch again. At that point, a small company might decide to sell it or close down, and without documentation, it is likely that no large company would even consider buying it [...] "[1] (p10e)

Four participants (40%) suggested partnering with or selling to larger companies to fund product development for start-ups and smaller companies. However, ownership changes were also seen as a risk, as the new owner might not want to continue the existing projects. Regardless, partnering with bigger companies was seen as valuable and might help to reach potential buyers more easily, as mentioned by a participant:

> "Conquering the American market with your own new brand can be incredibly challenging. It is perhaps better to consider distribution arrangements and private labelling, where the same product is sold under a brand like GE or another established name, allowing the customer to receive the product with that brand recognition." [1] (p8e)

As the context necessitates decision-making, the health technology market also has its own effects. Compared to commercial markets, the health tech market presents unique features, such as refund models and regulatory considerations, as discussed below.

4.4.3 Market driven decision

Six participants (60%) introduced a few market-driven decision factors. They named IP development, refund models, regulatory aspects, and understanding who to sell to as factors in their decision-making. Two (20%) participants described IP development guiding their development from two directions. First, does the idea create new IP for them, and second, do they have the freedom to operate, meaning do they have all the rights to the necessary patents to develop the idea, or would they breach other companies' IP rights?

A special property of the U.S. markets was mentioned affecting decision-making by two participants (20%). The insurance refund models, which classify existing products into different categories, make it challenging to introduce a new product

without refund approval, since customers must be convinced to buy a more expensive product. In addition, they might negatively affect the hospitals, creating a more complex layer for the decision-making, as explained by a participant:

> "But then it becomes a case of, 'Yes, our reimbursement model is such that when it reaches the doctor, the doctor can bill for this code, allowing them to benefit, while we are taking this business away from the hospital by doing it this way.' There are many layers involved in such arrangements." [1] (p6s)

An idea's implications for regulations were also deemed to affect the decision-making by two participants (20%). Ideas have been ranked based on the regulations they would introduce, and development has been directed to avoid heavier regulatory classes. In addition, different needs and requirements across markets, particularly the U.S. and EU, were seen as a challenge by another participant (n=1, 10%).

A participant (10%) also highlighted that, in the health technology industry, companies often do not sell their products to doctors or professionals who will use them, but rather to organisations such as hospitals. They further emphasised that this means that the actual users of the product might not have a say on the procurement of the equipment. In addition, they described how it can be hard to get doctors to adopt new tools, even though they can be proven to be better:

> "This is a very conservative field, and altering the content of doctors' training is quite difficult. They are educated with very traditional tools and technologies, and once they become accustomed to them, they continue with clinical work and specialise in them. It takes a great deal to introduce an innovation into this environment and convince them that it will improve their work. You may succeed in convincing an individual doctor, but then you have to persuade the entire organisation and explain why they should abandon a proven technology in favour of something new. This can also become an obstacle to product development." [1] (p5l)

While decisions are mostly made based on data and other context-driven factors, the human factor can never be ruled out. The following section describes how opinion-based decisions affect ideation.

4.4.4 Opinion driven decisions

Six participants (60%) mentioned experiencing decision-making based on opinions, relating to personal opinions and top-down decisions, with unclear reasoning. Four participants(40%) shared experiences in which decisions come from the top and seem to be personal opinions. Especially in larger companies, where other departments prepare the need-finding and product requirements and might choose which ideas to advance, this was felt to diminish the atmosphere, since the reasons were not clear to the developing team. However, a manager also recognised a learning experience from an earlier case of driving their opinion as described:

> "But that was a very good example. And there were some learnings for me as well that probably I should not be that difficult or very difficult because there might be ideas which do not sound promising in the beginning, but in the end, they can change our life in a way." (p3s)

In addition, a participant (10%) emphasised the importance of informal discussions and relationships before decision meetings, as decisions are often made beforehand of the formal meetings. Another interviewee (10%) emphasised the team's faith in the project and described how they had altered the idea ranking numbers to get their favourite idea through. This emphasises the personal understanding and gut feeling for the decision, and how processes might not be as strict as we thought, as described by a participant:

> "I mean to say that I would be ready to argue that if someone claims we have a process that solely goes through these formalities and nothing else matters, I would be prepared to bet some money that the person simply is not aware it is happening. We have this fine process, but in reality, you discussed this topic over lunch or wherever, and the idea and decision are actually shaped in those situations. To some extent, the formality is just about completing the paperwork." [1] (p8e)

5 Discussion

To better understand how ideation is conducted in a regulated field, this thesis investigated the drivers and limiters of ideation in the health technology industry through interviews with 10 product development team members and managers, as well as an association representative. The results reveal a variety of factors affecting ideation, with varying degrees of conformity. While data on ideation drivers were relatively uniform, data from other themes had more variation. Although some sub-themes, such as non-facilitated ideation, had apparent unity. As such, this thesis offers novel insights into how the ideation process is conducted in the health technology industry and how regulations impact it.

