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A case study on user involvement in an early-stage MedTech startup

TIØ-4945 Master Thesis

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Preface

This master thesis is written by two students at the NTNU School of Entrepreneurship (NSE), at the Norwegian University of Science and Technology (NTNU). Specifically, this master thesis is a specialisation in the subject TIØ4945 – Entrepreneurship. The thesis is written in collaboration with an early-stage Medical Technology (MedTech) startup, Vilje Bionics, a spin-off from NSE, advisors from St. Olav Hospital and the organisation ALS-Norge.

First of all, the researchers would like to thank Vilje Bionics for the opportunity to conduct a case study based upon their user-tests with patients. By providing insight into exploring the experience of user involvement in an early-stage MedTech development process. The researchers would like to express deep gratitude towards all the patients that participated, even through a critical stage of their life with the Amyotrophic Lateral Sclerosis (ALS) disease. Their hope to contribute for the future generation of ALS-patients was rendered through interesting key findings that supports and builds upon current research in the field of healthcare innovation and entrepreneurship; which can also be used to build upon future research.

Second, the researchers would like to thank their advisors at St. Olav hospital for advice along the process. Particular thanks to Tore Mesingseth, one of Vilje Bionics founders and Associate Professor, MD at NTNU's Department of Neuromedicine and Movement Science, for supporting with the approvals from the Regional Ethical Committee for Medical and Health Research Ethics (REC) in order to conduct the case study.

Finally, the researchers would like to give a sincere thanks to their supervisors for on-going guidance. Associate Professor, Marikken Høiseth, at the Depart of Design and Associate Professor, Elli Verhulst, at the Department of Industrial Economics and Technology Management. Their guidance contributed to building the methodological foundation and conducting the data analysis for this case study.

Trondheim, June 2021

Isabella McNeill Benestad

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Abstract

In recent years, there has been a pragmatic shift in the field of entrepreneurship and healthcare innovation with an increased focus on adapting user involvement practices within the MedTech industry (Pascal Lehoux et al. 2017; Pascale Lehoux et al. 2018; Schultz et al. 2016; Trigo et al. 2016). This shift results from a lack of understanding innovation processes within the field of healthcare (Altman et al. 2018). Current research shows that there is an increase of user involvement in the development of medical technology (MedTech), however limited research is dedicated to understanding the phenomenon of the experience entwined in user involvement.

The researchers' aim with this case study thesis was to explore, analyse, and explain the experience of user involvement in the development process of a medical technical device; from both a patient and a startup perspective. The purpose of the case study is achieved by obtaining empirical data through a qualitative research method with semi-structured interviews and a hermeneutic phenomenological research design to analyse the data. The hermeneutic phenomenological approach is well suited to illuminate the people's lived experiences, and thus explored as a phenomenon of research in this case study. For this purpose, the researchers conducted one-on-one interviews with 12 patients as well as a focus group interview with Vilje Bionics, an early-stage MedTech startup. Prior to this case study, the patients participated in a user-test conducted by Vilje Bionics connected to the development of a MedTech device known as the MotOrthosis. In the case study, the participants were asked questions about their experiences related to the participation in the user-test. The purpose was to highlight key experiences tied to user involvement from the perspective of both patients and an early-stage MedTech startup for answering the research question at hand. This case study demonstrates how hermeneutic phenomenology can provide insight into complex phenomena that are inextricably entwined in user involvement in MedTech development.

Through the case study the researchers identified three main findings of experience with user involvement in the development process of medical technology. These three key experiences were: (1) experience with the choice of methodology, (2) experience with possible improvement areas of the user-test, and (3) experience with healthcare professional participation in user involvement. The results indicate that the user-

test, which was conducted as a one-on-one semi-structured interview, was perceived as a satisfying experience connected to the choice of method from both perspectives. Although the feedback on the user-test was positive, both parts had suggestions for possible improvements. The proposals were mainly aimed at improvements of the product demonstration of the MedTech device, the MotOrthosis with regards to its functions and limitations. The most surprising finding in this case study revealed the experience connected to healthcare professionals participation in a MedTech user-test. Here, the feedback from the MedTech startup was that they experienced it as necessary to have healthcare professionals participate in the user-test, while this was not regarded as a necessity for the patients to participate in the user-test. In this finding, the complexity is evident in the fact that the patients were satisfied with the interview guide and the method of the user-test, while unaware that the interview guide and the planning had been done in close collaboration with healthcare professionals.

Finally, the case study's contributes directly to two fields of research; entrepreneurship and healthcare innovation. In the field of entrepreneurship research this case study reveals new perspectives on the *experience* of user involvement for MedTech startups and builds upon current research in the field. Moreover, the case study attributes to the field of healthcare innovation research through shedding light on the experience of user involvement with a MedTech startup from a patient perspective. Lastly, this case study thesis contributes to the intersection of entrepreneurship and healthcare innovation research with the use of hermeneutic phenomenology as a method, which has not been widely studied before.

Sammendrag

De siste årene har det vært et pragmatisk skifte innen entreprenøriell teori og helseinnovasjon som innebærer økt fokus på brukermedvirkning (Pascal Lehoux et al. 2017; Pascale Lehoux et al. 2018; Schultz et al. 2016; Trigo et al. 2016). Skiftet er et resultat av manglende forståelse for innovasjon innen helse og kunnskap om dette markedet (Altman et al. 2018). Selv om teorien viser at det er økt brukermedvirkning i utviklingen av medisinsk teknisk utstyr (MTU), er det få som har spurt om opplevelsene og erfaringene ved deltagelse i brukertester.

Formålet med denne case-studien var å belyse hvordan pasienter og et oppstartsselskap opplever, og erfarer, brukermedvirkning i utviklingsprosessen av et MTU. Case-studiens formål oppnås ved å innhente empirisk data gjennom en kvalitativ metode, ved bruk av en semi-strukturert intervjuprosess. For denne case-studien ble 12 pasienter intervjuet en-til-en, og et oppstartsselskap, Vilje Bionics, ble intervjuet som en fokusgruppe. Alle deltakerne fikk spørsmål knyttet til sine opplevelser og erfaringer med deltagelse i en brukertest. Dette for å kunne belyse begge partenes opplevelser og erfaringer, samt å svare på case-studiens vitenskapelige spørsmål. Innsamlet data har blitt analysert basert på teori innenfor fortolkende hermeneutisk fenomenologi, en analysemetode som er velegnet for å belyse menneskers opplevelser og erfaringer som et fenomen.

Resultatene viser til tre hovedfunn; (1) *opplevelser/erfaringer med valg av metode*, (2) *opplevelser/erfaringer med potensielle forbedringspotensialer for brukertesten* og (3) *opplevelser/erfaringer med deltagelse av helsepersonell i arbeid med brukermedvirkning*. Resultatene viser at brukertesten, som ble gjennomført som en-til-en semi-strukturert intervju, var tilfredsstillende både for pasient og oppstartsselskap. Selv om tilbakemeldingene på brukertesten var positive, hadde begge parter forslag til eventuelle forbedringer. Forslagene som partene kom opp med var rettet mot produktdemonstrasjon, samt at spørsmålene i brukertesten burde blitt sendt ut på forhånd. Det siste funnet i denne case-studien omhandler deltagelse av helsepersonell. Her var tilbakemeldingene fra oppstartsselskapet at de opplevde og erfarte det som nødvendig å ha med helsepersonell i prosessen med brukertesten. Pasientene mente derimot at det ikke var nødvendig for deres deltagelse. I dette funnet framstår kompleksiteten ved at pasientene, som var fornøyde med intervjuguiden og metoden

til brukertesten, var uten kjennskap til at intervjuguiden og planleggingen var gjort i tett samarbeid med helsepersonell.

Avslutningsvis bidrar case-studien til to forskningsfelt; entreprenørskap og helseinnovasjon. Innen entreprenørskapsforskning belyser denne case-studien nye perspektiver om opplevelsen og erfaringen av brukerinvolvering for MedTech oppstartsselskap og bygger videre på aktuell forskning innenfor feltet. Videre bidrar case-studien til feltet for forsking på helseinnovasjon ved å belyse opplevelsen og erfaringen av brukerinvolvering med en MedTech oppstartsselskap fra et pasientperspektiv. Til slutt bidrar denne case-studien til skjæringspunktet mellom forskning på entreprenørskap og helseinnovasjon med bruk av hermeneutisk fenomenologi, en metode som ikke har blitt studert mye tidligere.

Chapter 1
Introduction

In this chapter the researchers will explain the background and the motivation for this case study thesis. In addition, collaborating partners will be introduced and their role in the case study thesis will be explained. Then the researchers will present the case study research questions at hand. Last, the structure of the case study thesis will be presented, which provides an overview of what each chapter will present.

1.1 Background

Last fall, the researchers conducted a literature review that looked at the intersection between entrepreneurship, healthcare innovation and human-centered design (Benestad and Vaskinn 2020). In the literature review, the researchers identified the value of user involvement through human-centered design approaches in product development. Specifically, the researchers identified several methods of user involvement across the different fields and their intersection. Large investments with regards to resources and capital go into the development process of MedTech, however only up to 50 percent of MedTech devices make it to the market (De Jong and Hippel 2009). Research shows that MedTech products built in collaboration with users are more likely to succeed and increase customer satisfaction (Benestad and Vaskinn 2020). Current research shows that there is an increase of user involvement in the development of medical technology (MedTech), however limited research dedicated to understanding the phenomenon of the *experience* entwined in user involvement (Bate and Robert 2006; Benestad and Vaskinn 2020; Castner et al. 2016). Based upon these findings the researchers wanted explore, analyse and explain the *experience* of user involvement in the development process of a MedTech device. The researchers noticed a lack of research dedicated to understanding both the experience from an early-stage MedTech perspective and a patient perspective in a user involvement process. Moreover, the researchers identified qualitative research methods of user involvement to include patients in development processes with semi-structured

interviews and a hermeneutic phenomenological research design to analyse the data. The hermeneutic phenomenological approach is well suited to illuminate the people's lived experiences, and can be used to explore *experience* as a phenomenon of research.

For these reasons, the researchers decided to design a case study master thesis with the purpose to derive *key experiences* of user involvement in an early-stage MedTech development process by understanding the differences and similarities from both a MedTech startup and patient perspective. The MedTech startup in this case study was Vilje Bionics, a spin-off from the NTNU School of Entrepreneurship. The MedTech startup is developing a motorised exoskeleton product for patients with reduced arm functions. The primary patient group of users for the MedTech device are diagnosed with Amyotrophic Lateral Sclerosis (ALS). ALS is a motor neuron disease which affects and impairs the nerve cells in the brain and the spinal cord. As a result, the patients will not be able to move their arms nor legs after a while (Brown and Al-Chalabi 2017).

Prior to this case study, the startup conducted 13 semi-structured interviews with ALS-patients referred to as the user-tests throughout this case study. In this case study the researchers interviewed 12 of these patients applying the same method of semi-structured interviews to analyse the experience of this user involvement method. Moreover, the researchers interviewed the MedTech startup through a focus group interview to learn about their experiences related to the user-tests.

1.2 Motivation

In the literature review (Benestad and Vaskinn 2020), the researchers identified articles stating that there is an ongoing pragmatic shift within the healthcare industry, where users also known as the patients are taking a larger and more active role in development processes (Baldwin and Von Hippel 2011; Von Hippel 2006, 2007; Von Hippel and Katz 2002). Prior to the case study, the researchers had an hypothesis that healthcare professionals might have a crucial role in user involvement processes, thus decided to explore this in a literature review for this case study as well. Through the literature review of this case study the researchers found that sole a few scholars argue the importance of healthcare professionals role in user involvement processes in the development of MedTech. Since one of the researchers, Vårin Vaskin, is a registered nurse and contributed to the user-tests conducted by the MedTech startup this was another motivational factor. For these reasons, the researchers took the opportunity to use the MedTech startup, Vilje Bionics, as a case study and interviewed the participating patients from the user-tests to learn

from their experiences with user involvement. Moreover, it was motivational for the researchers to be able to explore this from both a patient and MedTech startup perspective, which the researchers could not find any current literature research on thus far.

1.3 Partners

In this chapter of this case study master thesis will be presented. The partners for the master thesis is Vilje Bionics, St. Olavs Hospital and ALS-Norway. These partners have had an important role for this thesis and their role will be presented here.

1.3.1 Vilje Bionics

Vilje Bionics is a spin-off startup company from the NTNU School of Entrepreneurship. The startup was established in January 2020 and the team consists of four individuals all student at NTNU. One of these students is also the researcher in this case study master thesis named Vårin Vaskinn. Her responsibilities are primarily within user contact and user involvement due to her background as a registered nurse. Since January 2020, Vårin Vaskinn has worked on finding out how to involve patients in the development process through a literature review in the field (Benestad and Vaskinn 2020), which essentially led up to the designed user-tests for the startup and this case study master thesis.

Vilje Bionics is developing a product known as the MotOrthosis in this case study, assisting exoskeleton with motorised movement for individuals with arm impairment (see figure 1.1). This MedTech helps with movements in the shoulder, elbow and wrist, in addition to this Vilje Bionics is developing a grip function. The development of the MotOrthosis started in 2015 when Mangor Lien was diagnosed with Amyotrophic Lateral Sclerosis (ALS). After the diagnosis his arm functions got impaired and this was the beginning of the search for MedTech devices that could potentially help him. He did not find any products that could help him receive some of his movements back. Thus, his brother professor emeritus Terje Lien started developing the motorised exoskeleton now known as the MotOrthosis. In 2020 a group of students joined the project and started a MedTech company with a goal to commercialise the MotOrthosis and make it available for people in the same situation as Mangor Lien .

Figure 1.1: Picture of the MotOrthosis

Vilje Bionics has developed two prototypes for two individual patients and have developed a third one with the intention to fit 95 percent of the Norwegian adult population. The startup is now in the process of developing and certifying their product, and they wanted to involve patients in this process. This supports the entrepreneurial process within healthcare innovation, which has developed from low user involvement to a high level of user involvement (Baldwin and Von Hippel 2011; Von Hippel 2006, 2007; Von Hippel and Katz 2002). In addition to this, involvement of users have shown to be beneficial for both the producers and end-users (Baglieri and Lorenzoni 2014; De Jong and Hippel 2009; Gandhi et al. 2014; Kuratko et al. 2001; Lettl and Gemünden 2005; Rochford and Rudelius 1997; Wise and Høgenhaven 2008) as then the end-users needs have a higher chance of being included in the product development (Baldwin and Von Hippel 2011; Von Hippel and Katz 2002). Thus, the researchers believed that the potential of user involvement could help Vilje Bionics develop their product further.

During this process of product development Vilje Bionics has used time to figure out *how* and when to involve the patients. The "when" part was decided early on that it should be after the 3rd prototype was finished, and the "how" part was evaluated by several factors. Particularly, the how part was evaluated thoroughly in the project thesis prior (Benestad and Vaskinn 2020) to this case study and covered in the literature review in this case study as well. Moreover, the startup had knowledge and experience from their team member and registered nurse, Vårin Vaskinn. Her knowledge about patient communication and background experience

provided the MedTech startup with trust in her role to identify the most applicable method to involve patients in a user involvement process. Based on the findings from the literature review (Benestad and Vaskinn 2020) the researchers including Vårin Vaskinn could only recommend the MedTech startup what method, but not how this experience of user involvement would unfold in practice. Since the findings in the literature review (Benestad and Vaskinn 2020) stated that an iterative process and focus on user involvement is the method that has shown the best results regarding user involvement (Pascal Lehoux et al. 2017; Von Hippel and Katz 2002). The startup looked at a method with an iterative process with the support from Vårin Vaskinn and other healthcare methodology theory from Christoffersen et al (2015) of how to interview patients. This was also done in collaboration with other healthcare professionals advice from St. Olavs Hospital. Thus, Vilje Bionics conducted 13 semi-structured interviews with ALS-patients with the goal of increased user involvement and development for the most applicable product.

1.3.2 St.Olavs Hospital

Vilje Bionics has a board of advisors that also assisted in this case study master thesis. In this board is Tore Mesingseth whom is the founder of Vilje Bionics product the MotOrthosis. He is a Neurologist with a background as a partitioning doctor and associate professor at NTNU, he assisted in applying for the ethical approvals for this case study thesis and for Vilje Bionics. Vilje Bionics user-tests were approved by the Regional Ethical Committee for Medical and Health Research Ethics (REC). Moreover, both the user-tests conducted by Vilje Bionics and this case study master thesis were approved by Data Protection Impact Assessment. An application that describes how the data is saved and handled before, during and after the case study thesis. In addition, Vilje Bionics collaborates with one occupational therapist, Mari-Anne Myrberget, and a specialised physiotherapist, Ole-Petter Norvang. These two are also in the board of advisors although not one of the founders. They have given advice related to product development and understanding the patient situation from an healthcare perspective.

1.3.3 Patient organisation

There are two patient organisations related connected to ALS in Norway, these organisations are known as *ALS-Norge* and *Alltid Litt Sterkere*. The MedTech startup Vilje Bionics has an official collaboration with ALS-Norge. This collaboration was essential for the MedTech startup to conduct user-tests with patients and for this case study master thesis to take place. Through ALS-Norge the MedTech startup

and researchers were able to recruit participating patients in the user-tests and case study.

1.4 Research questions

In the literature review in this case study, it reveals that the experience as a phenomenon is a critical component in order to gain an in-depth understanding and fully grasp the contextual meaning of user involvement (Castner et al. 2016). Nonetheless, the *experience* of user involvement from a startup and patient perspective when developing a new medical technical device is not identified in the current landscape of research. This is argued to be an area of research to further address in the MedTech industry (Bate and Robert 2006), which underpins the aim of this case study. Based upon this as well as the background and motivation (see sections 1.1. and 1.2) the researchers aims to answer the following research questions in this case study master thesis.

Main RQ: How do patients and startups experience user involvement in the development process of medical technical devices?

1.1 How do patients experience being involved in the development process of a new medical technical device?

1.2 How does a startup experience user involvement in the development process of a new medical technical device?

1.5 Structure of thesis

This section presents and overview of the case study master thesis Table 1.1. The case study master thesis starts with an introduction as mentioned with relevant background information. In chapter 2, the researchers will present the literature review which builds the foundation of this case study master thesis. In chapter 3, the researchers presents how the methodology was applied in this case study research. In chapter 4, the researchers presents the findings from the qualitative research, this section is divided into two parts; the patients perspective and the MedTech startup perspective. Next, in chapter 5 a discussion of the data analysis is presented based upon existing theory from the literature review and the researchers answers the research questions at hand from the findings and literature, and finally the researchers present the conclusion in chapter 6 – concluding with the key findings, the case study's contribution as well as limitations of the case study.

Chapter 1	Introduction
Chapter 2	Theoretical Foundation
Chapter 3	Methodology
Chapter 4	Findings
Chapter 5	Discussion
Chapter 6	Conclusion

Table 1.1: Structure of the thesis

Chapter 2
Literature Review

Prior to this case-study, the researchers reviewed literature on human-centered design (HCD) and its intersection between entrepreneurship and healthcare innovation (Benestad and Vaskinn 2020). The literature review highlighted that a HCD iterative process including user involvement in product development is highly valued and beneficial both in entrepreneurship and healthcare innovation (Benestad and Vaskinn 2020). Specifically, stating that the failure to involve users in the development of a medical technical device inevitably affects the quality of the final outcome (Grocott et al. 2007). In spite of that, the experience of benefits and barriers of user involvement in the development of a medical technical device has not been widely studied. Hence, the researchers will elaborate on the given research topic as well as the theoretical framework that is used to structure and analyse the findings in this case-study.

2.1 Human-centered design and innovation processes

Human-centered design (HCD) is a method where developers intend to study the users experience and preferences when developing new products (Ahrens, Hehenberger et al. 2015; De Jong and Hippel 2009). Steen et al (2004) states in their article that it is in addition to experience and preferences, is it important to observe the user in an everyday context while they use the product (Steen et al. 2004). Most articles refer to the International Organization for a Standardization (2019) definition of HCD. Here, HCD is defined as *"...an approach to systems design and development that aims to make interactive systems more usable by focusing on the use of systems and applying human factors/ergonomics and usability knowledge and techniques"* (Standardization 2019 p. 3). This method has roots in ergonomics, computer science and artificial intelligence (Giacomin 2014), and is based on using techniques that try to communicate, interact, empathize and simulate with the in-

volved users. The goal with HCD methods is to understand the users' needs and desires through deeper insight regarding the problem (Giacomin 2014). Koen (2015) further acknowledges that *" ... the heart of HCD is a focus on human values and deep empathy with users"* (Koen 2015 p.14). It is important to involve the users early in the development process to avoid costly design changes and to increase the chance of developing a product that the user will use (Kjørstad et al. 2018). Furthermore, Kujala's (2003) concludes in a review on the effect on user involvement that a positive outcome can be seen from both the user's and producer's perspective. Kujala (2003) summarizes the effects upon early user involvement in the figure below (2.1). The figure shows how 'Early User Involvement' affects the product development as well as consumers' requirements, which then affects the system quality. Together the elements make up for the 'user and customer satisfaction' with a beneficial effect (Cowley et al. 2019; Echeverri et al. 2013; Kujala 2003).

Figure 2.1: Early user involvement, Kujala (2003)

Furthermore, the work of Koen (2015) involving users in the development process poses three vital questions that should be addressed; (1) *"What is the right problem?"* (2) *"Who has the problem?"* and (3) *"What is the value to the user in solving the problem?"* These questions are an essential part of the process because most companies struggle at solving the right problem. Koen (2015) argues that the team can use the practice of mapping out the problem from the Point of View (POV) of the user to guide and expose the team to new opportunities. The users can provide a fresh perspective on the problem and help to build the right solution. The POV focuses on three elements: *"(1) the user, (2) the user's need, and (3) observation of the user in his or her environment and interpretation of the observations"* (Koen 2015 p.19). These elements are meant to guide teams in focusing on the right aspects of user involvement. Further, Koen (2015) states that the HCD process is an iterative approach that includes the end customer which entails much of the same nature as the lean start-up methodology.

Even though patients are included to assist with sharing their experience from

their POV, it has up until now not been a focus on patients' experience with the participation in user-tests. There is a scarce focus in current research literature on asking detailed questions about their experience in-depth, except asking what was good or not in the development process (Bate and Robert 2006). However, when including patients in the development process the explanation of *"why"* is key in order to understand the interactions, thoughts and experience between the patients and the MedTech startup. Furthermore, it is vital to overcome the challenges of understanding and translating the experiences that the patients and MedTech startup has into valuable data. In addition, how the startup gathers and analyses the information (data) from the patients is important to consider in the development process of a medical technical device (Bate and Robert 2006). When patients are included in studies with regards to MedTech development they are frequently asked to answer questions related to the POV (Koen 2015), but rarely about their experiences with participating in the development process (Bate and Robert 2006). The literature suggest that patients experience and knowledge about the problem and their needs should be taken into account as a crucial part in the development process (Ballegaard et al. 2008; Das and Svanæs 2013).

2.1.1 User involvement in entrepreneurship

Implementing entrepreneurial actions involving users in the process of creating new products and launching into new markets have shown to increase established firm's performance (Kuratko et al. 2001). In fact, user innovation has become a vital part of the innovative process and development of new technology. For the entrepreneur's users can have important roles such as co-developers, evaluators, and testers (Lettl and Gemünden 2005). User innovators are individuals or firms that get some type of benefit from using a design, product or service they have taken a part of the development (Baldwin and Von Hippel 2011; De Jong and Hippel 2009). User driven innovation is a process that identify users' knowledge in a development process. In essence, this process is based on understanding users' needs and involve them in a more systematic way (Wise and Høgenhaven 2008). These users hold an innovative role and influence the development process, and the products of most value are more likely to be transferred and generate the most value for the users (De Jong and Hippel 2009; Rochford and Rudelius 1997). These users can also be called lead users and they have high experience regarding a problem, or they have an unsatisfied need. In the most resent years empirical studies about user involvement have increased (Trigo et al. 2016), and studies have shown that the user can also be the innovator known as the user innovator. For instance, a user can also be the developer of a new product and/or have an important role in the innovation process. Jong and von Hippels

(2009) states that over half of the user innovators in their study would transfer their ideas without any compensation to others that could commercial and realise their idea. Baglieri and Lorenzini (2012) also considers users as both the scientists and end-user involved in the product development process, noting that entrepreneurship in this process can be used as an alternative way to gather information that allows them to shape the institutional environment and market boundaries to a much greater extent. In essence, they argue that users' insight both from a scientist and user's perspective put into an academic entrepreneurship view and practice can be applied to close the distance between academia and market (Baglieri and Lorenzoni 2014).

Users that take part in the innovative process are unique in the way that they will have a direct benefit from the innovation. These types of users have a unique insight tied to the problem the technology is trying to solve, thus their feedback is vital for the design- and product development process. Here, the value of the product or service is valued through the user's willingness to pay for a product that meets their needs (Baldwin and Von Hippel 2011). User involvement is an important part of the innovative process, starting from the idea generation to the design phase of the product. During this process the users' needs and wants are considered before the users gets involved in the test phase of the potential solution, last the producers retrieves feedback and information from the test users to identify drawbacks and then reiterate to improve the product and meet the users' needs. This process is well known amongst entrepreneurs and can be summed up in four steps; (1) identifying possible solutions, (2) building the solutions, (3) testing the solution with users and (4) evaluating feedback to identify if improvements are needed or not. Essentially, this interactive process involves the users throughout the innovation process in order to create a valuable product for the end user (Von Hippel and Katz 2002).

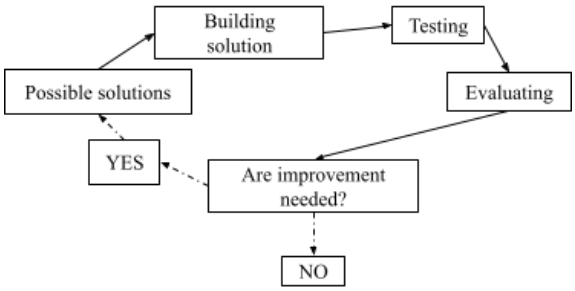

Figure 2.2: Overview of human-centered design processes, (Von Hippel and Katz 2002)

However, it is important to note that the downside of involving users in the design process is that it can require large costs for the companies. It has been estimated

that high tech firms spend an average of € 184,000 on their user innovation processes (De Jong and Hippel 2009). Even though this is a large cost, getting feedback from actual users reduces the costs in the long term, and with drastic changes in a later testing process. The earlier the users are involved in the product development process, it essentially saves the company time and money (Von Hippel and Katz 2002).

2.2 Entrepreneurship in healthcare

In the healthcare industry the hospitals are in general the leading innovators through developing new cutting-edge technology and treatments (Sindakis and Kitsios 2016). Here, the manufacturing job is outsourced to other companies that develop medical devices that needs to generate some type of wealth in order to produce the product and be profitable – usually some type of wealth that is connected to a market need such as a growing population, the demographic changes or to support patients with chronic diseases (Pascal Lehoux et al. 2017; Pascale Lehoux et al. 2018; Schultz et al. 2016). Large investments go into developing new medical devices, still only up to 50 percent of all new medical devices make it to the market (De Jong and Hippel 2009). The reason for this is often due to a wrong understanding of the problem and user needs of design and/or knowledge of the market. Thus, if a business model within the healthcare industry makes wrongfully assumptions about what type of product and for whom it is made, the product is more likely to fail (Altman et al. 2018). Further, entrepreneurs, investors and regulatory agencies influences the value proposition of the medical device by closing a gap through their technology and value proposition (Pascal Lehoux et al. 2017).

Medical devices can also be invented by spin-offs and startups that commercialise technology. According to Lehoux et al. (2017) it is important for a startup to specify the economic value and how to capture this value. MedTech startups has to comply with a range of institutional requirements in the same line as other companies. For instance, Lehoux (2017) uses a tree-step process that elaborates the roadmap and the range of institutional requirements that must be met in order to innovate and capture value in healthcare innovation (2.3). These steps include: (1) *measuring clinical risks that are convertible into business opportunities,* (2) *structuring technological entrepreneurship for growth and* (3) *mitigating economic risks in face of material challenges.* The first step applies to this case-study and includes clinical studies in order to ascertain the potential of the technology. The results of the clinical studies should be measured and transferred back to the business model. This step is seen as crucial in Lehoux model as other MedTech companies have experienced that the

technology they have been developing for years does not seem as promising as it once did (Pascal Lehoux et al. 2017).

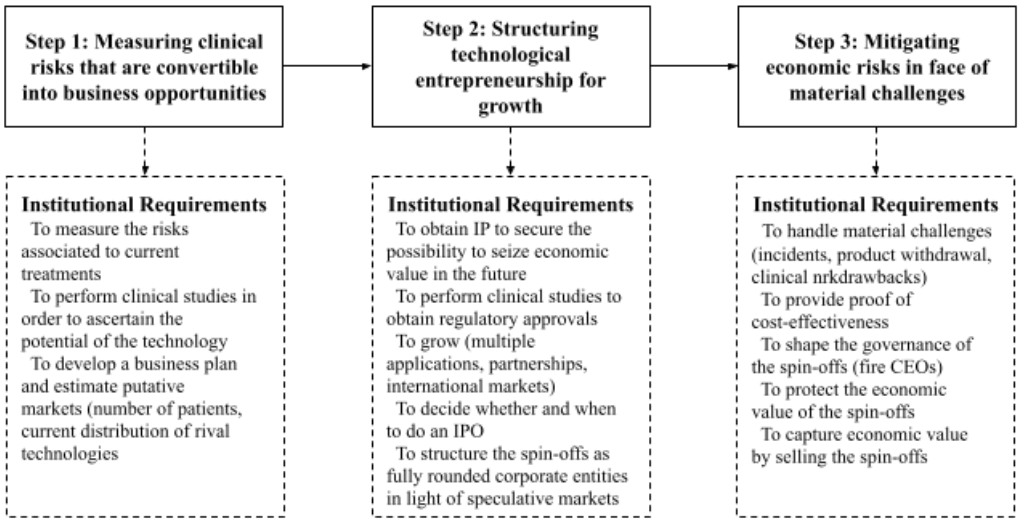

Figure 2.3: The three-step process of entrepreneurship within healthcare innovation (Pascal Lehoux et al. 2017 p.210)

2.3 User involvement in healthcare innovation

In the literature review conducted by the researchers prior to the case-study (Benestad and Vaskinn 2020), user involvement was shown to be a critical component in the development process of MedTech (Baglieri and Lorenzoni 2014; Baldwin and Von Hippel 2011; Caron-Flinterman et al. 2005; Rochford and Rudelius 1997; Trigo et al. 2016; Von Hippel and Katz 2002; Wise and Høgenhaven 2008). Innovation in the healthcare industry has over time experienced a shift where the user now holds a more active and major role as co-developers or innovators (Baldwin and Von Hippel 2011; De Jong and Hippel 2009; Von Hippel 1978a,b; Von Hippel and Katz 2002). The challenge is to develop technologies that benefit the patients also referred to as the users in this case-study (Benestad and Vaskinn 2020). The healthcare industry faces a high demand for services and products stretching available resources, however this is where user involvement has been viewed as a means to generate more ideas for new healthcare services (Trigo et al. 2016. For example, user involvement is shown to a beneficial factor contributing to quality improvement in Swedish healthcare; where the impact of user involvement appears to be highest in the phases of capturing experiences (e.g., identifying improvement areas) and taking actions from patients input (e.g., generating and implementing suggestions) (Gremyr et al. 2018). In essence, this *" ... shows that it is possible to suggest at what point in*

an improvement cycle patient involvement has the highest impact, which will enable more efficient use of the resources available for patient involvement." (Gremyr et al. 2018 pg. 1.) Further, Echeverri et al. (2013) argues that integrated user involvement can help to identify *"experience-drivers, value-creating activities and reasons for dissatisfaction and complaints, ideas for service development and innovation"* (Echeverri et al. 2013 p. 50). In addition, findings show that the combination of experience-based co-design and action research is a promising approach to address the challenges of patient involvement in healthcare improvement (Gustavsson and Andersson 2019). Moreover, Wiig et al. (2013) investigated the use of patient involvement and patient experience in quality improvement of the healthcare system showing that it is a valuable contribution to improve healthcare services. When the user is involved, the relevance, the pragmatism as well as the benefits of the product development in terms of usefulness, effectiveness and practical efficacy increase (Consoli and Mina 2009). Despite the benefits, Trigo (2016) highlights that although a number of studies on the topic of user involvement in healthcare innovation has demonstrated benefits there is still a scarce amount of research conducted on the topic.

2.3.1 User involvement in a medical device lifecycle

The contribution of user involvement in a medical device lifecycle can be divided into several stages including: *(1) the design stage, (2) testing and trial stage, (3) deployment stage, and (4) concept stage* (Shah and Robinson 2006). The development for a medical technical device requires in-depth consideration of the users' activities in their daily working life as well as functional limitations (Green et al. 2000; Kaufman et al. 2003; Kittel et al. 2002; Ostrander 1986; Rockwell 1999; Staccini et al. 2001; Wilkins and Holley 1998). The user requirements affect all aspects of device development, hence why it is critical to attain them properly through user involvement in the development process (Tsai et al. 1997), which aggregates in the production of a more successful medical technical device (Biemans 1991; Brockhoff 2003; Lin et al. 2001; Shaw 1998). In the stages of medical device technology lifecycle the highest user involvement usually happens in the first stage – the design stage; followed by testing and trial stage, deployment stage, and concept stage (Shah and Robinson 2006). According to Tsai (1997), Giuntini (2000) and McDonagh et al. (2002) the findings of higher user involvement in the early stages can save time and costs including later modifications on the device (Giuntini 2000; McDonagh et al. 2002; Tsai et al. 1997). In addition, the outcomes of the design stage resulting in final design are used to develop the medical technical device that have a higher market usuability (Gould and Lewis 1985). The users needs are regarded as import-

ant as it helps the developers to incorporate the users needs in the development of the device (Saiedian and Dale 2000; Sato and Salvador 1999; Truffer 2003). Thus, early user involvement has been suggested as vital since it is beneficial both for the producers and the users (Kyng 1991; Ornetzeder 2001; Sanford et al. 1998). There are numerous methods of capturing valuable user perspectives that contributes to the development and assessment of a new medical device. According to Shah and Robinson (2006) the most common methods used are usability tests, interviews and questionnaire surveys. For example, it is mainly common to conduct semi-structured and face-to-face interviews (Shah and Robinson 2006).

Moreover, the vital role of user involvement in healthcare innovation has been thoroughly studied by von Hippel (1976) who points to the dominant role of users in the development of medical technical devices. The study included a sample of one hundred and eleven scientific medical device innovations where users played an incremental role in the final output. Moreover, other scholars have pointed out that the understanding of users needs is a vital success criteria that can result in a higher value of the technological development (Cahill et al. 1994; Rochford and Rudelius 1997; Shaw 1998). According to the works of von Hippel (1976) the entrepreneurial process when developing a medical technical device states that in approximately 80 percent of the innovation cases there was a user that (1) *participate in opportunity recognition,* (2) *are the innovator of the instrument,* (3) *are building the prototype*, and (4) *gives the manufactures proof that there's value by applying it.* Despite the large amount of research dedicated to highlight the importance of user involvement there is a need to further research *"...the benefits and barriers associated with user involvement in the development and assessment of medical device technologies"* (Shah and Robinson 2006).

2.3.2 The role of nurses in medical device development

The role of nurses in medical device development has also been identified as key leaders in the improvements and redesign of future health care systems (Castner et al. 2016). Castner et al. (2016) states that *"...it is essential that nurses are involved in device development to inform the process and to provide insight from a patient-centered viewpoint of the human-technology interface."* (Castner et al. 2016 pg.300). Nurses are in a key position to bring this critical end-user focus to technology development teams, based on the profession's code of ethics (Epstein and Turner 2015). However, engineers or product developers are not expected to become nurses, or vice versa, but that each brings their own knowledge to the table (Castner et al. 2016). Although there are several research reports on the positive

outcomes of nurses working in technology and device development (Bridgelal Ram et al. 2008; McClelland and Kleinke 2013; Rantz et al. 2013; Weir et al. 2006) Castner et al. (2016) reports that there is little guidance on how to engage nurses in the early steps of medical device development. For this reason, Castner et al. (2016) designed a conceptual model for involving nurses in the medical device development process. The model is nonlinear and iterative including the following stages: "*needs assessment*", "*planned brainstorm*", "*feasibility determination*", "*concept design*", and "*prototype building*" (Castner et al. 2016, pg. 304). The model has led to an ongoing cycle of innovative and potentially disruptive technology development (Castner et al. 2016). The model known as "Strengthening the Role of Nurses in Medical Device Development Roadmap" is intended to be a guide for future research studies on the involvement of nurses in transdisciplinary collaborations and medical device development.

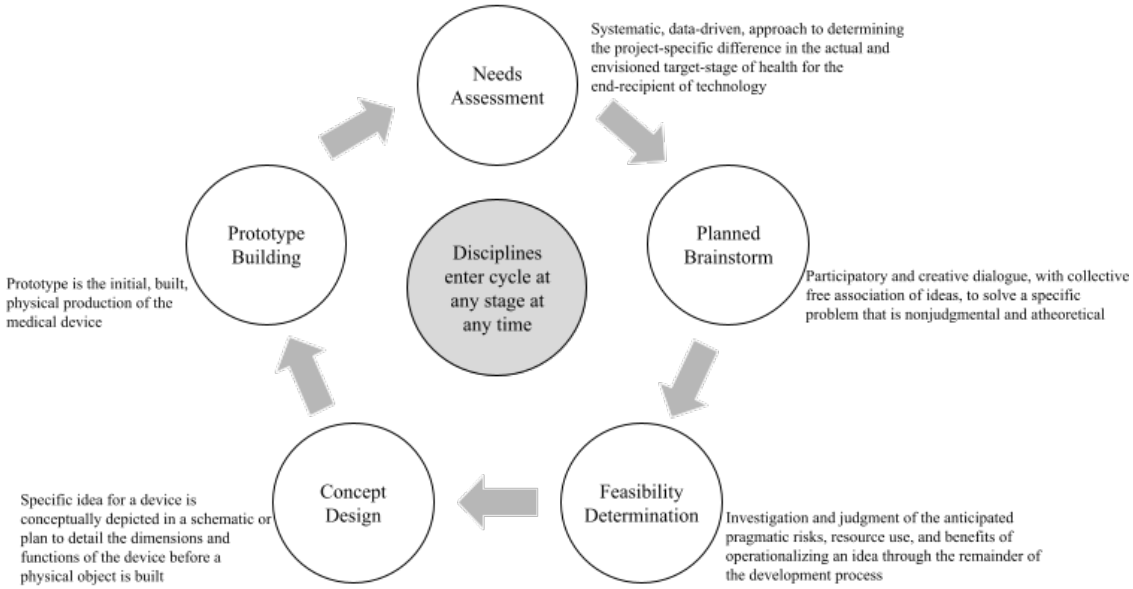

Figure 2.4: Strengthening the Role of Nurses in Medical Device Development Roadmap (Castner et al. 2016 p.302)

2.3.3 Research gap in the literature review

The literature review states that human-centered design (HCD) is about understanding the users needs, in combination with early user involvement, which in essence can increase the customer (user) satisfaction (Cowley et al. 2019; Echeverri et al. 2013; Giacomin 2014; Kujala 2003). Additionally, it is known that more than half of MedTech products do not make it to the market (De Jong and Hippel 2009). Many scholars argue that this is due to a wrong understanding of the market needs (Altman et al. 2018), thus creating a gap in the value proposition that the MedTech

company offers their customers (Pascal Lehoux et al. 2017). However, the literature review shows that there are several theories within HCD and entrepreneurship with identified methods on *how* to involve users in development processes of a MedTech company and other industries in order to increase the chance of creating a product that succeeds on the market (kilde). Here, the researchers identified semi-structured interviews as a method of user involvement in the development process of a new medical technical device. Yet, none of the identified literature states *how the experience* of user involvement is for a MedTech startup nor the patients perspective when developing a new medical technical device. According to the literature on experience as a phenomenon it is a critical component to research in order to fully grasp the possible contextual meaning of user involvement. Bate and Robert (2006) argues that this is an area which should be further addressed in the field of research within the MedTech industry. For this reason, the researchers aim with this case study is to contribute by taking into account the experience of the users (the patients) and the MedTech startup with regards to user involvement in an early stage development process of a new medical technical device.

2.4 Theoretical framework

In the following sections, the researchers will present literature on the research design that was applied to the case-study. The research was conducted through a phenomenological research design with experience as a phenomenon, which grounds the theory for discussion and analysis of the research topic.

2.4.1 Phenomenological research design

Phenomenology is a philosophical movement and a family of qualitative research methods that examine the structures of experience or consciousness (Neubauer et al. 2019). According to Neubauer et al. (2019) it is fundamental for scholars to learn from the experience of others. In particular, they argue that it is a foundational premise of research that includes the study of a subject in order to achieve a new understanding of the subject under investigation. Wherein such research "... often requires understanding the experiences of others so that we can glean new insights about a particular phenomenon" (Neubauer et al. 2019, pg. 91). The phenomenological research approach seeks to describe the essence of a phenomenon by exploring it from the perspective of those who have experienced it (Teherani et al. 2015). The end goal is to arrive at specific descriptions of the participants own understanding of the 'lived' event, situation or experience, were the researchers gain a more pro-

found understanding of the phenomenon being studied (Christoffersen et al. 2015). Specifically, the researchers aim is to describe the meaning of the experience – both in terms of *what* is experienced and *how* it was experienced (Neubauer, Witkop, Varpio). While some methodologies seek to determine opinions and a generalization through hypotheses, a phenomenological research design seeks to explore contextual meaning through the situational knowledge of the researched (Creswell, 2009).

2.4.2 Hermeneutic phenomenology

There are seven different types of phenomenology that roots in different schools of philosophy (Embree et al. 1997), but in common "...most approaches hold a similar definition of phenomenology's object of study (Neubauer et al. 2019, pg. 92). However, in order to choose what type of phenomenology the researchers must reflect on what school of philosophy that underpins the applicable method (Stubblefield and Murray 2002). The methodological decision is driven by the researchers epistemological assumptions (Lopez and Willis 2004; Neubauer et al. 2019). For instance, epistemological assumptions in transcendental (descriptive) phenomenology means that the researcher must separate him/herself from the state of the subject being studied in order to be bias-free. Whereas epistemological assumptions in hermeneutic (interpretative) phenomenology the researcher is part of the world and not bias-free, thus understands the phenomenon by interpretive means (Neubauer et al. 2019). The latter school of philosophy, hermeneutic (interpretative) phenomenology, builds the rationale for the chosen method applicable to this case-study further explained in the chapter on methodology.