Creating successful products is a complex challenge [49], and while as many as 40% of new products fail at launch [7], ideation is the starting point where a product's success or failure is founded. As the time and money invested in the development of the health technology industry are often significantly higher than in commercial fields [6], health technology companies cannot afford such a high failure rate. The consequences can be seen in the high user involvement from ground research through ideation, development, and manufacturing, as highlighted in the literature and the results of this research, aiming to ensure that the solutions developed meet users' needs and fill market gaps that can generate profit for companies. As such, the health technology industry can be seen as a problem-oriented field compared to commercial counterparts, where creating a solution to a problem that does not yet exist is a feasible option.

In the literature, market- and VoC-driven product development has been seen as a potential solution to combat the low success rate [18]. Supporting this, the participants described how clearly defining user requirements at the beginning of the process is crucial to success. The user needs, combined with the company's own requirements, form the product requirements, which serve as the foundation for further ideation and development. Additionally, participants described that during ideation, they try to involve users as much as possible, mainly through feedback on concepts and rough prototypes. This differs from the findings of Kirjavainen et al. [51] where engineering design professionals discussed testing final prototypes, rarely mentioning prototyping as an early step in idea development. The difference in findings could stem from varying levels of importance placed on user involvement across fields.

Other factors found to support ideation were the positive effects of ownership and psychological safety, giving participants enough space and time to get bored and pursue their own side projects, which might lead to potential ideas down the line. In addition, the participants highlighted the importance of feeling comfortable and supported to enable free sharing of ideas and creating an environment where failing is not frowned upon. These results support the findings of Cooper [49], who, in addition, emphasises the importance of creating the right environment for ideation, a finding also highlighted in this research. The participants emphasised the importance of team spirit and finding team members with matching motivation and values, as development timelines range from a few years to tens of years, with very few victories in between. Interestingly, Cooper [49] also notes that most businesses poorly implement

these practices. However, the participants in this research seemed to experience and implement these practices in their work.

As discussed earlier in this chapter, development in the health technology field mandates longer time investments and deeper pockets to ensure compliance with the regulations. Participants in this research highlighted the field's regulations and conservatism as the primary constraints on ideation, followed closely by resource limitations. The regulations require documentation from the earliest idea or development decision through development and, in many cases, after the product reaches the market. The results show that the other ideation limiters experienced by the partners stem mainly from regulations, as regulatory processes introduce obligations that slow ideation and development and incur additional costs, including documentation and laboratory and clinical testing. Which, in turn, strains the resources.

Furthermore, as going from regulatory Class II to Class III may increase the time from idea to market from three years to ten to twenty years, the participants described how the existing predicates often limit the ideation. The goal of the ideation is to come up with something close enough to the existing predicates that the clinical test can be avoided. In addition, the long time frames introduced selectivity of ideas, limiting idea generation as participants constantly evaluate whether the ideas they come up with would be relevant in three, five, or ten years, when the new product would reach the market, during ideation. In addition to resource limitations from time and money, these reasons were found to affect the ideation process.

While the regulations clearly emphasise the impact of ideation limiters, which create additional resource strains and constraints on ideation, the known ideation drivers from the literature seem to be better implemented in these health technology companies than in commercial ones. One reason for this could be as discussed, that as the minimum time to market in the health technology field is two to three years with a cost between 10 to 20 million U.S. dollars [6], the companies cannot afford failing products, "forcing" them to adopt and implement the known ideation drivers to their processes better than companies in the commercial fields. This could imply that the regulations, while creating challenges, also push the companies towards better ideation and development practices. The findings of Kagan et al. [47], that clear limits and constraints support ideation, could be seen supporting this argument. However, the environment is so different that it cannot be taken for certain, requiring further research.

Regarding facilitation of ideation, participants clearly preferred non-facilitated methods over facilitated ones. As facilitated ideation methods in general were found to be cumbersome and often too reliant on team dynamics, they often created unnecessary pressure on the ideation. This aligns with recent studies by Lindsey et al. [55, 61], which highlight the limited adoption of ideation methods developed in academia. They mentioned that methods resembling their current practices were implemented in companies, whereas those that did not suit the field were not. In addition, they highlighted the significant role of management in implementing new methods by allocating time for training and support, and by demanding their use. As many participants reported not using any advanced ideation methods, this raises questions about whether the low adoption rate of tools stems from a lack of suitable tools for the

field or from limited awareness of them and their benefits.