Hermeneutic phenomenology, also known as interpretive phenomenological analysis, has become a dominant qualitative research methodology in academic fields such as human, social and health care research (Christoffersen et al. 2015). The hermeneutic (interpretative) approach can particularly be drawn from the work of Martin Heidegger (Neubauer et al. 2019). Hermeneutic phenomenology is embedded in interpretation – interpreting phenomena and experience through the individual's *lifeworld* (Neubauer et al. 2019). This requires the hermeneutic phenomenologist to interpret the data provided by the research participants in relation to their contexts in order to grasp and structure their lived experiences (Heidegger 1962). The hermeneutic phenomenological approach "... recognizes that the researchers, the research subject itself, cannot separate his/her lifeworld (Neubauer et al. 2019, pg. 95). Here, the researchers past experience and linkage to the research topic is rather used as a valuable guide to the inquiry (Neubauer et al. 2019).

There are two primary goals with an interpretative phenomenological approach:

(1) to study in-depth how an individual makes sense of their experience and (2) provide a detailed interpretation of the data gathered to understand the experience (Tuffour 2017). This is an inductive research approach that seeks to explore 'what', 'why' and 'how' questions, rather than 'how much' and 'how many' preferred by quantitative studies. The phenomenological hermeneutic research approach starts by identifying the phenomenon of interest. Then an analyses of the phenomenological interview data is conducted to find the "essence" or common themes in their experiences (Neubauer et al. 2019). Last, the researchers role in data analyses is to reflect on the essential themes of the participants experience with the phenomenon in order to arrive at a more profound understanding of the whole phenomena being studied (Bynum and Varpio 2018). This last step is called the hermeneutic circle, which emphasises the practise of consciously considering how the data (the parts) contribute to the evolving understanding of the phenomena (the whole) and how each reinforces the meaning of the other (Bynum and Varpio 2018).

2.4.3 Experience as "Erfahrung" and "Erlebnis"

This case study thesis studies the phenomena of experience investigating how a user-test in product development was "experienced" from both a patient and startup perspective. Experience is a phenomenon that can be discussed from different angles and the English word for "experience" do not hold the same meaning as in the Norwegian language. Norwegian is in the Germanic family thus, the researchers looked to the German language in order to explain the different aspects of experience for this case study thesis. In the German language, experience and be explained as "Erlebnis" and "Erfahrung" (Mueller et al. 2020). *Erlebnis* can be translated to "lived experience" and is normally connected to a tacit experience or a pre-reflective experience. In addition to this, Erlebnis is usually connected to our own actions and bodily experiences. While *Erfahrung* means "a welter of different things" and comes after Erlebnis and is incorporated over time and with several phases of erlebnis. Erfahrung we get after the shared erlebnis and can be distributed to and incorporated by others over time (Mueller et al. 2020).

Chapter 3
Methodology

This chapter presents the research design and the rationale behind the chosen methodology of this case study thesis. First, the researchers will elaborate on the chosen methodology and give the readers a presentation of the phenomenological research design and approach for analysis. Second, the researchers will present an overview of the ethical standard for the chosen research study and the process of the data collection. Here, the inclusion and exclusion criteria for the selected research participants will be presented. Third, the researchers will explain how the study was conducted in more detail. In the end, the researchers present reflections on the quality and limitations of the methodology.

3.1 Research design

The researchers' have chosen to conduct this case study through a qualitative research method known as hermeneutic (interpretative) phenomenology. The fundamental goal of a phenomenological research design approach is to arrive at a description of an individual's lived experiences of a phenomena. Specifically, the researchers' seek to explore *how* the experience of user involvement in an early-stage MedTech startup is from both a patient and startup perspective. Although there is a well-established interpretive tradition in the social sciences and healthcare field, it is only in recent years that interpretive research in entrepreneurship has emerged (see example works from; Bouchikhi 1993; Chell and Pittaway 1998; Costello 1996; Hines and Thorpe 1995; Johannisson 1995; Rae 2000; Rae and Carswell 2000; Steyaert 1997; Steyaert and Bouwen 1997).

The startup company conducted a user-test with the patients prior to this case study thesis. Here, Vårin Vaskinn, one of the master thesis researchers' was involved as she works directly in the startup and has relevant patient experience from her nursing background. The primary goal of this master thesis case study was to demonstrate the experience of user involvement both from a startup and patient perspective. In order to gather information about the experiences from the

patients and startup after the user-test the researchers conducted semi-structured interviews. Consequently, the case study naturally gives insight into how the user-test affects the product development, although this is not the purpose of this case study. The researchers focus will therefore lay with the analysis of the patients and startup experiences'. This specific topic has not been widely studied, hence the researchers' motivation and decision to explore the given subject. Regarding the research design, the researchers chose to mainly use theoretical methodology from the healthcare field. The reason for this was because this case study includes critically ill patients with a deadly disease and parts of this study had to receive one of the highest standards for ethical approval. Thus, the researchers' saw it necessary to use methodology from the healthcare field to conduct the study and examine the data collection.

3.1.1 Qualitative methodology

Quantitative research would mean that the researchers would need to collect and analyse numerical data. This type of research approach includes independent and dependent variables that the researchers can quantify in order to make a generalisation. This is beneficial to arrive at specific predictions and generalize results to wider populations (Tjora 2020). However, the researchers may risk ignoring factors that are more significant in explaining important realities and relationships (Sofaer 1999). Here, qualitative research helps to understand complex, dynamic and multidimensional "wholes" (Patton, 1975). Furthermore, qualitative methods help provide rich descriptions of phenomena, which enhance understanding of the context of events as well as the events themselves. Moreover, qualitative methods may well help to identify patterns and configurations between variables and to make distinctions. Qualitative research, then, not only serves the desire to describe, but also helps move research toward more meaningful explanations (Sofaer 1999). In addition, qualitative case study methodology enables researchers to conduct an in-depth exploration of complex phenomena within some specific context (Rashid et al. 2019). A qualitative research case study method includes the defining features: (i) *empirical study of contemporary situations in a natural setting,* (ii) *a focus on asking 'how' and 'why' questions,* and (iii) *the treatment of each case as an experiment in which the behaviors cannot be manipulated* (Duxbury 2012). In designing a case study, the researcher must first determine that a case study is the best method to answer the research question at hand (Duxbury 2012). A case study approach can be conducted through different methods, including one-to-one interviews and/or focus group interviews (Kvale and Brinkmann 2019). These types of interviews seek to understand the *lifeworld* of the research participants perspective on the given

subject. Hence, a case study approach deemed the most prominent method for this master thesis.

Prior to the case study thesis, the researchers identified that there is a lack of research highlighting *how* to involve patients in the development process of a new medical device. Furthermore, there was a lack of research in the field of entrepreneurship and healthcare highlighting patient and startup experiences' with user involvement (Benestad and Vaskinn 2020). This was the reason why the researchers decided to look into this specific phenomena. The chosen method was also considered taking into account the practical matters of access to the research participants, patients, and their ability to participate. According to Tjora (2020), although there is a certain degree of ethical standards to consider when conducting studies with patients, it is also important to have an on-going and explicit dialogue between the researchers and research participants. Tjora (2020) states that this can enhance the participants' enthusiasm and own understanding of the participatory study which is vital for the quality of research (pg. 44). Kvale and Brinkmann (2019) characterises qualitative research practice in the healthcare field through an interview between patient and researchers' studying the opinions, behaviours, and experiences of the interviewees' (pg.77). A qualitative interview approach gives researchers' adequate insight from the interviewees' subjective perspective. Interviews can be conducted one-to-one or in focus groups, both methods allow researchers to study the research participants' understanding of a phenomena such as an experience of a specific event (Christoffersen et al. 2015). In essence, qualitative methodology is suitable for exploring the experiences of a specific phenomena (Malterud 2012).

Concretely, this study was established to gather information from patients being involved in a user-test that develops a new medical technical device. In addition, the researchers wanted to investigate the experience of user-involvement from an early-stage startup perspective. The reason for this is because both of these perspectives give a fundamental understanding of how user involvement is experienced from both parts in the development process in order to maximize its value and adjust the process accordingly in the future.

3.1.2 Research methods

The researchers gathered information for the case study through qualitative interviews. The interviews were semi-structured and conducted one-to-one as well as in a focus group. The patients were interviewed one-to-one and the startup company was interviewed in a focus group explained further below in this section.

Semi-structured interviews

Qualitative interviews can be conducted through a structured, semi-structured or unstructured process. Through the project thesis the researchers identified semi-structured interviews to be the most common method used within healthcare research (Bjørk and Solhaug, 2008; Kvale et al., 2015). Moreover, semi-structured interviews allow both the interviewer and the interviewee more flexibility and responsiveness to emerging themes. (Jackson et al. 2007). Additionally, semi-structured interviews was also found to be the most common used method for usability tests in the development of a new medical technical device (Shah and Robinson 2006). Based upon these findinga the researchers decided to go for a semi-structured interviews. Semi-structured interviews are close to a regular conversation and gathers information based upon chosen themes and pre-made questions. The pre-made questions are added to an interview guide which guides the interviewee through the process (Christoffersen et al. 2015; Fylan 2005; Kvale and Brinkmann 2019). Literature states that patients find it comforting to speak with and open up to healthcare professionals (Osmundsen et al. 2015). Thus, Vårin Vaskinn lead the interviews due to her professional background as a nurse. As the patients' had undergone an individual user tests with the startup company the researchers decided to conduct the interviews with the patients one-to-one.

Focus group interview

On the other hand, the researchers wanted to gather information from the startup and their experience of undergoing the user tests with the patients. For that reason, if the researchers wanted to explore phenomena that apply to common experiences, attitudes or points of view in an environment where people interact, focus groups are a relevant research method (Malterud 2012). Focus groups allow the research participants to share information in an open setting with the opportunity to ask each other questions and communicate each others point of view which may lead to fruitful discussions (Malterud 2012). Hence, this is why this type of method was relevant for the employees of the startup company, Vilje Bionics. Here, the goal of the focus group interview was to get the startup team, Vilje Bionics, to discuss their experiences related to the user-test interviews. Vilje Bionics discussed several parts of their experience with the user-test interview, from both a personal level and from a business perspective.

3.2 Data collection

In this section, the researchers will present the process of data collection. First the preparation will be presented, then the creation of the interview-guides, and last, how the interview process was conducted.

3.2.1 Preparation

In this part the researchers will explain how the preparation for the master thesis case study was conducted. This preparation consists of ethical approval, deciding inclusion and exclusion criteria, recruitment and selection of the research participants.

Ethical approval

Research and case studies that includes patients must comply with several legal demands. These demands consists of approvals regarding ethical responsible research and data protection. In Norway the Regional Ethical Committee for Medical and Health Research Ethics (REK) is in charge of ethical guidance regarding elements such as how to choose patients, get consent and give the research participants protection (Bjørk and Solhaug 2008). Due to regulations from REK, Vårin Vaskinn as part of the Vilje Bionics startup applied for the approval for REK to conduct the user-test for the startup company in March 2020 and was approved by REK in September 2020 (REK ref. 106114). The REK approval was required for the startup to conduct the user-test with the patients, which was necessary for this case study to take place in order to study the experiences of user involvement after the user-test. Simply put, this was needed in order for the user-test to be valid for a case study. Specifically, this case study needed to get approved by Data Protection Impact Assessment (DPIA ref. 2018/38113) and Norwegian Centre for Research Data (NSD ref. 650410). In sum, REK was approved for the startup to conduct the user-test and the DPIA and NSD was approved for this case study.

Inclusion and exclusion criteria

For the master thesis case study the inclusion and exclusion criteria were set based on Vilje Bionic's first target group and end-user; patients with reduced arm function diagnosed with Amyotrophic lateral sclerosis (ALS). Thus, the included patients were all diagnosed with ALS and over 18 years old.

	Criteria
Inclusion	Older then 18 years old Impaired function in the arm Completed the user-test with Vilje Bionics
Exclusion	Cognitive impairment that prevents the opportunity to give informed consent Research participants that due to the disease are not able to talk in full sentences Research participants with short life expectancy Research participants with high cormorbid disease burden or frailty that carries a high risk of hospitalization

Table 3.1: Inclusion and exclusion criteria

Recruitment of research participants

When recruiting research participants, the researchers and startup company chose to include participants that were in the same target group as their lead users – patients with ALS. This choice was made based upon the fact that the startup's first prototypes were tried-and-tested and evaluated by two ALS patients. Thus, the startup wanted to gather more valuable information and feedback from the same patient group. For this master thesis case study it made sense to give all the included patients in the user-test Vilje Bionics conducted the opportunity to participate in this study as well. In doing so, the researchers were exposed to similarities and differences within a homogeneous group of research participants (Christoffersen et al. 2015).

There are several ways of recruiting patients to a master thesis, case study or other studies. They can be recruited through different registers or ads online (Christoffersen et al. 2015). For the user-test and the master thesis case study the recruitment of patients happened over a period of two months through two posts on interest groups for ALS-patients on Facebook, see appendix B.1 for the Facebook post. During that time period 16 patients showed interest to participate in the user-test with the startup and in this master thesis case-study. In total, 13 of these were considered potential candidates based on the inclusion and exclusion criteria. After informing the identified research participants of questions and time frame, 12 out of the 13 identified patients choose to participate in this master thesis case study. Inclusively, the were 4 females and 8 male research participants that were interviewed in this case study.

3.2.2 Creation of the interview-guides

For this case study the researchers needed to create two different interview-guides. One for the interviews with the patients and one for the focus group interview with the startup. Next to this, Vårin Vaskinn, as part of the startup company was a part in the creation of the interview guide for the user-test that was conducted prior to this case study. The reasons for this is elaborated on in the section below named "*Interview guide for Vilje Bionics user-test*". All the interview guides related to Vilje Bionics user-test and this case study master thesis were developed based on theory from the fields of entrepreneurship- and healthcare methodology. Based upon the identified themes, sub-questions were created to give the researchers an opportunity to ask follow-up questions in order to capture as precise as possible the experiences the research participants expressed (Christoffersen et al. 2015). This was in line with the theory found in section 3.1.2. supporting that semi-structured interviews is balanced between standardized questions and flexibility to ask additional questions to get a better understanding of their statements and situation (Christoffersen et al. 2015).

In the development of the interview guides the researchers used Christoffersen et al. (2015) seven step model. Thus the interview guides were made in the following order; (1) introduction, (2) fact questions (3) introduction Questions, (4) transitional questions (5) key questions (6) complicated and sensitive questions and (7) ending phase (Christoffersen et al. 2015).

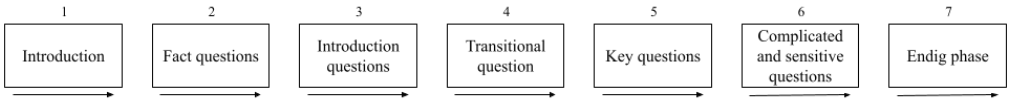

Figure 3.1: Development of of the interview guide

These phases describe different parts of the interview process. The (1) introduction is the part where the interviewer presents themselves and gives information about the interview based upon the written consent forms. In the (2) fact questions phase the interviewer asks simple questions about e.g. family or hobbies. This phase is about creating a relation to the research participant and gain their trust. Then (3) the interviewer goes on to ask a few introductory questions on the theme that the research explores. Furthermore, the (4) transitional questions phase is the questions that creates connection between phase 3 and 5. In this phase of the interview, personal experience and the research participants understanding of the situation is

connected. Then (5) the main part of the interview starts with the key questions. Within this part the interviewer aims to get most of the information regarding the chosen research questions. In addition, (6) regarding complicated and sensitive questions, the theory advice against asking complicated and sensitive questions which must be taken into account. Last, (7) when the interview is going to an end, the interviewer should have set aside time for comments or questions for the research participants (Christoffersen et al. 2015).

A solid interview guide is characterized by having a natural progression and some overlap of the themes and questions. When conducting a semi-structured interview, the guide should not be followed in chronological order, but with flexibility if needed, adjusted to the situation. This flexibility gives the researcher the opportunity to not include themes that already have been discussed and talk about new themes that might arise from the interview conversation (Christoffersen et al. 2015).

Interview guide for Vilje Bionics user-test

Based upon the theory of Christoffersen et al. (2015) the researchers and startup created the interview guide for the user-test coherently. Vårin Vaskinn was included in this process due to her role in the Vilje Bionics startup which included the responsibility of patient contact and partner network. She guided the startup in the creation of the interview guide with the patient in mind in order for the startup to gather the information needed to develop the MotOrthosis further. The theory in section 3.1.2 also elaborated that it would be beneficial to include the healthcare perspective into studies including patients which correlated with Vårin Vaskinn background as a nurse. The user-test built the foundation for this case study thesis in order for the researchers to investigate the experience of user involvement both from a patient and startup perspective. Thus, this illustrates how Vårin Vaskinn was connected to the user-test prior to building this case study thesis.

In essence, the process of creating the interview guide for Vilje Bionics was conducted through five steps. These steps where (1) empathizing, (2) define and ideation (3) reframing and ideation (4) creation of the interview guide (5) testing and evaluating (see figure 3.2). In appendix A.1 is an extract of the interview guide in Norwegian.

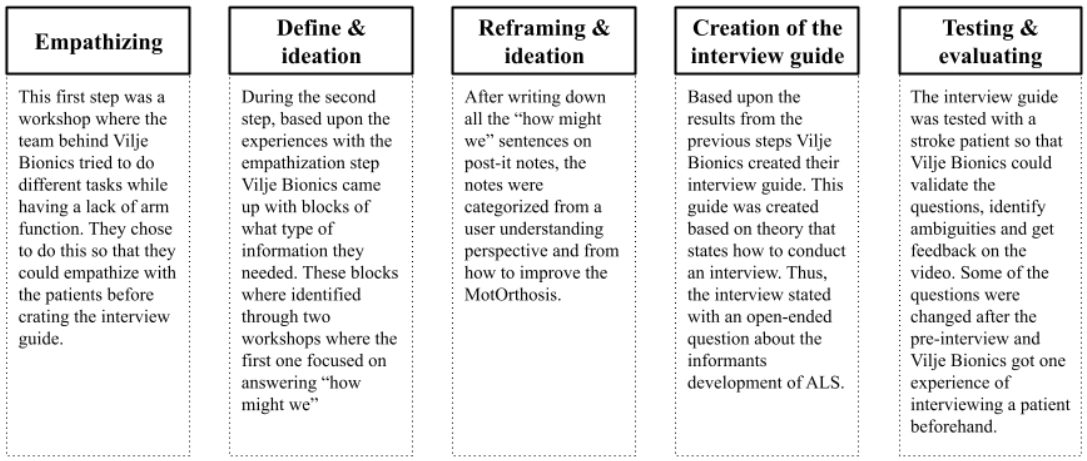

Figure 3.2: Vilje Bionics - creation of interview guide

The interview-guides for this case study

In this part the process of creating the interview guides for this case study thesis will be described. The interview guides were based upon the interview guide for the user-test that Vilje Bionics conducted with the patients prior to this case study. Both the startup, Vilje Bionics, and the patients were given the opportunity to evaluate and explain their experiences. Below the researchers will explain how the interview guides for the patients and the focus group interview with Vilje Bionics was created.

Interview guide for the patients

In order to answer the main research question (RQ), one of the sub-questions aim to look at the patients experience in the form of *'Erlebnis'* and *'Erfahrung'* with participating in a MedTech user-test. Thus, the interview guide was developed with the aim to let the patients give the startup both feedback and talk about their experiences regarding participating in the user-test. Before creating the interview guide, the researchers discussed what questions that were necessary to ask in order to answer the RQ. Before the researchers conducted the interviews with the patients they got feedback from healthcare professionals that work with evaluation of patient experience on a daily basis. The interview guide was then tested on the same person as Vilje Bionics used for testing their interview guide. After testing the interview guide the researchers did some small changes before conducting the interviews with the patients for this case study master thesis. The finished interview guide for the patients is in appendix A.2.

Interview guide for the startup, Vilje Bionics

The second sub-question of this case study master thesis aims to evaluate the ex-

perience from a startup perspective on user involvement in the development of a new medical device. Thus, it was important for the researchers to let the team behind Vilje Bionics evaluate and discuss their experiences regarding the user-test and patient involvement. In order to do so, the researchers created an interview guide similar to the guide for the patients. This way the researchers could analyse both perspectives and coherently analyse similarities and differences from both perspectives. The finished interview guide for the startup is found in the appendix A.3.

3.2.3 The interview process

The interview process with the research participants was technically divided into three parts, (1) the user-test, (2) the patient interview and (3) focus group interview with Vilje Bionics. However, in this case-study the researchers conducted the last two parts; the patient interview and the startup focus group interview.

Before conducting the interviews with the patients, they were contacted by the researchers and asked when they had time to conduct the interview. Each interview was conducted one-to-one as described in the section 3.1.2 on research methods. In this part of the interview process, one patient that had conducted the user-test choose not to participate in this case study master thesis, due to the lack of time. This research participant was therefore not included or pushed further to participate in this case study. Thus, there were 12 separate interviews held instead of 13 as originally planned.

In February the startup's user-test and interviews for this case-study master thesis was conducted over a period of two weeks. In the user-test with the startup the patients were asked questions regarding their own situation, MedTech devices they had already used and had experience with, and in the end giving direct feedback on the product, the MotOrthosis. All the user-tests were conducted through Zoom except one, the last one was conducted in the patient home, after own requirements. One to two days after the patients had conducted the user-test were they interviewed for this case study thesis. In this interview they were asked questions related to their experience with the user-test. Once all the patient interviews were completed the researchers conducted the focus group interview with the startup company, Vilje Bionics. All the interviews were conducted digital through Zoom. An example of how interviews with the patients was planned is shown in table below 3.2. Last, after all the interviews had been conducted with the patients and the startup company, the researchers transcribed all the interviews.

Monday	Tuesday	Wednesday	Thursday	Friday
1001	1003	M1001	1005	M1005
		M1002		M1006
1002	1004	M1003	1006	
		M1004		

Table 3.2: Plan for conduction of interviews

Selection of patient involvement

Patients has over a short period of time been more involved in development processes regarding changes in the healthcare industry, and this involvement has shown positive effects in development processes (Consoli and Mina 2009; Wiig et al. 2013). Thus, the researchers wanted to investigate the overall theme of how user involvement was experienced both from a startup and patient perspective. The patients underwent a user-test with the startup, wherein the researchers came in after to analyse their experiences. The interviews with the patients were conducted digital due to the restrictions of COVID-19 using the digital platform tool Zoom. During the digital call the patients were given the opportunity to give feedback on what they thought was satisfying and what could have been improved. The digital calls took around 30 minutes and were conducted normally 1-2 days after the initial user-test with the startup company, Vilje Bionics.

3.3 Data analysis

In this section, the researchers will explain the phenomenon of research and what research approach was used to conduct the analysis of the case study. The researchers decided to use a hermeneutic interpretative phenomenological approach described in this section. Furthermore, the researchers will discuss the research quality and how it was ensured in this case study.

3.3.1 ”Experience” as a phenomenon of research

In this case study the researchers are using hermeneutic (interpretative) phenomenology as a research method of analysis as it helps to gain an in-depth understanding and rich data from the experiences of the research participants. The methodology explained in chapter 3 is commonly described as the study of phenomena as it manifest in our experience, of the way we perceive and understand phenomena,

and of the meaning phenomena have in our subjective experience (Neubauer et al. 2019. The aim of this case study is to research the "experience" from the research participants as a phenomenon of research. For instance, the "experience" of user involvement might be experienced differently from a patient compared to a startup perspective. Moreover, the "experience" of perceived benefit of user involvement might also have a different meaning from a patient versus a startup perspective. The patients and startup had their own unique "experiences" of user involvement in a user-test in product development. However, it is argued that a more nuanced lexicon of the word "experience" can be beneficial in order to elaborate on the meaning of such experiences (Mueller et al. 2020). For this reason, as explained in the theoretical framework chapter 2 the researchers have chosen to distinguish the word "experience" in this case study in the German language. In the German language, "experience" and be explained as "*Erlebnis*" and "*Erfahrung*" (Mueller et al. 2020). "*Erlebnis*" can be translated to *"lived experience"* and is normally connected to a tacit experience or a pre-reflective experience. In addition to this, "*erlebnis*" is usually connected to our own actions and bodily experiences. While "*erfahrung*" means *"a welter of different things"* and comes after "*erlebnis*" and is incorporated over time and with several phases of erlebnis. "*Erfahrung*" we get after the shared erlebnis and can be distributed to and incorporated by others over time (Mueller et al. 2020).

3.3.2 Hermeneutic (interpretative) phenomenology

The researchers primary goal was to study the experiences that the research participants held after conducting the user-test in the development of a new medical technical device. For this reason, a case study and an interpretative phenomenological approach was deemed the most suitable methodology to achieve this goal. Specifically, the researchers analysed the 'lived experiences' of all the research participants as it allowed them to study the phenomenon that the case study investigated (Creswell, 2012). This methodology retrieves the opinions and experiences that the research participants have regarding the explored phenomenon. During the interviews, getting the research participants to explain their statements further helps to ensure that the content of meaning will be understood as precise as possible (Kvale and Brinkmann 2019). This allows the research participants to give specific feedback on the experience of the user-test, which is essential to answer the research question at hand. In account to this, the researchers collected the data from the researcher participants through interviews with open-ended questions to ensure the rapport and openness necessary to access their lived experiences. Accordingly, the data was transcribed and assembled into themes of analysis that formed the architecture of

the findings (Bynum and Varpio 2018; Kvale and Brinkmann 2019).

When analyzing the transcriptions from the interviews, did the researchers use hermeneutic (interpretative) phenomenology analysis method inspired by (Kvale and Brinkmann 2019). This method consists of five phases which is described in figure 3.3.

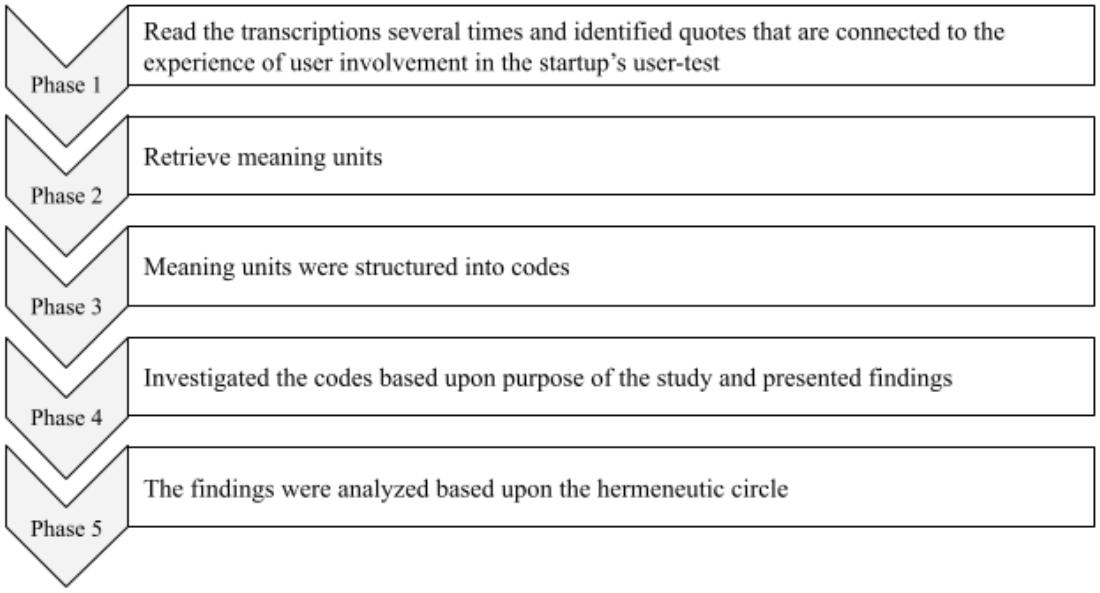

Figure 3.3: The hermenautic (interpretative) phenomenology analysis for this thesis

In this process did the researchers analyze each interview from phase one to three (see fig. 3.3) first before all codes were structured and stored. Furthermore, the codes were investigated based upon the purpose of this study and sorted into themes before the findings were presented. Figure 3.4 shows a detailed overview of how the *quotes form the transcribed interviews* were analyzed in order to investigate the purpose of this study before the researchers conducted the last phase of the analysis. The structure of the codes for both the patients and startup interview are presented in appendices C.1 and C.2.

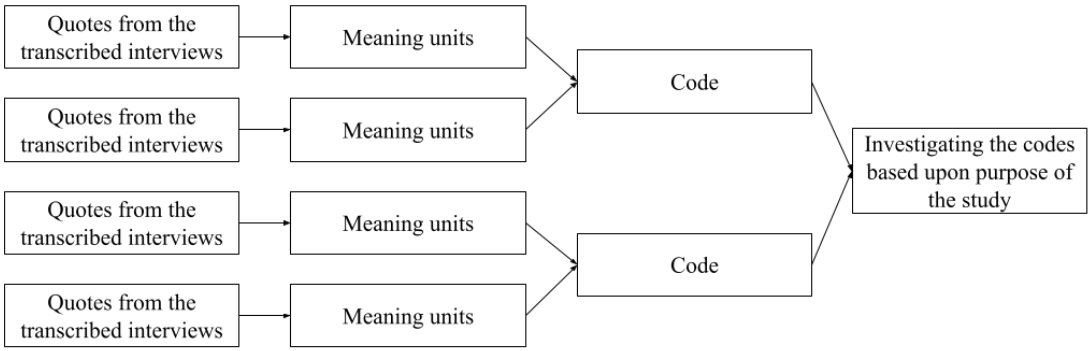

Figure 3.4: Detailed overview of code analysis

In the last phase, the researchers analyzed the findings of the hermeneutic circle (see fig.3.5), which emphasised how the data (*the parts*) contributed to the understanding of the phenomena (*the whole*) and how each part reinforced the meaning of the other (Bynum and Varpio 2018).

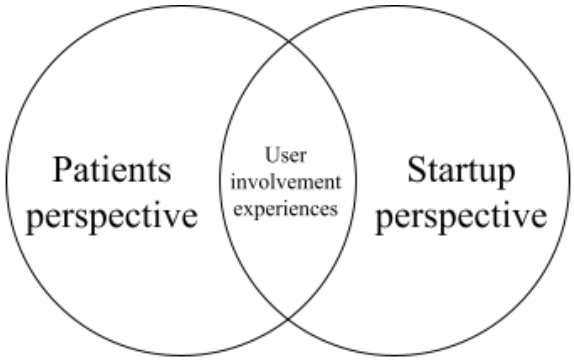

Figure 3.5: Hermeneutic circle of the phenomena of this case study

In order to analyse the parts of the whole the researchers' used the more nuanced lexicon of the word 'experience' in order to elaborate on the meaning of the experiences (Mueller et al. 2020). The researchers' used the German language to distinguish between the terms '*Erfahrung*' and '*Erlebnis*' (Mueller et al. 2020), as described in section 2.4.3 and 3.3.1. Moreover, the hermeneutic (interpretative) phenomenological approach take into account that the researchers' cannot separate their lifeworld connected to the research subject (Neubauer et al. 2019). The hermeneutic phenomenology interprets the data provided by the research participants in relation to the given context and use their prior background knowledge as a valuable guide in the research (Heidegger 1962; Neubauer et al. 2019). This was true given the fact that one of the researchers' were directly involved in the MedTech startup.

3.3.3 Research quality

The researchers will in this section discuss the three gold criteria of validity, reliability and generalizability that apply in principle to assess the quality of qualitative research (Leung 2015; Morgan and Bottorff 2010; Sica 2006; Smith and Noble 2014).

Validity in qualitative research means the "appropriateness" of the data, processes and tools (Leung). This can be assured through different steps of validation: (1) research question is valid for the desired outcome, (2) the choice of methodology is appropriate to answer the research question, (3) if the research is valid for the methodology, (4) if the sampling and data analysis is appropriate, and finally (5) if the results and conclusions are valid for the sample and context (Leung 2015). For the first three steps qualitative research can lack transparency, thus, the researchers must ensure openness to the methodological approach and make sure that the method is of relevance. In order to validate the first three steps the researchers investigated through their project thesis which applicable method would be of relevance to conduct this research topic which was also approved by the supervisors. The fourth and fifth steps can be prone to misunderstandings of the data collection as a result of different interpretations of the gathered data in a study (Smith and Noble 2014). For example, validity bias is a type of systematic misconception that affects research and gives a misrepresentation of the process (Sica 2006), and is about "*the fact that the results of research or an experiment are not accurate because a particular factor has not been considered when collecting the information*" (https://www.oxforddictionaries.com 2021). In order to avoid this risk factor, the researchers has focused on ensuring transparency and "appropriateness" of the data through dividing the research into specific steps (see fig. 3.5), transcribed the interviews and conducted quote checks with the patients and the startup. Moreover, the researchers organized a workshop to organize the collected data into themes of experience (see fig. 3.4). The themes were generated through an open discussion where the researchers agreed on the given themes in dialogue with the supervisors in order to avoid misinterpretations of the data. Reliability for qualitative research lies with consistency, which Noble and Smith (2015) defines as "*the consistency within the employed analytical procedures*" (Smith and Noble 2014 pg. 34). By this means, reliability within qualitative research aims to analyze the data with consistency. Qualitative studies generally involve studying a specific phenomenon or issue from the context of a specific group or population. Moreover, generalisability is about to what extent findings are transferable to other settings or contexts (Leung 2015). Generalisability is according to Noble and Smith "*the transferability of the findings to other settings and applicability in other contexts*" (Smith and Noble 2014 pg. 34). Thus, the researcher of this thesis, inspired by Noble (2015) table of "*Quantitative*

research terminology and approach to qualitative research" (Smith and Noble 2014 pg. 34) present this case study thesis' validity, reliability and generalizability in table (3.3).

	How it was ensured in this case study
Validity	Multiple sources of data collection (patient interview, startup interview, Vårin Vaskinn observed the user-tests and access to user-tests transcriptions). 12 out of 13 patients from the user-tests were included. The researchers assured validity through steps 1 to 5 as described above in section 3.3.3. Both researchers transcribed the interviews, and Isabella McNeill Benestad listened to the interviews and gave feedback to Vårin Vaskinn.
Reliability	Awareness of Vårin Vaskinns bias for being a part of designing the Vilje Bionics user-tests. All interviews followed the same interview guide. The analysis of the interviews were done by both researchers together and discussed with the supervisors. Reliability was assured through following the research methodology steps thoroughly as described in section 3.3.2 which was done in a transparent way in order to apply the same methodology in future research.
Generalisability	All the patients had the diagnosis ALS. The whole team from the startup, Vilje Bionics, participated in the focus group interview.

Table 3.3: Overview of how validity, reliability and generalisability was assured in this thesis

Chapter 4
Findings

In this section, the researchers will present the findings from the patient interviews and the focus group interview with the startup company Vilje Bionics. The researchers will first present the findings from the data analysis of the patients experience with user involvement. Next, the researchers will present the findings from the data analysis from the startup's experience of user involvement.

4.1 Patients experience with user involvement

In the analysis of the interviews with the patients, the researchers focused on identifying their experience in terms of *"erfahrung"* and *"erlebnis"* as described in the literature review (chapter 2.4.3). The understanding of experience can be explained by *"erfahrung"* which is achieved after several *"erlebnis"* (Mueller et al. 2020). Through the data analysis the researchers interpreted most of the patients experience as *"erlebnis"*. However, some of the patients compared previous experience *"erfahrung"* of participating in user-tests.

4.1.1 User involvement

Overall the patients were satisfied about the opportunity to participate in the startup's Vilje Bionics user-test. The patients initial feedback was that they were satisfied with the process and how the user-test was conducted, and all patients had a positive experience (*erlebnis*) related to the user-test. In addition to this, the patients found the user involvement process interesting and important to them in order to influence future development to meet their needs and future patients needs with the same dysfunctions. The patients were glad to participate in the development of the product, the MotOrthosis, and expressed that the user involvement process increased their hope for a medical technical device that can help them improve their quality of life with their current dysfunctions. During the user-test the patients described Vilje Bionics as a professional interviewer that showed interest in getting

to know the patients' and wanting to make a change for them.

Positive to user involvement

All the participating patients in the user-test were positive to user involvement and thought it was beneficial for the startup to include them in the development process. They experienced (*erlebnis*) it as rare that they as patients were asked to give their opinion, but believes it is a beneficial factor to the development process, and that the product is more likely to solve their problems with their voice in the process. Prior to this user-test, the patients experienced (*erfahrung*) from using or trying other medical technical devices that the solutions did not solve their problems. The patients were usually introduced to MedTech devices that were not user-friendly enough and created more hassle than actual help. The patients whom had more experience with the use of MedTech devices blamed the decreased ease of use as a result of low user involvement in the final product they received. One of the patients had over 20 years of experience with using MedTech devices and blamed a lack of user-friendly MedTech devices on a lack of user involvement. This patient stated that *"When I receive a MedTech device, e.g. a wheelchair with a pillow in it. I wonder if the people that brought it to me tested it out for a couple of hours? Because I need to use the MedTech device for twelve hours a day and then it feels and works differently. They have never asked me what I wish for or how the device function for me as a patient and my needs. So I am very pleased that you do that in this case study" - Patient.* The startup's, Vilje Bionics, inclusion of the patients was thus experienced (*erlebnis*) for them as *"close user involvement"* and *"important to develop a device"*. Moreover, the patients believed that more user involvement would reduce the error of designing products that do not meet the patients needs and requirements. E.g. the patients strongly believed that with close user involvement the startup, Vilje Bionics, can achieve a technical, well-functioned and usable product. These statements where supported by their experiences (*erfahrung*) from usage of other MedTech devices that was created with a lack of user involvement. Overall, the patients thought from their "lived experience" from their *lifeworld* that these product failed due to the lack of user involvement.

The patients where surprised to learn that there is a startup company that wants to help them to move their arms again by creating a new MedTech device, and were thus eager to participate. Reasons such as *"we need to help those how wants to help us"* and *"I want to help those who comes after me"* came up during the interviews in the case study. The patients experienced (*erlebnis*) that Vilje Bionics used *"proper user involvement"* when they put the user in the center of the development. This statement was connected to previous experiences (*erfahrung/erlebnis*) with short

online questionnaire that the producers called user involvement. The patients meant that online questionnaires created more questions after completing the studies, which they normally would not get the answers to. While in the user-test with Vilje Bionics, the patients received an opportunity to ask their outstanding questions and interact with the startup and researchers. The patients had a positive experience (*erlebnis*) with this method of gathering information since they preferably would like to talk to the developers instead of answering a dormant questionnaire. Prior to the user-test, one of the patients did not understand how important her voice was in the development process, and the patient expressed that *"Prior to the user-test did I not understand just how important my voice was, but during this process I experienced that Vilje Bionics wanted to use my voice differently then what others had done before"*. For some of the patients this was their first meeting with participating in a product development process, and they were very satisfied with the way they were included with regards to the applied method of one-to-one semi-structured interviews.

Taking into account what was appealing with the applied method of user involvement, the patients expressed that their motivation for participation also came from a hope for a better future and hopefully some day be able to move their arms again. All the patients that participated expressed that they hoped their contribution would be of value to the startup in order to create a product that would help them – and future ALS patients.

Recommends others to participate

When the patients were asked if they would recommend others to participate in a user-test such as the one Vilje Bionics conducted, all said that they would and especially if it was a product that had something to contribute with or could help increase their quality of life as well as future generations of ALS patients. Some of the patients added that they would consider who they recommended based on how far developed their symptom picture is as it may vary from patient to patient. When a company includes patients, it is critical to set the right inclusion and exclusion criteria. Participating in this user-test was for some of the patients physically hard, therefore they stressed the importance of evaluating the inclusion and exclusion criteria based on the patients symptom picture. In addition to this, the patients talked about the beneficial sides for themselves as patients, future ALS-patient generations and for the startup in this case Vilje Bionics. Personally for the patients it was the fact that they would get to be involved in the development of a new MedTech device that might give them and future generations value. One patient told the researchers that he/she have told several ALS-patients that *"You should try to influence while*

you can!", a belief that when a patient takes part of a process like the user-test, they are given the opportunity to influence the future of MedTech by sharing from their experience as patients (*erfahrung*).

4.1.2 Motivation and uncertainty related to the user-test

All the included patients had different combinations of motivations for participating in the user-test. The most frequently identified motivation was the hope that the MotOrthosis could help them in their everyday life, and help them move their arms again. In addition to this, the patients that participated in this process are hopeful that their contribution can potentially help the MedTech device be available sooner rather than later. Moreover, the patients have experienced a lack of MedTech device for their arm dysfunctions, and express a need for it now or in the future. Thus, the patients wanted to be proactive and help the startup develop a MedTech device that they can potentially benefit from in the near future.

Other factors that motivated the patients to participate in the user-test was the opportunity to create a better life for future ALS-patients. The MotOrthosis was described as a product that will be useful and help ALS-patients now and in the future. One patient choose to participate because he wanted to do all in his power to make both his/her life and future patients life better in terms of quality when living with the fatal disease. The patient expressed that they did not know if their children will get ALS, and if they do, they wanted to know that they did everything right to give them a better future and life then they has had with the disease. Some patients wanted to prepare for their own future, where they will not be able to move their arms. One participant stated that the comments on the Facebook-post for signing up for the user-test was a motivating factor for choosing to participate. When the patient saw that other people had commented that they were joining, they understood that also they could bring something important to the research project by participating.

Additionally, some patients were uncertain about their contribution towards the user-test and product development. During the interview for this case study thesis, the patients would ask the researchers questions such as *"Did you gain anything from my participation?"* and *"At the beginning of the user-test I was not aware of the importance of my voice in the development of the device, but I kind of realised it might have been important when they wanted my opinion, which no one else has asked for before."*. The researchers were not intentionally looking for their uncertainty, but 6 out of 12 patients mentioned this during the case study interviews. By means, more than half expressed an uncertainty related to their contribution and value of

participating in the user-test and case study. Other uncertainties the patients had is connected to spending more then the allotted time, which led to a concern for spending time that was set aside for other research participants or that they did not stick to the topic and shared other type of information as well.

4.1.3 Design of the user-test

During the case study interviews, the patients were asked to give feedback on the startup's user-test they had participated in. Specifically, the patients were encouraged to give feedback both in terms of what they experienced as positive and related to potential improvements. The researcher asked for feedback related to the design, the whole process and their experience with participating in the user-test. This resulted in feedback of what the patients experienced as a positive user-test with just a few potential improvement areas that the startup can do next time they conduct a user-test.

Positive experience with the design of the user-test

All the patients were satisfied with how Vilje Bionics' user-test was structured as an informal conversation with open-ended questions (semi-structured interviews) rather then close-ended questions. The patients experienced the representative(s) from Vilje Bionics as polite and curious about their life and home situation with ALS. In the beginning of the user-test the patients were asked some personal questions related to how their disease have developed, what they do in their everyday life and what challenges they have with their disease as this was recommended in the research methodology (see section 3.2.2.). When asking these types of questions, the patients experienced that the startup wanted to gain information about ALS in general and their situation. None of the participating patients experienced the *"key questions"* as intrusive or uncomfortable. One patient added that they are normally used to receiving help and in order to get the help they need it is crucial to share personal information regarding their experience of the disease. In addition, the patients found it necessary for Vilje Bionics to ask more personal questions so that the startup could get a better understanding of their situations and the fact that most cases of ALS develops differently from patient to patient.