However, the non-facilitated ideation methods preferred by the participants closely parallel the ideation drivers. For example, they included ideation alone, organic discussions and encounters, and rough prototyping and concepting. These methods require time, with tasks and meetings not planned, and a strong team spirit and a safe environment to allow free idea sharing and discussions without fear of judgment. Similarly, they include the same elements as found in other ideation methods studied by Kirjavainen et al. [53]. In addition, the finding that most participants found individual ideation methods to work better is not entirely out of line with existing research, as Rietzschel et al. [9] found that group ideation does not necessarily produce better ideas. Regardless, this poses a challenge for managers: how to ensure sufficient time and space for creativity while meeting the often-tight development timelines in the health technology field. In addition, some participants mentioned that facilitated ideation could be beneficial in the very early phase of ideation, when the problem space and the development goals are more abstract.

A few idea development and evaluation methods or practices are evident in the results. First, the organic ideation and encounters as described in the section 4.3.3 Non-facilitated ideation method, and secondly, the decision making process described in the section 4.4.1 Data driven decisions where decision pipeline through business case analysis, product requirements, and feasibility analysis is outlined by the participants. In addition, participants highlighted that the regulations also impact decision-making during ideation and idea creation. The long lead times and costs associated with changes prompt them to collect changes and updates and push them through at once. Different regulations across markets affect decision-making in the hunt for quicker market access, driving some companies to the U.S. market first. In addition, factors specific to the health technology industry, such as insurance refund models, guide decision-making. However, the human factor should not be underestimated in the decision making, since while the data driven decision-making was most emphasised by the participants, the opinion driven decision making did follow close after and few participants emphasised how the decisions are often made in the informal conversations before the meetings and how the gut feeling still place a role in the decision-making as the numbers might be modified to get the favourite idea concept trough as a participant highlighted.

Overall, the regulations create a distinctive ideation environment in the health technology industry, emphasising the importance of ideation and ideation drivers. User centricity is vital for the success of ideation and, subsequently, for the new products. At the same time, team spirit and an innovative environment ensure that employees have the space and time to use their preferred non-facilitated ideation methods. However, facilitation could be particularly helpful at very early stages and during idea selection. Furthermore, the regulations intertwine at all levels of ideation, introducing additional complexity to the process.

5.1 Limitations and future opportunities

A key limitation of this thesis is that the research relied on retrospective interviews, which depended on participants' perceptions of ideation methods and decision-making, as well as their recollections of events. Furthermore, reliance on a single informant in most companies and limited access to other data sources, such as ideation documentation and meeting memos, limit this research to perceptions of ideation practices. Future research should investigate the actual processes in health tech development through observation or multiple case studies, for example, by comparing the dynamics and actions in meetings and events with ideation literature.

In addition, as the dataset consisted of 10 interviews with seven companies and an association, the results cannot be generalised to the industry as a whole. However, it does provide insights into ideation practices, especially in Finland. Furthermore, it would have been ideal to conduct two interviews per company, one with the product development team member and one with the manager. Unfortunately, within the time and resource limitations for this master's thesis, it was not feasible. In the two cases where this was possible, the results provided interesting insights into team dynamics, decision-making, and the methods as viewed from different levels. Regardless, data from only two such cases cannot be considered representative and cannot be utilised for results in that context.

As discussed at the beginning of this chapter, it seems that the regulations "force" health technology companies to implement the ideation drivers better. It would be interesting to explore further the success rate of new health technology products, compared to the 40% in the consumer market. Additionally, the hypothesis of better implemented ideation drivers would require further research by comparing the health technology field with commercial fields and examining whether the results could be generalised to other regulated fields.

In addition, the ideation facilitation in the health technology field could be further explored from different perspectives. First, through the idea creation process, exploring existing ideation tools and methods for the regulated field and why they might not get implemented, and how idea creation could be better facilitated in highly regulated environments. Second, from a process facilitation perspective, exploring the implementation of existing and new approaches to enhance ideation and improve communication between teams, enabling transparent decision-making.

As part of broader research on innovation and decision-making, it would be interesting to examine how much gut feeling and personal opinions influence decision-making in the shadows. In this study, only a few participants noted that informal discussions and gut feelings influence decision-making. Leaving behind an uncertainty, whether it truly is a minor factor or if it did not come up during the other interviews, or even if it is not something that people like to disclose.