The patients experienced that the questions for the user-test was well structured and that it was the right amount of questions. Since this was a user-test with one-to-one interviews, and not a questionnaire the patients had the ability to ask follow-up questions during the interview. The ability to not have unanswered questions afterwards, like they normally would have after a questionnaire the patients described

this as a positive experience (*erlebnis*) to ask follow-up questions. The patients expressed that since the questions in the user-test were related to the product, MotOrthosis, it was easier to talk about its functions and limitations directly with the producer rather just answering a dormant questionnaire.

The given time-frame for each user-test was set to be around one hour. Some of the user-tests were cut shorter, but the majority were around one hour or a little over one hour. In the beginning, most of the patients had an initial reaction that one hour was a long time to talk, but once the user-test was conducted the patients experienced that the time-frame went by faster than they initially thought. Some patients were surprised when the user-test was completed and that they had been talking for over one hour. The whole process from the invite to the user-test and case study participation was experienced (*erlebnis*) well from the patients perspective according to all the research participations'.

Potential improvements with the user-test design

In addition to giving Vilje Bionics feedback on what was positive with the user-test process, the patients were asked about what Vilje Bionics could do to improve the user involvement process in the development of the product. Most of the patients expressed that speaking about the product was the most interesting part, and were missing more questions regarding the product in specific details. When the questions were concrete, the patients were able to give specific feedback on the MotOrthosis, which they thoroughly enjoyed. This findings revealed that some of the patients were highly educated engineers, and as a result wanted to know more about the technical parts of the product, e.g. how much it weighs, what motor Vilje Bionics use and so on. Moreover, some patients wanted to give feedback on the aesthetic parts of the product development.

When asking the questions about potential improvements of the user-test and the whole process, some patients shared that they experienced it could have been improved when demonstrating the MotOrthosis product's functionality and technical dimensions. During the user-test the patients got to see a 2 minute short video of the product. Here, the patients experienced a lack of information through the video and had to ask questions afterward to get a better understanding of the product. The patients shared several suggestions from the experience that could have made the product demonstration perhaps more appealing. For instance, the patients wanted to see more of the potential movements and to have the opportunity to see the video twice or the day before the user-test. Some of the patients also expressed that it was difficult and challenging to give feedback on a MedTech product based on such

a short video. One of the patients' expressed that seeing the video the day before might have given them an opportunity to reflect more around what the MotOrthosis should be able to do for the patient in their everyday life. Some patients also said that it would have been enough to just see a video or read a text that concretely maps out what the MotOrthosis is supposed to help them with, the patient did not necessarily need to see the product in order to give feedback. In addition to these potential improvements, one patient stated that *"It does not mater how it is built as long as we (the ALS-patients) can control it" - Patient.* Some of the included patients with the most severe lack of arm function whom expressed that the control-systems are the most important functions. These patients wanted more information and questions relating to the arm functions and technical details. This was because they had experience (*erfahrung*) from using other MedTech devices and had an understanding over what control-systems functions and which ones that are less functional with other MedTech devices.

4.1.4 Digital user-test and case study

The user-test and interviews for this case study was primarily conducted digitally with the software-based video tool known as Zoom. Those patients who had the user-test digitally where satisfied with conducting the interviews online and experienced Zoom as a suitable tool for user involvement. The patients experienced that their feedback was well communicated and understood by Vilje Bionics while conducting the user-test digitally. Many of the patients explained that it was easier and more comfortable to conduct the user-test digitally compared to physically. E.g. One of the reasons for this was the ability to log on their computer from home and conduct the user-test without a huge amount of planning. This made the process cheaper as well as way more practical and technical feasible. If the user-tests were to be conducted physically it would have demanded more planning and organization, and especially with the circumstances connected to COVID-19. Having the user-test digitally felt safer and trouble-free, in particular with regards to the physical limitations the patients have, thus the digital user-test was experienced as a great alternative compared to a physical user-test. In addition to this, some patients expressed concerns around the costs of having a physical user-test, they believed the startup would waste time and money on conducting it physically versus digitally. Some even stated that they would have chosen to conduct the user-test digitally even if they had the option regardless of the COVID-19 situation.

Besides the patients positive experience (*erlebnis*) with a digital user-test, they still expressed that they would have wanted to participate in a physical user-test

too, both for this research project and in the future. The patients did not experience (*erlebnis*) it as a deal breaker for their participation if they would have to travel to the startup or invite the startup to their home to conduct the user-test. Although the patients expressed that conducting the user-test physically would require more organization from their side, especially if they were to travel to the startup, thus inviting the startup to their home would be more practical.

One of the participating patients in Vilje Bionics user-test wanted the user-test to be conducted physically. This patient wanted to do it physically because the patient felt that it was easier to give concrete and specific feedback on the product in person. In addition to the video demonstration of the product that the rest of the patients viewed as well, this patient also got to experience the physical demonstration of the product. Through the physical demonstration the patient got the opportunity to ask the team from Vilje Bionics if they could try out different activities of daily living while using the product. This patient was satisfied to participate in the physical user-test and see the product live for demonstration.

4.1.5 Information about user-test participation

In the process of evaluating and looking at the patient experience from the user-test process. The patients were asked about where they want to receive information about the opportunity to participate in a MedTech user-test. Here, the patients expressed gratitude towards receiving this information from Vilje Bionics directly on interest groups for ALS-patients, instead of their general practitioner (GP). It was explicitly said that they did not want to receive this type of information from their GP. One of the main reasons that came up was because during a visit to the GP office, the patients already receive a lot of information. Remembering all the detailed information upon a visit at the GP is already difficult, and adding on a request to participate in a user-test for patients with ALS they would have probably forgotten about the request. Moreover, some of the patients explained that they experience (*erlebnis*) that their GP knows less about the ALS-disease than themselves as patients, which leads to a lack of trust. This lack of trust and previous experience from the doctors office are some of the reasons as to why the participating patients experienced (*erlebnis*) Vilje Bionics recruitment process through Facebook as a good platform to recruit patients.

It became clear from the interviews that most of the information related to the ALS environment are communicated through the interest groups own pages, where it seems like many patients are active. Although all the participating patients in the user-test and this case study received information through interest groups through

social media on Facebook, some stated that they would have also liked to receive the information from the ALS-teams in the neuro clinic at their local hospital. Specifically, they wanted to receive the information besides online directly from healthcare professionals that supported them in their daily living with the disease e.g. a nurse, occupational therapist, physiotherapist or sociologist. Additionally, they stated that if using the local clinic at the hospital to recruit patients for research projects, one would more likely identify elderly patients that are not usually present on social media. In addition to this, they expressed a thought that mostly elderly ALS-patients were to trust their hospital more then a post on social media.

4.1.6 Healthcare professionals participation

Vilje Bionics is an interdisciplinary team that consists of engineers and as mentioned in chapter 3 one healthcare professional which is a registered nurse was also a part of this case study. The researchers for this case study thesis found it interesting to analyse the experience that a healthcare professional could bring to the user-test in the development process of a MedTech device. Thus, the researchers asked the patients about the need for healthcare professionals in the user involvement process. Most patients believed from their experience (*erlebnis*) in the user-test that it was not necessary for their participation to include healthcare professionals in the process. Some expressed that they had not thought about or recognised that there was a healthcare professional in the startup team that participated in the user-test. Yet, those who knew that a healthcare professional was included in the process stated that they would participate with our without having one present. In essence, all the patients would have participated with or without a healthcare professional present in the user-test.

On the one side, the patients expressed that it was not necessary to include healthcare professional in the user-test since *"we as patients are only going to answer some questions"*. These patients experienced (*erlebnis*) that it was not important who asked the questions during the user-test, they just wanted to participate and give their knowledge and experience of MedTech to the startup. Even though it was not important for these patients, they reflected upon the value a healthcare professional would bring to the research project and to Vilje Bionics as a startup. The patients expressed this value to be that a healthcare professional might be better at *"seeing the whole picture", "bringing the human relations into the mechanical part of the product"* and *"that the team behind Vilje Bionics was interdisciplinary and could learn from each others experiences"*.

Furthermore, an advantage that the patients experienced (*erfahrung*) previously

with healthcare professional is their ability to empathise with the patients situation. One patient expressed that the conversation with the healthcare professional before Vilje Bionics' user-test started was beneficial by stating *"You (the healthcare professional) mentioned it when you came in today, that you noticed the color of my face might indicate that I am having a better day. That is a valid reason to include healthcare professionals. I believe that you see more of the symptom picture of my situation and how I experience this situation" - patient.* Regardless of this all patients would participate in future research projects with or without healthcare professionals.

4.2 Vilje Bionics experience with user involvement

The findings from the focus group interview with the startup, Vilje Bionics was also sorted between the terms of experience "*erfahrung*" and "*erlebnis*" (see chapter 2). Vilje Bionics conducted 13 user-tests, thus most of their experiences were based on "*erfahrung*" since they conducted the same user-test several times. Thus, in this section the researchers will present the findings from the data from the focus group interview with Vilje Bionics. The findings include six themes based on the findings in the data collection of the experience after conducting a user involvement method with the patients.

4.2.1 The experience of user involvement

In the focus group interview Vilje Bionics were satisfied with several parts of the user involvement process, but expressed a few factors that could potentially make a positive difference next time around. In this section the findings related to the startup's experience of the user involvement process will be presented.

Positive experience with the user involvement process

Overall, the startup team was satisfied about the user involvement process with the patients. The team expressed that their experience (*erfahrung*) with the user-test provided them with relevant data to further develop the technical device. All of Vilje Bionics' user-tests started with asking the patients if they could tell the interviewer a little bit about their development of the disease since the first symptoms came in place (see A.1). Through asking this *"key question"* as recommended in the methodology (see section 3.2.2) Vilje Bionics retrieved information that gave the

startup an experience (*erfahrung*) of increased user-understanding. Here, the team experienced (*erfahrung*) that *"It was an important question to get the interview started" - Vilje Bionics.*

The startup team put emphasis on the benefits of conducting their user-test through semi-structured interviews. This method of gathering data from the patients was beneficial in receiving concrete feedback to further develop the MotOrthosis product. Moreover, the team experienced (*erfahrung*) the existence of the individual differences in the symptom picture of the patients and that several technical aspects must be taken into consideration in the development in order to figure out the most critical key functions for the product. The team expressed that if they had conducted a structured data collection through an online questionnaire, that the results would have been more difficult for them to interpret without asking follow-up questions. Additionally, the team believed their lack of experience (*erfahrung*) and knowledge with the patient group prior to the user-test would have impacted the interpretations of the data negatively. One of the team members expressed that: "*It is very easy to collect structured information... But, I believe that this information will lack an understanding of context due to our lack of understanding the patient group, which then leads to a higher chance of false interpretations".* This experience (*erlebnis*) was verified when the team got to experience (*erfahrung*) the importance of being able to ask follow-up questions. The follow-up questions provided the team with a better understanding of the patients context and their specific needs. These follow-up questions helped the startup gather answers to *"why"* the patients thought the way they did or if they could elaborate on it further. The team experienced (*erfahrung*) that "*Now that we know the context of the bigger picture, it is easier to understand how we can bring further value to the end-users*".

Vilje Bionics conducted a reassessment of the interview-guide with healthcare professionals for their user-test to evaluate if there needed to be done any changes. The experiences (*erfahrung*) that Vilje Bionics got from the reassessment was expressed as important for the conduction of the user-test. After the user-tests with the patients were conducted, the startup concluded that this experience has provided them with *how* to conduct a user-test with patients in the future in a cost- and time effective manner.

In the focus group interview the team also discussed that they gained "experiential knowledge" that gave the team the ability to understand the context of the user in a different way than before the user-test. The team also came to the conclusion that this experience (*erfahrung*) taught them the importance of how much relevant information users hold that they have not taken into account from the start of the design phase during product development. The team wish they knew this from the

start, then they would have conducted the user-test at the beginning of the design stage and not towards a functioning third prototype of a minimum viable product (MVP). This was agreed to be an experience (*erfahrung*) that they recommend other MedTech startups to consider before developing any product at all. The team expressed that they could have probably gathered more than 90 percent of this information without a proper MVP. Moreover, *"There is a possibility that we could have come further in the development process if we had received these input of data over a year ago" - Vilje Bionics.* Moreover, *If someone would have told us one year ago to conduct a user-test from the beginning and how valuable this is, we would have done this from the start".*

Moreover, the team discussed that it would have been more cost- and time effective if they had started with user involvement earlier on, as this would have reduced time and resources on developing a feasible product according to the users requirements. The team experienced (*erfahrung*) that these requirements came from the patients through explaining their needs and limitations in their every day life. The team had initially used a lot of time and resources to map out these requirements before the user-test. After the user-tests the team experienced (*erfahrung*) that the patients gave them new insights and information regarding user requirements. This left the team afterwards in a position to reconsider some functions and elements of the product, which had not been identified nor considered prior to the user-test.

Even though Vilje Bionics experienced (*erfahrung*) the user involvement as important, the team also discussed the downsides of user involvement. Since the user involvement process started up until to this date the team experiences (*erfahrung*) that they spend a lot of time "nurturing" the connection with the patients as well as other whom are interested in their user involvement process. This "nurturing" process is in a form of giving updates, receiving information and now having put themselves in a receptive position to the input from others. The result has been time-consuming, and in a small startup team with limited resources this has added on to their tasks, although they do not consider it as negative it still takes time from their existing time and resources. However, Vilje Bionics experience (*erfahrung*) that there are more benefits to user involvement than barriers. The user-tests has given them the experience (*erfahrung*) that they are dependent on user involvement to further develop the MedTech product.

Potential improvements with the user-test

After conducting 13 user-tests with patients Vilje Bionics gathered several experiences (*erfahrung/erlebnis*) related to potential improvements with the user-test.

The team was asked if they could reflect upon which improvements they would have done after the experience (*erfahrung/erlebnis*) with the user-tests. The team discussed that they experienced (*erfahrung*) that the patients sometimes struggled to answer their questions without follow-up questions and that the patients had many questions particularly related to the product demonstration. For the most part, Vilje Bionics experienced (*erfahrung*) it as difficult to communicate *how* and *what* the MotOrthosis is supposed to help the patients with and vice versa, the patients struggled to understand *how* and *what* the product could help them with. One of the team members stated that *"Some of the patients would ask questions like can you open a door with it or can I make a sandwich?"*. The patients asked many questions with regards to the product's functions and limitations. This experience led the team to realise that they need to optimise their value proposition description of the MotOrthosis. The team acknowledged that the patients then might have gotten a better understanding and first impression of the product had the team spent more time on how to demonstrate the product to their potential users. The team discussed some solutions to increase the quality of the product demonstration in the future. Possible changes that came up were (1) *create a longer video that contains example of daily activities*, (2) *more focus on what the MotOrthosis should be able to do in the future*, (3) *showing the video twice during the user-test* or (4) *sending the video before the user-test*. However, the startup team discussed and ended up to discard the last step of sending the video out beforehand. The reason for this was because of the potential effects of showing the video demonstration before the user-test. They believed that this might influence the answers of the patients user requirements if they saw the video before the questions of their needs were asked in the user-test.

Vilje Bionics conducted one of the user-test's physically. This patient got in addition to the video, a live demonstration of the MotOrthosis product. The team experienced (*erlebnis*) that this patient got a better understanding of the product's functions and limitations. While demonstrating the MotOrthosis live the patient asked if the team could try to do different movements and activities. This process of demonstration was expressed as *"a great feedback scenario for the team"* that they might now consider doing a combination of digital and physical user-tests in the future. This experience (*erfahrung*) led up to a discussion whether to conduct a live demonstration on camera during digital user-tests with the product on themselves allowing the patients to ask them to demonstrate requested tasks. However, the team were concerned that this could be difficult and concluded that they would rather focus on creating a better product demonstration of the fixed video of the MotOrthosis.

4.2.2 Increased user understanding

Throughout the user-test process the startup experienced (*erfahrung*) an increased understanding of both the user and their problems; which the MedTech team is trying to solve with the MotOrthosis product. The user-tests has given the team knowledge about (1) *what it is like having ALS,* (2) *what it is like living with the disease* and (3) *the individual differences that occurs with the disease.* One of the team members exemplified this by stating that *"This new form of contact with the users and forming a network with them has really been important for us moving forward in the development process in understanding the pains points of our users".* Vilje Bionics experienced (*erfahrung*) it as important to interview more than 10 patients due to the complexity of the ALS-disease although it is recommended to interview between 5-10 patients. The team argue that other MedTech startups might not have the same the same need to interview more than 10 patients, but that it depends on the patient group. For this reason the team argued that for other startups it could be more appropriate to create "*an expert group*" of 3 to 4 patients identified as lead users and have several conversations with them. The team argued that for Vilje Bionics it was vital to understand the complexity of the disease and in order to do so they had to interview more patients. Even though this process was time-consuming they experienced (*erfahrung*) it an important part of the user-test design to gain insight into the complexity of the ALS-disease.

During the user-test the team experienced that their hypothesis of identified problems for patients with ALS were present, and that the MotOrthosis could have the ability to solve at least some of their problems in the future. One of the team members stated *"During the user-test we retrieved answers to our hypothesis that we had already mapped out, but also a lot of new additional information. The confirmations of some of the initial hypothesis came through gathering data on what requirements the users wanted. The patients also gave us a confirmation that our product is wanted with a wish for fast access to the MotOrthosis".* The team expressed that the user-tests gave them them a confirmation that there is a real need for their product on the market based on their direct users users feedback. This was explained further by the team member in charge of the user-test whom stated that *"I am coming out of this process with an experience that there is a need for our product in the market and that what our product is trying to solve is in the right direction.".*

4.2.3 Output from user involvement towards the product development process

Vilje Bionics discussed several outputs from the user involvement process towards the product development process, particularly related to the product requirements from the patients. These requirements were mainly related to (1) *function*, (2) *appearance* and (3) *control mechanisms*. The team discussed that by asking *"why"* certain aspect were important versus not for the user requirements helped them understand the whole context for why they wanted this function, appearance or control mechanisms. One of the team members stated that "Although I experience that the patients wish to be independent with using the MotOrthosis, it helped to ask them why they wanted this and specify reasons to why they wanted certain components in the product. This gave us a better understanding of the whole context". In addition, the team experienced (*erfahrung*) that the patients had a lot of relevant information about other MedTech devices. However, this was a subject the startup team had not thought about in advance nor realised the existing value of the users prior knowledge with MedTech devices. The team experienced (erfahrung) that this was a positive surprise in terms of further user involvement as they did not get to delve deep into this subject. The interview-guide was not prepared to delve into gathering data about other MedTech devices, however, the startup believes this type of information could be of relevance towards the product development process. Thus, wants to include this aspect in user involvement processes of the MotOrthosis as well as other MedTech devices in the future. One of the reasons mentioned was that some functions or control mechanisms from other MedTech devices can perhaps be transferred into the product development of the MotOrthosis. Although the team stressed that they experienced that the user-tests did provide them with more than enough relevant data to continue further development of the MotOrthosis. Yet, the team wants to continue with more user-tests with the patients to dive deeper into the topic of other similar MedTech devices in order to explore if any components can be transferred to improve the MotOrthosis. Moreover, the team discussed that an advantage of this is that the patients could perhaps explain them *why* they were not satisfied with the MedTech device and their experience (*erfahrung*), which the team could then take into consideration in the development process of the MotOrthosis.

4.2.4 Digital or physical user-test

In the process of planning the user-tests it was decided that due to COVID-19 the interviews should be conducted digitally although they were originally thought to be conducted physically. The main reason for this was due to the underlying symptoms

of the patients with the ALS-diagnosis. The team discussed and identified benefits for the startup by conducting the interview digitally. The main benefits that came up during the focus group interview with the startup included: (1) *the ability to interview patients from different geographical locations*, (2) *one could have several interviews per day and still have time to do other work*, and (3) *it reduced costs by not having to travel*. Moreover the team experienced (*erfahrung*) that they got to know the participating patients surprisingly well over Zoom.

The team also discussed the downside with conducting the interviews digitally, particularly with regards to when the patients wanted to show some of their MedTech devices or a how they did a movement. After the team read through their transcription from the user-tests there were several patients whom had stated that they wanted to show something but could not do it because it would be difficult digitally versus physically. Additionally, the user-test that was conducted physically was a stronger psychological strain than the user-tests conducted digitally. Meeting the patient in person left a stronger impact tied to feelings of empathy for the patient from the startup perspective. Furthermore, the team experienced (*erlebnis*) that the patient they met in person understood the limitations of the product better then the rest of the patients. The team discussed that this increased understanding of product limitations was connected to the live demonstration that the patient received in addition to seeing the video that the rest of the patients got to see. However, the team expressed that their experience with the user-tests done digitally was the right decision this early on in the development process. The team argued that they needed to make connections with the patients, understanding the disease and get *"first line"* feedback on the MotOrthosis, which they received during the user-tests. The team discussed that in the future development stages they would most probably combine a hybrid model where some user-tests are digital and some physical if feasible.

4.2.5 Healthcare professionals participation

Throughout the process of designing and conducting the user-tests the MedTech startup received support from healthcare professionals to assist in the process. Vårin Vaskinn whom was also a part of this case study as a registered nurse helped the startup in (1) *identifying the right method of user-testing with patients as well as designing the user-test* (Benestad and Vaskinn 2020), (2) *creating the interview guide*, and (3) *identifying, recruiting and organising the user-test process with the patients before they met the startup team.* The team experienced (*erlebnis*) this as more comfortable and safe throughout the user involvement process. The team

experienced safety through assurance that if they did something wrong or made a mistake, the healthcare professional would step in and take lead. They felt more safe in their position interviewing the patients with a healthcare professional present and as part of designing the user-test. The assistance from the healthcare professional was experienced (*erfahrung*) as critical in order to start the process of involving the users. Moreover the team experienced (*erfahrung*) that the healthcare professionals role and contribution was critical in order to conduct the user-test. E.g. during the user-tests the team experienced (*erlebnis*) themselves as a bit reserved, thus having the healthcare professional there was a big support and made the representative from Vilje Bionics feel more safe in the situation. They experienced (*erlebnis*) that the healthcare professionals normalized the situation and made it into a positive experience for them and the patients. The team also experienced (*erlebnis*) that the patients had bigger trust in them, since there was a healthcare professional present, due to the fact that most healthcare professional think a little bit differently then what engineers do in their perspective.

4.2.6 Overall experience after user involvement

The team discussed that their main experience from this user involvement process taught them: (1) *how to talk to a potential user*, (2) *how to formulate the questions* and (3) *how to capture information out of the conversation.* They exemplified this by saying that *"During these user-tests we had a limited time-frame, which put pressure on us to be smart with the questions and create a safe space for the patients"*. Furthermore, the team experienced (*erfahrung*) this patient group as a resourceful group despite the fact that they have a deadly disease. During the user-test process the team experienced that they have crossed a line going from a research project to more of a development process, and that together with the patients they can develop the MotOrthosis more like a collaboration where each part is involved in the development process of the MotOrthosis. This way of thinking has accrued from an experience (*erlebnis*) that the patients would like to have an active role and participate rather then just *"answer some questions"*.

In retrospective, the team reflected upon their experience prior to conducting the user-test. The team discussed that they had experienced (erlebnis) that they got several warnings from external parts of how much work it is do move forward with a MedTech product. The hard work is related to approvals, regulations, as well as large sums of time and costs that go into the development process. This was exemplified with the fact that *"Over a year ago we as a team had the feeling that it would be impossible to work with MedTech as a startup, and yes it has been hard and*

we have had work hard to get to where they are today, however it is impossible with right partners in forms of resources and capital, this is where user involvement has helped us strengthen these partnerships". In essence, the team discussed that the user-tests has in the aftermath given the MedTech startup an increased credibility when meeting external stakeholders which is important for the development process both in terms of capital and resources. This increased experience (*erfahrung*) of credibility was discussed as associated with the seriousness of the user involvement and user-test conducted by Vilje Bionics. Moreover, *"Had someone told us one year ago that if you get these approvals this way, with this method, then you can go out and interview the patients and this will increase your credibility"* the team would have started with user involvement in the beginning of the design phase of the product development. Finally, the team noted that user involvement is *"fresh knowledge"* that needs continuous refreshment, thus should be continued with during the development process.

Chapter 5
Discussion

In this chapter, the researchers will discuss the key findings from this case study and how they are connected and build upon existing research. The literature and theoretical framework presented in chapter 2 and 3 will be anchored in the discussion of this chapter. The research question (RQ) of this case study aims to analyse the experience of user involvement in the development of a new medical technical device from two perspectives (see RQ below). First, the researchers will discuss the experience of user involvement from a patient perspective. Second, the researchers will discuss how user involvement was experienced from the startup's perspective. Last, the researchers will discuss the differences and similarities between the different points of views in order to understand the phenomena the research questions seeks to answer.

The case study research question

RQ: How does a MedTech startup and patients experience user involvement in the development process of a medical technical device?

Subquestions

1.1 How do patients experience being involved in the development process of a new medical technical device?

1.2 How does a startup experience user involvement in the development process of a new medical technical device?

5.1 Experiences from a patient perspective

In this section of the case study thesis the researchers will discuss the patients' experiences of user involvement in terms of both *"erfahrung"* and *"erlebnis"* (see chapter 2). The research participants from the patient group in this case study were overall positive to the user-test as well as the case study interviews that were conducted. First, the researchers will discuss the patients' experience of medical technology. Second, the researchers will present how the patients experienced one-

to-one semi-structured interviews. Third, the motivational factors will be presented that led the patients' to participate in this case study. Fourth, the patients' experience with the user-test, and last the effects of including healthcare professionals in the case study from a patient perspective is discussed.

5.1.1 The patients experienced a lack of user-friendly MedTech products

Prior to this case study thesis, the patients had experiences (*erfahrung*) with MedTech devices that were not user-friendly, which resulted in MedTech devices that did not solve their problems. This contradicts with human-centered design theory that aims to generate products that solve the users' problems (Giacomin 2014; Koen 2015; Steen et al. 2004). The patients' experience (*erfahrung*) with inadequate user-friendly medical technology left them with an experience of dissatisfaction. This aligns with Kjørstad's (2018) research which states the necessity of companies including users early on in order to develop a product that the user actually will use, otherwise the users are left unsatisfied and will not use the product. One of the patients had more than 20 years of experience (*erfahrung*) with MedTech devices and stated that low user involvement affects the usability of a MedTech device. Prior to this case study, this patient stated that they had never experienced (*erfahrung*) that a producer/developer asked what their needs are nor their opinion of requirements to be satisfied with the product. This was also supported by several patients who experienced (*erfahrung*) that their voice had not been taken into consideration to a large degree beside dormant online questionnaires. This alludes that even though the theory states that user involvement is a critical component when developing new MedTech (Baglieri and Lorenzoni 2014; Baldwin and Von Hippel 2011; Caron-Flinterman et al. 2005; Rochford and Rudelius 1997; Trigo et al. 2016; Von Hippel and Katz 2002; Wise and Høgenhaven 2008), and there is shift towards more user involvement within development of MedTech, the patients experienced that there still is a lack of "proper" user involvement and refers to this case study's user test as a "proper" method (Baldwin and Von Hippel 2011; De Jong and Hippel 2009; Von Hippel 1978a,b; Von Hippel and Katz 2002). This substantiates theory that show how critical user involvement is in a development process (Tsai et al. 1997), and aligns with the scholars who suggest that user involvement increases the value of MedTech devices (Biemans 1991; Brockhoff 2003; Lin et al. 2001; Shaw 1998). The patients' experience of satisfaction, both in terms of "*erfahrung*" and "*erlebnis*" of user involvement after the user-test and this case study, is pursuant with Kujala's (2003) model of user involvement. Specifically, highlighting that early user

involvement lead both the user and producer (the startup) to a positive satisfaction (Kujala 2003).

5.1.2 Patients preferred one-to-one semi-structured interviews

Prior to the user-test, the patients had mainly participated through online questionnaires, but experienced (*erlebnis*) the user-test and case study interviews as a preferred method to be involved in a development process of a medical technical device. The startup had conducted their user-tests through semi-structured interviews, similar to this case study which was recommended as a method for user involvement when developing a MedTech device (Shah and Robinson 2006). In essence, the method of user involvement for this case study was received well from the patient perspective, which supports the recommended theory from the literature findings on conducting semi-structured interviews with patients (Benestad and Vaskinn 2020). With preferred user involvement method the patients' expressed an experience (*erlebnis*) of the fact that they were given the possibility to talk to the developers one-to-one and ask follow-up questions along the process.

Through the online questionnaires the patients often experienced that they had several questions afterwards. However, the barrier to get in touch with the researchers of the online questionnaire studies to ask their outstanding questions was high, as it was not a straightforward process, nor did they expect an answer since they had never experienced hearing back after completing the online questionnaires. Thus, the patients' outstanding questions were, according to the patient group, not taken into account in online questionnaire studies. For this reason, the patients found the one-to-one semi-structured interviews as a satisfying experience (*erlebnis*), leaving them with no outstanding questions. Thus, from this case study one can argue the value of using the human-centered design method of one-to-one semi-structured interviews as a method of user involvement when developing MedTech devices. This supports theory on user driven innovation processes which focus on identifying users' needs and involves them in a systematic way in the development process (Wise and Høgenhaven 2008). According to the researchers of this case study, semi-structured interviews allowed the startup to gather critical information about the patients' needs and provided the end-user (patients) with a positive experience (*erlebnis*) of user involvement. In specific, one patient exemplified that they experienced (*erlebnis*) the user-test with the startup as a *"normal conversation"* rather then being interviewed, which was received positive by this patient. Furthermore, the patients' overall experiences (*erfahrung*) with user involvement was that their participatory

role is vital to them as a user to influence the development of MedTech, thus highly recommends others to participate. Thus, it can be argued that Kujala's (2003) theory about user involvement (see. figure 2.1) does indeed affect the user and customer satisfaction. In addition, this finding supports theory that there is a significant value to include the users in the development process in order to incorporate their needs and requirements in the device in order to minimise inadequate MedTech devices (Saiedian and Dale 2000; Sato and Salvador 1999; Truffer 2003)

5.1.3 Patients' motivations to participate

The patients were also asked about their motivation for participating in the user-test. The most frequently identified motivation was that the participation gave the patients hope that the product, MotOrthosis, could eventually help them in their everyday life, and also help them move their arms again. The patients' also showed a strong sense of motivation to participate in order for the next generation of ALS-patients to have a better MedTech device to increase their coping mechanisms and quality of life with the disease. Previously, the patient group had not been introduced to a MedTech device that focuses on helping them with one of their most critical impaired function; reduced arm function, which would make them more independent (e.g. drinking a glass of water by themselves, picking up something from a table etc.). The participation was therefore vital for them to solve their own problems, but also to contribute to the future generation of ALS-patients whom will suffer from the same dysfunctions. The patients' motivation to participate and share their knowledge to solve their problems supports Trigo's (2016) research which suggests that the lead users had high experiences regarding a problem, thus should they be included in the development process.

5.1.4 Patients' experiences with the user-test

It is equivalent from the findings that the patients preferred to be invited to a user-test through their interest groups (e.g. ALS-Norge) rather than receiving information from their general practitioner (GP). This was a surprising finding in the case study, where the researcher suggest other MedTech startups to take into account in recruitment processes of patients as research participants in a user-test scenario. The patients experienced (*erlebnis*) that the structure of the user-test functioned well, which supports the theory on building the interview guides with healthcare professionals and use semi-structured interviews as a method (Christoffersen et al. 2015; Kvale and Brinkmann 2019; Tjora 2020). The user-test was not experienced (*erlebnis*) as an exam, but as a regular conversation where the representatives from the

startup were experienced (*erlebnis*) as polite and curious about how it is to live with the ALS-diagnosis. In the beginning of the user-test the patients were asked some personal questions regarding their disease and everyday life. Prior to the user-test the researchers were uncertain about how the patients would experience (*erlebnis*) these types of questions when preparing the interview guide. However, the patients were content about the personal questions as suggested from the methodology and some stated that it was important for the startup, Vilje Bionics, to ask personal questions to gain a better understanding of their situation. This finding supports existing research that states that the development process for a medical technical device requires in-depth considerations of the users' activities in their daily working life as well as functional limitations (Green et al. 2000; Kaufman et al. 2003; Kittel et al. 2002; Ostrander 1986; Rockwell 1999; Staccini et al. 2001; Wilkins and Holley 1998). Thus, the researchers argues that the "fact question" during the interview guide recommended in the model by Christoffersen et al. (2015) is beneficial from a patient perspective.

Furthermore, the patients' expressed their experience (*erlebnis*) with the design of the user-test. The case study demonstrated that human centered design (HCD) theory is applicable when trying to understand the users needs and desires, and moreover interact and empathise with them (Giacomin 2014; Koen 2015). Thus, it can be argued that HCD methods increase the experience of being included in development processes. Moreover, the patients experienced (*erlebnis*) that the set timeline for the user-test was satisfying. Even though the patients were pleased with how the startup, Vilje Bionics, included them in the user-test, they acknowledged some improvements areas which would increase their experience (*erlebnis*) of the user-test in a positive way. Specifically, the patients wanted supplemental questions about the product, MotOrthosis, both concerning the technical dimensions and physical outlook. Besides this, the design of the user-test was experienced (*erlebnis*) as professional and informative from start to finish. As mentioned, the user-test was primarily conducted digitally through Zoom, and the researchers thought that this would affect the experiences with the user-test negatively. Despite this, the patients were positive to participate in the user-test digitally. Reasons such as, "*It was easier*" and "*I experienced that Vilje Bionics understood my feedback even though the user-test was done digitally*" came up during the interviews. This shows that early user involvement increases the user satisfaction and that the theory from Kujala (2003) is transferable to the patient experience even though the user involvement was not conducted face-to-face like it traditionally would have been (Shah and Robinson 2006).

In addition, most patients were uncertain whether their contribution provided

value to the startup's user-test and this case study. The patients experienced (*erlebnis*) an uncertainty of their contribution in the research project's user-test by expressing statements such as "*Did you gain anything from my participation?*" and "*At the beginning of the user-test I was not aware of the importance of my voice in the development of the device, but I kind of realised it might have been important when they wanted my opinion, which no one else has asked for before*". Whilst it is evident from the literature review that user involvement can provide value for MedTech startups, this may not be experienced from a patient perspective. This key finding shows that it is vital to emphasise towards the patients', the lead users, the importance of user feedback in the development process in order to avoid this experience (*erlebnis*) of uncertainty from the patients perspective.

5.1.5 The patients' experiences with healthcare professionals' participation

The feedback from the patients was that they were beyond satisfied with the design of the user-test, both for the startup and this case study. Prior to the user-test the patients were not informed about how the startup, Vilje Bionics, had created the design including the interview-guides, and that it had been created with assistance from a healthcare professional perspective. The patients expressed that including healthcare professionals in the user-test was not necessary for their choice of participation. However, as the patients were not aware that the user-test was built based upon theory as presented in section 2.3.2, which supported healthcare professionals to be included (Castner et al. 2016), the researchers found it surprising that the patients did not experience (*erlebnis*) a need for healthcare professionals in order for them to participate. Based on this key finding, the researchers argue that although the patients were not aware of the impact of healthcare professionals participation's in the user-test, healthcare professionals should be included in future MedTech studies. This argument is also supported by the fact that the patients were satisfied with the applied user involvement method of gathering data. Thus, indicating that the role of nurses in a medical development process, as Castner et al. (2016) reports, is imperative in an era of technological transformations within the healthcare field. In essence, during the patients' explanations about their experiences with the user-test, the researchers interpret that the patients were satisfied with the user-test design and method, and that the healthcare professionals hold an incremental role for their positive experiences. By adding a healthcare professional when designing the research, the patients had an experience (*erlebnis*) of being positively included in the development process.

5.2 Experiences from a startup perspective

In this section the researchers will discuss the startup's experience of user involvement in terms of both *"erfahrung"* and *"erlebnis"* (see chapter 2). The researchers will present the key findings from the startup's experience with user involvement and elaborate on areas of improvements in the development cycle of the user-test. Last, the researchers will highlight the effects of healthcare professionals participation from a startup perspective.

5.2.1 Positive to user involvement for early-stage MedTech startups

The startup, Vilje Bionics, expressed after the experience of user involvement, that the user-tests provided the team with a great amount of value for the continuation of the development process. In particular, the value creation was received through feedback on possible requirements and considerations of the product's design. The startup also experienced that the user-test, and in general including the users in early-stage development, had increased their credibility in meetings with external stakeholders including partners and investors. The researchers argue that this finding supports that early-stage MedTech startups which work with medical technology for patients should involve the patients early on in the process of development. This supports the framework of involving users early on in development processes and that this provides a better chance for a MedTech company to succeed in the development process (Biemans 1991; Brockhoff 2003; Lin et al. 2001; Shaw 1998; Tsai et al. 1997).

5.2.2 The startup's experiences with user involvement

The startup, Vilje Bionics, described how the team, after conducting the user-test experienced *(1) how to talk to a potential user, (2) how to formulate their questions* and (3) *how to capture information out of the conversation.* Their experiences were retrieved through the human centered design (HCD) method of user involvement with conducting semi-structured interviews (Koen 2015; Shah and Robinson 2006). Moreover, from the findings the researchers see that the user-test gave the team a deeper understanding and experience of (1) *what it is like to be diagnosed with ALS* (2) *what it is like living with the disease* and (3) *the individual differences that occur with the diagnose.* Furthermore, the team experienced that as well as gathering information about the user and ALS, the team now have "experiential

knowledge" that was solely gained through the user-test experience. This was an unexpected experience from the startup perspective, which as a result, put the startup in a better position to understand the broader context of their users (the patients'). This supports the research work from Baglieri and Lorenzini (2012) which emphasises the involvement of users in the development process as an alternative way to gather information that allows them to perceive an understanding of the environment and market boundaries to a much greater extent. This reflects the experience one of the team members of the startup expressed by stating "*Now that we know the context of the bigger picture, it is easier to understand how we can bring further value to our end-users*". The researchers believe that the unexpected key finding here in the case study is another key benefit for future MedTech startups to conduct user-tests with patients in early-stage development processes. The reason for this, is that the researchers believe that an early-stage MedTech startup may then be able to synthesise a more valid understanding of their users and market needs.

Additionally, the startup, Vilje Bionics acknowledged, that based on their experiences (*erfahrung*), it was important for them to include more than 10 patients in order to gather information about the patients' needs and potential requirements of the medical device from their first target group (ALS-patients). Although it is recommended to include 5-10 patients in research with patient groups (Bjørk and Solhaug 2008; Christoffersen et al. 2015), the startup experienced that this depends on whom the MedTech device targets in terms of the patients' diagnosis and symptom picture. ALS-patients have a diverse symptom picture (Brown and Al-Chalabi 2017), thus the startup highlighted that it wanted to conduct research with a sample of at least 10 research participants in order to retrieve information about the most critical requirements for further development of the MotOrthosis, as the patients' symptom picture could vary. By conducting 13 patient user-tests, the team experienced (*erfahrung*) that the startup have a more in-depth understanding of the complexity of the deadly disease compared to before. Expressing that the user-test was of significant value for the startup to take the next step in the development process of the medical technical device. Based on this finding, the researchers argue that it could be beneficial for a MedTech startup to analyse the symptom picture of the patient group to figure out how many patients that need to be involved in order to fully grasp an understanding of the patients' needs.

All the experiences that the team from Vilje Bionics have gained through the user-test has given the team reasons to believe that they now are in a position to gather and structure data to make better interpretations of specified requirements for further development of the medical technical device. Prior to the user-test, the

startup acknowledged that they were not in the position, both in terms of knowledge and experience, to conduct user-tests with patients. They expressed that due to a lack of knowledge and experience with the patient group, they experienced being worried about making false assumptions and uncertainty about *how* to conduct the user-test with the patients. This was one of the reasons why the team wanted a nurse to be a part of the development process, as the researchers (Benestad and Vaskinn 2020) had recommended the team to use methodology from the healthcare field (Castner et al. 2016; Christoffersen et al. 2015; Kvale and Brinkmann 2019; Pascal Lehoux et al. 2017; Pascale Lehoux et al. 2018; Lettl and Gemünden 2005; Shah and Robinson 2006; Tjora 2020). The startup expressed gratitude towards having Vårin Vaskinn as a registered nurse to be a part of designing the user-test, preparing the team before meeting with the patients, and being an observant participant during the user-test interviews with the patients. Having a nurse present made the team experience (*erlebnis*) a feeling of safety during the user-tests. This supports the theoretical model from Castner et al. (2016) which argues that nurses should be involved in the development of medical technology "...to inform the process and to provide insight from a patient-centered viewpoint of the human-technology interface." (Castner et al. 2016 pg. 300). In addition, this can be connected with the research from Koen (2015) which states that user involvement should focus on the Point of View (POV) of the user by understanding (1) "*the user*, (2) *the user's need*, and (3) *observation of the user in their environment and interpretation of the observations*" which is also similar to the lean startup methodology (Koen 2015 pg. 19). Here, the role of the nurse plays a critical role according to Castner et al. (2016), as they have a close proximity to the patient experience and a scientific understanding of healthcare processes. Thus, the researchers believe this finding in this case study shows that the role of a nurse can have an impact in the development process of medical technology building on the theory from Castner et al. (2016), although more research is needed to be conducted on this topic to generalise the finding.

Preliminary to the user-test, the startup discussed the possibility that the problems they tried to solve for ALS-patients with the product, might not all truly exist for their users. However, during the user-test the team experienced that their hypothesis of identified problems for patients with ALS were present, and that the MotOrthosis could have the ability to solve at least some of their problems in the future. Hence, the startup experienced that the user-test indirectly gave them an opportunity to gather qualitative research data for validating their presumptions tied to which problems the product should try to solve for their target users (the patients), as well as confirming a market need for the product in development.

The researchers of this case study agrees that this stresses the importance of early user involvement with the highest impact rate in the beginning of design and testing/trial stage, which appears in capturing experiences of identifying improvement areas or suggestions for further development (Gremyr et al. 2018; Shah and Robinson 2006). In addition, this experience from the startup's perspective supports that user involvement can help to identify *"experience-drivers, value-creating activities and reasons for dissatisfaction and complaints, ... for development and innovation"* (Echeverri et al. 2013 p. 50). Emphasising the importance of exploring the experiences in order to derive valuable data for further development.