6 Conclusion

This thesis has explored ideation in the health technology industry by conducting a case study of ideation practices, interviewing 10 participants from 7 companies and an association, utilising semi-structured interviews, open coding, and thematic analysis. The research aimed to fill an existing gap in the literature on the effect of regulations on innovation, identified by Blind [13], as there has been little empirical research on the effect of regulation on innovation, especially ideation.

The results show how the identified ideation drivers, such as user needs and centricity, psychological safety, and team spirits, align well with the existing literature [18]. At the same time, the implementation rate appears to be higher in the health technology field than in commercial fields [51, 49]. This could be due to the health technology companies trying to avoid the high failure rates of new products experienced in commercial fields [7]. Supporting this argument, literature has recognised the long idea to market times as well as the high cost of development [6], and the participants of the research highlighted how getting the user need right from the early steps helps ensure that the products are still relevant when they reach the market tree to twenty years later.

The regulations affecting ideation stem mainly from monetary and time constraints imposed on it. The regulations introduce documentation and testing requirements, slowing down prototyping and imposing constraints on ideation. Interestingly, these are problems that could be at least partly solved through facilitation. However, the overwhelming majority of participants preferred non-facilitated ideation methods over facilitated ones, as the latter were seen as cumbersome and overly dependent on team dynamics. Similar results have been observed in research from other fields [55], highlighting that facilitation methods matching existing practices were implemented more often.

Regardless, a few processes emerged from the interviews. First, the organic ideation, highlighting the time to wonder and unplanned encounters; second, the decision-making pipeline, starting with business analysis, followed by product requirement evaluation and feasibility studies. However, the regulations also introduce context-driven factors into decision-making, such as avoiding the regulations, prioritising faster development timelines, and considering insurance refund models. Moreover, as the health technology field seems to strive for user-centric and market-based ideation and decision-making methods, the human factor cannot be forgotten. People will still adjust the numbers and get their favourite idea to the next phase if the gut feeling is strong enough.

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A The interview guide

Interview guide (60min)

Setup: (5 min)

- **Introductions**
- **Purpose of the study:** to understand and identify the good practices and support needs for successful criteria definition and decision making in ideation and concepting phases of development in the health technology industry.
- **Confidentiality:** Access limited to thesis worker Aaro Packalén and the Aalto University Design Factory research team.
    - Have you had time to view the GDPR privacy statement attached to the email?
- Is it okay for me to record this interview?

Role and background (5min)

Can you tell me a bit about your current role?

- Position, unit/function/product line, how long have you been in the company
    - How would you describe the current development culture at the company/your unit (low/high hierarchy etc…)
    - What kind of development projects or issues do you work with?
    - What kind of resources do you have typically available?
    - What limitations do you typically have?
    - How did you end up in your role?

Warm-up to the theme (10min)

- What is your most effective/favourite ideation method, and why?
- Are there any practices or tools you like to use to evaluate ideas?
- Who are involved in the idea creation and selection process?
- How do you choose the ideas to advance? (set quality goals, innovativeness etc.)

Ideation success criteria and evaluation “case examples” (5x6min)

I’d love to walk through some concrete examples to get a better understanding of your ideation and idea selection process. “Ideation flow”, from the ideation to selection

- Could you share an example of an ideation flow that you feel was successful?
    - Is this a typical ideation flow in your organisation?
- How about an ideation flow that went wrong in some way or you feel could’ve gone better?
- How is the decision making usually done during ideation & concepting phases?
- How is the ideation phase usually organised/approached? (Do you have set time, goals, requirements, etc.)

Prompts for all of the above idea cases:

- Can you give an example of how working in the medical field has affected the ideation & development process?

    - Do you typically separate ideation from selection?
    - How did you make the decision to move forward with an idea?
    - Where did the idea come from? Why did it seem promising or worth considering?
    - Can you walk me through what happened with it?
    - Did you record the idea somewhere? If not, why not?
    - Did you share it with anyone? Why?
    - If yes, when, where and how did you share it? What was their reaction?
    - What happened next?
    - What supported your efforts? Hindered them?
    - Anything that you wish you would have done differently in hindsight?
    - What are the next steps with this idea?

Future (5 min)

- Coming back to the bigger picture of development at XXx, what are the next steps you think XXx should take to enable creating and pursuing innovative ideas?
- If you could change one thing, what would that be?
- How about is there something you think absolutely should be held on?

Wrap-up (5min)

- Concluding: Anything to add, has something important still been left undiscussed?
- Recommendations for other people I should talk to? Any other developers or PM's available?
- Any questions for me regarding this study?