Furthermore, other research shows that high user involvement in early-stage development processes of MedTech devices can be time-effective and cost-effective (Tsai et al. 1997 Giuntini and Mc donagh et al.). This was applicable to the startup's experiences with user involvement. Vilje Bionics expressed that the development process would have been even more cost-effective for them if they had involved the users earlier on in the development process, as far back as at the beginning of the design stage which Castner et al. (2016) suggests. Had the startup chosen to include the patients back then, the startup would not have had to make that many changes to their third prototype. Here the team argued that "*Had someone told us prior to designing the third prototype to gather data through a user-test that could have been used as documentation for product development with more specified requirements from the users, this would have helped us design the product accordingly, then we would have implemented user involvement from the start*".

During the user-test the startup experienced (*erfahrung*) that the patients struggled to understand the ability of the MotOrthosis and were left confused about its function. Based upon this, the team discussed possible changes during the focus group interview that could potentially increase the patient's understanding in a user-test in the future. These proposals were *(1) create a longer video, (2) focus on what the MotOrthosis should be able to do in the future in terms of functionality, (3) send out the video beforehand* and *(4) show the initial video twice*. However, the team also reflected upon potential downsides with creating these changes and why they chose not to make them during the user-test. They thought, based on their experiences prior to the user-test, that showing what the MotOrthosis should be able to do in the future would influence the patients answers into just expressing the same functions as they were shown. Thus, the startup chose not to show functions, limitations nor the activities the product could help the patients achieve. However, in retrospect of the user-test, the startup now would want to erase that thought and create the video with an emphasis on the function and limitations of the product e.g. by showing the potential activities the users can achieve with the product.

5.2.3 The startup's experiences with healthcare professionals' participation

As mentioned before, one of the researchers of this case study, Vårin Vaskinn, assisted Vilje Bionics with the conduction of the user-test from start to finish. Next to involving Vårin Vaskinn due to her background as a registered nurse, the startup also received advice from other healthcare professional partners (see chapter 1). The startup experienced the contribution from a healthcare perspective as an important contribution to be able to design and conduct the user-test and gather the needed information from the patients to develop the MotOrthosis further. By including healthcare professionals the startup learnt how to gather information from the patients in an effective manner through building a thorough interview-guide prior to the user-tests. This was applied in accordance with Koen's (2015) theory which states that a correct interview-guide will expose new opportunities for a startup and increase the user understanding. The startup, Vilje Bionics, experienced what Koen's theory states through the support and cooperation from the healthcare professionals. Furthermore, the startup experienced (*erlebnis*) that the close cooperation and assistance from a healthcare perspective contributed especially with regards to designing the user-test and interview-guide by closing a gap between healthcare methodology theory and user involvement from an entrepreneurship perspective. The startup, Vilje Bionics, experienced that their questions for the patients were relevant and the buildup of the interview-guide (see appendix A.1) was efficient in gathering the needed data to further develop the medical technical device. Specifically, the startup experienced (*erlebnis*) that the method of gathering information from the patients was a useful method to receive feedback and information about improvements for the MotOrthosis. This is equivalent with Von Hippel and Katz's (2002) theory where user involvement is essential to improve product development. Moreover, the theory states that gathering user information affects the development of the product, hence why it is critical to conduct proper user involvement (Tsai et al. 1997), which is also critical to succeed when developing new MedTech devices (Biemans 1991; Brockhoff 2003; Lin et al. 2001; Shaw 1998). Thus, the researchers argue that the role of healthcare professionals in some or all of the parts of user involvement can increase the value of the assembled data collection. Essentially, the researchers believe that healthcare professionals can provide a unique value in a user-test scenario for a MedTech startup in terms of gathering relevant data for further product development.

5.3 The *experiences* of user involvement from a MedTech startup and patient perspective

In this section the researchers will elaborate on the experience with user involvement from both the startup and patients' perspective. Here, the researchers will discuss the overlaps, as well as differences and similarities, of the different themes of experience as discussed in the sections above which were revealed through the data analysis. The aim of this part is to discuss and answer the proposed main research question (RQ) at hand.

RQ: How does a MedTech startup and patients experience user involvement in the development process of a medical technical device?

Prior to the case study, the researchers found that user involvement with human-centered design practices are beneficial across several industries including the field of MedTech (Benestad and Vaskinn 2020). Through the literature review semi-structured interviews were shown to be a prominent method of user involvement with patients in the early stages of development in MedTech, specifically during the design and testing/trial stage. Accordingly, the literature review revealed that experience as a phenomenon is a critical component in order to gain an in-depth understanding and fully grasp the contextual meaning of user involvement. Nonetheless, the *experience* of user involvement from a startup and patient perspective when developing a new medical technical device was not identified in the current landscape of research. This was argued to be an area of research to further address in the MedTech industry (Bate and Robert 2006), which underpins the aim of this case study. In this section, the researchers aim to shed light on the key findings from the *experience* of user involvement. Through this case study analysis, several experiences from both the startup and patient perspective were revealed and the most prominent themes of experience in the findings were: experiences with the choice of methodology, experiences with possible improvement areas of the user-test and the experiences of healthcare participation in user involvement.

5.3.1 Experiences with the choice of methodology

The MedTech startup, Vilje Bionics, had prior to this case study, solely spoken to a few potential users about the patients limitations and need for the medical technical device they are developing known as the MotOrthosis. By this means, there was a possibility that the product, MotOrthosis, was not a solution for the identified

users being ALS-patients and those with reduced arm function. This was an area of uncertainty and risk tied to product development that the startup wanted to reduce by conducting a user-test. Here, the researchers of this case study recommended the startup to use a human-centered design approach known as semi-structured interviews as a method of user involvement based on the findings in the literature review (Benestad and Vaskinn 2020). The lean startup methodology has a similar nature as the human-centered design (HCD) methodology by having an iterative process with the user in focus (Koen 2015), here semi-structured interviews are a common method of practice with patients (Christoffersen et al. 2015; Shah and Robinson 2006; Tjora 2020). If one looks to Kujala's (2003) model of "*Early User Involvement*" (Figure 2.1) the customers' satisfaction is closely linked to the product development performance, requirements from the users as well as the actual usability of the product in solving the users problems (Kujala 2003). Thus, the researchers argue that it is evident that startups involve users in a product development process.

The case study revealed that the user-tests conducted through semi-structured interviews gave the startup the experience of retrieving answers to *"why"* certain elements were critical for further development of the MotOrthosis for the users. For instance, the startup received answers to "*why*" certain user requirements related to functions, appearance and control mechanisms were important to the users. Specifically, for the user requirements the startup received explanations to "*why*" the patients needed a specific function and which pain points they wished could be solved with the product. The startup experienced (*erfahrung*) the understanding of *"why"* as a valuable importance for the future development of the MotOrthosis. By knowing and understanding *"why"* the patients had certain needs and pain points, the startup received a more in-depth understanding of the problems and implications of their users from the patients' point of views (POV), which aligns with the work of Koen (2015) which suggest that it is vital to gather in-depth understanding of the users' need from their POV. Moreover, the startup experienced with the conduction of the user-test, that it provided them with a more in-depth understanding of the users' daily situations and context of usability of the product for the patient group. This is supported by work from other scholars who believe that the development process for a medical technical device requires in-depth consideration of the users' activities in their daily working life as well as functional limitations (Green et al. 2000; Kaufman et al. 2003; Kittel et al. 2002; Ostrander 1986; Rockwell 1999; Staccini et al. 2001; Wilkins and Holley 1998). Essentially, this provided the startup with a more in-depth understanding of their users, their needs and how to communicate with the patients in future processes with regards to the development of the MedTech device.

One of the key findings that came as a revelation from the startup's perspective was the experience (*erfahrung*) of receiving unexpected data from the patients through the user-test, that as a result provided the team with "experiential knowledge" in their retrospective. E.g. the startup gained "experiential knowledge" of ALS-patients and what it is like living with the diagnosis as well as answers to *why* certain elements of the product were critical to meet their needs. In essence, the unexpected "experiential knowledge" gains were solely gathered through the conducted user-test method. As a result, the startup assembled the context of the bigger picture with the users' daily situations, needs and critical pain points for further development of the product. Thus, the researchers argue that semi-structured interviews based on this case study gives the patients a satisfied experience of user involvement and increases the startup's understanding of the point of view (POV) of their users. In particular, based on these findings the researchers argue that this method of user involvement can bring valuable "experiential knowledge" that otherwise is potential unknown territory for the startup.

From a patient perspective, the patients had not experienced (*erfahrung*) this type of user involvement related to development or evaluation of medical technology before. They experienced (*erlebnis*) this as a rare opportunity for them to provide their opinion, expressing a satisfaction with the choice of methodology. The patients had previously experienced (*erfahrung*) that they were asked to give their opinion through a questionnaire on paper that was submitted. The patients experience after the user-test was that they would prefer one-to-one interviews instead of online questionnaires, particularly due to the interaction with the developers where both parts could ask each other open questions. Being involved in a development process through a user-test like Vilje Bionics conducted, was stated as a *"proper"* method by several of the patients. Thus, the researchers argue that one-to-one semi-structured interviews can provide value for other early-stage MedTech startups as well involving patients in a development process.

For this reason, the researchers of this case study argue, based on the findings, that there are three key factors a MedTech startup can experience from applying this type of user involvement methodology. First and foremost, the applied methodology in this case study can (1) *provide a more in-depth understanding of the users contextual setting including "experiential knowledge"*, (2) *uncover patients' needs and requirements for the product in order to identify functionalities and limitations* and (3) *provide a useful method of how to gather this data in a cost-effective manner.* In the last step, the researchers recommend as mentioned other MedTech startups to apply a semi-structured interview method in gathering data as this was perceived as a successful method in this case study.

In sum, based upon the positive experiences of the user involvement method from both the patients and the startup perspective; the case study suggests that the applied method of user involvement can be of value for other MedTech startups in an early-stage development process. As stated in the findings, Vilje Bionics will integrate patients in further development of the medical technical device due to the positive outcome of the user-test and the findings in this case study. Thus, the researchers believe other MedTech startups could potentially benefit from the same methodology and procedure involving patients in an early-stage development of medical technical devices.

5.3.2 Experiences with possible improvement areas of the user-test

All the research participants including the patients and startup were asked to reflect around possible improvement areas from their experience of the user-test. This resulted in examples of possible changes with the user-test from both the patients and the startup's perspective. The most prominent finding was connected to possible changes toward the product demonstration part of the user-test. The patients experienced that the video demonstration of the product was not optimal, thus they had to ask follow-up questions in order to understand the functionality and limitations of the MotOrthosis. From the startup perspective, the team experienced that the product demonstration also needed a few changes. The most prominent changes that came up from the suggestions based on the findings from both perspectives was to create a longer video with examples of daily activities, including specifications of functions and limitations of the product in order to see what the product could potentially help the patients with in practice. The researchers find it interesting that both perspectives experienced possible improvements towards the product demonstrations. Thus, the researchers argue that it is vital to invest time into how to best demonstrate the product towards the end-users, by e.g. emphasising and communicating the functionality and limitations of the product. In addition, the startup experienced (*erfahrung*) that the data collected from the user-tests would have saved them time in the product development process if they had conducted the user-test prior to the development of the third prototype. This aligns with previous research which shows that user involvement in early stage development processes of MedTech devices can be time-effective and cost-effective (Tsai et al. 1997 Giuntini and Mc donagh et al.). This suggests that user-involvement should be implemented at the very beginning of the design stage as suggested by Castner et al. (2016), and not necessarily be delayed until the testing/trial stage, as this case study shows that

it could have saved the startup time if they initiated user involvement at the start of the design stage.

Moreover, one of the surprising findings from the data analysis revealed that the patients experienced uncertainty with regards to their participation in the user-test and case study. This key finding shows that it is vital to communicate and stress the importance of lead users (the patients) role and value to avoid this experience (*erlebnis*) of uncertainty from the patients' perspective. This was surprising for the researchers as the patients seemed comfortable in regards to answering the questions during the user-test and case study. In order to fully understand *why* some of the patients had this experience, the researchers read the transcription from Vilje Bionics user-test interviews and discovered that the interviewer did not explicitly communicate this to the patients. However, the experience of uncertainty could also have been related to the fact that this was the first user involvement through this method all of the patients had participated in, thus, it is applicable to believe that this could have had an influence on this experience.

Whilst it is not an improvement of the user-test, the researchers want to shed light on the fact that the user-tests and case study interviews were conducted digitally due to the restrictions followed by COVID-19 as the patients are in a group at particular risk with their underlying fatal disease. Thus, prior to the conduction of the user-tests and the case study interviews the researchers had an hypothesis that the startup and patients experience of user-involvement would be negatively affected by the circumstance. However, the analysis of the findings suggests that the startup and patients' were highly satisfied with the digital interviews and that the startup received a lot of valuable data in a time effective manner and at low cost. The findings show that the startup experienced that they received more than enough data by conducting the user-test digitally, and believed that this method is just as time- and cost effective as a physical user-test. Although this finding cannot be generalised, it suggests that future MedTech startups can benefit from conducting digital user-tests by saving time and costs. The researchers believes that this could be an interesting topic to further research, by exploring the benefits and barriers of the effect upon digital versus physical MedTech user-tests.

5.3.3 Experiences of healthcare professionals' participation in user involvement

The presence of healthcare professionals participation in the user-test and case study showed positive effects upon the final results of the data analysis. Vilje Bionics experienced that it was essential to include a nurse when planning and conducting

the user-test. The knowledge and presence of the healthcare professional lead to an experience of safety for the startup. Moreover, the nurse contributed with value for the startup in terms of gathering sensitive information from the patients that the startup felt uncomfortable to do by themselves. For this reason, the researchers argue that this case study contributes to evidence that nurses play a critical role in medical device development, which contributes and builds upon the research from Robert and Bate (2006) as well as Castner et al. (2016).

On the other side, more than half of the patients expressed that it was not necessary for their motivation of participation to include healthcare professionals in the user-test and case study. However, the patients were satisfied with the design and method of user involvement and experienced this as a positive and *"proper"* way to include patients in a development process. In essence, the researchers argues that although the patients did not directly experience the role of healthcare professionals participation in the user-test and case study as necessary; they indirectly experienced (*erlebnis*) that it increased their satisfaction of user involvement by expressing satisfaction for the design and method of the user-test. Thus, their statements of expressing satisfaction for the design and method of the user-test, can be interpreted as a need for having healthcare professionals in the process of user involvement with patients, which supports and builds upon the research work of Castner et al. (2016) as well as Bate and Robert (2006) which states that the role of nurses are critical in the development of medical technology.

The researchers find the controversy of *"to include healthcare professionals"* or *"not to include healthcare professionals"* as an interesting discussion. As mentioned, it must be taken into consideration that the patients did not know of the contribution the healthcare professionals gave the startup prior to the user-test. These contributions were an essential part of the positive experiences that the patients, as well as startup, had after the user-test. Nevertheless, how significant it is to include healthcare professionals, and in which parts of the development process they have the highest impact, is not identified in this case study and can be further researched in future studies, but the researchers want to highlight that this finding from the case study suggest that if a startup is lacking experience with patient involvement they should use a methodology from the field of healthcare and seek advice from healthcare professionals. In addition to this, the startup experienced (*erfahrung*) increased trust from the patients and increased safety by using the applied methodology from the field of healthcare, involving a nurse in the user-test and gathering advice from other healthcare professionals. Moreover, the implication of the user-test with the support of healthcare professionals led the startup to experience enhanced credibility towards external stakeholders including partners and investors.

This experience suggests that it is even more critical with healthcare professionals' participation in user-involvement for early-stage MedTech startups which are in need of key partners and investors as large investments of resources and capital go into developing medical technology (De Jong and Hippel 2009). In sum, based on these findings, healthcare professionals provided the startup and patients with (1) *a satisfying experience of user involvement,* (2) *increased trust and safety of user involvement between the startup and patients* and (3) *increased credibility towards external stakeholders including partners and investors, which is critical in the early stage development of MedTech devices due to the high amount of costs and resources tied to product development in the MedTech industry.* Although the researchers cannot generalise these finding based upon this case study, the findings do support and build upon the work from Castner et al. (2016) and Bate and Robert (2006). Thus, the researchers argue that the contribution from healthcare professionals is valuable in the development of MedTech, however more research is needed to be dedicated to this field of research in order to generalise this finding.

Chapter 6
Conclusion

This case study thesis has researched how the experience of user involvement is from a patient and startup perspective. Specifically, by conducting 12 semi-structured interviews with patients who participated in this case study startup's user-test and exploring their experiences with the participation. Furthermore, the researchers conducted a focus group interview with the startup, Vilje Bionics, and researched their experiences from the user-test from a startup perspective.

The researchers' aim with this case study thesis was to elucidate the experience with user involvement in the development process of a medical technical device; from both a patient and startup perspective. The study explored experience as a phenomenon through hermeneutic phenomenology which provided insight into valuable data to learn from the experiences of others. By exploring experience as a phenomenon in a user involvement process the researchers were able to obtain new meanings and achieve a more in-depth understanding of how the experience of user involvement was. As a means in scholarly inquiry, this case study demonstrates how hermeneutic phenomenology can provide insight into complex phenomena that are inextricably entwined in user involvement in MedTech development. Based on the findings in this case study, the researchers believe that the application of phenomenology to research questions regarding user involvement will help to advance our understanding by learning from the experiences of others in future studies as well.

Through the case study the researchers identified three main findings of experience with user involvement in the development process of medical technology. These three key experiences were: (1) experience with the choice of methodology, (2) experience with possible improvement areas of the user-test and (3) experience with healthcare participation in user involvement.

First, the choice of methodology for this case study was inspired by previous research of human-centered design models methods of conducting semi-structured interviews with patients (Bjørk and Solhaug 2008; Christoffersen et al. 2015; Kujala 2003; Kvale and Brinkmann 2019; Shah and Robinson 2006; Tjora 2020). The ex-

perience of this methodology in this case study was perceived positively from both perspectives with valuable benefits for both parts. For this reason, the researchers believe that one-to-one semi-structured interviews create value for early stage MedTech startups when involving patients in development processes. This can be argued because of the patients positive experience (*erlebnis*) with this method and since the startup, Vilje Bionics, experienced (erfahrung) an in-depth understanding of their users as well as gaining "*experiential knowledge*" to their advantage. This experience established an increased understanding of the point of view (POV) of the users that gave the startup unique insight of their future customers. Overall, the researchers argue that MedTech startups benefit from adopting the methodology of this case study when involving patients in early stage development of medical technical devices. Furthermore, the findings of this case study shed light on the importance of understanding user involvement and how the experiences from both perspectives reflect upon and influence the results of the user-test.

Second, the experiences that resulted in suggestions for possible improvements was that both parts experienced possible improvements with regards to the demonstration of the product. The findings suggest that a startup should invest time in producing an informative product demonstration with emphasis on functions and limitations of the product. According to the patients' experience this would have given them a better understanding of how the MotOrthosis will provide them value in practice. Moreover, the startup experienced (*erfahrung*) that early user involvement gave them information which provided them with vital knowledge regarding user requirements which will affect the development of the MotOrthosis. This key experience aligns with other researchers' findings who suggested that the highest impact of user involvement appears in capturing experiences of identifying improvement areas or suggestions for further development (Gremyr et al. 2018; Shah and Robinson 2006). Emphasising the importance of exploring the experiences in order to derive valuable data for further development. Additionally, the startup emphasised that the team should have started with user involvement during the early design stage as this would have saved the startup time in the development process. Based on this finding and the work of Castner et al. (2016) the researchers argue that MedTech startups should implement user involvement from the beginning of the design stage in order to be time- and cost-efficient.

Third, the case study reveals that there was a surprising discovery of including healthcare professionals in the development process from both perspectives. The startup experienced that the involvement of healthcare professionals in the user-test built rapport with patients, investors, partners as well as giving them an experience of safety when conducting the user-tests. However, the experience from the patients'

perspective was that they did not consider the healthcare professionals' participation as important to their participation in the research, but were satisfied with the design and method of user involvement. However, the patients were not aware that the methodology and user-test was inspired and influenced by healthcare professionals' participation and the field of healthcare. Thus, the researchers argue that the patients indirectly experienced benefits of including healthcare professionals in the user-test. Based upon the complexity of the user-test the researchers argue that this case study provides evidence that healthcare participation influences the experience of user involvement, both directly and indirectly. Thus, in this case study thesis the researchers believe that the healthcare participation was crucial and increased the positive experience during the user-test.

6.1 Contributions

This case study thesis contributes directly to two fields of research; entrepreneurship and healthcare innovation. In the field of entrepreneurship research this case study reveals new perspectives on the *experience* of user involvement for MedTech startups and builds upon current research in the field. Specifically, the findings of this case study reveals key experiences that contributes to a more in-depth understanding of user involvement in an early-stage MedTech startup. Moreover, the identified key experiences in the case study can influence the implementation of user involvement in development processes of MedTech devices in the future. In essence, understanding the results of these experiences can affect how other MedTech startups will work with user involvement in the future. Moreover, the case study attributes to the field of healthcare innovation research through shedding light on the experience of user involvement with a MedTech startup from a patient perspective. By shedding light on patients' experiences about being included in MedTech studies, the case study can influence how healthcare researchers consider including patients in future research. In addition, the researchers believe that the case study findings can contribute to research across industries excluding innovation processes as well; through influencing how studies can explore a certain topic through exploring the *experience* as a phenomenon to understand the entwined complexities of the chosen topic. By exploring the experience as a phenomenon in this case study contributes to understand the topic of user involvement in a new light. Lastly, this case study thesis contributes to the intersection of entrepreneurship and healthcare innovation research with the use of hermeneutic phenomenology as a method, which has not been widely studied before.

6.2 Future research

Throughout writing this case study thesis, the researchers have identified other themes that can be further researched. Although this case study recommends semi-structured interviews with patients as a successful methodology supported by research in the field of healthcare, this cannot be generalised for MedTech startups from an entrepreneurship perspective. Thus, the researchers recommend to build on this case study and further explore what type of research methodologies can be applied in an early-stage MedTech user-test with patients. The researchers recommend this, since the case study thesis sole explores the experience and not the effect upon applied methodology, moreover there are other research methodologies that should be tried-and-tested. The researchers believe that a study investigating this could influence and build upon existing theoretical framework within healthcare innovation and entrepreneurship. Moreover, the researchers identified that the patients were positive to digitally user-testing, however this case study did not have a representative sample of patients in order to generalise this finding. Thus, the researchers suggest for further research to explore whether user-tests should be conducted digitally or physically and investigate the barriers and benefits between them. Lastly, the researchers have identified throughout this case study thesis a need to further research the value that a healthcare professional contributes to user involvement processes for early-stage MedTech startups. From the case study the researchers can conclude that healthcare professionals brought value to the MedTech startup, Vilje Bionics, but this answer cannot be generalised to other startups. Thus, the researchers recommends that future research explore the effects of including healthcare professionals in user involvement during the development process in an early-stage MedTech startup; and perhaps at what stage it has the highest impact rate.

6.3 Limitations

The presentation of limitations in a thesis is important to illuminate potential bias that can affect a study's results and discussion (Ross and Zaidi 2019). Thus, the researchers will in this section elaborate around this case study thesis' limitations. The first identified limitation is related to the design of the case study. The included patients can be categorised as "early adaptors", thus, the included patients are positive to user involvement and new MedTech devices coming to the market. Moreover, with the ALS-diagnosis comes an experience of helplessness, that can result in an overly positivism for an event they are able to participate in, especially one that is directed to improve their daily situation with the ALS-disease. To reduce

the chances of the patients to be overly positive in the user-tests and case study interviews, the researchers asked and encouraged the patients to be critical during the interview process for this case study thesis. Moreover, the researchers tried to make a safe space for the patients where they could express themselves without the feeling of discomfort.

Furthermore, the researchers have identified limitations regarding the data collection. The data collection was conducted through a qualitative method. Queiros et al. (2017) states that qualitative methods cannot be generalised, thus the finding of this case study thesis can elaborate a trend, and cannot be generalised to every early-stage MedTech startup company. Moreover, since this thesis is built as a case study, it can according to scholars be difficult to generalise findings from a small number of cases (Queirós et al. 2017). Furthermore, the patients interviews were conducted through a semi-structured interview process as recommended from the healthcare field of research (Bjørk and Solhaug 2008; Christoffersen et al. 2015; Kvale and Brinkmann 2019; Shah and Robinson 2006) and in the project thesis prior to this case study (Benestad and Vaskinn 2020) , a method of gathering information where the chances of bias can occur if the researchers do not reflect around which participants that can be included. As stated before, the patients included in this case study master thesis is defined as "early adaptors", thus, the researchers focused on identifying patients in this category. Lastly, the interview with Vilje Bionics was conducted as a focus group interview. Moreover, a focus group is not always representative (Queirós et al. 2017), but for this case study master thesis the whole team from the startup participated in the focus group interview, which was a valid representation from the startup side to share their experiences with early user involvement.

Moreover, a weakness might be tied to how the data collections was retrieved. The data collection was supposed to be conducted physically, but due to COVID-19 and governmental regulations, as well as the patients underlying symptoms putting them in a high risk group, the researchers decided to perform the case study interviews digitally. Thus, the researchers argue that the findings in this case study might potentially have turned out differently if they were conducted physically.

Regarding the data analysis, the transcripts were analysed in Norwegian before the findings were translated into English. Doing so, some of the meanings could perhaps have gotten "lost in translation". In addition to this, some of the patients had difficulties with speaking, which could have led to some potential misunderstandings. Thus, the transcripts were sent out to the patients as well as the startup for quote checks; they also received the full text of the transcribed interviews to approve the data collection from their own interviews. Moreover, the step-by-step process of

analysing the interviews can cause some findings to be missed. Although this can occur, the researchers tried to avoid this by analysing the interviews together, and discussed the findings with the supervisors.

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Appendix A
Interview guides

A.1 Interview guide by Vilje Bionics

Intro: Først vil jeg på vegne av hele Vilje Bionics si tusen takk for at du ønsker å være med på dette intervjuet. Det er beregnet til å ta ca. 1 time, men om du skulle trenge en pause underveis er det bare å gi beskjed. Du kan når som helst trekke deg fra intervjuet, uten å oppgi grunn. Jeg kommer til å stille deg noen spørsmål om ALS, og ditt forhold til hjelpemidler. Så kommer jeg til å vise deg en video der vi presenterer en prototype av hjelpemidlet vi utvikler. Så kommer jeg til å stille deg noen spørsmål relatert til dette. For at hjelpemidlet skal bli mest mulig funksjonelt for ALS-pasienter er vi interessert i dine ærlige synspunkter. Har du noen spørsmål før vi starter?

1) Jeg lurte på om du kunne først fortelle, hvordan sykdommen har utartet seg for deg, siden du fikk de første symptomene.

2) Hvilke utfordringer har svekkelsen i armer og hender for deg i det daglige.

3) Hvilke utfordringer med å ha en svekkelse i arm eller hender er det som de rundt deg ikke forstår?

4) Kan du fortelle hva du gjør fra du står opp til du legger deg?

5) Kan du beskrive en av disse aktivitetene i detalj?

6) Hva er ditt forhold til hjelpemidler?
a)Hvis vi kommer inn på relevante hjelpemidler, hva de liker og ikke liker med disse.

7) Hva er ditt forhold til hjelpemidler til hender eller arm
a) Hva tenker du om at det?
b) Hva mener du om eksisterende hjelpemidler i denne kategorien?

8) Hva mener du er forskjellen på å være selvhjulpen ved bruk av et hjelpemiddel, kontra å få hjelp eller assistanse fra en annen person.

Demonstrasjonsvideo av Vilje Bionics' MotOrtose vises

9) Er det noe du lurer på, eller noe som ikke kom klart frem i denne videoen?

10) Hva skal til for at du ville brukt dette hjelpemiddelet til daglig?

a) Ta av og på

b) Utseende - hva vil være sjenerende

c) Gripefunksjon, hvor viktig er det å kjenne med huden?

11) Hvilke aktiviteter kunne du tenkt deg å bruke dette hjelpemiddelet til?

a) Hvis bare ADL: Er det noen aktiviteter du ikke gjør i dag som du tror dette hjelpemiddelet kunne hjulpet deg med å gjøre.

b) Hvis bare hobby: Er det noen oppgaver du idag får hjelp til

12) Hvordan ville du helst styrt dette hjelpemiddelet?

a) Styre ved hjelpe av talekommandoer, øynestyring ved hjelp av skjerm eller briller. Joystick som kan opereres med fot, hånd eller hodet. Sug og blås der man puster lett inn eller ut. Små knapper som kan styres med deler av kroppen som fortsatt er bevegelige. Hodebevegelser uten joystick.

13) Hvor mye kontroll forventer du å ha over styring av et hjelpemiddel.

a) Hvis jeg forklarer litt dårlig hva jeg mener så kan jeg gjerne utdype litt? Jeg skal prøve å forklare hva jeg mener med å bruke en vanlig og en selvkjørende bil som analogi. En selvkjørende bil krever veldig lite involvering fra brukeren, mens en vanlig bil er avhengig av at en person aktivt styrer bilen. Noen liker å aktivt styre bilen, og ville ikke hatt en selvkjørende bil, mens andre synes det virker helt topp i slippe å kjøre. En selvkjørende bil vil være begrenset til noen områder og vær, mens en vanlig bil kan kjøre hvor som helst og når som helst. Det er også mulig å ha noe midt imellom, der bilen kjører litt selv, og brukeren styrer litt. Eksempelvis kan dette være en bil med cruisekontroll. Vi hvilken grad ønsker du at dette hjelpemiddelet skal være selvkjørende? Det vil si at man kan gi det et sett med

14) Hvor mye liker du at det tar avgjørelser på dine vegne?

15) Hvordan vil det fungere sammen med dine andre hjelpemidler (f.eks rullestol)?

16) Før vi avslutter intervjuet, er det noe mer du ønsker å tilføye til det vi har snakket om.

A.2 Interview guide with patients

Intro: Først vil jeg bare si atter en gang at vi er takknemlige for at du ønsker å bidra til både utviklingen av MotOrtosen og til masteroppgaven til meg og Isabella. Jeg har hørt igjennom intervjuet en gang til og svarene du har gitt oss vil bli brukt for å utvikle hjelpemidlet videre.

Nå er det tid for siste del av intervjurundene for denne gang. Likt som ved forrige intervju skal du bare gi beskjed om du trenger en pause eller ønsker å avbryte intervjuet. Om vi velger å avbryte intervjuet kan du gjøre dette uten å oppgi grunn. Under dette intervjuet får du muligheten til å gi tilbakemeldinger på brukertest intervjuet som ble gjennomført med Vilje Bionics. Vi setter stor pris på om du kan komme med eksempler underveis mens vi snakker sammen. Vi regner med at intervjuet vil ta rundt 30 minutter.

Har du noen spørsmål før vi setter i gang?

—

1) Hvordan syntes du at intervjuet med Vilje gikk?

2) Hva appellerte deg for å delta i en forskningsbasert studie som dette? Hvorfor ønsket du å delta i brukertesten?

3) Hvor vil du som bruker/pasient motta invitasjon for deltagelse i forskningsbaserte studier?

4) Var det viktig for deg å ha dialog med helsepersonell i løpet av prosessen? Hvorfor, hvorfor ikke?

5) Var brukertesten en positiv opplevelse for deg som bruker?
1 – Helt uenig

2 – Delvis uenig

3 – Nøytral

4 – Delvis enig

5 – Helt enig

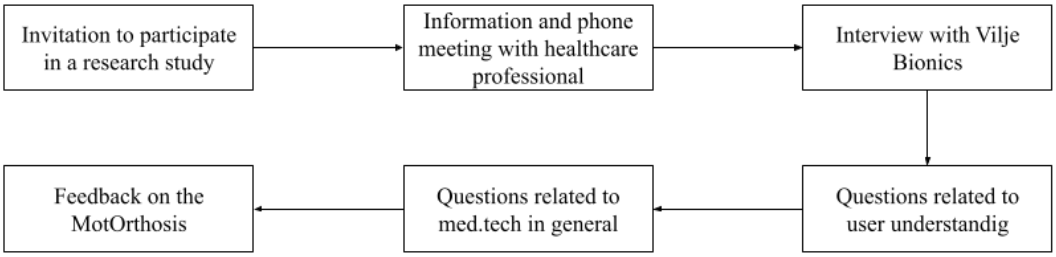
Utdyp? Hva var positivt/negativt med å være med på brukertesten?

6) Var tidsforløpet til brukertesten etter forventing?

7) Hvilke deler eller del av brukertesten vil du trekke frem som var viktig for deg? Vise figur / flowchart.

8) Hvordan kan brukertesten forbedres til neste gang? Savnet eller manglet brukertesten noe spesielt? Vise Flowchart
Tenk på de delene i prosessen av spørsmål 3 du ikke syntes var viktige for deg i

brukertesten. Gi eksempler.



Hva tenker du om at intervjuet blir gjort over nett/zoom?

Vil du anbefale andre som bruker hjelpemidler til å delta i brukertest?

Hvorfor, hvorfor ikke? Gi eksempler.

Før vi avslutter intervjuet så lurer vi på om det er noe mer du ønsker å tilføye? Er det noe vi ikke har spurt som kan være relevant for oss å vite for framtidig utvikling av hjelpemidler med brukermedvirkning?

A.3 Interview guide with Vilje Bionics

1) Hvordan synes dere at intervjuene gikk?

2) Var det noe funn/svar som var overraskende i brukertest intervjuet?

3) Hva sitter dere igjen med etter brukertesten, kan dere dele litt av deres erfaring?

4) Hvilke erfaringer har dere gjort dere tilknyttet pasientinvolvering og resultater?

5) Hvilken nytte fikk dere av brukertesten?

6) Hvilke tanker har dere om at intervjuene ble gjennomført over Zoom?

7)Hvilken nytte opplever dere at det har vært å ha med helsepersonell i prosessen?
a) Har det vært viktig for dere å ha helsepersonell for å utvikle intervjuguiden til brukertesten og komme i kontakt med pasienter?

8) Vis brukerreisen – Etter å ha gjennomført brukertesten, er det noe dere ville gjort annerledes i de ulike leddene, hva og hvorfor?

9) Vil dere anbefale andre Med.Tech oppstartsbedrifter å gjennomføre brukertesting i den fasen dere er i og på den måten dere har gjort det?

10) Hvilke erfaringer er det dere tar med dere i videre arbeid med Vilje Bionics, hva er det viktigste dere har erfart i denne prosessen?

Appendix B
Recruitment of patients

B.1 Text for recruitment of patients

Hei, mitt navn er Vårin, jeg er utdannet sykepleier og tar nå en mastergrad på NTNU. Jeg brenner for å fremme pasientenes meninger og situasjon i hjemmet, og jobber nå vedsiden av studiet i en bedrift, Vilje Bionics, som lager et hjelpemiddel til mennesker med svekket funksjon i armen. Vilje Bionics jobber med å videreutvikle hjelpemidlet som Mangor og Terje Lien har utviklet. Det er kritisk at ALS pasienter får gitt sin stemme og at apparatet er nyttig. Dermed skal jeg og resten av Vilje Bionics gjennomføre intervjuer av ALS-pasienter og trenger derfor din hjelp! Se bilde for mer informasjon og ta gjerne kontakt om dette er noe du kunne vært interessert i. Takk for hjelpen!

Figure B.1: Text presented on the facebook-post of interest groups for ALS-patients

Appendix C
Data analysis themes

C.1 Themes from analysis of patient interview

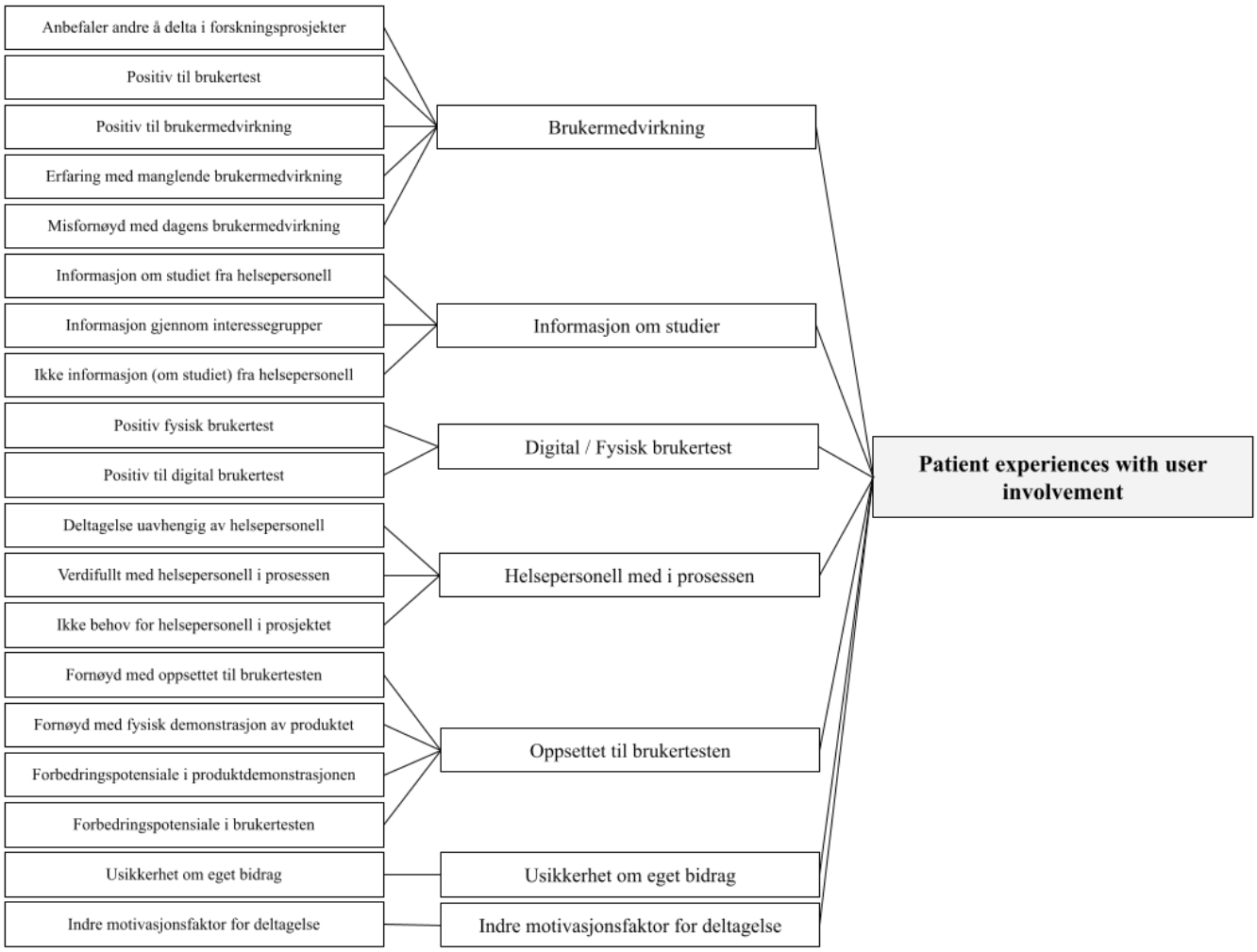


Figure C.1: Detailed overview of code analysis - the patient interviews

C.2 Themes from analysis of the startup interview

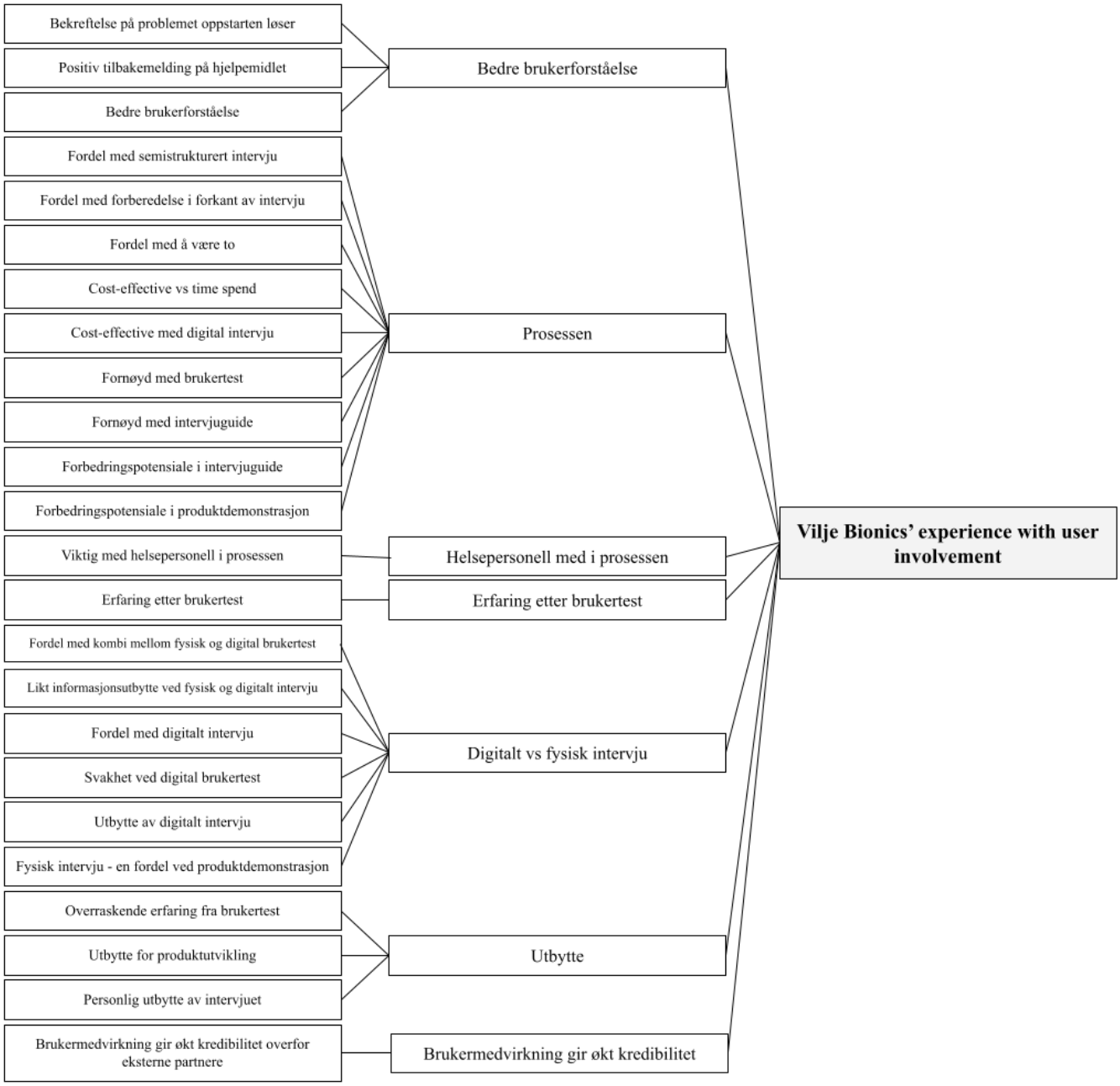


Figure C.2: Detailed overview of code analysis - the startup interview